# EFFECTS OF A THEORY-DRIVEN, DISCLOSURE-BASED FAMILY SUPPORT PROGRAMME ON FEAR OF CANCER RECURRENCE FOR COUPLES COPING WITH BREAST CANCER: A MULTI-CENTRE RANDOMISED CONTROLLED TRIAL

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# Effects of a Theory-Driven, Disclosure-Based Family Support Programme on Fear of Cancer Recurrence for Couples Coping with Breast Cancer: A Multi-Centre Randomised Controlled Trial

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**A thesis submitted in partial fulfilment of the requirements for the degree of Doctor of Philosophy**

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CERTIFICATE OF ORIGINALITY

I hereby declare that this thesis is my own work and that, to the best of my knowledge and belief, it reproduces no material previously published or written, nor material that has been accepted for the award of any other degree or diploma, except where due acknowledgement has been made in the text.

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## ABSTRACT

**Background** Breast cancer remains the most commonly diagnosed malignancy among women worldwide. Although the risk of recurrence varies, concerns about disease return or progression are pervasive after diagnosis. Fear of cancer recurrence (FCR) represents a leading unmet need for women with breast cancer and their partners, and evidence has indicated that FCR levels are correlated within couples. Although numerous interventions have focused on women's FCR, relatively few have been designed specifically for partners. Given the interdependent nature of FCR between women and their partners, addressing partners' FCR or adopting a dyadic approach may contribute to reducing women's FCR. Consequently, interventions that actively engage both members of the couple are needed.

**Aim** We aimed to develop a theory-driven, disclosure-based family support programme for women with breast cancer and their partners and to evaluate its effectiveness on FCR, social constraint, intrusive thoughts, avoidance, anxiety and stigma at six weeks post-intervention (T1) and 12-week follow-up (T2).

**Methods** This doctoral study was divided into four phases.

Phase I involved three reviews: two reviews examining risk factors of FCR among women with breast cancer and their caregivers, respectively, and a meta-analytic review assessing the effectiveness of family-involvement interventions for FCR management in this population. The findings informed the subsequent development and implementation of the FCR intervention.

Phase II focused on the development and validation of scales for assessing partners' affiliate stigma and social constraints as outcome measures. The Affiliate Stigma Scale for partners was developed through a literature review and semi-structured interviews, followed by psychometric evaluation including assessments of content validity, structural validity, construct validity, internal consistency and test–retest reliability. The

Social Constraints Scale (SCS), originally designed for adults with cancer, was adapted for use with partners and underwent validation using the same psychometric procedures.

Phase III centred on the development of the family support programme, informed by the findings of phase I and guided by Simonelli's integrative model. The content of the programme was reviewed and validated by a panel of five experts. A pre–post pilot study was conducted with 15 couples coping with breast cancer to assess feasibility, acceptability and preliminary effects. Insights from this pilot study informed modifications to the intervention protocol and the implementation strategy for phase IV.

Phase IV comprised a two-arm, parallel-group randomised controlled trial (RCT) involving 90 couples coping with breast cancer, who were randomly allocated to receive either the 6-week family support programme delivered via WeChat (n = 45) or 6-week of follow-up WeChat calls (n = 45). Generalised linear mixed models (GLMMs) were employed to evaluate the effectiveness of the family support programme, and Cohen's *d* was calculated and used in estimating between-group effect sizes for women and their partners at T1 and T2. In addition, couple-based qualitative interviews were undertaken as process evaluation, and data were analysed using thematic analysis.

**Results**

Phase I identified social constraints as a common factor associated with FCR in both women with breast cancer and their caregivers. The meta-analytic review concluded that family-involvement interventions, particularly those combining disclosure with education or counselling tailored to specific needs, produced significant short-term reductions in women's FCR. However, the evidence for their effectiveness among caregivers remains insufficient.

Phase II resulted in the development of the Affiliate Stigma Scale, comprising 24 items across four domains: internal stigma, social isolation, perceived stigma and reactions.

The scale demonstrated strong reliability and construct validity, with the total score showing a significant positive correlation with caregiving burden and significant negative correlations with self-esteem and social support. The SCS was adapted for partners of adults with cancer, covering three domains: alienation, health concern minimisation and emotional concealment. Cronbach's α values ranged from 0.719 to 0.863. The overall score was significantly and positively correlated with FCR and communication difficulties and negatively correlated with psychological resilience.

Phase III involved the development of the family support programme, informed by the findings of the three reviews and guided by Simonelli's model. Content validity was rated at 1.0. A pre–post pilot study showed the programme's feasibility and favourable effects in reducing FCR, intrusive thoughts, stigma and anxiety among women and their partners. Social constraints also decreased significantly among partners. Qualitative findings further supported the programme's acceptability. Based on the findings in pilot study, modifications were made prior to implementation in the RCT.

Phase IV assessed the programme through a two-arm RCT. GLMM analyses indicated that, compared with the follow-up WeChat-call group, the family support programme produced short-term effects in reducing women's social constraints, intrusive thoughts and anxiety and their partners' FCR. Qualitative process evaluation included 23 interviews, from which four themes were identified: the comprehensive and practical features of the intervention, perceived benefits, strategies to promote and sustain the programme and challenges in its implementation and sustainability.

**Conclusion** The six-week family support programme was developed and validated. Delivered via WeChat, the programme demonstrated short-term effectiveness in reducing social constraints, intrusive thoughts and anxiety among women and in reducing FCR in partners. These findings offer important insights to guide the future development of interventions aimed at mitigating FCR in this population.

## PUBLICATION AND ARISING FROM PHD STUDY

Journal Publication

**Bu X**, Jiang L, Leung DYP: Fear of Cancer Recurrence Prevalence and Its Associated Factors Among Family Caregivers of Women with Breast Cancer: A Systematic Review and Meta-Analysis. *J Clin Nurs* 2025, 34(7):2510-2524.

**Bu X**, Jiang L, Leung DYP: Family Involvement Interventions on Fear of Cancer Recurrence Management Among Women with Breast Cancer and Their Caregivers: A Systematic Review and Meta-Analysis. *J Clin Nurs* 2025.

**Bu X**, Chen X, Luo L, Fan R, Jiang L, Liu X, Leung DYP: Preliminary testing for affiliate stigma scale: A reliable and valid stigma measure for caregivers of women with breast cancer. *Asia Pac J Oncol Nurs* 2025, 12:100652.

**Bu X**, Liu X, Jiang L, Chung JOK, Jin C, Leung DYP. Effects of a theory-driven, disclosure-based family support programme on fear of cancer recurrence for couples coping with breast cancer: protocol for a multi-centre randomised controlled trial. Trials. 2025 Nov 19;26(1):523.

**Bu X**, Chung JOK, Jiang L, Jin C, Leung DYP. Effectiveness of interventions targeting social constraints among adults with cancer and their caregivers: a systematic review. Support Care Cancer. 2026 Jan 14;34(2):93.

Conference Presentation

**Bu X**, Chen X, Luo L, Fan R, Jiang L, Liu X, Leung DYP (Feb 2025). Affiliate stigma scale: a reliable and valid stigma measure for caregivers of women with breast cancer [Poster]. The Lancet Summit. China.

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# List of abbreviations

| | |
|---|---|
| ACT | Acceptance and Commitment Therapy |
| AR1 | First-order autoregressive |
| BMI | Body mass index |
| CARS | Concerns about Recurrence Scale |
| CBT | Cognitive behavioural therapy |
| CFA | Confirmatory factor analysis |
| CI | Confidence interval |
| CFI | Comparative fit index |
| CVI | Content validity index |
| EFA | Exploratory factor analysis |
| FCR | Fear of cancer recurrence |
| FCRI | Fear of Cancer Recurrence Inventory |
| FoP-Q-SF | Fear of Progression Questionnaire-short form |
| GLMM | Generalised linear mixed model |
| ICCs | Intra-class correlation coefficients |
| ITT | Intention to treat |
| I-CVI | Item-level content validity index |
| KMO | Kaiser–Meyer–Olkin |
| MRC | Medical Research Council |
| MD | Mean difference |
| MI | Modification indices |
| SD | Standard deviation |
| RMSEA | Root mean square error of approximation |
| PRISMA | Preferred Reporting Items for Systematic reviews and Meta-Analyses |
| QoL | Quality of life |
| RoB | Risk-of-bias tool |
| RCT | Randomised controlled trial |
| SE | Standard error |

| | |
|---|---|
| SR | Systematic review |
| SMD | Standardised mean difference |
| WHO | World Health Organization |

# CHAPTER ONE: INTRODUCTION

## 1.1 Introduction

This chapter provides background information on breast cancer, the prevalence of fear of cancer recurrence (FCR) among women with breast cancer and their partners, the consequences of FCR and communication needs associated with coping with FCR. It also outlines the problem statement and the significance of the study, followed by the organisation of the thesis and the aim and objectives of the research.

This chapter is organised into eleven sections. Section 1.1 introduces the chapter. Section 1.2 outlines the background of breast cancer, including its impact on women with breast cancer and their caregivers. Section 1.3 examines the impacts of breast cancer on women and their partners. Section 1.4 defines FCR and discusses its definition, prevalence, and consequences. Section 1.5 explores communication needs in coping with FCR. Section 1.6 addresses special considerations in breast cancer research within the Chinese context. Section 1.7 presents the statement of the problem, and Section 1.8 highlights the significance of the study. Section 1.9 provides a chapter summary, while Section 1.10 describes the organisation of the thesis. Finally, Section 1.11 outlines the aim and objectives of the study.

## 1.2 Background of breast cancer

### 1.2.1 Women with breast cancer

Breast cancer poses a major global health challenge. The World Health Organization (WHO) defines it as a disease in which abnormal breast cells proliferate uncontrollably, forming tumours that may spread throughout the body and become life-threatening if untreated (WHO, 2023). Between 1990 and 2019, the global incidence of breast cancer rose by 128.32% (Xu et al., 2021). By 2040, the annual number of newly diagnosed cases is projected to exceed three million, representing an increase of more than 40% compared with current figures. Although breast cancer occurs predominantly in women,

a small proportion of men are also affected, accounting for approximately 0.5%–1% of cases (WHO, 2023). In 2022, female breast cancer was the second most commonly diagnosed cancer worldwide, with an estimated 2.3 million new cases, representing 11.6% of all cancer cases (Bray et al., 2024). Mortality rates remain substantial. In 2022, breast cancer was the fourth leading cause of cancer death globally, and 666,000 deaths accounted for 6.9% of all cancer-related mortality (Bray et al., 2024). Compared with 1990, global deaths from breast cancer increased by 88.48% by 2021 (Xu et al., 2021). Among women, breast cancer is responsible for one in four cancer diagnoses and one in six cancer deaths (Bray et al., 2024). Projections indicate that annual deaths from breast cancer can increase by more than 50%, reaching an estimated one million by 2040 (Arnold et al., 2022).

In China, breast cancer represents a growing public health concern, and many women are living with and suffering from the disease. The incidence of breast cancer has shown a consistent upward trend since 1990 (Tao et al., 2023). In 2020, approximately 420,000 new cases were recorded in China, accounting for 18% of all breast cancer cases worldwide (Cao et al., 2021). The number of women living with a history of breast cancer has also risen markedly, with an estimated 7.8 million survivors in 2020 based on five-year prevalence (Arnold et al., 2022). The median age at diagnosis in China was 46 years during 2013–2017, more than a decade earlier than in many developed countries. For instance, the median age at diagnosis was 63 years in 2017 in Australia, 63 years during 2014–2018 in the United States and 60 years in 2017 in Japan (Tao et al., 2023). Owing to expanded access to essential anticancer drugs following national health reforms, the introduction of screening programmes, the adoption of multimodal therapies and continued advances in treatment efficacy, survival rates for breast cancer in China have improved considerably over the past decade. However, survival outcomes remain lower than those reported in developed countries (Tao et al., 2023). The age-standardised five-year relative survival rate in China increased from 73.1% among patients diagnosed in 2003–2005 to 82.0% among those diagnosed in 2012–

2015 (Tao et al., 2023).

### 1.2.2 Caregivers of women with breast cancer

A caregiver is a paid or unpaid person who helps an individual with activities of daily living (Charalambous & Charalambous, 2023). Family caregivers usually refer to relatives, friends, or neighbors who provide assistance related to an underlying physical or mental disability for at-home care delivery and assist in the activities of daily living who are unpaid and have no formal training to provide those services (*Family Caregiver Alliance*). The family is a social system (McCubbin et al., 1980) and represents the primary social unit for individuals (Yoshimochi et al., 2018). Families play a crucial role in supporting patients during periods of heightened vulnerability caused by illness, and mobilising family strengths that can facilitate adaptation to stress and hardship. Owing to the shift in cancer care from hospital- to home-based settings, family members are increasingly required to provide support to women with breast cancer after discharge. Breast cancer has frequently been conceptualized as a "couple's disease," highlighting the central role partners assume within the family system in delivering everyday care and emotional support to their wives (Yoshimochi et al., 2018). Nevertheless, the considerable responsibilities associated with caregiving often result in caregiver burden and exhaustion, which may compromise partners' capacity to maintain optimal physical and emotional intimacy with the women (Tao et al., 2022). In China, women are often diagnosed with breast cancer at a relatively young age typically during early or middle adulthood, which disrupts their life and career trajectories. This situation places a considerable burden on family members, particularly partners, who may experience profound strain as caregivers (Li et al., 2016).

## 1.3 Impacts of breast cancer

A diagnosis of breast cancer has profound effects on women and their partners. Women experience physical changes, emotional distress and major life disruptions after diagnosis and subsequent treatment. Adverse effects of treatment can result in physical

changes and symptoms, including chemotherapy-related fatigue, cognitive impairment, hair loss, nausea, vomiting, insomnia, bone pain and peripheral neuropathy. Fatigue, cognitive changes and hair loss are common physical symptoms after chemotherapy. Cancer-related fatigue is widely recognized as one of the most debilitating adverse effects of cancer treatment. It is widely recognized as one of the most debilitating adverse effects of cancer treatment. It is generally characterized as a persistent, distressing, and subjective experience of physical, emotional, and cognitive exhaustion. Distinct from typical tiredness, this form of fatigue may persist for months or even years following the completion of treatment (Bower, 2014). Cognitive impairment, often described as 'chemo brain', affects patients' ability to think clearly and to perform daily tasks (Selamat et al., 2014). Chemotherapy-induced alopecia is another highly distressing side effect. Certain classes of chemotherapy agents used in breast cancer treatment are strongly associated with hair loss (Chon et al., 2012). For some women, alopecia is perceived as even more traumatic than mastectomy (Trusson & Pilnick, 2017). Beyond its physical manifestation, hair loss carries a heavy emotional burden, drawing unwanted attention, undermining self-confidence and social engagement.

Women with breast cancer frequently experience emotional distress, including worry, fear, uncertainty, anxiety, depression and social isolation. A recent systematic review (SR) of supportive care needs for breast cancer survivors (Khajoei et al., 2023) found that women often expressed concern that the disease might be incurable and can ultimately result in permanent separation from their families; they also reported anxiety related to bodily changes, loss of independence and the risk of future recurrence. For those undergoing chemotherapy, treatment-related adverse effects frequently compromised their ability to fulfil maternal roles, leading to feelings of self-blame, sadness and depression. Under intense psychological strain, many women described a sense of powerlessness and despair, and some reported suicidal ideation or even suicide attempts (Liu, Wu et al., 2021).

Breast cancer and its treatment profoundly affect women's daily lives and, in some cases, their long-term survival. The literature identifies several key life changes experienced by women with breast cancer, including reduced functioning capacity, sense of role failure, and stigmatisation (Cebeci et al., 2012; Kocan et al., 2023; Liu, Wu et al., 2021). Firstly, treatment-related side effects often diminish their capacity to perform routine activities. Secondly, as wives, mothers and daughters, women frequently play central roles in maintaining family functioning. Under the combined weight of physical and emotional burdens, many women experience a sense of role failure within the household. Thirdly, treatment-related alterations in physical appearance and self-image intensify feelings of sensitivity and social withdrawal, often leading to experiences resembling stigmatisation.

The profound impacts of a breast cancer diagnosis extend beyond women themselves to their partners. Once treatment commences, partners often find themselves engulfed in a whirlwind of disruption and uncertainty (Fitch & Allard, 2007; Zahlis & Lewis, 2010). As many women are unable to sustain their family roles because of frequent medical examinations and hospitalisations (Gao et al., 2020), partners are drawn into the multiple aspects of the caregiving process, encompassing providing psychological support, accompanying women to hospital appointments and treatments and assisting with daily personal care (Hoga et al., 2008; Zahlis & Lewis, 2010). In addition, partners frequently assume responsibility for maintaining household routines and compensating for women's reduced capacity to provide family care. Tasks, such as cooking, laundry and caring for other family members often fall to partners (Hilton et al., 2000; Nasiri et al., 2016).

Partners of women with breast cancer frequently report negative experiences during the caregiving process. The literature documents that the burden of care is associated with numerous psychological and physical difficulties and traumatic experiences for partners (Jahani Sayad Noveiri et al., 2022; Younes Barani et al., 2019). For most partners, the

diagnosis of breast cancer entered their lives unexpectedly, and fear is the most common initial reaction. Partners expressed fear of malignancy, advanced disease stage, recurrence and metastasis (Catania et al., 2019). Uncertainty further compounded this distress. Owing to limited clarity surrounding the disease and its trajectory, partners have reported a heightened sense of unpredictability, not only the distant future but also concerns related to treatment outcomes and daily expectations (Traboulssi et al., 2022). This uncertainty often undermined their ability to plan ahead because they feared that any arrangement can be disrupted by the illness (Catania et al., 2019). They described the experience of living with persistent uncertainty and unresolved questions as a major challenge (Traboulssi et al., 2022).

Partners have frequently reported feeling overlooked by healthcare professionals because little information is directed specifically towards them to help them cope with or manage the situation (Cheng et al., 2014; Traboulssi et al., 2022). From the point of diagnosis through to the end of caregiving, partners expressed substantial unmet information needs (Cheng et al., 2014). They sought knowledge about the disease, treatment options, prognosis and practical aspects of care, such as preparing appropriate food or accompanying patients during exercise. Partners trusted information provided by healthcare professionals (Zhu et al., 2012), but their limited medical knowledge had often created communication barriers (Deng et al., 2014; P. Li et al., 2017). In addition, the quality of communication among doctors, patients and partners was reported to be inadequate because of the large number of patients in clinical settings (Zhang, Zhou et al., 2021). As the primary source of support for women, partners desired information tailored to their caregiving role. This information included guidance on their responsibilities during diagnosis and treatment, practical ways to provide assistance and strategies women can adopt for self-care. Partners expressed frustration at the absence of multidisciplinary professionals, such as psychologists, nutritionists and oncologists, within the care team. This lack of support left them uncertain about issues, such as dietary requirements (Deng et al., 2014) and how to respond when symptoms emerge

(Deng et al., 2014; Zhu et al., 2012). Beyond medical aspects, partners wanted to understand women's emotional responses to provide effective support. They sought practical guidance on coping strategies, particularly within the couple relationship, with children and in the family (Cheng et al., 2014). Many have noted that they had not been provided with written information specifically for partners nor informed about support groups. Consequently, they often felt self-reliant and isolated, managing their responsibilities with little direct support (Cheng et al., 2014). The only people who truly understood were those with similar experiences (Fitch & Allard, 2007). In the absence of adequate professional guidance, partners frequently turned to unofficial information sources, which often failed to provide satisfactory answers (Maleki et al., 2022). These findings highlight the critical importance of supporting partners through clear, consistent and tailored communication regarding the disease, treatment options, prognosis and caregiving strategies.

The influence of culture on stigma experienced by women with breast cancer and their partners has been widely documented in the literature. Studies conducted in both collectivist and individualist contexts, including the United States, Latin America, Brazil, Iran, Arab countries, and Ghana, have consistently highlighted the cultural and historical stigma surrounding breast cancer (Boamah Mensah et al., 2021; e Silva et al., 2010; Gutierrez et al., 2016; Nasiri et al., 2016; Traboulssi et al., 2022; Zahlis & Shands, 1991). Across these settings, breast cancer is often portrayed as an incurable condition and, in some cases, perceived almost as a death sentence. Both women and their family members may face discrimination and social rejection (Bu et al., 2025). Research has shown that high levels of stigma may prompt women to disclose their cancer experiences to others, thereby reducing intrusive thoughts (Tsai et al., 2019). Intrusive thoughts are considered indicators of incomplete cognitive processing and may contribute to elevated levels of FCR (Lepore & Revenson, 2007). While for caregivers, the isolation described by family caregivers may reflect an internalized, stigma-related process surrounding FCR, in which persistent fear is perceived as excessive,

burdensome, or no longer socially acceptable. As caregivers sensed that others had reached a “saturation point” and could not understand their ongoing distress, they withdrew from sharing their fears and managed FCR privately. This lack of validation led caregivers to question the normalcy of their emotions, further reinforcing loneliness and emotional isolation. In this way, stigma appears to operate relationally, constraining disclosure and social support and potentially intensifying the persistence of FCR (Lamarche, Ajmera, et al., 2025).

## 1.4 Fear of cancer recurrence

### 1.4.1 Definition and prevalence

Anyone diagnosed with cancer faces the possibility of recurrence after treatment. The American Cancer Society defines cancer recurrence as the return of cancer after treatment (American Cancer Society, 2023). Recurrence may occur at the original site or in another part of the body. In breast cancer, recurrence is influenced by a range of factors. Disease-related factors include lymph node involvement, tumour size and oestrogen receptor positivity (Pan et al., 2017). Personal factors, such as body mass index (BMI), physical activity and dietary habits, also play a role (Ecker et al., 2019; Hong & Lee, 2020; Jochems et al., 2018). In addition, Psychosocial stressors, such as negative life events, depressive or anxious symptoms, and insufficient social support, have been associated with suppressed immune functioning and increased pro-inflammatory activity. (Chen et al., 2023). A recent review reported metastatic recurrence rates in breast cancer ranging from 1.1% to 28.3% (Morgan et al., 2024). Although overall recurrence rates may appear relatively low, many women with breast cancer and their partners continue to live with a pervasive fear that the disease may return.

FCR refers to the fear, worry or concern that cancer may return or progress (Lebel et al., 2016). Even in cases where treatment is successful and survival rates are high, FCR can remain a lasting psychological burden (Soriano, Valera, et al., 2019). Clinical FCR

is characterised by persistent preoccupation with recurrence or worry and heightened vigilance to bodily symptoms lasting at least three months (Mutsaers et al., 2020). A Delphi study involving expert researchers, policymakers, trainees and patient advocates reached consensus on five defining features of clinical FCR: (1) intense preoccupation, worry, rumination or intrusive thoughts; (2) maladaptive coping strategies; (3) functional impairments; (4) excessive distress; and (5) difficulty planning for the future (Lebel et al., 2016). High or clinical FCR and can lead to persistent intrusive thoughts about possible progression, lasting for years or even until the end of life. Such experiences not only deteriorate quality of life (QoL) but also elevate the risk of developing further psychological problems (Tran et al., 2022).

FCR is one of the most highly ranked unmet needs among women with breast cancer and their caregivers throughout the whole journey after the diagnosis. Following a diagnosis, women frequently report unmet needs related to the disease and its treatment. A scoping review of 77 studies synthesising the current literature on supportive care needs among breast cancer survivors found that FCR was consistently identified as one of the top three unmet needs, with a pooled prevalence of 50% (Fan et al., 2023). In China, a large cross-sectional survey of 1210 women with breast cancer reported FCR as the most common unmet need (Bu, Jin et al., 2022). Previous studies focused on trajectory of FCR in women with breast cancer further reported that participants with high or moderate FCR level tended to maintain overtime. A longitudinal study conducted in the United States and Canada investigated FCR trajectories in 965 young breast cancer survivors assessed at 5 time points from newly diagnosed to 5 years post-diagnosis. The findings indicated that nearly one-third of women reported high FCR at baseline, which remained consistently high throughout follow-up or further worsened over time (Schapira et al., 2022). In Korea, 162 patients undergoing adjuvant endocrine therapy were assessed five times over 18 months following surgery and found that 21.80% exhibited a high FCR trajectory characterized by an initial decrease followed by a subsequent increase, whereas 38.31% and 39.89% demonstrated low and moderate

FCR trajectories, respectively, both showing a decreasing trend over time (Shim et al., 2020). In China, 300 women with breast cancer reported more than 60% of participants displayed a stable intermediate level of FCR during the 18 months after discharge (Yang et al., 2023).

Several possible reasons for experiencing FCR have been documented in the literature. For instance, after completing primary treatment, many women expressed concerns about treatment efficacy and questioned whether the cancer had truly been eradicated. Others continued to feel vulnerable and constrained by a pervasive sense of insecurity upon resuming everyday life (Lai et al., 2019).

FCR also presents a considerable challenge for caregivers of women with breast cancer. A meta-analytic review reported that the prevalence of FCR among caregivers ranged from 19% to 64.5%, with a pooled prevalence of 45% (Bu, Jiang, et al., 2025b). Evidence from systematic reviews (SRs) further indicates that FCR is a common unmet need in cancer caregivers (Smith et al., 2022; Webb et al., 2023). Webb et al. (2023) found that approximately 48% of cancer patients experienced clinically significant FCR, and Neves et al. (2023) reported that more than half of caregivers experienced moderate to high levels of FCR. Notably, one study identified higher levels of FCR in caregivers of women with breast cancer compared with the patients themselves (Janz et al., 2016). Caregivers often fear malignancy, disease progression, recurrence or the development of a new cancer (Younes Barani et al., 2019; Zhu et al., 2012). They also live with ongoing uncertainty and unresolved questions (Traboulssi et al., 2022). This uncertainty extends beyond the distant future to immediate concerns about the disease, treatment outcomes and day-to-day expectations, rendering caregivers a particularly vulnerable group in need of professional support (Fitch & Allard, 2007; Traboulssi et al., 2022).

### 1.4.2 Consequences of FCR

For women with breast cancer, FCR affects their lives physically, emotionally and

socially. In terms of physical impact, heightened FCR is often associated with sleep disturbance, particularly at night when women are alone. Studies have demonstrated the links of heightened FCR with functional impairments, excessive body-checking behaviours and reduced QoL (Hawkins et al., 2010; Simard et al., 2013). Furthermore, FCR has been identified as a stressor that adversely affects the emotional well-being of women. Women with high levels of FCR experience persistent anxiety and worry, continually fearing that the cancer may return (Hong & Shin, 2021). A qualitative study reported that once FCR becomes embedded in women's daily lives, it can negatively affect their social functioning. Some women concealed their distress by pretending to be content in their relationships, whereas others withdrew from social interactions altogether. In addition, some chose to resign from employment when they perceived stressful working conditions as a trigger for FCR (Şengün İnan & Üstün, 2019).

A SR of 63 studies reported the consequences of FCR in caregivers of individuals with cancer. Caregivers' FCR has been associated with poorer adjustment, negative illness perceptions, cancer-specific stress and concern, reduced QoL and impaired emotional and mental functioning (Smith et al., 2022). Moreover, caregivers' FCR may contribute to poor outcomes for patients, for instance, by reinforcing patients' own concerns about recurrence or by undermining caregivers' ability to provide effective support (Smith et al., 2022). Evidence suggests that caregivers' FCR is linked to heightened psychological morbidity and reduced QoL in both patients and caregivers (Smith et al., 2022). These consequences may be particularly pronounced for partners, who, as spousal caregivers, represent the closest and most involved source of support for women with breast cancer.

### 1.5 Communication needs in coping with FCR

Studies have found that the FCR levels of women with breast cancer and their partners influence one another (Bu, Jiang, et al., 2025b; Perndorfer et al., 2019; Soriano et al., 2021) and some of them have further demonstrated that women with breast cancer and

their partners influence each other's FCR through couple communication (Perndorfer et al., 2019; Soriano et al., 2021; Soriano, Perndorfer, et al., 2019; Zhang et al., 2023). People who feel unable to disclose concerns or lack supportive responses from significant others, they may experience social constraints that inhibit processing, thereby maintaining intrusive thoughts, avoidance, contributing to higher FCR (Lepore & Revenson, 2007, Soriano, Perndorfer, et al., 2018). A study of 72 couples in the US found that when women with breast cancer perceived social constraints on disclosing cancer-related concerns on a given day, they were likely to experience elevated FCR on that day (Soriano, Perndorfer, et al., 2018). Similarly, partners reported increased FCR when they perceived the women as unavailable or critical in response to their disclosure of cancer-related concerns (Soriano et al., 2021). Besides, Further evidence highlights the crucial role of couple communication. A cross-sectional study in China involving 332 women with breast cancer and their spouses found that disease-related communication influenced not only individuals' own FCR but also that of their partners (Zhang, Hu, et al., 2023). Another study investigated the mediating role of couple communication in the relationship between illness representations and FCR. Drawing on data from 54 couples coping with breast cancer, the findings indicated that illness representations were negatively associated with positive information disclosure, regardless of whether participants were patients or spouses. Crucially, disclosure of positive and negative information mediated the association between illness representations and FCR for both members of the couple. The study concluded that daily couple communication plays a critical role in buffering the relationship between illness representations and FCR (Xu et al., 2019). Overall, effective disease-related communication between women with breast cancer and their partners facilitates emotional exchange, mutual encouragement and support, which in turn can mitigate FCR in patients and caregivers.

Given this interdependence in FCR between the two parties, therefore, some researchers have suggested that women's FCR may be alleviated by including caregivers in

interventions or by directly addressing caregivers' FCR (Boehmer et al., 2016; Janz et al., 2016; Soriano et al., 2021). Family involvement interventions are particularly well suited to reduce inhibited disclosure of disease-related concerns because they can more effectively address social constraints on disclosure, protective buffering and the respective roles of both partners in maintaining these patterns. Cultivating a more supportive family climate may facilitate open communication between women with breast cancer and their partners, enabling them to express concerns, fears, and worries more freely. Such mutual disclosure may subsequently contribute to lower levels of FCR in both individuals.

However, several barriers to emotional expression among couples coping with breast cancer have been reported in the literature. Women often cannot express their true emotions and feelings because they do not wish to burden family members (Wang et al., 2020). Many conceal their worries, deny concerns or defer to their partners to avoid disagreement and to minimise distress or burden on their partners (Manne et al., 2007). Conversely, partners encounter challenges in expressing their experiences. Male partners reported that open emotional disclosure conflicted with their perceived gender role (Hilton et al., 2000; Zahlis & Lewis, 2010). Instead, they tended to keep their feelings private, believing that others would neither understand their situation nor benefit from hearing it (Hilton et al., 2000; Zahlis & Lewis, 2010). Some partners concealed their distress to avoid worrying family members or to prevent conflict, choosing instead to protect their wives' feelings. Many felt compelled to display strength consistently to provide reassurance and maintain their wives' morale (Zahlis & Lewis, 2010).

Additionally, cultural beliefs and limited cancer-related knowledge also act as barriers to emotional expression. Such barriers shape how women with breast cancer and their partners perceive the illness and often prevent them from seeking help (Gutierrez et al., 2016; Zhang, Zhou, et al., 2021). Within society, breast cancer is sometimes regarded

as incurable and stigmatised as a death sentence (Nasiri et al., 2016). This perception can have profoundly destructive effects on the psychological well-being of women and their families. After a diagnosis, women and their partners often notice changes in the behaviour of close relatives and acquaintances, which can trigger distress and heightened sensitivity to others' reactions (Nasiri et al., 2016; Bu, Li, et al., 2022). As a result, many feel compelled to conceal their diagnosis to avoid stigma (Boamah Mensah et al., 2021; Traboulssi et al., 2022), tending not to discuss the disease with friends or family members out of fear that doing so might be perceived as vanity or be met with disapproval and a lack of sympathy (Sandham & Harcourt, 2007; Zahlis & Shands, 1991). In addition, psychological stressors arising from treatment side effects, such as breast loss, visible scarring, hair loss and lymphoedema, can exacerbate experiences of stigma (Bu, Li, et al., 2022). These physical changes often alter body image and prompt others to perceive affected women as 'abnormal', further diminishing social engagement and reinforcing feelings of exclusion. Consequently, many women perceive a heightened sense of stigma associated with their condition (Bu, Li, et al., 2022).

The above barriers heighten social constraints on disclosure in communication about cancer-related concerns between couples, leading to a lack of open, authentic and validated exchanges. Perceived social constraints diminish the likelihood of disclosing worries or fears. When individuals withhold disclosure to protect their partners, this behaviour has been shown to correlate with increased FCR. Consequently, fostering open disclosure and communication between women with breast cancer and their partners is essential to alleviating FCR in both parties, positioning the couple as a unit of intervention.

Although several reviews on FCR management in women with breast cancer exist (Dawson et al., 2016; Lyu et al., 2022; Park & Lim, 2022), no review specifically addressing FCR management in caregivers or partners of women with breast cancer has

been identified. The existing reviews for women with breast cancer have primarily focused on psychological interventions, but none has examined the effect of family involvement interventions on FCR management (Lyu et al., 2022; Park & Lim, 2022). The literature has shown that interventions aimed to foster family involvement can enhance patient outcomes in other settings, such as adult acute care wards (Mackie et al., 2018). However, previous reviews of FCR management in breast cancer have largely focused on patients and healthcare providers, without incorporating family members. Partners' support plays a key role in women's adjustment to breast cancer given that the experience can generate considerable adjustment and relationship difficulties for couples, including increased conflict and reduced intimacy (Zimmermann, 2015). Moreover, given the interplay between the FCR of women with breast cancer and that of their partners, many studies have recommended alleviating women's FCR by addressing caregivers' FCR or by adopting interventions involving their families (Boehmer et al., 2016; Soriano et al., 2021). Therefore, a systematic review is warranted to synthesise evidence from existing randomised controlled trials (RCTs) on the effectiveness of family involvement interventions in managing FCR in women with breast cancer and their caregivers.

### 1.6 Special considerations of breast cancer research in the Chinese context

Breast cancer poses a substantial and growing survivorship burden in China, characterised by earlier age at diagnosis and improving survival. Within small nuclear-family structures, breast cancer is often experienced as a "couple disease" where male partners play primary caregiving roles, At the same time, stigma remains culturally patterned and operates not only at the individual level but at family-level, which may contribute to constraints on disclosure, hinder cognitive-emotional processing and heightened FCR. Finally, both women and their partners report strong information needs in survivorship, particularly regarding healthy diet and physical activity, which are often influenced by culturally circulating taboos and limited access to structured, evidence-based guidance.

**Male partner in the household as the major caregiver**

In China, an estimated 0.42 million new breast cancer cases were diagnosed among women in 2020, accounting for approximately 18% of global incident breast cancer cases, which underscores China's substantial contribution to the global disease burden (Cao et al., 2021). In contexts where heterosexuality is treated as the social default, research on breast cancer-related partnerships may consequently foreground male partners (e.g., husbands or boyfriends), particularly regarding their roles in emotional support, caregiving, and decision-making. Chinese marriage law is framed as a union entered into by "both man and woman". As a result, same-sex couples cannot access the full set of legal rights and protections associated with marriage (National People's Congress of the People's Republic of China, 2020). In addition to legal constraints, sexual minorities may face social stigma and discrimination, which can reduce visibility and increase incentives to conceal one's sexual orientation or gender identity. Accordingly, this study focuses on male partners of women with breast cancer to reflect dominant relational patterns in the setting under examination. Nevertheless, it is important to acknowledge that not all breast cancer occurs in women, and not all women have male partners; therefore, the analytical focus here reflects a socially structured norm rather than an exclusive definition of partnership.

A distinctive feature frequently emphasized in the literature is the earlier age at diagnosis in China compared with many Western settings. A median age at diagnosis of roughly 48–50 years in China was reported, with a substantial proportion of women diagnosed before age 50 (Fan et al., 2014). Advances in detection and treatment have increased the number of women living long-term after breast cancer. 5-year relative survival approached 89% in Eastern China, alongside clear improvement over time (Li et al., 2022). The national multicenter survival analyses indicate breast cancer has comparatively favorable 5-year survival in China, reinforcing that survivorship care has become a central public health and clinical priority (Zeng et al., 2024). Age-

standardized 5-year relative survival for breast cancer showed a clear upward trend from 78.5% (95% CI: 77.8–79.2) in 2008–2010 to 82.4% (95% CI: 81.9–82.9) in 2019–2021(Zeng et al., 2024).

In mainland China, breast cancer is commonly managed within a relatively small structure family, in which a middle-aged woman lives with her male partner and often with children, meaning that diagnosis and recovery are rarely experienced as an individual event but instead unfold within a family. Families are considered as the main social nucleus of individuals (Gao et al., 2020). Man is a family member that stands outs within the household context (Gao et al., 2020). Breast cancer is often described as a "couple disease" because the diagnosis and its consequences routinely affect both parties. Several reasons may account for this. First, breast cancer introduces shared stressors that must be managed jointly, such as treatment schedules, financial strain, childcare, and household re-organization. Second, breast cancer directly reshapes intimacy and identity within the relationship. Changes in body image, sexual functioning, and perceived femininity can influence emotional closeness and sexual intimacy (Bu, Li, et al., 2022), while partners' supportive or critical reactions, can either buffer or amplify FCR (Bu, Jiang, et al., 2025b). Third, coping is frequently dyadic rather than individual. How partners communicate about stress and respond together predicts both psychological outcomes. Supportive communication is generally linked to better dyadic functioning, while maladaptive processes such as protective buffering are associated with higher FCR (Perndorfer et al., 2019). Fourth, male partners commonly take on primary caregiving and household management roles in the family after the diagnosis. The partner usually is the primary caregiver, and the disease adds burden to partners and affects their quality of life and mental health (Tao et al., 2022).

In the Chinese breast cancer context, stigma structures how women and their families interpret breast cancer, manage disclosure, and access support across survivorship. Based on a systematic review and meta-analysis of postoperative breast cancer patients

synthesised evidence that stigma burden is substantial and culturally patterned in China (Yan et al., 2025). Traditional gender-role expectations can frame breast loss as a deficiency in female identity, generating fears of marital crisis, workplace discrimination, and social isolation, and it highlights a pronounced burden of silence, including reports that 76.7% of patients conceal their condition due to fear of discrimination (Yan et al., 2025). Importantly, stigma in China often operates at the family level, not only women with breast cancer experience stigmatisation, but also their family members may face discrimination and social rejection (Bu et al., 2025), especially within small nuclear-family structures in which male partners commonly serve as primary caregivers. Individuals associated with women with breast cancer, such as family members, friends and service providers, may be subjected to stigmatization from the public as well. Affiliate stigma refers to the internalisation of stigma by primary caregivers, based on the public's negative perceptions (Zhang et al., 2018). Research has shown that high levels of stigma may prompt Chinese American breast cancer survivors to disclose their cancer experiences to others, thereby reducing intrusive thoughts (Tsai et al., 2019). Intrusive thoughts are a maker of incomplete cognitive processing, which may prolong to higher FCR (Lepore & Revenson, 2007). Evidence from Chinese American breast cancer found stigma is a mediator of social constraints and FCR, suggesting that social constraints on disclosure may relate to higher FCR partly through stigma and related emotional expression processes (Yeung & Lu, 2022). This situation may be particularly salient in the Chinese cultural context, where 'acting normal' often serves as a strategy to preserve the integrity of social interactions and to avoid stigma. Within Chinese culture, emotional suppression is valued as a means of maintaining harmony in interpersonal relationships. However, this cultural may limit opportunities for open emotional expression and discourage individuals from communicating their feelings and concerns with others (Wang et al., 2020). Women with breast cancer may feel greater ambivalence about emotional expression if they experience more social constraints arising from higher levels of stigma because they may feel less comfortable disclosing their distress (Tsai et al.,

2019). Stigma may amplify FCR by increasing shame and social withdrawal, constraining cancer-related disclosure, and thereby impeding cognitive and emotional processing of recurrence concerns. In Chinese breast cancer samples, higher social constraints co-occur with higher stigma and greater FCR, indicating that stigmatizing beliefs and constrained communication may cluster with FCR (Cui et al., 2022).

**Needs for practical survivorship information**

Both women and their partners often require highly practical survivorship information. Most prominently about dietary management and physical activity (Tang et al., 2022). In the Chinese context, diet-related information needs are frequently shaped by culturally circulating "taboos" (e.g., avoiding certain "trigger" foods such as seafood because they are believed to increase relapse risk), and these beliefs can become family rules that guide shopping, cooking, and eating in the household. Empirically, a systematic review of Chinese cancer patients receiving chemotherapy highlights that food taboos are common and may lead to overly conservative intake and reliance on non-professional sources to guide eating practices (Tang et al., 2023). Related evidence also shows that many Chinese cancer patients engage in food avoidance behaviors driven by FCR, which can increase uncertainty and nutritional risk in day-to-day decision-making (Yung et al., 2022). Exercise information needs show a similar pattern. Hospital education in China often emphasizes postoperative limb rehabilitation, especially upper-limb functional exercise (e.g., shoulder range-of-motion, edema/lymphedema prevention), rather than providing structured guidance for long-term physical activity across survivorship. Higher physical activity after a breast cancer diagnosis may reduce recurrence risk and is associated with lower mortality (Zagalaz-Anula et al., 2022). A systematic review concluded that recreational physical activity reduces breast cancer–specific mortality and suggests potential benefits for recurrence outcomes, reinforcing physical activity as a survivorship-relevant protective behavior rather than only a short-term rehabilitation task (Zagalaz-Anula et al., 2022).

## 1.7 Statement of the problem

The prevalence of breast cancer among women is rising alarmingly, but survival rates remain high, particularly in China. Breast cancer is often regarded as a 'couple's disease', in particular, partners play a central role within the household context by providing care and support when women are discharged home. FCR is one of the most pressing unmet needs for women with breast cancer and their caregivers, especially partners, and their FCR levels strongly influence each other. Caregivers' FCR may exacerbate poorer outcomes in women with breast cancer, either by reinforcing concerns about recurrence or by undermining their own ability to provide support. Given this interplay, many studies have recommended alleviating women's FCR by addressing caregivers' FCR or by adopting a dyadic perspective. Couple communication is a key factor, as it can significantly shape FCR in women and their partners. However, social constraints on disclosure often hinder open discussion of cancer-related concerns within couples. Individuals who perceive such constraints are less likely to share worries or fears, and withholding disclosure to protect their partner has been shown to correspond with an increase in personal FCR. Therefore, effective interventions targeting women–partner dyads are urgently needed, where couples are treated as a unit of care. By fostering open disclosure and communication, couple-based interventions may help overcome social constraints and reduce FCR in women with breast cancer and their partners.

## 1.8 Significance of the study

Developed from the best available evidence on associated factors in women with breast cancer and their caregivers and the effectiveness of family involvement interventions in FCR management, an RCT was conducted to examine the feasibility, acceptability and effectiveness of a theory-driven, disclosure-based family support programme. The intervention targeted FCR, social constraints, intrusive thoughts, avoidance, anxiety and stigma in women with breast cancer and their partners. The study aimed to examine the effectiveness of this family support programme on these outcomes.

This RCT was designed to address three phases of the Medical Research Council (MRC) framework: intervention development, feasibility and evaluation (Skivington et al., 2021). The family support programme was developed based on Simonelli's integrative model for FCR (Simonelli et al., 2017), findings from literature reviews on associated factors of FCR in women with breast cancer and their caregivers (Bu, Jiang, et al., 2025b; Gormley et al., 2022), and meta-analytic evidence on the effectiveness of family involvement interventions (Bu, Jiang, et al., 2025a). A pilot study tested the feasibility, acceptability and preliminary effects of the programme on FCR and psychosocial outcomes in women with breast cancer and their partners. Based on the findings in the pilot study, modifications were made before conducting the main RCT with a 12-week follow-up to evaluate the effectiveness of the refined programme.

This research considerably contributes to the field of cancer care by providing empirical evidence on the impacts of couple-based interventions in alleviating FCR in couples coping with breast cancer. The findings demonstrate that such interventions benefit not only women with breast cancer but also their partners, offering objective support for a dyadic approach. Furthermore, the results yield valuable insights to inform the design and implementation of future couple-based interventions, particularly those aimed at enhancing disclosure within couples, thereby reducing FCR more effectively in both parties.

### 1.9 Chapter summary

Breast cancer is the most commonly diagnosed cancer among women worldwide. Anyone diagnosed with cancer may face the risk of recurrence, and concern about the return or progression of disease is widespread. FCR is one of the most frequently reported unmet needs among women with breast cancer and their partners (Bu, Jiang, et al., 2025b; Fan et al., 2023). Elevated FCR can trigger persistent intrusive thoughts about possible progression for years, undermining QoL and increasing psychological

distress (Cohee et al., 2017; Tran et al., 2022). Couple communication plays a critical role in shaping FCR in women with breast cancer and their partners. However, social constraints in disclosing feelings, concerns and worries in either partners can contribute to heightened FCR in both parties through inhibited disclosure. Couples as units in reducing FCR through disclosure and communication should be considered. Accordingly, this research project aimed to examine the feasibility, acceptability and effectiveness of a theory-driven, disclosure-based family support programme for couples coping with breast cancer.

### 1.10 Organisation of this thesis

This thesis is organised into 10 chapters. Chapter One introduces the doctoral research project, outlining the background, problem statement, significance and the aims and objectives of the study. Chapter Two provides a literature review on the associated factors of FCR in women with breast cancer and presents a systematic review and meta-analysis on the associated factors of FCR in caregivers of women with breast cancer. Chapter Three reports a systematic review and meta-analysis that synthesises the best available evidence on family involvement interventions for FCR management in women with breast cancer and their caregivers. Chapter Four describes the development of the family support programme, including the conceptual framework and details of the intervention. Chapter Five presents the cultural adaptation, development and psychometric properties of selected self-reported outcome measures used in this doctoral study. Chapter Six outlines the methods and results of the pilot study, assessing the feasibility, acceptability and preliminary effects of the family support programme. Chapter Seven details the methodology of the RCT conducted to evaluate the feasibility, acceptability and effectiveness of the intervention. Chapter Eight presents the findings of the RCT in relation to feasibility, acceptability and effectiveness on the selected outcomes. Chapter Nine provides a discussion of the RCT findings, along with the strengths and limitations of the doctoral study. Finally, Chapter Ten offers the study's implications, conclusions and recommendations. The thesis also includes appendices

and references.

## 1.11 Aim and objectives of the study

### 1.11.1 Aim of the research project

The overall aim of this doctoral study was to develop a theory-driven, disclosure-based family support programme for couples coping with breast cancer in China and to examine its feasibility, acceptability and effectiveness in mitigating FCR, social constraints, intrusive thoughts, avoidance, anxiety and stigma.

### 1.11.2 Objectives of the research project

In this doctoral study, four phases were conducted: (1) Phase I: literature reviews to explore associated factors of FCR in women with breast cancer and their caregivers, and to examine the effectiveness of family involvement interventions; (2) Phase II: adaptation/development and validation of scales for assessing partners' affiliate stigma and social constraints as outcome measures; (3) Phase III: development and pilot testing of a theory-driven, disclosure-based family support programme; (4) Phase IV: evaluation of the family support programme's feasibility, acceptability and effectiveness on selected outcomes for couples coping with breast cancer in China.

**Phase I**. The objective of Phase I is to review and synthesise the common factors associated with FCR in women with breast cancer and their caregivers through a comprehensive literature review. In addition, this phase aims to explore the effectiveness of family involvement interventions on FCR management among women with breast cancer and their caregivers by conducting a systematic review and meta-analysis, focusing on aspects, such as content, dosage, provider type, intervention duration and delivery mode. The findings from Phase I inform and guide the development of the family support programme in Phase II.

**Phase II**. The objective of Phase II is to adapt the Social Constraints Scale (SCS) and

to develop an Affiliate Stigma Scale for partners, followed by psychometric validation. The Affiliate Stigma Scale for partners was developed through a literature review and semi-structured interviews, whereas the SCS, originally designed for adults with cancer, was adapted for partners. Both scales underwent rigorous psychometric testing, including assessments of content validity, factorial validity, construct validity and reliability, encompassing internal consistency and stability. The primary aim was to establish these two scales as reliable and valid outcome measures for use in the subsequent pilot study and RCT.

**Phase III**. The objective of Phase III is to develop a theory-driven, disclosure-based family support programme incorporating the effective components of disclosure combined with education or counselling tailored to the specific needs identified in Phase I. Additional educational content on breast cancer-related knowledge and healthy lifestyle was integrated on the basis of Simonelli's integrative model of FCR. A pre–post pilot study was conducted to assess the feasibility, acceptability and preliminary effects of the programme on FCR, social constraints, intrusive thoughts, avoidance, anxiety and stigma in women with breast cancer and their partners. The primary aim of this phase is to refine the intervention content and protocol in preparation for the main RCT in Phase IV.

**Phase IV**. The objective of Phase IV is to examine the feasibility, acceptability and effectiveness of the adapted family support programme based on the pilot study in mitigating FCR, social constraints, intrusive thoughts, avoidance, anxiety and stigma in women with breast cancer and their partners. The primary focus of this phase is to assess the effectiveness of the family support programme for couples coping with breast cancer.

# CHAPTER TWO LITERATURE REVIEWS

## 2.1 Introduction

This chapter comprises two parts, which separately reports the risk factors of FCR in women with breast cancer and their caregivers. The first part presents a literature review of factors associated with FCR in women with breast cancer, synthesised from three published reviews. The second part reports a systematic review and meta-analysis on the prevalence of FCR and its risk factors in caregivers of women with breast cancer; the results of this review have been published (Bu, Jiang, et al., 2025b).

## 2.2 Factors associated with FCR in women with breast cancer

Recently, two meta-analytic reviews and one systematic review have been conducted to summarise factors associated with FCR in women with breast cancer (Gormley et al., 2022; He et al., 2023; J. Liu; Jin et al., 2021). However, a comprehensive synthesis remains necessary because these reviews differ in scope and focus. The meta-analytic review by He et al. (2023) included only studies on Chinese patients with breast cancer, whose FCR was assessed using the Chinese version of the Fear of Progression Questionnaire. Consequently, studies employing other FCR measures, such as the 7-item Fear of Cancer Recurrence Scale, the 9-item Fear of Cancer Recurrence Inventory–Short Form and the Concerns About Recurrence Scale, were excluded (Cai et al., 2018; Waroquier et al., 2022; Yang et al., 2023). The meta-analysis by Liu, Jin et al. (2021) did not limit studies to China, but 27 studies were excluded due to unavailable data. The systematic review by Gormley et al. (2022) focused on factors associated with FCR in young women under 45 years old and included both qualitative and quantitative studies. The two meta-analytic reviews included papers published in both Chinese and English whereas the systematic review included only English-language studies. The coverage of these three reviews varies; therefore, a synthesis is needed to provide a comprehensive overview of factors associated with FCR in women with breast cancer. Gormley et al. (2022) synthesised associated factors without statistical analysis, while the two meta-analytic reviews reported statistical results. Only factors that were

statistically significant and consistently reported across reviews were extracted (Table 2.1). These factors were then classified into five levels: demographic characteristics, treatment-related factors, psychological factors, psychosocial factors and cognitive factors (Table 2.2). Factors with different labels but similar meaning were combined, for example, disease status and cancer stage were grouped as disease status; unscheduled healthcare visits and breast self-examinations were combined as surveillance; and negative emotion, trait anxiety, psychological morbidity and emotional representation were grouped as psychological morbidity. A total of 22 factors were identified: 8 at the demographic level, 3 at the treatment-related level, 3 at the psychological level, 2 at the psychosocial level and 6 at the cognitive level.

Table 2.1 Significant factors extracted from each review

| | |
|---|---|
| Gormley et al. (2022) | Factors<br>Motherhood, parenting stress, social constraints, breast cancer reminders, trait anxiety, unscheduled visits to healthcare provider, frequent breast self-examinations, maladaptive metacognition, psychological morbidity, perceived risk of recurrence, cognitive processing mediator of social constraints and FCR,<br>Mediators<br>Illness intrusiveness mediates the relationship between age and FCR, anxiety mediates the relationship between age and FCR, |
| Liu, Jin et al. (2021) | Age, age at diagnosis, per capita of family income (monthly), tumor stage, negative emotions, emotional representation, social support, resignation |
| He et al. (2023) | Living region in China, age, educational level, marital status, residence, illness stage, and disease status. |

Table 2.2 Associated factors of FCR among women with breast cancer

| | positive correlation | negative correlation | mediator | Non-direction |
|---|---|---|---|---|
| Demographic characteristic level | / | Age, Age at diagnosis, Family income, Educational level | | Motherhood, Marital status, Residence, Living region in |

| | | | | |
|---|---|---|---|---|
| | | | | China |
| Treatment related level | Disease status, Breast cancer reminders, Surveillance | / | | / |
| Psychological level | Psychological morbidity, Parenting stress | / | Anxiety mediates the relationship between age and FCR | / |
| Psychosocial level | Social constraints | Social support | / | / |
| Cognitive level | Maladaptive metacognition, Illness representation, Perceived risk of recurrence, Resignation | / | Cognitive processing mediates the relationship of social constraints and FCR, Illness intrusiveness mediates the relationship of age and FCR | |

2.2.1 Demographic characteristic level

Eight factors were identified at the demographic level: age, age at diagnosis, family income, education level, motherhood, marital status, place of residence and living region in China. No mediators were reported at the demographic level.

Four demographic factors, namely, age, age at diagnosis, family income and education level, were found to be negatively correlated with FCR in women with breast cancer. According to the two meta-analytic reviews, young women exhibited significantly higher FCR levels than older women (He et al., 2023), with Liu, Jin et al. (2021) reporting a small correlation (*r*) of -0.162 (95%CI: [-0.268, -0.057]). Regarding age at diagnosis and family income, Liu, Jin et al. (2021) found that women diagnosed at a younger age (*r* = -0.313, 95%CI: [-0.362, -0.264]) and those with lower income (r = -0.174, 95%CI: [-0.229, -0.119] had significantly higher FCR than their counterparts. In terms of education level, He et al. (2023) reported that women with higher levels of education had significantly reduced FCR, while Liu, Jin et al found no significant result

($r$ = -0.005, 95%CI: [-0.196, 0.186]).

Motherhood, marital status, place of residence and living region in China were also identified as significant correlates of FCR among women with breast cancer. The SR of Gormley (2022) reported that women with children experienced higher FCR than those without children. Regarding marital status, place of residence and living region, He et al. (2023) found that women who were unmarried, living in rural areas or residing in the central region of China had significantly higher FCR than their respective counterparts.

### 2.2.2 Treatment level

The treatment related factors, disease status, breast cancer reminders and surveillance, were positively correlated with FCR. No factors at the treatment level were found to be negatively associated with FCR.

Regarding disease status, the two meta-analytic reviews reported that women with middle or advanced stages of breast cancer were likely to experience fear, with a correlation of 0.243 (95%CI: [0.156, 0.330]). There was no significant association between recurrent or metastatic cancer and higher FCR among women ($r$ = 0.007, 95%CI: [-0.321, 0.308]) (Liu, Jin et al., 2021). Regarding breast cancer reminders and surveillance, the SR of Gormley et al. (2022) found that unscheduled visits to healthcare providers, breast self-examinations and frequent breast cancer reminders were positively associated with women's FCR.

### 2.2.3 Psychological level

Three psychological factors were identified, including psychological morbidity and parenting stress, which were positively correlated with FCR, and one mediating factor (anxiety), which mediated the relationship between age and FCR. No factors at the psychological level were negatively associated with FCR.

Psychological morbidity and parenting stress were positively correlated with FCR. The SR of Gormley et al. (2022) and meta-anslysis of Liu, Jin et al. (2021) reported that women experiencing psychological morbidity, such as anxiety and negative emotional representation ($r$ = 0.609, 95%CI: [0.494, 0.724]) and those experiencing parenting stress had elevated levels of FCR. Regarding anxiety, Gormley et al. (2022) found that illness intrusiveness combined with trait anxiety mediated the relationship between age and FCR.

### 2.2.4 Psychosocial level

Two psychosocial factors were identified: social constraints, which was positively associated with FCR, and social support, which was negatively associated with FCR. No mediating factors were identified at the psychosocial level.

The systematic review of Gormley et al. (2022) reported that women experiencing higher social constraints had higher FCR, whereas the meta-analytic review of Liu, Jin et al. (2021) found that women with low social support experienced significantly high FCR ($r$ = -0.237, 95%CI: [-0.345, -0.128]).

### 2.2.5 Cognitive level

Six cognitive factors were identified, all reported in the systematic review of Gormley et al. (2022). Four factors, namely, maladaptive metacognition, illness representation, perceived risk of recurrence and resignation, were positively associated with FCR, whereas cognitive processing and illness intrusiveness acted as mediators. No cognitive factors were identified as negatively associated with FCR.

Maladaptive metacognition, illness representation, perceived risk of recurrence and resignation were also positively correlated with women's FCR. The systematic review of Gormley et al. (2022) reported that metacognitive style accounted for 36% of the

variability in FCR in young women and that women with strong illness representation or a high perceived risk of recurrence experienced elevated FCR. As for resignation, the review from Gormley et al. (2022) found that women who adopted resignation as a coping strategy were more likely to experience FCR because they regarded the illness as fate and believed that little can be done to change or control it.

Two mediating factors were identified in the review. Cognitive processing mediated the relationship between social constraints and FCR, while illness intrusiveness, combined with trait anxiety, mediated the relationship between age and FCR (Gormley et al., 2022).

#### 2.2.6 Summary of findings

In summary, a total of 22 factors associated with FCR in women with breast cancer were identified in the literature, including 11 modifiable factors at the psychological, psychosocial and cognitive levels. The findings suggest a potential mechanism for FCR. Social constraints are a significant positive factor, and cognitive processing mediates the relationship between social constraints and FCR in the target population. Future studies can focus on reducing FCR by targeting and modifying modifiable factors, such as social constraints and cognitive processing, in women with breast cancer.

## 2.3 Fear of Cancer Recurrence and its Associated Factors among Caregivers of Women with Breast Cancer: A Systematic Review

#### 2.3.1 Introduction

An increasing number of studies have investigated FCR among caregivers of women with breast cancer, as well as the multidimensional factors associated with their FCR. Evidence suggests that lower educational level, greater social constraints, reduced social support, and lower resilience, are significantly associated with higher levels of FCR in this population (Cohee et al., 2017; Perndorfer et al., 2019; Soriano et al., 2021; Soriano, Pasipanodya, et al., 2018; Wang et al., 2021; Zhang, Yu et al., 2023). Between

19% and 64.95% of caregivers of women with breast cancer experience clinically significant levels of FCR (Janz et al. 2016; Perndorfer et al., 2019; Soriano et al., 2021; Wang et al., 2021). Notably, one study found that caregivers may experience even higher levels of FCR than the patients themselves (Janz et al. 2016). However, to date, no systematic review has comprehensively synthesized factors associated with FCR in caregivers of women with breast cancer. Identifying these factors is crucial for informing strategies aimed at reducing FCR risk among caregivers. To address this gap, we conducted a systematic review to examine the associated factors of FCR in this population and evaluated the strength of evidence based on the quality of the reviewed studies. In addition, a meta-analysis was performed to estimate the prevalence of caregiver FCR. The overarching review question was: What are the factors associated with FCR in caregivers of women with breast cancer, and what is the prevalence of caregiver FCR?

### 2.3.2 Method

This systematic review was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis 2020 guideline (Page et al., 2021). The review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) in 2023 (CRD42023469754).

#### 2.3.2.1 Literature Search

A comprehensive literature search was conducted on 8 and 9 August 2023 across eight databases, including PubMed, Web of Science, CINAHL, Ovid, EMBASE, CNKI, Wanfang and Sinomed. Grey literature was not searched. After the removal of duplicate records, two authors independently screened the titles, abstracts, and full texts of the identified articles. Any discrepancies were resolved through discussion until consensus was reached regarding the final selection of studies for inclusion. The detailed search strategy in PubMed was shown in Appendix I.

2.3.2.2 Study Selection and Eligibility Criteria

Original observational studies that examined associations between FCR in caregivers with at least one other variable through correlation, comparison, or regression analyses were eligible for inclusion. Studies published in the English or Chinese language. Inclusion criteria as follows:

1. Participants: caregivers of women with breast cancer, including relatives, partners, friends, or neighbors with a close personal relationship to women with breast cancer.
2. Study design: observational studies, including cohort, longitudinal, and cross-sectional designs.
3. Outcome of Interest: FCR in caregivers must be reported as either a primary or secondary outcome at any point along the cancer trajectory. At least one associated factor must be assessed using either a validated or non-validated instrument.
4. Context: studies conducted in any setting were eligible, including homes, hospitals, or any other relevant environment where the context was adequately described.

Exclusion criteria:

1. Studies used the same sample as another included study, and no additional relevant data was presented.
2. Caregiver FCR was assessed as an independent variable rather than an outcome.
3. The sample included caregivers of individuals with various cancer types, but no subgroup analysis for caregivers of women with breast cancer.
4. Full-text articles were not available.

2.3.2.3 Selection

All retrieved records were imported into an EndNote library (EndNote X9.1), and duplicate studies were removed. The remaining records were exported to an Excel spreadsheet (Microsoft) for further screening. Two independent reviewers assessed the titles, abstracts, and full texts to determine eligibility based on predefined inclusion and exclusion criteria. Discrepancies between reviewers were resolved through discussion

or consultation with a third investigator when necessary.

2.3.2.4 Quality Assessment

The methodological quality of the included studies was evaluated by two reviewers independently by using a modified checklist adapted from Ge and Mordiffi (2017) and Zhao et al. (2015). The checklist covers five methodological domains across nine criteria (Table 2.3). These criteria were specifically designed for evaluating the methodological quality of observational studies and have been widely adopted in previous systematic reviews (Ge & Mordiffi, 2017; Gomes & Higginson, 2006; Xing et al., 2013; Zhao et al., 2015; Zhou et al., 2013). Disagreements between reviewers were resolved through discussion. A score of zero was assigned for unmet criterion. Total quality scores were calculated by summing the individual item scores, with a maximum possible score of 9. The scoring breakdown was as follows: population and participant selection (2 points), study design (3 points), outcome assessment (1 point), and data analysis and presentation (3 points) (Table 2.3). Based on their methodological quality scores and statistical analysis methods, studies were classified as high, moderate, or low quality (Table 2.4, upper section).

Table 2.3 Criteria for the assessment of the methodological quality of observational studies

| Aspect | Criterion | Score |
|---|---|---|
| Population | ① Sample size ≥ 50 and participation rate ≥ 80% | 1 |
| Participant selection | ② For cohort/longitudinal and case–control studies, selected subjects were representative of the study population; for cross-sectional studies, the inclusion criteria of caregivers were clearly defined, and subjects and settings were described in detail | 1 |
| Study design | ③ Cohort/longitudinal design with the follow-up duration reported | 2 |
| | ④ Case–control or cross-sectional design | 1 |
| | ⑤ Withdrawals ≤ 20% | 1 |
| Measurement of | ⑥ A validated FCR measurement tool was used | 1 |

| | | |
|---|---|---|
| outcome | | |
| Statistical analysis and presentation | ⑦ Appropriate statistical analyses were used | 1 |
| | ⑧ Multiple regression/multivariate analysis was performed | 1 |
| | ⑨ Frequencies of caregiver FCR were reported | 1 |

Table 2.4 Criteria for the assessment of the quality level of studies and best-evidence synthesis

| Item | Level | Subject selection |
|---|---|---|
| Quality level of included studies | High | Multivariate analysis was performed and quality score ≥ 7 |
| | Moderate | Multivariate analysis was performed and quality score < 7 or no multivariate analysis was performed and quality score > 5 |
| | Low | No multivariate analysis was performed and quality score ≤ 5 |
| Level of evidence | Strong | Minimum of three high-quality studies with generally consistent findings |
| | Moderate | Minimum of two moderate-quality studies with generally consistent findings |
| | Limited | Minimum of one low-quality study with generally consistent findings |
| | Conflicting | Converse findings in >25% of the studies |
| | None | No studies could be found |

2.3.2.5 Data Extraction

Data extraction was conducted independently by two reviewers using a predesigned standardized form in Microsoft Word to collect key information from the included studies. Any discrepancies were resolved through discussion with additional reviewers.

When necessary, the authors of the included studies were contacted to clarify or provide missing data. Extracted information included study characteristics (i.e., authors, publication year, country, study design, and sample size), caregiver demographics (i.e., age, gender, and relationship to the woman with breast cancer), clinical characteristics of the women with breast cancer (e.g., cancer stage), and caregiver FCR-related information (i.e., measurement instruments used, prevalence, mean (M) and standard deviation (SD) of FCR, and factors identified as associated with caregiver FCR.

#### 2.3.2.6 Data Analysis

Due to the heterogeneity in study designs, sample characteristics, and identified risk factors across the included studies, a meta-analysis could not be performed. Instead, we provided a descriptive summary of study designs and sample characteristics. In addition to quality appraisal, we graded the overall body of evidence. The findings were synthesized using a best-evidence synthesis model (see lower part of Table 2.4) to classify potential risk factors. Although less commonly applied, this approach has gained recognition for its capacity to integrate both study quality and outcome consistency when drawing conclusions (Gomes & Higginson, 2006; Xing et al., 2013; Zhou et al., 2013). The levels of evidence were defined as follows. 'Strong evidence' indicates that further research is very unlikely to alter confidence in the estimated effect. 'Moderate evidence' suggests that additional studies may influence the level of confidence and could potentially change the results. 'Limited evidence' implies that further research is very likely to affect the findings. 'Conflicting evidence' reflects substantial uncertainty in the estimated effect. 'No evidence' denotes that no statistically analyzed or discussed factors were presented in the study. Additionally, a subgroup analysis was performed based on caregiver type (spouse/partner versus other types of caregivers) to explore possible differences in FCR across caregiver roles.

#### 2.3.2.7 Meta-Analysis

Statistical analyses were conducted using RevMan Version 5.3. Mean difference (MD) with 95% confidence intervals (CIs) was calculated using the generic inverse variance method, accommodating variations in measurement tools across studies. The prevalence of FCR was extracted from each eligible study. Standard error (SE) was calculated using the formula of $(P \times [1 - P]/n)^{0.5}$, where P is the prevalence and n is the sample size from the original studies. FCR prevalence and SE were then input into Revman 5.3 for analysis. Initially, a fixed-effects model was employed. Heterogeneity across studies was evaluated using the $I^2$ statistic and the chi-square test, with $p < 0.10$

considered statistically significant for heterogeneity. For the Interpretation of $I^2$, $I^2$ values of 0%–40% were regarded as not important heterogeneity, those of 30%–60% as moderate heterogeneity, those of 50%–90% as substantial heterogeneity and those of 75%–100% as considerable heterogeneity (Higgins, 2019). If the $I^2$ value exceeded 50%, a random-effects model was applied. Sensitivity analysis was performed by excluding one study at a time to assess the stability of the pooled estimate. Publication bias was not evaluated due to the small number of studies (n = 5) included in the meta-analysis (Dalton et al., 2016).

### 2.3.3 Results

#### 2.3.3.1 Search Results

A total of 2,137 studies were identified through the initial systematic search of eight electronic databases. An additional three records were retrieved through manual searching. After removing 735 duplicate entries, 1,405 records remained for title and abstract screening. Of these, 56 full-text articles were assessed for eligibility. Ultimately, 14 articles reporting 15 studies met the inclusion criteria and were included in this review (Figure 2.1). One article reported two studies with different study designs, sample sizes and assessment tools (Soriano, Pasipanodya, et al. 2018).

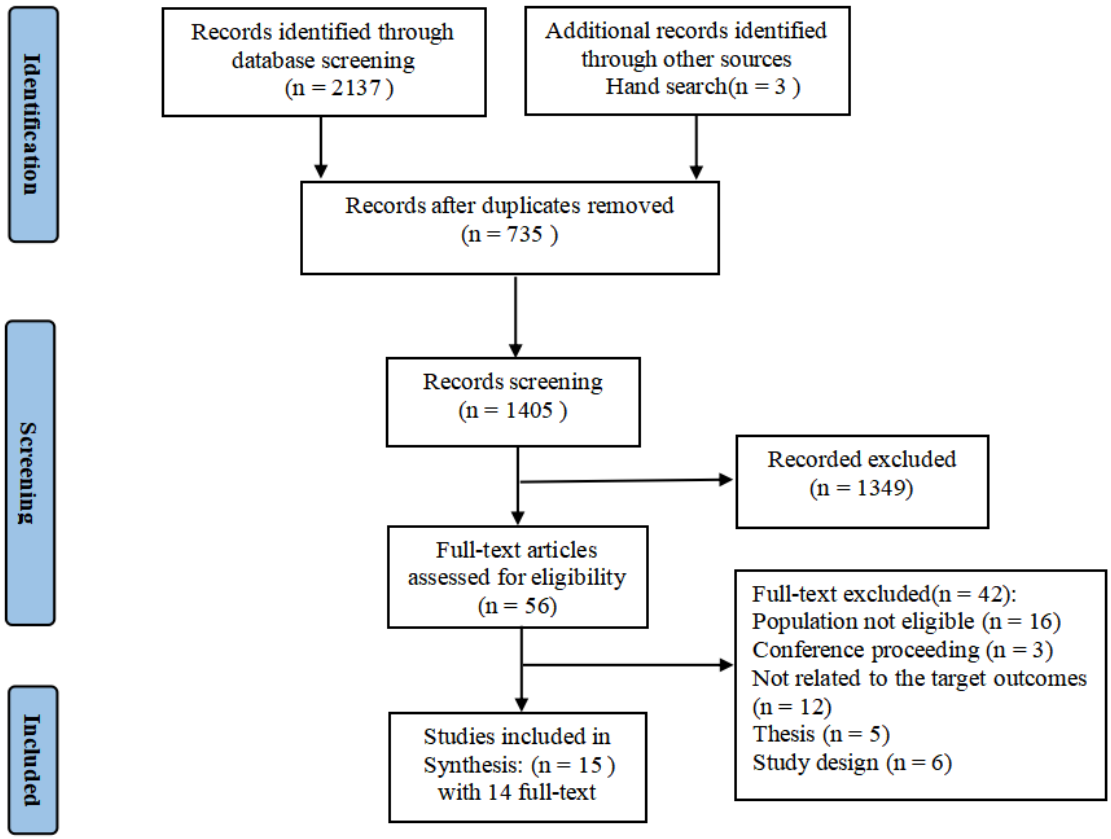


Figure 2.1 Flow diagram of the study selection procedure

2.3.3.2 Study Characteristics

Table 2.5 shows the characteristics of included studies. Of the 15 studies included in this review, five were conducted in China (Wang et al. 2021; Xia et al. 2023; Xu et al. 2019; Zhang, Hu et al. 2023; Zhang, Yu et al. 2023), nine in the United States (Boehmer et al. 2016; Cohee et al. 2017; Janz et al. 2016; Perndorfer et al. 2019; Soriano et al. 2021; Soriano, Perndorf et al. 2018; Soriano, Pasipanodya et al. 2018; Soriano et al. 2019) and one in Germany (Muldbücker et al. 2021). All studies were published between 2016 and 2023. The 15 studies involved 2461 eligible caregivers with sample sizes ranging from 46 to 510. Reported participation rates varied widely, ranging from 0.12 to 0.92. Almost all the studies focused on spouses or partners as caregivers. However, one study included other types of caregivers, such as other family members and friends (Boehmer et al. 2016). Five studies (Boehmer et al. 2016; Soriano et al. 2021; Soriano, Pasipanodya et al. 2018; Soriano et al. 2019; Janz et al. 2016) included

both male and female partners due to diversity in sex orientation. Three studies (Cohee et al. 2017; Perndorfer et al. 2019; Soriano, Perndorfer et al. 2018) did not report the gender of caregivers. One study included population with various cancer types but performed a subgroup analysis for caregivers of women with breast cancer (Muldbücker et al. 2021). All women with breast cancer were at cancer stages 0–IV.

Table 2.5 Characteristics of the included studies

| Author, year | Country | Study design | Sample size | Final sample size | Participation rate | Age (M ± SD) | Gender | Relationship to women with breast cancer | Cancer stage |
|---|---|---|---|---|---|---|---|---|---|
| Xu et al., 2019 | China | Longitudinal | 217 | 54 | 0.25 | 22–65 | Male | Spouses | I–III |
| Wang et al., 2021 | China | Cross-sectional | 237 | 214 | 0.90 | ≥25 | Male | Spouse | / |
| Xia et al., 2022 | China | Cross-sectional | 274 | 253 | 0.92 | / | Male | Spouse | I–IV |
| Zhang, Hu et al., 2023 | China | Cross-sectional | 350 | 332 | 0.95 | 25–74 (51.45 ± 8.76) | Male | Spouse | I–IV |
| Zhang, Yu et al., 2023 | China | Longitudinal | 224 | 192 | 0.86 | 18–75 | Male | Spouse | I–IV |
| Boehmer et al., 2016 | The USA | Cross-sectional | 297 | 167 (male = 43, female = 124) | 0.56 | Caregiver of heterosexual survivor: 62.4 ± 8, caregiver of sexual minority survivor: 55.8 ± 9.3 | Male and female | Spouse, partners, other family members and friends | In situ (ductal carcinoma) +I–III+ missing1 |
| Janz et al., 2016 | The USA | Cross-sectional | 774 | 510 | 0.66 | / | Inclusion criteria not | Partners | 0–III |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | limited by partner's gender | | |
| Cohee et al., 2017 ( | The USA | Cross-sectional | 397 | 222 | 0.37 | 30–75 | / | Partners | I–IIIa |
| Soriano, Perndorfer et al., 2018 | The USA | Longitudinal | 110 | 79 | 0.72 | / | / | Spouses | 0–III |
| Soriano, Pasipanodya et al., 2018 (1) | The USA | Cross-sectional (study 1) | 122 | 46 | 0.38 | 54.57 ± 13.31 | Male | Spouses | 0–IIIa |
| Soriano, Pasipanodya et al., 2018 (2) | The USA | Longitudinal study (study 2) | 463 | 72 (male = 70, female = 2) | 0.16 | 59.49 ± 10.34 | Male and female | Partners | 0–IIIa |
| Perndorfer et al., 2019 | The USA | Longitudinal | 271 | 69 | 0.25 | 58 ± 10 | / | Partners | 0–IIIa |
| Soriano et al., 2019 | The USA | Longitudinal | 353 | 57 | 0.12 | 60 ± 10 | Male and female | Partners | 0–IIIa |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Soriano et al., 2021 | The USA | Longitudinal | 270 | 79 (male = 77, female = 2) | 0.29 | 59.38 ± 10.39 | Male and female | Partners | 0–IIIa |
| Muldbücker, et al., 2021 | Germany | Cross-sectional | / | 115 | / | 52.9 ± 11.0 | Male | Partners | / |

2.3.3.3 Quality of Studies

A summary of the quality assessments of the included studies is presented in Table 2.6. Of the 15 included studies, three were rate as high quality, with one study had a quality score of 8 and two had a quality score of 7. The remaining 12 studies were assessed as moderate quality, comprising four studies with a score of 6, seven with a score of 5, and one study with a score of 4.

Table 2.6 Quality assessment results of the 16 reviewed studies in 15 published articles

| | ① | ② | ③ | ④ | ⑤ | ⑥ | ⑦ | ⑧ | ⑨ | Total score | Level |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Xu et al., 2019 | 0 | 1 | 2 | 0 | 0 | 0 | 0 | 1 | 0 | 4 | Moderate |
| Wang et al., 2021 | 1 | 1 | 0 | 1 | 0 | 1 | 1 | 1 | 1 | 7 | High |
| Xia et al., 2022 | 1 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 1 | 6 | Moderate |
| Zhang, Hu et al., 2023 | 1 | 1 | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 5 | Moderate |
| Zhang, Yu et al., 2023 | 1 | 1 | 2 | 0 | 1 | 1 | 1 | 1 | 0 | 8 | High |
| Boehmer et al., 2016 | 0 | 1 | 0 | 1 | 0 | 1 | 1 | 1 | 0 | 5 | Moderate |
| Janz et al., 2016 | 0 | 1 | 0 | 1 | 0 | 0 | 1 | 1 | 1 | 5 | Moderate |
| Cohee et al., 2017 | 0 | 1 | 0 | 1 | 0 | 1 | 1 | 1 | 0 | 5 | Moderate |
| Soriano, Perndorfer et al., 2018 | 0 | 1 | 2 | 0 | 1 | 1 | 0 | 1 | 0 | 6 | Moderate |
| Soriano, Pasipanodya et al., 2018 (①) | 0 | 1 | 0 | 1 | 0 | 1 | 1 | 1 | 0 | 5 | Moderate |
| Soriano, Pasipanodya et al., 2018 (②) | 0 | 1 | 2 | 0 | 0 | 1 | 1 | 1 | 0 | 6 | Moderate |
| Perndorfer et al., 2019 | 0 | 1 | 2 | 0 | 1 | 1 | 0 | 1 | 1 | 7 | High |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Soriano et al., 2019 | 0 | 1 | 2 | 0 | 0 | 1 | 0 | 1 | 0 | 5 | Moderate |
| Soriano et al., 2021 | 0 | 1 | 2 | 0 | 0 | 1 | 0 | 1 | 1 | 6 | Moderate |
| Muldbücker et al., 2021 | 0 | 1 | 0 | 1 | 0 | 1 | 1 | 1 | 0 | 5 | Moderate |

Note: ① Sample size ≥ 50 and participation rate ≥ 80%. ② For cohort and case–control studies: selected subjects were representative of the study population. For cross-sectional studies: inclusion criteria for caregivers were clearly defined, and subjects and settings were described in detail. ③ Cohort/longitudinal design with the duration of follow-up reported. ④ Case–control or cross-sectional design. ⑤ Withdrawals ≤ 20%. ⑥ A validated FCR assessment instrument was used. ⑦ Appropriate statistical analyses were used. ⑧ Multiple regression/multivariate analysis was performed. ⑨ Frequencies of caregiver FCR were reported.

2.3.3.4 Prevalence and Severity of Caregiver FCR

Detailed information regarding prevalence of and measurement tool assessing FCR of the included studies is presented in Table 2.7. Based on five studies reporting prevalence data, the proportion of caregivers experiencing significant level of FCR varied from 19% to 64.95% (Janz et al. 2016; Perndorfer et al. 2019; Soriano et al. 2021; Wang et al. 2021; Xia et al. 2023). In the United States, one cross-sectional and two longitudinal studies reported prevalence rates between 19% and 42.3% among partners of women with breast cancer (Janz et al. 2016; Perndorfer et al. 2019; Soriano et al. 2021). In contrast, two cross-sectional studies conducted in China reported higher rates ranging from 51.40% to 64.95% (Wang et al. 2021; Xia et al. 2023). The mean and/or SD of FCR scores were reported in the most studies (Boehmer et al. 2016; Cohee et al. 2017; Muldbücker et al. 2021; Perndorfer et al. 2019; Soriano et al. 2021; Soriano, Pasipanodya, et al. 2018; Soriano et al. 2019; Xia et al. 2023; Zhang, Hu et al. 2023). One study classified the trajectory of FCR into three categories, namely, late remission (32.8%), slow decline (50.5%) and persistent fear (16.7%) (Zhang, Yu et al. 2023). Across the studies, FCR was measured by using four different validated measurement

tools, including Fear of Progression Questionnaire—Short Form for Partner (Muldbücker et al. 2021; Wang et al. 2021; Xia et al. 2023; Zhang, Hu et al. 2023; Zhang, Yu et al. 2023), 22-item Fear of Cancer Recurrence Questionnaire (Boehmer et al. 2016), Concerns About Recurrence Scale (Cohee et al. 2017; Soriano et al. 2021) and Fear of Cancer Recurrence Inventory (Perndorfer et al. 2019; Soriano, Pasipanodya et al. 2018; Soriano, Perndorfer, et al. 2018; Soriano et al. 2019). One study (Soriano et al. 2021) used two measurement tools, whereas the other 14 studies used one tool to measure FCR in caregivers. Two studies applied non-validated tools. One used five items covering worries about the future, death, recurrence of cancer, diffusion of disease and treatment of cancer (Xu et al. 2019), while another study measured worry by one item 'how often they worry about the possibility that their spouse or partner's breast cancer might recur' on a 5-point Likert scale ('not at all' to 'a lot') (Janz et al. 2016).

Table 2.7 Outcome assessment tool and results

| Author | Assessment tool | Validated | Mean ± SD of FCR | Prevalence of FCR |
|---|---|---|---|---|
| Xu et al., 2019 | Adapted five items widely used in prior research: worries about the future, death, recurrence of cancer, diffusion of disease and treatment of cancer | × | 19.82 ± 17.77 | / |
| Xia et al., 2022 | FoP-Q-SF/P | √ | 34.3 ± 7.1 | 51.40% |
| Wang et al., 2021 | FoP-Q-SF/P | √ | 36.68 ± 10.21 | 64.95% (n = 139) had clinical FCR |
| Zhang, Hu et al., 2023 | FoP-Q-SF/P | √ | 18.48 ± 5.23 | / |
| Zhang,Yu et al., 2023 | FoP-Q-SF/P | √ | / | Late remission group (n = 63), slow descent |

| | | | | |
|---|---|---|---|---|
| | | | | group (n = 97), stable fear group (n = 32) |
| Boehmer et al., 2016 | 22-item Fear of Cancer Recurrence Questionnaire | √ | Caregiver of heterosexual survivors: 75.2 ± 13.6, caregiver of sexual minority survivors: 71.8 ± 16.5 | / |
| Janz et al., 2016 | Not validated; 'how often they worry about the possibility that their spouse or partner's breast cancer might recur' on a five-point Likert scale | × | / | 47.1% (n = 212) reported worry about recurrence |
| Cohee et al., 2017 | CARS | √ | 11.79 ± 5.02 | / |
| Soriano, Perndorfer et al., 2018 | Six items from the Distress, Insight and Severity subscales of the FCRI | √ | / | / |
| Soriano, Pasipanodya et al., 2018 (①) | Four-item Overall Fear subscale of CARS | √ | M: 3.18<br>between-person SD: 0.17 | / |
| Soriano, Pasipanodya et al., 2018 (②) | Used six items culled from the severity, distress and insight subscales of FCRI | √ | M: 1.51<br>between-person SD: 2.43<br>Within-person SD: 2.07 | / |
| Perndorfer et al., 2019 | Six items from the distress, insight and severity subscales of FCRI | √ | Mean: 1.43 | 39% (n = 27) reported clinical levels on the global FCRI-severity subscale |
| Soriano et al., 2019 | Six of the highest-loading items from FCRI | √ | 0.96 ± 1.78 | / |

| | | | | |
|---|---|---|---|---|
| Soriano et al., 2021 | Severity and distress subscales of FCRI; the overall fear subscale of the CARS | √ | / | 19% reported clinical levels of FCR at T1 |
| Muldbücker et al., 2021 | FoP-Q-SF/P | √ | 30.07 ± 8.2 | / |

Note: FoP-Q-SF/P: Fear of Progression Questionnaire-short form/partner; CARS: Concerns about Recurrence Scale; FCRI: Fear of Cancer Recurrence Inventory

2.3.3.5 Associated Factors of FCR

A detailed classification of the associated factors of FCR and the strength of evidence is presented in Table 2.8. A total of 29 factors were identified to be associated with high FCR in caregivers of women with breast cancer, with 10 were patient related and 19 were caregiver related. We further classified the 10 patient-related associated factors into five categories, namely, medical information, demographic information, psychological factors, psychosocial factors and relationship and the 19 caregiver-related associated factors into four categories, namely, demographic information, psychological factors, psychosocial factors and relationship.

Based on the synthesis of findings, five factors were identified with a moderate level of evidence, including one patient-related factor and four caregiver-related factors. Fifteen factors were supported by limited evidence, comprising four patient-related factors and 11 caregiver-related factors. Nine factors demonstrated conflicting evidence, including five patient-related and four caregiver-related factors.

2.3.3.5.1 Patient-Related Associated Factors

Among the patient-related factors, insufficient couple communication was identified as significantly associated with higher levels of caregiver FCR, supported by moderate evidence (Soriano, Perndorfer et al. 2018; Xu et al. 2019; Zhang, Hu et al. 2023). In addition, four factors, including comorbidities, responsiveness, and protective buffering, were found to be associated with higher caregiver FCR, though the supporting evidence

was at a limited level. For the remaining five patient-related factors, the evidence was conflicting, because it was supported by two or three studies (Table 2.8).

2.3.3.5.2 Caregiver-Related Associated Factors

Four caregiver-related associated factors were supported by moderate evidence: one psychological factor (i.e., resilience), two psychosocial factors (i.e., social constraints and protective buffering) and one relationship factor (i.e., communication). The findings indicated that a low level of resilience (Wang et al. 2021; Zhang, Yu et al. 2023), high social constraints (Cohee et al. 2017; Soriano et al. 2021; Soriano, Pasipanodya et al. 2018), high protective buffering (Perndorfer et al. 2019; Soriano et al. 2021) and insufficient couple communication (Soriano, Perndorfer et al. 2018; Xu et al. 2019; Zhang, Hu et al. 2023) were significantly associated with high FCR in caregivers. Eleven caregiver-related associated factors were supported by limited evidence because they were identified in only one high- or moderate-quality study. The evidence for the remaining four factors (i.e., age, comorbidities, social support and relationship quality) with caregivers FCR was graded as conflicting given that they were reported in two to four studies with significant and insignificant p values (Table 2.8).

Table 2.8 Summary of factors associated with high caregiver FCR

| Population | Group | Factors | Level of evidence | Modifiable | No. of caregivers in high-quality studies | No. of caregivers in moderate-quality studies |
|---|---|---|---|---|---|---|
| Patients | Medical information | Time since diagnosis | Conflicting | × | / | 282 (Boehmer et al., 2016; Muldbücker, et al., 2021) |
| | | Treatment | Conflicting | × | / | 677 (Boehmer et al., 2016; Janz et al., 2016) |
| | Demographic information | Comorbidities | Limited | × | / | 167 (Boehmer et al., 2016) |
| | | Age | Conflicting | × | / | 118 (Soriano, Pasipanodya et al., 2018) |
| | Psychological factors | FCR | Conflicting | √ | | 899 (Boehmer et al., 2016; Janz et al., 2016; Cohee et al., 2017) |
| | Psychosocial factors | Responsiveness | Limited | √ | | 79 (Soriano, Perndorfer et al., 2018) |
| | | Social constraints | Conflicting | √ | / | 118 (Soriano, Pasipanodya et al., 2018) |
| | | Protective buffering | Limited | √ | 69 (Perndorfer et al., 2019) | / |
| | Relationship | Communication | Moderate | √ | | 465 (Soriano, Perndorfer et al., 2018; Xu et al., 2019; Zhang, Hu et al., 2023) |
| | | Marital commitment | Limited | √ | | 253 (Xia et al., 2023) |

| | | | | | | |
|---|---|---|---|---|---|---|
| Caregivers | Demographic information | Age | Conflicting | × | 214 (Wang et al., 2021) | 625 ( Janz et al., 2016; Muldbücker, et al., 2021) |
| | | Caregiving time | Limited | × | 214 (Wang et al., 2021) | / |
| | | Residence | Limited | × | 192 (Zhang, Yu et al., 2023) | / |
| | | Comorbidities | Conflicting | × | 192 (Zhang, Yu et al., 2023) | 510 (Janz et al., 2016) |
| | | Race | Limited | × | / | 510 (Janz et al., 2016) |
| | | As primary caregiver | Limited | × | 192 (Zhang, Yu et al., 2023) | / |
| | Psychological factors | Resilience | Moderate | √ | 406 (Wang et al., 2021; Zhang, Yu et al., 2023) | / |
| | | Cognitive Processing | Limited | √ | / | 222 (Cohee et al., 2017) |
| | | Perceptions of positive information | Limited | × | / | 54 (Xu et al., 2019) |
| | | Depression | Limited | √ | / | 115 (Muldbücker et al., 2021) |
| | | Threat sensitivity | Limited | √ | / | 57 (Soriano et al., 2019) |
| | | Momentary negative affect | Limited | √ | / | 72 (Soriano, Pasipanodya et al., 2018) |
| | Psychosocial factors | Social support | Conflicting | √ | 192 (Zhang, Yu et al., 2023) | 677 (Boehmer et al., 2016, Janz et al., 2016) |
| | | Social constraints | Moderate | √ | / | 419 (Cohee et al., 2017; Soriano |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | et al., 2021; Soriano, Pasipanodya et al., 2018) |
| | | Protective buffering | Moderate | √ | 69 (Perndorfer et al., 2019) | 79 (Soriano et al., 2021) |
| | Relationship | Relationship quality | Conflicting | √ | / | 312 (Soriano, Pasipanodya et al., 2018, Soriano et al., 2021, Muldbücker et al., 2021)( |
| | | Responsiveness | Limited | √ | / | 79 (Soriano, Perndorfer et al., 2018) |
| | | Communication | Moderate | √ | / | 465 (Soriano, Perndorfer et al., 2018, Xu et al., 2019; Zhang, Hu et al., 2023) |
| | | Marital commitment | Limited | √ | / | 253 (Xia et al., 2023) |

#### 2.3.3.6 Subgroup Analysis by Caregiver Type

Although caregivers were broadly defined as relatives, partners, friends, or neighbors who had a close relationship with women with breast cancer, the included evidence predominantly reflected partners as 14 of the 15 included studies recruited partners. Only the study by Boehmer et al. (2016) included a mixed caregiver sample (i.e., spouse/partners, other family members, and friends). To examine whether this broader definition affected the applicability of the findings, a subgroup analysis was conducted by excluding this study. The subgroup analysis indicated that the key findings relevant to intervention development were robust. The number and level of evidence for the 19 caregiver-related factors remained unchanged. However, the evidence for three of the 10 patient-related factors was changed, with time since diagnosis and comorbidity factors shifted from limited to no evidence, while treatment shifted from conflicting to limited evidence. Consequently, the number of patient-related associated factors was reduced from 10 to eight in the subgroup analysis, with one moderate (communication), four limited (treatment, protective buffering, responsiveness and marital commitment) and three conflicting (age, social constraints and FCR) (Table 2.9).

Table 2.9 Patient-related factors in subgroup analysis by type of caregiver

| Population | Group | Factors | Level of evidence | Modifiable | No. of caregivers in high-quality studies | No. of caregivers in moderate-quality studies |
|---|---|---|---|---|---|---|
| Patients | Medical information | Time since diagnosis | None | × | / | |
| | | Treatment | Limited | × | / | 510 (Janz et al., 2016) |
| | Demographic information | Comorbidities | None | × | / | |
| | | Age | Conflicting | × | / | 118 (Soriano, Pasipanodya et al., 2018) |
| | Psychological factors | FCR | Conflicting | √ | | 732 (Janz et al., 2016; Cohee et al., 2017) |
| | Psychosocial factors | Responsiveness | Limited | √ | | 79 (Soriano, Perndorfer et al., 2018) |
| | | Social constraints | Conflicting | √ | / | 118 (Soriano, Pasipanodya et al., 2018) |
| | | Protective buffering | Limited | √ | 69 (Perndorfer et al., 2019) | / |
| | Relationship | Communication | Moderate | √ | | 465 (Soriano, Perndorfe et al., 2018; Xu et al., 2019; Zhang, Hu et al., 2023) |
| | | Marital commitment | Limited | √ | | 253 (Xia et al., 2023) |

2.3.3.7 Meta-Analysis on the Prevalence of Caregiver FCR

Five studies were included in the meta-analysis to estimate the prevalence of FCR among caregivers. The pooled prevalence of five studies was 45% (95% CI: 0.32 – 0.58) and showed substantial heterogeneity across studies ($I^2 = 93\%$, $p < 0.00001$) (Figure 2.2).

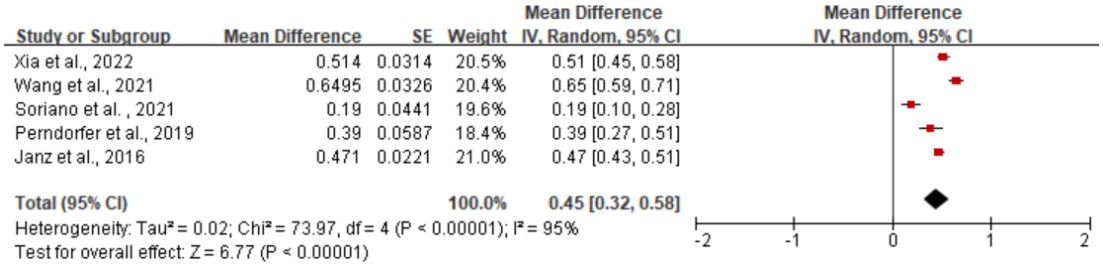


Figure 2.2 Forest plot of prevalence for caregiver FCR

Sensitivity analysis

Sensitivity analysis was conducted by sequentially excluding each study from meta-analysis. The pooled prevalence fluctuated between 39% (95% CI: [0.27, 0.52]) and 51% (95% CI: [0.42, 0.61]). Despite these fluctuations, the pooled effect sizes remained statistically significant across all iterations. This suggests that the overall prevalence estimate was robust and not unduly influenced by any single study.

2.3.4 Discussion

Caregivers experience a high level of uncertainty, often reporting FCR levels comparable to or even exceeding those patients with cancer (Webb et al. 2023). In this systematic review, the reported prevalence of FCR in caregivers of women with breast cancer ranged from 19% to 64.95% across individual studies (Janz et al. 2016; Perndorfer et al. 2019; Soriano et al. 2021; Wang et al. 2021; Xia et al. 2023). Our meta-analysis showed that the prevalence of caregiver FCR is 45%. This review also synthesized factors associated with high FCR in caregivers of women with breast cancer. Because of the limited number of primary studies and the heterogeneity in assessed

variables, most associations were supported by limited or conflicting evidence. Specifically, five factors were identified with moderate-level evidence, with one patient-related (communication) and four caregiver-related (resilience, social constraints, protective buffering, and communication). Meanwhile, 15 factors had limited evidence, and nine factors showed conflicting evidence.

#### 2.3.4.1 Patient-Related Factors

Poor couple communication emerged as the only patient-related factor with moderate-level evidence associated with high caregiver FCR. Women's expressions in response to negative information are readily perceived by their caregivers, thus contribute to increased partners' FCR (Xu et al. 2019). Obstacles may also exist between women with breast cancer and their caregivers; for instance, patients may conceal their fragile emotions from their families or avoid discussing their negative emotions, leading to insufficient communication. Consequently, the pressure on caregivers cannot be properly processed, and their level of concern about disease progression and prognosis gradually increases, thereby contributing to increased FCR level in caregivers (Zhang, Hu et al. 2023).

Other four patient-related associated factors, including comorbidities, responsiveness, protective buffering and marital commitment, were significantly associated with high caregiver FCR with limited evidence. Patients with multiple comorbidities may be too weak to fight against cancer, heighten caregivers' FCR. Patients’ responsiveness affected caregiver FCR as well. Caregivers disclose positive events to patients, and whether patients respond with interest or enthusiasm can influence their FCR levels. In caregivers, FCR was buffered when patients were perceived as responsive and interested. Protective buffering is the efforts to protect one's partner from distress and burden by concealing cancer-related concerns or avoid disagreements (Coyne & Smith, 1991). Both patients and caregivers may engage in protective buffering by avoiding

conversations about cancer or their worries to protect and reduce each other's distress and burden. They often find it stressful to share cancer-related concerns with friends or family because they do not want to upset them (Lai et al., 2019; Şengün İnan & Üstün, 2019). Women with breast cancer choose to protect their family members by withholding their concerns and carry the burden alone. Lastly, caregivers reported higher FCR when women with stronger marital commitment. This may be partly explained by the possibility that couples with better relationships care more about the impact of breast cancer on women's health than those with poorer relationships, thereby elevating caregivers' FCR.

#### 2.3.4.2. Caregiver-Related Factors

Among the caregiver-related factors, four were supported by moderate-level evidence. One psychological factor, namely low resilience, was significantly associated with high levels of FCR in caregivers. Resilience included both psychological and family resilience. Caregivers with higher levels of psychological resilience tend to report lower FCR. Studies have shown that psychological resilience could buffer the negative impact of stressful life events and promote acceptance of illness, facilitate adaptive coping and improve mental health (Zhang, Yu et al. 2023). In addition, family resilience was negatively correlated with FCR in partners. Families with high levels of family resilience were likely to respond positively to cancer events (Wang et al. 2021).

Two caregiver-related psychosocial factors, including social constraints and protective buffering, were supported by moderate level of evidence and were significantly correlated with caregiver FCR. Social constraint was a statistically significant predictor of high FCR in partners (Soriano et al. 2021; Soriano, Pasipanodya, et al. 2018). Numerous reasons account for partners' social constraints. First, some partners inhibit their disclosure of their experience because they thought it was inconsistent with their gender role (Hilton et al. 2000; Zahlis and Lewis 2010). Furthermore, similar with the

women, partners engage in protective buffering to spare their family members from worry, avoid conflict or protect women's feelings (Zahlis and Lewis 2010). Moreover, an unsupportive social environment, such as myths, misconceptions and beliefs about breast cancer, may contribute to gossip and stigmatization (Boamah Mensah et al., 2021; e Silva et al., 2010). All these reasons may limit partners' willingness to express. In addition, cognitive processing has been shown to mediate the relationship between social constraints and FCR in partners, suggesting that when caregivers feel constrained to discuss their experience, their processing of disease-related trauma is impeded (Cohee et al., 2017).

One relationship-related factor, insufficient communication, was identified as a moderate-level factor for caregiver FCR. Low intensity of communication contributing to increased FCR in caregivers probability because open communication and disclosure promote the relationship and intimacy between couples, which in turn enable couples to adapt to cancer and thereby reducing FCR (Manne & Badr, 2008). In addition, nine factors (five patient-related and four caregiver-related) demonstrated conflicting evidence, and 15 factors were supported by limited evidence. These findings highlight the need for future research to further examine and validate the relationships between these variables and caregiver FCR.

2.3.4.3. Strengths and Limitations

We conducted a comprehensive search, and all included studies were of high or moderate quality, employing cross-sectional and longitudinal designs. Best-evidence synthesis is useful to make clinical recommendations. Therefore, the results of this systematic review should be considered valid. Furthermore, the inclusion of studies from both Western and Asian countries, as well as caregivers of both heterosexual and sexual minority patients, greatly enhanced the generalizability of the review findings. However, this study has several limitations. First, the heterogeneity of measurement

tools to assess caregivers' FCR across the included studies limits the comparability of caregiver FCR amongst studies. Secondly, nearly all the caregivers included in the studies were partners or spouses of women with breast cancer. Only one study (Boehmer et al. 2016) examined other types of caregivers. Therefore, the evidence generated from this systematic review may limit to partners and cannot be extended to other types of caregivers, such as children and siblings.

#### 2.3.4.4 Implication

Identifying factors that contribute to FCR in caregivers of women with breast cancer is essential for informing the development of targeted interventions for those most in need and for mitigating FCR related adverse health outcomes. Future study may prioritize modifiable factors for intervention development. For example, communication, social constraints and protective buffering emerged as common modifiable associated factors of FCR in women with breast cancer and their caregivers. When people encounter social constraints on expressing disease-related concerns or issues, cognitive processing is impeded, and emotional distress intensifies. Similarly, protective buffering occurs when individuals suppress cancer-related discussions to protect and reduce other's distress and burden. Intervention fostering disclosure or and open communication between women with breast cancer and their caregivers promising for reducing social constraints and promoting protective buffering, thereby potentially decreasing FCR in patients and caregivers.

While this review offers valuable insights into factors associated with high caregiver FCR, future high-quality research with broader coverage of potential factors and rigorous statistical analysis are needed to estimate the effects of individual factors. Furthermore, considering the variations in social patterns, culture, value and family structure across different countries, researchers in other countries are encouraged to conduct similar studies because the current review only included studies from China,

the United States, and Germany, which may limit the generalizability of the findings to other cultural contexts.

### 2.3.4 Summary of findings

The prevalence of FCR among caregivers of women with breast cancer was 45%. This systematic review identified 29 factors associated with high levels of FCR in caregivers. Five were supported by moderate evidence, 15 by limited evidence and nine by conflicting evidence. Overall, caregivers who with lower level of resilience, greater social constraints, more protective buffering and insufficient communication tended to report higher FCR levels. Furthermore, caregivers tended to experience higher FCR if women with breast cancer had less communication. These findings highlight the need for targeted interventions that focus on modifiable factors such as resilience, communication, and emotional disclosure to reduce caregiver FCR and improve psychosocial outcomes. Results of the subgroup analysis on couple-based studies indicated that the key findings were robust. Specifically, the moderate-level factors associated with caregivers' FCR remained unchanged, including communication in women with breast cancer and, from partners, resilience, social constraints, protective buffering, and communication.

## 2.4 Summary of the chapter

A total of 7 seven common factors was found in both women and caregivers, including age, education, residence, cognitive processing, psychological morbidity, social support, social constraints. Social constraints was found to be a common factor of FCR among women and their partners in the two literature reviews on risk factors of FCR. Future studies may develop some dyadic intervention to reduce FCR by modifying social constraints through disclosure. Chapter 3 presents a systematic review and meta-analysis of the effectiveness of family involvement interventions on FCR management among women with breast cancer and their caregivers.

# CHAPTER THREE: A SYSTEMATIC REVIEW AND META-ANALYSIS

## 3.1 Introduction

This chapter presents a systematic review and meta-analysis of the effectiveness of family involvement interventions on FCR management among women with breast cancer and their caregivers, which has been published (Bu, Jiang, et al., 2025a). The results from RCT studies were reviewed and synthesized to generate evidence of the effectiveness of the intervention. This chapter is organized into six sections. Section 3.1 briefly introduces the chapter. Section 3.2 gives the background information of the review. Section 3.3 presents the methods, Section 3.4 presents the results, and Section 3.5 elaborates the discussion. Section 3.6 summarizes the chapter.

## 3.2 Background

Fear of cancer recurrence is one of the most frequently reported unmet needs in women with breast cancer (Fan et al., 2023) as well as a common unmet need among caregivers (Smith et al., 2022; Webb et al., 2023). FCR experienced by one family member can influence other members within the family. When caregivers have high levels of FCR, it may worsen patient outcomes by either heightening the patient's own worries about recurrence or by reducing the caregiver's capacity to provide effective support (Smith et al., 2022). This highlights the importance of viewing families as a system that may require supportive care. Many studies suggest addressing patients and caregivers together as a unit and offering joint support (Janz et al., 2016; Soriano et al., 2021). The family functions as a social system and serves as the main social nucleus for individuals (McCubbin et al., 1980; Yoshimochi et al., 2018). It plays a crucial role in the lives and well-being of patients, especially during times of illness when they are most vulnerable. Family strength is the ability to engage in family matters and exert coping capacity on the basis of strong and resilient cohesion in family members; such cohesion can be used to help families adapt to hardship and strain (Lee and Han 2024).

Family-based interventions include the participation or collaboration of family members within various intervention components, and this involvement influences the objectives and results of the intervention (Ali et al., 2023). Family involvement interventions have been applied to manage FCR in women with breast cancer, but findings were inconsistent, with some reporting significant positive results (Huang 2018; Zhang et al. 2019) while others found no significant impact (Northouse et al. 2005). Several reviews on FCR management exist, however, none have specifically examined the effect of family involvement interventions in women with breast cancer and their caregivers. Previous reviews addressing FCR in women with breast cancer showed positive outcomes but typically focused on patients and healthcare providers, excluding family members (Dawson et al., 2016; Lyu et al., 2022; Park & Lim, 2022). Other reviews on family involvement interventions mainly concentrated on outcomes such as relationships, overall quality of life, physical health, psychological health (e.g., anxiety, depression, well-being) and social adjustment rather than FCR management (Li et al., 2023). Research has shown that promoting family involvement can enhance patient outcomes (Mackie et al., 2018). Considering the high levels of FCR and its mutual influence between women with breast cancer and their caregivers, many studies advocate viewing them as an interdependent dyad to provide supportive cancer care (Boehmer et al. 2016; Janz et al. 2016; Soriano et al. 2021). Therefore, this systematic review and meta-analysis was performed to (1) provide high-quality evidence from existing family involvement RCTs on FCR for women with breast cancer and/or their caregivers; (2) comprehensively evaluate the effects of the RCTs on FCR in both women and/or their caregivers; (3) compare the effectiveness of different intervention components; and (4) identify future directions for family involvement interventions.

## 3.3 Methods

### 3.3.1. Design

This systematic review was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) 2020 statement

(Page et al., 2021) and was registered in the International Prospective Register of Systematic Reviews in 2023 (registration number: CRD42023480820).

### 3.3.2 Search strategies

Searches were performed across seven English-language databases (PubMed, Embase, the Cochrane Central Register of Controlled Trials, Web of Science, PsycINFO, Ovid and CINAHL) and three Chinese-language databases (CNKI, Wan Fang Data and Sinomed), from inception to October 24, 2023. Grey literature was not searched. Search terms included combinations of 'caregivers', 'breast cancer', 'recurrence', 'fear' and 'trial' applied as free-text and, where applicable, Medical Subject Headings (MeSH). An example of PubMed strategy is shown in Appendix I.

### 3.3.3 Eligibility criteria

Inclusion criteria followed the PICOS framework:

(1) Participants: women with breast cancer and their caregivers.

(2) Intervention: any intervention involving women with breast cancer and caregivers.

(3) Controls: any type of control group.

(4) Outcomes: FCR measured in women or caregivers or both.

(5) Study designs: randomised controlled trials.

Exclusion criteria:

(1) Studies without cancer type specification.

(2) Mixed cancer populations without breast cancer subgroup data.

(3) Lack of full-text availability.

### 3.3.4 Literature screening

Records from the searches were imported into an EndNote library (EndNote X9.1), and duplicates were removed. Remaining records were organized into an Excel spreadsheet (Microsoft, 2003). Two independent reviewers evaluated each study’s title, abstract,

and full text, excluding those that did not satisfy the predefined inclusion criteria. Any differences in judgment were settled through discussion or, when necessary, by consulting additional researchers.

### 3.3.5 Data extraction

Data extraction was completed by two reviewers (one reviewer extracted data from the included studies, and a second reviewer independently cross-checked the extracted data). Extracted data included study characteristics (country and sample size), participants details (caregivers' relationship to the patients and patients' characteristics, such as cancer type, age, stage and treatments and attrition rate), interventions (such as theoretical framework and detailed descriptions of the experimental interventions) and patients' and caregivers' outcomes and measurement tools used.

### 3.3.6 Risk of bias assessment

Two reviewers independently assessed the methodological quality of all included trials. Any disagreements were resolved through discussion or consultation with additional reviewers. The updated Cochrane risk-of-bias tool (RoB-2) was employed to evaluate the quality of the included RCTs (Higgins, 2019). This tool assesses five domains of bias, including 'risk of bias arising from the randomization process', 'risk of bias due to deviations from the intended interventions', 'missing outcome data', 'risk of bias in the measurement of the outcome' and 'risk of bias in the selection of the reported result'. Following the assessment, each study was classified into 'low risk of bias', 'high risk of bias', or 'some concerns'. The overall risk of bias for each study was then assigned accordingly.

### 3.3.7 Data analysis

Statistical analyses were conducted using RevMan Version 5.3. For continuous variables measured with different tools across studies, the standardized mean difference (SMD) and standard deviations (SDs) with 95% confidence intervals (CIs) were

calculated. A fixed-effects model was initially applied. Heterogeneity across studies was evaluated using $I^2$ statistics. For chi-squared test, a p-value < 0.10 was considered statistically significant, suggesting heterogeneity. $I^2$ values of 0%–40%, 30%–60%, 50%–90% and 75%–100% were regarded as not important, moderate heterogeneity, substantial heterogeneity and considerable heterogeneity, respectively (Higgins et al., 2019). If the $I^2$ value exceeded 50%, a random-effects model was used to summarize the evidence, under the assumption that the true treatment effects varied across studies due to difference in interventions, frequency, duration, numbers of sessions and measurement tools (Borenstein et al., 2010).

Subgroup analyses were conducted based on the characteristics of the interventions. P-values for between-group comparisons were calculated, with $P < 0.05$ considered statistically significant. Sensitivity analyses were conducted by sequentially excluding one study at a time to assess whether the overall results were influenced by any single study. For studies that were not comparable and could not be included in the statistical pooling were summarized narratively. Publication bias was not assessed because only six studies were included in the meta-analysis (Dalton et al., 2016).

## 3.4 Results

### 3.4.1 Search results

The initial search yielded 2,851 articles. After removing 545 duplicates, 2,306 titles and abstracts were screened. Of these, 29 full-text articles were assessed for eligibility, and seven studies met the inclusion criteria. The study selection process is illustrated in Figure 3.1.

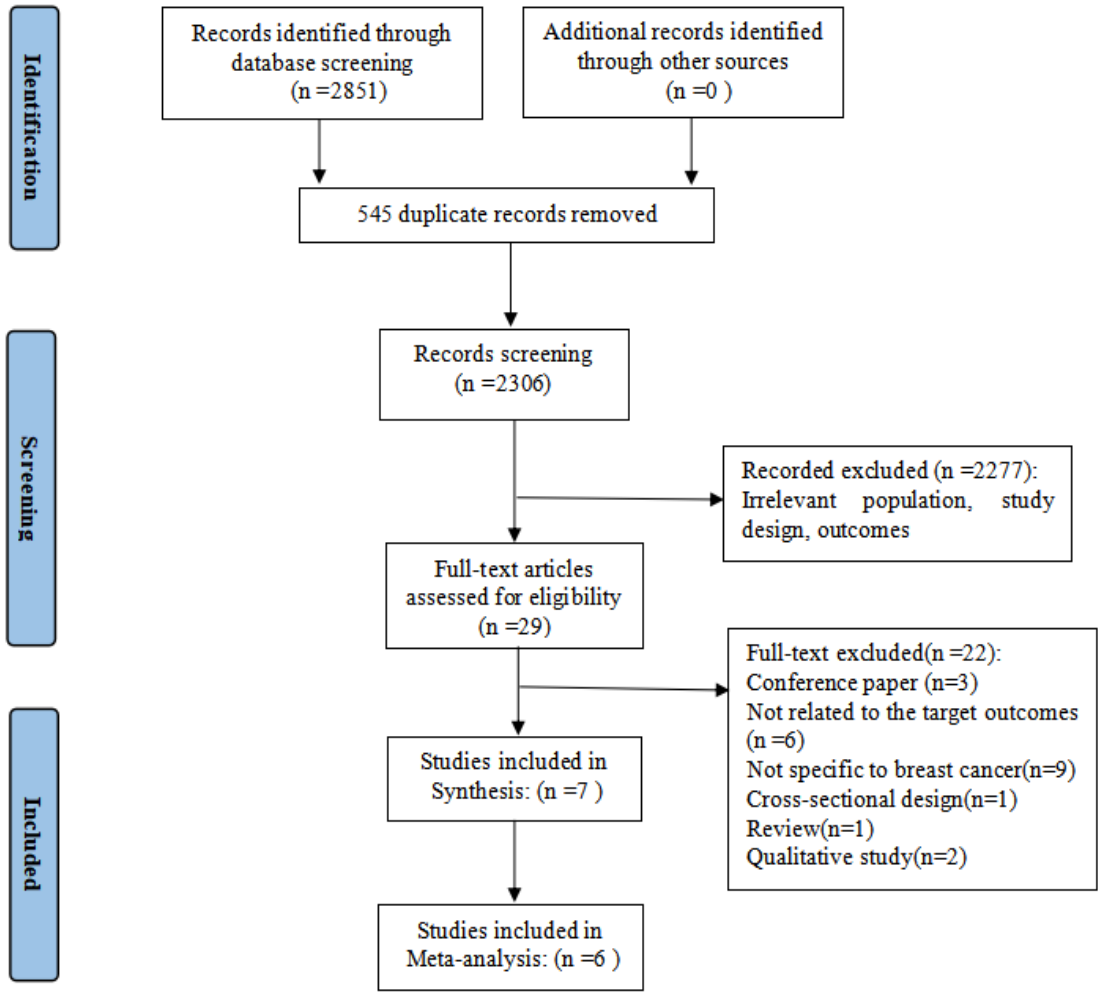


Figure 3.1 Flow diagram of study selection

3.4.2 Study characteristics and participants

Table 3.1 showed the details of the characteristics of the studies and included participants. Of the seven included studies, six were conducted in China and one in the USA. Together, these studies involved 610 women-caregiver dyads, with sample sizes ranging from 24 to 182 dyads. Four studies (Huang, 2018; Li & Zhu, 2022; Northouse et al., 2005; Tan, 2020) reported women's cancer stage (I–IV). Most of the women were undergoing chemotherapy. In the six Chinese studies, caregivers were exclusively spouses or partners, whereas the study in the USA involved family members as the caregivers. Reported dropout rates ranged from 0% to 24.18%. The mean ages of the women ranged from their thirties to fifties, whereas those of the caregivers ranged from their forties to fifties. Although family caregivers were involved in all interventions,

only one study (Northouse et al., 2005) reported outcomes for both women and their caregivers, whereas the remaining six studies reported outcomes for women only.

Table 3.1 Characteristics of the studies and participants in the seven included studies

| | | | Caregivers' characteristic | | | Patients' characteristic | | | |
|---|---|---|---|---|---|---|---|---|---|
| Author | Country | Research aim | Sample size of the dyads | Relationship | Age of caregivers (M ± SD) | Age of patients (M ± SD) | Stage of cancer | Treatments received by patients | Attrition (rate) |
| Northouse et al. 2005 | USA | To evaluate the effectiveness of a family-based intervention on quality of life and other psychosocial outcomes in patients with advanced breast cancer and their family caregivers | IG: 94, CG: 88 | Family member | 54.0 ± 11.0 | 52.0 ± 14.0 | III, IV | Chemotherapy or a combination of therapies, hormonal therapy alone, or bone marrow transplant | IG: 21, CG: 23 (24.18 %) |
| Huang, 2018 | China | To evaluate the effects of family synchronous cognitive therapy on recurrent fear, anxiety, depression and coping styles in patients with breast cancer | IG: 50 CG: 50 | Spouses | IG: 45.72 ± 11.28, CG: 46.15 ± 10.78 | IG:43.81 ± 8.17 CG: 44.45 ± 9.28 | I–IV | Undergoing chemotherapy | IG: 2; CG: 3 (5%) |
| Zhang et al., 2019 | China | To explore the effect of marital self-disclosure intervention on FCR in young patients with breast cancer | IG: 31 CG: 31 | Spouses | / | IG: 38.13 ± 4.39; CG: 37.87 ± 4.62 | / | Undergoing chemotherapy | IG: 1 (1.61 %) |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Tan, 2020 | China | To explore the effect of spouse's support education combined with strengthened psychological support on psychological resilience and fear of disease progression in patients with breast cancer | IG: 25<br>CG: 25 | Spouses | / | IG: 53.63 ± 2.15; CG: 53.89 ± 2. 11 | I–III | Undergoing chemotherapy or radiotherapy | 0 |
| Chen et al., 2022 | China | To explore the influence of self-disclosure intervention on the mood of patients with breast cancer | IG: 45<br>CG: 45 | Spouses | / | IG: 47.35 ± 8.39; CG: 48.69 ± 9.13 | I–IV | Undergoing chemotherapy | IG: 2 (2.22 %) |
| Li et al., 2022 | China | To explore the effects of conjugal self-disclosure therapy on cancer recurrence fear and marital quality in young patients with breast cancer | IG: 51<br>CG: 51 | Spouses | / | IG: 33.98 ± 10.13; CG: 34.76 ± 9.80 | / | Undergoing chemotherapy | 0 |
| Chen et al., 2023 | China | To analyse the effect of follow-up care based on structured family therapy on FCR and spousal sexual relations of postoperative patients with breast cancer | IG: 12<br>CG: 12 | Spouses | / | / | / | Undergoing surgery, chemotherapy, or radiotherapy | CG: 1 (4.17 %) |

IG: intervention group; CG: control group

### 3.4.3 Characteristics of the interventions

The key characteristics of the interventions are summarised and presented in Table 3.2.

#### 3.4.3.1 Contents of the interventions

Across the seven included studies, intervention content varied but generally comprised three main components delivered with differing intensities, including disclosure, psychological support, and education/counselling.

Disclosure is the expression of feelings, concerns, or experiences following a breast cancer diagnosis. Self-disclosure is communication by which one person reveals personal information to another. This information can be descriptive or evaluative, including thoughts, feelings, aspirations, goals, failures, successes, fears and dreams, and one's preferences (Ignatius & Kokkonen, 2007). Any intervention component that facilitated participants in expressing their feelings or thoughts was categorised as "disclosure." Psychological support aim to promotee and maintain an optimistic attitude, whereas education/counselling focused on coping strategies, symptom management and disease- or treatment-related knowledge. Disclosure was the most common component featured in six studies, except that by Tan et al. (2020), whose intervention incorporated psychological support and education/counselling.

Two studies focused primarily on disclosure between dyads by asking participants to share their feelings and concerns, with total disclosure time ranging from 160 to 300 minutes (Zhang et al., 2019; Chen et al., 2022). Except disclosure, Zhang et al. (2019) incorporated a Q&A session to allow participants to raise questions. Two studies employed education/counselling based on disclosure and provided education/counselling specific to their study populations (Chen et al., 2023; Li et al., 2022). Specifically, Li et al., (2022) integrated psychological support, and education on post-treatment self-care and disease progression into the intervention for those women undergoing chemotherapy. Meanwhile, Chen et al., (2023) incorporated sexual

functioning/relationship and counselling for couples with poor relationships.

Compared with interventions in four studies that were mainly based on disclosure, the intervention in Huang (2018) and Northouse et al. (2005) comprised a large proportion of psychological support and a small proportion of disclosure (i.e. some disclosure). The intervention in Northouse et al. (2005) mainly focused on education and psychological support, covering five core content areas: family involvement, optimistic attitude, coping effectiveness, uncertainty reduction and symptom management. Huang (2018) mainly delivered education on disease- and treatment-related knowledge and coping strategies for both patients and caregivers, incorporating a small proportion of disclosure by encouraging women to disclose.

Regarding the mode of disclosure, two studies adopted verbal and written disclosure (Li et al., 2022; Zhang et al., 2019), whereas the other four studies relied on verbal disclosure only (Chen et al., 2022; Chen et al., 2023; Huang, 2018; Northouse et al., 2005). In all studies, participants in the control groups received usual care for cancer management.

Only two studies had interventions that were formulated on the basis of theoretical frameworks, including family stress theory and positive psychology theory (Chen et al., 2022; Northouse et al., 2005).

3.4.3.2 Dosage of the interventions

The dosage of the included interventions was summarized according to amount, frequency and duration (Reed et al., 2007). Two studies did not provide detailed intervention dosages in terms of each session (Huang, 2018; Tan, 2020). In the remaining five studies, interventions were delivered weekly to monthly, with each session lasting 30 min to 1.5 hours. The total intervention period across the included studies ranged from three days to six months, with an estimated intervention duration

ranging from 150 min to 540 min totally.

#### 3.4.3.3 Delivery modes, formats and interventionists

The interventions were delivered through various modes, including face-to-face, WeChat, phone calls and video software. All six studies conducted in China adopted a couple-based approach, whereas that in the USA was family-based (Northouse et al., 2005). Four studies delivered interventions solely using a face-to-face format (Chen et al., 2022; Huang, 2018; Li et al., 2022; Tan, 2020), while the remaining three combined face-to-face sessions with phone calls, WeChat, or video software (Chen et al., 2023; Northouse et al., 2005; Zhang et al., 2019). Regarding venues, two studies conducted interventions through home visits (Chen et al., 2023; Northouse et al., 2005), while the other five studies took place in hospitals. Teaching and learning modalities included written materials, videos and interview outlines, with each study adopting a different combination of these modalities. All the interventions were delivered by nurses. Two studies (Chen et al., 2022; Chen et al., 2023) reported that the nurses received specific training for the study.

#### 3.4.3.4 Extent and nature of family involvement in included studies

The intervention delivery involved caregivers, rather than limited to women with breast cancer. Specifically, family members were involved through (1) joint attendance of intervention sessions, (2) dyadic disclosure (e.g., marital self-disclosure, responsiveness and supportive listening), (3) caregiver-targeted education/support (e.g., support education), and/or (4) family-based counselling/follow-up.

Table 3.2 Characteristics of the interventions in the included studies

| | Intervention group | | | | | | | | | | Control group |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Intervention component | | | | | | | | | |
| Authors | Theory | Psychological support | Disclosure | Education/counselling | Delivery mode | Teaching and learning modalities | Average time per session | Frequency | Duration | Interveners | |
| Northouse et al., 2005 | Family stress theory | √ | √ (Some disclosure) | √ | Face-to-face and phone calls | Home visit, phone calls | 1.5 h per visit, 30 min per call | Three home visits, monthly; two follow-up phone calls | Six months (330 min) | Nurses | Usual care |
| Huang et al., 2018 | / | √ | √ (Some disclosure) | √ | Face-to-face and WeChat | Lecture, video, WeChat | / | Five sessions, every three weeks | 15 weeks | Nurses | Usual care |
| Zhang et al., 2019 | / | | √ (Mainly disclosure) | | Face-to-face and telephone/WeChat | Interview outline | Verbal: 20–30 min, written: 20–30 min | Four sessions | 12 weeks (160–240 min) | Nurses | Usual care |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Tan., 2020 | / | √ | | √ | Face-to-face | Booklet | / | Every day | Three days (220 min) | Nurses | Usual care |
| Chen et al., 2022 | Positive psychology theory proposed by Seligman | | √ (Mainly disclosure) | | Face-to-face | Interview topic | 30–60 min | Five sessions, biweekly | Ten weeks (150–300 min) | Trained nurses | Usual care |
| Li et al., 2022 | / | √ | √ | √ | Face-to-face | Interview outline | Verbal: 25 min; written: 15–25 min | Four sessions | 12 weeks (160–200 min) | Nurses | Usual care |
| Chen et al., 2023 | / | | √ | √ | Face-to-face or video software | Home visit, interview outline | 1.5 h | Six sessions, weekly | Six weeks (540 min) | Trained nurses | Usual care |

### 3.4.4 Risk of bias of the studies

Seven RCTs were assessed using RoB-2 (Higgins, 2019). Table 3.3 shows the results of judgements of the individual risk of bias for each included study, presenting the worst-case scenario based on the outcome with the highest bias risk. Overall, one study was rated as having a high risk of bias (Northouse et al., 2005), while six studies were judged to have some concern (Chen et al., 2022; Chen et al., 2023; Huang, 2018; Li et al., 2022; Tan, 2020; Zhang et al., 2019).

For the domain of randomization, none of the studies reported details on allocation concealment. Two studies allocated participants using a random number table (Huang 2018; Tan 2020), three studies allocated participants according to their admission sequence (Chen et al., 2023; Zhang et al. 2019) or ward (Chen et al. 2022), and one study did not describe their allocation mechanism (Northouse et al. 2005).

For the deviations from the intended intervention domain, biases arise when deviations occur from the planned interventions. All studies were judged as having some concerns due to the absence of a protocol to assess whether the additional interventions were administered inconsistently with the trial protocol, failure to ensure that interventions were delivered as intended, or nonadherence by trial participants to their assigned intervention.

For the bias due to missing outcome data domain, one study was assessed as having a high risk of bias due to imbalances in missing data across groups and the absence of appropriate methods to address potential bias (Northouse et al. 2005). According to the Cochrane Handbook, a proportion of missing outcome data below 5% is generally considered small (Higgins et al. 2019). All other studies were rated as having some concerns.

With respect to the bias in outcome measurement domain, all included studies were

judged as having some concerns because the outcome assessment may have been influenced by knowledge of the intervention received. Furthermore, although all studies employed self-reported questionnaires, none reported whether the outcome assessors were blinded to group allocation (Chen et al. 2022; Chen et al., 2023; Huang 2018; Li et al., 2022; Northouse et al. 2005; Tan 2020; Zhang et al. 2019). One study used an electronic questionnaire (Chen et al., 2023), whereas three studies collected data face-to-face via questionnaires without reporting blinding (Chen et al. 2022; Li and Zhu 2022; Zhang et al. 2019). One study collected data using both an electronic questionnaire and a face-to-face questionnaire (Huang, 2018), whereas one study did not describe its data collection method (Tan, 2020).

For the bias in the selection of the reported result domain, all included studies were judged as having some concerns due to the absence of preregistered trial protocols (Chen et al. 2022; Chen et al., 2023; Huang 2018; Li et al., 2022; Northouse et al. 2005; Tan 2020; Zhang et al. 2019).

Table 3.3 Risk of bias of the RCTs

| Author | Randomisation | Deviations from the intended interventions | Missing outcome data | Measurement of the outcome | Selection of the reported result | Overall |
|---|---|---|---|---|---|---|
| Northouse et al., 2005 | Some concerns | Some concerns | High | Some concerns | Some concerns | High |
| Huang et al., 2018 | Some concerns | Some concerns | Low | Some concerns | Some concerns | Some concerns |
| Zhang et al., 2019 | Some concerns | Some concerns | Low | Some concerns | Some concerns | Some concerns |
| Tan., 2020 | Some concerns | Some concerns | Low | Some concerns | Some concerns | Some concerns |

| | | | | | | |
|---|---|---|---|---|---|---|
| Chen et al., 2022 | Some concerns | Some concerns | Low | Some concerns | Some concerns | Some concerns |
| Li et al., 2022 | Some concerns | Some concerns | Low | Some concerns | Some concerns | Some concerns |
| Chen et al., 2023 | Some concerns | Some concerns | Low | Some concerns | Some concerns | Some concerns |

3.4.5 Effects of Family Involvement Interventions

3.4.5.1 Study Outcome Assessment

Three different FCR scales were used to assess women's fear of cancer recurrence levels, namely Mishel's Uncertainty in Illness Scale (MUIS), the Fear of Progression Questionnaire-Short Form (FoP-Q-SF), and the Fear of Cancer Recurrence Inventory Chinese Version (FCRI-CV). For caregivers, only the MUIS was employed to assess FCR. All three scales have been validated. Table 3.4 summarizes the outcome measurement tools and key findings across the seven included studies. Notably, all studies measured outcomes immediately post-intervention, with no follow-up assessments conducted.

Table 3.4 FCR measurement tools and outcomes

| | Women with breast cancer | | | Caregivers | | |
|---|---|---|---|---|---|---|
| Author, year | FCR measurement | Assessment point | Key finding | FCR measurement | Duration | Key findings |
| Northouse et al., 2005 | MUIS | Post-intervention | FCR↓(P > 0.05) | MUIS | Postintervention | FCR↓ (P>0.05) |
| Huang et al., 2018 | FoP-Q-SF | Post-intervention | FCR↓ (P < 0.001) | / | / | / |
| Zhang et al., 2019 | FoP-Q-SF | Post-intervention | FCR↓ (P < 0.001) | / | / | / |
| Tan., | FoP-Q-SF | Post-intervention | FCR↓ (P < 0.05) | / | / | / |

| | | | | | | |
|---|---|---|---|---|---|---|
| 2020 | | | | | | |
| Chen et al., 2022 | FoP-Q-SF | Post-intervention | FCR↓ (P = 0.001) | / | / | / |
| Li et al., 2022 | FoP-Q-SF | Post-intervention | FCR↓ (P < 0.001) | / | / | / |
| Chen et al., 2023 | FCRI-CV | Post-intervention | FCR↓ (P < 0.05) | / | / | / |

MUIS: Mishel's Uncertainty in Illness Scale; FoP-Q-SF: Fear of Progression Questionnaire-Short; FCRI-CV: Fear of Cancer Recurrence Inventory Chinese Version

3.4.5.2 Women with Breast Cancer

3.4.5.2.1 Post-intervention

All seven studies reported a reduction in FCR among women after the intervention. In all the studies, except Northouse et al. (2005), the reductions in FCR were statistically and significantly greater in the intervention group compared to the control group. One study was excluded from the meta-analysis due to lack of reported mean and SD values for FCR (Tan 2020). Thus, six studies involving 503 women were included in the meta-analysis assessing the effectiveness of family involvement interventions on FCR levels immediately post-intervention (Chen et al. 2022; Chen and Qin 2023; Huang 2018; Li and Zhu 2022; Northouse et al. 2005; Zhang et al. 2019). Substantial heterogeneity was detected among these studies ($P < 0.0001$; $I^2 = 85\%$), leading to the use of a random-effects model. Figure 3.2 presents the meta-analysis results, which showed that family involvement interventions produced a significantly greater reduction in FCR among women with breast cancer immediately post-intervention compared to control groups (SMD = −0.79, 95% CI: [−1.27, −0.30], p = 0.001).

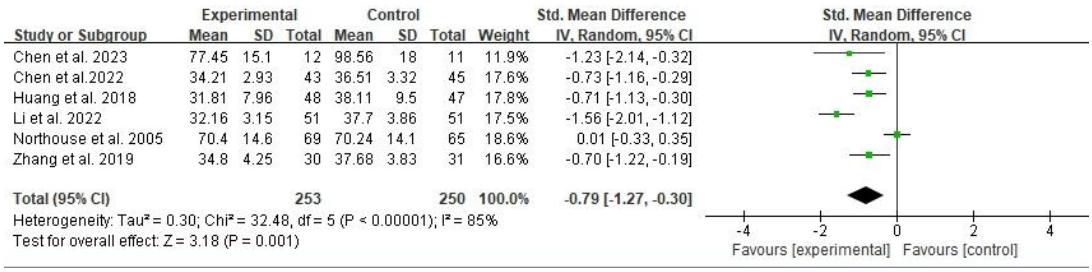


Figure 3.2 Effects of family involvement interventions on FCR in women with breast

cancer at post-intervention

3.4.5.2.2 Subgroup analysis by including studies involving women and their partners

As the caregivers in Northouse et al. (2005) were family caregivers rather than partners/spouses, a subgroup analysis was conducted by excluding this study and including only the five studies involving women with breast cancer and their partners. Consequently, five studies involving 369 women were included in the meta-analysis assessing the effectiveness of family-involvement interventions on FCR levels immediately post-intervention (Chen et al. 2022; Chen and Qin 2023; Huang 2018; Li and Zhu 2022; Zhang et al. 2019). Moderate heterogeneity was detected among these studies (P= 0.03; $I^2 = 69\%$), leading to the use of a random-effects model. Figure 3.3 presents the meta-analysis results, which showed that family involvement interventions produced a significantly greater reduction in FCR among women with breast cancer immediately post-intervention compared to control groups (SMD = −0.96, 95% CI: [−1.33, −0.59], $p < 0.0001$). Compared to intervention involving family caregivers, studies including partners generated larger effect size.

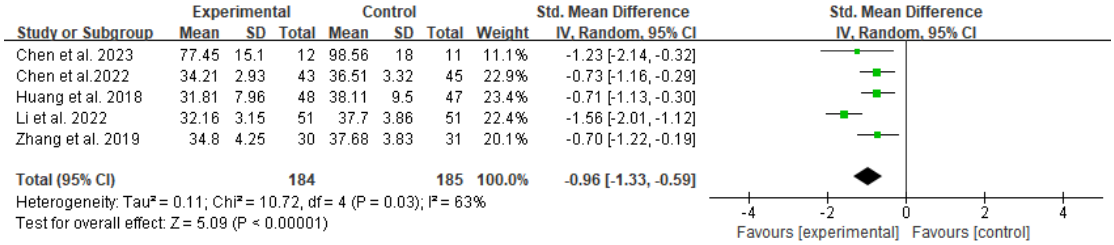


Figure 3.3 Effects of family involvement interventions on FCR in women with breast cancer at post-intervention

3.4.5.2.3 Subgroup Analysis by Intervention Component

All the six studies included in the meta-analysis incorporated a disclosure component in their interventions. Three subgroups were created for analysis based on the intensity of disclosure and additional components. Two studies involving 229 women with breast cancer that combined education/psychological support with some disclosure (Huang

2018; Northouse et al. 2005) showed substantial heterogeneity ($p = 0.008$; $I^2 = 86\%$). Two studies involving 149 women with breast cancer that employed solely disclosure between dyads (Chen et al. 2022; Zhang et al. 2019) showed no heterogeneity ($p = 0.95$; $I^2 = 0$) and the other two studies involving 125 women with breast cancer that used education/counselling based on disclosure content (Chen et al. 2023; Li et al. 2022) also showed no heterogeneity ($p = 0.52$; $I^2 = 0$). Therefore, a random-effects model was employed. Figure 3.3 presents the meta-analysis of three subgroups on FCR in women with breast cancer. The pooled results demonstrated that compared with usual care, education/psychological support plus some disclosure was ineffective (SMD = −0.34, 95% CI: [−1.05, 0.37], $p = 0.35$) and disclosure mainly had a moderate-to-large effect size (SMD: −0.72, 95% CI: [−1.05, −0.39], $p < 0.00001$), while disclosure based on education or counselling tailored to participants' specific needs showed an extremely large effect size (SMD: −1.50, 95% CI: [−1.90, −1.10], $p < 0.00001$). For the two RCTs in the third category of disclosure based on education or counselling, Li's (2022) study targeted patients with breast cancer undergoing chemotherapy and provided education on chemotherapy-related information. Meanwhile, in Chen et al.'s (2023) study, dyads with strained relationships related to sexual functioning received sexual counselling from a psychologist. The subgroup analysis revealed significant differences across subgroups ($p = 0.003$).

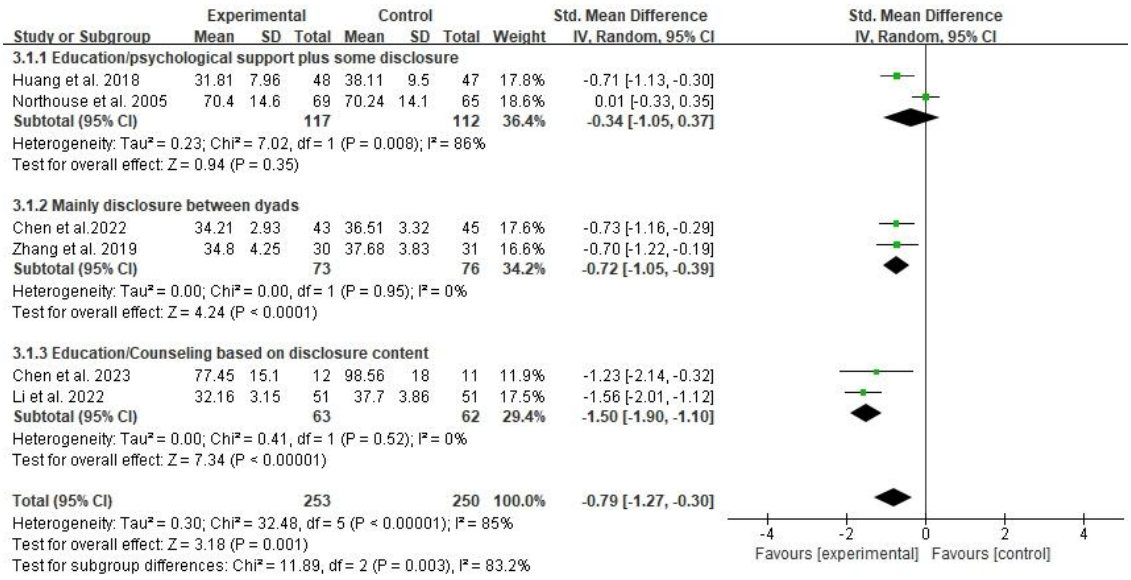


Figure 3.3 Effects of family involvement intervention on FCR in women with breast cancer at post-intervention in subgroups

3.4.5.2.3 Sensitivity Analysis

In the sensitivity analysis, which excluded one study at a time for the comparison between family involvement interventions and usual care at post-intervention, the pooled intervention effect ranged from -0.96 (95% CI: [−1.33, −0.59]) and -0.60 (95% CI: [−0.99, −0.20]). The pooled effect sizes remained significant in all cases, suggesting that the overall significant result was robust and not driven by any single study.

3.4.5.3 Caregivers

Only one study examined the effectiveness of a family involvement intervention on caregivers' FCR at post-intervention (i.e., at 6 months) (Northouse et al. 2005). Although the intervention group experienced a greater reduction in mean FCR scores at post-intervention (reduced by 5.39 points) than the control group (reduced by 2.6 points), the difference between groups was not statistically significant ($p > 0.05$).

## 3.5 Discussion

This systematic review is the first to evaluate the effectiveness of family involvement

interventions in alleviating FCR among women and their caregivers. FCR is prevalent and severe in both women and their caregivers, and the FCR levels in two parties can influence one another (Janz et al. 2016; Soriano et al. 2021). Seven studies were included in this review; although caregivers participated in all interventions, only one high-risk study reported FCR outcomes for caregivers (Northouse et al. 2005). However, the effectiveness of the intervention (i.e., education/psychological support plus some disclosure) in caregivers was insignificant, possibly because of the exclusion of data from dyads with patients in stage I and II cancers, as well as the loss of nearly 20% of participants to death before study completion. While attrition exceeding 20% is conventionally considered substantial (Higgins et al. 2019), a 20% attrition rate remains acceptable in metastatic breast cancer trials, where attrition has been reported to range from 9% to 53% (Nuzzolese & Montemurro, 2020). Moreover, the intervention in Northouse et al. (2005) may have provided insufficient time for caregivers to disclose and share fears and concerns, given its broad coverage of topics (e.g., coping, symptom management, education and psychological support) and was supplemented with a 17-page protocol manual, suggesting that increasing time for disclosure could enhance the effectiveness of such interventions for caregiver FCR. Overall, the reduction of FCR in caregivers of women with breast cancer remains markedly under-researched.

The meta-analysis demonstrated that family involvement interventions produced significant short-term reductions of FCR in women at post-intervention, with an overall moderate effect size of 0.70. Compared to intervention involving family caregivers, meta-analysis showed that studies including partners generated large effect size of 0.96. This evidence suggested that couple-based intervention may be particularly beneficial for reducing FCR in women with breast cancer, potentially because partners are usually the primary caregiver and couple-based interventions can directly target dyadic communication and shared coping processes. Subgroup analysis indicated that disclosure between women and their family members should be considered a core component for reducing FCR. Disclosure may alleviate barriers to emotional

expression in individuals who experience constraints on disclosure (Ignatius & Kokkonen, 2007), which could explain the observed beneficial effects of family involvement interventions. Literature consistently reported that people encounter difficulties in expressing emotions, particularly when facing social constraints (Soriano et al., 2021; Soriano, Pasipanodya, et al., 2018). Social constraints are negative social responses that can discourage people from discussing cancer, thereby potentially hindering cognitive processing and exacerbating emotional distress (Soriano et al. 2021). Social constraints on disclosure are one type of social constraints frequently reported in literature (Soriano et al., 2021; Soriano, Pasipanodya, et al., 2018). Women and their family members often experience social constraints on disclosure, making it difficult for them to express their true emotions and feelings (Soriano et al. 2021). They may conceal their worries, deny concerns and yield to their family members in an effort to avoid disagreement and alleviate their distress and burden (Manne et al., 2007). When such constraints are perceived, incomplete cognitive processing may occur, which has been associated with elevated FCR (Soriano et al. 2021). High heterogeneity was observed among the included studies. However, the minimal fluctuation in effect sizes and the consistent statistical significance across sensitivity analyses suggest that this heterogeneity is unlikely to be driven by any single study. Potential contributing factors include differences in intervention design (e.g., intensity, duration, delivery format), participant characteristics (e.g., age, cancer stage, treatment status), and outcome measurement tools. These factors warrant further investigation to clarify their role in explaining heterogeneity.

Six studies used disclosure, with five conducted in China showing promising results. This may be attributed to the Chinese cultural value of emotional suppression to maintain harmonious interpersonal relationships, which often creates barriers for people to express emotions and leads to reluctance in communication (Wang et al., 2020). Moreover, breast cancer in China is with culturally and historically stigmatization, frequently viewed as incurable and synonymous with a death sentence

(Wang et al. 2020). As a result, women and their caregivers tend to conceal cancer diagnosis to avoid stigma and refrain from discussing the disease with friends or family, as such disclosures might be seen as boasting or invite disapproval and lack of empathy (Wang et al., 2020; Zhu et al., 2012). Disclosure between women and their caregivers effectively addresses communication difficulties and creates a supportive environment. Talking with others may foster the cognitive processing of breast cancer-related experiences, particularly when met with supportive, receptive, or nonjudgemental social responses. Conversely, unsupportive or critical reactions may diminish these benefits. Empathic and supportive social networks help people maintain or rebuild a positive self-concept by validating their experiences and affirming that they are loved and esteemed. However, additional rigorous RCTs are needed to strengthen these findings because all the included studies in the meta-analyses had methodological limitations, including unclear random sequence generation, allocation concealment, masking of outcome assessors and inappropriate analysis of missing outcome data. One study rated as high risk (Northouse et al. 2005) and six rated as some concerns (Chen et al. 2022; Chen et al. 2023; Huang 2018; Li et al. 2022; Tan 2020; Zhang et al. 2019),

The current meta-analysis revealed that combining disclosure with education or counselling tailored to participants' specific needs resulted in an extremely large, pooled effect size in reducing FCR in women. This finding indicates that disclosure supplemented with cancer related education or support could further strengthen the effect of the intervention. Incorporating components focused on healthy lifestyles, such as physical exercise and nutrition, may help develop interventions applicable for a broad range of women with breast cancer and their caregivers. Supplementary education on healthy lifestyles may further enhance the intervention effect. First, by providing dyads with accessible knowledge that they can easily understand to increase their topics during disclosure. Second, increased exercise and healthy dietary can reduce illness representation and the risk of cancer recurrence in patients with breast cancer (Chlebowski et al., 2006; Jochems et al., 2018). Since cancer has a chance to

recur in all the cancer patients and survivors, in addition to medical treatment, healthy lifestyles, such as physical activity and healthy dietary can also reduce cancer recurrence risk. Physical activity substantially alters whole body homeostasis. Every cell and organ in the whole body might be ultimately affected by the biological perturbation induced by physical activity and exercise (Hong & Lee, 2020). Besides, physical activity can reduce side-effects and symptoms from cancer treatment, slow age-related declines in physical function and improve emotional well-being (Misiąg et al., 2022). In addition to physical activity, evidence also shows that healthy diet can reduce cancer recurrence. A low-fat diet, a diet rich in fruit and vegetables and a prudent diet are beneficial for breast cancer survivors, while a Western diet is detrimental for breast cancer survivors (Jochems et al., 2018). A lifestyle intervention was shown to reduce dietary fat intake may improve relapse-free survival in breast cancer patients receiving conventional cancer management (Chlebowski et al., 2006)(. Therefore, incorporating healthy lifestyle components with disclosure can be potentially strengthen the impact on reducing FCR as well as the chance of cancer recurrence. These benefits may subsequently alleviate FCR in women and their caregivers.

The interventions were delivered via mainly a face-to-face format or through a combination of face-to-face format with telephone calls, WeChat or video software. Given the widespread availability of smartphones and the Internet access, technology-based delivery could offer greater flexibility in timing and location, which is particularly beneficial for caregivers who often face financial constraints and work obligations that limit their ability to attend in-person sessions. Internet-based intervention programmes for caregivers of older adults could improve mental health outcomes (Sherifali et al., 2018). This suggests that exploring the feasibility and effectiveness of technology-based interventions for cancer patient–caregiver dyads is warranted. Further research should examine interventions with the most appropriate mode and intensity for their sustainability to achieve long-term effects. In addition, none of the studies in this review assessed the long-term effects of family involvement

interventions for FCR alleviation in women and their caregivers.

### 3.5.1 Limitations

This review has several limitations. Firstly, most studies exhibited methodological shortcomings, such as unclear sequence randomization, inadequate allocation concealment, absence of blinding for the data collectors and inappropriate analysis of missing outcome data. These issues may have introduced bias into the pooled meta-analysis results. Secondly, only two included study explicitly adopted theoretical framework, which restricts our ability to identify proposed mechanisms of change, compare interventions on common theoretical constructs, and explain between-study heterogeneity. Future family-involvement interventions for FCR should be theory-informed and transparently reported (e.g., specifying the framework, targeted constructs, and hypothesized pathways). Thirdly, most of the studies were conducted in China limited the generalizability of the review findings to other cultural or healthcare settings. This geographic concentration likely reflects publication and retrieval dynamics, including coverage of major Chinese databases and Chinese-language dissemination, the inclusion criterion requiring explicit family caregiver participation, whereas many FCR interventions elsewhere are evaluated primarily at the patient level; and contextual features of care delivery in China, where family members often assume a central caregiving role that may facilitate implementation of family-involvement interventions. Fourthly, one study was excluded from the meta-analysis because it did not report the mean and standard deviation of FCR scores. Attempts to obtain this information from the authors were unsuccessful due to the absence of contact details. The missing data may have influenced the accuracy of the pooled effect estimates. Finally, publication bias was not assessed, as fewer than 10 studies were included.

### 3.5.2 Implications for Practice

This review demonstrated that family involvement interventions can produce substantial short-term effects in FCR among women. Therefore, these interventions

may be recommended for delivery to patient–caregiver dyads as part of supportive care strategies to improve FCR in women in practice. In all included studies, the interventions were delivered by nurses, highlighting that nurses can play a promising role in the administration of FCR interventions. Given their frequent and direct contact with patients and caregivers, nurse-led interventions are highly likely to be integrated into routine clinical practice. To maximize effectiveness, nurses should further develop skills in patient and caregiver education, as well as in establishing strong therapeutic relationships, to facilitate intervention delivery. As caregivers often assume long-term home care responsibilities, determining the most effective ways to implement and sustain such interventions remains an important area for exploration. In this review, most of the interventions were delivered face-to-face when the women underwent treatment. Not many studies were delivered through home visits, WeChat, telephone calls, and video software. This limits flexibility and accessibility for caregivers who face time and financial constraints. Therefore, future clinical practice should consider combining face-to-face delivery with technology-based formats to offer more flexible and acceptable options.

### 3.5.3 Implications for Research

Given the methodological limitations identified in the included studies, future RCTs should adopt more rigorous designs. As the studies in this review were conducted only in China and the USA, further research in diverse cultural and healthcare settings is warranted to enhance generalizability. Another important gap is the absence of follow-up assessments in all studies, making it impossible to determine the long-term effectiveness of family involvement interventions. Additionally, although caregivers often experience high levels of FCR, only one study in this review measured caregiver outcomes. Current family-involvement interventions remain largely patient-centered in terms of outcome evaluation. Therefore, the available data are insufficient to draw robust conclusions about caregiver-specific effects. More studies on caregivers' FCR are needed. This evidence gap is particularly important for partner, who are typically

the primary caregivers for women with breast cancer. Since FCR in women with breast cancer and their caregivers can influence one another, future research could adopt a dyadic perspective or directly address FCR in caregivers, as recommended by previous studies (Janz et al. 2016; Soriano et al. 2021; Boehmer et al. 2016). Given that physical activity and a healthy dietary have been shown to reduce cancer recurrence, future studies may explore interventions that combine disclosure with education on these behavioral components, such as physical activity and healthy dietary, to reduce FCR from a family perspective. These components can reduce FCR by helping patients and caregivers to perceive a low risk of cancer recurrence in patients and generate topics for disclosure.

### 3.6 Chapter summary

The review findings suggest that family involvement interventions, particularly coupled-based and those using integrating disclosure with education or counselling tailored to participants' specific needs, can produce substantial short-term reductions in FCR among women with breast cancer. In contrast, evidence for their effectiveness in caregivers remains limited, with only one included study showing no significant benefit. The main contents of effective family involvement interventions included disclosure, education/psychological support plus some disclosure and education/counselling based on disclosure content. This study showed that interventions encompassing disclosure combined with education or counselling and those mainly including disclosure produced promising effects to reduce FCR in women. Further high-quality RCTs on family involvement for women with breast cancer and/or their caregivers with follow-ups are encouraged to generate adequate evidence. Chapter 4 presents the theory framework and intervention development of the doctoral study.

# CHAPTER FOUR: THEORETICAL FRAMEWORK AND DEVELOPMENT OF INTERVENTION

## 4.1 Introduction

This chapter presents the theoretical framework and conceptual framework used to guide the development of the intervention. Simonelli's integrative model for FCR, the findings from the literature reviews on factors associated with FCR in women with breast cancer and their caregivers presented in Chapter Two, and the results of the systematic review and meta-analysis on the effectiveness of family involvement interventions in women with breast cancer and their caregivers presented in Chapter Three, were all used to inform the development of the intervention.

This chapter is organised into five sections. Section 4.1 provides an introduction to the chapter. Section 4.2 presents Simonelli's integrative model, including the rationale for selecting the model, an overview of its theoretical constructs and the targeted factors within the model. Section 4.3 outlines the conceptual framework used to guide the development of the family support programme. Section 4.4 details the development of the intervention programme. Finally, Section 4.5 provides a summary of the chapter.

## 4.2 Theoretical framework and Development of the intervention

### 4.2.1 Definition for theoretical framework

The theoretical framework is defined as an explicit, named set of selected theory (or theories) that provides an established explanation of relevant phenomena and relationships, and thereby structures how the study is approached "philosophically, epistemologically, methodologically, and analytically." Thus, the theoretical framework consists of the selected theory (or theories) that undergirds the thinking with regards to how to understand and plan to research the topic, as well as the concepts and definitions from that theory that are relevant to the study (Grant & Osanloo, 2014). The theoretical framework is used to (a) justify the study rationale and research questions, (b) specify theoretically grounded mechanisms, and (c) guide the choice of constructs/variables

and the logic of interpretation (Grant & Osanloo, 2014). So, in this study, we used Simonelli's integrative model as the theoretical framework.

### 4.2.2 Simonelli's integrative model for FCR

In this study, the integrative model for FCR proposed by Simonelli et al. (2017) was adopted to guide the development of the intervention. This integrative model was derived from a review of six theories on FCR, namely the self-regulation model of illness (Lee-Jones et al., 1997), the self-regulatory executive functioning model (Butow et al., 2015), a family-based model (Mellon et al., 2007), uncertainty in illness theory (Mishel, 1990), social-cognitive processing theory (Baum & Andersen, 2001) and terror management theory (Greenberg et al., 1994). These theories share several overlapping components; thus, key elements were selected to form a more parsimonious model for understanding the mechanisms underlying FCR (Simonelli et al., 2017; Figure 4.1). The integrative model postulates that FCR is triggered by specific cues, which are processed and appraised cognitively, with two sets of factors, environment and person -related, modulating this cognitive processing and appraisal. All the six theories included in the integrative model have been used in adults with cancer and their caregivers (Guan et al., 2023; Lewis, 2017; Mellon et al., 2007; Rashmi & Vanlalhruaii, 2023; Soriano et al., 2021; Zhang et al., 2024), providing evidence to support the applicability of the model in guiding this study. A brief account of each of the six theories on FCR is provided below.

#### 1) The self-regulation model of illness

The self-regulation model of illness proposes that individuals develop cognitive and emotional representations of their illness, which guide coping behaviours and appraisal of outcomes (Lee-Jones et al., 1997). This model suggested that personal factors, such as illness representations, one's predispositions, past coping styles and family concerns could contribute to the degree of FCR. The model highlights the dynamic feedback loop between illness-related appraisals, coping strategies, and subsequent emotional

adjustment, which may contribute to the persistence of FCR over time (Lee-Jones et al., 1997)

2) Self-Regulatory Executive Function model

The Self-Regulatory Executive Function (S-REF) model explains persistent emotional distress through maladaptive patterns of metacognitive processing and attentional control. People may have excessive worry and rumination, heightened threat monitoring, and unhelpful coping strategies such as avoidance and repeated reassurance seeking. In FCR, individuals may hold positive beliefs about worry (e.g., “worrying helps me stay prepared”) or negative beliefs about uncontrollability of worry (e.g., “I cannot stop worrying”), which reinforces ongoing threat-focused processing. As a result, people may remain hypervigilant to internal and external cues associated with recurrence, increasing anxiety and maintaining FCR. This model provides a theoretical basis for interventions that target metacognitive beliefs (personal factor), reduce threat monitoring, and strengthen attentional flexibility and emotional regulation (Lawrie, 2000).

3) Family-based model

Family-based models conceptualise cancer-related distress as a shared experience embedded within the family system rather than occurring solely at the individual level (Mellon et al., 2007). Personal characteristics, such as having a younger partner, existing health conditions, simultaneous family stressors, and how cancer is interpreted, significantly shaped both survivors' and partners' experiences of FCR. Within this framework, FCR may be shaped by how couples interpret cancer-related cues, respond to uncertainty, and engage in supportive or avoidant interactions. This perspective supports couple- or family-oriented interventions aimed at enhancing appraisal of the meaning of cancer.

4) Uncertainty in illness theory

The uncertainty theory focused on how people cognitively process and apprasial illness-related stimuli and construct meaning in these events (Mishel, 1990). In line with this perspective, breast cancer survivors often experience uncertainty about recurrence and long-term treatment-related side effects. Physical symptoms (such as pain) and learning about someone else's cancer diagnosis are the two most frequent triggers of this uncertainty. This theory provides a rationale for interventions that reduce physical symptoms to faciliatate their apprasial of their disease.

5) Social-cognitive processing theory

Social-cognitive processing theory suggests that environment factors (e.g.,social constraints) affect FCR through how people cognitively process their experience. When people feel constrained to disclose concerns or lack supportive responses from significant others, they may experience social constraints that inhibit cognitive processing of cancer experience, maintaining intrusive thoughts, avoidance, and FCR. This theory provides a rationale for interventions that reduce social constraints by promoting disclosure and supportive communication to faciliatate their cognitive processing of cancer-related experiences (Lepore & Revenson, 2007). This theory has been used to guide studies for couples coping with breast cancer (Soriano etal., 2021; Soriano, Perndorfer, et al., 2019).

6) Terror management theory

Terror management theory suggests that becoming aware of one's mortality can trigger existential anxiety, which individuals manage through psychological defences that protect self-esteem and sustain meaning and cultural worldviews (Zanna & Olson, 2015). TMT may provide a more comprehensive framework for understanding the triggers of FCR, adaptive and maladaptive defense responses, as well as the occasionally unhelpful behaviors shown by individuals within a person's support

network.

### 4.2.1 Rationale for selecting Simonelli's integrative model for FCR

There are several reasons for selecting Simonelli's integrative model on FCR as the theoretical framework in the study. Firstly, the literature review presented in Chapter Two identified social constraints on disclosure as a modifiable factor contributing to heightened FCR, common to women with breast cancer and their partners, which was supported in the subgroup analysis by including studies on partners. When either party experiences constraints in discussing breast cancer–related issues, they are less likely to process the trauma associated with the disease effectively (Cohee et al., 2017). This may lead to intrusive thoughts and avoidance behaviours, thereby increasing FCR. Thus, targeting social constraints on disclosure for both parties is expected to reduce FCR simultaneously. Additionally, women's illness representation is one of the risk factors of their FCR identified from Chapter 2. Physical activity and healthy dietary can reduce illness representation (or physical symptom and treatment side effects) and the risk of cancer recurrence, which can reduce their FCR by reducing their perception of cancer recurrence risk. Chapter 3 showed that subgroup analysis showed couples-based intervention was effective in reducing women's FCR with large effect size, and interventions encompassing disclosure combined with education or counselling and those mainly including disclosure produced promising effects to reduce FCR in women. Therefore, the guiding model should incorporate social constraints on disclosure and physical activity and healthy dietary as a central concept for developing an effective intervention aimed at reducing FCR through open disclosure and education.

Secondly, the guiding model should be developed specifically for cancer adjustment rather than relying on general frameworks, such as the family stress model (Conger et al., 1992) because the postulated mechanisms need to be directly relevant to the cancer context. Specifically, given the marked differences between various diseases and their treatments, a cancer diagnosis and its subsequent treatment can profoundly and

sometimes permanently reshape an individual's life. The prospect of death is salient at diagnosis, while the threat of recurrence generates enduring concerns. Furthermore, treatments are often invasive and painful, frequently resulting in long-term adverse effects.

Thirdly, the theoretical framework should emphasise the importance of including patients with cancer and their partners to reduce social constraints on disclosure through open communication. At the same time, it should identify potential factors or mechanisms, such as alleviating physical symptoms or treatment-related side effects, which are modifiable and can contribute to reducing FCR.

A detailed description of the mechanisms of FCR within the integrative model is provided below.

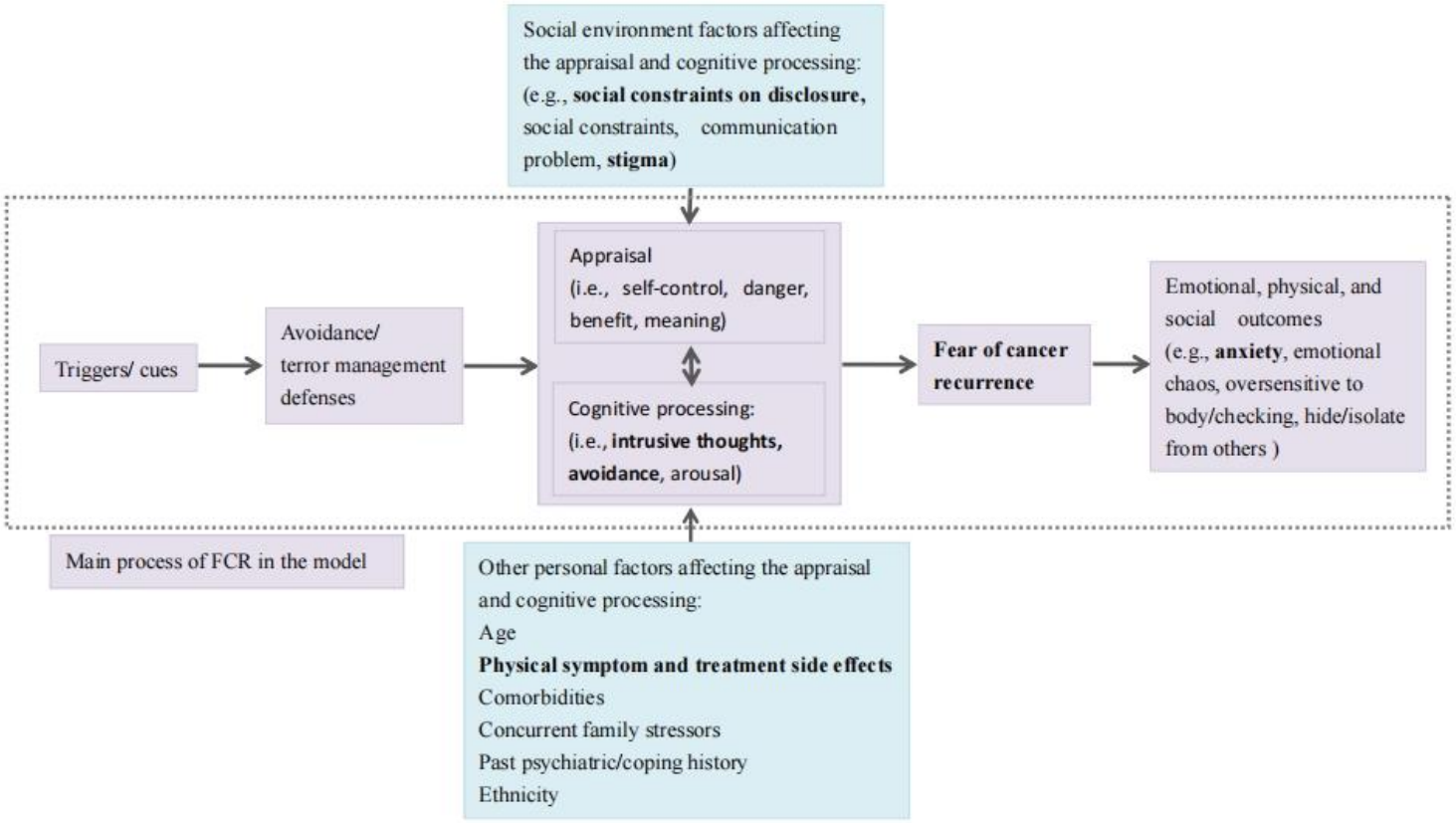


Figure 4.1 Integrative model for FCR adapted from Simonelli et al. (2017)

#### 4.2.2.1 Main cognitive processing and appraisal procedure of FCR

a. Triggers or cues

Triggers or cues are considered the starting point of the main cognitive processing and appraisal procedure in this integrative model. Triggers are inevitable in life and include external triggers, such as hearing others discuss breast cancer, the attitudes of those around them, life stressors and medical follow-ups, in addition to internal triggers, such as treatment-related memories, long-term effects of breast cancer treatment, hormone therapy and lifestyle changes (Şengün İnan & Üstün, 2019). These cues activate FCR-related cognitive schemas and are interpreted through an appraisal process. For example, treatment side effects may be perceived as a reminder of the original breast cancer or as a possible symptom of recurrence (Simonelli et al., 2017).

b. Avoidance or terror management defences

Cues and triggers can be prevented or filtered through terror management defences, which are of two types: proximal and distal. Proximal defences are implemented rapidly after explicit mortality reminders to suppress death-related thoughts, distract attention and rationalise the problem (Kosloff et al., 2019; Simonelli et al., 2017). In this stage, people do not focus on thoughts of death, nor do they deny their physical vulnerability; instead, death-related thoughts may increase at an unconscious level, activating distal defences. Distal defences are engaged when individuals exhibit thoughts and behaviours aimed at symbolic transcendence of death. They mobilise psychological resources to foster a sense of personal connection to forms of immortalising heroism. If cues and triggers cannot be avoided or filtered through these terror management defences, they proceed to the cognitive processing and appraisal stage (Kosloff et al., 2019).

c. Cognitive processing and appraisal

FCR cues that cannot be avoided or filtered by defenses enter the cognitive processing

and appraisal stage. Cognitive processing involves efforts to integrate a stressful or traumatic event into existing mental models (also referred to as schemas) of the self, others and the world (Lepore, 2001). This processing is characterised by alternating cycles of intrusion, where unbidden thoughts and images of the event enter consciousness, and avoidance behaviours, which involve attempts not to think about the event (Lepore, 2001). Intrusive thoughts arise from attempts to incorporate trauma-related information into existing cognitive schemas and indicate incomplete cognitive processing. They can stimulate cognitive processing by bringing aspects of the trauma into consciousness. However, incomplete cognitive processing may persist, contributing to high FCR. Although intrusions can be adaptive, they are distressing and may lead individuals to rely on avoidant coping to prevent emotional overwhelm when confronted with trauma reminders.

d. FCR

Through this process, individuals may achieve meaningful appraisal and emotional acceptance, which can ease trauma-related distress. Disclosure and communication with others may facilitate cognitive processing of traumatic experiences. Benefits are realised when conversations are met with supportive, receptive and non-critical social responses, but not when responses are unsupportive, unreceptive or critical. Supportive, empathic social networks help individuals maintain or re-establish a positive self-concept by validating their experiences and affirming their worth. Conversely, unsupportive or critical social networks impede cognitive processing and adjustment (Lepore & Revenson, 2007). Disclosing stressful experiences in negative or only partially supportive contexts can heighten psychological distress, such as FCR. Attempts to suppress thoughts tend to prolong intrusive thoughts.

e. Emotional, physical and social outcomes

Once FCR is aroused, it can contribute to emotional outcomes (e.g. emotional turmoil and anxiety), physical outcomes (e.g. heightened bodily vigilance and frequent

checking) and social outcomes (e.g. hiding from or isolating oneself from others; Şengün İnan & Üstün, 2019).

#### 4.2.2.2 Factors affecting the main procedure

In brief, the integrative model postulates that cues and triggers of FCR are interpreted through a cognitive processing and appraisal procedure, producing coping responses that vary in their adaptiveness. When FCR cues cannot be avoided or filtered out by defenses during cognitive processing and the appraisal stage, the model further posits that this appraisal and processing mechanism can be influenced by two sets of factors: social environmental factors (i.e. social constraints, social constraints on disclosure and stigma) and personal contextual factors (i.e. physical symptoms, treatment side effects, financial issues and medical follow-up).

##### a. Social environmental factors

##### Social constraints

People encounter social constraints when they are compelled by others to regulate, restrict or modify their thoughts, feelings or actions. Social constraints are objective, external conditions, for example, the ways others act, think or feel, which shape an individual's experience (Durkheim & Catlin, 1966). Lepore and Revenson (2007) described social constraints as arising from social facts and individuals' interpretation of them. Social constraints represent negative social responses to the disclosure of cancer-related experiences. Such responses can influence how individuals communicate about and appraise their illness and relationships, thereby affecting their adaptation to cancer. Both overt reactions (e.g. criticism and urging a person to suppress worry) and subtle cues (e.g. visible discomfort) can prompt avoidance of cancer-related discussion or thoughts, impeding cognitive processing and heightening emotional distress. Many factors shape social constraints, one of which is social networks. People with cancer typically disclose first to healthcare professionals, then to family and friends. For instance, a person with cancer may choose to share concerns and worries

with a partner but withhold them from children to protect them from anxiety (Lepore & Revenson, 2007).

### Social constraints on disclosure

Social constraints on disclosure arise from social conditions (i.e. others' criticism, denial or withdrawal) that lead individuals to feel unsupported, misunderstood or alienated when seeking help or attempting to express themselves (Lepore & Revenson, 2007). A previous study has shown that perceived increased constraints on the disclosure of cancer-related concerns on a given day and failure to fully express thoughts can result in incomplete cognitive processing, which in turn increases FCR (Soriano, Pasipanodya, et al., 2018).

### Intrusive thoughts

The presence of intrusive thoughts reflects that cognitive processing of the traumatic event remains unresolved. By forcing trauma-related content into conscious awareness, these thoughts can prompt further cognitive engagement with the experience. They can present as emotional memories, flashbacks, nightmares or unwanted images (Lindgren et al., 2013). Intrusive thoughts are unpleasant memories or ideas that frequently occur in an individual's everyday thinking, often preventing them from focusing on other matters, and are typically triggered by stress or anxiety. Individuals experiencing intrusive thoughts may interpret them as indicators of actual risk, leading to negative appraisals of their health. These interpretations can reinforce the belief that cancer recurrence is imminent, potentially resulting in high levels of FCR. A recent study found that cognitive processing, including intrusive thoughts and avoidance, mediated the relationship between social constraints and FCR in both women with breast cancer and their partners, identifying intrusive thoughts and avoidance as key mechanisms through which interpersonal barriers contribute to heightened and prolonged FCR (Cohee et al., 2017).

## Avoidance

Avoidance is a core component of cognitive processing during the cancer experience, referring to the suppression or disregard of or disengagement from cancer-related thoughts, emotions, conversations or situations. Avoidant coping strategies have been associated with poor well-being and health outcomes (Kvillemo & Bränström, 2014). A recent cross-sectional study demonstrated that family avoidance of discussing cancer is dyadically linked with FCR in couples coping with breast cancer. An individual's avoidance of communication about cancer was correlated with their own FCR and that of their partner (Zhao et al., 2024). Additionally, avoidance has been reported as the one of mediating factors between social constraints and FCR (Cohee et al., 2017). For instance, in individuals diagnosed with cancer, perceived social constraints may promote avoidance of cancer-related thoughts and discussions. Deliberate efforts to suppress these thoughts can paradoxically extend the persistence of intrusive cognitions and intensify psychological distress. Furthermore, avoidance may limit opportunities to habituate to cancer-related cues, obtain alternative viewpoints from others, and construct meaning around the illness or life following cancer.

## Stigma

Not only do women with breast cancer experience stigmatisation but also their family members may face discrimination and social rejection (Wang et al., 2020; Yeung et al., 2019). Stigma is defined as the co-occurrence of its components: labelling, stereotyping, separation, status loss and discrimination (Link & Phelan, 2001). Individuals associated with women with breast cancer, such as family members, friends and service providers, may be subjected to stigmatization from the public as well. Affiliate stigma refers to the internalisation of stigma by primary caregivers, based on the public's negative perceptions (Zhang et al., 2018). Research has shown that high levels of stigma may prompt women with breast cancer to disclose their cancer experiences to others, thereby reducing intrusive thoughts (Tsai et al., 2019). Women with breast cancer may feel greater ambivalence about emotional expression if they experience more social

constraints arising from higher levels of self-stigma because they may feel less comfortable disclosing their distress (Tsai et al., 2019).

b. Personal factors

Contextual factors, including age, physical symptoms, treatment side effects, comorbidities, concurrent family stressors, psychiatric or coping history and ethnicity, can influence the perception of cues or triggers that cannot be avoided or filtered by defensive mechanisms during the cognitive processing and appraisal stage of FCR (Anderson et al., 2021; Cho et al., 2018; Han et al., 2024; Simonelli et al., 2017). For example, if a woman with breast cancer hears someone describe the disease as fatal (a trigger) and is unable to filter this cue through defensive strategies, the cue enters cognitive processing and appraisal procedure, resulting in an increase in FCR. Similarly, if she is currently experiencing severe treatment side effects, such as pain and fatigue, she may interpret these symptoms as indicative of cancer recurrence, which amplify the magnitude of her FCR.

### 4.2.3 Applicability of the model to partners of women with breast cancer

This integrative model is applicable not only to women with breast cancer but can also be adapted for their partners. Partners experience the same cognitive processing and appraisal procedure of FCR when exposed to certain cues or triggers. These cues may trigger uncertainty, and if they cannot be avoided or filtered out, they initiate the cognitive processing and appraisal procedure, potentially resulting in heightened FCR. The cognitive processing and appraisal in partners are influenced by two sets of factors: environment and patient related. For example, if partners are aware that the women has a larger tumour compared with other patients, they may perceive it as a considerable threat and ruminate on it, thus showing increased level of FCR. Furthermore, if partners experience social constraints on disclosure (an environmental-related factor) or the patient reports severe pain and fatigue (a patient-related factor), these circumstances may further amplify the intensity of FCR in the partners.

4.2.4 Reasons for selecting social constraints on disclosure and physical symptoms and treatment side effects.

This study selected social constraints on disclosure and physical symptoms/treatment-related side effects as two key modifiable factors for intervention development. Within Simonelli's integrative model, these factors are theorised to influence FCR by shaping individuals' opportunities for cognitive processing and appraisal of the cancer experience. Importantly, both factors are relevant to women with breast cancer and their partners, supporting a couple-based intervention.

a. Social constraints on disclosure in women with breast cancer

The literature has documented several reasons why women with breast cancer experience social constraints on disclosure. Firstly, FCR can be highly stressful to discuss with friends and family, as women often seek to avoid upsetting them (Lai et al., 2019; Şengün İnan & Üstün, 2019). To protect their families, women may refrain from discussing FCR, bearing the burden alone. They may also attempt to conceal their cancer diagnosis to minimise its impact on family life and maintain a harmonious atmosphere. Such concerns often contribute to feelings of loneliness and silent suffering (Lai et al., 2019). In addition, myths, misconceptions and causal beliefs surrounding breast cancer frequently lead to gossip and societal stigma (Boamah Mensah et al., 2021; e Silva et al., 2010). Close relatives and acquaintances may respond differently, sometimes with discomfort, upon learning of the diagnosis (Nasiri et al., 2016; Zahlis & Shands, 1991). Furthermore, breasts are commonly regarded as symbols of physical and sexual attractiveness and femininity, so mastectomy can have substantial psychological consequences. Accordingly, women may feel constrained in expressing their cancer-related thoughts or worries. Finally, the type and severity of the disease, along with treatment side effects, can strongly influence both the extent and nature of social constraints experienced by women with breast cancer (Badr & Taylor, 2006).

b. Social constraints on disclosure in partners

Previous studies have identified several reasons why partners of women with breast cancer may experience social constraints on disclosure. Firstly, some partners refrain from discussing their experiences because they perceive such disclosure as inconsistent with their gender role; instead, they keep their feelings private (Hilton et al., 2000; Zahlis & Lewis, 2010). They may also avoid sharing their concerns to prevent burdening others or because they believe others would not understand (Zahlis & Lewis, 2010). Moreover, similar to women with breast cancer, partners may seek to avoid causing worry or conflict within the family or to protect the woman's feelings (Zahlis & Lewis, 2010). They often feel the need to remain strong at all times to support the women (Zahlis & Lewis, 2010). In addition, an unsupportive social environment can exacerbate these constraints. Myths, misconceptions and causal beliefs about breast cancer frequently generate gossip and societal stigma (Boamah Mensah et al., 2021; e Silva et al., 2010), and close relatives and acquaintances may behave differently or even uncomfortably upon learning of the diagnosis (Nasiri et al., 2016). Collectively, these factors may contribute to partners feeling constrained in expressing themselves to their loved ones with breast cancer.

c. Physical symptoms and treatment side effects

Physical symptoms/treatment-related side effects is another modifiable factor for intervention development. Within Simonelli's integrative model, physical symptoms/treatment-related side effects may intensify recurrence-related threat appraisals in both women and partners. For example, people may appraisal physical symptoms/treatment side effects (fatigue, pain, sleep disturbance, and functional limitations) as a sign of cancer recurrence, thereby exacerbating FCR. Evidence indicates that physical activity and healthier dietary patterns are associated with improved breast cancer prognosis. Physical activity can reduce side-effects and symptoms from cancer treatment and alters whole body homeostasis (Misiąg et al., 2022; Hong & Lee, 2020). Reducing dietary fat intake may improve relapse-free

survival in breast cancer patients receiving conventional cancer management (Chlebowski et al., 2006). Therefore, incorporating educational components on healthy lifestyle to support symptom management and perceived cancer control which may influence FCR.

In summary, within the integrative model, social constraints and physical symptoms or treatment side effects are two key modifiable factors for intervention development. The model posits that the social environment can either facilitate or inhibit cognitive processing and appraisal of the cancer experience in both women and their partners. Social constraints on disclosure are evident in Chinese individuals because of cultural values. In Chinese culture, the norm of emotional suppression to maintain interpersonal harmony creates barriers to expressing emotions and may lead to reluctance in communicating personal concerns (Wang et al., 2020). When social constraints are perceived, individuals tend to avoid thinking or talking about cancer-related thoughts and feelings, especially with the person associated with those emotions. Social constraints on disclosure adversely affect cognitive processing and appraisal processes. One manifestation of incomplete cognitive processing is prolonged intrusive thoughts about cancer, which can contribute to elevated FCR. Regarding physical symptoms and treatment side effects, the severity of the cancer and associated treatments can significantly influence FCR levels in patients and their partners (Kim et al., 2012; Lebel et al., 2013). When the physical symptoms or treatment side effects are severe, patients and partners may appraise the cancer as serious or perceive a high likelihood of recurrence, leading to heightened FCR. Therefore, either women with breast cancer or their partners may benefit from open disclosure within the dyad, as well as providing education on physical activity and healthier diet. Interventions involving both parties are particularly well-suited to reduce inhibited disclosure because they can effectively address social constraints on communication in both individuals (Soriano et al., 2021).

### 4.3 Development of the intervention programme

### 4.3.1 Theoretical base of the intervention development

The meta-analytic results presented in Chapter Three revealed that none of the studies employing family involvement interventions has reported FCR outcomes in partners of women with breast cancer. In addition, the included studies were generally of low quality. According to the updated MRC Framework for developing and evaluating complex interventions (Skivington et al., 2021), Phase I corresponds to intervention development and identification. The key steps in this phase involve exploring the research evidence and relevant theory underpinning the problem. In this doctoral study, the intervention protocol was developed using four sources: 1. Simonelli's integrative model for FCR, which posits that social constraints on disclosure and treatment side effects or physical symptoms are major modifiable factors influencing the main cognitive processing and appraisal procedure in FCR; 2. factors associated with FCR in women and partners, as reported in Chapter Two, identified social constraints as a modifiable factor common to women with breast cancer and their partners. As a core construct in the integrative model, it was therefore selected as a major component of the intervention; 3. meta-analytic evidence on family involvement interventions for FCR management among women with breast cancer and their caregivers, as presented in Chapter Three, provided an evidence base regarding intervention effectiveness, dosage, frequency, content and delivery medium; 4. disclosure content and educational materials, which were developed with reference to published studies (Chen et al., 2022; Li et al., 2022; Zhang et al., 2019). Education on physical activity and healthy dietary practices followed the *Guidelines and Norms for Diagnosis and Treatment of Breast Cancer* issued by the Breast Cancer Professional Committee of the Chinese Anti-Cancer Association (2021).

The drafted intervention comprised two components designed to alleviate FCR by targeting the appraisal and cognitive processing mechanisms outlined in the integrative model: (1) disclosure between the couples, which involves the sharing of feelings, thoughts, life changes and coping strategies related to breast cancer diagnosis and its

impact and (2) education on healthy lifestyle, which includes guidance on physical activity and healthy dietary practices aimed at mitigating treatment side effects and improve sense of cancer control for women, with support from their partners. As illustrated in Figure 4.2, the intervention primarily emphasises couple-based disclosure regarding emotions, lifestyle adjustments and coping strategies after diagnosis. Simultaneously, it provides education on recommended physical activity and healthy dietary practices for cancer managementand improve sense of cancer control. Moreover, physical activity and healthy dietary content are intentionally positioned as a brief educational content rather than an individualized behaviour change programme because FCR is a psychological outcome. The lifestyle component is included to support survivorship self-management by addressing symptom burden (e.g., fatigue) and enhancing sense of cancer control, which may influence recurrence-related appraisal and worry. The anticipated outcomes of the intervention include reductions in FCR, social constraints, intrusive thoughts, avoidance, anxiety and stigma among couples coping with breast cancer as shown in the conceptual framework in Figure 4.3. The conceptual framework is defined as the study's integrated system of concepts and assumptions that supports and informs the research design. Maxwell describes the conceptual framework as "the system of concepts, assumptions, expectations, beliefs, and theories that supports and informs your research" (Maxwell, 1996). In addition, Miles and Huberman's widely cited operationalisation defines a conceptual framework as a visual or written product that explains the key factors/constructs/variables to be studied and "the presumed relationships among them" (Miles & Huberman, 1994). The conceptual framework functions as the overarching structure that aligns (a) the research problem and purpose, (b) focal constructs and their hypothesised relationships, and (c) methodological and analytic choices; it is treated as a dynamic, sense-making structure that is refined as the study is developed and executed. In this study, the conceptual framework is the relationship between the family support programme and the outcome variables.

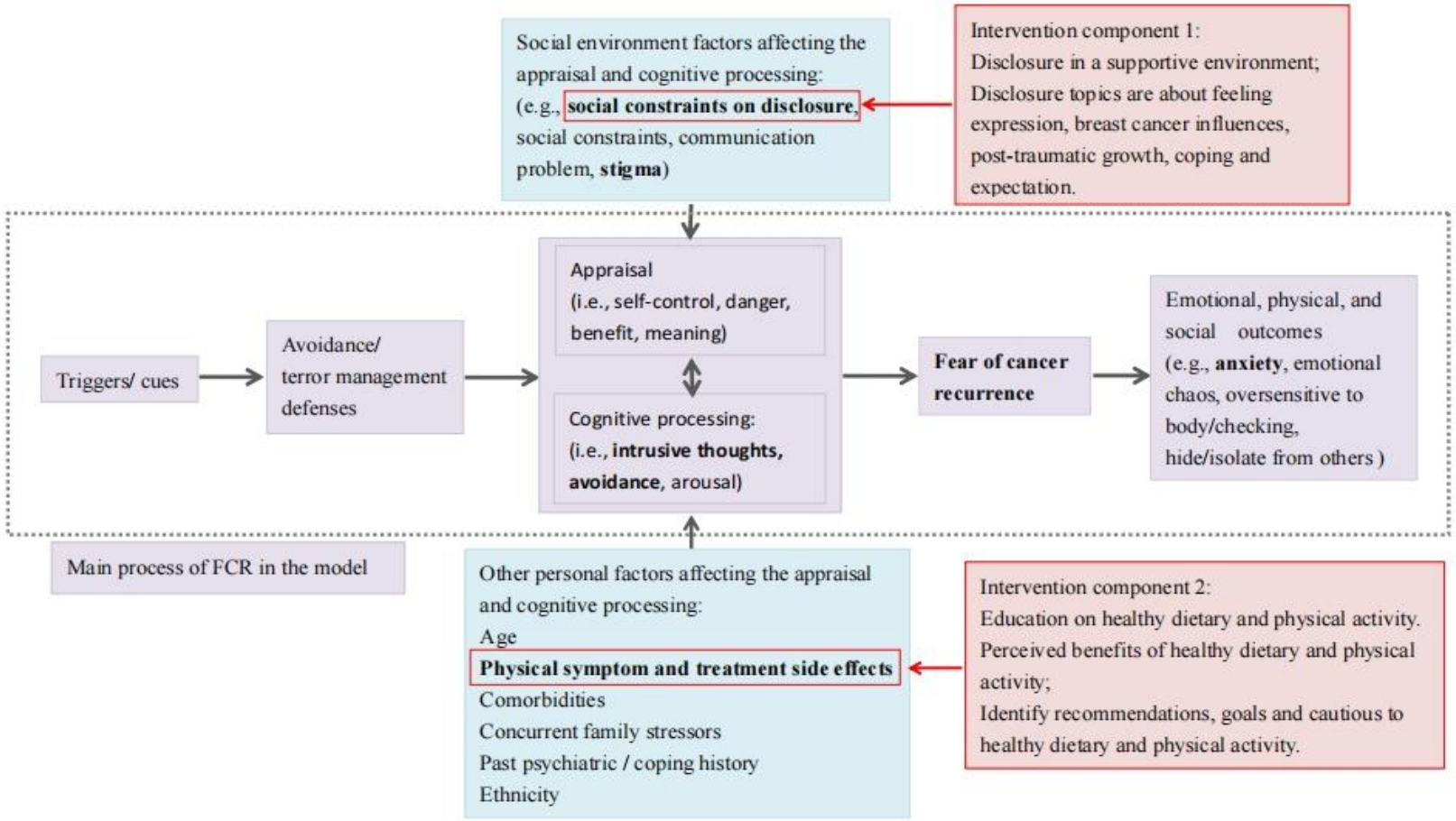


Figure 4.2 The intervention development by the integrative model

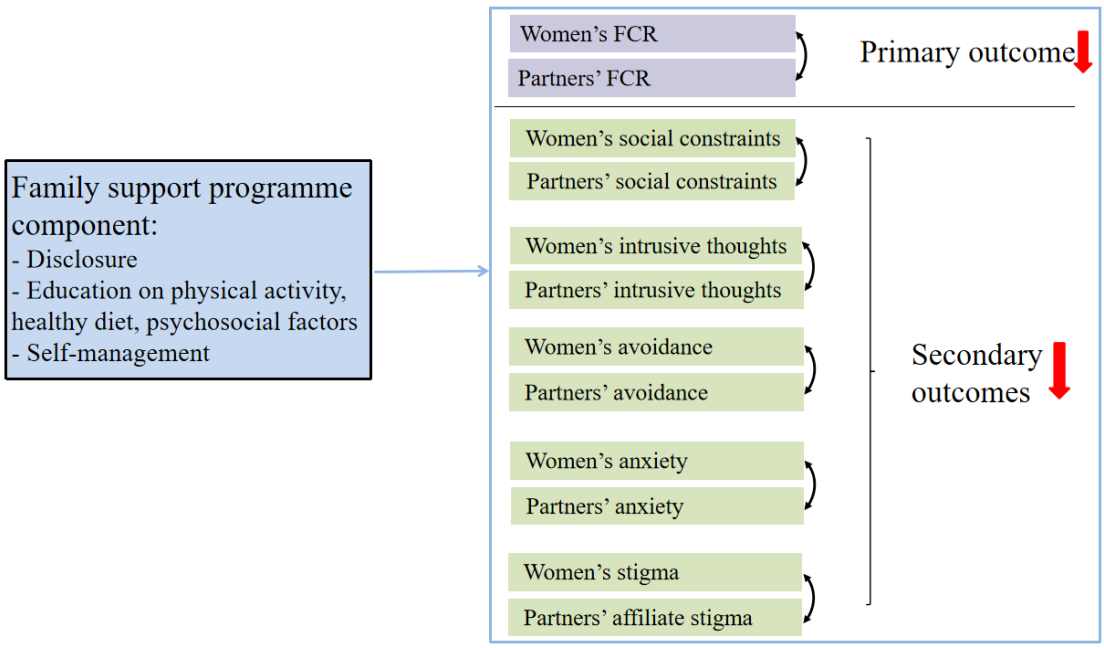


Figure 4. 3 Conceptual framework

4.3.2 Component of the intervention contents

The intervention was a nurse-led support programme designed for couples coping with breast cancer, comprising women with breast cancer and their partners. The family support programme consisted of six WeChat sessions, incorporating two core activities aimed at alleviating FCR among dyads in mainland China: 1) education on healthy lifestyle (physical activities and healthy dietary) and 2) disclosure between couples. In addition, an educational handbook in electronic format was provided to the couples to support the implementation of these activities.

The family support programme comprises four content areas: (i) a brief introduction to breast cancer, (ii) education on physical activity, (iii) education on healthy dietary practices and (iv) disclosure between couples. The content was delivered by the doctoral student, an oncology nurse, over six sessions, with each session lasting approximately 60 minutes, which is considered an acceptable duration for patients with cancer (Table 4.1). Both members of the couple were required to participate in all sessions and receive the full programme. On the basis of the conceptual

framework, the contents of the intervention were developed from three sources: i) physical activity recommendations, extracted from the *Guidelines and Norms for Diagnosis and Treatment of Breast Cancer of the Chinese Anti-Cancer Association* (Breast Cancer Professional Committee of the Chinese Anti-Cancer Association, 2021); ii) healthy dietary recommendations, derived from the *Chinese Residents' Balanced Diet Pagoda* and the aforementioned guidelines for breast cancer diagnosis and treatment; and iii) guiding principles for conducting disclosure, informed by relevant previous studies (Chen et al., 2022; Li et al., 2022; Zhang et al., 2019). Disclosure interventions have been widely used in various health contexts, including palliative care, cancer care, asthma and inflammatory bowel disease (Guo et al., 2020; Manne et al., 2011; McInnerney et al., 2021; Paudyal et al., 2014). As identified in Chapter Three, several studies have already implemented disclosure between couples to alleviate FCR in the breast cancer population in China. Therefore, contents from these published studies were adopted to guide the development of the disclosure component in the current intervention protocol.

## 4.4 Details of the intervention

### 4.4.1 Content development

Part 1: Intervention for couples coping with breast cancer

Electronic educational materials were developed to facilitate the delivery of the intervention. The doctoral student prepared materials covering a brief introduction to breast cancer, self-management of treatment side effects, healthy dietary practices and physical activity. These materials incorporated pictures alongside concise text to enhance comprehension. In addition, a brief introduction for each disclosure session topic was prepared. Table 4.1 presents the details of the educational materials, including session content and delivery schedule, for panel review.

1) Educational handbook: electronic educational materials cover the following contents:

a) A brief introduction about breast cancer and its management was provided, including the definition, overview of diagnostic criteria, risk factors, prevalence and self-

management of treatment side effects, are addressed.

b) Physical activity recommendations were extracted from the *Guidelines and Norms for Diagnosis and Treatment of Breast Cancer* of the Chinese Anti-Cancer Association. Breast cancer patients are advised to avoid a sedentary lifestyle following diagnosis and to resume their pre-diagnosis daily physical activity as soon as possible. Adults aged 18–64 years are recommended to engage in at least 150 minutes of moderate-intensity exercise (approximately 30 minutes, five times per week) or 75 minutes of vigorous-intensity aerobic exercise per week. Strength training targeting major muscle groups is recommended at least twice weekly. Exercise sessions should ideally last around 10 minutes each, and daily activity is encouraged. Older adults aged over 65 should exercise in accordance with these guidelines as much as possible. For those with chronic conditions limiting mobility, the duration and intensity of exercise should be adjusted under the guidance of a physician, and prolonged inactivity should be avoided. Guidance on how partners can support patients in performing the recommended physical exercises is also included.

c) Healthy dietary recommendations were extracted from the *Guidelines and Norms for Diagnosis and Treatment of Breast Cancer* of the Chinese Anti-Cancer Association and the *Chinese Residents' Balanced Diet Pagoda*. Patients are advised to select food according to the 'Chinese Balanced Diet Pagoda' and to appropriately distribute food portions across three daily meals. A diet rich in fruits, vegetables, whole grains, poultry and fish, alongside reduced consumption of refined grains, red and processed meats, desserts, high-fat dairy products and fried foods, is recommended for individuals with breast cancer. Guidance on how partners can support patients in adhering to these nutritional recommendations is also provided.

d) The disclosure content was developed with reference to published RCTs derived from the Chapter 3 employing disclosure as an intervention for couples coping with breast cancer (Chen et al., 2022; Li et al., 2022; Zhang et al., 2019). Key topics included expression of feelings, the impact of breast cancer, post-traumatic growth, coping strategies and future expectations. Specifically, couples were encouraged to discuss

their emotions after breast cancer diagnosis, express negative feelings and concerns regarding disease progression, reflect on the impact of breast cancer on personal life and family, share details of worries or fear of recurrence and its consequences and discuss their experiences, coping strategies and plans for the future.

In each session, couples are encouraged to set weekly goals related to healthy lifestyle and disclosure, guided and supported by the facilitator delivering the programme. For physical activity, women are advised to engage in at least 150 minutes of moderate-intensity exercise per week (approximately 30 minutes, five times per week) or 75 minutes of vigorous-intensity aerobic exercise per week. For healthy dietary goals, women are guided to avoid unhealthy foods. Regarding disclosure, couples are encouraged to engage in discussions at least three times per week, with each lasting approximately 15 minutes. Each session includes a five-minute recap, during which the facilitator invites the couple to review and present their achievements from the previous week, evaluating progress against the goals set. Additionally, time is allocated at the end of each session for couples to ask questions or seek clarification.

Table 4.1 Drafted content of the intervention

| Week and session | Topic | Content |
|---|---|---|
| 1 | Brief introduction about breast cancer and self-management of treatment side effects | Breast cancer definition, risk factors and prevalence; self- management of treatment side effects |
| 2 | Healthy dietary and physical activity education | Benefits of healthy dietary and physical activity,<br>recommendations of healthy dietary and anti-cancer food and physical activity;<br>cautions on healthy dietary and physical activity;<br>goal plan for nutrition and physical activity. |
| 3 | Communicating | Expression of one's feelings after the diagnosis of |

| | | |
|---|---|---|
| | feelings | breast cancer, negative feelings and concerns of cancer progression;<br><br>Women and their partners are encouraged to express their emotion and personal feelings by using empathy, encouragement and inspiration, and promote the release of bad emotions. |
| 4 | Breast cancer influences | Talking about the effects that having breast cancer on personal life and family; talking about the details of worry or fear of recurrence and its influence;the facilitator will explore patients' perceptions of breast cancer prognosis, share successful cases and experiences in those people with late stage but with good treatment outcome and strengthen patients' positive perceptions of prognosis. |
| 5 | Post-traumatic growth | Talking about what have been done/changed; talking about the worry and its influence; express concern and fear of cancer recurrence at the current stage.<br><br>The facilitator will help patients think about positive changes they have made, including personal emotions, relationships with partners, and feelings. The facilitaor will guide couples to think from each other's side and promote intimate relationship between couples. |
| 6 | Coping and expectation | Talking about the changes in couples' perceptions of cancer recurrence; talking about the experience and coping strategies; talking about the future plans.<br><br>The facilitator will help patients think about positive experience and coping strategies they have made. Help them organize positive plans of future. |

4.4.2 Format

WeChat was selected as the delivery modality for this study. As the leading social platform in China, it allows users to send instant messages at no cost, either to an individual or to groups. Although most of the RCTs included in Chapter Three were delivered face-to-face or via a combination of face-to-face and telephone or WeChat, this study utilised WeChat as the sole platform for intervention delivery for several reasons. Firstly, the systematic review presented in Chapter Three demonstrated that disclosure delivered through a combination of face-to-face and WeChat was effective.

Therefore, a more flexible delivery modality solely using WeChat was tested in this study. The intervention was structured so that Sessions 1 and 2 focus on education regarding brief introduction of breast cancer and self-management, physical activity and healthy dietary practices, allowing rapport and trust to be established between the couples and the facilitator. This foundation supports the subsequent four sessions (Sessions 3–6), which focus on disclosure. Moreover, the educational content in Sessions 1 and 2 provides topics that facilitate discussion during the disclosure sessions. Secondly, WeChat has been shown to be acceptable for intervention delivery. Previous studies in China have successfully used WeChat for similar interventions without reporting issues (Liu et al., 2018; Zhang et al., 2020; Zhang, Xu et al., 2021). Thirdly, WeChat offers flexibility, removing constraints related to venue and timing. Women with breast cancer often spend most of their time at home after diagnosis and attend hospital visits only for scheduled treatments. Chemotherapy and other treatments may result in side effects, such as fatigue and nausea. Partners often have work and caregiving responsibilities, and a face-to-face intervention requiring travel and fixed schedules can impose additional burden to both parties. Fourthly, WeChat is free, including voice and video calls. Given the high cost of cancer treatment, partners often need to work to cover living expenses and medical fees. A free, flexible and online intervention is therefore more feasible and appropriate in this context than a face-to-face format. Intervention materials were prepared in electronic format and sent to each couple one week before each session via WeChat. For Sessions 1 and 2, the facilitator delivered the educational content and established rapport with the couples. Sessions 3–6 focused on disclosure, guided by the facilitator through discussions. Each session was scheduled to accommodate the couples' availability while maintaining privacy. The doctoral student, an oncology nurse, acted as the facilitator for the intervention, delivering all sessions online via WeChat to each couple individually.

### 4.4.3 Intervention dosage

According to the systematic review of RCTs for FCR alleviation presented in Chapter

Three, most included studies incorporated four disclosure sessions in their interventions, and each session ranged from 15 minutes to 60 minutes. In this study, a mean duration of 60 minutes was selected for each of the four disclosure sessions, which were delivered on a weekly basis. The six sessions of the family support programme were arranged as follows: Session 1 covered a brief introduction to breast cancer and self-management of treatment side effects; Session 2 focused on education regarding healthy dietary practices and physical activity; Sessions 3–6 were dedicated to disclosure between couples. The programme was delivered consecutively over six weeks, and women and their partners participated together in all sessions.

### 4.4.4 Validation of the interventional materials

The physical activity component was designed as general patient education rather than an individualized prescription. All content was extracted verbatim or adapted directly from authoritative sources, including the Guidelines and Norms for Diagnosis and Treatment of Breast Cancer of the Chinese Anti-Cancer Association (Breast Cancer Professional Committee of the Chinese Anti-Cancer Association, 2021) and existing hospital patient education materials that are routinely used in clinical practice. The expert panel then conducted a detailed review to verify consistency with these sources, and to assess clinical safety, clarity of wording, and feasibility for breast cancer survivors. On this basis, the education content was considered validated for its intended scope. The intervention content validity was assessed in two stages. The first stage involved the content validation of the family support programme, which was evaluated using the content validity index (CVI) calculated from the responses of an expert panel, which were collected using a four-point Likert scale. The second stage focused on examining the feasibility and preliminary effects of the family support programme for couples coping with breast cancer, using a single-group pretest–posttest pilot study. The methodology and results of this pilot study are presented in Chapter Six.

#### 4.4.4.1 Expert panel

The content validity of the intervention was assessed by a multidisciplinary expert panel comprising physicians, nurses and psychologists with experience in breast cancer management. The inclusion criteria for experts were as follows: (1) at least a bachelor's degree; (2) professional background as a physician, nurse or psychologist; (3) involvement in oncology research or academia; and (4) a minimum of five years of professional or research experience in breast cancer management. Purposive sampling was employed to select the experts. Five individuals were invited to form the panel, including two physicians, two nurses and one psychologist, all of whom had over ten years of professional experience.

#### 4.4.4.2 Assessment questionnaire

A self-developed content validity assessment questionnaire was used to gather the experts' opinions on the content of the intervention materials and the intervention protocol. The intervention materials were divided into two sections. The first section comprised basic information, including a brief introduction to breast cancer and self-management of treatment side effects (Session 1 of the family support programme), and education on physical activity and healthy dietary practices (Session 2). The second section encompassed the four disclosure sessions (Sessions 3–6). The contents of the intervention handbook were evaluated across three dimensions within the context of breast cancer management: relevance, appropriateness and feasibility (Table 4.2). Each item was independently rated by each panel member using a four-point Likert scale (1 = 'very inappropriate' to 4 = 'very appropriate'). Additionally, an open-ended question was included at the end of the questionnaire, allowing experts to provide further feedback for improving the handbook.

Table 4.2 Content validity assessment of the handbook

| | Relevance to FCR management | | | | Appropriateness of the content | | | | Feasibility to the target subject | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Not relevant | Somewhat relevant | Quite relevant | Very relevant | very inappropriate | inappropriate | appropriate | very appropriate | Not feasible | Somewhat feasible | Quite feasible | Very feasible |
| Session 1: Brief introduction about breast cancer and self-management of treatment side effects | | | | | | | | | | | | |
| Session 2: Healthy dietary education and physical activity education | | | | | | | | | | | | |
| Session 3: Communicating feelings | | | | | | | | | | | | |
| Session 4: Breast cancer influences | | | | | | | | | | | | |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Session 5: Post-traumatic growth | | | | | | | | | | | | |
| Session 6: Coping and expectation | | | | | | | | | | | | |
| Any other suggestions: | | | | | | | | | | | | |

#### 4.4.4.3 Data collection

Potential expert members were identified through recommendations within the research team's professional network. Invitation messages were sent to the prospective experts via WeChat. Upon obtaining their consent, the experts were provided with either a printed or electronic version of the draft intervention handbook along with the content validity assessment questionnaire. The experts independently rated the materials and provided their comments. The topic-level CVI was calculated for relevance, appropriateness and feasibility. After the incorporation of their feedback, the revised intervention materials were returned to the experts for further evaluation. This iterative process continued until the content validity of the family support programme materials was deemed acceptable.

#### 4.4.4.4 Data analysis

The item-level content validity index (I-CVI) and the overall CVI were calculated (Polit et al., 2007). The I-CVI was defined as the proportion of experts who rated the item as 'very appropriate' or 'appropriate' (Rubio et al., 2003). The overall CVI was calculated as the average of the I-CVIs across all items. The cutoff value for an acceptable I-CVI depends on the number of experts (Polit et al., 2007). According to the widely cited criteria proposed by Lynn (1986), the I-CVI should be 1.00 for a small panel of five or fewer experts, while a panel of six experts has a minimum suggested I-CVI of 0.83. In this doctoral study, five experts were recruited; therefore, the cutoff value for both the I-CVI and overall CVI was set at 1.00. Comments from the open-ended questions were summarised descriptively and served as qualitative indicators to assess content validity and guide modifications.

#### 4.4.4.5 Results of the content validation

Educational handbook

Two rounds of content validity assessment were conducted by the expert panel. In both the first and second rounds, the I-CVI of all items and the overall CVI of the educational

handbook were 1.0, indicating that the content was relevant, appropriate and feasible. During the first round, the experts provided four comments: 1) include content on the prevention, early recognition and self-management of lymphedema; 2) incorporate psychosocial factors related to cancer recurrence; 3) add a video presenting successful cases, showing adults diagnosed with cancer who achieved a good prognosis, to strengthen participants' confidence; and 4) revise the goal of healthy dietary practices to follow the guidelines of the *Chinese Residents' Balanced Diet Pagoda* rather than simply advising patients to avoid unhealthy foods. In response, the family support programme content was modified as follows: 1) lymphedema-related information and psychosocial factors related to cancer recurrence were extracted from hospital publicity materials, booklets and relevant published literature (Chen et al., 2023); 2) a video of successful cancer management cases was provided by the psychologist on the expert panel; and 3) the goal for healthy dietary practices was aligned with the *Chinese Residents Balanced Diet Pagoda* guidelines. The revised handbook was then sent to the experts for a second evaluation, and it was subsequently approved for future use.

In line with the guiding conceptual framework (Simonelli et al., 2017), the inclusion of content on psychosocial factors related to cancer recurrence in the family support programme aligns closely with the integrative model because coping history is one of the personal factors influencing the appraisal and cognitive processing mechanisms of FCR. Specifically, FCR can be mitigated by providing education on coping strategies to address cancer-related psychosocial factors, such as negative emotional responses, while simultaneously enhancing social support and resilience. Negative emotional responses, including grief, disappointment, anger and anxiety, are common in women with breast cancer and can adversely affect their mental health and overall health outcomes (Yuan et al., 2021). Evidence indicates that women experiencing depression are more susceptible to developing cancer compared with non-depressed women (Chen et al., 2023). As discussed in Chapter Two, social support is an associated factor of FCR in women with breast cancer, whereas resilience is an associated factor of FCR in

caregivers. Consequently, this new component (Intervention Component 3) was added to the family support programme, and the revised conceptual framework is presented in Figure 4.3.

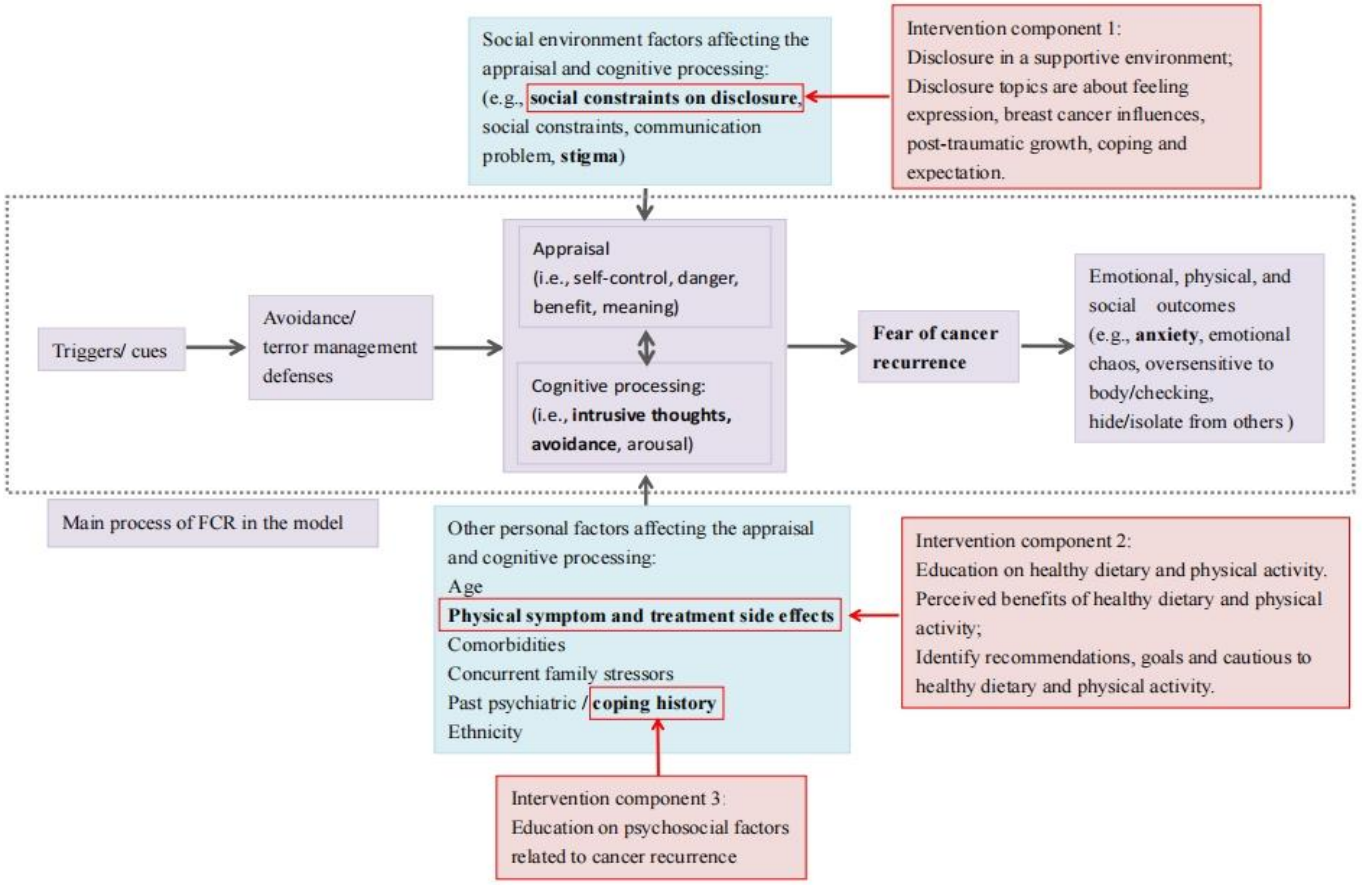


Figure 4. 4 Revised conceptual framework to guide the intervention development by the integrative model after review by expert panel

In summary, the contents of the six sessions of the family support programme aimed at reducing FCR by providing knowledge on breast cancer and self-management of side effects (Session 1), providing education on physical activity (Session 2), healthy dietary (Session 2) and coping skills in addressing cancer-related psychosocial factors (Session 3) and fostering communication and enhancing partners' responsiveness (Sessions 3–6). By enabling mutual understanding, the family support programme is expected not only to reduce social constraints from both parties but also enhance responsiveness and intimacy within the couple, thereby fostering a supportive marital environment that may facilitate emotional disclosure and lower FCR in both parties. The content of the family support programme after review by the expert panel is presented in Table 4.3.

Table 4.3 Content of the family support programme after review by the expert panel

| Sessions | Topic | Content |
|---|---|---|
| 1 | Brief introduction about breast cancer and self-management of treatment side effects, **particularly lymphoedema** | Breast cancer definition, risk factors and prevalence; self- management of treatment side effects targeting their treatment (surgery, chemotherapy, radiotherapy, hormone therapy and target therapy); prevention, early recognition and self-management of lymphoedema. |
| 2 | Healthy dietary education and physical activity education | Benefits of healthy dietary and physical activity,<br>recommendations of healthy dietary and anti-cancer food and physical activity;<br>cautions on healthy dietary and physical activity;<br>goal plan for healthy dietary based on the *Chinese Residents' Balanced Diet Pagoda* and physical activity based on the recommendation from the Chinese Anticancer Association |
| 3 | Communicating feelings | Expression of one's feelings after the diagnosis of breast cancer, negative feelings and concerns of cancer progression;<br><br>Help patients to find the personal and **psychosocial** |

| | | |
|---|---|---|
| | | **risk factors of breast cancer recurrence**, guide couples to use non-violent communication methods, encourage them to express their feelings and concerns in daily life and supplemented with some coping skills; women with breast cancer and their partners are encouraged to express their emotions by using empathy, encouragement and inspiration and promote the expression of negative emotions. Emphasise the relationship of negative emotions with breast cancer occurrence. |
| 4 | Breast cancer influences | Talking about the effects that having breast cancer on personal life and family; talking about the details of worry or fear of recurrence and its influence; the facilitator will explore women's perceptions of breast cancer prognosis, share successful cases and experiences in those people with late stage but with good treatment outcome and strengthen patients' positive perceptions of prognosis; **share a video of a patient with late-stage cancer but with good prognosis after the session** and invite them to express their feelings in the next session. |
| 5 | Post-traumatic growth | Talking about what have been done/changed; talking about the worry and its influence; express concern and fear of cancer recurrence at the current stage.<br><br>The facilitator will ask couples to recall positive changes they have made, such as emotions, healthy dietary, physical activity, sleep and relationships with family members, and help patients to deal with their treatment side effect. They will guide couples to think from each other's side and promote intimate relationship between couples. |
| 6 | Coping and expectation | Talking about the changes in couples' perceptions of cancer recurrence; talking about the experience and coping strategies; talking about the future plans.<br><br>The facilitator will help patients to recall positive experience and their own coping strategies and will develop a plan to prevent cancer recurrence from five aspects: cancer mindset, emotion, healthy dietary, physical activity and sleep. |

## 4.5 Chapter summary

Based on the findings from the preceding chapters, social constraints were identified as a shared factor contributing to FCR in women with breast cancer and their caregivers. Meta-analytic evidence supports the short-term benefits of family involvement interventions incorporating disclosure combined with education or counselling for women, although evidence for caregivers remains limited. Consequently, Simonelli's integrative model of FCR was selected to guide the development and evaluation of a couple-focused, disclosure-based intervention, namely, the family support programme. Following expert review, the programme was expanded to provide broad content coverage. It comprised six weekly 60-minute sessions, supported by an electronic educational handbook and a video of successful cases and was delivered via WeChat by an oncology nurse to each couple individually. The contents of the six sessions were validated by a panel of five experts (CVI = 1.0). The sessions were as follows: Session 1, which includes a brief introduction to breast cancer, prevention, early recognition and self-management of treatment side effects, particularly lymphedema; Session 2, which includes education on physical activity and healthy dietary practices; and Sessions 3–6, which provides the disclosure, and Session 3 additionally covers psychosocial factors related to breast cancer recurrence. The modified family support programme was subsequently pilot-tested. The methodology and results of the pilot study, which explored the feasibility and preliminary effects of the programme for couples coping with breast cancer, are presented in Chapter Six. Chapter Five details the development or adaptation and validation of two scales designed to measure outcomes in partners for use in the subsequent phases of the doctoral study.

# CHAPTER FIVE: DEVELOPMENT/ADAPTATION AND PSYCHOMETRIC PROPERTIES OF OUTCOME MEASURES

## 5.1 Introduction

This chapter presents the adaptation or development and psychometric evaluation of two scales: one measuring social constraints in partners of adults with cancer and the other measuring affiliate stigma in caregivers of women with breast cancer. The chapter is broadly organised into three sections. Section 5.1 introduces the chapter. Section 5.2 describes the adaptation of the revised SCS and its psychometric properties in a sample of partners of adults with cancer. Section 5.3 details the development of the Affiliate Stigma Scale and its psychometric properties in a sample of caregivers of women with breast cancer; the results presented in this section have been published (Bu et al., 2025). Finally, Section 5.4 summarises the chapter.

## 5.2 Adaptation and Psychometric Properties of the Revised Social Constraints Scale among Partners of Adults with Cancer

### 5.2.1 Background

Similar to cancer patients, their partners may also experience social constraints. The literature documents that an unsupported social environment, such as myths, misconceptions and causal beliefs about cancer, can lead to gossip and stigmatisation from society (Boamah Mensah et al., 2021; e Silva et al., 2010). Close relatives and acquaintances of patients with cancer may behave differently, sometimes feeling uncomfortable, after being informed of the diagnosis (Nasiri et al., 2016). Partners may refrain from sharing concerns to avoid worrying family members, prevent conflict or protect the patients' feelings (Zahlis & Lewis, 2010). They often feel compelled to maintain strength to support the patient (Zahlis & Lewis, 2010). Moreover, some male partners may avoid discussing their experiences because they perceive it as inconsistent with their gender role, keeping their thoughts private (Hilton et al., 2000; Zahlis & Lewis, 2010). They may also avoid disclosure because they do not want to burden others or feel that others would not understand (Zahlis & Lewis, 2010). Consequently,

partners may experience constraints in expressing their thoughts, feelings or concerns to their loved ones living with cancer. This highlights the importance of measuring social constraints in partners of patients with cancer.

### 5.2.2 Social Constraints Scale

Social constraints are commonly measured using the SCS developed by Lepore et al., which exists in three versions: 5-, 12- and 15-item (Lepore & Revenson, 2007). The 15-item version is the most widely used, assessing the frequency of social constraints experienced by individuals with cancer. The scale was designed as unidimensional and includes versions tailored to different sources of social constraints, such as life-threatening illness, victimisation or bereavement, with reference to particular stressors from a spouse, other family members or friends (Lepore & Revenson, 2007). The SCS has been applied across various cancer populations, demonstrating excellent internal consistency ($\alpha$ = 0.85–0.95) and satisfactory test-retest reliability (r = 0.69–0.71; Lepore & Revenson, 2007). In terms of convergent validity, the SCS has been shown to correlate positively with psychological distress and intrusive thoughts (Koutrouli et al., 2016).

The 15-item SCS has been successfully adapted and validated across diverse cultural contexts, including Greece and China, demonstrating its applicability in different populations. Yeung et al. (2017) translated and adapted the original SCS into a 13-item Traditional Chinese version, which was used in a sample of Chinese-American patients with breast cancer to assess social constraints from their partners. This traditional Chinese version demonstrated excellent internal consistency, with a Cronbach's $\alpha$ of 0.94, and was positively associated with intrusive thoughts and negative affect among breast cancer survivors, indicating strong construct validity (Yeung et al., 2017). Considering geographical and cultural differences, Luo et al. (2023) conducted a cross-cultural adaptation of the original 15-item SCS into a simplified Chinese version. This version was validated in a sample of cancer patients, showing excellent internal

consistency (α = 0.902) and strong test-retest reliability (r = 0.826). Unlike the original unidimensional scale, the simplified Chinese version demonstrated a two-factor structure comprising 'perceptual avoidance' and 'reveal and conceal'. Similarly, the Greek version of the SCS revealed a three-factor structure: 'unsupported behaviours', 'avoidant behaviours' and 'suggestions for distraction and pretense'. The internal consistency of these subscales ranged from 0.77 to 0.88, and they were significantly positively correlated with psychological distress and intrusive thoughts, supporting the reliability and validity of the Greek version (Koutrouli et al., 2016).

The SCS has been used with partners of patients with cancer in US; however, its psychometric properties were not reported (Cohee et al., 2017; Soriano et al., 2021). Moreover, no scale currently exists to assess partners' social constraints from patients in the simplified Chinese language. To address this gap, the present study aimed to culturally adapt and test the psychometric properties of the simplified Chinese version of the SCS for partners (SC-SCS-P), which was specifically designed to measure partner-specific social constraints from adults with cancer.

### 5.2.3 Adaption of SCS for partners of adults with cancer

In this study, the adaptation was based on the Simplified Chinese version of the 15-item SCS developed by Luo et al. (2023), with reference to the items in the original SCS (Lepore et al., 2007) for measuring social constraints in partners of adults with cancer. The doctoral student revised the scale to reflect the context of partners of adults with cancer. The adaptation involved contextual modifications to the items in the Simplified Chinese version by rephrasing statements to capture partners' experiences. All items, except for Items 2, 6 and 9, were modified by changing the subject from 'partner' to 'patient'. Specifically, Item 2 ('Your partner does not understand your health condition') was revised to 'The patient does not understand your feelings/concerns'. Item 6 ('When you mention your own illness, your partner appears uncomfortable') was revised to 'When you mention the patient's illness, the patient appears uncomfortable'. Item 9

('Family members appear cheerful in your presence to hide their true feelings or concerns about you') was adapted to 'The patient appears cheerful in your presence to hide his/her true feelings or concerns about his/her own illness'.

The proposed scale was reviewed by a panel of five experts to establish content validity. Content validity refers to the extent to which a scale accurately reflects the concept it is intended to measure. In this study, content validity was evaluated at the item level using the I-CVI. For each item, the I-CVI was calculated as the proportion of experts assigning a relevance rating of 4 or 5 relative to the total number of participating experts (Polit et al., 2007). An I-CVI of ≥0.8 was predefined as the threshold for item inclusion. Experts were recruited from the research team's professional network and were eligible if they had more than five years of cancer-related research or clinical experience, held at least a master's degree and had published at least one paper in a peer-reviewed journal. The panel comprised three experts in nursing and research, one in clinical nursing and one statistician. The proposed scale was sent to the experts at least two days prior to the individual meetings, which took place within two days in May 2024. The panel confirmed that the language used in the revised scale was appropriate, ensuring that the items were easily understandable and relevant to the target population. One recommendation was implemented: in Item 2, the word 'situation' was replaced with 'feeling/concern'. The I-CVI for all items in this version of the scale was 1.0. To further assess comprehensibility, a pilot test was conducted with 10 partners of adults with cancer to evaluate the wording, expression and appropriateness of the items. No additional modifications were required following this pilot phase. Consequently, a preliminary SC-SCS-P was generated for subsequent psychometric testing.

### 5.2.4 Method

This study employed a psychometric validation design comprising two components. The first component was a cross-sectional study conducted to evaluate internal consistency, factor structure and construct validity. The second component was a

longitudinal study designed to assess test–retest reliability.

#### 5.2.4.1 Participants

The inclusion criteria were as follows: (1) self-identified partners of adults diagnosed with cancer at any stage and receiving any form of treatment, including surgery, chemotherapy, radiotherapy or targeted therapy; (2) aged 18 years or older; (3) fully conscious and capable of completing questionnaires; and (4) provision of informed consent. Individuals with a diagnosed psychiatric disorder were excluded. Using convenience sampling, partners of adults with cancer were recruited from four tertiary A hospitals (three in Hunan Province and one in Jiangsu Province, China) between June and September 2024.

#### 5.2.4.2 Sample size

For the exploratory factor analysis (EFA), the recommended sample size is typically 3–20 times the number of items in the scale (Williams et al., 2010). Accordingly, a sample of approximately 150 participants (10 participants × 15 items) was planned for the EFA. For the confirmatory factor analysis (CFA), a general guideline suggests a minimum of 200 participants. Accounting for an anticipated 10% rate of invalid questionnaires, the target sample size for recruitment was set at no fewer than 389 participants.

#### 5.2.4.3 Measures

Social constraints

The newly revised Simplified Chinese version of the 15-item SC-SCS-P was used to assess social constraints for the target population. The participants rated their experiences of social constraints by using a 4-point Likert-type scale ranging from 1 (‘never’) to 4 (‘often’). Scores ranged from 15 to 60, with higher scores indicating higher levels of social constraints.

Psychological resilience:

Psychological resilience refers to the mental processes and behaviours that strengthen personal resources and protect an individual from the potential negative effects of stressors (Fletcher & Sarkar, 2013). In this study, resilience was measured using the 10-Item Connor-Davidson Resilience Scale (CD-RISC-10, Campbell-Sills & Stein, 2007). The original scale, developed by Connor and Davidson (2003), consisted of 25 items and was later simplified by Campbell-Sills and Stein to form the CD-RISC-10. The scale was translated into Chinese and adapted by Wang et al. (2010). The Chinese version comprises 10 items and uses a 5-point Likert scale (0 = 'never,' 1 = 'rarely,' 2 = 'sometimes,' 3 = 'often,' and 4 = 'always'). Total scores are calculated by summing the scores of all items, with higher scores indicating greater psychological resilience. The Chinese version of CD-RISC-10 has been widely used in China and demonstrates good reliability and validity (Wang et al., 2010). In the present study, the Cronbach's α coefficient was 0.882.

Fear of cancer recurrence (FCR)

FCR in partners was assessed using the Fear of Progression Questionnaire-Short Form (FoP-Q-SF; Mehnert et al., 2006). The FoP-Q-SF is a 12-item self-report instrument that provides a multidimensional evaluation of FCR. Items are rated on a 5-point Likert scale, ranging from 1 ('never') to 5 ('very often'), with higher total scores indicating greater levels of FCR. A total score of 34 or above is considered indicative of clinically significant FCR (Wu, 2016). The Chinese version of the FoP-Q-SF has been validated, showing a Cronbach's α of 0.853 in partners (Wu, 2016). In the present study, the scale demonstrated good internal consistency, with a Cronbach's α of 0.855.

Communication problem

Communication problems between partners and adults with cancer were measured using the 15-item Cancer-related Communication Problem Scale (CRCP) developed by Kornblith et al. (2006), which reported a Cronbach's α of 0.81 in a sample of male partners. Items are rated on a 3-point Likert scale, ranging from 1 ('incorrect') to 3

('correct'), with higher total scores indicating greater communication problems within the couple. In studies of Chinese partners of cancer patients, the CRCP has demonstrated good internal consistency, with Cronbach's α ranging from 0.719 to 0.88 (Cheng et al., 2021; Yang et al., 2022). In the present study, the scale showed a Cronbach's α of 0.636.

In addition, demographic information, including age, gender, employment status and education level, and patients' demographic and disease-related information were obtained from the participants.

5.2.4.4 Data collection procedure

Data were collected by the doctoral student and four trained data collectors. Partners were recruited via referral from adults with cancer at the participating hospitals. Upon presenting at the hospital, data collectors screened participants for eligibility and explained the study procedures. After providing informed consent, partners self-completed the questionnaires, with assistance provided by the data collectors if required. For participants who experienced difficulty reading the items, the data collectors read the items and response options aloud without prompting or influencing responses. For the test–retest survey, partners who had completed the baseline questionnaire were invited to complete the SC-SCS-P again within a 21-day interval.

5.2.4.5 Statistical analysis

All statistical analyses were conducted using IBM SPSS Statistics Version 26.0, with a two-sided P-value of $<0.05$ considered statistically significant. Demographic and disease-related characteristics of the partners were summarised using frequencies, means and standard deviations. Validity assessment included evaluation of factor structure and convergent validity, while reliability was assessed through internal consistency and test–retest reliability. The sample was randomly split into two subsamples in SPSS, with one subsample used for EFA and the other for CFA.

Factor structure

The factor structure was examined in three steps. In Step 1, item reduction was performed based on item–total correlations using Pearson's r. This correlation, calculated between an individual item and the total test score, helps identify items that do not adequately reflect the underlying psychological construct and may therefore be removed or revised (Wolf, 1967). Items with $r < 0.30$ were excluded from further analysis (Tavakol & Wetzel, 2020).

In Step 2, EFAs were conducted on the items retained after Step 1. Maximum likelihood estimation with direct oblique rotation was employed. The appropriateness of conducting EFA was assessed using the Kaiser–Meyer–Olkin (KMO) measure and Bartlett's test of sphericity. KMO values $\geq 0.60$ were considered acceptable, while values $\geq 0.70$ indicated good sampling adequacy. A statistically significant Bartlett's test ($P < 0.05$) suggested that the correlation matrix was not an identity matrix, thus justifying factor extraction (Suan et al., 2017). Factor retention was guided by four criteria: (i) eigenvalues of >1, (ii) inspection of the scree plot, (iii) interpretability of the retained factors and (iv) factor loadings of $> 0.30$. Eigenvalues indicate the proportion of variance explained by each factor, with values above 1 considered stable. The scree plot displays the eigenvalues of the factors or principal components to aid in determining the number of factors to retain. Factor loadings represent the correlation between an item and a factor, with loadings over 0.30 generally interpreted as moderate associations (Tavakol & Wetzel, 2020). The EFA subsample was used for the analyses in Steps 1 and 2.

In Step 3, the factor structure obtained from the EFA was further tested using CFA. The CFA was performed on the covariance matrix using the CFA subsample. Maximum likelihood estimation was employed for model estimation and covariance indices. The adequacy of model fit was assessed using multiple fit indices (Hooper et al., 2008). The

root mean square error of approximation (RMSEA) is an absolute fit index that evaluates the discrepancy between the model and the data per degree of freedom. RMSEA values between 0.05 and 0.08, together with a 90% confidence interval (CI) with a lower bound of 0.05 and an upper bound of 0.10, are considered acceptable, whereas values of <0.06 are considered excellent (Hu & Bentler, 1999; MacCallum et al., 1996). The comparative fit index (CFI) reflects the relative fit of the specified model compared with the null model; CFI values > 0.95 indicate good fit, whereas values of >0.90 indicate acceptable fit (Hu & Bentler, 1999). Although a non-significant chi-square test (P > 0.05) suggests good model fit (Barrett, 2007), chi-square values are often statistically significant in large samples (Hooper et al., 2008). Therefore, the chi-square test results were reported for descriptive purposes only and were not used as the primary criterion for evaluating model fit.

Model modifications were guided by the modification indices (MIs), which identify potential improvements in model fit by suggesting additional paths or constraints that can be added. The interpretation of MI values was based on statistical significance and practical relevance. An MI value greater than 3.84 indicates that releasing the constraint (e.g., adding a path or covariance) would result in a significant improvement in model fit at P < 0.05 and should be considered for modification. An MI value exceeding 6.63 indicates a significant improvement at p < 0.01 and warrants strong consideration for modification. An MI value greater than 10.83 reflects a highly significant improvement at P < 0.001 and should be prioritised in model modifications (https://benwhalley.github.io/just-enough-r/modification-indices.html). However, only paths that are theoretically plausible would be considered for model modifications.

Reliability

Internal consistency was evaluated using Cronbach's α across the entire sample. A Cronbach's $\alpha \geq 0.70$ was considered indicative of good internal reliability (Hendriks et al., 2013). Values at or above this threshold suggest that the items are sufficiently

consistent, confirming that the scale is reliable. Test–retest reliability was assessed using intra-class correlation coefficients (ICCs) over a 21-day interval. An ICC of >0.75 indicates good test–retest reliability, while values between 0.50 and 0.75 indicate moderate reliability (Koo & Li, 2016).

Floor and ceiling effects

The domains of the SC-SCS-P were examined for floor and ceiling effects and defined as the proportions of respondents achieving the minimum or maximum possible scores on the scale. Floor or ceiling effects were considered present if more than 30% of the total sample obtained the lowest or highest possible score, respectively (Kane, 2006).

Convergent validity

Convergent validity was assessed for the entire sample using correlation analysis. Pearson's correlation was applied for variables with a normal distribution, while Spearman's correlation was used for variables that were non-normally distributed. Variables were considered non-normally distributed if the absolute value of skewness exceeded 2 or the absolute value of kurtosis exceeded 7 (Kim, 2013). We hypothesised that social constraints in partners would be negatively correlated with psychological resilience and positively correlated with FCR and communication problems.

Homogeneity testing

To examine differences in partners' social constraints across demographic characteristics, univariate analyses were performed. Pearson's correlation was used for continuous variables (age and time since diagnosis), independent *t*-tests for binary variables (gender, employment status, surgery, chemotherapy, radiotherapy and targeted therapy), and one-way ANOVA for other categorical variables (educational level, cancer type and cancer stage).

5.2.4.6 Ethical considerations

This study was approved by the Ethics Committee of the participating hospital (Approval ID: 20240101) and conducted with the cooperation of the nursing department managers at each site. All participants provided written informed consent prior to enrolment.

5.2.5 Results

5.2.5.1 Sociodemographic characteristics

A total of 415 questionnaires were distributed to partners of adults with cancer, of which 401 were returned as valid, yielding a response rate of 96.63%. The mean age of the partners was 48.46 years (SD = 9.41), ranging from 25 to 72 years. Nearly two-thirds were male (63.1%), the majority completed junior secondary school (31.9%) or high secondary school or college (31.4%) and approximately half were employed (49.9%). Regarding the patients' characteristics, the mean age was 48.16 years (SD = 9.84), ranging from 23 to 74 years. Nearly two-thirds were female (63.1%), one-fourth were diagnosed with breast cancer (25.9%) and 28.4% were in stage IV. Among the 401 patients, 41.4% had undergone surgery, 51.4% received chemotherapy, 23 underwent radiotherapy and 92 received targeted therapy. Further details are presented in Table 5.1.

Table 5.1 Sociodemographic characteristics of the partners (n = 401)

| | Variable | Group | n | （%） |
|---|---|---|---|---|
| Partners | Age | 25-72 (48.46±9.406) | 336 | 83.8 |
| | Gender | Female | 147 | 36.7 |
| | | Male | 253 | 63.1 |
| | | Unclear | 1 | 0.2 |
| | Education level | Primary school or below | 41 | 10.2 |
| | | Junior secondary school | 128 | 31.9 |
| | | High secondary school or college | 126 | 31.4 |
| | | University or above | 63 | 15.7 |
| | | Unclear | 43 | 10.7 |
| | Employment status | Unemployed | 200 | 49.9 |
| | | Employed | 155 | 38.7 |
| | | Unclear | 46 | 11.5 |
| | | | | |

| | | | | |
|---|---|---|---|---|
| Patients | Age | 23-74 (48.16±9.835) | 397 | 99.0 |
| | Gender | Female | 253 | 63.1 |
| | | Male | 147 | 36.7 |
| | | Unclear | 1 | 0.2 |
| | Time since diagnosis (months) | 0-195 (8.01±22.53) | / | / |
| | Cancer type | Breast cancer | 104 | 25.9 |
| | | Thyroid Cancer | 40 | 10 |
| | | Nasopharyngeal Carcinoma | 39 | 9.7 |
| | | Colorectal Cancer | 39 | 9.7 |
| | | Lung Cancer | 38 | 9.5 |
| | | Oral Cancer | 37 | 9.2 |
| | | Gynecological Cancers | 36 | 9 |
| | | Urological Cancers | 11 | 2.7 |
| | | Neurological Cancers | 10 | 2.5 |
| | | Liver Cancer | 9 | 2.2 |
| | | Osteosarcoma | 9 | 2.2 |
| | | Gastric Cancer | 9 | 2.2 |
| | | Others (including Head and Neck Cancers, Pancreatic Cancer, Esophageal Cancer, etc.) | 20 | 4.99 |
| | Stage | 0 | 12 | 3.0 |
| | | 1 | 82 | 20.4 |
| | | 2 | 68 | 17.0 |
| | | 3 | 91 | 22.7 |
| | | 4 | 114 | 28.4 |
| | | Unclear | 34 | 8.5 |
| | Surgery | No | 227 | 56.6 |
| | | Yes | 166 | 41.4 |
| | | Unclear | 8 | 2.0 |
| | Chemotherapy | No | 187 | 46.6 |
| | | Yes | 206 | 51.4 |
| | | Unclear | 8 | 2.0 |
| | Radiotherapy | No | 370 | 92.3 |
| | | Yes | 23 | 5.7 |
| | | Unclear | 8 | 2.0 |
| | Targeted therapy | No | 301 | 75.1 |
| | | Yes | 92 | 22.9 |
| | | Unclear | 8 | 2.0 |

5.2.5.2 Item-total correlation

Table 5.2 shows the item–total correlation statistics of all the 15 items in the scale,

ranging from 0.394 to 0.667. Thus, all items were retained in the scale for EFA.

Table 5.2 Item–total statistics of the scale

| Number | Items | Item-total correlation |
|---|---|---|
| 1 | When you try to talk to the patients about his/her disease, he/she changes the topic. | 0.581 |
| 2 | You feel that the patient does not understand your concern/feeling | 0.394 |
| 3 | You feel that the patient avoids being with you. | 0.473 |
| 4 | When you bring up concerns or ideas related to health, the patient ignores or downplays them. | 0.566 |
| 5 | You feel that the patient hides his/her emotions or feelings from you. | 0.667 |
| 6 | When you mention patient's illness, the patient appears uncomfortable | 0.589 |
| 7 | You feel that the patient thinks your problem is unimportant. | 0.569 |
| 8 | When you try to talk to the patient, he/she only complains about his/her own problems. | 0.569 |
| 9 | The patient appears cheerful in your presence to hide his/her true feelings or concerns about his/her own illness | 0.578 |
| 10 | The patient tells you not to worry so much his/her health. | 0.447 |
| 11 | The patient asks you to think less thing related to his/her disease | 0.552 |
| 12 | You feel that the patient doesn't want to hear things related to his/her disease | 0.654 |
| 13 | You feel you have to hide your feelings related to the disease because your feeling makes the patient uncomfortable. | 0.590 |
| 14 | You feel you have to hide your feelings related to the disease because your feeling makes the patient unpleasant. | 0.602 |
| 15 | You feel unhappy because the patient doesn't care/love you as you expected. | 0.509 |

5.2.5.3 Exploratory factor analysis

The total sample was randomly split into two subsamples: an EFA-subsample (n = 200) and a CFA-subsample (n = 201). Table 5.3 presents the EFA results. For the EFA-subsample, the KMO measure of sampling adequacy was 0.807, and Bartlett's test of sphericity yielded and $\chi^2$ value 912.78 and P-value of <0.0001, indicating that the data were suitable for factor analysis.

A three-factor solution was retained based on eigenvalues of > 1 and the marked inflection point after three factors in the scree plot (Figure 5.1), explaining 50.16% of the total variance. All items had factor loadings of > 0.3, and no item loaded significantly on more than one factor; therefore, all 15 items were retained. Unlike the original unidimensional structure, the SC-SCS-P demonstrated a three-factor structure. Factor 1 covers 11 items of 'Alienation', factor 2 has two items in 'Minimisation of health concern' and factor 3 has two items in 'Emotional concealment'.

Table 5.3 Results of exploratory factor analysis (n = 200)

| | Intended dimensions | Factor 1 | Factor 2 | Factor 3 |
|---|---|---|---|---|
| Item 1 | Alienation | 0.063 | 0.021 | **0.438** |
| Item 2 | | 0.070 | -0.026 | **0.313** |
| Item 3 | | -0.125 | -0.028 | **0.515** |
| Item 4 | | 0.045 | 0.019 | **0.494** |
| Item 5 | | 0.147 | 0.197 | **0.477** |
| Item 6 | | 0.065 | -0.056 | **0.571** |
| Item 7 | | -0.035 | -0.076 | **0.680** |
| Item 8 | | -0.002 | 0.141 | **0.548** |
| Item 9 | | 0.052 | 0.262 | **0.397** |
| Item 12 | | 0.100 | 0.187 | **0.490** |
| Item 15 | | 0.011 | -0.025 | **0.404** |
| Item 10 | Health Concern Minimization | -0.051 | **1.005** | -0.103 |
| Item 11 | | 0.065 | **0.595** | 0.145 |
| Item 13 | Emotional Concealment | **1.024** | -0.116 | 0.009 |
| Item 14 | | **0.726** | 0.108 | 0.056 |

Figure 5.1. Scree plot

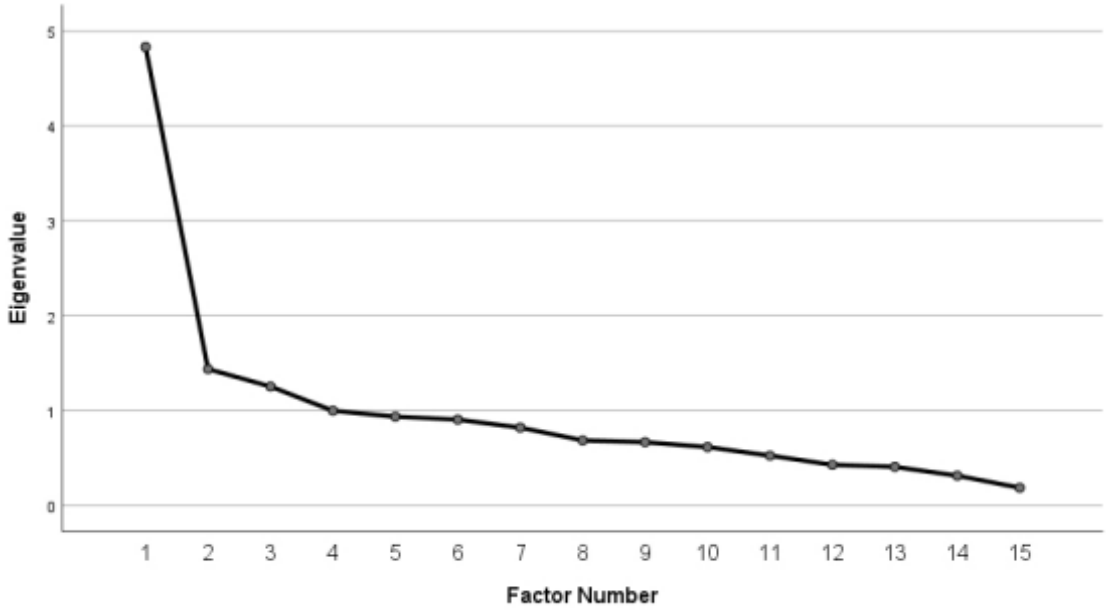


Figure 5. 1 Scree plot

5.2.5.4 Confirmatory factor analysis

To evaluate the appropriateness of both the original single-factor structure and the three-factor structure obtained from EFA, CFA were conducted using the maximum likelihood method. Two models were tested: a single-factor model (Model 1) and the three-factor model derived from EFA (Model 2). The results are presented in Table 5.4. The single-factor model (Model 1) showed a poor model fit to the data ($\chi^2$ = 367.089, df = 90, RMSEA = 0.124 [90% CI: 0.111-0.137], CFI = 0.667]. The three-factor model (Model 2) has model fit indexes that are close to their cut-off points ($\chi^2$ = 173.568, df = 87, RMSEA = 0.071 [90% CI: 0.041-0.075], CFI = 0.896]. The MI results indicated that adding a path from Factor 2 to Item 9 would yield the highest MI value (21.691); however, this modification was not implemented because the content of Item 9 was deemed only weakly relevant to Factor 2 (Minimisation of Health Concern).

Further examination of the MI results indicated that model fit can be improved by allowing the residuals of Items 6 and 15 to correlate (MI = 14.752). The model was rerun with this adjustment, producing a respecified model (Model 3) with acceptable fit indices: $\chi^2$ = 155.162, df = 86, RMSEA = 0.063 (90% CI: 0.047–0.079) and CFI =

0.917 (Table 5.4). No additional modifications were made. The final three-factor model is illustrated in Figure 5.2.

Table 5.4 Fit statistics

| Model | $\chi^2$ | df | P-value | RMSEA (90% CI) | CFI |
|---|---|---|---|---|---|
| Model 1–Original one factor model | 367.089 | 90 | <.0001 | 0.124 (0.111–0.137) | 0.667 |
| Model 2–Three-factor model from EFA | 173.568 | 87 | <.0001 | 0.071 (0.055–0.086) | 0.896 |
| Model 3–Model 2 plus correlation between Items 6 and 15 | 155.162 | 86 | <.0001 | 0.063 (0.047–0.079) | 0.917 |

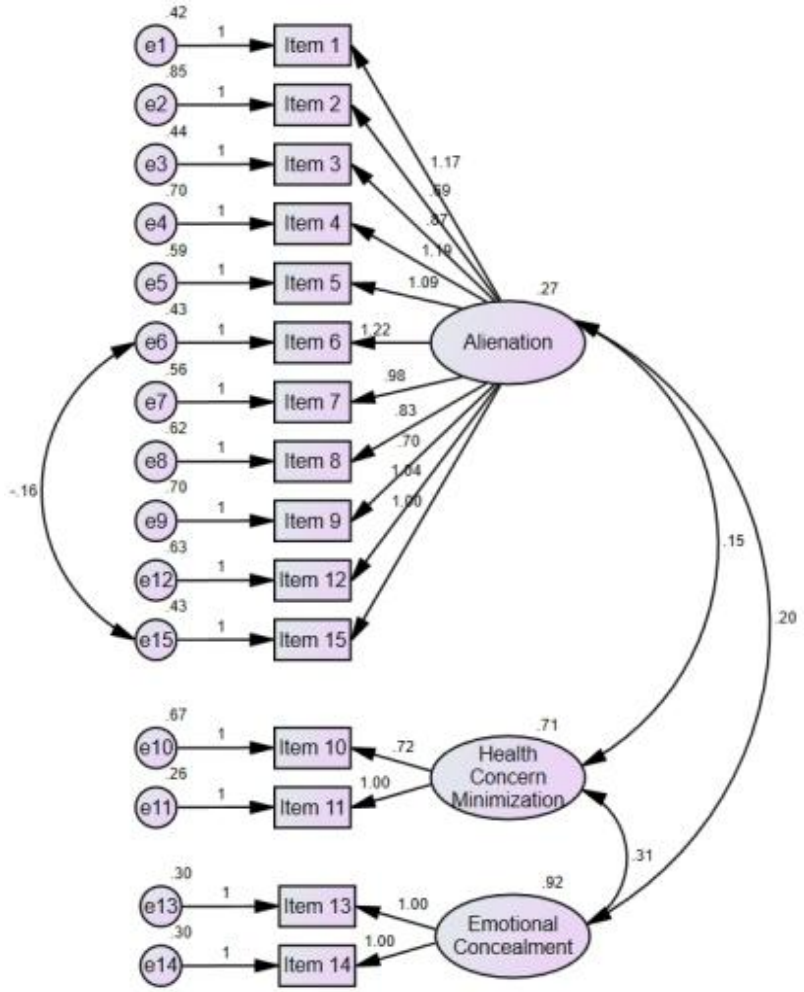


Figure 5.2 Final three-factor model indicated by CFA (n = 201)

5.2.5.5 Reliability of the scale

Table 5.5 presents the number of items, internal consistency and ceiling and floor effects of the SC-SCS-P. The overall Cronbach's α was 0.841, and subscale values ranged from 0.719 to 0.863, indicating good internal consistency. A total of 33 partners completed the SC-SCS-P again within 21 days. Test–retest reliability was strong for the overall scale and the 'Alienation' and 'Emotional Concealment' subscales (ICCs > 0.80), whereas the 'Minimisation of Health Concern' subscale demonstrated moderate reliability (ICC = 0.643). Ceiling and floor effects were examined for the total scale and all three subscales. Across the overall scale and subscales, only 0.2%–11.2% of respondents achieved the highest possible score (<30%), indicating no ceiling effect. For the floor effect, 2.5%–26.2% of participants obtained the lowest possible score, showing no floor effect.

Table 5.5 Internal consistency, test–retest reliability, ceiling and floor effects of the scale

| Scale/dimensions | Number of Items | Cronbach's α | ICC | Ceiling Effect n (%) | Floor Effect n (%) |
|---|---|---|---|---|---|
| Overall | 15 | 0.841 | 0.900 | 1 (0.2%) | 10 (2.5%) |
| Alienation | 11 | 0.817 | 0.846 | 1 (0.2%) | 17 (4.2%) |
| Health Concern Minimization | 2 | 0.719 | 0.643 | 24 (6.0%) | 70 (17.5%) |
| Emotional Concealment | 2 | 0.863 | 0.808 | 45 (11.2%) | 105 (26.2%) |

ICC: intra-class correlation coefficien

5.2.5.6 Convergent validity

All variables met the criteria for normality (skewness < 2 and kurtosis < 7), and Pearson correlations (r) were computed. As shown in Table 5.6, the total SC-SCS-P score and its three subscales were significantly and negatively correlated with psychological resilience and positively correlated with FCR and communication problems, supporting convergent validity. The only exception was the 'Minimisation of Health Concern'

subscale, which did not show a significant correlation with psychological resilience. These results indicate that higher social constraints are associated with lower resilience and higher FCR and communication difficulties, consistent with theoretical expectations.

Table 5.6 Correlations of the overall and three domain scores of SC-SCS-P with psychological resilience, FCR and communication problem in partners of adults with cancer

| Social constraints | Psychological resilience | | FCR | | Communication problem | |
|---|---|---|---|---|---|---|
| | Correlation | P-value | Correlation | P-value | Correlation | P-value |
| Overall | -0.182 | ＜.001 | 0.338 | ＜.001 | 0.139 | 0.005 |
| Dimensions | | | | | | |
| Alienation | -0.208 | ＜.001 | 0.283 | ＜.001 | 0.111 | 0.026 |
| Health Concern Minimization | 0.032 | 0.512 | 0.222 | ＜.001 | 0.111 | 0.026 |
| Emotional Concealment | -0.125 | 0.012 | 0.292 | ＜.001 | 0.117 | 0.019 |

5.2.5.7 Level of social constraints in partners and its correlation with other demographic variables

Table 5.7 shows the level of social constraints in partners and correlation with other demographic variables. According to the homogeneity test, education level demonstrated a significant difference in the level of social constraints in partners (P = 0.003). Based on pairwise comparisons, significantly higher levels of social constraints were observed in partners who had completed primary school education, the levels were higher than those with junior secondary school; high secondary school or college; or university or above. Variables of age, gender and employment status in partners, variables of age, gender, time since diagnosis, cancer type, stage, surgery, chemotherapy, radiotherapy and targeted therapy in adults with cancer showed non-significant results.

Table 5.7 Social constraints level in partners of adults with cancer by demographic variables

| | Variable | Group | n | Social constraints (Mean ± SD) | P-value |
|---|---|---|---|---|---|
| Characteristic in partners | Age | / | 397 | Pearson's r: 0.013 | 0.792 |
| | Gender | Female | 253 | 29.79±7.89 | 0.179 |
| | | Male | 147 | 30.89±7.96 | |
| | Education level | Primary school or below | 41 | **33.44±8.64** | 0.003* |
| | | Junior secondary school | 128 | 30.35±6.97 | |
| | | High secondary school or college | 126 | 28.47±7.97 | |
| | | University or above | 63 | 29.17±7.59 | |
| | Employment status | Unemployed | 200 | 30.54±7.54 | 0.071 |
| | | Employed | 155 | 29.05±7.92 | |
| | | | | | |
| Characteristic in adults with cancer | Age | / | 336 | Pearson's r: 0.042 | 0.443 |
| | Time since diagnosis | / | 388 | Pearson's r: 0.090 | 0.077 |
| | Cancer type | Breast cancer | 104 | 29.54±8.18 | 0.852 |
| | | Thyroid Cancer | 40 | 28.98±7.14 | |
| | | Nasopharyngeal Carcinoma | 39 | 30.72±7.42 | |
| | | Colorectal Cancer | 39 | 30.15±7.87 | |
| | | Lung Cancer | 38 | **31.55±7.38** | |
| | | Oral Cancer | 37 | **31.65±8.80** | |
| | | Gynecological Cancers | 36 | 30.67±9.13 | |
| | | Urological Cancers | 11 | 27.45±7.65 | |
| | | Neurological Cancers | 10 | 29.40±10.02 | |
| | | Liver Cancer | 9 | **31.67±7.19** | |
| | | Osteosarcoma | 9 | 28.89±6.70 | |
| | | Gastric Cancer | 9 | 29.33±7.81 | |
| | | Others (including | 20 | | |

| | | | | | |
|---|---|---|---|---|---|
| | | Head and Neck Cancers, Pancreatic Cancer, Esophageal Cancer, etc.) | | 31.75±6.97 | |
| | Stage | 0 | 12 | 29.25±7.81 | 0.742 |
| | | 1 | 82 | 30.44±8.08 | |
| | | 2 | 68 | 29.41±7.77 | |
| | | 3 | 91 | 30.12±7.84 | |
| | | 4 | 114 | **30.96±7.82** | |
| | Surgery | No | 227 | 30.34±7.61 | 0.824 |
| | | Yes | 166 | 30.16±8.39 | |
| | Chemotherapy | No | 187 | 30.32±8.26 | 0.909 |
| | | Yes | 206 | 30.22±7.65 | |
| | Radiotherapy | No | 370 | 30.17±8.00 | 0.346 |
| | | Yes | 23 | 31.78±6.83 | |
| | Targeted therapy | No | 301 | 30.32±7.946 | 0.815 |

5.2.6 Discussion

We have culturally adapted and tested the psychometric properties of the Simplified Chinese version of SCS for partners (SC-SCS-P), which measures partner-specific social constraints from adults with cancer. The scale demonstrated excellent convergent validity and internal consistency, indicating that the 15-item SC-SCS-P is a valid and reliable measurement tool for assessing a partner's social constraints from adults with cancer. Consistent with prior literature, partners across collectivist and individualist contexts (e.g. Iran, Canada, the UK and the USA) frequently report feeling constrained in expressing their thoughts, emotions or concerns to loved ones with cancer (Boamah Mensah et al., 2021; e Silva et al., 2010; Gutierrez et al., 2016; Nasiri et al., 2016; Traboulssi et al., 2022; Zahlis & Shands, 1991). The probable reasons were factors, such as an unsupported social environment, protective buffering and gender role. Thus, assessing social constraints in the partners of cancer patients is essential. Therefore, this scale can serve as a unique instrument for evaluating such constraints in partners of adults with cancer in China and in different countries.

Factor analysis indicated that the SC-SCS-P with a three-factor solution was optimal,

explained 50.16% of the variance. All the 15 items were retained: eleven items in the factor of alienation, two items in the factor of health concern minimisation and two items in emotional concealment. The first factor of alienation refers to a sense of disconnection or estrangement from oneself, others or society. It can manifest emotionally, socially or existentially. The second factor of health concern minimisation refers to downplaying or dismissing health issues, either by individuals (e.g. ignoring symptoms) or institutions (e.g. healthcare providers underestimating patient complaints). The third factor of emotional concealment refers to hiding or suppressing emotions to conform to social norms, avoid conflict or protect privacy. The three dimensions align with the three sources of social constraints identified by Lepore et al. (1996), including (1) inappropriate or insensitive behaviours from the available social network, (2) absence of supportive people to talk and (3) outright negative reactions of others (Lepore et al., 1996). Factor analysis of the SC-SCS-P indicated three types of social constraints, namely, alienation, health concern minimisation and emotional concealment. The first dimension of alienation, encompassing items, such as patients changing the topic when discussing their illness (Item 1), appearing not to understand their partners' feelings (Item 2), avoidance (Item 3), ignoring or minimising the partners' feelings (Item 4), hiding their own feelings (Item 5) and showing discomfort in discussing the illness (Items 6, 7, 8, 9, 12 and 15), reflects social constraints stemming from inappropriate or unsupportive social behaviours. These constraints may cause feelings of misunderstanding, dismissal and emotional isolation. The second dimension of health concern minimisation (Items 10 and 11), characterised by patients downplaying their health concerns or discouraging caregivers from worrying excessively, corresponds to social constraints related to avoidance or denial, limiting open communication about trauma-related thoughts and feelings. The third dimension of emotional concealment (Items 13 and 14), where partners feel the need to hide their emotions about the illness to avoid causing discomfort or unhappiness in patients, reflects the impact of negative social reactions and avoidance within the support network.

We have replicated the three-factor solution from EFA in the CFA by using an independent random subsample. Acceptable model fit was obtained after a post hoc modelling adjustment with the addition of the correlation between the residuals of the Items 6 and 15. The potential reason for the negative correlation between Items 6 and 15 lies in how the health-related stress in adults with cancer impacts relational dynamics, creating emotional distance and perceived neglect. Item 6 of 'When you mention the disease in adults with cancer, they seem uncomfortable' describes partners' perception of the discomfort with discussing cancer from the adult with cancer. This reaction may stem from anxiety, denial, vulnerability and cultural stigma. The patient may withdraw emotionally as a coping mechanism to avoid confronting distressing emotions or to maintain psychological defense, which is very likely in the context of the Chinese culture (Zhang et al., 2024). Item 15 'You feel unhappy because the adult with cancer doesn't seem to care about you as much as you expected.' describes partners' perception of reduced love or care. The negative correlation between Items 6 and 15 may reflect that in some cases, partners interpret the patients' discomfort in discussing cancer (Item 6) not as emotional neglect but as an attempt to protect them from distress (i.e. protective buffering). In the Chinese cultural context, where indirect expression of care is common, such avoidance can be perceived as a form of concern, thereby reducing the feeling of being uncared for (Item 15).

The SC-SCS-P and its three domains exhibited good internal consistency and test–retest reliability, with a range between 0.719 and 0.863. No ceiling or floor effects were observed for the overall scale. Good test–retest reliability of the proposed scale was observed, but reliability in the health concern minimisation subscale was moderate. The moderate test–retest reliability in the health concern minimisation subscale may reflect the inherently variable nature of its content. This subscale consists of two items: 'The patient tells you not to worry so much about his/her health' and 'The patient asks you to think less about things related to his/her disease'. These items capture interpersonal

expression of reassurance or downplaying health concerns. Such behaviours are likely to fluctuate over time depending on the patient's current health condition, emotional state or recent experiences, leading to temporal variability higher than that of stable constructs. In addition, the limited number of items in this dimension may have further reduced the stability of the estimate. Amongst the existing scales used to assess social constraints in adults with cancer, only one study reported test–retest reliability of the scale, which was 0.826 (Luo et al., 2023). This finding has extended the evidence in reliability of the scale from the patient population to the partner population.

The current findings of the correlational analysis were strongly supported by the integrative model developed by Simonelli et al. (2007) and hence support the convergent validity of the scale. As postulated by the integrative model, significant results were found, in which social constraints negatively correlated with psychological resilience, and positively correlated with FCR and communication problem were identified in the overall scale and all the three dimensions. The weak correlations with psychological resilience and communication problems suggest that evidence for convergent validity is partial rather than uniform across all external constructs. Conceptually, social constraints are perceived responses from others that inhibit cancer-related disclosure and appear more proximal to FCR, which is consistent with the moderate association observed with FCR. In contrast, psychological resilience is a trait-like personal resource and may operate more as a moderator rather than showing a strong linear association with perceived constraints. Similarly, communication-problem measure captures more general communication difficulties, whereas the social constraints scale is specific to responses that inhibit cancer-related disclosure; therefore, only small associations are expected. These findings also indicate that the social constraints scale is not redundant with resilience or general communication problems, supporting construct distinctiveness. However, the negative correlation between health concern minimisation and psychological resilience was non-significant. Partners with strong psychological resilience and reduced communication problem tended to have a

low level of social constraint. Social constraints reflect behaviours, cognitions and feelings and the individual's construal of them (Lepore & Revenson, 2007). Resilience denotes positive adaptation or the capacity to sustain or regain mental health in the face of adversity (Herrman et al., 2011). Therefore, partners with strong psychological resilience are likely to maintain mental conditions regardless of unfavourable social constraints. The non-significant correlation between health concern minimisation and psychological resilience is theoretically reasonable because the factor 'health concern minimisation' refers to the situation that the partners perceived that patients downplay their own health concerns or discourage their loved ones from worrying excessively, which is partners' perception of the behaviours from the adults with cancer, and may thus not relate to partners' psychological resilience. However, research in social constraints in partners of adults with cancer is very limited. The results in partners' social constraints with other theoretically linked variables such as FCR, communication problem and psychological resilience should be examined in future studies with the availability of the validated SC-SCS-P produced in this study for measuring social constraints from their partners with cancer.

In line with a previous study in breast cancer patients (Cui et al., 2022), we found that educational level was the only demographic variable associated with social constraints in partners of adults with cancer. Pairwise comparisons showed that the mean levels of social constraint in individuals with education levels of primary school or below were higher than those with education levels of junior secondary school, high secondary school, college, university or above. Interventions may target individuals with low education levels, especially those who completed primary school education or below. In China, low education often correlates with limited health literacy (Shan et al., 2023) and low income (Liu et al., 2025), exacerbating financial stress from cancer-related cost and restricting social participations. Healthcare providers can assess social constraint levels of partners of adults with cancer with the SC-SCS-P and provide timely and appropriate support.

Strengths and limitations

Our study has several strengths. Firstly, it was a multi-centre study, recruiting participants in central and eastern China. Furthermore, we included partners of adults newly diagnosed with cancer and the partners of survivors capturing a broad span of the caregiving trajectory. These two sample characteristics enhanced the generalisability of the study findings. Secondly, the scale was adapted with a rigorous procedure, including expert panel validation and pilot testing, and was psychometrically tested in a large sample, thus enhancing the reliability and validity of the scale. However, the study had several limitations. The reliability of the validated scale for communication problem in the current study was questionable and might have impacted the validity of the findings. However, findings with the two other variables (psychological resilience and FCR) did provide evidence to support the convergent validity of the SC-SCS-P. Future studies are needed to explore other psychometric properties, such as the predictive validity of the scale.

5.2.7 Conclusions

The adapted version of the SC-SCS-P has good psychometric properties in a sample of 415 participants. The EFA results showed a three-factor solution (alienation, health concern minimisation and emotional concealment) was optimal and explained 50.16% of the variance. The Cronbach's α values of the overall scale and three dimensions ranged from 0.719 to 0.863, and the ICCs ranged from 0.643 to 0.900. The overall score of the scale was significantly and positively correlated with FCR ($r = 0.338$, $P < 0.001$) and communication problem ($r = 0.139$, $P = 0.005$) and negatively with psychological resilience ($r = -0.182$, $P < 0.001$). The 15-item SC-SCS-P is a reliable and valid tool with strong evidence and can thus be used in measuring partner-specific social constraints from adults with cancer in China. The development of the scale has filled the practice gap of no specific measurement of social constraints in partners of adults with cancer. This study is a crucial step for studies on social constraints in partners of

adults with cancer and may guide the development of effective interventions for individuals who experience social constraints.

## 5.3 Psychometric Properties of the Affiliate Stigma Scale for Caregivers of Women with Breast Cancer

### 5.3.1 Background

Misconceptions and myths surrounding breast cancer not only contribute discrimination and social rejection toward patients, but also their family members. As noted by Mak & Cheung (2008), affiliate stigma refers to the self-stigma and related psychological reactions experienced by individuals closely associated with targeted individuals. Within caregiving contexts, caregivers who experience affiliate stigma may have heavier burden and strain, as stigma can distort their perceptions of care recipients and negatively affect their relationships (Mak & Cheung, 2008). In the Chinese culture, maintaining "face" is highly valued, affiliate stigma may be specifically pronounced in caregivers. Those who limit disclosure to protect their social image may consequently lose social support, face increased stress and affiliate stigma Mak et al. (2008). Up to now, four scales are available to measure affiliate stigma among caregivers. Of these four scales, one targets caregivers of cancer patients (Squiers et al., 2021), while the other three are for caregivers of individuals with mental disorders (Mak & Cheung, 2008; Werner et al., 2011; Yin et al., 2014).Specifically, the only scale, developed by Squiers et al. for assessing affiliate stigma among caregivers of cancer patients, comprises three dimensions, including perceived, experienced and internalised stigma (Squiers et al., 2021). This instrument was initially adapted from an HIV-related stigma (Dos Santos et al., 2014; Visser et al., 2008) and modified to fit the Indian cancer context. However, its psychometric evaluation was conducted only with 20 cancer patients rather than caregivers, raising concerns about its applicability. Furthermore, several items do not directly reflect affiliate stigma (e.g., 'Have you ever been denied healthcare?'; 'Have you ever been denied health insurance?'; 'Have you ever lost a job or a source of income?'), which also in doubt of its content validity. To better understand

the stigma faced by caregivers of women with breast cancer and to inform the development of effective interventions, it is essential to create a reliable and context-specific tool to evaluate affiliate stigma. Hence, the present study aimed to develop and validate an instrument tailored to the affiliate stigma experienced by caregivers of women with breast cancer.

### 5.3.2 Method

This study employed a mixed-method study design, with two phases. The first phase was conceptualization and development of an initial item pool for the affiliate stigma scale. There were four components: (1) literature review, (2) qualitative interviews, (3) content validity of the initial scale, and (4) pilot testing. The second phase involved psychometric evaluation of the affiliate stigma scale using a sample of caregivers of women breast cancer. This study followed COSMIN checklist to guide the design of the validation process (Prinsen et al., 2018). We also referred to the method proposed by Clark and Watson for evaluating construct validity in newly developed instruments to enhance measurement objectivity (Clark & Watson, 2019).

### 5.3.3 Phase1: scale development and item generation

#### 5.3.3.1 Literature Search

A comprehensive literature review helps clarify whether a proposed scale will either offer a theoretical or an empirical improvement over existing measures or fills a key measurement gap. Therefore, we performed a thorough literature review to understand the stigma that is unique to caregivers of women with breast cancer. Eight databases, PubMed, Web of Science, Embase, CINAHL, CNKI, Wanfang, VIP, and CBM were systematically searched from each database's inception to Oct 2022 to explore stigma in caregivers of women with breast cancer. The final search strategy combined the terms caregivers, breast cancer as well as experience or their related words. Meanwhile, we reviewed the literature for existing stigma scales for caregivers.

5.3.3.2 Qualitative interviews

Semi-structured interviews were conducted in April 2023 with 18 caregivers of women diagnosed with breast cancer. The interviews were facilitated by the doctoral student, who has substantial training in qualitative research methodologies. Interviews were conducted face-to-face in a private room or somewhere outside the wards at two Tertiary A hospitals in China, with each lasted between 15 and 90 minutes. For those interviews conducted outside the ward, it was ensured that conversations could not be overheard. All interviews were recorded using a digital voice recorder and transcribed verbatim within 24 hours. A deductive approach was applied using Colaizzi's method for data analysis 24. The concepts derived from the qualitative data served as the conceptual foundation for the scale's development. Scale items were from direct quotations in the interviews, complemented by a review of existing affiliate stigma scales. An item pool was formed for further testing.

5.3.3.3 Content validity

The Delphi method was employed to assess the content validity of the newly developed scale. This method is widely used to obtain reliable expert consensus through a series of structured questionnaires (Keeney et al., 2001). Across two rounds of Delphi, we presented the expert panel with the proposed dimensions in the concept of affiliate stigma of caregivers of women with breast cancer and the item pool. Revisions were made between rounds based on the feedback provided from the experts. Experts were recruited from the research team's network. Invitations, along with a detailed content description, were distributed to experts via WeChat message. Eligible experts were required to have more than five years of working or research experience in breast cancer, stigma, or psychology, hold a master's degree or higher, and have at least one related publication in a peer-reviewed journal. Seven experts participated, two of them with backgrounds in psychology and five in nursing. Among them, two had extensive research experience in stigma-related topics.

Each expert independently evaluated the content, provided comments on item phrasing, and assessed the relevance of each item using a 5-point Likert scale (1 = "not relevant" to 5 = "highly relevant"). Upon receiving the feedback, the research team compiled and reviewed all comments. Appropriate revisions were incorporated into the scale. After completing two rounds of Delphi, an expert-validated version of the scale was finalized.

5.3.3.4 Pilot testing

To assess the wording, and suitability of each item, a pilot test was conducted with 10 caregivers of women diagnosed with breast cancer. Participants were invited to complete the expert-validated version of the scale and provide feedback on the comprehensibility of the items. Based on insights gathered from this stage, a preliminary version of the scale was refined for subsequent psychometric evaluation.

5.3.4 Phase II: Psychometric evaluation of the affiliate stigma scale

A psychometric assessment examined structural validity, internal consistency, reliability and test–retest reliability of the newly developed scale.

5.3.4.1 Participants

Participants were recruited using convenience sampling from four Tertiary A and provincial hospitals in Hunan Province and one tertiary A and municipal hospital in Jiangsu Province between May and June 2023. In accordance with established guidelines for exploratory factor analysis (EFA), which recommend a sample size to be three to twenty times than the number of items in the scale (Williams et al., 2010), we aimed to recruit approximately 390 participants (15 cases x 26 items).

The inclusion criteria were: (1) individuals who self-identified as caregivers of women with breast cancer (stages I–IV) receiving treatment, including surgery, chemotherapy, radiotherapy, hormone therapy, or targeted therapy; (2) aged 18 years or above; (3) with clear consciousness and able to finish the questionnaire independently; and (4) provided

consent to participate. Individuals with any psychiatric conditions were excluded from the study.

5.3.4.2 Measures

Demographic information, including age, religion, place of residence, employment status, educational background, family history of cancer, relationship to the patient, discussing the family member's disease with others, and duration of caregiving.

The newly developed 26-item affiliate stigma scale

The study utilized a newly developed 26-item Affiliate Stigma Scale designed specifically for caregivers of women with breast cancer. Participants assessed their stigma-related experiences using a 4-point Likert-type scale, ranging from 1 (strongly disagree) to 4 (strongly agree). The scale is structured to capture four dimensions of affiliate stigma. Higher total scores reflect greater levels of affiliate stigma.

The Chinese version of the Zarit Caregiver Burden Interview (ZBI)

The ZBI scale was used to assess the level of burden experienced by caregivers, including caregiver's health, psychological well-being, social life, finances and the relationship between the caregiver and patient (Lu et al., 2009; Zarit et al., 1980). The scale consists of 22 items, each rated on a 4-point Likert scale ranging from 0 (never) to 4 (always), based on the frequency or intensity of the caregiver's experiences. The total score ranges from 0 to 88, with higher scores indicating greater caregiver burden. The Chinese version of the ZBI has demonstrated strong internal consistency, with a Cronbach's α of 0.875 (Lu et al., 2009). In the current study, the scale showed excellent reliability, with a Cronbach's α of 0.892.

The Chinese version of the Rosenberg Self-esteem Scale

This scale was employed to assess participants' levels of self-esteem (Rosenberg, 1965; Yan et al., 2021). This scale consists of 10 items, with each rated on a 4-point Likert

scale ranging from 1 (strongly disagree) to 4 (strongly agree). The total score ranges from 10 to 40, with higher scores reflecting higher self-esteem. The Chinese version of the scale has demonstrated strong internal consistency, with a Cronbach's α of 0.875 (Yan et al., 2021). In the present study, the scale showed strong internal consistency, with a Cronbach's α of 0.833.

The Chinese version of the Social Support Rating Scale

This 10-item scale was developed by Xiao et al. to assess individual's social support, including objective support, subjective support and utilization of social support (Xiao, 1994). An overall score of social support is calculated. The total score ranges 12 – 66 points, with higher values reflecting higher levels of social support. This scale is widely used in China, with test–retest reliability of 0.92 (Xiao, 1994). In the current study, the internal consistency of the scale was acceptable, with a Cronbach's α of 0.743.

5.3.4.3 Data collection procedure

Data collection was carried out by five trained data collectors. Caregivers were recruited through referrals from women with breast cancer at the participating hospitals. Data collectors assessed the eligibility of each caregiver and provided a detailed explanation of the study procedures during their hospital visits. Caregivers met the inclusion criteria and agreed to participate were asked to provide written informed consent. After providing informed consent, the participants self-completed the questionnaires. Data collectors were available to clarify any questions related to the items in the questionnaires. For participants had difficulty in reading, the data collectors read the questions and response options to them without inducement. For the test-retest assessment, we identified caregivers who previously completed the questionnaire and approached them again within 7 to 21 days of the initial administration.

5.3.5 Statistical Analyses

The statistical analysis plan for psychometric evaluation of the affiliate stigma scale

was the same as that for evaluating the social constraints scale (Section 5.2.8 in this chapter), with an exception of CFA. Briefly, the validity of the affiliate stigma scale was assessed through analyses of content validity by I-CVI, factor structure by EFA, and convergent validity by correlational analysis with caregiver burden, self-esteem and social support. It was hypothesized that the scale would positively correlate with caregiver burden and negatively with self-esteem and social support, consistent with prior literature (Mak & Cheung, 2008; Saffari et al., 2019; Yin et al., 2014). The reliability was evaluated by examining the scale's internal consistency using Cronbach's alpha and test-retest reliability by ICC. In addition, homogeneity tests across demographic variables and assessment of floor and ceiling effects in the domain level were also conducted.

### 5.3.6 Ethical Considerations

Ethical approval for this study was obtained from the Ethics Committee of the participating hospital (Quick Review No. 34, 2023). The research was carried out with the support and coordination of nursing department managers at each of the participating hospitals. All participants received detailed information about the study and gave their written informed consent prior to participation.

### 5.3.7 Results

#### 5.3.7.1 Phase I: Conceptualisation and generation of items

##### 5.3.7.1.1 Literature review results

In addition to self-blame and stigma often experienced by women diagnosed with breast cancer, their family members may also encounter social rejection and discrimination (Wang et al., 2020; Yeung et al., 2019). The misconceptions, myths, and beliefs about breast cancer result in gossip and stigmatizing attitudes from others (Boamah Mensah et al., 2021; e Silva et al., 2010). The perception of cancer as an refractory disease and its strong association with death (e Silva et al., 2010; Traboulssi et al., 2022) can intensify caregivers' emotional distress, making them more sensitive to the behaviours

and attitudes of others (Nasiri et al., 2016). When relatives or acquaintances respond differently after knowing the diagnosis, caregivers may interpret these reactions negatively, viewing them as disruptive or emotionally damage to the patient and the family (Zahlis & Shands, 1991) (Nasiri et al., 2016). Caregivers also consider it difficult when dealing with unsupportive individuals, such as those who are uncomfortable when knowing their family member's diagnosis (Zahlis & Shands, 1991). Moreover, some caregivers struggle to respond appropriately to others' responses, as they wish to avoid discouraging them. As a result, they put up a shell (Zahlis & Shands, 1991).

'Misplaced sympathy' was used to describe situations in which people use phrases or words in a tone that hurts caregivers' feeling (Nasiri et al., 2016). Encountering with friends or colleagues who inquire about the disease may be particularly uncomfortable for caregivers (Hilton et al., 2000). Moreover, those who are associated with cancer patients, regardless of husband or even distant relatives, may also face social distancing, as others avoid contact with them due to their perceived connection to the disease (Gürsoy et al., 2017). As a result, caregivers may feel compelled to conceal the diagnosis to avoid actual and perceived stigma, often bearing the caregiving responsibilities alone (Boamah Mensah et al., 2021; Traboulssi et al., 2022). Meanwhile, a cancer diagnosis limits caregivers' social life, discourages their engagement in social activities due to the gossip and others' negative attitudes (Boamah Mensah et al., 2021). Furthermore, breasts are seen as symbols of femininity, physical appeal, and sexual identity (Bu, Li et al., 2022). Because breast cancer often results in mastectomy, caregivers find it hard to discuss breast reconstruction with friends or even family members. They may feel such discussions were perceived as vanity or met with misunderstanding from those without similar experiences (Sandham & Harcourt, 2007). Moreover, acting normally serves as a strategy to maintain the integrity of social interactions and avoid stigma. This behavior may also reflect the cultural of 'saving face' (Mak & Cheung, 2012). When it comes to affiliate stigma, to some extent, a diagnosis of breast cancer within a family may affect other family members. Thus,

given the beliefs towards breast cancer and the culture of saving 'face', affiliate stigma among caregivers may be particularly salient. Caregivers who withhold their disclosure to protect their social image may result in reduced social support, heightened stress and affiliate stigma (Mak & Cheung, 2008).

5.3.7.1.2 Qualitative Interview

A total of 18 caregivers of women with breast cancer participated in the qualitative interviews, and their ages ranged from 20 to 66 years. Among the participants, 15 were males and 3 were females; 14 were partners while 4 were children of the women with breast cancer. The transcripts were analyzed independently by the research team through bracketing data on preconceived ideas and strictly following Colaizzi's method. The findings were then compared and discussed within the research team until consensus was reached on themes, theme clusters and categories. The analysis revealed four core structural concepts underpinning the stigma related experience: 'perceived stigma', 'internal stigma', 'social isolation' and 'reactions towards women with breast cancer'.

**Theme 1: Internal stigma**

'Internal stigma' refers to the shame and expectation of discrimination that inhibit caregivers from discussing their experiences and seeking support. This worsened the internal unrest of the caregivers and heightened their sensitivity.

'*We did not tell anyone as there were too many negative effects...When people ask about us, we just say it's a cough. We went to the hospital for treatment.*' (Caregiver 1)

'*Relatives may be afraid that we borrow money from them (to pay for the treatment) when we disclose the diagnosis to them*' (Caregiver 3)

Theme 2: Social isolation

'Social isolation' is an objective lack of connection, characterized by few social

contacts or small social network, which can result in feelings of loneliness, while loneliness is a subjective feeling of being alone or disconnected: an individual can feel lonely without being socially isolated. Social isolation is a state of complete or near-complete absence of connection between an individual and society. Unlike loneliness, social isolation reflects short-term and involuntary absence of interactions with other individuals in the world 40. After the diagnosis of cancer was disclosed, noticeable shifts in the attitudes and behaviors of family members and acquaintances were observed.

'*Cancer is hui qi. Taboo is the biggest characteristic in China, and sometimes they are reluctant to communicate.*' (Caregiver 2)

'*When others know you have cancer, they are fear. They will alienate you and will not visit your family anymore*' (Caregiver 4)

'*Several of my old classmates' wives were diagnosed with breast cancer, and I just told them "You have to be strong, and I give you a blessing from my heart." I did not say too much because others may feel uncomfortable and they also need face.*' (Caregiver 1)

Theme 3: Perceived stigma

'Perceived stigma' is the fear of being discriminated against or the fear of enacted stigma, which arises from society's belief. It is rooted in misconceptions and causal beliefs about breast cancer, which may negatively affect the spirit of caregivers.

'*Cancer is scruple. Being afraid of other's strange vision.*' (Caregiver 9)

'*People may say it behind your back, for example, you have a high income, you should get this disease. People in rural areas may have an unbalanced mentality.*' (Caregiver 10)

Theme 4: Reaction

'Reaction' refers to actions taken by caregivers following the breast cancer diagnosis of the women.

'*I think the wife's illness has something to do with what my father had done before. I will go back and ask my father why they used to eat vegetarian food.*' (Caregiver 1)

'*I bought her artificial breasts. After wearing the artificial breast, it is unrecognizable and same with the health breast.*' (Caregiver 7)

5.3.7.1.3 Delphi study and pilot testing

The initial item pool was generated based on qualitative interview. Items were extracted from affiliate stigma related content identified in these interviews, including 15 items for the internal stigma domain, 8 items for the social isolation domain, 9 items for the perceived stigma domain, and 6 items for the reaction domain. Following two rounds of Delphi study, revisions were made to the initial version of the scale. In total, 15 items were deleted, with nine items were irrelevant to stigma and six items were identified as redundant. Three new items were added based on expert's suggestions. The wordings of 10 items were revised for better expression or avoiding jargons. No changes were made to the domain structure. Details of the changes in the two Delphi rounds were shown in Appendix XIV.

5.3.7.2 Phase II: Psychometric evaluation

5.3.7.2.1 Sociodemographic characteristics

A total of 426 questionnaires were distributed to caregivers of women with breast cancer, and 400 valid questionnaires were received, yielding a response rate of 93.90%. The mean age of the participants was 43.66 years (SD = 12.567), ranging from 15 to 74 years. Majority of the caregivers resided in 13 cities and one autonomous prefecture within Hunan Province, while a small portion of respondents came from two cities in Jiangsu Province, as well as from other provinces including Anhui, Jiangxi, and Xinjiang. Detailed demographic information is presented in Table 5.8.

Table 5.8 Sociodemographic characteristics of the caregivers (n = 400)

| Variable | Group | n | （%） |
|---|---|---|---|
| Age | ≤44 | 216 | 54.0 |
| | 45-54 | 137 | 34.25 |
| | ≥60 | 47 | 11.75 |
| Religion | Yes | 28 | 7.0 |
| | No | 372 | 93.0 |
| Place of residence | City | 212 | 53.0 |
| | Township | 101 | 25.25 |
| | Village | 87 | 21.75 |
| Employment status | Unemployed | 121 | 30.25 |
| | Employed | 279 | 69.75 |
| Education level | Primary school or below | 31 | 7.8 |
| | Junior school | 96 | 24.0 |
| | High school or college | 124 | 310 |
| | University or above | 149 | 37.3 |
| Family history of cancer | Yes | 132 | 33.0 |
| | No | 268 | 67.0 |
| Relationship with the patient | Partner | 220 | 55.0 |
| | Others (e.g., children, parents, relatives) | 180 | 45.0 |
| Discussing the family member's disease with others | Yes | 175 | 43.75 |
| | No | 225 | 56.25 |
| Time for caring | ≤1year | 350 | 87.5 |
| | 1-5 years | 30 | 7.5 |
| | ≥5 | 20 | 5.0 |

5.3.7.2.2 Item total correlation

Table 5.9 presents the item–total correlation coefficients for all the 26 items in the scale. Item 26 ('I do not hope others sympathize with me due to my family member being diagnosed with breast cancer') from the reaction domain has an item–total correlation below 0.3, indicating a poor correlation with the overall scale. Consequently, this item was removed. The remaining 25 items were retained to assess four subdomains, including internal stigma (7 items), social isolation (8 items), perceived stigma (5 items) and reaction (5 items). These 25 items were subsequently included in EFA.

Table 5.9 Item–total statistics of the scale

| Number | Items | Item-total correlation |
|---|---|---|
| 1 | I would avoid talking too much about my family member's breast cancer disease with others. | 0.594 |
| 2 | When I'm with my family member who has breast cancer, I'm sometimes more reticent. | 0.623 |
| 3 | After my family member was diagnosed with breast cancer, I had less contact with relatives and friends. | 0.615 |
| 4 | After my family member was diagnosed with breast cancer, I was more concerned about others' opinions. | 0.615 |
| 5 | After my family member was diagnosed with breast cancer, I was afraid to participate in social activities because I was afraid of people asking about my family's breast cancer status. | 0.713 |
| 6 | I was reluctant to allow my family to attend social activities because I was worried that others would find out she had breast cancer. | 0.708 |
| 7 | I am afraid to attend breast cancer-related activities in case others suspect that my family member has breast cancer. | 0.682 |
| 8 | I get nervous or embarrassed when my family member needs to talk about her breast cancer in public. | 0.482 |
| 9 | After a family member was diagnosed with breast cancer, I was afraid of others paying attention or judging her sex life. | 0.456 |
| 10 | I didn't want people to know that my family member was diagnosed with breast cancer. | 0.563 |
| 11 | I feel embarrassed when others talk with me about my family member having breast cancer. | 0.649 |
| 12 | I feel shame and remorse about not being able to afford the expensive treatment. | 0.422 |
| 13 | After my family member went through breast cancer treatment, I felt uncomfortable when people stared at her chest or head. | 0.461 |
| 14 | I didn't want others to see my family member emaciated after suffering from breast cancer. | 0.384 |
| 15 | I have advised my family not to tell others that someone in our family has breast cancer. | 0.608 |
| 16 | I was worried that others would think there was a hereditary risk of breast cancer in my family. | 0.614 |
| 17 | After my family member suffered from breast cancer, I felt the strange looks from others. | 0.687 |
| 18 | After my family member suffered from breast cancer, I felt like someone was talking about our family or about her disease. | 0.651 |

| | | |
|---|---|---|
| 19 | After my family member was diagnosed with breast cancer, I often felt someone was staring at her chest or head. | 0.635 |
| 20 | After my family member was diagnosed with breast cancer, others were unwilling to have contact with our family. | 0.665 |
| 21 | After my family member was diagnosed with breast cancer, my family and I were discriminated against or excluded from social activities (meals, parties, etc.). | 0.638 |
| 22 | After my family member was diagnosed with breast cancer, I avoided communicating with her. | 0.594 |
| 23 | After my family member was diagnosed with breast cancer, I tried to distance myself from her. | 0.447 |
| 24 | After my family received treatment for breast cancer, I felt humiliated or ashamed about her appearance (e.g., missing breasts, hair loss, hyperpigmentation, and weight change). | 0.608 |
| 25 | I am afraid that others will think that my ancestors did something bad that caused breast cancer in my family. | 0.59 |
| 26 | I do not want others to sympathise with me because my family member has breast cancer. | **0.223** |

5.3.7.2.3 Exploratory factor analysis

The results of the EFA are presented in Table 5.10. The maximum likelihood analysis with direct oblique rotation was performed on the remaining 25 items. KMO measure of sampling adequacy was 0.942 and Bartlett's test of sphericity was significant ($P < 0.0001$), suggesting the appropriateness of the data for EFA. A four-factor solution was retained in the EFA based on eigenvalue greater than 1, and the sharp drop in the slope after the fourth factor on the scree plot (Figure 5.3). Item 16 ('I was worried that others would think there was a hereditary risk of breast cancer in my family') exhibited factor loadings below 0.30 across all factors and was therefore removed from the scale.

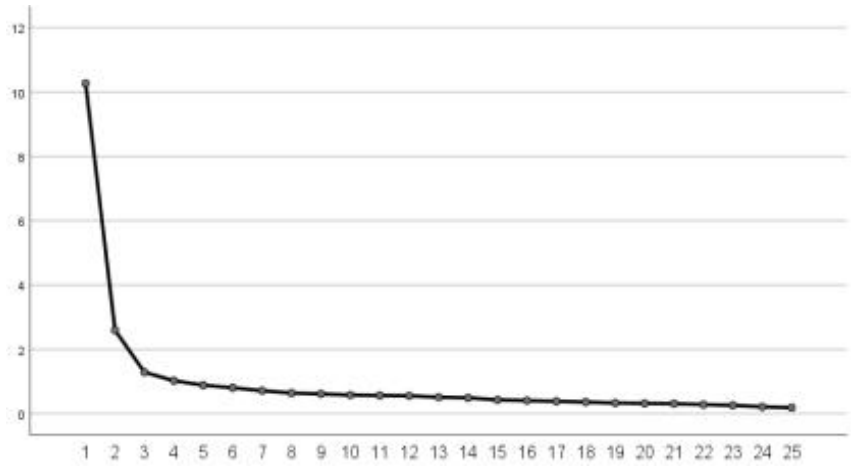


Figure 5.3. Scree plot for the 25-item scale

We re-ran EFA on the remaining 24 items. The KMO measure was 0.939 and Bartlett's test was statistically significant ($P < 0.0001$), suggesting the appropriateness of the data for EFA. Four factors were retained in accordance with the eigenvalue criteria, the scree plot (Figure 5.4), which explained 61.44% of the total variance. The 4-factor solution resembles the designed 4-factor structure, with factor 1 covering items of the internal stigma domain, factor 2 with items in social isolation, factor 3 with items in perceived stigma and factor 4 with items of the reaction domain. However, a total of 7 items were cross-loaded on factors. Three items (Items 1, 7 and 15) doubled on factors 1 and 2. Items 1 and 7 were retained in factor 1 because of the larger factor loading on factor 1 than that on factor 2. Item 15 ("I have advised my family not to tell others that someone in our family has breast cancer") had factor loadings with similar magnitude on both factors but was retained in factor 2 based on interpretation because the content of Item 15 is closer to factor 2 of social isolation by keeping the diagnosis of the patient from others rather than factor 1 of internal stigma regarding the shame and expectation of discrimination. Items 20 and 21 were double-loaded on factors 3 and 4. Item 20 was retained on factor 3, while Item 21 was retained on factor 4 based on the higher factor loadings. Items 22 and 25 were double-loaded on factors 1 and 4. Item 25 was assigned to factor 4 because of the higher factor loadings while Item 22 ("After my family member was diagnosed with breast cancer, I avoided communicating with her.") was

also retained in factor 4 based on factor interpretation because avoiding communication with the patient is a behavioral reaction to the diagnosis, rather than a feeling of perceived stigma.

Table 5.10 Results of EFA (n = 400)

| | | First round with 25 items | | | | Second round with 24 items | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Intended domain | Factor 1 | Factor 2 | Factor 3 | Factor 4 | Factor 1 | Factor 2 | Factor 3 | Factor 4 |
| Item 1 | Interel stigma | **0.439** | 0.296 | 0.120 | -0.138 | **0.430** | **0.302** | 0.119 | -0.130 |
| Item 2 | | **0.503** | 0.078 | 0.104 | 0.093 | **0.497** | 0.082 | 0.104 | 0.096 |
| Item 3 | | **0.608** | -0.046 | 0.206 | -0.044 | **0.601** | -0.040 | 0.207 | -0.040 |
| Item 4 | | **0.436** | 0.163 | 0.158 | 0.079 | **0.432** | 0.165 | 0.156 | 0.081 |
| Item 5 | | **0.838** | 0.023 | -0.032 | 0.032 | **0.831** | 0.027 | -0.027 | 0.032 |
| Item 6 | | **0.827** | -.092 | 0.041 | 0.103 | **0.830** | -0.092 | 0.046 | 0.099 |
| Item 7 | | **0.486** | **0.327** | -.037 | 0.112 | **0.486** | **0.328** | -0.033 | 0.111 |
| Item 8 | Social isolation | 0.042 | **0.545** | -0.026 | 0.153 | 0.044 | **0.544** | -0.025 | 0.152 |
| Item 9 | | -0.081 | **0.705** | 0.034 | 0.023 | -0.078 | **0.703** | 0.033 | 0.022 |
| Item 10 | | 0.157 | **0.745** | -0.142 | 0.036 | 0.155 | **0.747** | -0.141 | 0.038 |
| Item 11 | | 0.253 | **0.536** | -0.090 | 0.224 | 0.253 | **0.537** | -0.088 | 0.223 |
| Item 12 | | 0.024 | **0.33** | 0.204 | 0.025 | 0.023 | **0.331** | 0.202 | 0.026 |
| Item 13 | | 0.073 | **0.559** | 0.169 | -0.218 | 0.072 | **0.561** | 0.169 | -0.214 |
| Item 14 | | -0.104 | **0.598** | 0.145 | -0.127 | -0.106 | **0.598** | 0.141 | -0.122 |
| Item 15 | | **0.363** | **0.364** | 0.023 | 0.052 | **0.360** | **0.367** | 0.025 | 0.055 |
| Item 16 | | 0.286 | 0.137 | 0.231 | 0.163 | / | / | / | / |
| Item 17 | Perceived stigma | 0.117 | 0.070 | **0.616** | 0.173 | 0.118 | .075 | **0.611** | 0.179 |
| Item 18 | | 0.003 | 0.116 | **0.732** | 0.086 | 0.007 | .119 | **0.724** | 0.092 |
| Item 19 | | 0.141 | 0.022 | **0.734** | -0.031 | 0.145 | .024 | **0.733** | -0.028 |
| Item 20 | | 0.156 | -0.057 | **0.505** | **0.369** | 0.158 | -.054 | **0.505** | **0.375** |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Item 21 | Reaction | 0.027 | 0.022 | **0.374** | **0.588** | 0.026 | 0.026 | **0.370** | **0.595** |
| Item 22 | | **0.421** | -0.039 | 0.045 | **0.415** | **0.419** | -0.036 | 0.046 | **0.414** |
| Item 23 | | -0.022 | 0.040 | 0.047 | **0.719** | -0.021 | 0.041 | 0.044 | **0.720** |
| Item 24 | | 0.275 | 0.054 | 0.140 | **0.409** | 0.276 | 0.056 | 0.141 | **0.409** |
| Item 25 | | **0.327** | -0.077 | 0.126 | **0.486** | **0.328** | -0.076 | 0.124 | **0.483** |

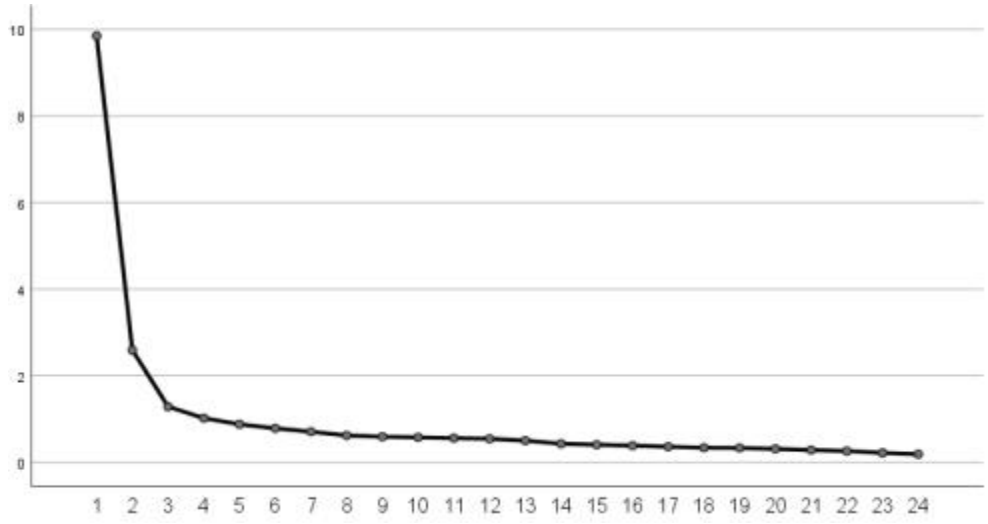


Figure 5.4. Scree plot for the 24-item scale

5.3.7.2.4 Reliability and ceiling and floor effects

Table 5.11 presents the number of items, internal consistency, the presence of ceiling and floor effects for the final version of affiliate stigma scale. Cronbach's α values > 0.82 demonstrated good internal consistency and ICCs > 0.74 demonstrated good test-retest reliability in the overall scale and the four domains. Ceiling and floor effects were evaluated for the total scale and the individual domains. Very small proportions of the participants attained the highest score, ranging from 0.3% to 0.8% (< 30%), indicating that there were no ceiling effects. There was also no evidence of floor effect because the percentages of the respondents who had achieved the lowest score in the whole scale and the four domains ranged from 0.8% to 15.8%.

Table 5.11 The internal consistency, test–retest reliability, ceiling, and floor effects of the scale

| Scale/dimension | Number of Items | Cronbach's α | ICC | Ceiling Effect n (%) | Floor Effect n (%) |
|---|---|---|---|---|---|
| Internal stigma | 7 | 0.876 | 0.789 | 3 (0.8%) | 18 (4.5%) |
| Social isolation | 8 | 0.827 | 0.756 | 2 (0.5%) | 4 (1%) |
| Perceived stigma | 5 | 0.887 | 0.813 | 2 (0.5%) | 40 (10%) |
| Reaction | 4 | 0.825 | 0.749 | 1 (0.3%) | 63 (15.8%) |
| Total scale | 24 | 0.932 | 0.914 | 1 (0.3%) | 3 (0.8%) |

ICC: intra-class correlation coefficient

5.3.7.2.5 Convergent validity

Convergent validity was assessed using Pearson correlation coefficients (r), because all the variables were normally distributed according to the criteria of skewness (> 2) and kurtosis (> 7). The results are summarized in Table 5.12. Specifically, the total scale score was significantly and positively correlated with caregiving burden ($r = 0.194$, $P < 0.001$) and negatively with self-esteem ($r = -0.278$, $P < 0.001$) and social support ($r = -0.135$, $P < 0.001$). Internal stigma and social isolation were correlated significantly and negatively with self-esteem and social support, and positively with caregiving burden (Ps < 0.05). Perceived stigma was negatively correlated with self-esteem and positively correlated with caregiving burden, while reaction was negatively correlated with self-esteem and social support. However, the correlations of perceived stigma with social support, and reaction with caregiving burden were non-significant, although they were in the expected directions.

Table 5.12 Relationship of affiliate stigma overall scores and domain scores with self-esteem, social support and caregiving burden

| Stigma | Self-esteem | | Social support | | Caregiving burden | |
|---|---|---|---|---|---|---|
| | Correlation | p-value | Correlation | p-value | Correlation | p-value |
| Overall | -0.278 | ＜.001 | -0.135 | 0.007 | 0.194 | ＜.001 |
| Domain | | | | | | |
| Internal stigma | -0.18 | ＜.001 | -0.112 | 0.025 | 0.183 | ＜.001 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Social isolation | -0.297 | ＜.001 | -0.15 | 0.003 | 0.209 | ＜.001 |
| Perceived stigma | -0.237 | ＜.001 | -0.072 | 0.148 | 0.145 | 0.004 |
| Reaction | -0.214 | ＜.001 | -0.105 | 0.036 | 0.065 | 0.192 |

5.3.7.2.6 Homogeneity tests

Based on homogeneity tests, four demographics and caregiving characteristics were found to be significantly associated with caregivers' affiliate stigma, including age, family history of cancer, relationship with the patient and communication with others about family member's disease (Table 5.13). Post-hoc pairwise comparisons revealed that significantly higher level in affiliate stigma was reported in caregivers who aged between 45 and 54 years old, who did not have family history of cancer, who were partners of the cancer patients and who did not discuss the patients' disease with others than their counterparts.

Table 5.13 Homogeneity tests of Affiliate stigma level in caregivers by demographics and caregiving characteristics (n = 400)

| Variable | Group | n | （%） | Affiliate stigma M±SD | P value |
|---|---|---|---|---|---|
| Age | ≤44 | 216 | 54.0 | 49.41±11.08 | 0.016* |
| | 45-59 | 137 | 34.25 | 52.50±8.23 | |
| | ≥60 | 47 | 11.75 | 50.70±7.20 | |
| Religion | Yes | 28 | 7.0 | 53.68±8.89 | 0.089 |
| | No | 372 | 93.0 | 50.39±9.90 | |
| Place of residence | City | 212 | 53.0 | 50.13±10.00 | 0.506 |
| | Township | 101 | 25.25 | 50.84±9.36 | |
| | Village | 87 | 21.75 | 51.56±10.13 | |
| Employment status | Unemployed | 121 | 30.25 | 50.43±9.76 | 0.61 |
| | Employed | 279 | 69.75 | 51.06±10.12 | |
| Education background | Primary school or below | 31 | 7.8 | 53.23±9.95 | 0.562 |
| | Junior school | 96 | 24.0 | 51.97±7.72 | |
| | High school or | 124 | 310 | 50.31±8.97 | |

| | | | | | |
|---|---|---|---|---|---|
| | college | | | | |
| | University or above | 149 | 37.3 | 49.48±11.53 | |
| Family history of cancer | Yes | 132 | 33.0 | 49.23±9.88 | 0.047* |
| | No | 268 | 67.0 | 51.31±9.80 | |
| Relationship to the patient | Partner | 220 | 55.0 | 52.32±8.62 | 0.022* |
| | Others (e.g., children, parents, relatives) | 180 | 45.0 | 48.55±10.87 | |
| Discussing the family member's disease with others | Yes | 175 | 43.75 | 47.71±9.21 | <0.001* |
| | No | 225 | 56.25 | 52.88±9.78 | |
| Duration of caring | ≤1year | 350 | 87.5 | 50.58±9.89 | 0.562 |
| | 1-5 years | 30 | 7.5 | 61.63±11.19 | |
| | ≥5 | 20 | 5.0 | 60.99±10.98 | |

5.3.8 Discussion

The study aimed to develop and evaluate the psychometric properties of a newly developed affiliate stigma scale for caregivers of women with breast cancer. Compared to the existing scale of affiliate stigma in caregivers of cancer patients, which originally designed for measuring HIV-related stigma and without psychometric testing, the newly developed scale incorporated insights from caregivers and healthcare professionals to ensure a comprehensive coverage of the stigma experience, and then psychometrically tested with a comprehensive coverage of caregivers of women with breast cancer. The findings support the reliability and validity of the 24-item scale as an instrument for assessing affiliate stigma among caregivers of women with breast cancer. Based on our literature review of caregivers' experience, affiliate stigma in caregivers was frequently reported. Studies from collective and individual countries, such as America, Latin, Brazil, Iran, Arab, and Ghana, consistently reported the cultural and historical stigma of breast cancer (Boamah Mensah et al., 2021; e Silva et al., 2010; Gutierrez et al., 2016; Nasiri et al., 2016; Traboulssi et al., 2022; Zahlis & Shands, 1991). In many of these contexts, breast cancer is perceived as incurable and associated with death. Gossiping and stigmatization from society usually trigger others' uncommon behaviours (e Silva et al., 2010). Caregivers usually inhibit their disclosure

and conceal the diagnosis to protect their social image (e Silva et al., 2010). Thus, this scale can serve as a unique instrument for the assessment of affiliate stigma amongst caregivers of women with breast cancer in China and potential worldwide.

Factor analysis indicated the 24-item scale with four factors was as optimal structure, explaining 61.44% of the total variance. The first factor of internal stigma reflects the shame and expectation of discrimination that prevents caregivers from discussing their experiences and seeking help (Gray, 2002). Caregivers experience stigma commonly, for example, when others used certain phrases or words, especially in a tone that cause emotional harm (Nasiri et al., 2016). The second factor of social isolation refers to absence of social connections. While some individuals are physically isolated, others may feel emotionally isolated despite being socially surrounded (Veazie et al., 2019). Caregivers sometimes intentionally avoid social contact, for example, they declined to take patients out or to allow others to visit their family in order to avoid gossip and stigma (Boamah Mensah et al., 2021). The third factor of perceived stigma is the fear of being discriminated against or the fear of enacted stigma, which arises from society's beliefs 44. In some cultural contexts, breast cancer is perceived as incurable or as a death sentence, which intensifies the stigma (Traboulssi et al., 2022). Consequently, caregivers often choose to withhold the diagnosis from others to avoid perceived and actual stigma and solely assumed the caregiving responsibilities (Boamah Mensah et al., 2021). The fourth factor of reaction towards the patient refers to behavioural responses of caregivers following the diagnosis of cancer in the patients. Changes in how close friends and family members behave after knowing the disease often result in unfavourable reactions from caregivers, which are perceived as damaging to the spirit of the family (Nasiri et al., 2016). The scale showed good internal consistency and test–retest reliability in the overall scale and the four dimensions as well. Furthermore, for the overall scale, no significant ceiling or floor effects were observed.

According to the homogeneity test, caregivers' affiliate stigma levels differed

significantly by variables of age, family history of cancer, relationship to the patient, and discussing with others about family member's disease. Caregivers aged 44 or younger reported the lowest level of affiliate stigma. This may be attributed to their greater access to information and health education through online platforms. As a result, they may have more understanding of breast cancer and not deem breast cancer as an incurable disease. Besides, caregivers without family history of cancer reported significantly higher affiliate stigma than those with such history. One possible explanation is that caregivers without prior experience may perceive cancer as more frightening or stigmatizing. In contrast, caregivers with family history of cancer have experience in dealing with the situation and may become more accustomed to some negative social reactions, potentially taking the experience less seriously. Regarding relationship to the patient, partners reported higher level of affiliate stigma than others, such as children, parents, or relatives. Breast cancer is couple disease and may affect their sex life, which might have partly explained the observation of the higher affiliate stigma in partners. Additionally, all the partners in this study are male. Previous studies suggest that men are less likely to discuss their experience and seek social support because they perceive these behaviors conflict with gender role (Hilton et al., 2000; Zahlis & Lewis, 2010). A significant difference in affiliate stigma level was also observed in the subgroups based on whether there was discussion with others about family member's disease. Caregivers who communicated with others about their family member's disease were more likely to have higher social support, because they might feel they have someone understand and empathize with them. This finding is consistent with previous study that communication with others and disclosure foster acceptance and promote understanding and support from others. Participants were more likely to share when they felt less initial stigma and judgement. Communication helps mitigate loneliness and social isolation, and foster empowerment as a way to break the affiliate stigma. While it is possible that the longer-term duration of caregiving might dilute the negative feeling of stigma, there is also possibility that caregivers with family history of cancer might interpret the items differently from those caregivers without family

history of cancer. Further research may explore the scale's psychometric properties across diverse sub-populations.

Strong evidence for the convergent validity of the scale was demonstrated because all the three tested hypotheses were supported in the current study (Mak & Cheung, 2008; Saffari et al., 2019; Werner et al., 2011; Yin et al., 2014). Affiliate stigma was negatively correlated with social support, aligning with previous research findings (Saffari et al., 2019; Wang et al., 2019; Yin et al., 2014) that individuals experiencing prejudice and discrimination may be more likely to withdraw socially and conceal their situation. In contrast, caregivers with higher levels of social support often stay in a friendly and understanding environment. Rather than looking down on caregivers or delivering socially stigmatising information, others tend to provide support and demonstrate understanding toward caregivers (Yin et al., 2014). Higher social support level improves caregivers' ability to perform better in their caregiving role. Considering the 'face' concern in China, caregivers with high affiliate stigma isolate themselves because they fear disclosure and possible discrimination. Rather, they conceal the diagnosis, thereby distancing themselves from potential support networks (J. Li et al., 2017). Additionally, caregivers with more social support tend to receive affection and care, resulting in higher levels of positive affect and lower levels of negative affect (J. Li et al., 2017). The study also found a negative association between self-esteem and affiliate stigma, suggesting that individuals with higher self-esteem may be more affected by perceived negative attitudes in the society. Furthermore, a positive correlation between caregiving burden and affiliate stigma was identified, consistent with the findings of Mak et al.(2008). Higher caregiving burden appears to intensify feelings of affiliate stigma. This finding also aligns with previous studies among caregivers of individuals with mental illness, where a meta-analytic review reported positive correlations of affiliate stigma with social support and caregiver burden. On the other hand, a notable difference is observed regarding self-esteem, which was not significantly associated with affiliate stigma in that meta-analysis (Shi et al., 2019).

Meanwhile, internal stigma and social isolation are all correlated with self-esteem, social support and caregiving burden. However, the correlations between perceived stigma and social support, as well as between reaction and caregiving burden were not statistically significant. One possible explanation for the non-significant association of social support and reactions with caregiving burden lies in traditional Chinese culture values, where caregiving for an ill family member is viewed as a familial obligation rather than a burden (Kılıçaslan et al., 2024). In this study, most caregivers were family members or relatives, and they are willing to take care of patients due to their love for the patient, thereby weakening the perceived burden and its effect on their reactions. Similarly, the lack of a significant correlation between perceived stigma and social support might be attributed to cognitive biases commonly experienced by individuals who perceive stigma. Caregivers may construct their own "subjective reality", which may lead to perceptual distortions, inaccurate judgments, and irrational interpretations of social interactions (Haselton et al., 2015; Kahneman & Tversky, 1972). As a result, caregivers may sometimes misinterpret others' words or behaviours. This may account partially for the non-significance association between perceived stigma and social support. In addition, elevated affiliate stigma among caregivers is commonly accompanied by shame and feelings of inferiority because of their relationship with the affected family member (Mak & Cheung, 2008). Affiliate stigma is a significant contributor to reduced self-esteem and increased social isolation, which potentially result in changes in social roles, acceptance and challenges related to employment (Bu, Li et al., 2022). Therefore, an accurate assessment of the affiliate stigma amongst caregivers of women with breast cancer is essential to promote their psychological well-being.

Test–retest reliability was assessed using ICCs, and the results demonstrated good test–retest reliability, with ICC values exceeding 0.74. Amongst the four existing scales that have been applied to assess affiliate stigma in caregivers, none have reported test–retest

reliability (Mak & Cheung, 2008; Squiers et al., 2021; Werner et al., 2011) (Yin et al., 2014). Therefore, this finding provides further evidence and support for its application in caregiving research and oncology practice.

#### 5.3.8.1 Strengths and Limitations

Our study offers several strengths. First, this is a multi-center study that has enabled us to recruit participants from different provinces in the middle region in China. These participants visited the selected five hospitals in Hunan and Jiangsu Provinces for medical service. Furthermore, we did not only invite the caregivers of newly diagnosed breast cancer patients but also those with long-term caregiving experience, thus ensuring a wide coverage of caregiving journey in the caregivers. These two characteristics imply that the study's findings have good generalizability. Second, the scale was developed with a rigorous procedure, with items generated from informants from the target population. Third, the instrument was developed through a rigorous process. Items were generated from literature review and qualitative interviews from the target population. Then the scale was psychometrically evaluated in a large caregiver sample, strengthening reliability and validity.

Despite these advantages, limitations remain. First, we have relied on a data-driven approach of EFA in determining the number of factors to retain in the scale. Moreover, because the observed variables can be influenced by extraneous factors, such as response bias or measurement error, further studies examining the factor structure of the scale by CFA are warranted. Besides, we used a common method, correlational analyses, to examine convergent validity of the scale in the study. The psychometric testing could be improved if we had measured other related variables of stigma in caregivers of women with breast cancer, such as psychological resilience, psychological distress, and quality of life, and examine their interrelations with the new scale within a structural equation modeling framework (Viswesvaran & Ones, 1995). Moreover, future studies should investigate additional psychometric properties, particularly

predictive validity.

### 5.3.9 Conclusion

The Affiliate Stigma Scale for assessing partner's affiliate stigma was developed and psychometrically tested on a sample of 426 caregivers of women with breast cancer. The final version of the scale consisted of 24 items covering four domains (internal stigma, social isolation, perceived stigma, and reactions), with 61.44% of the variance explained in EFA. The scale showed good reliability in the overall scale and the four domains (Cronbach's alphas > 0.82 and ICCs > 0.75) and construct validity, with the total score significantly and positively correlated with caregiving burden ($r = 0.194$, $P < 0.001$), and negatively with self-esteem ($r = -0.278$, $P < 0.001$) and social support ($r = -0.135$, $P < 0.001$). The item-level CVI was acceptable (0.8–1.0). The scale was developed through a rigorous process, including qualitative interviews and two rounds of Delphi study, ensuring that it comprehensively captures the relevant dimensions of stigma experienced by caregivers. It also provides a foundation for developing and evaluating targeted interventions aimed at reducing stigma and improving caregiver wellbeing.

## 5.4 Chapter summary

This chapter presented the adaptation, development and psychometric evaluation of two scales: the SC-SCS-P and the Affiliate Stigma Scale for caregivers of women with breast cancer. Preliminary evidence supports their utility in assessing partner-reported social constraints and caregiver-reported affiliate stigma, respectively. Although further studies are warranted to examine additional psychometric properties, these two validated scales are now ready for use in measuring the outcomes of social constraints and affiliate stigma among partners and caregivers in the subsequent phases of the doctoral study.

# CHAPTER SIX: PILOT STUDY

## 6.1. Introduction

This chapter presents the pilot study conducted as a preparatory step prior to the RCT. The primary aim of this pilot study was to evaluate the feasibility of the family support programme, including the appropriateness of the intervention, participants' ability to understand the content and their willingness to engage in disclosure and share feelings and to explore its preliminary effects on couples coping with breast cancer.

This chapter is structured as follows: Section 6.1 provides the introduction, followed by the objectives of the pilot study in Section 6.2. Section 6.3 describes the study design, study setting, participant eligibility and intervention delivery mode. Section 6.4 details the data collection procedures, while Section 6.5 outlines the data analysis methods. Ethical considerations are presented in Section 6.6. The results of the pilot study are reported in Section 6.7 and discussed in Section 6.8, including comparisons with existing similar studies and adaptations made to the intervention protocol. The chapter concludes with a brief summary in Section 6.9.

## 6.2. Objectives of the pilot study

The objectives of this pilot study were as follows:

1) To evaluate the feasibility of study procedure and data collection process

2) To examine the feasibility and acceptability of the family support programme delivered via WeChat on FCR reduction and other health-related outcomes in couples coping with breast cancer

## 6.3. Methods

### 6.3.1 Study design

This pilot study adopted a pre–post study design, embedded with a qualitative study. Quantitative data were collected at baseline (T0) and post-intervention (T1), and qualitative data were collected at T1.

### 6.3.2 Study setting

This research was carried out in two large tertiary Grade A hospitals in mainland China, each containing more than 1,000 beds and providing services to both rural and urban populations. One of the study sites was the Affiliated Cancer Hospital of Xiangya School of Medicine, Central South University, located in Hunan Province. Five departments within this hospital participated in recruiting women diagnosed with breast cancer, including two breast surgery wards, an oncoplastic surgery ward, a breast medical oncology ward, and a thoracic radiotherapy ward. Together, these departments manage the care of roughly 2,500 breast cancer patients each year. The two breast surgical wards admit newly diagnosed breast cancer patients for surgery or chemotherapy. The oncoplastic surgery ward recruits newly diagnosed patients undergoing surgery or chemotherapy and patients who have completed their primary treatment (i.e. surgery, chemotherapy and radiotherapy) and are scheduled for breast reconstruction using autologous fat. The breast medical ward admits newly diagnosed patients for post-surgical chemotherapy, those newly diagnosed at stage IV and patients with recurrent breast cancer. The thoracic radiotherapy ward recruits patients with cancer, including those with breast cancer who are undergoing radiotherapy.

The other study site was the Affiliated Suzhou Hospital of Nanjing Medical University, located in Jiangsu Province. This hospital includes two breast surgery wards and one oncology ward distributed across two campuses, and it delivers care to approximately 600 patients with breast cancer each year. The two surgical wards admit patients undergoing surgery or chemotherapy, and the oncology ward recruits patients receiving chemotherapy and targeted therapy.

### 6.3.3 Participants

The eligibility criteria for couples coping with breast cancer in the pilot study were as follows:

Inclusion criteria:

1) Dyads in which the woman was diagnosed with breast cancer (stages I–IV) and receiving treatment (regardless of whether primary treatment had been completed). The male partner was identified by the woman as her caregiver.

2) Both members were aged 18 years or above.

3) At least one member of the dyad had a clinically significant level of FCR, indicated by a score ≥34 on the FoP-Q-SF.

4) Both members of the dyad provided written informed consent to participate in the study.

Exclusion criteria:

1) At least one member of the dyad had a physical impairment, such as blindness or paralysis.

2) At least one member of the dyad was unable to speak or understand Putonghua, as the intervention was delivered in Putonghua.

3) At least one member of the dyad had a history of mental illness.

6.3.4 Recruitment and baseline data collection

Couples coping with breast cancer were treated as the sampling unit. The doctoral student initially identified potential couples in the participating hospitals. One member of the dyad, typically the woman, was invited to complete the screening questionnaire (FoP-Q-SF) first. When her score was below the FCR threshold (FoP-Q-SF < 34), the other member of the dyad was invited to complete the same questionnaire. When the partner was not present in the hospital and the woman's score was below 34, with an electronic version of the questionnaire was provided for her partner's responses. Eligible women were then asked to nominate their male partners, identified as caregivers, to participate in the study. For partners present in the hospital during recruitment, the doctoral student approached them directly, explained the study objectives and procedures and obtained written informed consent from both members

of the dyad. When the nominated partner was not present in the ward, the woman was asked to communicate their willingness to participate via telephone or WeChat. Written consent was subsequently obtained either when the partner visited the hospital during the woman's hospitalisation or via WeChat if they were unable to attend. Following consent, couples completed the baseline questionnaire separately via WeChat.

### 6.3.5 Sample size

According to the general rule of thumb for pilot study sample sizes recommended by Machin et al. (2018), the sample size for single-group studies can be determined by multiplying the recommended sample size for two-group pilot studies by an adjustment factor of 0.5. Given that the minimum recommended sample size for two-group pilot studies is 20, a sample size of 15 was planned for this pilot study.

### 6.3.6 Intervention content

The participants then received the six-week family support programme, and one session delivered per week, as described in Chapter Four. A brief overview of the three components of the programme is provided: (1) education on breast cancer management and healthy lifestyle (physical activity and healthy diet) to improve management of treatment side effects and reduce cancer recurrence, delivered to women with the support of their partners (Sessions 1 and 2); (2) disclosure of feelings and thoughts between the couples (Sessions 3–6); and (3) additional education on psychosocial factors related to cancer recurrence provided in Session 3. The family support programme was delivered to each couple via WeChat by the doctoral student, who had received training from a psychologist with over ten years of clinical experience in oncology and extensive practice in facilitating disclosure.

### 6.3.7 Outcomes

Two sets of outcomes were assessed in this pilot study. The first set comprised feasibility outcomes, including eligibility rate, recruitment rate, retention rate, session

attendance, adherence to tasks, acceptability of the intervention and intervention fidelity. The second set comprised the primary and secondary outcomes, including FCR, social constraints, stigma, anxiety, intrusive thoughts and avoidance.

6.3.7.1 Feasibility outcomes

a) Eligibility rate refers to the rate of eligible subjects from those screened (eligible/screened).

b) Recruitment rate refers to the rate of subjects recruited from those eligible (recruited/eligible).

c) Retention rate refers to the number of subjects who remained in the study among those who were enrolled (completed/enrolled).

d) Compliance to session attendance in the intervention represents the number of sessions attended by the couple out of six. Both members of the dyad completing at least five sessions of the family support programme was considered as compliance to session attendance.

e) Adherence rate of tasks represents the proportion of tasks completed relative to the total number of tasks assigned (completed/assigned). Three types of tasks were assigned: the physical activity and healthy dietary tasks of the patients and disclosure tasks between the couples. Adherence to physical activity and healthy dietary tasks in women were recorded from session 3 to session 6, yielding four adherence records for each woman. For adherence to physical activity, women are recommended to achieve at least 150 min of moderate-intensity exercise or 75 min of vigorous-intensity aerobic exercise per week. For adherence to healthy dietary practice, women were advised to follow ‘Chinese Balanced Diet Pagoda’ and Guidelines and Norms for Diagnosis and Treatment of Breast Cancer of the Chinese Anti-Cancer Association to appropriately distribute food portions across three daily meals. For adherence to disclosure, couples was required to share their feelings, thoughts, worries, and concerns with each other three times per week, with each lasting approximately 15 min. Adherence to disclosure was recorded from session 4 to session 6.

f) Acceptability of the intervention indicates the level of acceptability perceived by couples coping with breast cancer. Semi-structured interviews were conducted to explore the acceptability of the intervention among the couples.

g) Intervention fidelity was assessed using a self-developed checklist addressing the distribution of electronic handbook materials, duration of intervention delivery, delivery of all contents in each session according to the session plan, delivery mode and implementation of disclosure between couples. Three possible responses were provided (Yes/No/Not applicable). All sessions delivered were audio-recorded, and at least 20% of the recorded sessions were randomly selected and reviewed by a senior registered oncology nurse using the checklist (Appendix XV). The total possible number of sessions to be delivered was 90 sessions (15 dyads × 6 sessions). The percentage of accomplishment was calculated.

6.3.7.2 Co-primary outcomes

Fear of cancer recurrence (FCR)

FCR was assessed separately in women diagnosed with breast cancer and in their partners using the 12-item short form of the Fear of Progression Questionnaire (FoP-Q-SF; Mehnert et al., 2006). This instrument offers a multidimensional evaluation of FCR. Each item is scored on a five-point Likert scale from 1 (never) to 5 (very often), with higher total scores reflecting greater levels of FCR. A cutoff score of 34 or higher has been suggested to indicate clinically significant FCR (Wu, 2016). The Chinese version of the FoP-Q-SF has undergone thorough validation and demonstrated satisfactory internal consistency, with Cronbach's α coefficients of 0.886 for patients and 0.853 for partners (Wu, 2016).

6.3.7.3 Co-secondary outcomes

(i) Social constraints

For women with breast cancer, the social constraints was assessed using the Lepore Social Constraints Scale, which measures social responses that inhibit the expression

of cancer-specific thoughts, feelings and experiences (Lepore, 1999). Participants were asked to respond to 15 questions on a 1–4 Likert scale, ranging from 1 (never) to 4 (often), regarding their perception of constraining behaviours from their partners over the past four weeks. The overall social constraints score was obtained by summing responses to the 15 items, resulting in a possible score range of 15 to 60. Higher total scores indicate greater levels of perceived social constraints in communication. The Chinese version of the scale has been thoroughly validated, demonstrating strong internal consistency (Cronbach's α = 0.91; Acquati et al., 2020).

For partners, social constraints were assessed using the adapted Simplified Chinese version of the Social Constraints Scale for partners of adults with cancer， as presented in Chapter Five. This instrument consists of 15 items covering three domains: alienation (11 items), minimization of health concerns (2 items), and emotional concealment (2 items). Consistent with the version used for women, items are rated on a 4-point Likert scale ranging from 1 (never) to 4 (often). Total scores range between 15 and 60, with higher scores representing stronger perceived social constraints. The Cronbach's α coefficients for the overall scale and its three subscales ranged from 0.719 to 0.863.

(ii) Intrusive thoughts and avoidance

Intrusive thoughts and avoidance were assessed using the corresponding subscales of the Impact of Event Scale–Revised (IES-R; Guo et al., 2007). The IES-R contains 22 items evaluating three domains: intrusion (8 items), avoidance (6 items), and hyperarousal (8 items). In the present study, participants completed the 14 items related to intrusion and avoidance, rating each item on a 5-point Likert scale from 0 ("not at all") to 4 ("extremely"). Scores for the intrusion and avoidance subscales range from 0 to 32 and 0 to 24, respectively, with higher scores indicating more severe intrusive thoughts and avoidance symptoms. The Chinese version of the IES-R has been applied in breast cancer populations and has demonstrated good internal consistency, with Cronbach's α coefficients of 0.90 for women with breast cancer and 0.85 for their male

partners (Bu, 2023).

(iii) Anxiety

For women and their partners, anxiety was evaluated using the 7-item Generalized Anxiety Disorder scale (GAD-7; Spitzer et al., 2006), a self-administered questionnaire designed to assess anxiety symptoms. Participants reported how frequently they had experienced the seven core symptoms of generalized anxiety disorder during the preceding two weeks. Total scores range from 0 to 21, with higher scores representing more severe anxiety symptoms. A cutoff score of 10 or above was applied to identify clinically significant anxiety. The Chinese version of the GAD-7 has been psychometrically validated and shows strong internal consistency (Cronbach's $\alpha$ = 0.898; He et al., 2010).

(iv) Stigma

Among women diagnosed with breast cancer, stigma was assessed using the Chinese version of the Breast Cancer Stigma Scale (Bu, Li et al., 2022). This 15-item self-administered instrument evaluates stigma across four domains: disturbed self-image (5 items), self-perception (4 items), social isolation (2 items), and perceived discrimination (4 items). Responses are recorded on a Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree). Possible total scores range from 15 to 60, with higher scores reflecting greater levels of stigma. The Chinese version has demonstrated satisfactory internal consistency, with a Cronbach's $\alpha$ of 0.86 in women with breast cancer (Bu et al., 2022).

For partners, affiliate stigma was measured using the Chinese version of the Affiliate Stigma Scale for Caregivers of Women with Breast Cancer (see Chapter Five; Bu, Chen, et al., 2025). This 24-item measure captures multiple aspects of affiliate stigma among caregivers and consists of four subscales: internalized stigma (7 items), social isolation (8 items), perceived stigma (4 items), and emotional or behavioral reactions (5 items).

Items are rated on a 4-point Likert scale, ranging from 1 (strongly disagree) to 4 (strongly agree). The total score ranges from 24 to 96, with high scores indicating high levels of stigma. The Chinese version of the scale has demonstrated good internal reliability, with a Cronbach's α of 0.932 for caregivers of women with breast cancer (Bu, Chen, et al., 2025).

Sociodemographic variables, including age, educational level, employment status, residence and whether living in the same household as their partner, were obtained from the women with breast cancer. Cancer stage, current treatment, time since diagnosis and recurrence were retrieved from medical records. Data on age, educational level and employment status were obtained from the partners.

6.3.8 Data collection procedure

Quantitative data collection

Outcome assessments were conducted at two time points: baseline (T0: after recruitment) and post-intervention (T1: six weeks after recruitment) via WeChat. Details are shown in Table 6.1. Questionnaire Star (www.wjx.cn) was used to collect data, and forced responses were set for each item to prevent missing data. The doctoral student sent a WeChat message to the participating couples containing a hyperlink to access the questionnaire. Couples completed the questionnaire separately by clicking the link. The doctoral student provided continuous supervision to ensure completeness of the responses. Follow-up messages were sent to participants as reminders to complete the questionnaire. Cancer stage, treatment and time since diagnosis for the women with breast cancer were retrieved from medical records.

Table 6.1 Outcome assessment at the two time points by participant type

| outcome | Source of information | Time-point outcomes collected |
|---|---|---|
| Primary outcomes | | |
| FCR | patients + partners | T0 and T1 |
| Secondary outcomes | | |

| | | |
|---|---|---|
| Social constraint | patients + partners | T0 and T1 |
| Stigma | patients + partners | T0 and T1 |
| Anxiety | patients + partners | T0 and T1 |
| Intrusive thoughts and avoidance | patients + partners | T0 and T1 |
| Exercise adherence | patients | Week 3-6 |
| Healthy dietary adherence | patients | Week 3-6 |
| Disclosure adherence | patients + partners | Week 4-6 |
| Acceptability of the intervention | patients + partners in the intervention group | T1 |

Note: T0: Baseline; T1: Post-intervention

Qualitative data collection

The process evaluation was assessed according to Medical Research Council guidance, including mechanisms of impact and context (Moore et al., 2015). Mechanisms of impact and contextual determinants were derived from qualitative interviews to explain how the programme worked and what shaped implementation. The doctoral student conducted the interviews to obtain perspectives from the couples regarding the family support programme they received. Individual interviews with each couple, rather than focus groups, were selected because individual couples would be willing to express their own perceptions and experiences of the programme without feeling pressured to provide socially desirable responses. From an implementation perspective, coordinating a common time for several couples to join the same focus group interview was challenging. At the beginning of the interviews, the study's aim and rationale were explained, and consent for recording the discussion was obtained. Consent forms, participant information sheets and other relevant research materials were distributed via WeChat one day in advance to allow time for review. To protect confidentiality, nicknames were used. The interview guide included four open-ended questions regarding: (1) overall perceptions of the family support programme; (2) the sequencing of sessions; (3) the intervention dosage or intensity; and (4) suggestions for additional content and programme improvements (Table 6.2). The individual interviews were recorded using a digital voice recorder. The doctoral student has been trained and is experienced in conducting qualitative studies and has conducted several studies

employing mixed-methods designs, with results published in international journals (Bu, Li, et al., 2022; Huang et al., 2023; Bu et al., 2024). In addition, the doctoral student received training in qualitative research methodology through a course offered by The Hong Kong Polytechnic University and conducted a meta-synthesis on the experiences of male partners of women with breast cancer in the first year of the PhD study.

Data collection ceased when the dataset provided sufficient depth and breadth to address the research aims and no substantively new insights relevant to programme acceptability and implementation were identified during ongoing analysis. That is, no new codes revealing previously unidentified patterns emerged (Charmaz, 2014). In general, sample sizes in qualitative research should not be extremely small in such a manner nor so large that conducting a deep, case-oriented analysis becomes impractical. Specifically, qualitative researchers are often advised to perform the following: (a) study one culture-sharing group in ethnography, (b) examine three to five cases in a case study, (c) interview 15–20 individuals for grounded theory studies and (d) explore the narrative story of a single individual in narrative research. Additionally, conducting interviews with up to 10 participants in phenomenological research and 20–30 participants in grounded theory studies is appropriate (Onwuegbuzie & Leech, 2007). In this pilot study, data collection was concluded after interviews with 10 couples, as the dataset provided sufficient depth and breadth.

Table 6.2 Open-ended questions of the interviews for couples

| | |
|---|---|
| Q1 | Overall, what do you think about the family support programme?<br>Prompts:<br>- Can you understand the content?<br>- Can you tell me how you think about the suggested content?<br>- How may the information be suitable and useful for you?<br>- Which session do you think is most important? Why?<br>- Which session do you think maybe deleted? Why?<br>- What do you think should be added? |
| Q2 | What do you think about the number of sessions, the length of sessions?<br>Prompts:<br>- What do you think about the number of sessions? |

| | |
|---|---|
| | - How many sessions do you think is most appropriate?<br>- What do you think about the mode, duration, contents and frequency of each session?<br>- Which sessions do you think should be put at the front? Which do you think should be put at the back? |
| Q3 | Any other comments and suggestions for us to improve the family support programme? |

6.3.9 Data analysis

SPSS version 26.0 was used to analyse the quantitative data. Descriptive statistics were performed. To assess the differences between pre-test and post-test scores for the outcomes, paired-samples *t*-tests were conducted as appropriate. A P-value of less than 0.05 was considered statistically significant. Within-group effect sizes (Hedges' g) for the outcomes were calculated and interpreted as follows: approximately 0.2 indicates a small effect, 0.5 a medium effect and 0.8 a large effect (Cohen, 1988).

For the qualitative data, the data were transcribed verbatim within 24 hours by the doctoral student and double-checked by a research assistant (RA), both of whom were trained in qualitative methods. Transcripts were organised and coded using NVivo software version 11 (https://lumivero.com/products/nvivo/). Thematic analysis was conducted to explore the acceptability of the intervention. This qualitative research method identifies, analyses and reports patterns (themes) within textual data, going beyond simply counting words or phrases (as in content analysis) to interpret various aspects of the research topic (Ahmed et al., 2025). An inductive, semantic coding strategy was adopted to explore participants' experiences and perceptions of the family support programme within the process evaluation. Coding was conducted independently by the doctoral student. Thematic analysis followed Braun and Clarke's six-phase framework (Braun & Clarke, 2006). Firstly, the researchers familiarised themselves with the data and noted initial ideas. Secondly, initial codes were generated. Thirdly, codes with similar content were collated into potential themes. Fourthly, each potential theme was checked for internal consistency and against the entire dataset.

Fifthly, themes were defined and named. Finally, the report was prepared by selecting illustrative quotes for each theme and discussing them in relation to the research questions and relevant literature. Principles for revision were generated from the themes and categories in a Word document and sent to the participating couples for member checking. The chief supervisor of this doctoral study supervised all stages of the analysis. Trustworthiness was verified through member checking, with comments and suggestions from the couples extracted and used to revise codes where necessary. Credibility was supported by involving two independent data analysts and obtaining confirmation of the findings from key informants (Thórarinsdóttir et al., 2019). Confirmability was ensured through a detailed audit trail documenting each analytic step to safeguard neutrality.

### 6.3.10 Ethical considerations

Ethical approvals of the present study were obtained from Research Committees at the Hong Kong Polytechnic University (reference number: HSEARS20230201001).

## 6.4 Results

### 6.4.1 Subject recruitment

Figure 6.1 presents the study procedure in a flow chart. Subjects were recruited at the two hospitals between June and July 2024. Consistent with the participating hospitals' schedules for recruiting women with breast cancer for hospitalisation, subject recruitment was conducted on every working day, with five working days at the Affiliated Suzhou Hospital of Nanjing Medical University in June 2024 and 18 working days at the Affiliated Cancer Hospital of Xiangya School of Medicine, Central South University from June to July 2024.

A total of 351 couples were approached for eligibility screening, and 252 dyads (163 patients and 89 partners) were excluded. The reasons for exclusion among the 163 patients were as follows: lack of interest (n = 106), unavailability (n = 32), unfamiliarity

with smartphones (n = 10), single, divorced or widowed (n = 8), inability to speak Mandarin (n = 5) and inability to understand Chinese (n = 2). The reasons for exclusion among the 89 partners were as follows: unavailability (n = 63) and lack of interest (n = 26). The remaining 99 couples were then assessed for FCR using the FoP-Q-SF, and 60 dyads met the inclusion criteria, yielding an eligibility rate of 17.09% (60/351). All 60 couples consented to participate; however, 45 couples subsequently withdrew their consent, resulting in a recruitment rate of 25.00% (15/60). The reasons for withdrawing consent were loss of contact (n = 28), unavailability (n = 14) and perceiving the questionnaire as bothersome (n = 3). Recruitment of all 15 women with breast cancer and 12 partners was conducted at the participating hospitals, while 3 partners were recruited via WeChat.

### 6.4.2 Retention

A high retention rate was achieved in the pilot study. Among the 15 couples, 14 couples completed the assessment at T1 (93.33%), with only one couple dropping out after attending three sessions of the family support programme. The mean time to complete the questionnaire at T1 was 16.47 minutes (SD: 13.62) for women with breast cancer and 15.63 minutes (SD: 7.95) for their partners, which was considered acceptable.

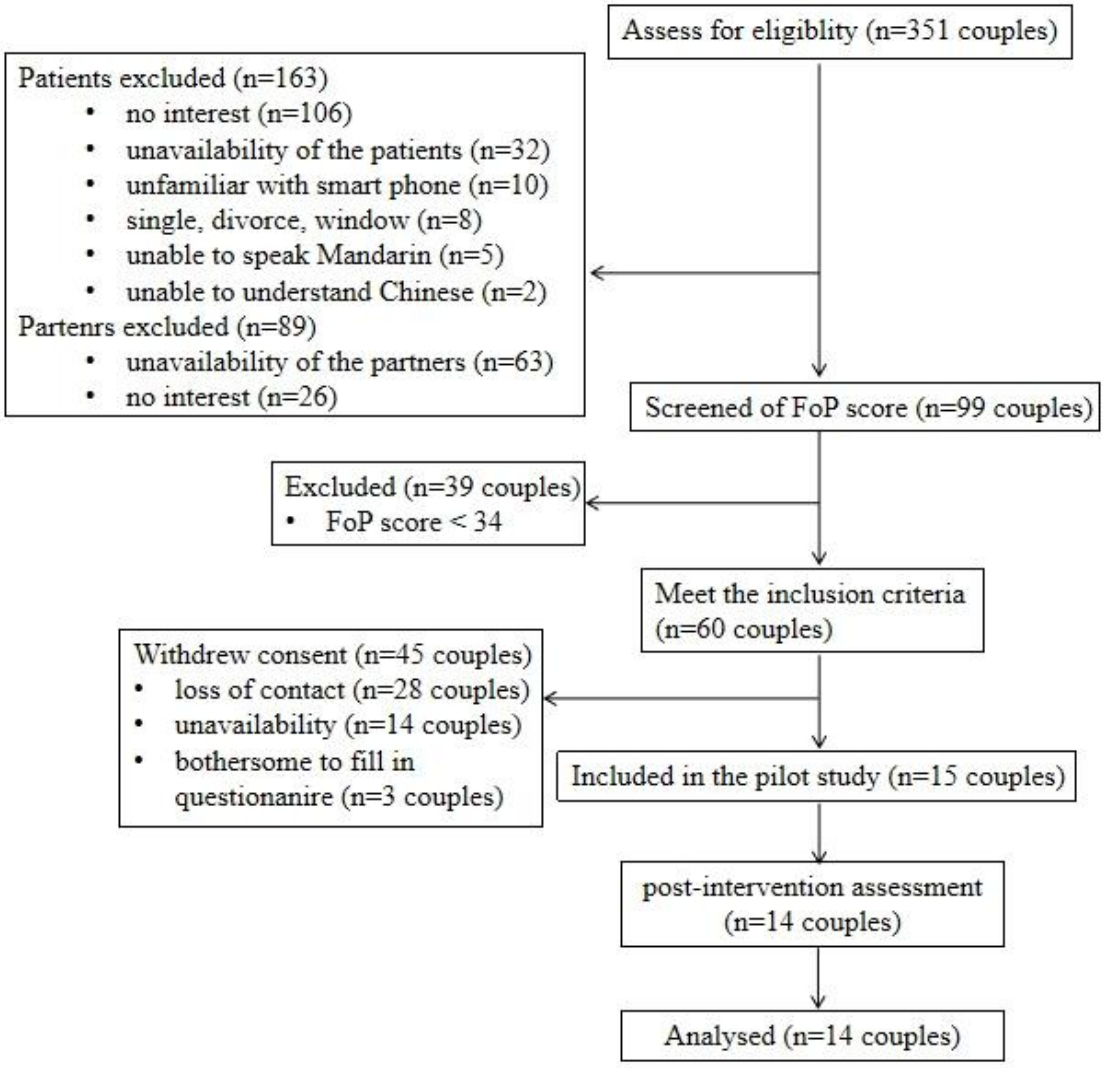


Figure 6.1 Flow diagram of the pilot study

6.4.3 Session attendance

High compliance with session attendance was observed. Among the 15 couples, 11 couples attended at least five sessions, yielding a compliance rate of 73.33%. Four couples completed all six sessions together, four couples had one member missing one session, and three couples completed five sessions. For the remaining four couples, two had the woman missing one session and the partner missing two sessions, whereas the other two had the women completing three sessions and the partner completing two sessions. The mean attendance was 5.2 sessions for the women and 4.8 sessions for the partners. When only one member of the dyad attended a disclosure-focused session, the session was delivered to the attending participant as scheduled. The primary reason for

missed sessions among women with breast cancer was distressing symptoms following chemotherapy, whereas partners were mainly unavailable. Regarding the specific sessions missed by the ten partners, one partner missed Session 1 on a brief introduction to breast cancer and self-management of treatment side effects, particularly lymphedema; two partners missed Session 2 on healthy diet and physical activity education; three partners missed Session 3 on communicating feelings and Session 5 on post-traumatic growth; and five partners missed Session 4 on breast cancer influences and Session 6 on coping and expectation. Among the eight women with breast cancer who missed sessions, six missed Session 4 on breast cancer influences, three missed Session 5 on post-traumatic growth and three missed Session 6 on coping and expectation. The mean duration of Session 1 was 42 minutes and Session 2 was 27 minutes. For the four disclosure sessions (Sessions 3–6), mean durations ranged from 35 to 46 minutes, with individual sessions varying from 25 to 90 minutes. Although each session was originally planned for 60 minutes, the duration was adjusted to approximately 40–60 minutes to allow for flexibility.

6.4.4. Adherence

i. Adherence to physical activity and healthy dietary in women

In terms of homework completion, adherence to physical activity and healthy dietary tasks in patients was recorded each time in the 5-minute recap time from Sessions 3–6. Thus, a total of four adherence records were obtained for each patient. Six of the 15 patients had undergone breast reconstruction surgery at the time of recruitment, and strenuous exercise was not permitted within one-month post-surgery. In addition, patients undergoing autologous breast reconstruction often require a longer duration of surgical drain placement, sometimes up to one month, which makes them unsuitable for large-range or vigorous physical activity.Furthermore, the intervention took place during the summer months, with ambient temperatures reaching 37–42 °C. Consequently, postoperative patients were advised against engaging in strenuous exercise to avoid sweating and an increased risk of surgical site infection. Accordingly,

the criterion for adherence to physical activity in this pilot study was modified to 'walking for at least 30 minutes, five days per week'. One patient was unable to perform the task because metastatic tumour cells had affected her leg, causing pain and rendering walking impossible; she was therefore excluded from the adherence calculation. Ten patients (71.42%) completed the physical activity task all four times, achieving 100% adherence. Two patients (14.29%) completed the task three times due to severe chemotherapy side effects, achieving 75.00% adherence. The remaining two patients (14.29%) completed the task once, as they only participated in three sessions, achieving 25.00% adherence. The mean adherence rate to physical activity was 85.71% (SD = 27.24%).

For adherence to a healthy diet, all patients except two (13/15) reported 100% adherence. The two exceptions attended only three sessions, achieving 25.00% adherence. Therefore, the mean adherence rate was 90.00% (SD = 26.39%).

ii. Adherence of disclosure

For adherence to disclosure within couples, the couples were required to share their feelings, thoughts, worries and concerns with each other three times per week. Two patients attended only Sessions 1–3 and, to be conservative, were considered non-adherent to the intervention. Twelve couples (80.00%) completed the three-week disclosure task, resulting in 100% adherence, while one couple (6.67%) completed the disclosure task for two weeks, yielding 66.67% adherence. The mean adherence to disclosure was 84.44% (SD = 36.31%).

### 6.4.5 Intervention fidelity

Intervention fidelity was assessed using a self-developed checklist covering five aspects: the distribution of electronic handbook materials, the duration of intervention delivery, the delivery of all session content according to the session plan, the delivery mode and the implementation of disclosure between couples. All 78 delivered sessions were

recorded, and 18 sessions (23.08%) were randomly selected and reviewed by a senior registered oncology nurse, who completed the checklist with three possible responses (Yes/No/Not applicable). Three recordings for each of Sessions 1–6 were examined. The accomplishment rate was 100% for the distribution of electronic handbook materials, the delivery of all session content according to the session plan, the delivery mode and the implementation of disclosure between couples. However, among the 18 checked sessions, only four sessions lasted approximately 60 minutes, resulting in an accomplishment rate of 22.22% for session duration.

6.4.6 Characteristics of the participants

The characteristics of the couples are presented in Table 6.2. The mean age of the women with breast cancer was 46 years (30–59 years). Most had completed high school education (33.33%), were unemployed (53.33%), resided in urban areas (40.00%) and were at cancer stage II (53.33%). All the women were undergoing primary treatment (93.33%), except one who had been diagnosed four years earlier, was on hormone therapy and was undergoing reconstruction surgery at recruitment. Among those receiving primary treatment, one underwent mastectomy (6.67%), four had reconstruction surgery (26.67%) and nine received chemotherapy (60.00%). One woman with recurrent breast cancer (6.67%) was first diagnosed in 2018, whereas the remaining women were newly diagnosed (93.33%). Thirteen couples were living in the same household, whereas two couples resided in separate locations because of work commitments. The mean age of the partners was 49.1 years (35–67 years), and most completed a bachelor's degree (33.33%) and were employed (66.67%).

Table 6.3 Characteristics of the couples (N = 15)

| | Groups | Women with breast cancer (M±SD)/ n (%) | Partners (M±SD)/ n (%) |
|---|---|---|---|
| Age | / | 46.00±8.34 (Range: 30-59) | 49.13±9.13 (Range: 35-67) |
| | Junior or below | 4 (26.67%) | 3 (20.00%) |

| | | | |
|---|---|---|---|
| Educational level | High school | 5 (33.33%) | 4 (26.67%) |
| | College | 2 (13.33%) | 3 (20.00%) |
| | University | 3 (20.00%) | 5 (33.33%) |
| | Post-graduate | 1 (6.67%) | 0 (0%) |
| Employment | Employed | 7 (46.67%) | 10 (66.67%) |
| | Unemployed | 8 (53.33%) | 5 (33.33%) |
| Location | City | 6 (40.00%) | / |
| | Town | 5 (33.33%) | / |
| | Rural | 4 (36.67%) | / |
| Living in the same household | Yes | 13 (86.67%) | |
| | No | 2 (13.33%) | |
| Current treatment | Mastectomy | 1 (6.67%) | |
| | Reconstruction surgery for primary treatment | 4 (26.67%) | / |
| | Reconstruction surgery not for primary treatment | 1 (6.67%) | |
| | Chemotherapy | 9 (60.00%) | / |
| Stage | I | 3 (20.00%) | / |
| | II | 8 (53.33%) | / |
| | III | 2 (13.33%) | / |
| | IV | 2 (13.33%) | / |
| Recurrent breast cancer | Yes | 1 (6.67%) | / |
| | No | 14 (93.33%) | / |
| Time since diagnosis | <3 months | 3 (20.00%) | / |
| | 3-6 months | 9 (60.00%) | / |
| | >6 months | 3 (20.00%) | / |

6.4.7 Effects of the intervention in women with breast cancer

Table 6.3 presents the outcome scores of women with breast cancer, including FCR, social constraints, intrusive thoughts, avoidance, stigma and anxiety before and after participation in the family support programme. Significant changes were observed between pre-test and post-test scores, including decreases in FCR (38.57 ± 7.09 vs. 28.07 ± 8.87; P = 0.001), intrusive thoughts (9.93 ± 3.43 vs. 7.86 ± 2.25; P = 0.012), total stigma score (40.21 ± 5.91 vs. 36.00 ± 5.44; P = 0.005), the social isolation dimension of the stigma scale (5.07 ± 1.33 vs. 4.21 ± 1.12; P = 0.022), the self-perception dimension of the stigma scale (11.71 ± 1.93 vs. 10.14 ± 2.07; P = 0.003) and

anxiety (7.21 ± 4.98 vs. 4.00 ± 3.68; P = 0.013). Positive changes supporting the intervention were found across all outcomes from pre-test to post-test, with within-group Hedges' g ranging from 0.193 to 1.104. Large effect sizes were observed in FCR, total stigma score and the self-perception dimension of stigma, ranging from 0.90 to 1.104. Avoidance, self-image disorder and the discrimination dimension of stigma showed small effects, ranging from 0.193 to 0.432. Medium effect sizes were seen in the remaining outcomes, including social constraints, intrusive thoughts, social isolation, the social isolation dimension of stigma and anxiety, ranging from 0.517 to 0.698.

Table 6.4 Descriptive statistics and within-group effect sizes for outcomes in women with breast cancer (n = 14)

| | Pre-test | Post-test | Paired t test | | Within-group effect size (Hedges' *g*) |
|---|---|---|---|---|---|
| Variables | Mean±SD | Mean±SD | t | P | |
| FCR total score | 38.57±7.09 | 28.07±8.87 | 4.132 | .001* | 1.104 |
| Social constraints total score | 32.79±5.67 | 29.21±7.53 | 1.933 | .075 | 0.517 |
| Intrusive thoughts | 9.93±3.43 | 7.86±2.25 | 2.899 | .012* | 0.774 |
| Avoidance | 14.71±6.20 | 13.50±4.60 | .727 | .480 | 0.193 |
| Anxiety total score | 7.21±4.98 | 4.00±3.68 | 2.870 | .013* | 0.766 |
| Stigma total score | 40.21±5.91 | 36.00±5.44 | 3.372 | .005* | 0.900 |
| Stigma (self-image disorder) | 13.29±2.34 | 12.29±1.94 | 1.612 | .131 | 0.430 |
| Stigma (social isolation) | 5.07±1.33 | 4.21±1.12 | 2.604 | .022* | 0.698 |
| Stigma (discrimination) | 10.14±1.88 | 9.36±2.02 | 1.629 | .127 | 0.432 |
| Stigma (self-perception) | 11.71±1.93 | 10.14±2.07 | 3.562 | .003* | 0.953 |

6.4.8 Effects of the intervention in partners

Table 6.4 presents the outcomes for partners, including FCR, social constraints, intrusive thoughts, avoidance, affiliate stigma and its four dimensions and anxiety. Significant decreases were observed after the intervention: FCR (36.07 ± 7.03 vs. 31.21 ± 6.81; P < 0.0001), social constraints (32.50 ± 7.34 vs. 29.00 ± 5.32; P = 0.033), intrusive thoughts (10.79 ± 3.36 vs. 8.36 ± 2.13; P = 0.024), the perceived stigma

dimension of the affiliate stigma scale (8.64 ± 1.50 vs. 7.43 ± 1.51; P = 0.020) and anxiety (6.36 ± 5.06 vs. 3.50 ± 3.78; P = 0.004). Positive changes supporting the intervention were observed across all outcomes, with within-group Hedges' g ranging from 0.185 to 1.248. Large effect sizes were found in FCR and anxiety, at 1.248 and 0.942, respectively. Social constraints, intrusive thoughts, social isolation and the perceived stigma dimension of affiliate stigma exhibited medium effect sizes, ranging from 0.525 to 0.703, whereas avoidance, the total score of affiliate stigma, internal stigma and the reaction dimension of affiliate stigma demonstrated small effect sizes, ranging from 0.185 to 0.466.

Table 6.5 Descriptive statistics and the within-group effect sizes for outcomes in partners

| | Pre-test | Post-test | Paired t test | | Within-group effect size (Hedges' *g*) |
|---|---|---|---|---|---|
| Variables | Mean±SD | Mean±SD | t | P | |
| FCR total score | 36.07±7.03 | 31.21±6.81 | 4.660 | <.0001* | 1.248 |
| Social constraints total score | 32.50±7.34 | 29.00±5.32 | 2.386 | .033* | 0.637 |
| Intrusive thoughts | 10.79±3.36 | 8.36±2.13 | 2.547 | .024* | 0.681 |
| Avoidance | 12.79±5.04 | 11.14±3.74 | 1.427 | .177 | 0.383 |
| Affiliate stigma total score | 51.21±7.80 | 45.64±8.47 | 1.746 | .104 | 0.466 |
| Affiliate stigma (internal stigma) | 15.50±4.29 | 14.00±2.75 | 1.050 | .313 | 0.281 |
| Affiliate stigma (social isolation) | 18.50±2.65 | 16.21±3.85 | 1.963 | .071 | 0.525 |
| Affiliate stigma (perceived stigma) | 8.64±1.50 | 7.43±1.51 | 2.645 | .020* | 0.703 |
| Affiliate stigma (reaction) | 8.57±2.38 | 8.00±2.18 | .694 | .500 | 0.185 |
| Anxiety total score | 6.36±5.06 | 3.50±3.78 | 3.523 | .004* | 0.942 |

6.4.9 Qualitative interview results

Ten of the 15 couples completed the semi-structured interviews at T1. The reasons for

non-participation included dropout (n = 1) and being occupied with other events (n = 4). Among the ten couples, the mean FCR levels decreased from 38.4 to 30.0 in women (a reduction of 8.4 points) and from 37.1 to 32.6 in partners (a reduction of 4.5 points). One woman showed an increase in FCR by 2 points, whereas nine women demonstrated decreases in their FCR levels. Of these nine women, five exhibited reductions greater than 8.4 points and four exhibited reductions of less than 8.4 points. Two partners showed increases in FCR levels by 1 and 2 points, respectively. Among the eight partners with decreased FCR levels, four had reductions greater than 4.5 points and four had reductions of less than 4.5 points.

Three themes were extracted from the interview transcripts: (1) overall feelings regarding the intervention; (2) perceptions of the intervention content; and (3) suggestions for further improvement. The qualitative results indicate that the intervention was acceptable to the participants.

(1) Theme 1: Overall perceptions of the intervention

The intervention was positively evaluated by the participating couples, who perceived the e-handbook as comprehensive and well-structured. Key components, including strategies for managing treatment-related side effects and evidence-based recommendations on physical activity and healthy diet, were consistently endorsed as important. The majority of participants considered the session frequency and duration acceptable, but two divergent perspectives emerged: one participant suggested tailoring the intervention for participants with low distress by reducing the number of sessions, whereas another participant proposed extending the duration of the family support programme to enhance long-term adherence to tasks related to physical activity, healthy diet and disclosure. All participants emphasised the feasibility of the WeChat delivery model, particularly its accessibility and adaptability to daily routines. Below are the examples of meaning units:

*'I think the e-hankbook is comprehensive. Whenever I forget something, I refer back to it.'* (Partner 5)

*"I feel that weekly sessions for six weeks are appropriate to me.'* (Patient 9)

*'Face to face mode may be more effective because we can see each other, but WeChat is more convenient considering the site and time.'* (Partner9)

(2) Theme 2: Perceptions of the contents of the intervention

The interview data revealed that participants demonstrated a comprehensive understanding of breast cancer epidemiology and acquired various strategies for recurrence prevention, which markedly enhanced their perceived safety and self-efficacy in managing cancer. Notably, couples emphasised the critical role of maintaining open communication within a mutually supportive environment, particularly highlighting how interactions with empathetic interventionists facilitated deeper self-disclosure. Furthermore, they noted the importance of communication skills in daily life to prevent arguments. Participants expressed high satisfaction with the intervention, reporting that their inquiries were addressed through two complementary modalities: (1) real-time, disease-specific and treatment-related clarification during structured intervention sessions and (2) asynchronous professional guidance via WeChat messaging between sessions. The prompt responses and professional consultations were particularly highlighted as a key factor in enhancing the perceived accessibility and effectiveness of the family support programme. Below are the examples of meaning units:

*'You help us find the reasons accounting for breast cancer. We learnt strategies to reduce cancer recurrence. We feel safer. However, if my wife did not exercise, my concerns and worry increase.'* (Partner 4)

*'I felt at ease after your WeChat call.'* (Partner 12)

*'Before I participated, I thought I had nothing to disclose to you because you look so young. After I participate, every time I just say a few words, but you know what I want to say and what I am thinking.'* (Patient 12)

*'I told you everything, I feel like you're my lifeline.'* (Patient 1)

*'One day we had some arguments on daily issues. My husband apologized to me immediately, and anger disappeared quickly. I found we really benefit from what you taught us, and our relationship is better than before.'* (Patient 12)

*'Whenever we have questions, we can ask you and you respond much quicker than my chief doctor. The answer from you is same with the doctor.'* (Patient 1)

(3) Theme 3: Suggestions for further improvement

Participants' feedback revealed several recommendations for intervention adaptation. Two couples provided divergent suggestions regarding session frequency: one advocated reducing the number of sessions for individuals experiencing low anxiety, while another proposed extending the intervention duration beyond one year to facilitate adherence. Regarding the emotional response and management components, participants recommended supplementing the third session on communicating feelings with materials analogous to the e-handbook for asynchronous access. Multiple respondents emphasised the importance of independently seeking online health information due to time constraints during consultations with physicians managing high clinical workloads. Consequently, additional information about treatments and medications was recommended. Notably, some couples expressed a preference for examples illustrating positive prognoses at different cancer stages, with one partner explicitly requesting tailored examples that excluded advanced cancer cases, as his wife was in an early stage. Additionally, some participants proposed incorporating information on government-provided financial assistance and accessible resources for

economically disadvantaged cancer patients.

*'Provide more sessions for those more anxious couples.'* (Patient 4)

*'I thought it is good to have this kind of sessions. The time of this family support programme should be designed for one year, or even three years. I am willing to participate in it.'* (Partner 12)

*'Sometimes, I forgot what you say during the session. So, it would be better to provide some materials similar to the e-handbook. Especially for the effects of emotional response on cancer recurrence rate. Before, I thought the incidence of breast cancer may be related to my negative emotional response, because there are issues that bother me. But I just guessing, after you told me, I am more confident in this hypothesis.'* (Patient 8)

*'Our doctor is too busy, we cannot find him/her. We would like to know more about our treatment, if your sessions cover more on our treatment and drug would be better.'* (Partner 6)

*'You are experienced and have more opportunity to see the prognosis of different patients in the hospitals. I want to know more about this, so, if you can provide more examples of patients with good prognosis is better, which may boost my confidence to fight breast cancer.'* (Patient 2)

*'My wife's disease is not severe, we do not want to know people who have advanced cancer.'* (Partner 1)

*'The cancer treatment is expensive, it is better to provide information related to government-provided financial assistance and accessible information channels for*

*economically disadvantaged cancer patients.'* (Partner 12)

## 6.5 Discussion of the pilot findings

Six feasibility outcomes (eligibility rate, recruitment rate, intervention compliance, delivery mode, acceptability of the intervention and adaptations to the intervention protocol prior to the pilot study) were used to assess whether delivering the family support programme to couples coping with breast cancer was feasible.

### 6.5.1 Eligibility screening

Recruiting couples for interventional studies is challenging, and the eligibility rate in the pilot study was low (17.09%). The two primary reasons for this low eligibility rate were lack of interest (n = 141) and unavailability (n = 90). Several factors may have contributed to potential participants' lack of interest. One possible factor is the environment of the one participating hospital, where many staff members from insurance and commercial companies were promoting insurance packages and post-mastectomy bras. Consequently, couples may have perceived the doctoral student as representing a commercial interest and declined participation to avoid potential fraud. To mitigate trust issues in future studies, enhanced support from staff within the participating wards is necessary. For instance, involving ward staff in the recruitment process or asking them to introduce the researchers to potential participants can enhance credibility. Additionally, placing posters within wards, including background information about the study, may increase participants' understanding and willingness to engage. Another contributing factor may have been the concurrent implementation of three nursing-related projects targeting the same population of breast cancer patients during the recruitment period. This overlap may have led to participant fatigue given that patients were repeatedly approached for different studies.

### 6.5.2 Subject recruitment

The recruitment rate was 25.00%. The primary factor contributing to this low rate was

the high withdrawal of consent, which affected 75.00% of participants (45/60). Many couples who had initially provided consent were lost to follow-up after the patient's discharge but prior to the commencement of the intervention. To minimise the likelihood of consent withdrawal, it is recommended that Session 1 of the family support programme be delivered in the hospital as soon as possible after the baseline assessment, rather than after discharge. This approach may help participants perceive immediate benefits from the programme, thereby increasing retention across all six sessions.

### 6.5.3 Intervention compliance

Intervention compliance was relatively high (73.33%). The primary factors hindering attendance were patients' distressing symptoms following chemotherapy, such as fatigue, nausea and vomiting, and the unavailability of partners. Although the challenges faced by women with breast cancer were largely unavoidable, the issue of partner unavailability can be mitigated by offering separate individual sessions for partners when they are unable to attend joint sessions with the patient.

### 6.5.4 Delivery mode

WeChat is the most widely used social media platform in China and was therefore selected as the medium for delivering the intervention. During the semi-structured interviews, couples reported that receiving the sessions via WeChat was both convenient and acceptable. Although some participants indicated a preference for face-to-face delivery, they acknowledged the practicality of WeChat and expressed willingness to continue using it as the mode of intervention delivery.

### 6.5.5 Acceptability of the intervention

The couples expressed satisfaction with the design and organisation of the family support programme and with the WeChat delivery mode. Although the programme was considered highly successful in this pilot study, several areas for improvement were

identified. Participants suggested adjusting the number of sessions according to individual needs, that is, more sessions should be provided for participants experiencing higher levels of anxiety and fewer sessions for those with lower levels. They also recommended providing materials to facilitate review of the content after each session. Additionally, couples expressed a desire for more information related to their treatments, particularly regarding medications and the results of physical examinations. Furthermore, they suggested including more examples of individuals with a favourable prognosis at a similar stage of cancer, as learning about others' positive outcomes may help alleviate psychological burden.

### 6.5.6 Adaptations to the intervention protocol

This pilot study indicated that the family support programme can produce favourable effects in reducing FCR, intrusive thoughts, stigma and anxiety in women with breast cancer and their partners ($P < 0.05$), with medium to large effect sizes. Additionally, social constraints decreased significantly in partners after the six sessions ($P < 0.05$). Insights from individual interviews revealed that couples experienced psychological comfort after participating in the programme, which enhanced their confidence in coping with cancer, alleviated perceived FCR and improved marital relationships. Patients reported acquiring strategies to reduce the risk of cancer recurrence, thereby fostering a sense of safety. Partners not only gained caregiving knowledge but also learned how to support their wives in minimising the risk of recurrence. Furthermore, couples highlighted the value of engaging with a person who understood them and providing an opportunity to disclose concerns within a supportive environment, which helped reduce worry and address their issues effectively.

Based on participant feedback, five adaptations were made to the protocol of the family support programme for implementation in the main RCT: (1) two additional examples of individuals with cancer who had experienced favourable prognoses and recovery were included to further enhance couples' confidence in rehabilitation; (2) educational

content on psychosocial factors related to cancer recurrence was incorporated into the e-handbook and emphasised in Session 3, allowing participants to review the material and reinforce confidence in their recovery as needed; (3) Session 1 was scheduled to commence in the hospital, as soon as possible after completion of the baseline questionnaire, to minimise loss to follow-up after discharge and potentially improve recruitment rates; (4) the physical activity goal for women was revised to 'walk at least 30 minutes on five days each week'; and (5) the duration of each session was adjusted to approximately 40–60 minutes to allow for flexibility. Although some participants suggested including information on government-provided financial assistance and accessible information channels for economically disadvantaged patients, these recommendations were not incorporated because they were incompatible with the conceptual framework guiding the intervention. While the cost of treatment may contribute to FCR, supplementing funding sources lies outside the core mechanisms addressed by the programme. Consequently, the family support programme for couples affected by breast cancer was revised and prepared for testing in the main RCT, while retaining its three core components: (i) disclosure of feelings and thoughts; (ii) education on healthy lifestyle practices, including guidance on physical activity and health diet to improve treatment side effects and perceptions of cancer recurrence, with support from partners; and (iii) management of psychosocial factors through education on reducing cancer recurrence risk.

### 6.6 Summary

This chapter presents the details of the pilot study. While the study procedure and intervention protocol required some revisions, the findings indicated that the study procedure and data collection process were generally feasible. The family support programme, delivered via WeChat, was well-received by women with breast cancer and their partners, as reflected by a high retention rate (93.33%) and strong session attendance (women: 5.2 out of 6 sessions; partners: 4.8 out of 6 sessions). Mean adherence rates were also high for physical activity (85.71%), healthy dietary practices

(90.00%) and disclosure of feelings (84.44%). Qualitative findings indicated a high level of satisfaction with the programme, and the participants valued the comprehensive knowledge provided and supportive environment for disclosure. Moreover, the programme demonstrated favourable effects in reducing FCR, intrusive thoughts, stigma and anxiety in women with breast cancer and their partners, with medium to large effect sizes. Social constraints decreased significantly in partners after the six sessions. Based on the results of this pilot study, the study protocol was subsequently modified. Given these promising preliminary findings, the next step is to conduct an RCT with a follow-up period for the evaluation of the effectiveness of the revised intervention in couples affected by breast cancer.

# CHAPTER SEVEN: METHODOLODY

## 7.1 Introduction

This chapter outlines the methods of the main RCT designed to evaluate the effectiveness of a theory-driven, disclosure-based family support programme on FCR, social constraints, intrusive thoughts, avoidance, anxiety and stigma among couples coping with breast cancer in China.

Section 7.2 presents the study aim and objectives, followed by a discussion of the study design in Section 7.3 and the study setting in Section 7.4. Section 7.5 introduces the target participants, while Section 7.6 provides a detailed description of the intervention. Sample size calculation is presented in Section 7.7. Subject recruitment is outlined in Section 7.8, with randomisation and blinding procedures described in Section 7.9. Section 7.10 details the data collection procedures, and Section 7.11 presents the study measures, including feasibility outcomes, couple-reported outcomes, acceptability evaluation and quality control. Data management and statistical analysis are documented in Section 7.12, and ethical considerations are addressed in Section 7.13.

## 7.2 Aim and objectives of the RCT

The primary aims of this RCT were: (1) to examine the effectiveness of a theory-driven, disclosure-based family support programme on FCR, social constraints, intrusive thoughts, avoidance, anxiety and stigma in women with breast cancer and their partners in China; and (2) to evaluate the acceptability of this programme in couples coping with breast cancer in China.

The specific objectives of the RCT were as follows:

(1) To determine the recruitment and retention rates of women with breast cancer and their partners

(2) To examine the effects of the theory-driven, disclosure-based family support programme on FCR, social constraints, intrusive thoughts, avoidance, anxiety and

stigma, compared with follow-up calls via WeChat, in women with breast cancer and their partners

(3) To assess the acceptability (i.e., overall perceptions and satisfaction, perceived benefits, barriers and facilitators to participation, and suggestions for further improvement) of the family support programme after modifications informed by pilot study findings in women with breast cancer and their partners in the intervention group

Three research questions for the effects of the family support programme were examined in the RCT.

(1) Whether the interventional effects differ by role (i.e. women vs. partners)

(2) Whether the intervention is effective in improving women outcomes as compared with WeChat follow-up calls

(3) Whether the intervention is effective in improving partner outcomes as compared with WeChat follow-up calls

### 7.3 Study design

A two-arm, parallel-group RCT with a 1:1 allocation ratio, two follow-up assessments at post-intervention (T1) and 12 weeks after recruitment (T2) and an embedded qualitative interview component for process evaluation were conducted. The RCT design was employed because it is widely regarded as the gold standard for evaluating intervention effects and minimising bias (Abel & Koch, 1999). Figure 7.1 presents the flow diagram depicting participant enrolment, outcome assessments and acceptability evaluation at each time point of the RCT.

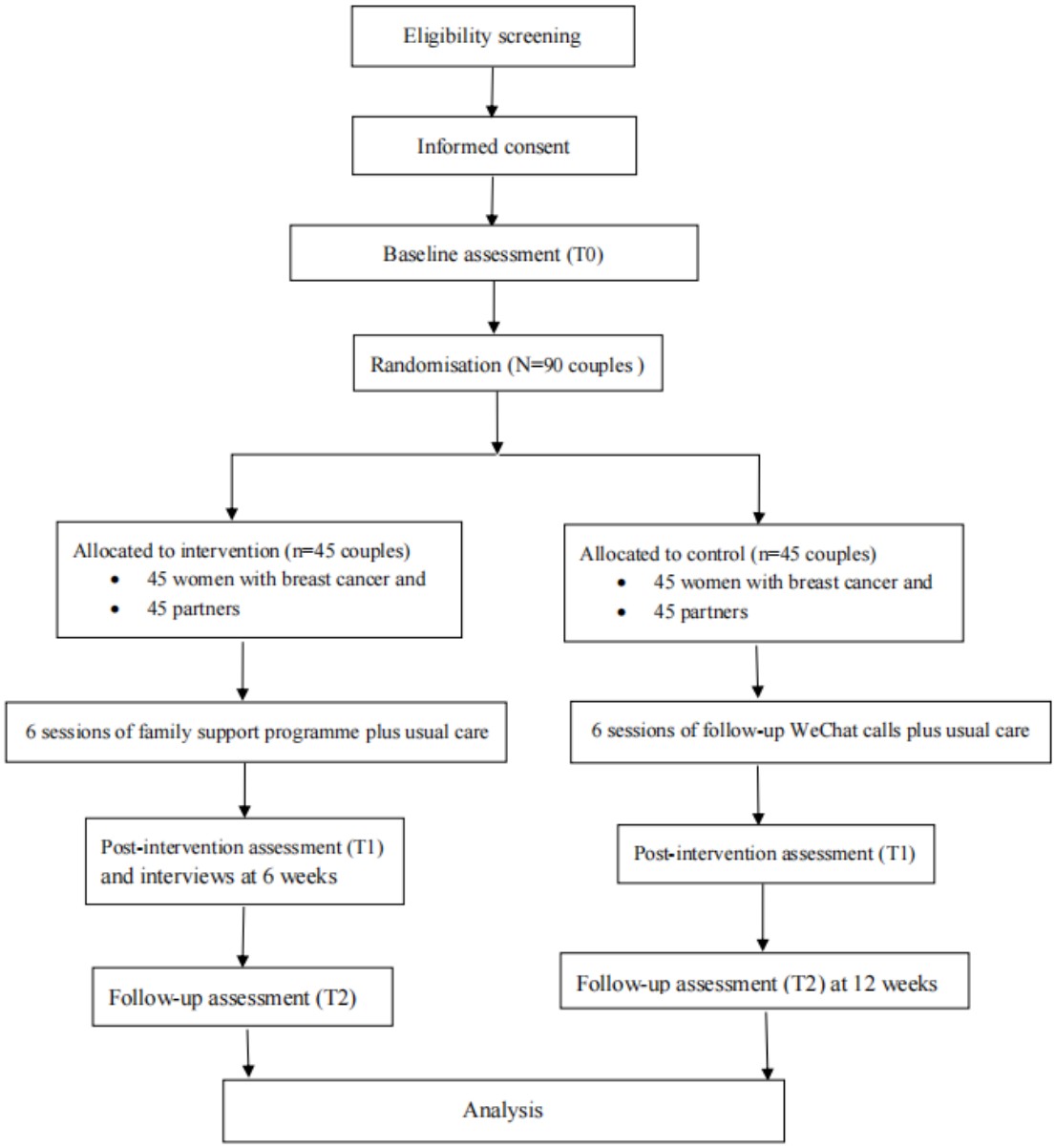


Figure 7.1 Flow diagram for enrolment of the participants and assessments of outcome and acceptability

### 7.3.1 Study setting

The study was conducted in the same settings as the pilot study described in Chapter Six: the Affiliated Cancer Hospital of Xiangya School of Medicine, Central South University and the Affiliated Suzhou Hospital of Nanjing Medical University in Jiangsu Province. Detailed descriptions of these hospitals are provided in Section 6.3.2 of Chapter Six. Permission to access both hospitals for participant recruitment in the main

RCT was obtained, and a good rapport was established with the staff at both sites.

### 7.3.2 Participants

Participants in the study were couples consisting of women with breast cancer and their partners. The eligibility criteria for participants in the RCT were identical to those applied in the pilot study described in Chapter 6.

### 7.3.3 Intervention description

#### 7.3.3.1 Intervention for arms

Participants were randomly assigned to either the control or the intervention arm. The control group received six weekly follow-up calls via WeChat, while the intervention group received the six-week, theory-driven, disclosure-based family support programme. In addition, all women continued to receive standard care provided by the participating hospitals.

Usual care

Usual care for breast cancer patients provided by the participating hospitals included routine inpatient and discharge education following surgery. Patients scheduled for breast cancer surgery and admitted to the breast surgery ward received post-operative position management, dietary guidance, drainage tube care, wound care and functional exercise as part of standard care. Patients scheduled for chemotherapy, admitted to the breast medical ward or for radiotherapy, admitted to the thoracic radiotherapy ward, received pharmaceutical management, including education on chemotherapy and radiotherapy side effects, such as leukopenia, and guidance on nutrition, hygiene, activity and side effect management. In addition, self-help health education materials, including booklets, were available in the wards at no cost. Hospital nurses contacted patients to remind them of scheduled treatments. During hospital visits, nurses or physicians obtained a health history and performed a physical examination. Brief explanations regarding breast cancer and rehabilitation guidance were provided.

However, detailed on-site education is not routinely delivered because of limitations in the hospital workforce.

7.3.3.1.1 Intervention group

In addition to usual care, the intervention group received the six-week, theory-driven, disclosure-based family support programme, supplemented with an e-handbook and a video. Following the pilot study, five modifications were made to the intervention content, as detailed in Section 6.8.6 of Chapter Six. The revised intervention content to be tested in this RCT is presented in Table 7.1. The programme comprises an educational package and six weekly sessions, each lasting 40–60 minutes, delivered via WeChat by the doctoral student. The six sessions address three core components: (1) education on healthy lifestyle behaviours, including physical activity and diet, to mitigate treatment side effects and reduce cancer recurrence, with guidance provided to women and supported by their partners (Sessions 1 and 2). Partners were informed of the guideline-based targets for physical activity and healthy diet in breast cancer survivorship, and the couple set weekly goals together. Partners were encouraged to accompany women to complete the activity goals (e.g., walking) and to support adherence through planning (scheduling activity, assisting with meal planning and preparation). The family support programme also included concrete suggestions on how to prepare healthier meals and what types of exercises were appropriate, with basic safety advice and adaptation strategies to address common barriers, such as fatigue or other issue; (2) disclosure of feelings and thoughts between the couples (Sessions 3–6); and (3) additional education on psychosocial factors related to cancer recurrence, provided in Session 3. When only one member of the couple attended a disclosure-focused session, the session was delivered to the attending participant as scheduled. To enhance attendance, pragmatic strategies has been adopted tailored to chemotherapy-related symptoms and work constraints, including flexible scheduling (e.g., aligning sessions with treatment cycles when feasible), reminder messages, and providing catch-up content in the next session.

Table 7.1 Components of the theory-driven, disclosure-based family support programme for testing in the RCT

| Sessions | Topic | Content |
|---|---|---|
| 1 | Brief introduction about breast cancer and self-management of treatment side effects, particularly lymphoedema | Breast cancer definition, risk factors and prevalence; self- management of treatment side effects targeting their treatment (surgery, chemotherapy, radiotherapy, hormone therapy and target therapy); prevention, early recognition and self-management of lymphoedema. |
| 2 | Healthy dietary education and physical activity education | Benefits of healthy dietary practice and physical activity,<br>recommendations of healthy dietary and anti-cancer food and physical activity;<br>cautions on healthy dietary and physical activity;<br>goal plan for healthy dietary based on the *Chinese Residents' Balanced Diet Pagoda* and physical activity based on the recommendation from the Chinese Anticancer Association |
| 3 | Communicating feelings | Expression of one's feelings after the diagnosis of breast cancer, negative feelings and concerns of cancer progression;<br><br>Help patients to find the personal and psychosocial risk factors of breast cancer recurrence, guide couples to use non-violent communication methods, encourage them to express their feelings and concerns in daily life and supplemented with some coping skills; women with breast cancer and their partners are encouraged to express their emotions by using empathy, encouragement and inspiration and promote the expression of negative emotions. Emphasise the relationship of negative emotions with breast cancer occurrence. |
| 4 | Breast cancer influences | Talking about the effects that having breast cancer on personal life and family;<br>talking about the details of worry or fear of recurrence and its influence; |

| | | |
|---|---|---|
| | | the facilitator will explore women's perceptions of breast cancer prognosis, share successful cases and experiences in those people with advanced stage but with good treatment outcome and strengthen couples' positive perceptions of prognosis; share a video of a patient with advanced stage cancer but with good prognosis after the session and invite them to express their feelings in the next session. |
| 5 | Post-traumatic growth | Talking about what have been done/changed;<br>talking about the worry and its influence;<br>Expressing concern and fear of cancer recurrence at the current stage.<br><br>The facilitator will ask couples to recall positive changes they have made, such as emotions, healthy dietary, physical activity, sleep and relationships with family members, and help women to deal with their treatment side effect. The facilitator will guide couples to think from each other's side and promote intimate relationship within couples. |
| 6 | Coping and expectation | Talking about the changes in couples' perceptions of cancer recurrence;<br>talking about the experience and coping strategies;<br>talking about the future plans.<br><br>The facilitator will help women to recall positive experience and their own coping strategies and will develop a plan to prevent cancer recurrence from five aspects: cancer mindset, emotion, healthy diet, physical activity and sleep. |

7.3.3.1.2 Control group

The control group received usual care in addition to six weekly follow-up sessions via WeChat. Participants were able to ask questions related to breast cancer; however, no guidance was provided regarding disclosure of feelings, physical activity or dietary recommendations specifically for breast cancer management. If participants inquired about physical activity or diet, brief general advice was offered, but this was less detailed than the guidance provided to the intervention group. Each WeChat follow-up session lasted approximately 5–10 minutes.

7.3.3.2 Facilitator training

The doctoral student, following further training delivered by the psychologist, conducted the six-week, theory-driven, disclosure-based family support programme for the intervention group. The training, which lasted over 1.5 months, focused on enhancing communication and disclosure skills and other relevant psychological techniques.

For the control group, a registered nurse with a clinical background in breast cancer, trained by the doctoral student, delivered the six weekly WeChat follow-up sessions. All sessions were conducted individually with each couple. Attendance at scheduled sessions was recorded by the facilitator. Participants in both groups were instructed not to share or discuss the content of the intervention with others, either during hospital visits or elsewhere.

7.3.4 Sample size calculation

A power analysis was conducted using G*Power (Version 3.1; https://g-power.apponic.com/) with the following parameters: (1) repeated measures MANOVA; (2) power = 80%; (3) significance level set at 0.025 (i.e. 0.05/2) to control the overall Type I error at 5% for the co-primary outcomes of FCR in couples; (4) intra-correlation between repeated measures = 0.8; and (5) effect size = 0.48 (Chen et al., 2022). This analysis yielded a required sample size of 81 couples. Allowing for an anticipated attrition rate of 10%, a total of 90 couples (45 per group) were planned for recruitment.

For the qualitative component, couple-based interviews involving both women with breast cancer and their partners were conducted to explore the acceptability of the support programme. When both members of a couple were unable to attend together, separate individual interviews were conducted. Based on recommendations by Onwuegbuzie and Leech (2007), a sample size of 10 couples was considered sufficient in this qualitative component.

### 7.3.5 Subject recruitment

Convenience sampling was employed for participant recruitment in the RCT, with couples of women with breast cancer and their partners serving as the sampling unit. A research assistant (RA1) identified eligible women and their partners at the participating hospitals. Within each dyad, one member, usually the woman, was invited to complete the screening questionnaire (FoP-Q-SF) first. If the first respondent did not meet the eligibility criteria (FoP-Q-SF score < 34), the other member of the couple was invited to complete the same questionnaire. When the partner was not present at the hospital and the woman's score was < 34, RA1 provided an electronic version of the questionnaire for the partner to complete via WeChat, with the woman's permission). Couples were eligible if at least one member scored ≥ 34. After screening, eligible women were asked to nominate their male partners who were providing care. RA1 then approached the nominated partners to assess eligibility. Eligible couples were informed about the objectives and procedures of the study, and written informed consent was obtained from both of them prior to participation. Once eligibility was confirmed, RA1 explained the study purpose and procedures to the woman, who then discussed participation with her partner. If both agreed to participate, written consent was obtained from both members. For partners not present in the hospital, written consent obtained via WeChat. After consent, couples completed the baseline e-questionnaire (T0) independently.

For the qualitative component, convenience sampling was employed, and the couples served as the sampling units. Where possible, couples in the intervention group who demonstrated varied changes in FCR (decreased, unchanged or increased) after participating in the family support programme were selected to capture a diverse range of experiences.

### 7.3.6 Randomisation and blinding

Following the baseline assessment, couples were randomly allocated to either the control group, which received usual care plus WeChat follow-up calls, or the intervention group, which received the theory-driven, disclosure-based family support programme. The allocation sequence was generated by an independent statistician who had no involvement in recruitment and no contact with potential participants, using an online randomization program (http://www.randomization.com). A separate sequence of group assignments, based on the computer-generated random codes, was prepared and placed in serially numbered opaque sealed envelopes prior to the start of the RCT. RA1 opened an envelope to assign each couple to a study group after they had completed the baseline questionnaires. Owing to the nature of the intervention, neither participants nor intervention providers were blinded. However, post-intervention and 12-week follow-up data were self-reported by participants via WeChat. A second research assistant (RA2), responsible for managing the WeChat database and data collection at these time points, remained blinded to group allocation.

### 7.3.7 Data collection procedure

Outcome assessments were conducted at three time points: baseline (T0), post-intervention at six weeks (T1) and at 12-week follow-up (T2). A detailed description of the data collection procedures is provided in Table 7.2.

Baseline assessment (T0) was conducted using e-questionnaires prior to randomisation. For partners recruited via WeChat, written consent was obtained electronically and the baseline assessment was also completed via WeChat. Post-intervention assessment (T1) for both groups was conducted immediately following completion of the intervention, with women and partners completing the questionnaires independently via WeChat. RA2 sent participants a WeChat message containing a hyperlink to the questionnaire, and participants returned the completed questionnaires by replying to the message. Follow-up assessment (T2) was conducted 12 weeks after recruitment using the same procedure via WeChat, managed by RA2. For the qualitative component of the RCT,

the doctoral student invited couples in the intervention group to participate in WeChat interviews conducted by RA1 to explore their perceptions of the intervention's acceptability following T1. Each interview lasted approximately 20–40 minutes.

Table 7.2 Outcome assessment at the three time points by participant type

| Outcome | Source of information | Time-point outcomes collected |
|---|---|---|
| Primary outcomes | | |
| FCR | women + partners | T0, T1, and T2 |
| Secondary outcomes | | |
| Social constraint | women + partners | T0, T1, and T2 |
| Intrusive thoughts | women + partners | T0, T1, and T2 |
| Avoidance | women + partners | T0, T1, and T2 |
| Anxiety | women + partners | T0, T1, and T2 |
| Stigma | women + partners | T0, T1, and T2 |
| Disclosure adherence | women+ partners | Sessions 4 - 6 |
| Physical activity adherence | women | Session 3 - 6 |
| Healthy dietary adherence | women | Session 3 - 6 |
| Acceptability of the intervention | women + partners in the intervention group | T1 |

Note: T0: Baseline after recruitment; T1: 6-week after recruitment; T2: 12-week follow-up after recruitment

### 7.3.8 Measures

#### 7.3.8.1 Feasibility outcomes

Feasibility outcomes were consistent with those assessed in the pilot study and included eligibility rate, recruitment rate, retention rate, session attendance, adherence to programme tasks (disclosure and healthy diet), intervention acceptability and intervention fidelity. Further details are provided in Section 6.3.7.1 of Chapter Six. Based on the findings from the pilot study in Chapter 6 among 15 couples, the criterion for adherence to physical activity changed to 'walking for at least 30 min on 5 days per week'. This criterion is adopted for safety because the study was taken place during the summer when ambient temperatures usually reach 37–42 °C. Women recovering from

surgery were advised to avoid strenuous physical activity, as excessive sweating may increase the risk of surgical site infection. Furthermore, some patients undergo autologous breast reconstruction, during which surgical drains may remain in place for an extended period, rendering vigorous or high-impact exercise unsuitable.

#### 7.3.8.2 Couple reported outcomes

The main RCT employed the same primary and secondary outcomes as the pilot study. Details of these outcomes, including FCR, social constraints, intrusive thoughts, avoidance, anxiety and stigma, are provided in Section 6.3.7.2 of Chapter 6. The same sociodemographic variables were collected.

#### 7.3.8.3 Acceptability evaluation

Consistent with the pilot study, couple-based interviews were conducted via WeChat calls with participants in the intervention group following completion of the programme. The interviews explored participants' perceived acceptability of the intervention, including overall perceptions and satisfaction, perceived benefits, barriers and facilitators to participation, and suggestions for further improvement. These interviews served as a process evaluation of the RCT, providing insight into unanticipated causal pathways and generating ideas for potential modifications to the intervention protocol (Moore et al., 2015). The interview guide is provided in Table 7.2.

Table 7.3 Open-ended questions of the individual interview for couples

| Items | Questions |
|---|---|
| Q1 | How do you think about the intervention?/ How is your feeling after the intervention? |
| Q2 | How do you evaluate the intervention? Are you satisfied with it? Why? |
| Q3 | What are the barriers and facilitators of the intervention? |
| Q4 | Any other comments and suggestions for us to improve the intervention? |

### 7.3.9 Quality control

The quality of the RCT was ensured through four key aspects: (1) the family support

programme was theory-driven (Chapter 4) and validated by an expert panel and 14 couples of women with breast cancer and their partners; (2) intervention fidelity was assessed during the pilot study; (3) self-reported outcomes were measured using validated scales; (4) all study activities were consistently supervised by the doctoral student.

#### 7.3.10 Statistical management and analysis

##### 7.3.10.1 Data management

All questionnaires administered at T0–T2 were completed electronically via the Wenjuanxing platform and exported for analysis with IBM SPSS Version 26.0. No manual data entry was performed. After randomisation, RA1 assigned a unique identifier to each participant to maintain confidentiality. RA2, who was blinded to group allocation, managed data collection at T1 and T2 by sending participants a hyperlink to the electronic questionnaires via WeChat. The questionnaire links were generated from the Wenjuanxing website (https://www.wjx.cn/). In addition, RA2 sent reminders via WeChat to encourage timely completion and maximise response rates. Upon the completion of data collection, RA2 downloaded the dataset from the Wenjuanxing platform and provided it to the doctoral student without group allocation information, ensuring that the doctoral student remained blinded during data analysis. All trial data will be securely stored for a minimum of five years following study completion and will be destroyed thereafter.

##### 7.3.10.2 Quantitative Data Analysis

Descriptive analyses were conducted for sociodemographic variables and outcome measures, including FCR, social constraints, intrusive thoughts, avoidance, anxiety and stigma, in women and their partners separately at each of the three time points. The intention-to-treat (ITT) principle was applied whenever appropriate given that it is suitable for analysing longitudinal data in which scores at subsequent time points depend on prior measurements. For feasibility outcomes, eligibility and recruitment

rates were calculated using recruitment data, whereas retention rates were derived from follow-up data. Descriptive results were presented as means and standard deviations for continuous variables and as counts and percentages for categorical variables. Baseline comparability between groups was assessed using independent-samples *t*-tests for continuous variables and Chi-square tests for categorical variables. When significant baseline differences were identified between groups (intervention vs. control) or between completers and participants lost to follow-up, the variables were controlled for in subsequent analyses. A P-value of $<0.05$ was considered statistically significant. The effect sizes of the theory-driven, disclosure-based family support programme on outcomes were estimated using between-group Cohen's *d*, with values of 0.2, 0.5 and 0.8 indicating small, medium and large effect sizes, respectively (Cohen, 1988).

Generalised linear mixed-effects models (GLMMs) were employed to analyse longitudinal data with incomplete observations through maximum likelihood estimation. This approach accommodates missing data under the assumption of missing at random and utilises all available data points without requiring imputation. In GLMMs, random effects represent unobserved heterogeneity or subject-specific variability not captured by fixed effects, and GLMMs account for correlations within clusters or repeated measures within the same unit. In the context of this RCT, random effects were modelled to account for clustering both within couples and within individuals over time. The random effect at the couple level captures shared variance, recognising that members of a couple may influence each other and exhibit correlated responses due to shared experiences, emotions or environments. The random effect at the individual level captures variability between participants, allowing each person to have their own baseline or trajectory over time (Burghoff, 2016). For example, within the same group, some individuals may begin with higher FCR levels or respond differently to the intervention. Including random effects ensures that the independence assumptions of the model are not violated and provides more accurate estimates of the fixed effects, such as group, time, role and their interactions. This approach facilitates

generalisation beyond the study sample, assuming that the included random effects are representative of a large population. To account for the dependence of repeated measures, we treated time as a repeated factor for each participant (i.e. women and partners analysed separately). This models the residual correlation between a participant's scores over T0, T1 and T2, yielding accurate standard errors, allowing flexible specification of the temporal covariance structure and maximising the use of all available data points.

GLMMs were conducted using IBM SPSS Statistics Version 26.0 to address three primary research questions: (1) whether the interventional effects differ by role (i.e. women vs. partners); (2) whether the intervention is effective in improving outcomes for women compared with control group; and (3) whether the intervention is effective in improving outcomes for partners compared with control group. To address Research Question 1, we analysed all outcomes except stigma for women and partners given that different stigma scales were used for each member of the couple. These scales had different items, subscales and total scores. The GLMM included the main effects Group, Time and Role, their two-way interactions (Group × Time, Group × Role and Time × Role) and their three-way interaction (Group × Time × Role). The three-way interaction term served as as the primary effect of interest. Time was treated as a repeated measure to appropriately model the longitudinal structure of the data and capture correlations of observations within individuals across time points. Random effects were included at both the couple level (to account for shared variance within couples) and the individual level (to account for repeated measures nested within individuals). Robust estimation was applied to address potential violations of model assumptions and to test fixed effects. To ensure that observed differences between the intervention and control groups reflected the intervention effect rather than pre-existing imbalances, covariates showing significant baseline differences between groups or between completers and participants lost to follow-up were included in the model. For the outcome of stigma, GLMMs were not be used in examining differential impacts by role because of differences in

measurement tools, which varied in scoring systems and dimensionality, for women and partners.

For Research Questions 2 and 3, analyses were conducted separately for women and partners for all outcomes. Each GLMM included the main effects of Group and Time and their interaction (Group × Time). The two-way interaction served as the primary effect of interest for the assessment of changes over time within each group. Variables exhibiting significant between-group differences at baseline or between completers and participants lost to follow-up were included as covariates. Outcomes analysed included FCR, social constraints, intrusive thoughts, avoidance, anxiety and stigma. Time was treated as a repeated measure to account for the correlation of observations within individuals across the three time points. Random effects were specified at the individual level to capture variability in baseline scores and trajectories over time. For all analyses, both the repeated covariance type and random effect covariance type were set as first-order autoregressive (AR1). Robust estimation was applied to address potential violations of model assumptions and to test fixed effects and coefficients. Covariates demonstrating significant baseline differences between groups or between completers and non-completers were adjusted for in all models.

When conducting GLMMs, coefficient estimates (β) with corresponding 95% confidence intervals (CIs) were generated. The coefficients of the fixed effects represent the expected change in the dependent variable for a one-unit change in the associated independent variable, and all other variables in the model were assumed to be constant. The SPSS output provided the coefficient estimates and confidence intervals. Table 7.3 summarises the interpretation of coefficient estimates in the GLMMs.

Table 7.4 Interpretation of coefficient estimates in generalised linear mixed-effects models

| Parameter | Interpretation |
|---|---|
| Intercept | The estimated mean value of the dependent variable when all other variables are at their reference level. |
| Group | The effect of being in Group 1 (intervention group) compared to Group 0 (control group, reference). |
| Time | The effects of T1 or T2 compared to T0 (reference) |
| Role | The effect of women with breast cancer (Role = 1) compared to partners (Role = 0, reference) |
| Group × Time | Interaction between Group and Time. It examines whether the effect of Time on the dependent variable differs between Group 1 and Group 0 (control group, reference) |
| Group × Role | Interaction between Group and Role. It examines whether the effect of Group on the dependent variable varies depending on the Role. |
| Time × Role | Interaction between Time and Role. It investigates whether the effect of Time on the dependent variable differs across Role. |
| Group × Time × Role | Interaction among Group, Time, and Role. This three-way interaction assesses whether the two-way interaction between Group and Time on the dependent variable is further influenced by Role. |

7.3.10.3 Qualitative data analysis

For the qualitative component, data were transcribed verbatim from the notes and audio recordings of the discussions in Chinese by the doctoral student, who has experience in qualitative data transcription and conducted the interviews. RA1 double-checked the transcripts for accuracy. NVivo 11 (https://lumivero.com/products/nvivo/) was used in the management and analysis of qualitative data. Transcripts were cross-checked against the audio recordings and notes for accuracy and completeness.

Data analysis of interviews

Thematic analysis was employed to explore the acceptability of the intervention. This qualitative research method enables the identification, analysis and reporting of patterns (themes) within textual data. Unlike content analysis, which primarily focuses on counting words or phrases, thematic analysis facilitates the interpretation of the data, providing deep insights into various aspects of a research topic (Ahmed et al., 2025). A reflexive thematic analysis approach was adopted, using primarily inductive, semantic

coding to capture participants' accounts of the programme. The analysis was guided by a clear thematic focus aligned with the process evaluation aims, including (1) perceived acceptability and satisfaction, (2) perceived benefits and relevance of programme content, (3) barriers and facilitators to engagement, and (4) suggestions for optimisation and improvement.

Data analysis process

Data were transcribed verbatim within 24 hours by the doctoral student and double-checked by RA1, both of whom had received training in qualitative research. Transcripts were organised and coded using NVivo software Version 11 (https://lumivero.com/products/nvivo/). Coding was conducted independently by the doctoral student. Thematic analysis was performed following the six-phase framework of Braun and Clarke (2006). Detailed methodology is provided in Chapter Six.

Trustworthiness

Credibility was ensured by involving two independent analysts in the data analysis and by obtaining confirmation of the results from key informants (Thórarinsdóttir et al., 2019). Confirmability was supported through a comprehensive audit trail documenting each step of the analysis to maintain neutrality. To enhance the transferability and dependability of the study findings, detailed information regarding the theoretical underpinnings, study context, design and implementation was provided (Lincoln & Guba, 1986).

### 7.3.11 Ethical considerations

Ethical approval for the study was obtained from the Human Subjects Research Ethics Subcommittee (HSRESC) of The Hong Kong Polytechnic University (HSEARS20240202001). The trial was registered with the Chinese Clinical Trial Registry (http://www.chictr.org.cn/searchprojen.aspx, ChiCTR2400087252). Permissions were also obtained from The Affiliated Cancer Hospital of Xiangya School

of Medicine, Central South University, and the Affiliated Suzhou Hospital of Nanjing Medical University. The study was conducted in accordance with the Declaration of Helsinki and adhered to the ethical principles of autonomy, beneficence, non-maleficence and confidentiality.

Autonomy: Autonomy primarily reflects respect for participants (Komesaroff et al., 2002). The research team provided comprehensive information regarding the study's aims, objectives, procedures, benefits and potential risks to prospective participants prior to recruitment. Participants were informed that their involvement was voluntary, and they were encouraged to ask questions and given sufficient time to make an informed decision. They were assured that refusal or withdrawal at any stage, without justification, would not incur any consequences. The researcher explained the information sheet and consent form, and written informed consent was obtained from all participants who agreed to participate.

Non-maleficence and Beneficence: The principles of beneficence and non-maleficence entail avoiding harm to participants while maximising potential benefits and minimising risks (Komesaroff et al., 2002). Participants in the intervention and control arms continued to receive routine hospital care, without restrictions on their regular healthcare services. Couples in the intervention arm received the family support programme designed to alleviate FCR, whereas couples in the control group were offered the same materials upon the completion of the study. Although discussing FCR experiences can evoke emotional distress, the risk was considered minimal because of the structured problem-solving approach of the intervention. Participants were not required to engage in any activities that could cause discomfort, and the intervention would be stopped immediately if emotional problems arose. In such cases, participants were referred to the hospital's psychological care department or to a psychologist.

Confidentiality: In accordance with the principle of confidentiality, participants'

information and records were treated confidentially and were not disclosed or used without their consent (Komesaroff et al., 2002). All data collection was conducted anonymously, and unique codes replaced names and other identifiers. Personal details were removed prior to analysis. Hard-copy records were stored in a locked cabinet, and electronic files were kept on a password-protected drive accessible only to the doctoral student.

### 7.4 Chapter summary

A two-arm, parallel-group RCT involving 90 couples coping with breast cancer was designed for implementation. The intervention group received the six-week family support programme in addition to usual care, whereas the control group received six weekly WeChat follow-up calls alongside usual care. The intervention was delivered by the doctoral student over six consecutive weeks via WeChat, and follow-up calls for the control group were conducted by a trained registered nurse. Outcomes, including FCR, social constraints, intrusive thoughts, avoidance, anxiety and stigma, were assessed in both women with breast cancer and their partners at baseline (T0), post-intervention (6 weeks) and follow-up (12 weeks). GLMMs were planned to examine differential interventional effects by role and the effects of the family support programme on outcomes over time. The effects were analysed separately for women and partners. Couple-based interviews were conducted as a process evaluation. Study quality was ensured through multiple strategies, and ethical approval was obtained from The Hong Kong Polytechnic University. The results of the RCT are presented in Chapter Eight.

# CHAPTER EIGHT: RESULTS

## 8.1 Introduction

This chapter presents the results of a RCT evaluating the effectiveness of a theory-driven, disclosure-based family support programme on FCR, social constraints, stigma, intrusive thoughts, avoidance and anxiety in women with breast cancer and their partners in China. Outcomes were assessed at three time points: baseline (T0), 6 weeks post-intervention (T1) and 12 weeks follow-up (T2). The acceptability of the intervention was explored among participants in the intervention group through qualitative interviews conducted at T1.

The chapter is organised into eight main sections. Section 8.1 provides an introduction. Section 8.2 presents participant recruitment and retention in the RCT. Section 8.3 describes the sociodemographic characteristics and baseline outcomes of the participants. Section 8.4 compares the sociodemographic characteristics of completers and non-completers at T1 and T2. Section 8.5 examines changes in outcome scores across the three assessment points by treatment group. Section 8.6 presents the effects of the family support programme on outcomes using generalized linear mixed models (GLMMs) for women with breast cancer and their partners. Section 8.7 reports the qualitative findings, and Section 8.8 provides a summary of the chapter.

## 8.2 Participant recruitment and retention

### 8.2.1 Recruitment

Figure 8.1 illustrates the flow of participant recruitment and retention in this study. Women with breast cancer were approached on every working day between September and October 2024 at the Affiliated Suzhou Hospital of Nanjing Medical University and the Affiliated Cancer Hospital of Xiangya School of Medicine, Central South University, in accordance with the hospitals' schedules. During this period, a total of 668 couples were screened for eligibility. Of these, 422 couples (223 women and 199 partners) were excluded. Reasons for women exclusion included lack of interest (n =

115), unavailability (n = 59), unfamiliarity with smartphones (n = 12), not having a partner (n = 15), inability to speak Mandarin (n = 9) and difficulty in understanding Chinese (n = 13). Among partners, exclusions were due to unavailability (n = 159) or lack of interest (n = 40). The remaining 246 couples completed the FoP-Q-SF for further screening, of which 183 couples met the eligibility criteria, resulting in an overall eligibility rate of 27.40% (183/668). Among these 183 eligible couples, 93 pairs withdrew consent, yielding a recruitment rate of 49.18% (90/183). Reasons for withdrawal included loss of contact (n = 19), unavailability (n = 12) and failure to complete the baseline questionnaire (n = 62). Ultimately, 90 couples were enrolled and randomly assigned to either the intervention group or the control group, with 45 couples in each group. All 90 women and 73 partners were recruited through hospital channels, while the remaining 17 partners were recruited via WeChat.

### 8.2.2 Retention

The follow-up assessment was successfully completed in February 2025, with a high retention rate observed in the RCT. Of the 90 enrolled couples, 81 women (90.00%) and 78 partners (86.67%) completed the post-intervention assessment (T1), while 77 women (85.56%) and 76 partners (84.44%) completed the 12-week follow-up assessment (T2), indicating consistently high retention at both time points. At T1, attrition rates in women were 8.89% (4/45) in the intervention group and 11.11% (5/45) in the control group, with no statistically significant difference (P = 1.00). For partners, attrition rates were 15.56% (7/45) in the intervention group and 11.11% (5/45) in the control group, also showing no significant difference (P = 1.00). At T2, attrition rates in women (Intervention: 13.33% [6/45] vs. Control: 15.56% [7/45]; P = 1.00) and in partners (Intervention: 13.33% [6/45] vs. Control: 17.78% [8/45]; P = 1.00) were similarly not statistically significant between groups. The time required to complete the questionnaires was generally acceptable. The average completion time for women was 10.72 minutes at T1 (SD = 11.51) and 6.75 minutes at T2 (SD = 4.91), and for partners, 10.72 minutes at T1 (SD = 8.02) and 10.04 minutes at T2 (SD = 9.07). These findings

suggest that the assessment burden was manageable for both members of the dyads, even across repeated measurement points.

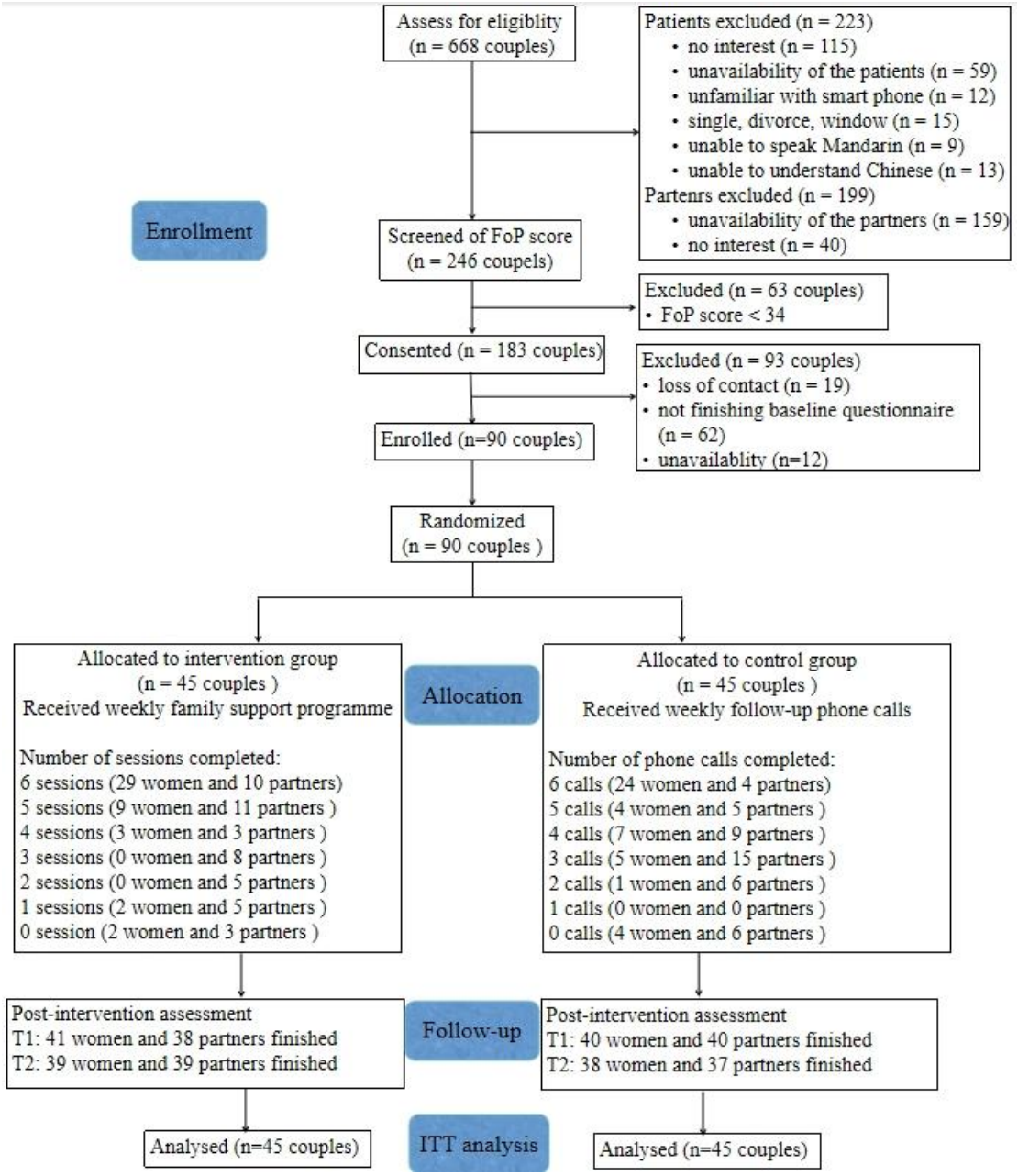


Figure 8.1 CONSORT flow diagram for study procedure

### 8.2.3 Session attendance

Intervention group

Table 8.1 presents the session attendance rates for women with breast cancer and their

partners in the intervention group. Overall, high attendance was observed among women, whereas partners demonstrated a moderate level of compliance. The mean number of sessions attended was 5.18 (SD = 1.60) for women, corresponding to 233 out of 270 possible sessions (86.30%), and 3.69 (SD = 1.95) for partners, corresponding to 166 out of 270 sessions (61.48%). Among the 45 couples, 38 women and 21 partners attended at least five sessions, resulting in compliance rates of 84.44% and 46.67%, respectively. Two couples undergoing chemotherapy withdrew before attending any sessions. Among the women, 38 (84.44%) attended at least five sessions, three (6.67%) attended four sessions, and two (4.44%) attended only one session. Among partners, 21 (46.66%) attended at least five sessions, three (6.67%) attended four sessions, eight (17.78%) attended three sessions, five (11.11%) attended two sessions, five (11.11%) attended one session and one partner (2.22%) did not attend any session.

Table 8.1 Attendance in women with breast cancer and their partners in the intervention group (N = 45 couples)

| Number of sessions attended | Women with breast cancer (N = 45) | Partners (N = 45) |
|---|---|---|
| | n (%) | n (%) |
| 0 | 2 (4.44%) | 3 (6.67%) |
| 1 | 2 (4.44%) | 5 (11.11%) |
| 2 | 0 (0.00%) | 5 (11.11%) |
| 3 | 0 (0.00%) | 8 (17.78%) |
| 4 | 3 (6.67%) | 3 (6.67%) |
| 5 | 9 (20.00%) | 11 (24.44%) |
| 6 | 29 (64.44%) | 10 (22.22%) |

Table 8.2 presents the session absences for women with breast cancer and their partners. Session 1 (brief introduction to breast cancer and management of treatment side effects) was missed by two women (4.44%) and four partners (8.89%). Session 2 (nutrition and physical activity education) was missed by four women (8.89%) and eleven partners (24.44%). Session 3 (Communicating feelings) was missed by eight women (17.78%) and seven 18 (40.00%). Session 4 (Breast cancer influences) had the highest number of

absences, and ten women (22.22%) and 25 partners (55.56%) absent. Session 5 (post-traumatic growth) was missed by five women (11.11%) and 27 partners (60.00%), while Session 6 (coping and future expectations) was missed by eight women (17.78%) and 19 partners (42.22%). Among the women, the most common reason for missing sessions was distressing symptoms following chemotherapy. For partners, the primary reason for absence was general unavailability. Additionally, two women and three partners did not attend any session primarily because of loss of contact or scheduling conflicts.

Table 8.2 Absences of sessions in women with breast cancer and their partners

| Sessions | Women with breast cancer | Partners |
|---|---|---|
| | n (%) | n (%) |
| 1 (Brief introduction to breast cancer and management of treatment side effects) | 2 (4.44%) | 4 (8.89%) |
| 2 (Physical activity and healthy dietary education) | 4 (8.89%) | 11 (24.44%) |
| 3 (Communicating feelings) | 8 (17.78%) | 18 (40.00%) |
| 4 (Breast cancer influences) | 10 (22.22%) | 25 (55.56%) |
| 5 (Post-traumatic growth) | 5 (11.11%) | 27 (60.00%) |
| 6 (Coping and future expectations) | 8 (17.78%) | 19 (42.22%) |

Control group

Compared with the intervention group, compliance with WeChat follow-up calls was notably lower among couples in the control group. The average number of calls completed was 4.64 (SD = 1.87) for women and 3.16 (SD = 1.68) for partners, indicating a moderate level of engagement among women and low involvement among partners. Of the 45 couples assigned to the control group, 28 women and nine partners received at least five calls, corresponding to compliance rates of 62.22% and 20.00%, respectively. Four couples withdrew from the study without participating in any calls. Among the remaining participants, seven women attended four calls, five completed three calls and one woman participated in only one call. For partners, participation varied: nine attended four calls, fifteen attended three, six attended two and two did not

participate at all. Similar to the intervention group, the most frequently reported barrier to participation among women was physical discomfort and distressing symptoms following chemotherapy. In addition, many women perceived that their partners' participation was unnecessary, which may have contributed to the low compliance rate among partners. The four women and six partners who did not attend any WeChat follow-up calls were primarily absent because of loss of contact or unavailability.

8.2.4 Adherence in the intervention group

i. Adherence to physical activity and healthy dietary in women with breast cancer

Women's adherence to physical activity and healthy dietary behaviours was assessed four times during the intervention, specifically in Sessions 3–6. In total, three women did not attend Session 6, and their final adherence was therefore recorded as 75.00%. Additionally, two women attended only one session, and two women did not attend any of the four sessions; consequently, their adherence rates for physical activity and dietary behaviours were also recorded as zero.

The overall mean adherence rate to physical activity among women was 83.33% (SD = 28.70%). Of the 45 participants, 27 women (60.00%) achieved 100% adherence, 14 women (31.11%) achieved 75.00% adherence, and four women (8.89%) achieved non-adherence, corresponding to two women who attended only one session and two women who did not attend any sessions.

For healthy dietary behaviour, the mean adherence rate was slightly higher at 89.44% (SD = 28.94%). Among the 45 women, 38 (84.44%) maintained full adherence across all four assessments. Three women (6.67%) missed the final session and were therefore assigned 75.00% adherence, while four women (8.89%), two of whom attended only one session and two who did not attend any of the four sessions, were assigned 0% adherence.

ii. Adherence of disclosure between couples in the intervention group

Couples in the intervention group were instructed to engage in emotional disclosure, that is, sharing their feelings, thoughts, worries and concerns, three times per week over a three-week period (Sessions 4–6). The overall mean adherence rate to this disclosure task was 86.67% (SD = 29.64%). Specifically, 35 couples (77.78%) fully completed the three-week protocol, achieving 100% adherence. Six couples (13.33%) completed the task in two of the three weeks, corresponding to 66.67% adherence, while four couples (8.89%) did not engage in the disclosure task at all and were recorded as non-adherent.

### 8.2.5 Intervention fidelity

To ensure consistency and quality of intervention delivery, fidelity was monitored using a self-developed checklist encompassing five key dimensions: (1) distribution of the electronic handbook materials, (2) duration of intervention sessions, (3) delivery of all session content in alignment with the session plan, (4) adherence to the planned delivery mode and (5) implementation of emotional disclosure between couples. A total of 233 sessions were delivered, of which 202 sessions (86.70%) were recorded; the remaining 31 sessions (13.30%) were not recorded because of a malfunction of the digital recorder. From the recorded sessions, 30 were randomly selected and independently reviewed by a senior registered oncology nurse, who completed the fidelity checklist using predefined response options (‘Yes’, ‘No’ or ‘Not applicable’). Analysis of the reviewed sessions indicated 100% fidelity across all assessable components, suggesting that the intervention was delivered as intended in all evaluated cases.

## 8.3 Sociodemographic characteristics and outcomes of the participants at baseline

### 8.3.1 Sociodemographic characteristics of the participants

Table 8.3 presents the sociodemographic characteristics and clinical profiles of women with breast cancer and their partners for the full sample (n = 90 couples), the family support programme group (n = 45 couples) and the control group (n = 45 couples) at

baseline. No statistically significant between-group differences were observed for any of these characteristics among women or among partners. Overall, the mean age of women with breast cancer was 42.28 years (30–59 years). The majority of women had completed a university degree (28.89%), followed by senior high school (22.22%) and junior college (14.44%). Employed women comprised 55.56% of the sample, and approximately 65.56% resided in urban areas. For partners, the mean age was 44.06 years (31–60 years). Most partners had completed junior high school (23.33%), senior high school (20.00%) or university (22.22%), whereas a small proportion had primary education or below (5.56%) or postgraduate qualifications (8.89%). The majority of partners (71.11%) were employed.

Regarding the clinical profile, the majority of women were newly diagnosed with breast cancer (85.56%), and over half (54.44%) received their diagnosis within the preceding three months. Stage II was the most prevalent (37.78%), followed by Stage I (31.11%). The most frequent treatments were chemotherapy alone (41.11%) or chemotherapy combined with targeted therapy (23.33%).

Table 8.3 Baseline characteristics of women with breast cancer and partners

| Variables | Total (N=90) | Intervention group (n = 45) | Control group (n = 45) | Statistics | |
|---|---|---|---|---|---|
| | | | | Value | p-value |
| **Women with breast cancer** | | | | | |
| Sociodemographic characteristics | | | | | |
| Age in years (M± SD, range) | 42.28±6.55, 30-59 | 42.40±6.60, 31-59 | 42.16±6.58, 30-56 | 0.176[a] | 0.861 |
| Educational level | | | | | |
| Primary school or below | 6 (6.67%) | 1 (2.22%) | 5 (11.11%) | 5.944[b] | 0.312 |
| Junior high school | 20 (22.22%) | 8 (17.78%) | 12 (26.67%) | | |
| Senior high school | 20 (22.22%) | 11 (24.44%) | 9 (20.00%) | | |
| Junior college | 13 (14.44%) | 9 (20.00%) | 4 (8.89%) | | |

| | | | | | |
|---|---|---|---|---|---|
| University | 26 (28.89%) | 14 (31.11%) | 12 (26.67%) | | |
| Postgraduate | 5 (5.56%) | 2 (4.44%) | 3 (6.67%) | | |
| Employment | | | | | |
| Employed | 50 (55.56%) | 29 (64.44%) | 21 (46.67%) | 2.880[b] | 0.090 |
| Unemployed | 40 (44.44%) | 16 (35.56%) | 24 (53.33%) | | |
| Residence | | | | | |
| City | 59 (65.56%) | 30 (66.67%) | 29 (64.44%) | 0.334[b] | 0.846 |
| Town | 15 (16.67%) | 8 (17.78%) | 7 (15.56%) | | |
| Village | 16 (17.78%) | 7 (15.56%) | 9 (20.00%) | | |
| Living in the same household with partner | | | | | |
| Yes | 74 (82.22%) | 38 (84.44%) | 36 (80.00%) | 0.304[b] | 0.581 |
| No | 16 (17.78%) | 7 (15.56%) | 9 (20.00%) | | |
| **Clinical Profile** | | | | | |
| Recurrent breast cancer | | | | | |
| Yes | 13 (14.44%) | 5 (11.11%) | 8 (17.78%) | 0.809[b] | 0.368 |
| No | 77 (85.56%) | 40 (88.89%) | 37 (82.22%) | | |
| Time since diagnosis | | | | | |
| <3 months | 49 (54.44%) | 24 (53.33%) | 25 (55.56%) | 5.508[b] | 0.064 |
| 3-6 months | 22 (24.44%) | 15 (33.33%) | 7 (15.56%) | | |
| >6 months | 19 (21.11%) | 6 (13.33%) | 13 (28.89%) | | |
| Stage | | | | | |
| I | 28 (31.11%) | 13 (28.89%) | 15 (33.33%) | 1.961[b] | 0.581 |
| II | 34 (37.78%) | 20 (44.44%) | 14 (31.11%) | | |
| III | 13 (14.44%) | 5 (11.11%) | 8 (17.78%) | | |
| IV | 15 (16.67%) | 7 (15.56%) | 8 (17.78%) | | |
| Current treatment | | | | | |
| Surgery | 30 (33.33%) | 14 (31.11%) | 16 (35.56%) | 2.805[b] | 0.423 |
| Chemotherapy | 37 (41.11%) | 20 (44.44%) | 17 (37.78%) | | |
| Chemotherapy + target therapy | 21 (23.33%) | 9 (20.00%) | 12 (26.67%) | | |
| Radiotherapy | 2 (2.22%) | 2 (4.44%) | 0 (0%) | | |

| Partners | | | | | |
|---|---|---|---|---|---|
| | Total (N=90) | Intervention group (n = 45) | Control group (n = 45) | Statistics | |
| | | | | Value | p-value |
| Age in years (M± SD, range) | 44.06±6.49, 31-60 | 43.98±6.35, 34-60 | 44.13±6.69, 31-57 | -0.113[a] | 0.910 |
| Educational level | | | | | |
| Primary school or below | 5 (5.56%) | 2 (4.44%) | 3 (6.67%) | 1.940[b] | 0.857 |
| Junior high school | 21 (23.33%) | 9 (20.00%) | 12 (26.67%) | | |
| Senior high school | 18 (20.00%) | 10 (22.22%) | 8 (17.78%) | | |
| Junior college | 18 (20.00%) | 11 (24.44%) | 7 (15.56%) | | |
| University | 20 (22.22%) | 9 (20.00%) | 11 (24.44%) | | |
| Postgraduate | 8 (8.89%) | 4 (8.89%) | 4 (8.89%) | | |
| Employment | | | | | |
| Employed | 64 (71.11%) | 30 (66.67%) | 34 (75.56%) | 0.865[b] | 0.352 |
| Unemployed | 26 (28.89%) | 15 (33.33%) | 11(24.44%) | | |

Note: M: mean, SD: Standard Deviation, a: Independent samples t-test statistics, b: Chi-square test statistics

8.3.2 Baseline outcomes in couples

Tables 8.4 and 8.5 present the means and standard deviations (SDs) of the outcome variables for women with breast cancer and their partners, respectively, at baseline (T0). All variables demonstrated normal distributions. Baseline comparisons of outcome variables between the intervention and control groups were conducted using independent-samples *t*-tests.

Among women with breast cancer, no statistically significant differences were observed between the intervention and control groups across any of the measured outcome variables ($P > 0.05$; Table 8.4). The mean FCR score was 36.81 (SD = 7.53) on a scale ranging from 12 to 60, with a clinical cutoff of 34, indicating a clinically significant

level of recurrence-related fear. The mean score on the SCS was 31.92 (SD = 7.13) on a 15–60 scale, reflecting a moderate degree of perceived social restriction. Scores for intrusive thoughts (M = 10.99, SD = 4.07) on a 0–24 scale and avoidance (M = 16.37, SD = 5.36) on a 0–32 scale both lay within the mid-range, suggesting moderate cognitive and behavioural coping responses. Anxiety levels were relatively low (M = 6.83, SD = 4.69) on a 0–21 scale. The mean stigma score was 37.36 (SD = 7.34) on a 15–60 scale, corresponding to a moderate level of perceived stigma.

Table 8.4 Baseline outcome variables of women with breast cancer

| Variables | Total (N = 90) | Intervention group (n = 45) | Control group (n = 45) | Statistics | |
|---|---|---|---|---|---|
| | | | | Value | p-value |
| | (M±SD) | (M±SD) | (M±SD) | | |
| FCR | 36.81±7.53 | 36.51±8.01 | 37.11±7.09 | -0.376 | 0.708 |
| Social constraints | 31.92±7.13 | 32.33±7.14 | 31.51±7.18 | 0.545 | 0.587 |
| Intrusive thoughts | 10.99±4.07 | 11.18±4.09 | 10.08±4.08 | 0.438 | 0.662 |
| Avoidance | 16.37±5.36 | 16.69±5.62 | 16.04±5.13 | 0.568 | 0.572 |
| Anxiety | 6.83±4.69 | 6.87±4.85 | 6.80±4.59 | 0.067 | 0.947 |
| Stigma | | | | | |
| Overall score | 37.36±7.34 | 37.78±7.57 | 36.93±7.18 | 0.543 | 0.588 |
| Self-image disorder | 12.54±2.90 | 12.69±2.98 | 12.40±2.84 | 0.471 | 0.639 |
| Social isolation | 4.57±1.42 | 4.64±1.63 | 4.49±1.18 | 0.519 | 0.605 |
| Discrimination | 9.47±2.46 | 9.56±2.45 | 9.38±2.49 | 0.342 | 0.733 |
| Self-perception | 10.78±2.39 | 10.89±2.42 | 10.67±2.37 | 0.439 | 0.661 |

Table 8.5 presents the means and standard deviations of outcome variables between the two groups of partners at T0. Overall, the mean scores were comparable across groups, with two notable exceptions. FCR was significantly higher in the intervention group than in the control group (37.76 ± 6.76 vs. 34.42 ± 7.08; P = 0.025). Furthermore, the mean score on the social isolation subscale of affiliate stigma was also higher in the intervention group compared with the control group (17.96 ± 3.69 vs. 16.40 ± 3.16; P = 0.034). In the combined sample, the mean FCR score was 36.09 (SD = 7.08) on a 12–60 scale, exceeding the clinical cutoff of 34 and therefore indicating a clinically

significant level of recurrence-related fear. The SCS averaged 33.24 (SD = 7.94) on a 15–60 scale, reflecting a moderate degree of perceived social restriction. Scores for intrusive thoughts (M = 10.74, SD = 4.35) on a 0–24 scale and avoidance (M = 14.92, SD = 5.93) on a 0–32 scale both fell within the mid-range, suggesting that partners experienced moderate levels of cognitive intrusion and behavioural avoidance. Anxiety levels were relatively low (M = 7.72, SD = 4.58) on a 0–21 scale. The overall Affiliate Stigma score was 50.94 (SD = 9.50) on a 24–96 scale, corresponding to a moderate level of stigma by association.

Table 8.5 Baseline outcome variables of partners in the whole sample, intervention group and control group

| Variables | Total (N = 90) | Intervention group (n = 45) | Control group (n = 45) | Statistics | |
|---|---|---|---|---|---|
| | | | | Value | p-value |
| | (M±SD) | (M±SD) | (M±SD) | | |
| FCR | 36.09±7.08 | 37.76±6.76 | 34.42±7.08 | 2.285 | **0.025*** |
| Social constraints | 33.24±7.94 | 33.78±7.58 | 32.71±8.34 | 0.635 | 0.527 |
| Intrusive thoughts | 10.74±4.35 | 10.33±4.14 | 11.16±4.57 | -0.895 | 0.373 |
| Avoidance | 14.92±5.93 | 14.96±5.68 | 14.89±6.24 | 0.053 | 0.958 |
| Anxiety | 7.72±4.58 | 7.58±4.25 | 7.87±4.93 | -0.298 | 0.767 |
| Affiliate Stigma | | | | | |
| Overall score | 50.94±9.50 | 52.09±9.49 | 49.80±9.48 | 1.145 | 0.255 |
| Internal stigma | 16.47±3.92 | 16.80±3.91 | 16.13±3.95 | 0.804 | 0.423 |
| Social isolation | 17.18±3.50 | 17.96±3.69 | 16.40±3.16 | 2.150 | **0.034*** |
| Perceived stigma | 8.61±2.04 | 8.78±2.09 | 8.44±1.99 | 0.774 | 0.441 |
| Reaction | 8.69±2.65 | 8.56±2.98 | 8.82±2.29 | -0.476 | 0.635 |

8.3.3 Characteristics of the completers and non-completers

8.3.3.1 Characteristics of the completers and non-completers at T1

Table 8.6 presents the results of comparative analyses of characteristics between completers and non-completers among women with breast cancer and their partners at T1. No statistically significant differences were observed in baseline characteristics between completers and non-completers ($P > 0.05$).

Table 8.6 Characteristics of completers and non-completers at T1 in women with breast cancer and their partners

| **Women with breast cancer** | | | | |
|---|---|---|---|---|
| Variables | Completers (n = 81) | Non-completers (n = 9) | Statistics | |
| | | | Value | p-value |
| Age in years (M± SD) | 41.85±6.558 | 46.11±5.372 | -1.877[a] | 0.664 |
| Educational level | | | | |
| Primary school or below | 4 (4.93%) | 2 (22.22%) | 10.271[b] | 0.068 |
| Junior high school | 16 (19.75%) | 4 (44.44%) | | |
| Senior high school | 19 (23.46%) | 1 (11.11%) | | |
| Junior college | 11 (13.58%) | 2 (22.22%) | | |
| University | 26 (32.10%) | 0 (0%) | | |
| Postgraduate | 5 (6.17%) | 0 (0%) | | |
| Employment | | | | |
| Employed | 46 (56.79%) | 4 (44.44%) | 0.500[b] | 0.480 |
| Unemployed | 35(43.21%) | 5 (55.6%) | | |
| Residence | | | | |
| City | 54 (66.67%) | 5 (55.56%) | 0.449[b] | 0.799 |
| Town | 13 (16.05%) | 2 (22.22%) | | |
| Village | 14 (17.28%) | 2 (22.22%) | | |
| Living in the same household with partners | | | | |
| Yes | 68 (83.95%) | 6 (66.67%) | 1.655[c] | 0.198 |
| No | 13 (16.05%) | 3 (33.33%) | | |
| Recurrent breast cancer | | | | |
| Yes | 12 (14.81%) | 1 (11.11%) | 0.090[b] | 0.764 |
| No | 69 (85.19%) | 8 (88.89%) | | |
| Time since diagnosis | | | | |
| <3 months | 45 (55.56%) | 4 (44.44%) | 0.513[b] | 0.774 |
| 3-6 months | 19 (23.46%) | 3 (33.33%) | | |
| >6 months | 17 (20.99%) | 2 (22.22%) | | |
| Stage | | | | |
| I | 26 (32.10%) | 2 (22.22%) | 1.353[b] | 0.717 |
| II | 29 (35.80%) | 5 (55.56%) | | |
| III | 12 (14.81%) | 1 (11.111%) | | |
| IV | 14 (17.28%) | 1 (11.1%) | | |
| Current treatment | | | | |
| Surgery | 28 (34.57%) | 2 (22.22%) | 1.048[b] | 0.790 |
| Chemotherapy | 33 (40.74%) | 4 (44.44%) | | |
| Chemotherapy + target therapy | 18 (22.22%) | 3 (33.33%) | | |
| Radiotherapy | 2 (2.47%) | 0 (0%) | | |

| Partners | | | | |
|---|---|---|---|---|
| | Completers (n = 78) | Non-completers (n = 12) | Statistics | |
| | | | Value | p-value |
| Age in years (M± SD, range) | 43.82±6.63 | 45.58±5.44 | 0.875[a] | 0.384 |
| Educational level | | | | |
| Primary school or below | 3 (3.85%) | 2 (16.67%) | 6.353[b] | 0.273 |
| Junior high school | 17 (21.79%) | 3 (25.00%) | | |
| Senior high school | 16 (20.51%) | 3 (25.00%) | | |
| Junior college | 15 (19.23%) | 3 (25.00%) | | |
| University | 19 (24.35%) | 1 (11.11%) | | |
| Postgraduate | 8 (10.26%) | 0 (0%) | | |
| Employment | | | | |
| Employed | 56 (71.79%) | 8 (66.67%) | 0.133[b] | 0.715 |
| Unemployed | 22 (28.21%) | 4 (33.33%) | | |

Note: M: mean, SD: Standard Deviation, a: Independent samples t-test statistics, b: Chi-square test statistics

8.3.3.2 Characteristics of the completers and non-completers at T2

Table 8.7 presents comparative analyses of baseline characteristics between completers and non-completers at T2 among women with breast cancer and their partners. A statistically significant difference was observed in the age of women with breast cancer (P = 0.008), and younger women were more likely to have completed the survey.

Table 8.7 Characteristics of completers and non-completers at T2 in women with breast cancer and partners

| Women with breast cancer | | | | |
|---|---|---|---|---|
| Variables | Completers (n = 77) | Non-completers (n = 13) | Statistics | |
| | | | Value | p-value |
| Age in years (M± SD) | 41.53±6.423 | 46.69±5.677 | -2.720[a] | **0.008*** |
| Educational level | | | | |
| Primary school or below | 4 (5.19%) | 2 (15.38%) | 3.583[b] | 0.611 |
| Junior high school | 16 (20.78%) | 4 (30.77%) | | |
| Senior high school | 18 (23.38%) | 2 (15.38%) | | |
| Junior college | 11 (14.29%) | 2 (15.38%) | | |
| University | 23 (29.87%) | 3 (23.08%) | | |
| Postgraduate | 5 (6.49%) | 0 (0%) | | |

| | | | | |
|---|---|---|---|---|
| Employment | | | | |
| Employed | 43 (55.84%) | 7 (53.85%) | 0.018[b] | 0.893 |
| Unemployed | 34(44.16%) | 6 (46.15%) | | |
| Residence | | | | |
| City | 50 (64.94%) | 9 (69.23%) | 0.095[b] | 0.953 |
| Town | 13 (16.88%) | 2 (15.38%) | | |
| Village | 14 (18.18%) | 2 (15.38%) | | |
| Living in the same household | | | | |
| Yes | 65 (84.42%) | 9 (69.23%) | 1.754[c] | 0.185 |
| No | 12 (15.58%) | 4 (30.77%) | | |
| Recurrent breast cancer | | | | |
| Yes | 12 (15.58%) | 1 (7.69%) | 0.561[b] | 0.454 |
| No | 65 (84.42%) | 12 (92.31%) | | |
| Time since diagnosis | | | | |
| <3 months | 41 (53.25%) | 8 (61.54%) | 0.388[b] | 0.536 |
| 3-6 months | 19 (24.68%) | 3 (23.08%) | | |
| >6 months | 17 (22.08%) | 2 (15.38%) | | |
| Stage | | | | |
| I | 24 (31.17%) | 4 (30.77%) | 0.027[b] | 0.999 |
| II | 29 (37.66%) | 5 (38.46%) | | |
| III | 11 (14.29%) | 2 (15.38%) | | |
| IV | 13 (16.88%) | 2 (15.38%) | | |
| Current treatment | | | | |
| Surgery | 26 (33.77%) | 4 (30.77%) | 2.253[b] | 0.522 |
| Chemotherapy | 33 (42.86%) | 4 (30.77%) | | |
| Chemotherapy + target therapy | 16 (20.78%) | 5 (38.46%) | | |
| Radiotherapy | 2 (2.60%) | 0 (0%) | | |
| Partners | | | | |
| Variables | Completers (n = 76) | Non-completers (n = 14) | Statistics | |
| | | | Value | p-value |
| Age in years (M± SD) | 43.71±6.53 | 45.93±6.12 | 1.178[a] | 0.242 |
| Educational level | | | | |
| Primary school or below | 3 (3.94%) | 2 (14.29%) | 5.293[b] | 0.381 |
| Junior high school | 17 (23.37%) | 4 (28.57%) | | |
| Senior high school | 16 (21.05%) | 2 (14.29%) | | |
| Junior college | 14 (18.42%) | 4 (28.57%) | | |
| University | 18 (23.68%) | 2 (14.29%) | | |
| Postgraduate | 8 (10.53%) | 0 (0%) | | |
| Employment | | | | |

| | | | | |
|---|---|---|---|---|
| Employed | 55 (72.7%) | 9 (62.29%) | 0.376[b] | 0.540 |
| Unemployed | 21 (27.3%) | 5 (35.71%) | | |

Covariates for adjustment in GLMM

On the basis of the results presented in Tables 8.4–8.7, significant differences were identified in partners' baseline FCR and partners' baseline social isolation between the intervention and control groups and in women's age between completers and those lost to follow-up at T2. These three variables were therefore considered as covariates in the subsequent analyses. However, social isolation was not included as a covariate in the analyses addressing Research Question 1, which examined the intervention effects by role because the three-way interaction (Group × Time × Role) requires that each covariate be defined and comparable for both women and partners. The scales used to measure stigma in women and partners differed in dimensionality and scoring system, rendering them non-comparable. Consequently, the social isolation subscale scores from women and partners were not pooled or directly compared as a single covariate. For this reason, only two covariates, that is, couples' age and baseline FCR, were included in the model to control for their potential confounding effects.

8.4 Changes in scores of outcome variable across three assessment timepoints

Table 8.8 presents the means and standard deviations for all outcomes in women with breast cancer at T0, T1 and T2. At baseline (T0), mean FCR scores were comparable between the intervention and control groups (36.51 ± 8.01 vs. 37.11 ± 7.09). FCR subsequently decreased in both groups, with a greater reduction observed in the intervention group at T1 and T2 (T1: 30.12 ± 7.57 vs. 33.70 ± 8.49; T2: 30.46 ± 7.04 vs. 32.42 ± 8.75). Scores on social constraints showed only minimal change and remained similar between groups over time. Intrusive thoughts declined more markedly in the intervention group than in the control group. Avoidance scores decreased slightly in both groups and were comparable by T2 (14.21 ± 6.28 vs. 14.55 ± 5.49). Anxiety levels declined in both groups, and a greater reduction again evident in the intervention group. Overall stigma and its four subscales demonstrated only minor fluctuations

across time.

Table 8.8 Comparison of women's outcome variables between the study groups at T0, T1 and T2

| Time | Intervention group (n = 45) (M±SD) | Control group (n = 45) (M±SD) |
|---|---|---|
| FCR | | |
| T0 | 36.51±8.01 | 37.11±7.09 |
| T1 | 30.12±7.57 | 33.70±8.49 |
| T2 | 30.46±7.04 | 32.42±8.75 |
| Social constraints | | |
| T0 | 32.33±7.14 | 31.51±7.18 |
| T1 | 29.95±7.82 | 31.78±7.73 |
| T2 | 31.69±10.50 | 31.55±8.09 |
| Intrusive thoughts | | |
| T0 | 11.18±4.09 | 10.08±4.08 |
| T1 | 8.10±3.69 | 9.73±4.10 |
| T2 | 8.31±4.08 | 9.45±3.53 |
| Avoidance | | |
| T0 | 16.69±5.62 | 16.04±5.13 |
| T1 | 15.51±5.40 | 14.88±5.57 |
| T2 | 14.21±6.28 | 14.55±5.49 |
| Anxiety | | |
| T0 | 6.87±4.85 | 6.80±4.59 |
| T1 | 3.44±2.95 | 5.68±4.36 |
| T2 | 3.82±3.23 | 4.66±3.50 |
| Stigma overall score | | |
| T0 | 37.78±7.57 | 36.93±7.18 |
| T1 | 34.90±7.60 | 35.10±7.18 |
| T2 | 35.59±8.59 | 35.55±7.83 |
| Self-image disorder | | |
| T0 | 12.69±2.98 | 12.40±2.84 |
| T1 | 11.51±2.68 | 11.95±3.08 |
| T2 | 11.56±3.36 | 12.03±3.44 |
| Social isolation | | |
| T0 | 4.64±1.63 | 4.49±1.18 |
| T1 | 4.41±1.40 | 4.28±1.22 |
| T2 | 4.44±1.35 | 4.21±1.47 |
| Discrimination | | |
| T0 | 9.56±2.45 | 9.38±2.49 |

| | | |
|---|---|---|
| T1 | 8.83±2.52 | 8.75±2.28 |
| T2 | 9.13±2.64 | 9.03±2.28 |
| Self-perception | | |
| T0 | 10.89±2.42 | 10.67±2.37 |
| T1 | 10.15±2.42 | 10.13±2.19 |
| T2 | 10.46±2.43 | 10.29±1.99 |

Table 8.9 presents the means and standard deviations for all outcomes in partners at T0, T1 and T2. At baseline (T0), partners in the intervention group reported higher FCR than those in the control group (37.76 ± 6.76 vs. 34.42 ± 7.08). At T1 and T2, mean FCR scores were comparable between groups (T1: 32.21 ± 8.66 vs. 32.55 ± 8.27; T2: 31.44 ± 6.72 vs. 31.54 ± 8.03). Levels of social constraints declined more markedly in the intervention group than in the control group, though a slight increase was observed at T2 (31.72 ± 7.81 vs. 32.59 ± 8.74). Intrusive thoughts decreased in both groups at T1, with the intervention group continuing to decline at T2, while the control group showed a slight increase. Avoidance and anxiety also decreased over time in both groups; however, by T2, mean scores for avoidance and anxiety were lower in the control group than in the intervention group. Partners in the intervention group reported higher overall affiliate stigma at T0 compared with controls (52.09 ± 9.49 vs. 49.80 ± 9.48). Affiliate stigma scores declined from T0 to T1, followed by an increase at T2 in both groups, with the increase being slightly greater in the intervention group (T2: 50.44 ± 12.56 vs. 47.97 ± 9.25). The subscales of affiliate stigma (internal stigma, social isolation, perceived stigma and reaction) followed similar trajectories across time.

Table 8.9 Comparison of partners' outcome variables between the study groups at T0, T1 and T2

| Time | Intervention group (n = 45) (M±SD) | Control group (n = 45) (M±SD) |
|---|---|---|
| FCR | | |
| T0 | 37.76±6.76 | 34.42±7.08 |
| T1 | 32.21±8.66 | 32.55±8.27 |
| T2 | 31.44±6.72 | 31.54±8.03 |
| Social constraints | | |

| | | |
|---|---|---|
| T0 | 33.78±7.58 | 32.71±8.34 |
| T1 | 31.39±7.88 | 32.05±8.73 |
| T2 | 31.72±7.81 | 32.59±8.74 |
| Intrusive thoughts | | |
| T0 | 10.33±4.14 | 11.16±4.57 |
| T1 | 9.76±4.29 | 9.18±4.08 |
| T2 | 8.97±3.61 | 9.38±4.33 |
| Avoidance | | |
| T0 | 14.96±5.68 | 14.89±6.24 |
| T1 | 12.74±6.74 | 12.67±4.75 |
| T2 | 12.87±5.32 | 11.97±5.54 |
| Anxiety | | |
| T0 | 7.58±4.25 | 7.87±4.93 |
| T1 | 5.66±4.74 | 5.30±3.84 |
| T2 | 5.23±4.19 | 4.41±2.94 |
| Affiliate stigma overall score | | |
| T0 | 52.09±9.49 | 49.80±9.48 |
| T1 | 46.63±11.15 | 47.23±10.17 |
| T2 | 50.44±12.56 | 47.97±9.25 |
| Internal stigma | | |
| T0 | 16.80±3.91 | 16.13±3.95 |
| T1 | 15.24±4.16 | 14.68±3.31 |
| T2 | 15.69±4.25 | 15.05±2.69 |
| Social isolation | | |
| T0 | 17.96±3.69 | 16.40±3.16 |
| T1 | 15.76±4.13 | 15.63±3.68 |
| T2 | 16.90±4.20 | 15.76±3.74 |
| Perceived stigma | | |
| T0 | 8.78±2.09 | 8.44±1.99 |
| T1 | 8.16±2.41 | 8.20±2.20 |
| T2 | 8.87±2.41 | 8.32±2.17 |
| Reaction | | |
| T0 | 8.56±2.98 | 8.82±2.29 |
| T1 | 7.47±2.09 | 8.73±2.36 |
| T2 | 8.97±2.96 | 8.84±2.36 |

## 8.5 Estimation of effects of the family support programme using GLMM for women with breast cancer and their partners

### 8.5.1 Interventional effects by role

The interventional effects of the family support programme by role were evaluated

using a linear mixed-effects model. The analysis included 180 observations across three time points: 180 at T0, 159 at T1 and 153 at T2, and 48 cases of missing data were found in the dataset. In the model specification, baseline measurements, the control group and the partner role served as reference categories, and dummy variables were coded as 0.

To address Research Question 1, whether the interventional effects differed by role (i.e. women vs. partners), GLMMs were employed. Specifically, the three-way interaction of Group × Time × Role was tested for outcomes that were measured in both members of the couple using the same instruments, namely FCR, social constraints, intrusive thoughts, avoidance and anxiety. This three-way interaction examined whether the two-way interaction between group and time on the dependent variable was further moderated by role. Table 8.10 summarises the fixed effects of the two-way interaction between group and time on the dependent variables, as moderated by role, along with the variance estimates of the random effects for each outcome. Figures 8.2–8.6 present the corresponding trajectories of outcomes over time by group and role.

FCR

As shown in Table 8.10, the Group × Time × Role interaction for FCR was not significant at either T1 ($\beta = 1.05$, 95% CI [−3.57, 5.68], $P = 0.654$) or T2 ($\beta = 2.35$, 95% CI [−2.16, 6.85], $P = 0.306$), indicating that the intervention–control difference in FCR change did not vary between women with breast cancer and their partners.

Figure 8.2 illustrates FCR trajectories over time by group and role for women and partners.

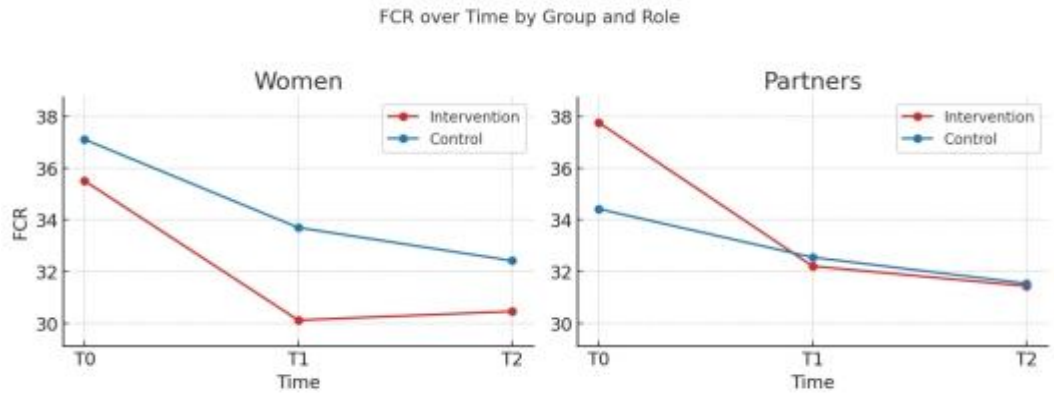


Figure 8.2 FCR over time by group and role

Social constraints

The Group × Time × Role interaction for social constraints was not significant at either T1 (β = −1.03, 95% CI [−4.90, 2.84], P = 0.602) or T2 (β = 1.04, 95% CI [−4.65, 6.74], P = 0.719), indicating that the intervention–control difference in changes in social constraints did not vary between women with breast cancer and their partners. Figure 8.3 illustrates social constraint trajectories over time by group and role.

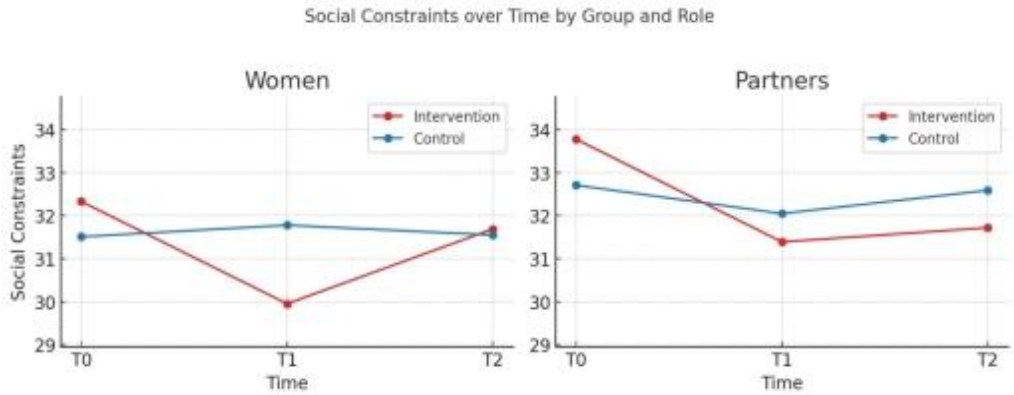


Figure 8.3 Social constraints over time by group and role

Intrusive thoughts

The Group × Time × Role interaction for intrusive thoughts was negative and statistically significant at T1 (β = −3.17, 95% CI [−5.59, −0.75], P = 0.010), indicating that women experienced a greater short-term reduction in intrusive thoughts from the

intervention compared with their partners. However, at T2 the interaction was not significant (β = −1.65, 95% CI [−4.57, 1.27], P = 0.268), suggesting that the intervention–control difference in changes in intrusive thoughts did not differ between women with breast cancer and their partners in the longer term. Figure 8.4 illustrates the trajectories of intrusive thoughts over time by group and role.

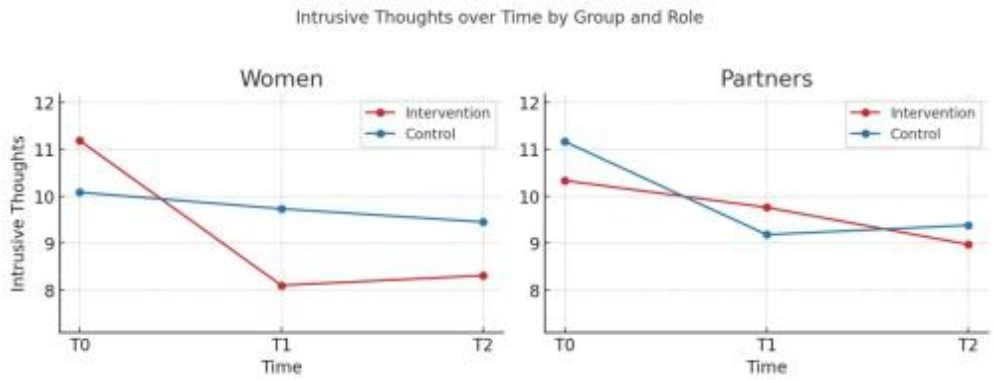


Figure 8.4 Intrusive thoughts over time by group and role

Avoidance

The Group × Time × Role interaction for avoidance was not significant at either T1 (β = 0.32, 95% CI [−2.98, 3.62], P = 0.850) or T2 (β = −1.59, 95% CI [−5.02, 1.84], P = 0.363), indicating that the intervention–control difference in changes in avoidance did not differ between women with breast cancer and their partners. Figure 8.5 illustrates avoidance trajectories over time by group and role.

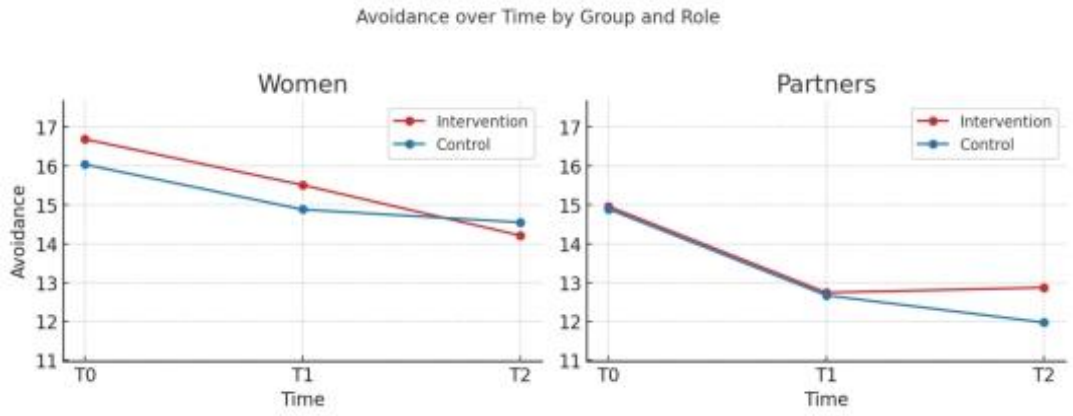


Figure 8. 5 Avoidance over time by group and role

Anxiety

The Group × Time × Role interaction for anxiety was negative and statistically significant at T1 (β = −2.76, 95% CI [−5.43, −0.08], P = 0.044), indicating that women experienced a greater short-term reduction in anxiety from the intervention compared with their partners (Table 8.10). However, at T2 the interaction was not significant (β = −1.73, 95% CI [−4.52, 1.06], P = 0.224), suggesting that the intervention–control difference in changes in anxiety did not differ between women with breast cancer and their partners. Figure 8.6 depicts anxiety trajectories over time by group and role.

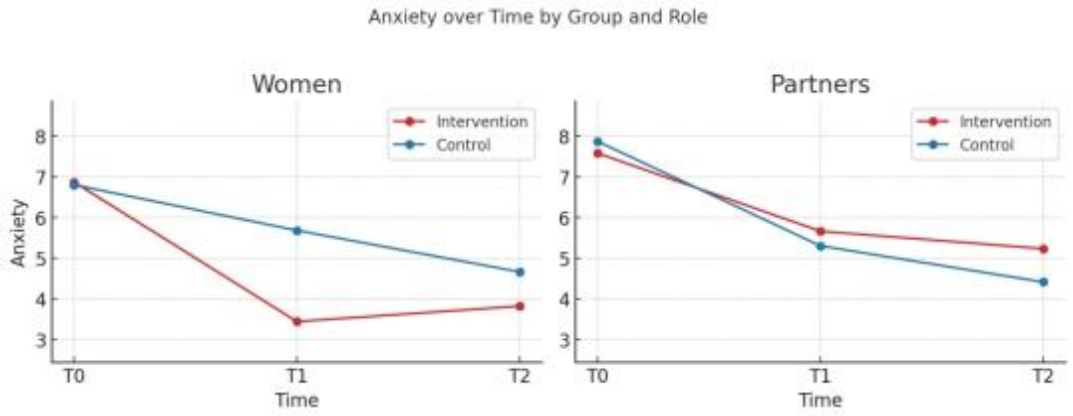


Figure 8.6 Anxiety over time by group and role

Table 8.10 Estimates of fixed effects of Group x Time x Role interaction term and random effects in GLMM

| | LMM Group ×Time × Role interaction effect | |
|---|---|---|
| Time | β (95% CI) | P-value |
| FCR | | |
| T1 | 1.05 (-3.57, 5.68) | 0.654 |
| T2 | 2.35 (-2.16, 6.85) | 0.306 |
| Social constraints | | |
| T1 | -1.03 (-4.90, 2.84) | 0.602 |
| T2 | 1.04 (-4.65, 6.74) | 0.719 |
| Intrusive thoughts | | |
| T1 | -3.17 (-5.59, 0.75) | 0.010* |
| T2 | -1.65 (-4.57, 1.27) | 0.268 |
| Avoidance | | |
| T1 | 0.32 (-2.98, 3.62) | 0.850 |
| T2 | -1.59 (-5.02, 1.84) | 0.363 |
| Anxiety | | |
| T1 | -2.76 (-5.43, -0.08) | 0.044* |
| T2 | -1.73 (-4.52, 1.06) | 0.224 |

Note: Two covariates including Age and Baseline FCR were controlled in the models

8.5.2 Effects of intervention in women with breast cancer

The analysis included 90 observations across three time points: 90 at T0, 81 at T1 and 77 at T2, and 22 instances of missing data were found in the dataset. In the linear mixed-effects model, baseline measurements and the control group were specified as reference categories, and dummy variables were coded as 0.

To address Research Question 2, whether the intervention was effective in improving outcomes among women, GLMMs were employed to test the two-way interaction of Group × Time across all outcome variables, including FCR, social constraints, intrusive thoughts, avoidance, anxiety, overall stigma and each stigma subscale. Random intercepts were specified at the individual level to account for the nested structure of repeated measures. Three covariates, namely, women's age, partners' baseline FCR and partners' baseline social isolation, were included in the models to control for potential confounding factors. The fixed-effect estimates of the intervention effect, represented

by the Group × Time interaction terms, are presented for each outcome variable. In addition, Cohen's *d* was reported to quantify the magnitude of the intervention effects.

8.5.2.1 Primary outcome

8.5.2.1.1FCR

FCR

Table 8.11 shows that the Group × Time interactions were not statistically significant. The estimated interaction effect (β) at T1 was −3.00 (95% CI [−6.34, 0.35], P = 0.079), and at T2, β = −1.01 (95% CI [−4.31, 2.30]; P = 0.549), indicating no statistically significant difference in FCR change over time between the intervention and control groups for women with breast cancer. Despite the absence of statistically significant interaction effects, greater reductions in mean FCR levels were observed in the intervention group (6.50 points at T1 and 5.95 points at T2) compared with the control group (3.50 points at T1 and 4.95 points at T2). These corresponded to a small effect size at T1 (Cohen's *d* = 0.380) and at T2 (Cohen's *d* = 0.120). Figure 8.7 illustrates the trajectories of FCR over time by group in women.

Table 8.11 GLMM results for FCR in women with breast cancer by the group over the study period

| | Intervention group (*n* = 45) | Control group (n = 45) | GLMM Group × Time interaction effect | | Cohen's *d* |
|---|---|---|---|---|---|
| Time | Estimated mean ± SE | Estimated mean ± SE | β (95% CI) | P-value | |
| T0 | 36.06 ± 1.18 | 37.56 ± 1.03 | | | |
| T1 | 29.56 ± 1.12 | 34.06 ± 1.27 | -3.00 (-6.34, 0.35) | 0.079 | 0.380 |
| T2 | 30.11 ± 1.14 | 32.61 ± 1.35 | -1.01 (-4.31, 2.30) | 0.549 | 0.120 |

Note: Three covariates including women' age, partner's baseline FCR, and partners' baseline social isolation were controlled in the model

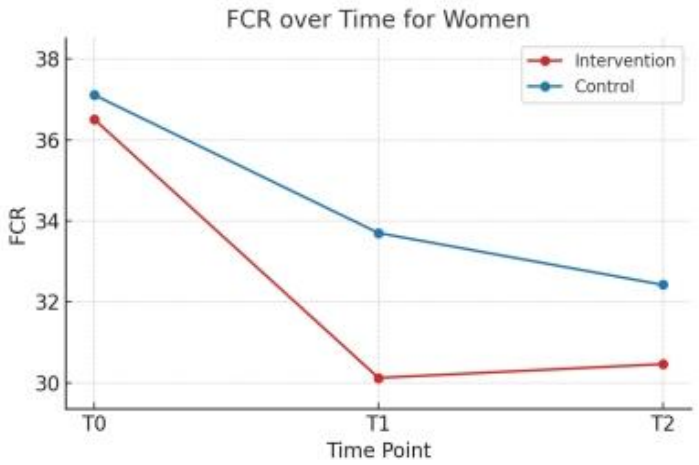


Figure 8.7 FCR over time by group in women with breast cancer

8.5.2.2 Secondary outcomes

8.5.2.2.1 Social constraints

As shown in Table 8.12, a significant negative Group × Time interaction was observed at T1 (β = −2.83, 95% CI [−5.61, −0.05], P = 0.046), indicating that women in the intervention group reported a significantly greater reduction in perceived social constraints compared with those in the control group. At T2, the mean reduction in social constraints was also larger in the intervention group than in the control group (0.9 points vs. 0.02 points), although this difference was not statistically significant (β = −0.88, 95% CI [−4.44, 2.67], P = 0.625). The family support programme outperformed the WeChat support calls at T1, with a moderate effect size (Cohen's *d* = 0.444). By T2, the effect size had reduced to a small level (Cohen's *d* = 0.100). Figure 8.8 illustrates the trajectories of social constraints over time by group in women with breast cancer.

Table 8.12 GLMM results for social constraints in women with breast cancer by the group over the study period

| | Intervention group (n = 45) | Control group (n = 45) | GLMM Group× Time interaction effect | | Cohen's d |
|---|---|---|---|---|---|
| Time | Estimated mean ± SE | Estimated mean ± SE | β (95% CI) | P-value | |

| | | | | | |
|---|---|---|---|---|---|
| T0 | 31.84 ± 1.13 | 32.08 ± 1.03 | | | |
| T1 | 29.33 ± 1.12 | 32.40 ± 1.13 | -2.83 (-5.61, -0.05) | 0.046* | 0.444 |
| T2 | 30.94 ± 1.58 | 32.06 ± 1.20 | -0.88 (-4.44, 2.67) | 0.625 | 0.100 |

Note: Three covariates including women' age, partner's baseline FCR, and partners' baseline social isolation were controlled in the model

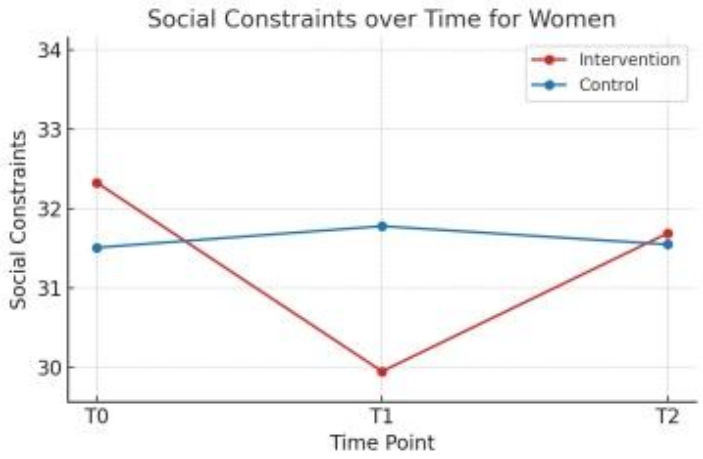


Figure 8.8 Social constraints over time by group in women with breast cancer

8.5.2.2.2 Intrusive thoughts

As shown in Table 8.13, a significant Group × Time interaction was observed at T1 (β = −1.85, 95% CI [−3.48, −0.23], P = 0.025), whereas the interaction at T2 was not significant (β = −1.29, 95% CI [−3.15, 0.58], P = 0.174). Women in the intervention group experienced a substantial reduction in intrusive thoughts at T1, followed by a slight increase at T2. By contrast, women in the control group showed a smaller reduction in intrusive thoughts at T1, with mean levels remaining stable at T2. The corresponding effect size was moderate at T1 (Cohen's *d* = 0.462) and small at T2 (Cohen's *d* = 0.207). These findings indicate that the theory-driven, disclosure-based family support programme produced a significant short-term impact on intrusive thoughts among women with breast cancer, but the effect was not sustained at the 12-week follow-up. Figure 8.9 illustrates the trajectories of intrusive thoughts over time by group in women with breast cancer.

Table 8.13 GLMM results for intrusive thoughts in women with breast cancer by the group over the study period

| | Intervention group ($n$ = 45) | Control group (n = 45) | GLMM Group × Time interaction effect | | Cohen's $d$ |
|---|---|---|---|---|---|
| Time | Estimated mean ± SE | Estimated mean ± SE | β (95% CI) | P-value | |
| T0 | 11.05 ± 0.65 | 10.92 ± 0.58 | | | |
| T1 | 7.99 ± 0.58 | 9.72 ± 0.64 | -1.85 (-3.48, -0.23) | 0.025* | 0.462 |
| T2 | 8.26 ± 0.66 | 9.42 ± 0.54 | -1.29 (-3.15, 0.58) | 0.174 | 0.207 |

Note: Three covariates including women' age, partner's baseline FCR, and partners' baseline social isolation were controlled in the model

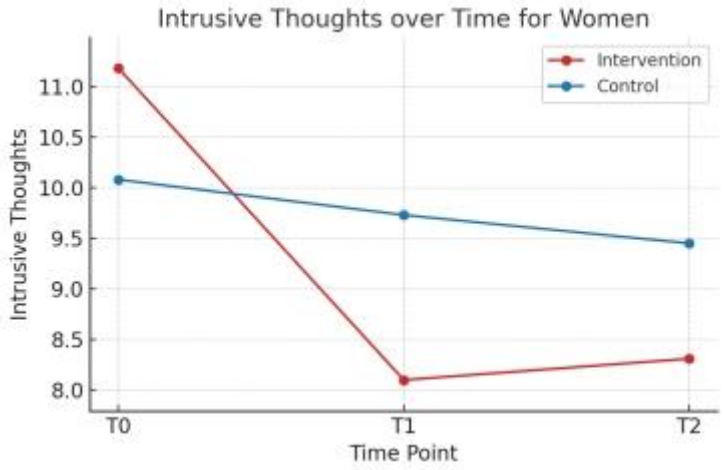


Figure 8.9 Intrusive thoughts over time by group in women

8.5.2.2.3 Avoidance

Table 8.14 presents the GLMM results for avoidance. No statistically significant differences were found in changes in avoidance between the two groups of women with breast cancer over the study period (T1: β = 0.27, 95% CI [−1.77, 2.31], P = 0.795; T2: β = −0.69, 95% CI [−2.93, 1.56], P = 0.549). Both groups exhibited reductions in avoidance, with the control group showing a greater decrease from T0 to T1, whereas the intervention group demonstrated a larger reduction from T0 to T2. The corresponding effect sizes were small (Cohen's $d$ = 0.090 at T1; Cohen's $d$ = 0.134 at T2). Figure 8.10 illustrates the trajectories of avoidance over time by group in women

with breast cancer.

Table 8.14 GLMM results for avoidance in women with breast cancer by the group over the study period

| | Intervention group ($n$ = 45) | Control group (n = 45) | GLMM Group × Time interaction effect | | Cohen's $d$ |
|---|---|---|---|---|---|
| Time | Estimated mean ± SE | Estimated mean ± SE | β (95% CI) | P-value | |
| T0 | 16.52 ± 0.88 | 16.20 ± 0.71 | | | |
| T1 | 15.39 ± 0.85 | 14.81 ± 0.83 | 0.27 (-1.77, 2.31) | 0.795 | -0.090 |
| T2 | 14.09 ± 0.10 | 14.45 ± 0.81 | -0.69 (-2.93, 1.56) | 0.549 | 0.134 |

Note: Three covariates including women' age, partner's baseline FCR, and partners' baseline social isolation were controlled in the model

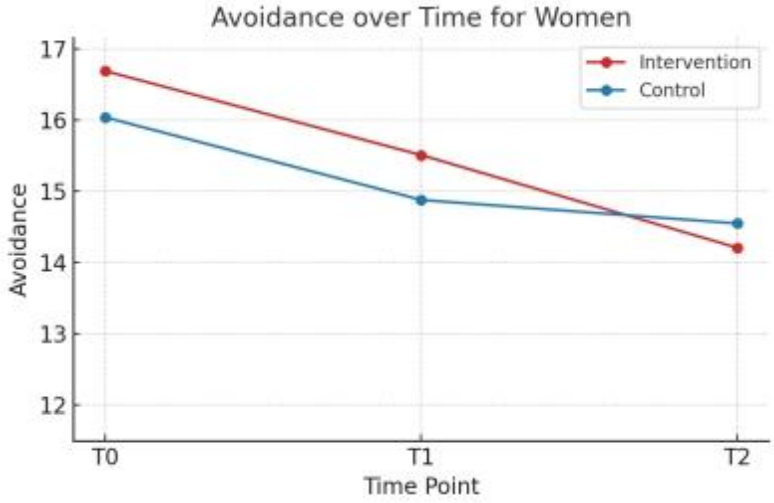


Figure 8.10 Avoidance over time by group in women with breast cancer

8.5.2.2.4 Anxiety

As shown in Table 8.15, the intervention group outperformed the control group in reducing anxiety at T1 (β = −2.22, 95% CI [−4.32, −0.12], P = 0.039). However, this effect was not sustained at T2 (β = −0.78, 95% CI [−2.81, 1.26], P = 0.451). In the intervention group, mean anxiety levels declined substantially at T1 and remained stable at T2, whereas the control group showed a gradual reduction across the study

period, although the overall decrease was smaller. The corresponding effect sizes were moderate at T1 (Cohen's *d* = 0.423) and small at T2 (Cohen's *d* = 0.082). Figure 8.11 illustrates the trajectories of anxiety over time by group in women with breast cancer.

Table 8.15 GLMM results for anxiety in women with breast cancer by the group over the study period

| | Intervention group (*n* = 45) | Control group (n = 45) | GLMM Group × Time interaction effect | | Cohen's *d* |
|---|---|---|---|---|---|
| Time | Estimated mean ± SE | Estimated mean ± SE | β (95% CI) | P-value | |
| T0 | 6.63 ± 0.71 | 7.04 ± 0.64 | | | |
| T1 | 3.21 ± 0.46 | 5.84 ± 0.66 | -2.22 (-4.32, -0.12) | 0.039* | 0.423 |
| T2 | 3.62 ± 0.53 | 4.82 ± 0.53 | -0.78 (-2.81, 1.26) | 0.451 | 0.082 |

Note: Three covariates including women' age, partner's baseline FCR, and partners' baseline social isolation were controlled in the model

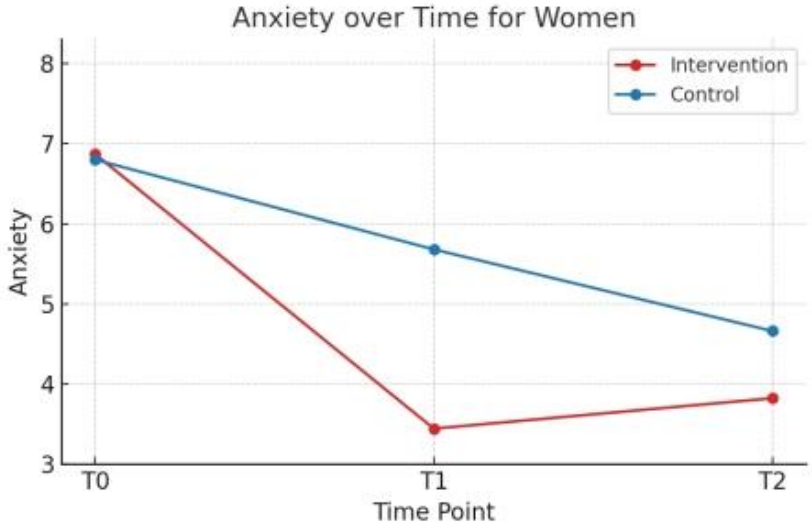


Figure 8.11 Anxiety over time by group in women with breast cancer

8.5.2.2.5 Stigma

Table 8.16 presents the GLMM results for overall stigma and its four subscales. None of the Group × Time interactions at T1 or T2 were statistically significant, and all estimated effect sizes were small. For the overall stigma scale, although the intervention

group exhibited larger reductions than the control group, the interaction effects were not significant at either T1 (β = −1.10, 95% CI [−4.10, 1.90], P = 0.472) or T2 (β = –0.60, 95% CI [−4.20, 2.99], P = 0.741), with small effect sizes (Cohen's *d* = 0.158 at T1 and 0.073 at T2). Similar findings were observed for the self-image disorder subscale. While reductions were greater in the intervention group (1.14 points at T1 and 1.07 at T2) than in the control group (0.39 at T1 and 0.34 at T2), the Group × Time interaction effects were not significant (T1: β = −0.75, 95% CI [−2.12, 0.63], P = 0.286; T2: β = −0.73, 95% CI [−2.22, 0.76], P = 0.338), with small effect sizes at both time points (d = 0.240 at T1, d = 0.229 at T2). For the self-perception subscale, reductions were similar across groups, with non-significant Group × Time interaction terms (T1: β = −0.23, 95% CI [−1.14, 0.69], P = 0.627; T2: β = 0.06, 95% CI [−0.94, 1.05], P = 0.914). Effect sizes were small (d = 0.108 at T1; d = −0.015 at T2). For the social isolation subscale, no significant group differences in change were observed (T1: β = 0.01, 95% CI [−0.51, 0.53], P = 0.959; T2: β = 0.08, 95% CI [−0.66, 0.82], P = 0.836). Reductions were marginally greater in the control group than in the intervention group, with small negative effect sizes (Cohen's *d* = −0.044 at T1; Cohen's *d* = −0.077 at T2). For the discrimination subscale, both groups showed initial reductions from T0 to T1 followed by a slight increase at T2. Group × Time interaction effects were again non-significant (T1: β = −0.13, 95% CI [−1.26, 0.82], P = 0.959; T2: β = −0.04, 95% CI [−1.19, 1.11], P = 0.947), with negligible effect sizes (Cohen's *d* values of 0.03 at T1 and 0.04 at T2). Overall, these results suggest that the intervention did not significantly impact stigma or its subcomponents, with only small and clinically modest differences observed. Figure 8.12 illustrates the trajectories of overall stigma and subscales over time by group.

Table 8.16 GLMM results for overall stigma and subscales in women with breast cancer by the group over the study period

| | Intervention group (*n* = 45) | Control group (n = 45) | GLMM Group × Time interaction effect | Cohen's *d* |
|---|---|---|---|---|

| Time | Estimated mean ± SE | Estimated mean ± SE | β (95% CI) | P-value | |
|---|---|---|---|---|---|
| Overall Stigma | | | | | |
| T0 | 37.07 ± 1.08 | 37.57 ± 0.99 | | | |
| T1 | 34.35 ± 1.14 | 35.95 ± 1.08 | -1.10 (-4.10, 1.90) | 0.472 | 0.158 |
| T2 | 35.04 ± 1.28 | 36.15 ± 1.13 | -0.60 (-4.20, 2.99) | 0.741 | 0.073 |
| Self-image Disorder Subscale | | | | | |
| T0 | 12.46 ± 0.44 | 12.59 ± 0.39 | | | |
| T1 | 11.32 ± 0.42 | 12.20 ± 0.48 | -0.75 (-2.12, 0.63) | 0.286 | 0.240 |
| T2 | 11.39 ± 0.50 | 12.25 ± 0.49 | -0.73 (-2.22, 0.76) | 0.338 | 0.229 |
| Self-perception Subscale | | | | | |
| T0 | 10.72 ± 0.36 | 10.83 ± 0.34 | | | |
| T1 | 9.99 ± 0.37 | 10.33 ± 0.32 | -0.23 (-1.14, 0.69) | 0.627 | 0.108 |
| T2 | 10.33 ± 0.36 | 10.38 ± 0.30 | 0.06 (-0.94, 1.05) | 0.914 | -0.015 |
| Social Isolation Subscale | | | | | |
| T0 | 4.55 ± 0.22 | 4.56 ± 0.16 | | | |
| T1 | 4.37 ± 0.21 | 4.37 ± 0.18 | 0.01 (-0.51, 0.53) | 0.959 | -0.044 |
| T2 | 4.38 ± 0.21 | 4.31 ± 0.22 | 0.08 (-0.66, 0.82) | 0.836 | -0.077 |
| Discrimination Subscale | | | | | |
| T0 | 9.35 ± 0.33 | 9.59 ± 0.34 | | | |
| T1 | 8.65 ± 0.37 | 9.02 ± 0.33 | -0.13 (-1.26, 0.99) | 0.815 | 0.060 |
| T2 | 8.94 ± 0.39 | 9.22 ± 0.33 | -0.04 (-1.19, 1.11) | 0.947 | -0.003 |

Note: Three Covariates including women' age, partner's baseline FCR, and partners' baseline social isolation were controlled in the models

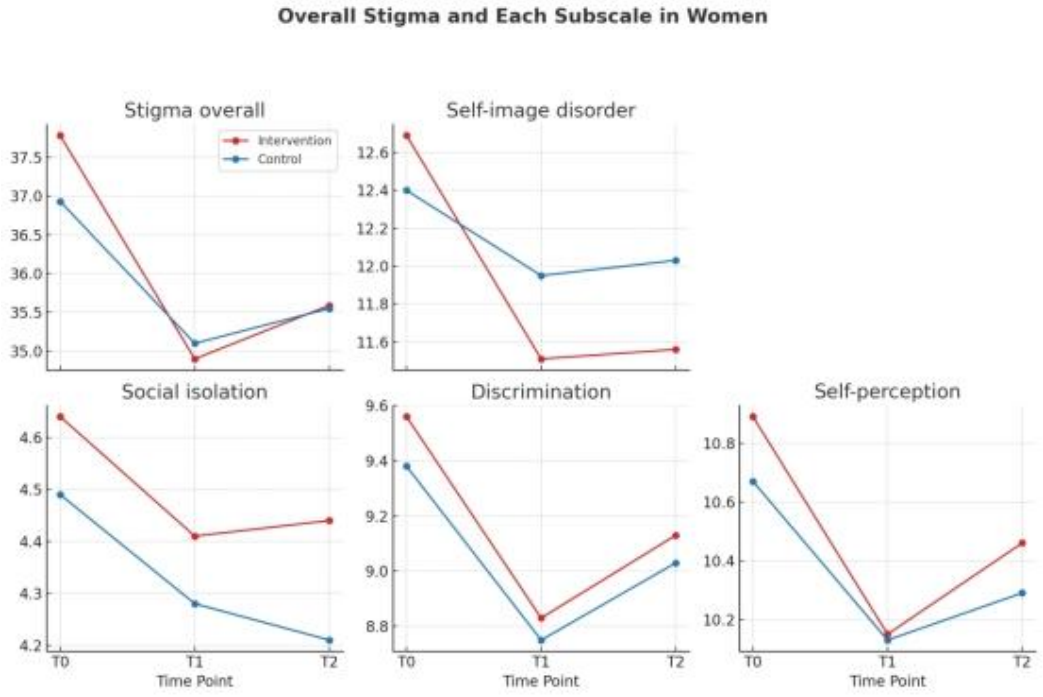

Figure 8.12 Overall Stigma and the four subscales over time by group in women with breast cancer

8.5.3 Outcomes in partners of women with breast cancer

The analysis encompassed 90 partner observations across three time points: 90 at T0, 78 at T1, and 76 at T2, with 27 instances of missing data. Baseline measurements and the control group were used as references in the linear mixed model, with dummy variables coded as 0.

To address Research Question 3, which examined whether the intervention was effective in improving partner outcomes, GLMMs were conducted. Specifically, two-way Group × Time interaction terms were tested across all outcome variables, including FCR, social constraints, intrusive thoughts, avoidance, anxiety, overall affiliate stigma and the four affiliate stigma subscales. The analytic approach mirrored that used for women with breast cancer, incorporating random intercepts to account for the nested structure of repeated measures and relevant covariates. Effect sizes for the intervention were estimated using Cohen's *d*.

8.5.3.1 Primary outcome

8.5.3.1.1FCR

As shown in Table 8.17, a significantly negative Group × Time interaction for FCR was observed at T1 (β = −4.11, 95% CI [−7.47, −0.75], P = 0.018), whereas the interaction at T2 did not reach statistical significance (β = −3.67, 95% CI [−7.36, 0.02], P = 0.051). Partners in the intervention group demonstrated a substantial reduction in FCR at T1, which was maintained at T2, while those in the control group showed only a slight decline over the study period. These findings suggest that the theory-driven, disclosure-based family support programme was more effective than the control WeChat follow-up calls in reducing partners' FCR immediately post-intervention. However, the effect was not sustained at the 12-week follow-up. The corresponding effect sizes were

moderate at both T1 (Cohen's $d = 0.521$) and T2 (Cohen's $d = 0.466$).

Table 8.17 GLMM results for FCR in partners of women with breast cancer by the group over the study period

| | Intervention group (n = 45) | Control group (n = 45) | GLMM Group × Time interaction effect | | Cohen's *d* |
|---|---|---|---|---|---|
| Time | Estimated mean ± SE | Estimated mean ± SE | β (95% CI) | P-value | |
| T0 | 37.42 ± 1.11 | 34.78 ± 1.11 | | | |
| T1 | 31.54 ± 1.18 | 33.01 ± 1.16 | -4.11 (-7.47, -0.75) | 0.018* | 0.521 |
| T2 | 30.98 ± 1.18 | 32.02 ± 1.21 | -3.67 (-7.36, 0.02) | 0.051 | 0.466 |

Note: Three covariates including women' age, partner's baseline FCR, and partners' baseline social isolation were controlled in the model

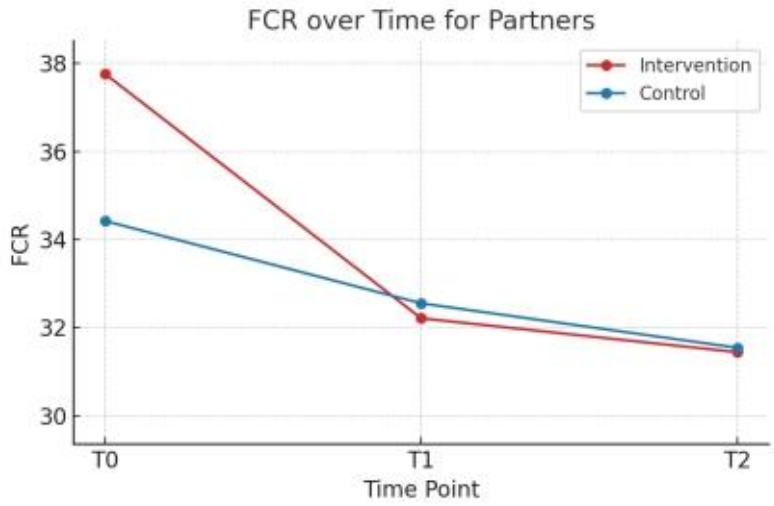


Figure 8.13 FCR over time by group in partners

8.5.3.2 Secondary outcomes

8.5.3.2.1 Social constraints

As shown in Table 8.18, although partners in the intervention group reported larger reductions in social constraints (−2.69 points at T1 and −2.17 points at T2) compared with the control group (–0.77 points at T1 and –0.15 points at T2), the estimated Group × Time interaction effects were not statistically significant at either T1 (β = −1.91, 95% CI [−5.48, 1.67], P = 0.294) or T2 (β = −2.00, 95% CI [−6.20, 2.20], P = 0.350).

Corresponding effect sizes were small at both time points (Cohen's *d* = 0.160 at T1; Cohen's *d* = 0.141 at T2).

Table 8.18 GLMM results for social constraints in partners of women with breast cancer by the group over the study period

| | Intervention group (n = 45) | Control group (n = 45) | GLMM Group × Time interaction effect | | Cohen's *d* |
|---|---|---|---|---|---|
| Time | Estimated mean ± SE | Estimated mean ± SE | β (95% CI) | P-value | |
| T0 | 33.09 ± 1.11 | 33.45 ± 1.12 | | | |
| T1 | 30.40 ± 1.20 | 32.68 ± 1.17 | -1.91 (-5.48, 1.67) | 0.294 | 0.160 |
| T2 | 30.92 ± 1.19 | 33.30 ± 1.22 | -2.00 (-6.20, 2.20) | 0.350 | 0.141 |

Note: Three covariates including women' age, partner's baseline FCR, and partners' baseline social isolation were controlled in the model

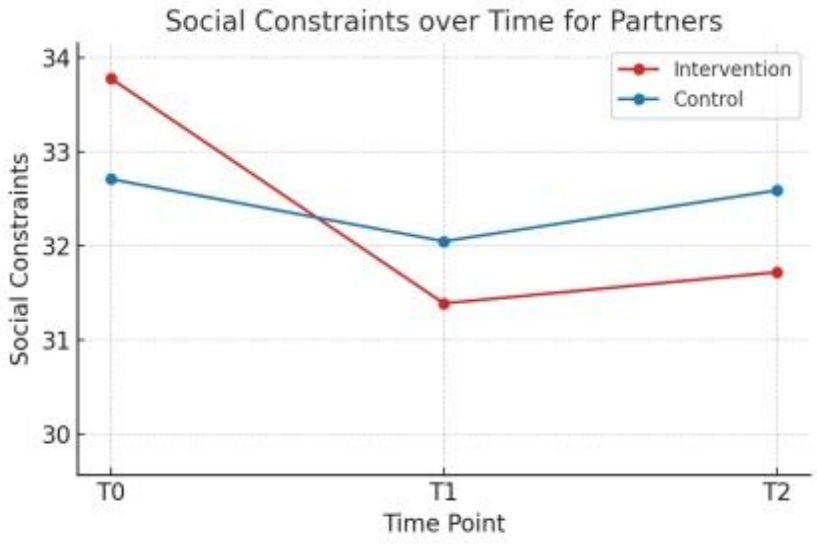


Figure 8.14 Social constraints over time by group in partners

8.5.3.2.2 Intrusive thoughts

Table 8.19 presents the GLMM results for intrusive thoughts among partners. No statistically significant Group × Time interaction effects were observed across the study period (T1: β = 1.25, 95% CI [−0.68, 3.17], P = 0.203; T2: β = 0.31, 95% CI [−1.91, 2.52], P = 0.786). Notably, partners in the control group demonstrated larger reductions

in intrusive thoughts (−2.00 points at T1 and −1.72 points at T2) compared with those in the intervention group (−0.75 points at T1 and −1.41 points at T2). The corresponding effect sizes were small (Cohen's *d* = –0.301 at T1; Cohen's *d* = 0.130 at T2).

Table 8.19 GLMM results for intrusive thoughts in partners of women with breast cancer by the group over the study period

| | Intervention group (n = 45) | Control group (n = 45) | GLMM Group× Time interaction effect | | Cohen's *d* |
|---|---|---|---|---|---|
| Time | Estimated mean ± SE | Estimated mean ± SE | β (95% CI) | P-value | |
| T0 | 9.91 ± 0.57 | 11.62 ± 0.57 | | | |
| T1 | 9.16 ± 0.62 | 9.62 ± 0.61 | 1.25 (-0.68, 3.17) | 0.203 | -0.301 |
| T2 | 8.50 ± 0.62 | 9.90 ± 0.63 | 0.31 (-1.91, 2.52) | 0.786 | 0.130 |

Note: Three covariates including women' age, partner's baseline FCR, and partners' baseline social isolation were controlled in the model

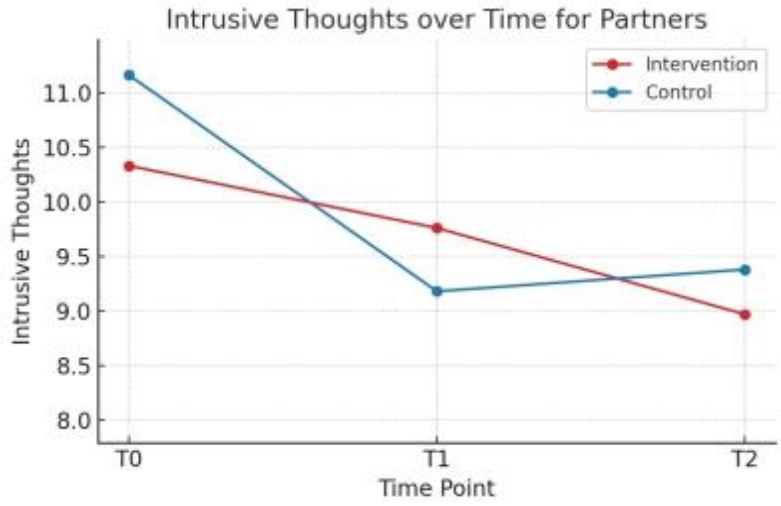


Figure 8.15 Intrusive thoughts over time by group in partners

8.5.3.2.3 Avoidance

Table 8.20 presents the GLMM results for avoidance among partners. No statistically significant Group × Time interaction effects were observed over the study period (T1: β = −0.22, 95% CI [−2.89, 2.45], P = 0.871; T2: β = 0.74, 95% CI [−2.33, 3.81], P = 0.636). Both groups showed reductions in avoidance. However, the intervention group

experienced a greater decrease from T0 to T1, whereas the control group demonstrated a larger decline from T0 to T2. The estimated effect sizes were negligible at T1 (Cohen's $d = -0.013$) and small at T2 (Cohen's $d = 0.182$).

Table 8.20 GLMM results for avoidance in partners of women with breast cancer by the group over the study period

| | Intervention group (n = 45) | Control group (n = 45) | GLMM Group × Time interaction effect | | Cohen's *d* |
|---|---|---|---|---|---|
| Time | Estimated mean ± SE | Estimated mean ± SE | β (95% CI) | P-value | |
| T0 | 14.36 ± 0.79 | 15.54 ± 0.87 | | | |
| T1 | 11.90 ± 0.86 | 13.31 ± 0.84 | -0.22 (-2.89, 2.45) | 0.871 | -0.013 |
| T2 | 12.20 ± 0.85 | 12.65 ± 0.87 | 0.74 (-2.33, 3.81) | 0.636 | 0.182 |

Note: Three covariates including women' age, partner's baseline FCR, and partners' baseline social isolation were controlled in the model

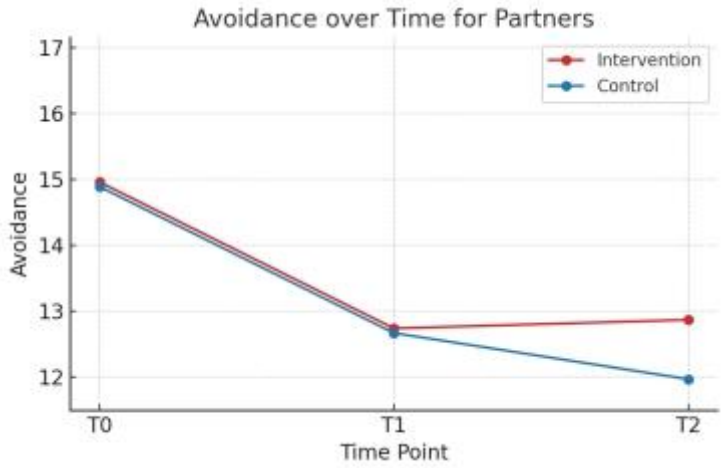


Figure 8.16 Avoidance over time by group in partners

8.5.3.2.4 Anxiety

As shown in Table 8.21, the GLMM results indicated no statistically significant Group × Time interaction effects for anxiety among partners of women with breast cancer (T1: β = 0.54, 95% CI [−1.39, 2.48], P = 0.581; T2: β = 0.10, 95% CI [−1.28, 3.27], P = 0.389). Both groups demonstrated reductions in anxiety; however, the control group

exhibited greater decreases from T0 to T1 and from T0 to T2. The corresponding effect sizes were small (Cohen's $d = -0.159$ at T1; Cohen's $d = -0.182$ at T2).

Table 8.21 GLMM results for anxiety in partners of women with breast cancer by the group over the study period

| | Intervention group (n = 45) | Control group (n = 45) | GLMM Group × Time interaction effect | | Cohen's *d* |
|---|---|---|---|---|---|
| Time | Estimated mean ± SE | Estimated mean ± SE | β (95% CI) | p-value | |
| T0 | 7.23 ± 0.61 | 8.25 ± 0.61 | | | |
| T1 | 5.28 ± 0.65 | 5.76 ± 0.64 | 0.54 (-1.39, 2.48) | 0.581 | -0.159 |
| T2 | 4.91 ± 0.65 | 4.93 ± 0.66 | 0.10 (-1.28, 3.27) | 0.389 | -0.182 |

Note: Three covariates including women' age, partner's baseline FCR, and partners' baseline social isolation were controlled in the model

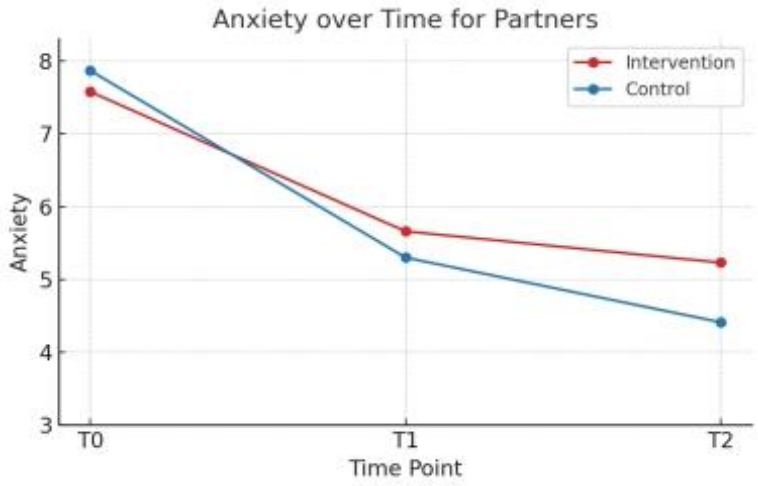


Figure 8.17 Anxiety over time by group in partners

8.5.3.2.5 Affiliate stigma

As shown in Table 8.22, the GLMM analyses for the overall affiliate stigma score and its four subscales revealed no statistically significant Group × Time interactions at either T1 or T2 among partners. Effect sizes were generally small or negligible, with the exception of a moderate effect size observed for the reaction subscale at T1. For the overall affiliate stigma scale, partners in the intervention group reported larger

reductions than those in the control group, although the differences were not statistically significant. The estimated interaction effect was β = −3.27 (95% CI [−8.51, 1.98], P = 0.221) at T1 and β = −0.10 (95% CI [−5.72, 5.52], P = 0.972) at T2. The corresponding effect sizes were small (Cohen's *d* = 0.239 at T1; Cohen's *d* = −0.015 at T2).

For the internal stigma subscale, the estimated Group × Time interaction was not significant at either T1 (β = −0.22, 95% CI [−2.15, 1.72], P = 0.824) or T2 (β = −0.11, 95% CI [−2.17, 1.96], P = 0.918). Reductions in internal stigma scores were similar across the two groups, with minimal effect sizes (Cohen's *d* = 0.024 at T1; Cohen's *d* = −0.046 at T2). For the social isolation subscale, the estimated interaction effects were also not statistically significant (T1: β = −1.60, 95% CI [–3.47, 0.27], P = 0.092; T2: β = −0.51, 95% CI [−2.49, 1.48], P = 0.614). Nonetheless, partners in the intervention group reported greater reductions (−2.35 points at T1; −1.10 at T2) than those in the control group (−0.75 points at T1; –0.60 at T2). Corresponding effect sizes were small (Cohen's *d* = 0.348 at T1; Cohen's *d* = 0.128 at T2). Similarly, no statistically significant Group × Time interactions were observed for the perceived stigma subscale (T1: β = −0.46, 95% CI [−1.64, 0.72], P = 0.442; T2: β = 0.12, 95% CI [−1.04, 1.27], P = 0.839). Perceived stigma decreased from T0 to T1 and then rose slightly by T2 in both groups, with greater overall change observed in the intervention group. Effect sizes were small (Cohen's *d* = 0.172 at T1; Cohen's *d* = 0.011 at T2). For the reaction subscale, no significant Group × Time interaction effects were detected at T1 (β = −0.10, 95% CI [−2.38, 0.40], P = 0.159) or T2 (β = 0.40, 95% CI [−1.12, 1.91], P = 0.604). Both groups demonstrated a similar trajectory, with decreases from T0 to T1 followed by increases above baseline at T2, although the magnitude of change was greater in the intervention group. Specifically, the intervention group exhibited a larger reduction in reaction scores at T1 (−1.07 points) compared with the control group (−0.07 points), yielding a small effect size (Cohen's *d* = 0.253). By T2, both groups experienced small increases, more pronounced in the intervention group (+0.43 points vs. +0.04 points), with the effect size remaining small (Cohen's *d* = −0.158).

Table 8.22 GLMM results for overall affiliate stigma and its subscales in partners of women with breast cancer by the group over the study period

| | Intervention group (n = 45) | Control group (n = 45) | GLMM Group × Time interaction effect | | Cohen's *d* |
|---|---|---|---|---|---|
| Time | Estimated mean ± SE | Estimated mean ± SE | β (95% CI) | P-value | |
| Overall affiliate stigma | | | | | |
| T0 | 50.85 ± 1.39 | 51.05 ± 1.39 | | | |
| T1 | 45.07 ± 1.51 | 48.54 ± 1.47 | -3.27 (-8.51, 1.98) | 0.221 | 0.239 |
| T2 | 49.11 ± 1.49 | 49.40 ± 1.53 | -0.10 (-5.72, 5.52) | 0.972 | -0.015 |
| Internal stigma | | | | | |
| T0 | 16.38 ± 0.51 | 16.56 ± 0.51 | | | |
| T1 | 14.70 ± 0.55 | 15.10 ± 0.54 | -0.22 (-2.15, 1.72) | 0.824 | 0.024 |
| T2 | 15.24 ± 0.55 | 15.53 ± 0.56 | -0.11 (-2.17, 1.96) | 0.918 | -0.046 |
| Social isolation | | | | | |
| T0 | 17.73 ± 0.55 | 16.63 ± 0.55 | | | |
| T1 | 15.38 ± 0.59 | 15.88 ± 0.58 | -1.60 (-3.47, 0.27) | 0.092 | 0.348 |
| T2 | 16.63 ± 0.59 | 16.03 ± 0.60 | -0.51 (-2.49, 1.48) | 0.614 | 0.128 |
| Perceived stigma | | | | | |
| T0 | 8.58 ± 0.31 | 8.63 ± 0.31 | | | |
| T1 | 7.91 ± 0.34 | 8.41 ± 0.33 | -0.46 (-1.64, 0.72) | 0.442 | 0.172 |
| T2 | 8.66 ± 0.34 | 8.58 ± 0.35 | 0.12 (-1.04, 1.27) | 0.839 | 0.011 |
| Reaction | | | | | |
| T0 | 8.45 ± 0.38 | 8.92 ± 0.38 | | | |
| T1 | 7.38 ± 0.41 | 8.85 ± 0.40 | -0.10 (-2.39, 0.40) | 0.159 | 0.253 |
| T2 | 8.88 ± 0.41 | 8.96 ± 0.42 | 0.40 (-1.12, 1.91) | 0.604 | -0.158 |

Note: Three covariates including women' age, partner's baseline FCR, and partners' baseline social isolation were controlled in the models

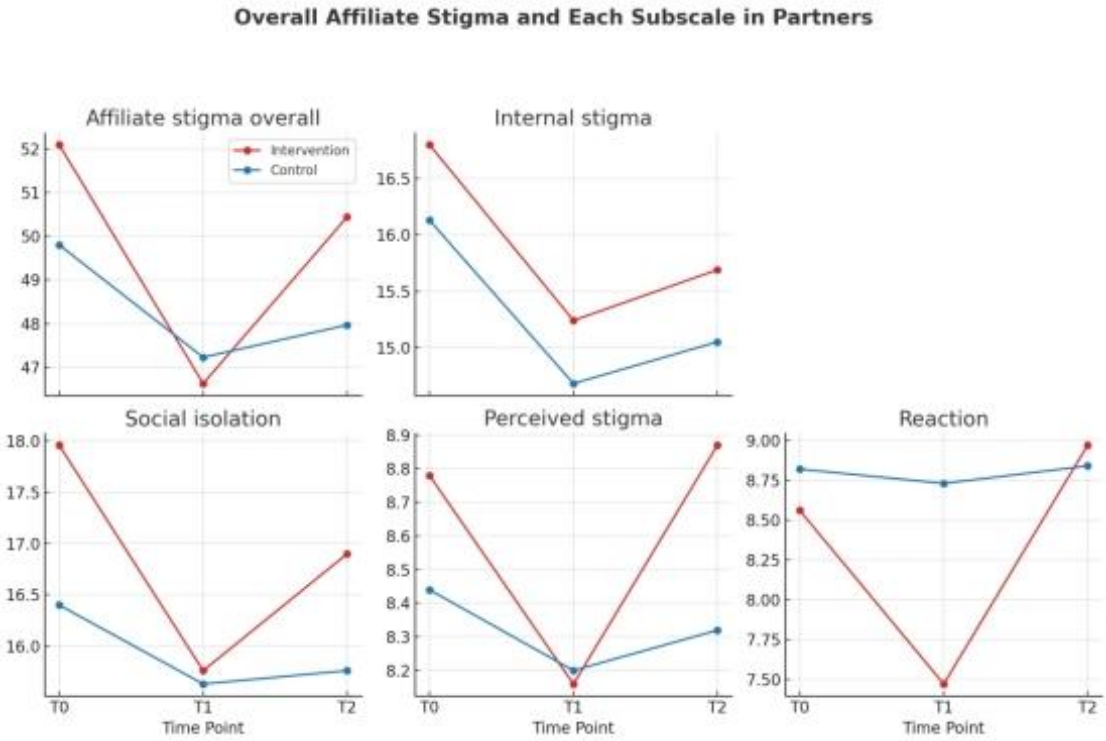


Figure 8.18 Overall affiliate stigma and each subscale over time by group in partners

### 8.6 Results of the qualitative study

A total of 23 interviews were conducted between November 2024 and February 2025, involving six women individually and 17 couples who had received the family support programme. Data collection took longer than anticipated, with the completion of 23 cases on 28 February 2025. Five interviews were conducted after T1 but before T2 by RA1, and the remaining interviews were conducted after T2 by the doctoral student. All interviews were held via WeChat and lasted between 12 and 37 minutes, with a mean duration of 25 minutes. Table 8.23 presents the characteristics of the women (N = 23) and their partners (N = 17) who participated in the interviews. The mean age of the women with breast cancer was 41.7 years (31–59 years). Most participants held a bachelor's degree (34.78%), were employed (65.22%), resided in urban areas (65.22%) and were diagnosed at stage II (34.78%). Regarding treatment, seven women (30.43%) were undergoing surgery, eight (34.78%) were receiving chemotherapy and seven (30.43%) were undergoing chemotherapy combined with targeted therapy. Four women (17.39%) had recurrent breast cancer. In terms of living arrangements, 18 couples

(78.26%) resided in the same household, while five couples (21.74%) lived separately due to work commitments. The mean age of the partners was 45.00 years (range: 35–60 years). The majority had a junior college education and were employed (64.71%).

Table 8.23 The Characteristics of the women (N=23) and partners (N = 17)

| | Groups | Women with breast cancer (N=23) (M±SD)/ n (%) | Partners (N=17) (M±SD)/ n (%) |
|---|---|---|---|
| Age | / | 41.70±7.38 (Range: 31-59) | 45.00±7.87 (Range: 35-60) |
| Educational level | Primary school or below | 0 (0%) | 0(0%) |
| | Junior high school | 2 (8.70%) | 1 (5.88%) |
| | Senior high school | 7 (30.43%) | 2(11.76%) |
| | Junior college | 5 (21.74%) | 8 (47.06%) |
| | University | 8 (34.78%) | 4 (23.53%) |
| | Postgraduate | 1 (4.34%) | 2 (11.76%) |
| Employment | Employed | 15 (65.22%) | 11 (64.71%) |
| | Unemployed | 8 (34.78%) | 6 (35.29%) |
| Residence | City | 15 (65.22%) | / |
| | Town | 4 (17.39%) | / |
| | Village | 4 (17.39%) | / |
| Living in the same household | Yes | 18 (78.26%) | / |
| | No | 5 (21.74%) | / |
| Recurrent breast cancer | Yes | 4 (17.39%) | / |
| | No | 19 (82.61%) | / |
| Time since diagnosis | <3 months | 10 (43.48%) | / |
| | 3-6 months | 9 (39.13%) | / |
| | >6 months | 4 (17.39%) | / |
| Stage | I | 7 (30.43%) | / |
| | II | 8 (34.78%) | / |
| | III | 3 (13.04%) | / |
| | IV | 5 (21.74%) | / |
| Current treatment | Surgery | 7 (30.43%) | / |
| | Chemotherapy | 8 (34.78%) | / |
| | Chemotherapy + target therapy | 7 (30.43%) | / |
| | Radiotherapy | 1 (4.34%) | / |

Among the interview participants, three women and one partner did not complete the questionnaire at T2, one woman passed away and the others were lost to follow-up. Therefore, changes in FCR levels from T0 to T1 were assessed in 23 women and 17 partners, and changes from T0 to T2 were calculated in 20 women and 16 partners. At T1, decreased FCR was observed in 20 women (86.96%), with a reduction range of 1–19 points, and three women reported increased FCR, ranging from 2–5 points. At T2, 18 women (90.00%) reported decreased FCR (range: 1–28 points), whereas two women experienced increases of 1–3 points. Clinically significant FCR (defined as FCR score of ≥34) was reported in six women (26.09%) at T1 and five women (25.00%) at T2. For partners, decreased FCR (range: 4–20 points) was observed in 13 participants (76.47%) at T1, while one partner reported no change and three partners showed increased FCR (range: 2–14 points). At T2, 12 partners (75.00%) reported decreased FCR (range: 1–27 points), one partner had no change, and three partners reported increases (range: 3–12 points). Clinically significant FCR was identified in eight partners (47.06%) at T1 and seven partners (43.75%) at T2. Figure 8.19 presents the changes in FCR levels among women with breast cancer and their partners at T1 and T2.

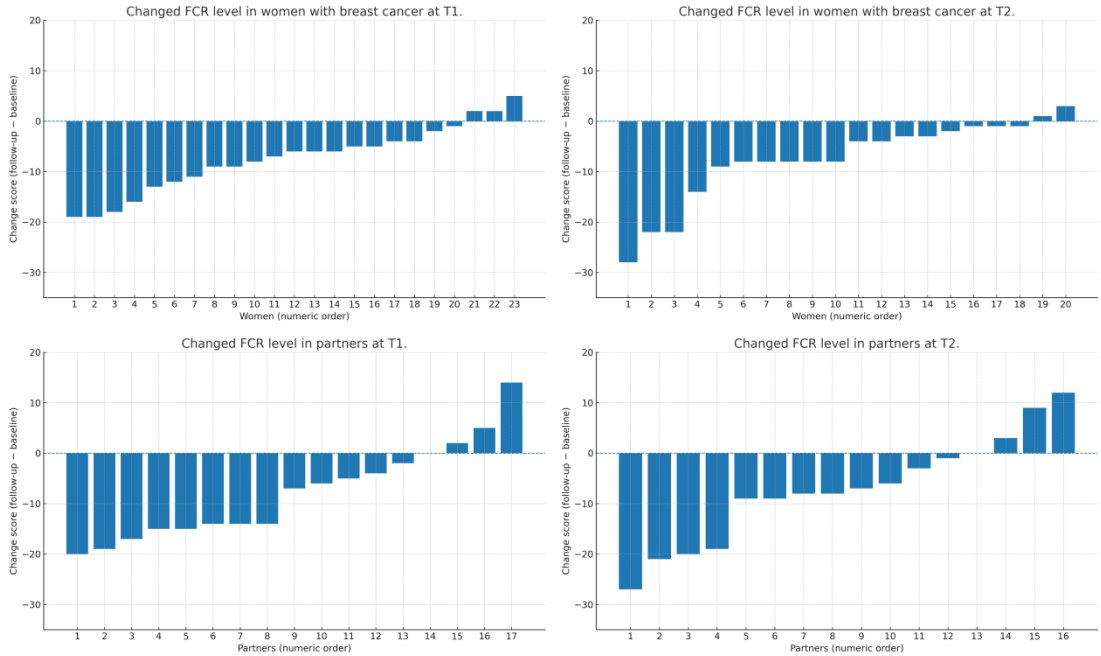

Figure 8.19 Changed FCR level in women with breast cancer and partners at T1 and T2

Four key themes emerged from the qualitative analysis of the 23 interviews (Table 8.24): (1) comprehensive and practical features of the intervention, (2) perceived benefit of the intervention, (3) strategies to promote and sustain the intervention and (4) challenges in practising and sustaining the intervention.

Table 8.24 Themes and Subthemes of Perceptions and Experiences of Participating in family support programme for FCR

| Themes | Subthemes |
|---|---|
| 1.Comprehensive and practical features of the intervention | 1.1 Systematic, comprehensive knowledge on disease and health management |
| | 1.2 Supportive disclosure environment |
| | 1.3 WeChat delivery advantages |
| 2.Perceived Benefits of the intervention | 2.1 Reduced fear and improved confidence |
| | 2.2 Enhanced active self-management and emotional adjustment |
| | 2.3 Improved communication and intimacy within couple |
| 3. Strategies to promote and sustain the intervention | 3.1 Targeted to meet needs in specific groups |
| | 3.2 Expanded to action-based and peer-driven interventions |
| | 3.3 Diversified modes of delivery for educational materials |
| 4. Challenges in practising and sustaining the intervention | 4.1 Challenges and conflicts in participation |
| | 4.2 Barriers to openness in daily life |

8.6.1 Theme 1: Comprehensive and practical features of the intervention

Many women and partners felt that the family support programme provided professional, systematic and reliable information that helped them to better understand their condition and treatment. Several participants also appreciated the use of simple language and metaphors to explain professional knowledge in an accessible way. Women and partners described the sessions as emotionally relieving, comforting and empowering. For many, disclosure-based conversations with the facilitator brought a

sense of lightness and ease because the conversations were natural and enjoyable. The online format was regarded as a more accessible and comfortable means of delivering the intervention. Overall, the programme offered clear guidance, particularly in relation to diet, exercise and mindset, supporting participants to develop a balanced approach to managing their illness.

Sub-theme 1: Systematic and comprehensive knowledge on disease and health management

Many women and partners felt that the programme provided personalised information tailored to their needs, which boosted their confidence in managing the illness and reduced their reliance on unreliable sources. They found the information particularly valuable in shaping a healthier lifestyle and reported feeling better equipped to support recovery from cancer.

> *'After attending the family support programme, I started to realize these aspects (I should pay attention to). You also gave examples, some of them I heard before, such as maintaining a good mood, but that kind of knowledge was not systematic. After all the sessions, I understood everything in a more systematic way.'* (patient 07)

> *'Information online can be true or false, and we still have to figure out by ourselves. But when I talk to you (the facilitator), you use your professional knowledge to give me an accurate answer. No need for me to guess anymore.'* (patient 08)

> *'When patients do not understand, the facilitator is able to use simple and easy-to-understand language to explain the basic knowledge. If you speak too professionally, we are able to understand because we are not in this field. But by using simple language and metaphors, you can explain the issue in a way that patients can fully comprehend. I think this approach is very effective.'* (partner 19)

*'Every session left a deep impression on me, and I remember them all. Every session was comprehensive, covering everything from our diet to daily routines and addressing all aspects.'* (patient 23)

*'To be honest, since I was diagnosed with breast cancer, I have not searched much information online because I did not want to face it. ... But through what you explained to me, I am able to understand more about the disease, how it develops, and what I can do to avoid it. I feel that this has given me a great sense of security and confidence. Regarding what to eat and how to manage diet, I am now more focused on what foods are beneficial and how to eat better for recovery. This includes what to eat during radiation or chemotherapy, which I think is very useful. It also talks about how to maintain a balanced diet and what kind of exercise to do. I believe this document is very helpful to me, and it will continue to be helpful in the future.'* (patient 06)

Sub-theme 2 Supportive Disclosure Environment

Some women emphasised the value of emotional resonance, noting that unlike friends or family who might not fully understand their experience, the facilitator offered empathetic understanding and made them feel genuinely supported. Several participants also highlighted the facilitator's emotional presence and patience during vulnerable moments. This calm and steady support created a safe environment that reduced stress, encouraged openness and helped restore psychological balance amid the uncertainty of cancer.

*'I feel really good talking with you (the facilitator). There is no communication barrier at all. It truly gives me confidence and lifts my spirits.'* (patient 02)

*'From the way you (the facilitator) spoke with my wife just now, and from our heart-to-heart talk, I felt that your way of thinking is quite forward-thinking for people like*

*us. I really hope we can keep communicating more in the future. Just listening to your smooth and open communication (with my wife) makes me feel genuinely happy and at ease.'* (partner 15)

*'It is really nice—talking with you takes a lot of the pressure off. People around me don't really understand, and when I try to talk to them, they just get anxious and say a few quick words. But talking with you and other patients feels much more comforting and puts my mind at ease.'* (patient 03)

*'I know you've been working really hard during this time—sometimes even staying up late just to teach us and talk with us. My partner and I felt comfortable opening up to you, and you never seemed tired of listening. I even told a close colleague that the long trip here was totally worth it. The hospital in Changsha has psychologist who keeps communicating with us and helps heal our emotional wounds.'* (patient 15)

Sub-theme 3 WeChat delivery advantages

All the women and partners found it convenient to use WeChat for delivery. They felt less pressure than in face-to-face interactions. The online format allowed them to communicate more freely and openly, without the burden often associated with direct, in-person exchanges. When asked about their opinion of face-to-face delivery, participants acknowledged that while it might be more effective in promoting understanding, it was often inconvenient or difficult to arrange due to scheduling conflicts.

*'Online communication might not be as convenient, especially since it's not always easy to use my phone. The current method (WeChat) is better. If there's an opportunity for face-to-face communication, that would be even better, but most people probably don't have that chance. If you have the time, maybe the patient won't; if the patient has the time, you might not.'* (partner 14)

*'Face-to-face communication is more difficult. Speaking face-to-face might help with understanding better. However, there are certain factors that make face-to-face communication inconvenient at times.'* (patient 22)

*'I feel like I can open up more when we talk via WeChat. If you were giving me a face-to-face session, I might not be able to come up with the answers to your questions right away, and I'd feel some pressure. ... But when we chat via WeChat, I feel more relaxed and open. I feel like I can talk freely about anything you say.'* (patient 23)

### 8.6.2 Theme 2: Perceived Benefits of the intervention

Women and partners reported reductions in FCR and anxiety, alongside improvements in confidence, after attending the family support programme. Through professional guidance, participants gained a better understanding of cancer and its treatment, which enabled them to feel more in control and less fearful. Some participants described experiencing love and hope from the programme, which helped them to recognise society's concern for their illness. They reflected that love and support from others are powerful tools for healing. Overall, the programme provided vital support by boosting confidence and encouraging proactive health adjustments, thereby greatly aiding recovery. In addition, it offered ongoing connections that allowed individuals to continue feeling supported even after the sessions had ended.

#### Sub-theme 1: Reduced fear and improved confidence

Initially, many patients feared that cancer would lead to imminent death. However, as they gained knowledge about treatment options and recovery, they developed a greater sense of optimism. Clear treatment plans and awareness of rapid medical advancements further reassured them.

*'The family support programme was a great help to me. It has helped me stop fearing this disease and gave me a better understanding of it. When I was first diagnosed, I was really scared. But after you taught me, I realized that this illness is not as scary as I thought. You mentioned that as long as I can regulate myself, the disease is not as frightening as I imagined. I do not worry so much anymore, and the psychological pressure about the potential recurrence in the future has decreased.'* (patient 11)

*'At least the fear is definitely not as strong as it was in the beginning. You (the facilitator) also provide examples and share other patients' experience, which helps a lot. After surgery, many people go on to live normal lives, so why can't we be one of them?'* (partner 24)

*'Many patients are actually very anxious when they first diagnosed with the disease. They are scared and panicked, so at this time, family's care and concern are actually helpless because they cannot truly understand the patient's psychological state. ... the family support programme and professional education, enabling them to correctly understand the disease, regardless its risks, development, or precautions need to be taken in the future, it is an enormous help for them. ... When it comes to cancer, the topic itself feel extremely heavy and serious. However, if patients regularly receive your professional explanations and psychological support, it can make a significant difference, as well as boosts their confidence. ... That's why your role in providing psychological support is truly a very important part of the overall care process.'* (partner 19)

*'Facing the fear, intimidation, confusion, and anxiety at first. After going through the family support programme, I gained a more comprehensive understanding. Fear arises from ignorance, but after gaining the correct knowledge and knowing that there are proper medications to treat the disease, the programme certainly plays an important role in calming both the mind and the emotions.'* (patient 20)

*'I feel the family support programme is quite meaningful. At least it helps my wife realize that there are many people in society who pay attention to and care about this illness. Because in a society where you have to pay for many services when you're ill, it adds a significant amount pressure. But if there are many kind-hearted people paying attention to this issue, it changes the way we perceive the world. It helps us realize that the world is full of love, and helps us see more hope.'* (partner 07)

Subtheme 2 Enhanced active self-management and emotional adjustment

Women and their partners reported gaining a greater sense of control and described a transition from a passive to an active role in health management after receiving guidance on lifestyle changes through the family support programme. Some women initially had not considered exercise, a healthy diet, or other psychosocial factors to be significant, but after the programme, they recognised their importance and began incorporating these changes into their daily routines. Others sought to make actionable adjustments to improve their overall condition. Partners echoed this perspective, noting that lifestyle modifications, such as maintaining regular routines, healthy eating and engaging in exercise are essential for sustaining health and preventing major health issues.

*'I had never thought about exercising before. I just wanted to stay in bed. But after you told me that I needed to exercise, I decided to start. You also explained that it is not just about walking casually; I need to reach a certain intensity or state for it to really be effective. As for managing my emotions, now that I understand how getting angry could affect my condition, I will definitely work harder to control my temper. I also learned about the importance of diet, exercise, emotions, and sleep, all the five key aspects you taught me. I am committed to putting them into practice seriously. Now, I truly recognize the importance of these changes, and I believe I will not relapse, because I will actively change my lifestyle, adjust my temper, and*

*work on improving my habits. I am determined to make these changes.'* (patient 02)

*'What I fear the most is when people tell me, 'It is just fate, you just accept it.' I am especially afraid when doctors say things like, 'Don't think about it, don't try to figure out the cause, don't even worry about your mindset. It is all just fate.' It really makes me feel powerless in the face of it. But you explained things (during the intervention) gave me a completely different feeling. At least now I believe that making certain changes can truly make a difference, and that there is real hope. I feel that, emotionally, I have become much more stable.'* (patient 24)

*'People who have health issues often experience some degree of irregularity in various aspects of their lives, such as daily routines, diet, and sleep. By making adjustments in these areas, whether establishing a more regular lifestyle, maintaining a healthy diet, or exercising consistently, and by strengthening the immune system through these changes, if one can stick to it consistently and carry it out properly, I believe that for most patients, though perhaps not all, there should be no major issues.'* (partner 19)

Moreover, participants described notable changes in their emotional and behavioural responses after attending the family support programme. They reported becoming more conscious and rational in managing their negative emotions, particularly anxiety and anger. In addition, they adopted a more proactive attitude in coping with FCR, recognising the importance of avoiding negative thoughts and worrying less. This shift towards positive thinking and emotional regulation also extended to their daily lives, particularly within marital relationships. Women and their partners noted improvements in relational dynamics, with partners making more deliberate efforts to accommodate the women, especially during moments of anger, by remaining calm and preventing conflict escalation. Overall, the family support programme was regarded as particularly

valuable in guiding participants towards healthier emotional regulation and self-care practices.

*'I've become more rational when it comes to emotional management and more consciously proactive in recognizing them. In the past, I never notice the problem. If I got angry, I just got angry. If not, I didn't think about it at all. Or sometimes I wasn't even aware I was angry. But now, I can recognize when something is off emotionally. Another point is realizing that I need to release, express, or regulate it. I developed that awareness and corresponding behavior.'* (patient 13)

*'Before attending the session, I had no idea how to approach things. I used to act on my own temperament. Now, I definitely try to accommodate her more. For example, when she gets angry, I just stay silent and give in to her.'* (partner 22)

Subtheme 3 Improved communication and intimacy within couple

Women and their partners reported growth in communication, emotional awareness, understanding and mutual support. The experience of illness prompted deep reflection on each other's needs, fostering more active care, empathy, emotional intimacy and cooperation within the relationship. Many participants described becoming more attentive to women's emotions, more responsive and more willing to adapt their own behaviour not only to support women's recovery but also to enhance the well-being of the relationship and the family as a whole.

*'Previously, I always tried to avoid communication whenever possible. But after attending these sessions where you mentioned the importance of adjusting one's mindset and making changes, I realized that suppressing communication might negatively affect my mood. I started wondering - maybe if I tried communicating (with my partner), it might help improve my state of mind. So, I decided to talk with him, and after our conversation, not only did my mood genuinely improve, but his*

*mood seemed to lighten up too.'* (patient 01)

*'Sometimes it's really hard to change one's personality all of a sudden. At the very least, when it comes to communication, I have to find ways to talk with her in order to lift her mood and not let her feel down. These are things I definitely need to pay attention to. If it weren't for you all pointing it out to me, I wouldn't have realized it was a personality issue. Sometimes I even cannot say two sentences to my wife before we end up arguing. My way of speaking has definitely changed a lot.'* (partner 21)

*'We've always communicated quite a lot with each other in terms of the disease, but for couples who may not talk much to begin with, this could definitely help promote and improve their communication.'* (patient 19)

*'After you (the facilitator) told him about the importance of communication and to pay attention to my emotions, he generally does so. Before, he didn't care at all. Sometimes, I would be angry about this for a whole day. ... But now, it's different. He usually replies to my messages immediately unless he's really busy. So now I can understand him. And I've also become more understanding than I was before. So, I think this course really helped. It's definitely beneficial for the psychological recovery of patients.'* (patient 23)

*'He also pays more attention to my subtle emotions now. Like you said, he might be more rational, and I've come to understand and accept that about him. In the past, I was deeply caught up in my own feelings, thinking that *he* should be the one making the effort, that *he* should understand and care for me — I never really considered his side. I didn't realize that he had his own needs too. But now, I feel like it's mutual — emotions and care should go both ways. It's not just about him taking care of me anymore.'* (patient 21)

Two participants described making conscious efforts to improve communication and manage emotions more effectively. They recognised that mutual understanding and cooperation were essential not only for the patient's recovery but also for the overall well-being of the family.

> *'I try my best not to argue and to lose my temper less often. After all, I am sick, and he supported me through the treatment. Now, he is doing everything at home, so for the sake of this family, we both try to be more understanding and cooperative, and to work together to build a better home.'* (patient 12)

> *'She has made some progress. she used to get angry all the time. I am a bit better than her. I do not argue with her much. But even now, she still has not fully changed, though it has gotten a bit better. I believe she will gradually become more mindful in the future. One is for the sake of her own illness, and the other is for this family. Getting this illness does not just affect her alone, but also impacts the whole family.'* (partner 14)

8.6.3 Theme 3. Strategies to promote and sustain the intervention

Three strategies relating to the content and delivery model of the family support programme to promote and sustain the intervention were identified in the interviews. Firstly, participants highlighted the need for breast cancer health education to be clearer, more personalised and easier to understand. Secondly, they emphasised the importance of expanding the programme beyond verbal support towards more action-based, peer-driven interventions. Thirdly, participants recommended the use of more diverse delivery media to reduce cognitive load, alleviate anxiety and encourage more informed and proactive engagement.

Subtheme 1 Targeted to meet needs in specific groups

Women and partners emphasised that materials should be tailored to meet the needs of

subgroups with varying levels of knowledge, emotional readiness and personal requirements. For newly diagnosed patients, more detailed explanations about treatment side effects were considered essential, whereas those already familiar with their condition might benefit more from emotional support and open conversation than from professional jargon. In addition, women and partners expressed the need for practical financial guidance, including advice on applying for medical aid and understanding insurance.

*'You need to tailor your approach for different individuals. For some people who are aware of their conditions, presenting them with too much professional information might not be effective. They might need more emotional support or a conversational approach. ... For these patients (do not know their conditions well), it's important to provide some basic information, not necessarily too professional ... Using different methods for different individuals might be more effective, but it's certainly challenging. It's like teaching according to the needs of the student, adjusting your approach for each person. If you can adjust your methods to suit different patients' situations and emotions, it would definitely yield better results.'* (partner 16)

*'The side effects of surgery, radiotherapy, and chemotherapy, and the extent of their impact on the body, are issues that everyone is quite concerned about. In the sessions you have conducted, most of the focus has been on mindset adjustment and physical adjustments. However, for patients who are just beginning to face breast cancer, ... particularly eager to understand the specific side effects of (the treatment) and how it would affect personally… and it would be beneficial to know the different levels of severity. I think this could be explored more thoroughly.'* (patient 06)

*'There should be a clear pathway on how to apply for financial assistance, including which channels to go through. This would help eliminate patients' worries about the financial burden during treatment. Many patients do not lack the belief to fight cancer.*

*The main issue is their family's financial situation. Continuing treatment could potentially overwhelm the entire household, which creates a lot of anxiety. However, if financial aid is available, they would have fewer concerns and might be more motivated to pursue treatment actively.'* (patient 08)

Subtheme 2 Expanded to action-based and peer-driven interventions

Suggestions included implementing peer support group formats (e.g. ward-based gatherings and peer salons) and introducing structured activities (e.g. developing hobbies, competitive challenges). Peer support groups were seen as valuable for facilitating emotional exchange and social bonding among patients with similar experiences or treatment stages. Such groups can provide platforms for mutual support and act as bridges between patients and healthcare professionals, thereby improving access to specialist knowledge and fostering reassurance. Structured activities were regarded as a practical means of encouraging psychological resilience and supporting adherence to daily routines.

*'The family support programme should not only remain at the level of verbal support, instead, more emphasis should be placed on actions. For instance, the programme could be extended into hospital wards or implemented in the form of small peer groups or micro-salons, which could function as bridges of friendship among patients, particularly among those with similar diagnoses or undergoing treatment at the same stage. ... patients with comparable educational backgrounds and life experiences could be brought together to open up and communicate in a safe space. ... These groups could also serve as a bridge between patients and medical staff: providing practical information, such as which doctors specialize in which specific areas. ... In this way, patients may feel more secure and informed throughout their treatment journey.'* (patient 20)

*'It may be beneficial to establish peer support groups to facilitate collective*

*behavioral change among patients. For example, implementing daily group activities such as sharing nutritional meal plans or logging physical exercise routines could help foster a positive atmosphere. Additionally, disseminating successful cases of individuals who have recovered well may enhance people's motivation. Spreading this kind of uplifting information can be very powerful and inspiring for everyone involved.'* (partner 06)

*'I often persuade my wife, who is currently undergoing chemotherapy, to engage in hobbies like embroidery or calligraphy. For people like us, having hobbies is rare. Our working lives leave little room for leisure. But for her, this might be a suitable period to cultivate new interests. It might also be helpful to share examples of what others have done during this stage of treatment, as a way to create emotional resonance and mutual encouragement.'* (partner 24)

Subtheme 3 Diversified modes of delivery for educational materials

Thirdly, women and partners suggested that the delivery formats of the educational materials within the programme should be diversified. Short videos, visual slides and concrete examples were preferred over lengthy and text-heavy documents. Such changes were seen as ways to enhance engagement with the content, reduce anxiety and enable participants to take more informed and proactive roles in their care.

*'I feel that the document is full of text, and it is not very engaging or clear. If it were made into a PPT format, with just a few key words highlighted on each slide, I think it would be more effective. Combined with your verbal explanation during the session, it would probably be more vivid and easier to follow. The current PDF feels a bit too wordy to me.'* (patient 13)

*'Many people are now addicted to short videos. … Some people prefer talking, some prefer quiet reading, and more people nowadays enjoy watching short videos. If you*

*edit and create short videos to explain, I think it would be more effective. You could show these videos before session, like a preview, so that later, when they have more information, they can understand the key points. For example, during the session, we could outline the main points before starting, go over them in detail, and then summarize the key takeaways at the end. This would make the content more systematic and easier to follow.'* (patient 08)

8.6.4 Theme 4 Challenges in practising and sustaining the intervention

Couples reported that their attitudes changed positively after the first session because they recognised the programme's value in improving understanding of the diagnosis and in alleviating anxiety. Women often encounter barriers to openness in everyday life, particularly when discussing their illness. Although they may gradually come to terms with their condition, challenges remain when communicating with others. Conversations with people who do not share the experience of the disease are often met with superficial or anxious responses, such as being told to 'be strong', which do little to address the genuine emotional and physical pain they endure.

Sub-theme 1 Challenges and Conflicts in Participation

Women and partners initially expressed scepticism towards the family support programme, with some feeling uncertain or perceiving it as a potential sales pitch. Over time, however, they came to recognise its value in enhancing understanding of their diagnosis and alleviating anxiety. Challenges included scheduling conflicts and limited partner engagement, but in several cases, once participants committed to the programme, they found it helpful and appreciated the guidance, having a positive shift in attitude.

*'Before participating, I thought you (the facilitator) might be some kind of salesperson. After my wife was diagnosed, the doctor's suggestions and treatment plans were always vague and unclear. There was no definitive answer. He left it up*

*to us to choose, but didn't explain exactly what would happen if we didn't go with a particular option. ... But after talking to you (the facilitator), I think maybe you were just hired by the hospital to guide us into accepting a particular plan. That was my initial impression. However, after spending more time and getting to know you, I realized I was overthinking it.'* (partner 08)

*'In my previous experiences, some facilitators treated the sessions like a task or just going through the motions. They would just say a few words and stop. I had no interest in really engaging. But I saw that you were genuinely dedicated every time, and I could tell you (the facilitator) really take it seriously. After attending these sessions, I truly learned a lot, so I am willing to listen, learn, and understand more. I really feel like I gained something valuable.'* (patient 12)

*'I was very busy before and didn't feel like I had the time to take the family support programme. My life was still in chaos. ... In the beginning, I was a bit frustrated, and there were also many things to deal with, so I didn't want to bother with these complicated matters.'* (patient 01)

*'Before attending, my husband was also quite busy, and we didn't have much time together at that point. Now, he made some adjustments and is trying to spend more time with me. During that time, I did not attend the first session, and I wasn't sure what the family support programme would be. But after I attend the first session, I realized it was really beneficial.'* (patient 16)

*'Sometimes I have a lot of things to deal with, and it can be inconvenient. There are times when I was not at home, and talking about this (the disease) while I was out made me feel quite inappropriate. I also do not always check my phone regularly, so I occasionally miss your messages and forget to reply.'* (patient 22)

*'My unavailability may have caused some inconvenience for you.'* (partner 24)

*'The challenges might be having my partner accompany me to attend the sessions. Besides work, he did not understand or have a mindset for it. He did not listen, learn, and engage, and this is his attitude. I feel like he did not care about what I am going through. It is because of my family situation, and it really frustrates me.'* (patient 13)

Sub-theme 2 Barriers to openness in daily life

Women reported finding it more comforting to speak those who genuinely understood their experiences, such as the facilitator and fellow patients who can empathise with the specific anxieties and challenges of undergoing treatment. These connections provided essential emotional support and a safe space for sharing, which was not always available in their everyday interactions.

*'You speak in such a warm and friendly way, which feels like chatting with a friend. Honestly, even when I talk to my own friends, it doesn't feel like this. Like you said, they can't really relate to what I'm going through, but you can. That's why I'm very willing to talk with you.'* (patient 16)

*'Patients really need someone who can listen to them, as others may not fully understand. For example, some people, who don't understand, might say things like 'there's no need to worry' or 'what's there to worry about?' but they can't truly grasp what it feels like."* (patient 24)

## 8.7 Chapter summary

A two-arm parallel-group RCT was conducted with 90 couples coping with breast cancer, with 45 couples randomly allocated to either the intervention arm, which received the six-weekly family support programme delivered via WeChat by the

doctoral student, or the control group, which received six-weekly follow-up WeChat calls delivered by a registered nurse. GLMMs were used to examine the effectiveness of the family support programme, and Cohen's *d* was calculated to estimate between-group effect sizes for outcomes in women and partners at T1 and T2. Compared with the control group, the family support programme demonstrated short-term effects with medium effect sizes in reducing women's social constraints (β = −2.83, 95% CI [−5.61, −0.05], P = 0.046, Cohen's *d* = 0.444), intrusive thoughts (β = −1.85, 95% CI [−3.48, −0.23], P = 0.025, Cohen's *d* = 0.462) and anxiety (β = −2.22, 95% CI [−4.32, −0.12], P = 0.039, Cohen's *d* = 0.423) and in reducing partners' FCR (β = −4.11, 95% CI [−7.47, −0.75], P = 0.018, Cohen's *d* = 0.521). The Group × Time × Role interaction for intrusive thoughts (β = −3.17, 95% CI [−5.59, −0.75], P = 0.010) and anxiety (β = −2.76, 95% CI [−5.43, −0.08], P = 0.044) was significant at T1, indicating that women experienced a greater short-term reduction in these outcomes than their partners. Qualitative interviews were conducted with participants following completion of the family support programme to serve as a process evaluation of the RCT. A total of 23 interviews (six women and 17 couples) were transcribed and analysed using thematic analysis. Four key themes emerged from the qualitative data: comprehensive and practical features of the intervention, perceived benefits of the intervention, strategies to promote and sustain the intervention and challenges in practising and sustaining the intervention. The findings from the RCT are discussed in the following chapter.

# CHAPTER NINE: DISCUSSION OF THE FINDINGS FROM THE RCT

## 9.1. Introduction

This chapter discusses and interprets the main findings of the RCT. The results of this study are compared with those of similar investigations, including studies employing disclosure-based interventions in women with breast cancer and their partners and family-based interventions aimed at improving health outcomes in couples coping with breast cancer. The chapter also addresses the strengths and limitations of the study and concludes with a brief summary.

The chapter is organised into six sections. Section 9.1 provides an introduction. Section 9.2 presents a discussion of the feasibility outcomes. Section 9.3 examines the efficacy of the intervention among couples. Section 9.4 discusses the findings from the qualitative process evaluation of the RCT. Section 9.5 outlines the strengths and limitations of the study. Finally, Section 9.6 provides a summary of the chapter.

## 9.2 Discussion for feasibility outcomes

Five feasibility outcomes, namely, eligibility screening, participant recruitment, intervention adherence, attrition and delivery mode, were used in evaluating the feasibility of conducting the RCT and delivering the family support programme to couples coping with breast cancer.

### 9.2.1 Eligibility screening

Recruiting couples for interventional studies remained challenging, although the eligibility rate in the RCT (27.40%) was higher than that observed in the pilot pre–post study (17.09%). The two primary reasons for the low eligibility rate were ‘lack of interest’ (115 women and 40 partners) and ‘unavailability’ (59 women and 159 partners). During the project introduction, the study emphasised that the family support programme included healthy lifestyle guidance for cancer management and strategies to prevent recurrence, aiming to enhance perceived relevance and motivate potential

participants. Several factors may have contributed to the reported lack of interest. Firstly, the research team was not permitted to display study posters in the ward, relying instead on ward staff to promote the RCT. Although this strategy was effective in the initial recruitment phase, staff engagement gradually diminished over time. Secondly, comprehensive outreach to all breast cancer patients in the wards was not achieved given that ward staff were responsible for only a subset of patients, and not all staff members participated in promoting the study. Additionally, some potential participants, particularly those undergoing chemotherapy, did not have sufficient time to receive a full introduction and explanation of the study because of high patient turnover, which further limited recruitment coverage. Thirdly, two other nursing-related projects targeting the same population were ongoing during the recruitment phase, leading to patient fatigue from being repeatedly approached for different studies. Finally, some couples perceived participation as demanding because it involved attending multiple intervention sessions and completing three rounds of questionnaires. For patients and partners already coping with the challenges of cancer treatment, employment and caregiving responsibilities, the perceived time commitment and burden may have deterred engagement.

Several factors may explain the unavailability of 59 women and 159 partners. For some women, particularly those undergoing chemotherapy, balancing regular treatment cycles with employment commitments significantly restricted their availability to participate in research. Many women reported experiencing fatigue, nausea or general malaise during chemotherapy, which reduced both their willingness and capacity to engage in the study. Such adverse physical effects, common during and after chemotherapy, may substantially limit patients' energy and motivation to participate in additional psychological or behavioural activities beyond routine treatment. For partners, the majority were employed and typically assumed increased caregiving and domestic responsibilities after the women's diagnosis, which further constrained their availability to participate in the study.

To improve the eligibility rate in future studies, several strategies may be considered. Firstly, collaboration with hospitals can be strengthened by inviting hospital staff to participate as co-investigators, thereby securing full institutional support for the study. Their involvement would facilitate more effective promotion, such as displaying study posters in wards and providing direct recommendations to potential participants. Secondly, engaging additional hospitals would expand the eligible participant pool. Finally, to reduce the time burden on participants, the intervention can be modified to incorporate video presentations of the educational materials, supplemented by WeChat calls.

### 9.2.2 Subject recruitment

The recruitment rate in the RCT was 49.18%, representing a substantial improvement compared with the pilot study (25.00%). The primary factor affecting recruitment in the current study was the failure to complete the baseline questionnaire (66.67%) often because of perceptions that it was lengthy or burdensome. Nonetheless, the recruitment rate in this doctoral study was not low and was comparable to previous research involving couples affected by cancer. Three studies examining couples coping with breast cancer reported recruitment rates ranging from 13.1% to 50% (Fergus et al., 2014; Fredman et al., 2009; Shields & Rousseau, 2004). Across 17 cancer studies involving couple-based interventions included in a review published in 2013, 48.8% of eligible couples agreed to be randomised, with recruitment rates ranging from 13% to 94.1%. Specifically for breast cancer, the average recruitment rate was 45.3% (Regan et al., 2013). Furthermore, the recruitment rates of seven RCTs from a recent systematic review in 2023 on couple-based communication interventions for cancer ranged from 15.2% to 95.7%, with five reporting rates below 34% and two exceeding 89% (Zhou et al., 2023). Commonly reported reasons for declining participation included being too busy, living too far away, poor health, lack of interest or perceiving no need for the intervention (Zhou et al., 2023). The use of WeChat as the delivery mode in the current

RCT likely mitigated issues related to distance, as participants were not constrained by travel time, costs or logistics when attending the family support programme.

The lengthy baseline outcomes questionnaire also contributed to non-completion among potential couples, thereby lowering the recruitment rate. Consequently, future studies should consider streamlining the assessment measures, for example by excluding scales on stigma. This observation also highlights the need to develop abridged versions of validated scales to reduce the burden of questionnaire completion. Additionally, conducting the study while women with breast cancer are hospitalised may provide them with more free time to gain a thorough understanding of the study and appreciate the potential benefits of the family support programme.

### 9.2.3 Intervention compliance

In this doctoral study, the compliance rate in the intervention group was high among women with breast cancer (84.44%) and moderate among partners (46.67%). None of the seven RCTs employing family involvement interventions for FCR management in women with breast cancer and their caregivers, as reviewed in Chapter Three, reported intervention compliance (Bu, Jiang, et al., 2025a), and thus direct comparisons with previous studies were impossible. In the current RCT, two couples in the intervention group and four couples in the control group did not attend any sessions. The main factors hindering attendance were distressing symptoms following chemotherapy in patients (e.g. fatigue, nausea and vomiting) and unavailability of partners. These barriers are largely unavoidable. Despite a modest recruitment rate, the high compliance observed reflects the acceptability of, and the perceived value attached to, the family support programme by participants.

Compared with the pilot study, the compliance rate improved substantially in this RCT. In the pilot study, 28 out of 45 couples (62.22%) did not attend any sessions, whereas in the current RCT this number fell to 6 out of 90 couples (6.67%). This improvement

can be attributed to a key modification to the family support programme based on the pilot study findings: initiating Session 1 immediately after completion of the baseline questionnaires, particularly while patients were still hospitalised. By contrast, couples who had not started the programme before discharge were difficult to reach, as they often did not respond to WeChat messages once at home. Conducting the first session during hospitalisation was therefore a practical strategy, allowing in-person engagement, helping participants appreciate the potential benefits of the programme and enhancing their motivation to continue participating.

### 9.2.4 Attrition

In this RCT, the attrition rate for women was 10.00% at T1 and 13.33% at T2, while for partners it was 14.44% at T1 and 15.56% at T2. These rates are comparable to those reported in the RCTs discussed in Chapter Three, where attrition ranged from 0 to 24.18%, and in studies of couple-based interventions for breast cancer patients, which reported an average attrition of 14.8% at the first follow-up (mean = 11 weeks from baseline) and 19.4% at the final follow-up (mean = 33 weeks from baseline) for patients, with corresponding rates of 16.9% and 26.7% for partners (Regan et al., 2013). Although attrition above 20% is conventionally considered high (Higgins, 2019), studies involving metastatic breast cancer have reported attrition rates ranging from 9% to 53% (Nuzzolese & Montemurro, 2020), suggesting that the attrition observed in this RCT is acceptable.

### 9.2.5 Delivery mode

Similar to the pilot study, some couples in the qualitative interviews highlighted the convenience and acceptability of receiving sessions via WeChat, while others suggested that face-to-face delivery might be more effective. The ability to access intervention sessions from home, without the need to travel, was particularly appreciated by couples with jobs or caregiving and household responsibilities. This flexible format enabled them to integrate the intervention into their daily routines more easily. However, several

participants expressed a preference for face-to-face sessions, noting that in-person delivery can enhance engagement and emotional connection. Non-verbal communication, such as facial expressions, eye contact and gestures, and timely emotional responses, which are often weakened or lost in virtual interactions, can be addressed in face-to-face settings. For future practice, a hybrid delivery mode can be considered, combining the flexibility of online sessions with face-to-face interactions to accommodate the schedules and needs of different couples. This hybrid approach is supported by previous studies in cancer populations (van de Wal et al., 2017, 2018). For example, evidence from an RCT demonstrated a favourable effect of blended cognitive behavioural therapy (CBT) on FCR in 88 breast, prostate and colorectal cancer survivors, consisting of five face-to-face and three online sessions ($P < 0.0001$, van de Wal et al., 2017). Additionally, a breast cancer case study showed sustained improvement following seven face-to-face sessions and one phone session, with benefits still evident at six- and twelve-month follow-ups (van de Wal et al., 2018).

### 9.3 Discussion of the efficacy of the intervention among couples

The study found that the family support programme had a short-term effect in reducing FCR in partners, with a moderate effect size. However, the impact on FCR in women with breast cancer was not statistically significant, despite the decreases in FCR levels over time being more apparent in the intervention group than in the control group. Among women with breast cancer, the programme demonstrated short-term effects in reducing social constraints, intrusive thoughts and anxiety at T1, with moderate effect sizes. Notably, the programme exhibited significant differential effects by role on intrusive thoughts and anxiety, with women experiencing a greater short-term reduction in these outcomes than their partners at T1. For avoidance, a smaller decrease at T1 but a larger decrease at T2 was observed in the intervention group than in the control group. Regarding stigma, three subscales (self-perception, social isolation and discrimination) showed similar reductions in both groups, and decreases in overall stigma and the self-image disorder subscale were more pronounced in the intervention group. Among

partners, although the family support programme did not have significant effects on the secondary outcomes, reductions in social constraints, overall affiliate stigma and the social isolation subscale at both T1 and T2 were more apparent in the intervention group than in the control group. Reductions were similar in three stigma subscales, namely, internal stigma, perceived stigma and reaction, across both groups. However, reductions in intrusive thoughts and anxiety were larger in the control group at both T1 and T2. For avoidance, the intervention group showed a larger reduction at T1, which became smaller than that of the control group at T2.

The following sections discuss the results of the co-primary and secondary outcomes in the couples.

### 9.3.1 Co-primary outcome

#### 9.3.1.1 FCR

FCR in women with breast cancer

The study found that the effect of the family support programme on FCR in women with breast cancer was not significant at post-intervention or at the 12-week follow-up. This finding is not consistent with the meta-analytic results on family involvement interventions for FCR management presented in Chapter Three (Bu, Jiang, et al., 2025a). One possible explanation is that, although the family support programme was structured, it may not have been intensive enough to sustain long-term behavioural and cognitive changes. Unlike trials that incorporated booster sessions or prolonged follow-up support (Northouse et al., 2005), the programme in this RCT did not include any sessions beyond the initial six weeks. Another potential reason is the use of an active control group in this RCT, compared with the ‘usual care’ control groups in the RCTs included in the meta-analysis (Bu, Jiang, et al., 2025a). Participants in the control group in this study received six professional follow-up calls via WeChat, delivered by a registered nurse in oncology. This platform provided ongoing access to healthcare professionals, which may have functioned as an additional form of intervention, thereby

reducing the difference in FCR changes between the groups. This could explain why both groups demonstrated substantial reductions in FCR. Furthermore, the longer follow-up period in this RCT may have attenuated the observed short-term advantage of the intervention, as earlier RCTs (Chapter Three) often measured outcomes immediately post-intervention without extended follow-up assessments.

Interestingly, partners in the intervention group experienced a significantly greater reduction in FCR than those in the control group. There are some potential explanations. Firstly, the family support programme included education on physical activity and healthy dietary practice. Women's illness representation may be reduced by encouraging them to do physical activity and healthy dietary practice. Besides, they may perceive lower cancer recurrence rate by providing knowledge on psychosocial factors related to recurrence and physical activity and healthy dietary, improving their perception of cancer recurrence. Based on Lee-Jones et al., (1997) and Simonelli et al., (2017), once women's illness representation improved and grasped knowledge of prevention cancer recurrence, partners may perceive a sense of control, contributing to their alleviated FCR. Meanwhile, the partners know how to support the women, and perceive it meaningful to provide food and accompany them doing activity, reducing their FCR. Another component is disclosure. It addressed their overlooked emotional needs, though the social constraints and intrusive though with small decrease, but small change may also contribute the significant drop of FCR. Other possible explanation is that many partners in the control condition did not actively engage with the WeChat sessions, limiting their exposure to professional support. By contrast, the family support programme offered partners structured opportunities for disclosure and education, which may have addressed their frequently overlooked emotional needs. Another contributing factor could be the inclusion of healthy dietary education in the programme. As primary caregivers responsible for meal preparation, partners may have found this information directly relevant to their caregiving role, enhancing their sense of control and reducing anxiety about recurrence. Compared with women, who often already had

multiple channels of professional support, partners may have derived unique benefits from these tailored elements.

As reported by participants in the qualitative process evaluation of this RCT, incorporating advanced clinical knowledge and objective indicators could enhance motivation to engage in healthy lifestyle behaviours. Therefore, future studies can consider including clinical information, such as biological markers, including NK cell activity, cortisol rhythms and cytokine levels, within the family support programme. Providing such objective evidence of the underlying psychoneuroimmunological mechanisms in reducing cancer recurrence (Fairey et al., 2005; Ramirez et al., 2017) can increase participants' engagement in programme activities. This approach not only would strengthen the clinical relevance of the family support programme but also would facilitate its integration into survivorship care plans. By demonstrating improvements at psychological and biological levels, interventions can achieve greater acceptance, thereby supporting the notion that the programme can address both emotional well-being (i.e. FCR) and physical health outcomes if positive results are observed.

FCR in partners

Although the positive effect of the family support programme on FCR in partners was not sustained at the 12-week follow-up, a moderate interventional effect size of 0.466 was observed. Several factors may explain this finding. Firstly, FCR is a chronic and fluctuating concern, often triggered by upcoming follow-up appointments, new symptoms or abnormal test results (Simonelli et al., 2017). Without ongoing support, partners may gradually revert to previous maladaptive coping strategies, such as emotional suppression or protective buffering, which can reactivate FCR. The family support programme was delivered over a limited period without booster sessions or follow-up support, and thus maintaining behavioural and emotional changes over the longer term was difficult. Secondly, as suggested by the qualitative findings, partners often prioritised their caregiving roles over their own emotional needs. Over time,

competing family and work responsibilities may have limited their ability to continue applying the strategies learned in the programme, reducing its long-term impact. To achieve more sustainable effects, future interventions could incorporate booster sessions after the initial programme to reinforce skills in disclosure, coping and healthy lifestyle practices. Additionally, some sessions in this RCT were conducted individually for partners who were unable to attend joint sessions with the women. Facilitator observations indicated that partners may benefit more from one-to-one sessions because they tended to disclose more openly than in couple-based sessions. Tailoring the intervention to address partners' unique emotional needs and caregiving burdens could further enhance the long-term effects of the family support programme. Future studies should consider developing and evaluating tailored interventions for this subgroup of partners to optimise outcomes.

Research on reducing FCR in caregivers of women with breast cancer remains limited. Only a few interventional studies have reported FCR outcomes in caregivers of patients with cancer. Two studies focused solely on caregivers of women with breast cancer (Northouse et al., 2005; Zhang & Kwekkeboom, 2020), one targeted women with breast or gynaecological cancer (Heinrichs et al., 2012) and one included caregivers of adults with cancer (Lamarche, Nissim, et al., 2025). All were RCTs except Zhang & Kwekkeboom (2020), which employed a pre-post design. The interventions in these studies involved psychological support incorporating disclosure, training in behavioural and cognitive coping skills or communication training, with total durations ranging from 5.5 hours to 14 hours. The three RCTs reported non-significant effects on caregivers' FCR, and Zhang and Kwekkeboom (2020) even found an increase in caregivers' FCR following the intervention. These findings suggest that the length or content coverage of the interventions may not be the critical factors in reducing caregivers' FCR. However, these studies share several limitations, including small sample sizes, heterogeneous populations (often involving mixed cancer types or lacking subgroup analyses) and absence of long-term follow-up. Given that the family support

programme in this RCT demonstrated positive short-term effects on partners' FCR, future research can incorporate booster sessions or ongoing support to sustain these benefits and integrate more personalised content, targeting disclosure and coping strategies specific to partners. Similar to recommendations for women with breast cancer, measuring biological markers such as NK cell activity, cortisol rhythms and inflammatory cytokines can provide objective evidence of psychoneuroimmunological pathways linking emotional changes to health outcomes, thereby enhancing partners' motivation to support women in engaging with healthy lifestyle practices.

### 9.3.2 Co-secondary outcomes

#### 9.3.2.1 Social constraints

Social constraints in women with breast cancer

Social constraints in women decreased significantly at T1, although the effect diminished by the T2 assessment. Social constraints refer to external and peripheral conditions, including others' actions, thoughts and emotions, which shape an individual's own responses (Lepore & Revenson, 2007). Women with breast cancer and their partners commonly encounter social constraints, such as criticism, denial or withdrawal from others. These experiences often leave individuals feeling unsupported, misunderstood or isolated when seeking social support or attempting to express themselves (Bu, Chen, et al., 2025; Lepore & Revenson, 2007). A core component of the family support programme was structured disclosure, and four sessions addressed different topics: communicating feelings, breast cancer influences, post-traumatic growth and coping and expectations. Sessions 1 and 2 and part of Session 3 focused on breast cancer treatment, physical activity, healthy diet and psychosocial factors related to recurrence. These educational components complemented disclosure topics, facilitating ongoing conversation between couples and providing repeated opportunities for emotional sharing in subsequent sessions (Sessions 3–6). The supportive and structured environment likely contributed to the observed reduction in social constraints. The potential reasons as follows:

(1) Safe and supportive environment. Based on Simonelli et al (2017) and Lepore & Revenson (2007), their social constraints reduce through disclosure. The programme was delivered individually to each couple, providing a secure space for expression. Compared with group-based sessions, individual sessions reduce the embarrassment or inhibition that may arise from sharing negative feelings in front of strangers. Qualitative research has shown that dissatisfaction with support groups can lead participants to leave or avoid such groups if they cannot relate to other members or find the group unsuitable (Ussher et al., 2008). In this RCT, process evaluation indicated that the facilitator maintained a safe atmosphere, guided conversations, modelled empathetic listening and prevented misunderstandings or conflicts (Mackie et al., 2024).

(2) Role of the facilitator. Women often reported feeling misunderstood when discussing worries with others, yet they felt deeply understood by the facilitator, who combined empathy with professional medical and psychological knowledge. This trust increased women's willingness to disclose, thereby reducing perceived social constraints.

(3) Practice of disclosure. The family support programme reduced women's inhibition in sharing their thoughts and feelings by encouraging disclosure, which in turn helped to reduce psychological burden. Research has shown that women with breast cancer and their partners often engage in protective buffering, making efforts to shield their partner from distress by concealing or minimising cancer-related worries and yielding to avoid disagreements. The facilitator observed that prior to attending the programme, couples tended to avoid discussing cancer or related worries in order to protect each other and reduce mutual distress. During the programme, the facilitator sought to change their beliefs about emotional disclosure by emphasising that sharing concerns in a supportive context can alleviate stress, foster mutual understanding and strengthen emotional intimacy. As a result, women became more willing to express themselves. Furthermore, couples were encouraged to practise disclosure three times a week, which reinforced the habit and promoted more open communication. As women engaged in greater disclosure, their perceived social constraints naturally decreased.

Although the family support programme effectively reduced social constraints in women with breast cancer at T1, this effect was no longer evident at T2. The reduction in social constraints can be considered an immediate response to the programme. However, once the sessions ended, these improvements were not sustained. This finding have two potential explanations.

(1) Unchanged communication patterns of partners. Although social constraints in partners decreased, the change was not statistically significant compared with the control group, suggesting that some partners may have maintained similar communication patterns as before. Since social constraints are shaped by the responses and actions of others, long-term effects require dynamic changes in both women and their partners. If partners continue to engage in protective buffering and remain reluctant to disclose, women may gradually revert to previous patterns of emotional suppression. Consequently, the initial reduction in social constraints among women diminished over time. Future studies may explore strategies to facilitate open and sustained disclosure among partners.

(2) Lack of continued practice. After the programme ended, women no longer had the opportunity to practise disclosure in the safe and supportive environment created by the facilitator. During the sessions, women felt understood and supported, which encouraged them to share openly. Social constraints may be deeply rooted in Chinese culture, and achieving long-term improvements may require concerted efforts from women, partners and their wide social network. To sustain the effects on social constraints, the family support programme could be extended in duration and supplemented with booster sessions. Furthermore, involving more family members, such as parents and children, could enhance understanding of the caregiving process and foster appropriate responses to women's psychosocial needs, thereby promoting healthier family communication as a unit.

The findings on social constraints from this RCT add evidence supporting the use of

multicomponent interventions to reduce social constraints in adults with cancer. Expressive writing has been a commonly used strategy to alleviate social constraints, typically aiming to reduce physical and psychological symptoms by encouraging individuals to explore deeper thoughts and emotional experiences (Tonarelli et al., 2017). However, a recent review found limited evidence supporting expressive writing alone in reducing social constraints (Bu, Chung, et al., 2025). Social constraints are characterised by objective, external factors, including other people's actions, thoughts and emotions (Lepore & Revenson, 2007). Because expressive writing primarily targets individuals' internal processes while neglecting external sources of constraint or responses to these sources, its capacity to reduce social constraints may be limited. Synthesis of three RCTs focusing on social constraints in women with breast cancer suggests that expressive writing, when supplemented with psychological adjustment interventions, may be more effective than expressive writing alone. Two RCTs that used expressive writing only reported non-significant changes (de Moor et al., 2008; Jensen-Johansen et al., 2013), whereas an RCT using psycho-educational writing supported by audio-visual content on psychological adjustment to cancer observed a significantly greater decrease in social constraints from baseline to during and after the intervention compared with the control group ($P < 0.05$, Lally et al., 2019). The RCT in this doctoral study employed the integrative model for FCR proposed by Simonelli et al. (2017), which synthesises six theoretical frameworks relevant to understanding FCR and emphasises the importance of targeting both personal and environmental factors to reduce social constraints, thereby alleviating FCR and related psychological distress. Future interventions could incorporate multicomponent strategies and booster sessions to determine whether such interventions produce larger effect sizes and promote long-term, sustainable reductions in social constraints.

Social constraints in partners

While the family support programme provided a supportive environment and improved women's short-term social constraints, the level of social constraints in partners did not

decrease significantly neither at six weeks post-intervention nor at the 12-week follow-up. Social constraints are negative social responses to attempts to discuss the cancer experience, and they are typically modifiable through disclosure in a supportive environment. Several factors may account for the non-significant results in partners in this RCT:

(1) Cultural expectations of emotional expression. Social norms regarding masculinity and femininity influence the expression of emotions (Wester et al., 2002). Men often exhibit restrictive emotionality, inhibiting the expression of certain feelings and being reluctant to self-disclose in daily life (Fischer, 2000). By contrast, women express emotions more frequently on average (Kring & Gordon, 1998). Consequently, male partners may find it difficult to share feelings, worries, and concerns in line with their perceived gender role (Hilton et al., 2000; Zahlis & Lewis, 2010). Most partners in the family support programme disclosed less during the four disclosure sessions compared with the women with breast cancer. Women's greater willingness to disclose provided them with more opportunities to share with patients in the wards, friends and relatives. Partners, on the other hand, often suppressed their emotions and maintained high levels of protective buffering, which limited reductions in social constraints.

(2) Lower disclosure session attendance. Partners missed nearly three times as many disclosure sessions as women, with 31 sessions missed by women and 89 by partners. This lower exposure suggests that the effect of the family support programme on social constraints in partners may not have been fully realised, which could partly explain the non-significant results. Social constraints involve perceptions of emotional inhibition and communication barriers; therefore, regular participation in structured sessions is likely necessary to achieve meaningful changes. With reduced exposure, partners may not have received sufficient guidance and opportunities for disclosure to facilitate change.

(3) Low engagement and participation. Beyond lower session attendance, qualitative interviews revealed limited engagement of partners in the disclosure process. Consistent with the literature (Hasson-Ohayon et al., 2022), some partners perceived

the intervention as irrelevant to them, viewing themselves solely as caregivers and believing the primary beneficiary was the woman. For example, when asked about their feelings or worries, some partners responded: 'You may talk to the patient about this, it's not really about me' and 'Your main focus is on solving her problems. I have nothing to disclose. Once she gets better, I would be fine too'. These statements reflect a perception that they had no major role in the intervention, reducing their motivation to engage fully. These responses also indicate that some partners' emotional needs were not fully addressed by the programme. This was further observed during individual sessions offered to partners who could not attend the joint sessions with the women. In these one-to-one sessions, some partners disclosed more openly than in couple-based sessions, suggesting that private interactions with the facilitator provided a safer space for expressing fears, concerns and emotional struggles. To enhance the family support programme, it may be beneficial to offer greater flexibility in the structure of disclosure sessions for partners. A hybrid model combining joint couple sessions with individual sessions for each partner can be considered. This approach accommodates busy schedules, allows both members to benefit from shared emotional communication and creates space for personal reflection and expression.

The non-significant findings in social constraints among partners of women with breast cancer are consistent with previous research. In a recent review of RCTs aimed at alleviating social constraints in adults with cancer and their caregivers (Bu, Chung, et al., 2025), only one study reported results for caregivers of patients with lung cancer, which were also non-significant (Mosher et al., 2016). This RCT compared an intervention guided by cognitive-behavioural and emotion-focused therapy and was designed to manage anxiety, depressive symptoms, pain, fatigue and breathlessness, using strategies, such as relaxation, cognitive restructuring, problem-solving, self-soothing/emotion-focused approaches, pleasant activities, activity pacing, communication and planning for continued skills practice. Additionally, an educational support intervention was implemented to modify social constraints. Similar to our RCT,

a greater decrease in social constraints was observed in the intervention group, although this difference was not statistically significant (Mosher et al., 2016).

Although this RCT adopted a dyadic approach to cultivate a supportive environment by offering assistance to both individuals in the couple (Bu, Jiang, et al., 2025b), the intensity of the family support programme for partners appears to have been insufficient. Future studies should explore techniques to engage partners more effectively in disclosure, such as adopting a hybrid approach that provides flexible structures and individual sessions tailored to partners' specific needs.

#### 9.3.2.2 Intrusive thoughts

Intrusive thoughts in women with breast cancer

The family support programme significantly reduced intrusive thoughts in women with breast cancer at post-intervention, but this effect was no longer statistically significant at 12 weeks. These results are similar to those observed for social constraints in women with breast cancer, which aligns with the predictions of the Simonelli's integrative model of FCR (2017) and Lepore & Revenson (2007): reducing perceived social constraints enables more complete cognitive processing, helping women to reappraise their cancer experience and integrate it into their life narrative and thereby reducing intrusive thoughts. Our RCT delivered the intervention via WeChat and demonstrated effective results, consistent with a recent systematic review concluding that telehealth programmes are effective in reducing intrusive thoughts in women with breast cancer (Koç et al., 2024). The significant impact of the family support programme delivered via WeChat in this RCT provides further evidence supporting the expansion of telehealth interventions. Telehealth offers advantages, such as time and cost savings, easy accessibility and the potential for effective implementation by nurses to support the mental health of women with breast cancer.

However, the effect of the family support programme on intrusive thoughts disappeared

at 12 weeks. This finding is consistent with some previous RCTs. One RCT explored the long-term effects of an eight-week psychoeducational group intervention at 12 months in African American women with breast cancer. Similar to the RCT in this doctoral study, intrusive thoughts were not the primary outcome and showed non-significant results (Taylor et al., 2003), suggesting that both studies may have lacked sufficient power to detect between-group differences in intrusive thoughts. Another study employed a management intervention consisting of a scripted CD and guide booklet, supplemented by four scripted 20-minute weekly training calls conducted by nurse interventionists, while the control group received only the weekly calls. This study also reported non-significant results at post-intervention and follow-up (Germino et al., 2013). Overall, these findings indicate that psychologically focused interventions alone may not be sufficient to achieve long-term reductions in intrusive thoughts.

Using medication to manage intrusive thoughts is a potential approach. A few studies have examined the effects of medication on intrusive thoughts. One study reported that beta-blockers reduced negative intrusive thoughts in adults with cancer, while another found no evidence of a protective effect of beta-blocker therapy against intrusive thoughts (Ehrencrona et al., 2024; Lindgren et al., 2013). Heightened emotional arousal following a major stressor can sustain adrenergic activation, increasing the risk of post-traumatic symptoms. Antihypertensive beta-blockers block adrenergic activation and are known to reduce traumatic memories and associated distress (Lindgren et al., 2013). However, no meta-analytic studies have synthesised the evidence regarding the effects of beta-blockers on intrusive thoughts. Therefore, if future meta-analyses support the efficacy of beta-blockers in reducing intrusive thoughts, studies could combine the family support programme with beta-blocker therapy to enhance both short-term and long-term improvements in intrusive thoughts. This approach would integrate a biological mechanism of pharmacological adrenergic dampening as a possible adjunctive route. Physiological markers, such as heart rate and cortisol levels, could be incorporated to assess how reductions in adrenergic activation mediate psychological

and intrusively triggered responses.

Intrusive thoughts in partners

The family support programme showed non-significant effects on intrusive thoughts in partners, neither post-intervention nor at the 12-week follow-up. Several factors may explain this. Firstly, session attendance among partners was notably lower than among women with breast cancer, with a mean of 5.18 sessions attended by women and 3.69 by partners. With fewer opportunities to engage in structured disclosure and emotional processing, partners may not have received sufficient dosage of the intervention to achieve meaningful reductions in intrusive thoughts. This is supported by the observation that women in the intervention group showed greater reductions in mean intrusive thought levels than their partners at both T1 and T2. Secondly, all partners were male, and prior research indicates that men are more likely to inhibit emotional expression and avoid discussing fears due to gender role expectations (Hilton et al., 2000; Zahlis & Lewis, 2010). This restrictive emotionality may have limited partners' willingness to engage fully in emotional disclosure, thereby reducing the intervention's impact on intrusive thoughts. Finally, although the intervention targeted the couple, its content was primarily tailored to women's needs, such as disease management and coping with treatment side effects. Partners may have benefited from additional individual sessions specifically addressing their caregiving responsibilities, personal fears and coping strategies. These factors likely account for the differential effects of the family support programme on intrusive thoughts between women with breast cancer and their partners in this study.

9.3.2.3 Avoidance

Avoidance in women with breast cancer

According to Simonelli's integrative model of FCR (Simonelli et al., 2017), avoidance is a key component in cognitive processing and appraisal. Avoidance prevents individuals from fully engaging with the cognitive and emotional processing of cancer-

related experiences, thereby sustaining negative appraisals. The present study found no significant change in avoidance among women with breast cancer, which may be explained by several factors. Firstly, avoidance is a deeply ingrained emotional regulation strategy. Experiential avoidance can create a cycle of emotional suppression, attentional bias towards threat-related cues and impaired working memory and cognitive flexibility (Wang et al., 2024). This pattern may reinforce negative interpretations of cancer-related stimuli rather than resolving them. Although the family support programme promoted disclosure, it did not include components specifically targeting avoidance. Without directly addressing avoidance, behavioural patterns reinforced over time are unlikely to change. Meta-analytic evidence suggests that acceptance and commitment therapy (ACT) can reduce experiential avoidance in cancer survivors (Yin et al., 2025). Therefore, future studies may incorporate ACT strategies to help individuals accept their thoughts without struggling against them, thereby reducing their negative impact (Hayes et al., 2006). Integrating such strategies into family-based interventions may facilitate deeper emotional processing and lead to greater reductions in FCR.

Avoidance in partners

Similarly, avoidance was not improved among partners at any assessment time point. Several factors may explain these findings. Firstly, as indicated by the qualitative interview results, many partners relied on emotional suppression as a coping strategy. Their gender role may predispose them to suppress emotions, thereby reinforcing avoidance (Hilton et al., 2000; Zahlis & Lewis, 2010). Without targeted components addressing these coping tendencies, partners may not have been motivated to explore or modify their avoidance. Secondly, partners' engagement in the intervention was lower than that of women. Reduced attendance, limited active participation and the perception among many partners that the programme primarily addressed the needs of the women with breast cancer likely restricted opportunities for self-reflection and behavioural change. Thirdly, although the intervention promoted communication, it did

not explicitly include modules focused on partners' own coping skills, emotional burden or beliefs about cancer. As a result, avoidance in partners was not effectively addressed. Similar to women with breast cancer, an ACT approach can be incorporated into the family support programme to facilitate reductions in avoidance among partners, as they undergo the same cognitive processing and appraisal procedures.

#### 9.3.2.4 Anxiety

Anxiety in women with breast cancer

The family support programme effectively reduced anxiety levels in women at post-intervention, with a medium effect size, which aligns with the mechanisms proposed by Simonelli et al. (2017), Lepore & Revenson (2007), and their social constraints reduce through disclosure. According to this model, cognitive processing and appraisal play a critical role in maintaining FCR, and anxiety improves as FCR decreases. The family support programme targeted these mechanisms through three pathways: (1) facilitating the disclosure of thoughts and feelings to reduce social constraints, (2) providing education on healthy lifestyle behaviours to decrease illness representation and perceived risk of recurrence and (3) addressing psychosocial factors related to cancer recurrence to enhance coping strategies, such as managing negative emotional responses and reducing perceived cancer recurrence. Additionally, women's anxiety may have been alleviated by receiving professional explanations to previously unresolved questions. As reflected in the qualitative interviews, participants reported gaining specific knowledge about how exercise and healthy dietary habits can reduce their risk of recurrence and how to adjust their coping strategies. This deeper understanding of the mechanisms underlying cancer recurrence appeared to mitigate their anxiety. The more they learned, the more they recognised that their illness was controllable rather than untreatable. The family support programme helped them to reframe breast cancer as a manageable condition, similar to other chronic diseases, and to appreciate that while the disease is not inherently fatal, neglecting self-care could have serious consequences.

The positive effects on women's anxiety observed in the RCT may also be attributed to the inclusion of exercise as a component of the family support programme. Evidence from multiple meta-analyses has demonstrated the effectiveness of physical activity in reducing anxiety in adults with breast cancer. Zhang's meta-analysis showed that multicomponent training significantly alleviated anxiety in breast cancer survivors, with training conducted ≥3 times per week and ≤60 minutes per session being the most effective (Zhang et al., 2025). Fang's meta-analysis reported that muscle relaxation training can significantly reduce anxiety in breast cancer patients (Fang et al., 2022). Similarly, Nero's meta-analysis indicated that physical exercise, regardless of modality, significantly reduces anxiety (Nero et al., 2024). Collectively, these findings provide consistent evidence that multicomponent physical activity is a robust non-pharmacological strategy for alleviating anxiety in women with breast cancer.

However, the effect was not sustained at 12 weeks. Similar to other outcomes, once the family support programme ended, women were no longer exposed to regular professional support or structured opportunities for disclosure. New cancer-related stressors, such as follow-up appointments or physical symptoms, likely reactivated intrusive thoughts and catastrophic appraisals (e.g. interpreting a cough as lung metastasis or bone pain as bone metastasis), thereby renewing FCR and anxiety. This pattern aligns with Simonelli's model, which emphasises that incomplete cognitive processing contributes to prolonged FCR. Without continuous professional support, women with breast cancer may revert to avoidance or emotional suppression, further impeding full cognitive-emotional processing of their experiences. These findings suggest that the short-term benefits of the family support programme may diminish without ongoing support or booster sessions, as disclosure, cognitive processing and appraisal require sustained guidance to become internalised. Future interventions should incorporate booster sessions at key stress points, such as follow-up appointments or the emergence of new symptoms, to maintain cognitive processing and appraisal and

enhance long-term effects.

Anxiety in partners

In contrast to the positive findings in women with breast cancer, the family support programme did not significantly reduce anxiety levels in partners, either post-intervention or at 12 weeks, and the programme effect at six weeks was differential by gender, with a greater impact on women. Several factors may explain this observation. Firstly, some partners reported in the qualitative interviews that their anxiety increased when they perceived the women were not engaging in recommended lifestyle behaviours, such as regular exercise, which could reduce recurrence risk. Secondly, partners generally attended fewer sessions than women and demonstrated lower engagement in disclosure exercises. Limited exposure to the intervention components may have reduced its effectiveness in alleviating their anxiety. Thirdly, partners often viewed their primary role as caregivers rather than as core participants in the family support programme, leading them to overlook their own emotional needs. Some expressed that they were not the 'core targeted person' in the intervention and were therefore less motivated to share their feelings, limiting the benefits of emotional disclosure. Lastly, partners' inhibition of disclosure may have hindered the programme's impact on their cognitive-emotional processing. These findings underscore the need for future interventions to include strategies specifically for partners, such as individual sessions focusing on their emotional needs, coping skills and psychoeducation on managing FCR and anxiety. Booster sessions and personalised support may further help partners address their anxiety and enhance their engagement in the coping process.

Unlike the family support programme, some strategies have been found to be effective in reducing anxiety in caregivers of women with breast cancer, including mindfulness-based stress reduction and psychological support (Liu et al., 2023). This discrepancy may be explained by differences in the control conditions. In the previous studies, usual

care was used as the control, whereas in this RCT the control group received weekly WeChat follow-up calls for six weeks. These follow-up calls provided participants with consistent access to professional advice and information, which may have alleviated anxiety and FCR, thereby reducing the additional effect of the intervention. Furthermore, the intensity of the family support programme in this RCT was lower than in the previous studies. Two of the studies involved eight weekly 2-hour sessions plus daily home practice, while the other consisted of 90-minute sessions over three months. The dosage of the family support programme may therefore have been insufficient to generate significant between-group differences in anxiety, particularly when both groups received active support.

Another meta-analysis including five studies revealed that mHealth-based psychosocial interventions can reduce anxiety in caregivers of breast cancer patients (Tan et al., 2025). Of the five studies, two that reported significant effects used telephone-based interpersonal counselling. In these studies, the control groups received attention-matched brief phone calls or supportive health education with the same frequency. Importantly, the sessions for patients and caregivers were delivered on an individual basis. In comparison, the family support programme in this RCT was a couple-based intervention. Partners' low engagement in the disclosure sessions may have reduced the programme's effectiveness. The lack of an individualised focus may have limited partners' willingness to disclose their own distress, as they often perceived themselves as 'not the important one' relative to the women, in addition to gender-related tendencies to suppress emotional expression.

In summary, the discrepancy between the family support programme and previous evidence suggests that the lack of significant effects on anxiety in partners cannot be attributed solely to the active control condition, as prior RCTs have demonstrated benefits even over active controls. Rather, the non-significant finding in this doctoral study may be explained by the programme's lower intensity, limited partner

engagement and absence of partner-specific content. Future interventions could combine couple-based sessions to promote mutual understanding and disclosure with separate modules tailored for partners, addressing their unique sources of anxiety.

#### 9.3.2.5 Stigma

Stigma in women with breast cancer

The study findings indicated that the family support programme did not produce short-term or long-term effects on stigma levels among women with breast cancer, neither for the overall score nor for its four dimensions, including self-image disorder, social isolation, discrimination and self-perception, although some decreases in stigma scores were observed. Several factors may explain this finding. Firstly, the intervention focused on disclosure to improve couple communication but did not include components specifically targeting cognition or beliefs related to stigma reduction. Consequently, reductions in overall stigma and its four dimensions were small compared with the active control group, particularly for women's self-image disorder, which is often associated with reduced femininity (Bu et al., 2022). Changes in appearance, such as breast loss or hair loss, can be addressed through breast reconstruction or hair regrowth after chemotherapy, potentially blunting the effects of both the family support programme and the WeChat calls delivered to the control group. Secondly, women's stigma arises not only from internalised beliefs but also from social and cultural factors. In Chinese culture, cancer is often considered taboo (Bu, Chen, et al., 2025), associated with notions of incurability and death. Family members and acquaintances may behave differently, sometimes uncomfortably, after learning of the diagnosis, contributing to perceived discrimination and social rejection. As societal beliefs are slow to change, women with breast cancer may continue to experience stigma from external sources. Consequently, they may conceal their diagnosis and limit social interactions to protect their social image, resulting in stable scores for self-perception, social isolation and discrimination dimensions regardless of the intervention. Overall, these findings suggest that community- or population-based

interventions targeting sociocultural beliefs and norms, using a public health approach, may be more effective in reducing stigma among women with breast cancer.

In the literature, many factors have been reported to be associated with breast cancer stigma. A meta-analytic study concluded that breast cancer-related stigma was positively associated with employment status, surgical type, resignation coping, depression, ambivalence about emotional expression and delayed help-seeking behaviour, and negatively associated with age, education, income, QoL, social support, confrontation coping, psychological adaptation, self-efficacy and self-esteem (Tang et al., 2022). Based on this review, all three components of the family support programme could theoretically address some modifiable factors of breast cancer stigma. Firstly, disclosure was employed to reduce ambivalence over emotional expression, education was provided to address delayed help-seeking behaviour and support from a professional facilitator and partner was provided to strengthen social support. To enhance the programme's effects on breast cancer stigma, additional components targeting other associated factors should be incorporated. Previous interventional studies have shown that psychoeducation and cognitive-behavioural approaches, such as correcting misconceptions, can help reduce stigma in women with breast cancer (Chang et al., 2019; Esplen et al., 2018). Future studies could consider integrating these components into the intervention. Extending the intervention duration and providing booster sessions may also help strengthen and sustain the effects. Moreover, because stigma often originates from societal attitudes, community-based health programmes should be considered. These programmes may enhance accurate understanding of breast cancer and counter misconceptions that the disease is inevitably fatal or socially taboo, thereby fostering a more accepting and supportive context for women who experience elevated levels of stigma. In addition, empathetic and supportive social networks can assist individuals in maintaining or rebuilding a positive sense of self, as such responses acknowledge their experiences and reinforce feelings of being valued and cared for (An et al., 2024).

Affiliate stigma in partners

Similar to women, neither the overall level of affiliate stigma nor its four dimensions, namely, internal stigma, social isolation, perceived stigma and reaction, showed short-term or long-term effects in partners following the intervention. Several potential reasons may explain this observation. Firstly, disclosure was not fully achieved during the sessions. Although the family support programme was designed for both members of the couple, partners often positioned themselves in a supportive role or regarded themselves as companions rather than central participants. Consequently, they suppressed their own disclosure and missed opportunities to express their experiences, contributing to unchanged levels of internal stigma. Secondly, just as women with breast cancer experience self-blame and stigmatisation, their families may face discrimination and social rejection (Wang et al., 2020). Social isolation or perceived stigma arising from societal attitudes is unlikely to change through a family-involvement intervention alone. Lastly, the family support programme did not include specific content directly targeting affiliate stigma.

Nevertheless, this study represents the first RCT to examine affiliate stigma in caregivers of adults with cancer, specifically partners of women with breast cancer, due to the previous lack of attention in this area and the absence of a validated scale to assess affiliate stigma in cancer caregivers. In this doctoral study, an affiliate stigma scale for caregivers of women with breast cancer was developed and validated (Chapter 5; Bu, Chen, et al., 2025), providing a valuable tool that can undoubtedly accelerate research in this important field.

## 9.4 Experience and perception of the couples after attending the family support programme

This qualitative study demonstrated the importance of involving couples as a unit of care for reducing FCR, highlight the role of nurse-led sessions that foster disclosure,

improve healthy lifestyle behaviors, and coping strategies. Across the 23 interviews, participants reported lower FCR, reduced anxiety and increased confidence after attending the programme. This qualitative study provides insight into how the programme was perceived to achieve these effects.

Theme 1 and theme 2 explained feature of the family support programme and the benefits couples obtained, supporting acceptability of the programme. Theme 1 described the comprehensive and practical features of the intervention with three subthemes. The first sub-theme is systematic, comprehensive knowledge on disease and health management. Personalised information tailored to their needs was provided, which reduced their anxiety and boosted their confidence in managing the illness. They found the information particularly valuable in shaping a healthier lifestyle and reported feeling better equipped to support recovery from cancer. Indeed, previous literature reported evident information needs among women and their partners, such as the disease, treatment options, and prognosis. They lack of access to care services, information, medical team. They usually found information from the internet (Chen et al., 2025). The overwhelming information however is a hardship for them in sorting through all the information and making real sense of it. It is not an uncommon for them to face some difficult situations such as coming to terms with disagreement existed among professionals, separating out the facts that applied to the women. Besides, Existing literature indicates that partners seek information specifically tailored to their role as the primary source of support for their wives. Such information includes clarification of their responsibilities during the diagnostic and treatment stages, practical strategies for supporting women effectively, and guidance on how women can engage in self-management and self-care (Ayim-Aboagye et al., 2025; Fitch & Allard, 2007). Therefore, tailored information for both women and their partners contribute to the observed acceptability of the programme. We provided education on strategies of side effect management, physical activity, and healthy dietary, which helped them support the women. The second subtheme is supportive disclosure environment. The

participating women valued the facilitator's empathetic understanding and patience, which their family and friends are unable to provide, and created a supportive environment that lowered their stress, fostered openness, and helped re-balance emotions. The third subtheme is WeChat delivery mode, which contributed to the successful implementation by reducing travel and scheduling demands and allowing participation when feeling unwell. Indeed, previous studies have reported that face-to-face delivery imposes travel and time burdens, creates scheduling conflicts with work and caregiving, and can depress attendance when patients feel unwell (Buitrago et al., 2024; Thomson et al., 2023; Taylor et al., 2021). Besides, compared to face-to-face interaction, participants felt more freely and openly to communicate through WeChat delivery mode, without direct, in-person exchanges burden. This is consistent with previous study that some people self-disclose or act out more frequently or intensely than they would in person (Suler, 2004).

Theme 2 describe the perceived benefits of the intervention among couples and the mechanism of the intervention with three subthemes, including reduced fear and improved confidence, enhanced active self-management and emotional adjustment, improved communication and intimacy within couple. By promoting understanding of the disease and factors related to cancer recurrence, they developed a greater sense of optimism. Without clarity of disease, couples felt living with a high degree of uncertainty. This uncertainty was not limited to whether the cancer would not be cured (44), but also the malignancy of the disease, recur, another cancer forming, and the death, (41, 37, 44, 6, 26, 43) (Catania et al.; 2019; Dockery, 2014; Fitch et al,; 2007). Partners imagined the beginning of the disease as a farewell to joys or a reminder of future hardship especially when the malignancy of cancer. They felt a greater sense of control for cancer through the education on physical activity and healthy dietary practice, and other psychosocial factors related to cancer recurrence. They made actionable adjustments to improve their overall condition. By facilitating disclosure and communication between couples, fostering their emotional intimacy, and improved

partner responsiveness. Some women reported that their partners became more caring and responsive after the intervention, for instance, partners who previously ignored messages for a day began replying promptly and expressing greater concern for their feelings. The facilitator created a safe and supportive environment, where couples could openly share their emotions and concerns. Consistent with the model from Simonelli et al. (2017) and Lepore et al (2007), reducing social constraints and enhancing expression may help patients cognitively process their cancer experience more thoroughly, facilitating psychological adjustment and lowering FCR. Besides, engaging in disclosure reduced social constraints and enabled more effective cognitive processing and appraisal. This aligns with meta-analytic findings that disclosure-based family involvement interventions can reduce perceived social constraints and FCR (Chapter 3; Bu, Jiang, et al., 2025a). Additionally, based on Simonelli et al. (2017) and Lee-Jones et al.'s (1997), improvements in physical symptoms and treatment side effects through physical activity and healthy dietary behaviours can reduce women's illness representation, which in turn may lower FCR in women and their partners. Although the RCT did not show a statistically significant intervention effect on women's FCR at T1 and T2, most participants who participated in the qualitative interviews reported decreases in FCR. Specifically, 86.96% of women at T1 and 90.00% at T2, and 76.47% of partners at T1 and 75.00% at T2, showed reductions in FoP-Q-SF scores obtained in the RCT and described experiencing relief following the intervention, both in the short and long term. A minority of participants remained at clinical FCR levels (i.e., FoP-Q-SF scores ≥ 34) (women: 26.09% at T1 and 25.00% at T2; partners: 47.06% at T1 and 43.75% at T2). Qualitative interviews provide a context-rich environment in which participants can reflect on their experiences, identify specific benefits and describe internal shifts in mindset or emotional coping. Such narrative expressions can reveal meaningful improvements that may not be detectable through quantitative measures. In addition, self-report bias and cultural influences may help explain the non-significant quantitative findings. In Chinese culture, individuals tend to suppress negative emotions and avoid disclosing psychological distress (Wang et al., 2020). Some

participants reported deliberately rating their scores lower to conceal their emotional state, despite reassurances of confidentiality provided by the outcome assessor at baseline. This emotional suppression may have led to artificially low baseline FCR scores, masking the actual improvements at post-intervention.

Theme 3 described the strategies to promote and sustain the intervention, with three subthemes, including targeted to meet needs in specific groups, expanded to action-based and peer-driven interventions, and diversified modes of delivery for educational materials. For the first subtheme of targeted to meet needs in specific groups, our findings align with a systematic literature review summarized 32 studies showing that partners' and family members' information needs vary by phase (Adams et al., 2009). For example, at diagnosis/early treatment, priorities centre on treatment-related and diagnosis/prognosis information, alongside guidance on likely emotional reactions and how to access and provide emotional support. Post-treatment/survivorship needs then shift towards lifestyle changes and social re-entry, rehabilitation and longer-term care, and information on late effects and recurrence/metastasis (Adams et al., 2009). Some couples mentioned financial toxicity for breast cancer treatment. China as a developing country and interventions on financial navigation is significant for those in need. For the second subtheme of expanding to action-based and peer-driven interventions, peer groupconstitute a form of social support. Previous study revealed that higher social support was negatively correlated with FCR in women with breast cancer and their caregivers (Li et al., 2024). According to the model from Simonelli et al. (2017), social support can affect FCR through cognitive processing and appraisal their experience. Beyond exchanging information, the peer groups function as a platform for women to share personal experiences without judgment and feel understood (Clougher et al., 2024). Partners perceived as a source of support for the patients also affected by the cancer. Inviting partners in the group may help them gain a understanding of the disease and emotional relief. Based on our interviews, one partner proposed establish peer support groups to facilitate collective behavioral change among patients while one

partners proposed share examples of what others have done during treatment stage. A qualitative systematic review showed that members in the peer groups strongly benefit from the identification with other group members and learn from others, such as evolving new daily routines (Jablotschkin et al., 2022). Over time, group dynamics can foster strong camaraderie and cohesion (Jablotschkin et al., 2022). Trial evidence supports the value of peer group. A RCT employed online group sessions by focusing on metacognitive strategies, values-clarification, and education about follow-up behavior showed decreased FCR in women with breast cancer (Tauber et al., 2023). In addition to FCR, meta-analytic evidence showed that peer support is effective in improving quality of life and anxiety in breast cancer patients (Tan et al., 2023). Therefore, integrating the family support programme with peer groups may serve as a plausible way in reducing FCR. For the third subtheme of diversified modes of delivery for educational materials, couples preferred diversified educational materials, such as short videos, visual slides and concrete examples, rather than over lengthy and text-heavy documents. This is consistent with the cognitive theory of multimedia learning that people learn more effectively from multimedia than from words alone and lowers cognitive load and improves comprehension (Candido & Cattaneo, 2025). Future studies may employ multimedia method and evaluate its effects.

Theme 4 was challenges in practising and sustaining the programme. Two issues were raised: (1) challenges and conflicts in participation and (2) barriers to openness in daily life. Strategies to improve participation was discussed in the eligibility rate and recruitment rate. The latter maps directly onto the social constraints that unsupportive responses inhibit disclosure and cognitive processing and are associated with greater distress (Lepore et al., 2007). Some participating women mentioned that only the facilitator and fellow patients understand their specific anxieties and challenges of undergoing treatment. They suggested that future interventions may be implemented in small peer groups or micro-salons in a hospital ward, with participants having similar breast cancer type, stage, educational backgrounds and life experiences. Besides,

women mentioned they faced social constraints when disclose their experience to people around them. Given this, the most immediate lever is the proximal network, interventions may also target on family members and close friends with simple and concrete communication skills.

Some couples reported financial toxicity and asked for financial navigation support to manage treatment cost. Previous study found that financial toxicity has a direct effect on FCR in women and their caregivers (Li et al., 2024). Cancer progresses typically represent increased treatment expenses, exacerbating their FCR. In China, out-of-pocket spending for cancer care remains high. A national systematic review estimated annual medical costs of USD 7,421–10,297 per patient, with inpatient care and self-purchased drugs as major cost drivers, and many households experiencing catastrophic expenditures (Jia et al., 2023). Breast-cancer–specific surveys show catastrophic health expenditure in 66.28% of households even after insurance reimbursement (87.95% before), underscoring the scale of the problem (Sun et al., 2021). Previous study showed preliminary benefits financial navigation programmes (Shankaran et al., 2018). Against the backdrop in China, financial navigation programmes, which optimise insurance, link patients to assistance, and proactively manage bills are needed for those with huge financial toxicity. Future studies may adapt those financial navigation programmes in China to help with those in need, which may potentially reduce their FCR.

## 9.5 Strengths and limitations of the doctoral study

### 9.5.1 Strengths

There are several strengths in this doctoral study. Firstly, it is the first RCT to explore a theory-driven, disclosure-based family support programme aimed at alleviating FCR among couples coping with breast cancer. This study addresses the research gap identified in the previous review (Chapter Three), which highlighted that interventions targeting FCR in caregivers remain insufficient, as existing programmes primarily focus on women with breast cancer.

Secondly, the intervention development process was rigorously theory-driven, and the intervention content was evidence-based. Its development was guided by Simonelli's integrative model of FCR, the review of factors associated with FCR among women with breast cancer and their caregivers, and the meta-analytic findings on family involvement interventions for FCR management in women with breast cancer and their caregivers (Chapters Two and Three). The intervention content was informed by the Guidelines and Norms for Diagnosis and Treatment of Breast Cancer of the Chinese Anti-Cancer Association and by evidence from peer-reviewed journals. The content and protocol were validated through consultations with local experts and pilot testing among 15 couples coping with breast cancer.

Thirdly, social media has become increasingly popular in recent years. This study delivered the intervention via WeChat, providing couples with a convenient alternative to attend the sessions, thereby reducing their burden. Moreover, the use of the Wenjuanxing platform via WeChat for electronic data collection at post-intervention and 12-week follow-up substantially reduced the manpower required and potentially helped minimise attrition rates, compared with traditional face-to-face data collection. In addition, the use of validated scales for the Chinese population to assess study outcomes, along with the development and psychometric testing of the Affiliate Stigma Scale for partners in this doctoral study, helped minimise measurement errors attributable to the instruments themselves.

Fourthly, this was a multi-centre RCT, with participants recruited from two hospitals in China, covering breast cancer patients and their partners from four provinces served by the two hospitals. This wide recruitment enhances the generalisability of the RCT findings. The study was implemented rigorously, with high intervention fidelity and low attrition rates, which strengthens the validity of the results. Additionally, the post-intervention qualitative interviews provided in-depth feedback on the family support

programme, furthering our understanding of how the disclosure process operates in the target population, particularly among partners of women with breast cancer.

### 9.5.2 Limitations

The first limitation is the potential for contamination in the study. Although participants were advised not to share information from the family support programme, some reported disseminating the knowledge and e-handbook within their personal networks. Two women indicated that they had sent the e-handbook to WeChat groups containing multiple women diagnosed with breast cancer, while others shared it with whom they had close relationships with. Some participants also shared key learnings, particularly the mechanisms for reducing FCR, such as engaging in physical activity, maintaining a healthy diet and understanding psychosocial factors related to cancer recurrence. While this behaviour reflects the acceptability and perceived value of the intervention, it may have introduced contamination across study arms. Specifically, some participants in the control group may have inadvertently received exposure to intervention content through peer-to-peer sharing, which could have reduced observable between-group differences and potentially underestimated the true effect of the intervention in ITT analyses.

The second limitation concerns the resource requirements for intervention delivery. The family support programme required considerable time and professional resources. The total duration of the programme ranged from 150 minutes to 270 minutes (approximately 2.5–4.5 hours). Delivery necessitated trained facilitators and individualised scheduling with each couple for the sessions. These requirements increase the implementation burden and may limit scalability in routine clinical services, particularly in settings with constrained staffing.

Thirdly, the use of convenience sampling in participant recruitment limits the generalisability of the RCT findings, as participants were recruited from two hospitals with which the research team had established collaborations. In addition, the

recruitment rate in this study was modest (49.18%) partly because of incomplete baseline questionnaires, loss of contact and participants' time constraints. These factors may have introduced selection bias, as couples experiencing heavier caregiving or disease-related burdens may have been less likely to participate. Although the overall recruitment rate was not high, once enrolled, couples demonstrated strong willingness to engage in the intervention (women: 86.30%; partners: 61.48%). Importantly, missed sessions were primarily attributable to objective barriers, such as post-chemotherapy symptoms or partners' work schedules, rather than lack of interest, which further underscores the perceived value of the family support programme. However, as disclosure constituted a core component of the programme, relatively high non-attendance in disclosure-focused sessions may have reduced participants' exposure to key intervention content and attenuated overall intervention effects, particularly for dyadic outcomes that depend on joint participation and practice to consolidate disclosure.

Fourthly, couples receiving the active control treatment were not included in the process evaluation, and thus their experiences and satisfaction with the WeChat follow-up calls remain unknown. This finding precludes further exploration of the mechanisms through which the active control may have produced comparable effects on certain outcomes, such as FCR in women. Specifically, whether the observed effects were driven by non-specific factors inherent to weekly contact (e.g. professional support) or by specific, theory-driven processes inadvertently elicited during the WeChat calls (e.g. problem-solving) remains unclear.

Fifthly, involvement of the theoretical model was insufficient. Although the intervention development was guided by Simonelli's integrative FCR model, not all components of the model were included because of the scope of the study. Broader contextual factors, including societal influences, and certain personal-related factors were not addressed. For example, environmental factors such as historical stigma

associated with cancer were not targeted. Community-based health programmes aimed at promoting accurate knowledge about cancer and reducing societal taboos could be developed. Similarly, personal factors, such as coping strategies like avoidance, were not fully customised. Participants with strong avoidance coping tendencies may require additional guidance and support to facilitate effective disclosure.

Sixthly, this study did not include biological outcome measurements, positive outcomes, outcomes related to physical symptoms/treatment side effects and coping. Although the intervention incorporated components targeting healthy lifestyle behaviours and coping with negative emotions and psychological stress, physiological indicators such as immune markers, cortisol levels or inflammatory responses were not assessed. This limits the ability to evaluate potential biological mechanisms underlying the intervention effects, particularly regarding the psycho-neuro-immunological pathways linking lifestyle, stress and cancer recurrence. Additionally, positive outcomes relevant to the intervention, such as marital satisfaction and sense of coherence, were not measured, which would have provided a more comprehensive understanding of the full effects of the family support programme. The disclosure and communication between couples may improve mutual understanding and intimacy, thereby promoting marital satisfaction. Sense of coherence, comprising comprehensibility, manageability and meaningfulness (Antonovsky, 1993), may also be enhanced through educational components of the programme, which increase participants' perceptions of comprehensibility and control. Furthermore, several theoretically relevant outcomes were not measured. Specifically, key mechanism-related constructs included in the theoretical framework, such as physical symptoms/treatment side effects or coping, were not incorporated into the outcome assessment, which hindered a comprehensive understanding of the pathways through which the family support programme may influence FCR, as the component 2 and component 3 in the family support programme were providing education on physical activity, healthy diet, and psychosocial factors related to cancer recurrence. Moreover, all outcomes were self-reported, which may

have introduced recall bias and/or social desirability bias, potentially leading to over- or under-estimation and inaccuracies in the results (Duhamel et al., 2007).

Finally, owing to the nature of the intervention, implementing double-blinding in the RCT is infeasible because of the possibility of bias. Double blinding requires that study participants, interventionists and outcome assessors remain unaware of group allocation throughout the study. In this RCT, participants were not blinded. Knowledge of the assigned treatment and participants' expectations of the intervention may have influenced their behaviours or responses to health outcome assessments (Schulz & Grimes, 2002). The two facilitators were also not blinded to group allocation, although they were responsible only for delivering the intervention to their assigned group. To mitigate potential bias from unblinded interventionists, a standardised protocol was followed to ensure consistent delivery of the intervention. The facilitators had contact only with participants in their own treatment group and were not involved in outcome assessments. Furthermore, data were collected via the Wenjuanxing platform, and the data were handled by RA2 who was blinded to group allocation. These strategies minimised potential sources of bias and enhanced the internal validity of the study.

### 9.6 Summary of the chapter

This chapter presents the quantitative and qualitative results of the RCT. The feasibility outcomes, including eligibility screening, participant recruitment, intervention compliance, attrition and delivery mode, are comprehensively discussed. Compared with the pilot study, the eligibility rate improved. However, recruiting couples for interventional studies remained challenging, and several possible strategies for improvement are proposed. Consistent with previous couple-based studies in breast cancer, the average recruitment rate was 45.30%. Nevertheless, once enrolled, intervention compliance was high, with couples demonstrating strong willingness to engage (women: 84.44%, partners: 46.67%). Notably, missed sessions were primarily due to objective barriers, such as post-chemotherapy symptoms or partners' work

schedules, rather than a lack of interest, reflecting the perceived value of the family support programme. The attrition rate in this RCT was acceptable. Furthermore, couples expressed appreciation for the convenience and acceptability of receiving sessions via WeChat, with this flexible format facilitating integration of the intervention into their daily routines.

The RCT successfully measured all outcomes. The results indicated that the family support programme had short-term effects in reducing women's social constraints, intrusive thoughts and anxiety, and in reducing the partners' FCR. These findings were thoroughly discussed in relation to the existing literature, and strategies to enhance the family support programme were proposed. The next chapter addresses the implications for future research and clinical practice, followed by the study's conclusions and recommendations.

# Chapter 10 Implication and conclusion

## 10.1 Introduction

This chapter presents the implications, conclusions and recommendations of the thesis. The study findings have important implications for research and clinical practice. Psychometric testing of two self-reported scales was conducted, and the results demonstrated acceptable to good reliability and validity. The RCT's findings indicate that adequately recruiting subjects with good intervention compliance is possible. Furthermore, the intervention materials can be utilised in future research and clinical practice. The RCT aimed to examine the feasibility and effectiveness of the family support programme on FCR, social constraints, intrusive thoughts, avoidance, anxiety and stigma among couples coping with breast cancer. The programme, delivered via WeChat, showed short-term effects in improving social constraints, intrusive thoughts and anxiety in women and in reducing FCR in partners.

The chapter is organised into five sections. Section 10.1 presents the implications of the doctoral study. Section 10.2 outlines the implications for future research arising from the RCT. The implications for clinical practice are discussed in Section 10.3. The conclusions of the doctoral study are provided in Section 10.4. Finally, Section 10.5 highlights the recommendations based on the findings of the doctoral study.

## 10.2 Implication for future research

This study is the first RCT to examine the effects of a theory-driven, disclosure-based family support programme on FCR and other psychological outcomes in women with breast cancer and their partners. The programme specifically involved partners to facilitate disclosure, aiming to reduce FCR by modifying social constraints and providing education on healthy lifestyle behaviours for cancer management among couples coping with breast cancer in China. The study addressed three steps of the MRC framework: intervention development, feasibility/pilot testing of study methods and evaluation of the effectiveness of the final intervention (Skivington et al., 2021). The

intervention was systematically developed based on Simonelli's integrative model for FCR (Simonelli et al., 2017), the review of factors associated with FCR in women with breast cancer (Chapter Two), the review of associated factors in caregivers of women with breast cancer (Bu, Jiang, et al., 2025b) and a meta-analysis of family involvement interventions for FCR management in women with breast cancer and their caregivers (Bu, Jiang, et al., 2025a). The intervention materials were prepared in the form of an electronic educational handbook, videos and disclosure content, all of which were validated by experts.

The delivery mode of the family support programme can be further optimised. A hybrid model combining joint couple sessions with individual sessions is recommended for future investigation. This approach offers adequate flexibility to accommodate partners' schedules, particularly for those who are employed and cannot always attend sessions alongside women with breast cancer. More importantly, individual sessions may provide a safe space for participants experiencing disclosure difficulties or couples facing sensitive issues, allowing them to communicate more openly on a one-to-one basis. Integrating this hybrid model into the family support programme may enhance emotional outcomes and relational dynamics, especially in couples with longstanding communication difficulties or patterns of emotional avoidance. Additionally, the low intensity of the family support programme may have contributed to the non-significant results observed in the RCT. Booster sessions may be necessary to sustain long-term effects. The programme was delivered over a limited period without follow-up support, which may have hindered the maintenance of behavioural and emotional changes. Future RCTs should test a family support programme incorporating these two strategies to generate high-quality evidence regarding its effectiveness.

Additionally, the family support programme could be supplemented with strategies to enhance disclosure more effectively. Future iterations may incorporate expressive writing and an ACT approach to foster acceptance rather than avoidance or suppression

of negative emotions associated with breast cancer. The ACT approach is particularly suitable as it addresses intrusive thoughts and avoidance by promoting acceptance, cognitive defusion, present-moment awareness, values clarification and committed action (Hayes et al., 2006). Expressive writing may also facilitate disclosure by helping couples create psychological distance from distressing experiences related to breast cancer, thereby reducing intrusive thoughts and avoidance and enabling healthier cognitive processing (Baikie & Wilhelm, 2005). Integrating these strategies into the family support programme may support deeper emotional and cognitive processing, potentially leading to greater reductions in FCR.

The family support programme included a healthy lifestyle component and a module addressing psychosocial factors to enhance coping skills for managing negative emotions and psychological stress, with the aim of reducing cancer recurrence. Participants in the qualitative process evaluation of the RCT reported that incorporating advanced clinical knowledge could further motivate engagement in healthy lifestyle behaviours. Therefore, future studies could consider including physiological indicators, such as immune markers, cortisol levels or inflammatory responses, in women with breast cancer. The inclusion of these measures could not only promote better cancer management and potentially reduce FCR, but also allow for evaluation of the biological mechanisms underlying the intervention's effects, particularly in relation to the psycho-neuro-immunological pathways linking lifestyle, stress and FCR.

Furthermore, relevant positive outcomes or protective mediating factors of FCR, such as marital satisfaction, resilience and sense of coherence, can be assessed to gain a more comprehensive understanding of the full effects of the family support programme. Marital satisfaction can be considered a personal factor (concurrent family stressor) within the integrative model of FCR. Enhanced disclosure and communication between couples may improve mutual understanding and intimacy, thereby promoting marital satisfaction, which in turn can support positive reappraisal and cognitive processing to

alleviate FCR (Kroenke et al., 2016; Yuan et al., 2023). Resilience has been reported as a moderately associated factor of FCR (Chapter 2). Sense of coherence, which comprises comprehensibility, manageability and meaningfulness, can be influenced by the intervention (Antonovsky, 1993). The educational components of the family support programme may directly enhance participants' perceptions of comprehensibility and control, while also strengthening their resilience in managing cancer. Assessing outcomes such as marital satisfaction, resilience and sense of coherence could potentially extend the integrative model by incorporating protective factors that mitigate FCR.

A cost-effectiveness analysis was not conducted in the present study. Given the ongoing rise in oncology and psychosocial care costs, it is important, not only to demonstrate clinical benefits but also to determine whether the family support programme can reduce the financial burden on participants and health services. A recent SR has concluded that FCR is associated with increased use of primary healthcare and suggested that CBT-based interventions may cost-effectively reduce the severity of FCR or the prevalence of clinically significant FCR (Williams et al., 2021). However, CBT-based treatments generally require intensive and costly manpower, particularly licensed facilitators for intervention delivery. Estimating the cost-effectiveness of the family support programme through a high-quality study would provide valuable evidence for the management of FCR and inform future implementation of efficient and sustainable interventions.

Interventions specifically targeting stigma reduction should be developed separately, as stigma is often socially produced and maintained through cultural and societal beliefs and fear of discrimination by others. Breast cancer-related stigma among Chinese couples coping with the disease is evident because of these cultural and societal factors (Bu, Chen, et al., 2025). Future studies can implement community-based, China-adapted health programmes that disseminate accurate information about breast cancer,

challenge the belief that cancer is incurable and reduce taboos surrounding disclosure. Collaborating with local community groups and clinical staff may help create a more accepting environment for women with breast cancer and their partners experiencing high levels of stigma. Simultaneously, supportive and empathic social networks, including partners, family and peers, should be strengthened through brief skills training in validating responses, because such interactions help patients maintain or re-establish a positive self-concept by affirming their worth and normalising their lived experiences.

The Affiliate Stigma Scale, developed and validated in this doctoral study, can serve as a valuable outcome measurement tool in future intervention studies involving partners of women with breast cancer. Affiliate stigma may be particularly salient among caregivers in cultural contexts such as China, where social norms emphasise 'saving face'. To protect their social image, caregivers often limit their disclosure, which may lead to reduced social support, heightened stress and increased affiliate stigma. Together with the stigma scale for women with breast cancer developed by Bu, Li, et al. (2022), future studies can explore levels of stigma and associated factors across both members of couples coping with breast cancer. Such investigations could inform the development of family-centred interventions aimed at alleviating stigma within the broader family system. Nevertheless, the psychometric properties of the scale should be further examined, including predictive validity, and its factorial structure should be confirmed using CFA with an independent sample.

Moreover, with the availability of patient- and partner-version scales for measuring stigma and social constraints in the target population, future studies could explore the mechanisms underlying the interplay of stigma and social constraints between women with breast cancer and their partners simultaneously. Such investigations could support the development of family-centred interventions aimed at alleviating stigma and social constraints within the broader family system.

## 10.3 Implication for clinical practice

The RCT suggests that the family support programme demonstrates certain positive effects for couples coping with breast cancer. In clinical practice, women with breast cancer and their partners should be routinely assessed for FCR to identify cases of clinically significant concern. For such cases, the family support programme can be recommended, with healthcare professionals regarding the couple as a family unit for intervention. Session 1 of the programme can be conducted in the hospital to enhance intervention compliance, while subsequent sessions can be delivered via WeChat to improve engagement. This approach provides an alternative e-platform-based support option for couples with clinically significant FCR, complementing hospital-based education on breast cancer management. Moreover, the programme was facilitated by trained nurses, who can deliver all components independently, although a multidisciplinary approach may further optimise outcomes.

The SC-SCS-P may serve as a useful screening tool to identify partners of women with breast cancer who may be experiencing social constraints, enabling healthcare professionals to provide appropriate support, particularly for those with lower educational levels. Similarly, the Affiliate Stigma Scale can be used to identify caregivers of women with breast cancer who are experiencing stigma and provide timely psychological support. Healthcare professionals can incorporate these two scales into routine assessments of breast cancer caregivers to facilitate early detection, prevention and targeted intervention.

## 10.4 Conclusion

The output of this doctoral study has made a substantial contribution to research on cancer caregivers by developing two validated scales to assess outcomes in partners of women with breast cancer and by evaluating the effectiveness of a theory-driven, disclosure-based family support programme for couples coping with clinically

significant FCR. The six-week family support programme was developed and validated, encompassing a brief introduction to breast cancer and self-management of treatment side effects, education on physical activity and healthy diet, psychosocial factors related to cancer recurrence and disclosure practices. Delivered via WeChat by an oncology nurse, the programme produced short-term improvements in social constraints, intrusive thoughts and anxiety in women and reductions in FCR in partners. However, the effects on FCR, avoidance and stigma in women and on social constraints, intrusive thoughts, anxiety and affiliate stigma in partners were not statistically significant. Furthermore, the long-term effects of the programme were modest when compared with the control condition of WeChat follow-up calls. These findings provide valuable insights for the development of future interventions targeting this population to more effectively reduce FCR.

### 10.5 Recommendations

1) Family involvement interventions should be promoted to achieve better clinical and psychosocial outcomes for couples coping with breast cancer.

2) The nurse-led family support programme demonstrated promising effects on social constraints, intrusive thoughts and anxiety in women and on FCR in partners. Therefore, nurses could deliver all the components of the programme.

3) Future research could explore various modifications to the family support programme: (i) strategies to enhance disclosure, such as an ACT-based approach and expressive writing, to facilitate deeper emotional expression; (ii) incorporation of physiological indicators to increase engagement and assess potential biological mechanisms; and (iii) a hybrid model combining joint couple sessions with individual sessions to accommodate participants' schedules and meet individual needs.

4) Future studies can examine the effects of the family support programme on relevant positive outcomes.

5) Further psychometric testing of the outcome measures should be conducted given that only internal consistency and construct validity were assessed.

## Appendix

Appendix 1 Search strategies for Chapter Two and Chapter Three

Search strategy for associated factors of caregivers' FCR in Pubmed in Chapter Two

| | |
|---|---|
| 1 | "breast"[MeSH Terms] OR ("breast"[Title/Abstract] OR "mammary"[Title/Abstract])) AND ("neoplasms"[MeSH Terms] OR "carcinoma"[MeSH Terms] OR ("tumor*"[Title/Abstract] OR "carcinoma*"[Title/Abstract] OR "neoplasm*"[Title/Abstract] OR "cancer*"[Title/Abstract] |
| 2 | "fear"[MeSH Terms] OR "anxiety"[MeSH Terms] OR ("fear"[Title/Abstract] OR "afraid"[Title/Abstract] OR "anxi*"[Title/Abstract] OR "worr*"[Title/Abstract] |
| 3 | "back"[MeSH Terms] OR "recurrence"[MeSH Terms] OR "disease progression"[MeSH Terms] OR "disease free survival"[MeSH Terms] OR "back"[Title/Abstract] OR "progress*"[Title/Abstract] OR "recur*"[Title/Abstract] OR "relaps"[Title/Abstract] OR "reoccur*"[Title/Abstract] OR "return*"[Title/Abstract] OR "spread"[Title/Abstract] |
| 4 | "caregivers"[MeSH Terms] OR "spouses"[MeSH Terms] OR "carer*"[Title/Abstract] OR "caregiv*"[Title/Abstract] OR "care give*"[Title/Abstract] OR "famil*"[Title/Abstract] OR "parent*"[Title/Abstract] OR "spouse*"[Title/Abstract] OR "partner*"[Title/Abstract] OR "husband*"[Title/Abstract] OR "child*"[Title/Abstract] |

Search strategy for family involvement interventions on FCR management in Chapter Three

| | |
|---|---|
| 1 | ('breast'[MeSH Terms] OR 'breast'[All Fields] OR 'mammary'[All Fields]) AND ('neoplasms'[MeSH Terms] OR 'carcinoma'[MeSH Terms] OR 'tumor*'[All Fields] OR 'carcinoma*'[All Fields] OR 'neoplasm*'[All Fields] OR 'cancer*'[All Fields]) |
| 2 | 'fear'[MeSH Terms] OR 'Uncertainty'[MeSH Terms] OR 'fear'[All Fields] OR 'afraid'[All Fields] OR 'worr*'[All Fields] OR 'Uncertainty'[All Fields] |
| 3 | 'back'[MeSH Terms] OR 'recurrence'[All Fields] OR 'disease progression'[All Fields] OR 'disease free survival'[All Fields] OR 'back'[All Fields] OR 'progress*'[All Fields] OR 'recur*'[All Fields] OR 'relaps'[All Fields] OR 'reoccur*'[All Fields] OR 'return*'[All Fields] OR 'spread'[All Fields] |
| 4 | 'caregivers'[MeSH Terms] OR 'spouses'[MeSH Terms] OR 'carer*'[All Fields] OR 'caregiv*'[All Fields] OR 'care give*'[All Fields] OR 'famil*'[All Fields] OR 'parent*'[All Fields] OR 'spouse*'[All Fields] OR 'partner*'[All Fields] OR 'husband*'[All Fields] OR 'child*'[All Fields] OR 'son'[All Fields] OR 'daughter*'[All Fields] |
| 5 | 'RCT'[All Fields] OR 'random*'[All Fields] OR 'trial*'[All Fields] OR |

| | |
|---|---|
| | 'group*'[All Fields] OR 'intervention*'[All Fields] OR 'experiment*'[All Fields] OR 'control*'[All Fields] |
| 6 | #1 AND #2 AND #3 AND #4 AND #5 |

MeSH: Medical Subject Headings

Appendix 2 Ethical approval for the pilot study and RCT

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

| | | | |
|---|---|---|---|
| To | Leung Yin Ping (School of Nursing) | | |
| From | YING Tin Cheung, Delegate, PolyU Institutional Review Board | | |
| Email | htmying@ | Date | 22-May-2024 |

**Application for Ethical Review for Teaching/Research Involving Human Subjects**

I write to inform you that approval has been given to your application for human subjects ethics review of the following project for a period from 01-Apr-2024 to 31-Aug-2025:

| | |
|---|---|
| **Project Title:** | Effects of a theory-driven, disclosure-based family support programme on fear of cancer recurrence for couples coping with breast cancer in mainland China: A randomized controlled trial |
| **Department:** | School of Nursing |
| **Principal Investigator:** | Leung Yin Ping |
| **Project Start Date:** | 01-Apr-2024 |
| **Project type:** | Human subjects (clinical) |
| **Review type:** | Expedited Review |
| **Reference Number:** | HSEARS20240202001 |

You will be held responsible for the ethical approval granted for the project and the ethical conduct of the personnel involved in the project. In case the Co-PI, if any, has also obtained ethical approval for the project, the Co-PI will also assume the responsibility in respect of the ethical approval (in relation to the areas of expertise of respective Co-PI in accordance with the stipulations given by the approving authority).

You are responsible for informing the PolyU Institutional Review Board in advance of any changes in the proposal or procedures which may affect the validity of this ethical approval.

YING Tin Cheung

Delegate

PolyU Institutional Review Board

Appendix 3 Information sheet for the pilot study - English version

The Hong Polytechnic university

School of nursing

Study title: Effects of a theory-driven, disclosure-based family support programme on fear of cancer recurrence for couples coping with breast cancer in mainland China: A pilot study

You are invited to participate in a study supervised by Dr. Doris Y.P. Leung (Associate Professor), Dr. Liu Xiangyu (Professor), Jiang Ling (Professor) and conducted by BU Xiaofan (PhD candidate) of the School of Nursing in The Hong Kong Polytechnic University. The project has been approved by the PolyU Institutional Review Board (PolyU IRB) (or its Delegate) (Reference Number: HSEARS##########). Please read the following information carefully before deciding whether to participate in this study. If you have any questions or would like more information, please contact the researcher.

**What is the purpose of the project?**

The purpose of this study is to develop a theory-based, disclosure-based family-support programme and explore the feasibility, acceptability, and preliminary effectiveness of programme. The objectives of the study in phase I is to evaluate the feasibility and acceptability of the theory-based, disclosure-based family-support programme.

**Why are you invited?**

A total of 15 dyads of women with breast cancer and their male partners will be included in this study.

Inclusion criteria:

1) the dyad (i.e. couples that married, engaged, or otherwise romantically) involves women diagnosed with breast cancer, in stage I-IV, either undergoing treatment or have completed treatment, and their male partners whom is identified by the women as the

caregivers,

2) each dyad is living in the same household,

3) both members in the dyad aged 18 years or above,

4) at least one member in the dyad has clinically significant FCR level (i.e. the score in fear of progression scale (FoP-Q-SF)≥34), and

5) both members in the dyad sign written informed consents to participate in the study.

Exclusion criteria:

1) at least one of them has physical impairment such as blindness, paralysis;

2) both are unable to speak and understand Putonghua. Since the intervention will be given in the Putonghua, the participants who are unable to speak and understand the language may face the difficulty of continuing all the sessions;

3) at least one of them has a history of mental illness; or

4) the cancer cells in breast coming from other organs, not original from breast cancer.

Do I have to agree to participate in the study?

Participation in the study was voluntary. If you decide to participate, you will retain this "study data" and sign the consent form. You can drop the study at any time without explaining any reason, and there are no any consequences.

What should I do if I participate in this study?

During your hospitalization, we will assess whether you or your partner are eligible for the study. If you and your partner are eligible, we will obtain your written consent and collect your contacts for future contact. After completing the written informed consent, both of you will be invited to complete a baseline assessment (a set of questionnaires and measurements, details introduced later).

You and your partner will receive usual care from the hospital from plus a 6 weekly 40-min support programme via WeChat. If you and your partner agree to participate in the

study, you and your partners will receive a 6 weekly 40-min intervention programme. The programme will provide 2 sessions on education on physical activity and healthy dietary. Besides, couples will be required to disclosure to each other in the remaining 4 sessions with the guidance from the researcher.

You need to complete a set of questionnaires and measurements, including fear of cancer recurrence, social constraints, anxiety, stigma, intrusive thoughts, and avoidance, at two different time points: before the intervention and 6-week. Each set of questionnaires and measurements will take you about a total of 30 minutes. You will be asked to complete the questionnaires via WeChat at mutually agreed time. Besides, you will be invited to participate a cognitive interview post-intervention at 6 weeks. The open-ended questions regarding the overall feelings of the suggested content, such as the sequence of the sessions, the dosage of the intervention, and suggestions on content are covered. The duration of comment is expected to be 15min to 30min. The interview will be recorded by a digital voice recorder.

What are the benefits of participating in the study?
You can know more about breast cancer and cancer recurrence.

What are the potential risks and downsides of participating in the study?
There are possibilities that you may have emotional frustration during the intervention sessions. Intervention will be stopped immediately if emotional problems are caused. You and your partner will be referral to the psychological care department or the psychologist in the hospital, if needed.

What would happen if new information came?
The researchers will inform you of new information related to this study. You can decide whether to continue to participate in the study. If you decide to proceed, you will sign an updated consent form. However, if you opt out, the researcher will not arrange any

further assessment/follow-up with you.

Will all the information I provide be kept confidential after participating in the study?
All information related to you will remain confidential and will be identifiable by codes only known to the researchers. The information collected will be kept 5 years after project completion. The Hong Kong Polytechnic University takes reasonable precautions to prevent the loss, misappropriation, unauthorized access or destruction of the information you provide. Subject's personal data will not be transferred and only the research team at PolyU has the right to access the data.

What will happen to the research results?
The results of the study will be published upon completion of the study, and you may request a copy of the study report from our research team.

Which organization sponsored the study?
The study was organized by the Hong Kong Polytechnic University School of Nursing, with the support from the Affiliated Cancer Hospital of Xiangya Medical College, Central South University and Suzhou Hospital of Nanjing Medical University.

Who reviews the research?
This study was approved by the Institutional Review Board of the Hong Kong Polytechnic University (ref. HSEARSXXXXXXX).

If you have any questions, you may ask our assistant now or later, even after the study has started. Should you have any complaints about the conduct of this research study, you may contact Secretary, PolyU Institutional Review Board in writing (institutional.review.board@polyu.edu.hk) stating clearly the responsible person and department of this study as well as the Reference Number.

You may contact BU Xiaofan (tel. no.:1836034 /
email: xiaofan123.bu@ ) of PolyU under the following situations:

a. if you have any other questions in relation to the study;

b. if, under very rare conditions, you become injured as a result of your participation in the study; or

c. if you want to get access to/or change your personal data before (the expiry date).

In the event you have any complaints about the conduct of this research study, you may contact Secretary, PolyU Institutional Review Board in writing (institutional.review.board@polyu.edu.hk) stating clearly the responsible person and department of this study as well as the Reference Number.

In case of a serious adverse event[1], please report to the Principal Investigator/Chief Investigator immediately and the Principal Investigator/Chief Investigator will be required to report it to the PolyU IRB within 48 hours upon the receipt of your report.

Thank you for your interest in participating in this study.

Principal Investigator/Chief Investigator
Dr. Doris Y.P. Leung (Email: doris.yp.leung@ )

PhD student:
BU Xiaofan
Tel：1836034
mail：xiaofan123.bu@

SAE any adverse event that:
• Results in death
• Is life threatening, or places the participant at immediate risk of death from the event as it occurred

• Requires or prolongs hospitalization
• Causes persistent or significant disability or incapacity
• Results in congenital anomalies or birth defects
• Is another condition which investigators judge to represent significant hazards (Reference: NIA Adverse Event and Serious Adverse Event Guidelines.
https://www.nia.nih.gov/sites/default/files/2018-09/nia-ae-and-sae-guidelines-2018.pdf)

Appendix 4 Consent form to participate in the pilot study - English version

CONSENT TO PARTICIPATE IN RESEARCH

Study title: Effects of a theory-driven, disclosure-based family support programme for couples coping with breast cancer in mainland China: a pilot study

I _____ hereby consent to participate in the captioned research supervised by Leung Y.P. Doris, Liu Xiangyu, and Jiang Ling and conducted by BU Xiaofan.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e., my personal details will not be revealed. The procedure as set out in the attached information sheet has been fully explained. I understand the benefits and risks involved. My participation in the project is voluntary. I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind. I understand that any personal data provided in this study will be kept strictly confidential unless I expressly consent to its release. Data will be kept for 5 years after completion of the project.

_____ (researcher's name) have explained to me the details of the study and have answered my questions. I understand that the Institutional Review Committee of the Hong Kong Polytechnic University (Ref. HSEARSXXXXXXXXX) has been authorized to access my information for ethical review purposes.

For more information on this study, please contact the researcher:

BU Xiaofan

The Hong Kong Polytechnic University

Tel: 1836034

E-mail: xiaofan123.bu@

Name of the participant:

Signature of participant:

Name of researcher:

Signature of researcher:

Date:

Appendix 5 Information sheet for the RCT - English version

Study title: Effects of a theory-driven, disclosure-based family support programme for couples coping with breast cancer in mainland China: A randomized controlled trial

You are invited to participate in a study supervised by Dr. Doris Y.P. Leung (Associate Professor), Dr. Liu Xiangyu (Professor), Jiang Ling (Professor) and conducted by BU Xiaofan (PhD candidate) of the School of Nursing in The Hong Kong Polytechnic University. The project has been approved by the PolyU Institutional Review Board (PolyU IRB) (or its Delegate) (Reference Number: HSEARS##########). Please read the following information carefully before deciding whether to participate in this study. If you have any questions or would like more information, please contact the researcher.

**What is the purpose of the project?**

The purpose of this study is to develop a theory-based, disclosure-based family-support programme and explore the feasibility, acceptability, and preliminary effectiveness of programme. The objectives of the study in phase II are:

(1) To explore its efficacy on alleviating FCR, social constraint, communication problem, stigma, anxiety, intrusive thoughts and avoidance in dyads of women with breast cancer and their partners in China;

(2) To assess the acceptability of the support programme for the dyads in the intervention group.

**Why you are invited?**

A total of 90 dyads of women with breast cancer and their male partners will be included in this study.

Inclusion criteria:

1) the dyad (i.e., couples that married, engaged, or otherwise romantically) involves

women diagnosed with breast cancer, in stage I-IV, either undergoing treatment or have completed treatment, and their male partners whom is identified by the women as the caregivers,

2) each dyad is living in the same household,

3) both members in the dyad aged 18 years or above,

4) at least one member in the dyad has clinically significant FCR level (i.e. the score in fear of progression scale (FoP-Q-SF)≥34), and

5) both members in the dyad sign a written informed consent to participate in the study.

Exclusion criteria:

1) at least one of them has physical impairment such as blindness, paralysis;

2) both are unable to speak and understand Putonghua. Since the intervention will be given in the Putonghua, the participants who are unable to speak and understand the language may face the difficulty of continuing all the sessions;

3) at least one of them has a history of mental illness; or

4) the cancer cells in breast coming from other organs, not original from breast cancer.

**Do I have to agree to participate in the study?**

Participation in the study was voluntary. If you decide to participate, you will retain this "study data" and sign the consent form. You can drop the study at any time without explaining any reason, and there are no any consequences.

**What should I do if I participate in this study?**

During your hospitalization, we will assess whether you or your partner are eligible for the study. If you and your partner are eligible, we will obtain your written consent and collect your contacts for future contact. After completing the written informed consent, both of you will be invited to complete a baseline assessment (a set of questionnaires and measurements, details introduced later). And then, the researcher will randomize

you to the intervention group or control group at a ratio of 1: 1, and the study group cannot be changed arbitrarily.

If you are assigned into the intervention group, you and your partner will receive usual care from the hospital from plus a 6weekly 40 min support programme via WeChat. The programme will provide 2 sessions on education on physical activity and healthy dietary. Besides, couples will be required to disclosure to each other in the remaining 4 sessions with the guidance from the researcher. If you are arranged to the control group, you will receive the usual care from the hospital plus 6 weekly follow-up WeChat calls. After 12 weeks, for those in the control group, the researchers will provide you with the same educational handbook as those in the intervention group without charge.

You need to complete a set of questionnaires and measurements including fear of cancer recurrence, social constraints, anxiety, stigma, intrusive thoughts, and avoidance, at three different time points: before randomization, 6-week, and 12-week. Each set of questionnaires and measurements will take you about a total of 30 minutes. You will be asked to complete the questionnaires via WeChat at mutually agreed time. Besides, you will be invited to participate an interview at week 12. The open-ended questions regarding your perception of the acceptability of the intervention. The duration of interview is expected to be around 20min. The interview will be recorded by a digital voice recorder.

**What are the benefits of participating in the study?**

The information you provide will help in advancing care for breast cancer patients and their caregivers.

**What are the potential risks and downsides of participating in the study?**

There are possibilities that you may have emotional frustration when disclosure during the interventional sessions. Intervention will be stopped immediately if emotional

problems are caused. You will be referral to the psychological care department or the psychologist in the hospital if needed.

**What would happen if new information came?**

The researchers will inform you of new information related to this study. You can decide whether to continue to participate in the study. If you decide to proceed, you will sign an updated consent form. However, if you opt out, the researcher will not arrange any further assessment/follow-up with you.

**Will all the information I provide be kept confidential after participating in the study?**

All information related to you will remain confidential and will be identifiable by codes only known to the researchers. The information collected will be kept 5 years after project completion and the hardcopies of the data will be destroyed. The Hong Kong Polytechnic University takes reasonable precautions to prevent the loss, misappropriation, unauthorized access or destruction of the information you provide. Subject's personal data will not be transferred and only the research team at PolyU has the right to access the data.

**What will happen to the research results?**

The results of the study will be published upon completion of the study, and you may request a copy of the study report from our research team.

**Which organization sponsored the study?**

The study was organized by the Hong Kong Polytechnic University School of Nursing, with the support from the Affiliated Cancer Hospital of Xiangya Medical College, Central South University and Suzhou Hospital of Nanjing Medical University.

**Who reviews the research?**

This study was approved by the Institutional Review Board of the Hong Kong Polytechnic University (ref. HSEARSXXXXXXX).

If you have any questions, you may ask our assistant now or later, even after the study has started. Should you have any complaints about the conduct of this research study, you may contact Secretary, PolyU Institutional Review Board in writing (institutional.review.board@polyu.edu.hk) stating clearly the responsible person and department of this study as well as the Reference Number.

You may contact BU Xiaofan (tel. no.:1836034 /
email: xiaofan123.bu@ ) of PolyU under the following situations:
a. if you have any other questions in relation to the study;
b. if, under very rare conditions, you become injured as a result of your participation in the study; or
c. if you want to get access to/or change your personal data before (the expiry date).

In the event you have any complaints about the conduct of this research study, you may contact Secretary, PolyU Institutional Review Board in writing (institutional.review.board@polyu.edu.hk) stating clearly the responsible person and department of this study as well as the Reference Number.
In case of a serious adverse event[1], please report to the Principal Investigator/Chief Investigator immediately and the Principal Investigator/Chief Investigator will be required to report it to the PolyU IRB within 48 hours upon the receipt of your report.

Thank you for your interest in participating in this study.
Principal Investigator/Chief Investigator
Dr. Doris YP Leung (Email: doris.yp.leung@ )

PhD student:

BU Xiaofan

Tel：1836034

E-mail：xiaofan123.bu@

SAE any adverse event that:
• Results in death
• Is life threatening, or places the participant at immediate risk of death from the event as it occurred
• Requires or prolongs hospitalization
• Causes persistent or significant disability or incapacity
• Results in congenital anomalies or birth defects
• Is another condition which investigators judge to represent significant hazards (Reference: NIA Adverse Event and Serious Adverse Event Guidelines. https://www.nia.nih.gov/sites/default/files/2018-09/nia-ae-and-sae-guidelines-2018.pdf)

Appendix 6 Consent form to participate in the RCT - English version

Consent to participate in research

Study title. Effects of a theory-driven, dislosure-based family support programme for couples coping withbreast cancer in mainland China: a randomized controlled trial

I _____ hereby consent to participate in the captioned research supervised by Leung Y.P. Doris, Liu Xiangyu, and Jiang Ling and conducted by BU Xiaofan.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e., my personal details will not be revealed. The procedure as set out in the attached information sheet has been fully explained. I understand the benefits and risks involved. My participation in the project is voluntary. I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind. I understand that any personal data provided in this study will be kept strictly confidential unless I expressly consent to its release. Data will be kept for 5 years after completion of the project.

_____ (researcher's name) have explained to me the details of the study and have answered my questions. I understand that the Institutional Review Committee of the Hong Kong Polytechnic University (Ref. HSEARSXXXXXXXXX) has been authorised to access my information for ethical review purposes.

For more information on this study, please contact the researcher:

BU Xiaofan

The Hong Kong Polytechnic University

Tel: 1836034

E-mail: xiaofan123.bu@

Name of the participant:_____

Signature of participant:_____

Name of researcher:_____

Signature of researcher: _____

Date: _____

Appendix 7 Questionnaire for pilot study and RCT for women with breast cancer-English version

**Fear of Progression Questionnaire-Short Form (Fo P-Q-SF)**

Below are a list of statement that are related to your illness and possible future concerns. Please place an "X" in the appropriate column as the statement pertains to you. Your may choose among "never", "seldom", "sometimes", "often"and "very often". Please do not skip any questions. Some questions may not apply to you. For example, if you are retired, you will not be able to answer the questions about your employment. Please make an"X" under "never" in these cases.

| | never | seldom | sometimes | often | Very often |
|---|---|---|---|---|---|
| 1.I become anxious if I think my disease may progress. | | | | | |
| 2.I am nervous prior to doctors' appointments or periodic examinations. | | | | | |
| 3.I am afraid of pain. | | | | | |
| 4.The thought that I might become less productive at my job disturbs me. | | | | | |
| 5.When I am anxious, I have physical symptoms, e.g., rapid heartbeat, stomachache, nervousness. | | | | | |
| 6.The possibility of my children contracting my disease disturbs me. | | | | | |
| 7.It disturbs me that I may have to rely on strangers for activities of daily living | | | | | |
| 8.I am worried that at some point in time, because of my illness I will no longer be able to pursue my hobbies. | | | | | |
| 9.I am afraid of severe medical treatments in the course of my illness. | | | | | |
| 10.I worry that my medications could damage my body. | | | | | |
| 11.I worry about what will become of my family if something should happen to me. | | | | | |
| 12.The thought that I might not be able to work due to my illness disturbs me. | | | | | |

**Social Constraints Scale**

Instruction: Below is a list of social experiences. For each question, please circle a number for how often you have had that experience.

| | never | rarely | sometimes | often |
|---|---|---|---|---|
| 1.Change the subject when you tried to discuss the event or its effects on your life? | | | | |
| 2.Not seem to understand your situation? | | | | |
| 3.Avoid you? | | | | |
| 4. Minimize your problems? | | | | |
| 5.Seem to be hiding their feelings? | | | | |
| 6.Act uncomfortable when you talked about the event or its effects? | | | | |
| 7. Trivialize your problems? | | | | |
| 8.Complain about their own problems when you wanted to share yours? | | | | |
| 9.I am afraid of severe medical treatments in the course of my illness. | | | | |
| 10.Tell you not to worry so much about the event or its effects? | | | | |
| 11.Tell you to try not to think about the event or its effects? | | | | |
| 12.Give you the idea that they didn't want to hear about the event or its effects? | | | | |
| 13.Make you feel as though you had to keep your feelings about the event or its effects to yourself because they made them feel uncomfortable? | | | | |
| 14.Make you feel as though you had to keep your feelings about the event or its effects to yourself, because they made them feel upset? | | | | |
| 15.Let you down by not showing you as much love and concern as you would have liked? | | | | |

**Impact of Event Scale - Revised (IES-R)**

Instructions: Below is a list of difficulties people sometimes have after stressful life events. Please read each item, and then indicate how distressing each difficulty has been for you during the past

seven days with respect to (the event: cancer diagnosis). How much were you distressed or bothered by these difficulties?

| | Not at all | A little bit | Moderately | Quite a bit | Extremely |
|---|---|---|---|---|---|
| Intrusive thoughts | | | | | |
| Any reminder brought back feelings about it | | | | | |
| Other things kept making me think about it | | | | | |
| I thought about it when I didn't mean to | | | | | |
| Pictures about it popped into my mind | | | | | |
| I found myself acting or feeling as though I was back at that time | | | | | |
| I had waves of strong feelings about it | | | | | |
| Avoidance | | | | | |
| I avoided letting myself get upset when I thought about it or was reminded of it | | | | | |
| I felt as if it hadn't happened or wasn't real | | | | | |
| I stayed away from reminders about it | | | | | |
| | | | | | |
| I tried not to think about it | | | | | |
| I was aware that I still had a lot of feelings about it, but I didn't deal with them | | | | | |
| My feelings about it were kind of numb | | | | | |
| I tried to remove it from my memory | | | | | |
| I tried not to talk about it | | | | | |

**Breast cancer stigma scale**

Below are a list of statement that are related to your feeeling. Your may choose among "strongly agree", "agree", "disagree", "strongly disagree". Please do not skip any questions. Some questions may not apply to you. For example, if you do not start take chemotherapy, you will not be able to answer the questions about hair loss. Please make an“X” under “never” in these cases.

| | Strongly agree | agree | disagree | Strongly |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| | | | | disagree |
| 1.I care about the changes to my breasts. | | | | |
| 2.I feel I am imperfect after surgery. | | | | |
| 3.I do not want to see or touch the scars left by surgery. | | | | |
| 4.After the surgery, I feel more anxious and less confident about my appearance than before. | | | | |
| 5.I feel the treatment has made me less physically attractive and less feminine. | | | | |
| 6.I do not think I am a healthy person. | | | | |
| 7.I cover my breasts when I am intimate with my partner. | | | | |
| 8.I am afraid of intimate physical contact, such as hugging. | | | | |
| 9.People usually sympathize with me because of my illness. | | | | |
| 10.I often feel people staring at me after my diagnosis. | | | | |
| 11.After my illness, I often hear people secretly talking about me after my diagnosis | | | | |
| 12.I was ridiculed for wearing a hat due to the loss of hair caused by chemotherapy. | | | | |
| 13.I do not want anyone other than those closest to me to know I have been diagnosed with breast cancer. | | | | |
| 14.I feel unnatural when someone looks at my chest. | | | | |
| 15.I do not want anyone to see how I look after my illness. | | | | |

**GAD-7 Anxiety**

Over the last two weeks, how often have you been bothered by the following problems?

| | Not at all | Several days | More than half the days | Nearly every day |
|---|---|---|---|---|
| 1. Feeling nervous, anxious, or on edge | | | | |

| | | | | |
|---|---|---|---|---|
| 2. Not being able to stop or control worrying | | | | |
| 3. Worrying too much about different things | | | | |
| 4. Trouble relaxing | | | | |
| 5. Being so restless that it is hard to sit still | | | | |
| 6. Becoming easily annoyed or irritable | | | | |
| 7. Feeling afraid, as if something awful might happen | | | | |

Appendix VII Questionnaire for pilot study and RCT for partners- English version

Fear of Progression Questionnaire-Short Form (FoP-Q-SF)

BELOW ARE A LIST OF STATEMENTS that are related to the illness of your partner and possible future concerns. Please place an "X" in the appropriate column as the statement pertains to you. You may choose among "never", "seldom", "sometimes", "often",and "very often". Please do not skip any questions. Some questions may not apply to you. For example, if you are retired, you will not be able to answer the questions about your employment.Please make an "X"under "never"in these cases.

| | never | seldom | sometimes | often | Very often |
|---|---|---|---|---|---|
| 1.I become anxious if I think my disease may progress. | | | | | |
| 2.I am nervous prior to doctors' appointments or periodic examinations. | | | | | |
| 3.I am afraid that my partner may have pain. | | | | | |
| 4.I have concerns about my partner reaching her/his professional goals because of her/his illness. | | | | | |
| 5. When I am anxious, I have physical symptoms (e.g.,rapid heartbeat, stomachache, nervousness). | | | | | |
| 6.The possibility of my children contracting the disease disturbs me. | | | | | |
| 7. It disturbs me that my partner may have to rely on strangers for activities of daily living. | | | | | |
| 8.I am worried that at some point in time, because of my partner's illness, I | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| will no longer be able to pursue my hobbies. | | | | | |
| 9.I am afraid of severe medical treatments over the course of the illness. | | | | | |
| 10.I worry that the medications could damage my partner's body. | | | | | |
| 11.I worry about what will become of my family if something should happen to my partners. | | | | | |
| 12.The thought that my partner might not be able to work due to her/his illness disturbs me. | | | | | |

Social constraints scale

Instruction: Below is a list of social experiences. For each question, please circle a number for how often you have had that experience regarding THE EVENT THAT LED TO YOUR PARTICIPATION IN THIS STUDY

| | never | rarely | sometimes | often |
|---|---|---|---|---|
| 1.When you try to talk to the patients about his/her disease, he/she changes the topic. | | | | |
| 2.You feel that the patient does not understand your concern/feeling | | | | |
| 3.You feel that the patient avoids being with you. | | | | |
| 4.When you bring up concerns or ideas related to health, the patient ignores or underestimates them. | | | | |
| 5.You feel that the patient hides his/her emotions or feelings from you. | | | | |
| 6.When you mention patient’s illness, the patient appears uncomfortable | | | | |
| 7.You feel that the patient thinks your problem is unimportant. | | | | |
| 8.When you try to talk to the patient, he/she only complains about his/her own problems. | | | | |
| 9.The patient appears cheerful in your presence to hide his/her true feelings or concerns about his/her own illness | | | | |
| 10.The patient tells you not to worry so much about his/her health. | | | | |
| 11.The patient asks you to think less thing related to | | | | |

| | | | | |
|---|---|---|---|---|
| his/her disease | | | | |
| 12.You feel that the patient doesn't want to hear things related to his/her disease | | | | |
| 13.You feel you have to hide your feelings related to the disease because your feeling makes the patient uncomfortable. | | | | |
| 14.You feel you have to hide your feelings related to the disease because your feeling makes the patient unpleasant. | | | | |
| 15.You feel unhappy because the patient doesn't care/love you as you expected. | | | | |

Impact of Event Scale - Revised (IES-R)

Instructions: Below is a list of difficulties people sometimes have after stressful life events. Please read each item and then indicate how distressing each difficulty has been for you DURING THE PAST SEVEN DAYS with respect to (the event). How much were you distressed or bothered by these difficulties?

| | Not at all | A little bit | Moderately | Quite a bit | Extremely |
|---|---|---|---|---|---|
| Intrusive thoughts | | | | | |
| Any reminder brought back feelings about it | | | | | |
| Other things kept making me think about it | | | | | |
| I thought about it when I didn't mean to | | | | | |
| Pictures about it popped into my mind | | | | | |
| I found myself acting or feeling as though I was back at that time | | | | | |
| I had waves of strong feelings about it | | | | | |
| Avoidance | | | | | |
| I avoided letting myself get upset when I thought about it or was reminded of it | | | | | |
| I felt as if it hadn't happened or wasn't real | | | | | |
| I stayed away from reminders about it | | | | | |
| | | | | | |
| I tried not to think about it | | | | | |
| I was aware that I still had a lot of feelings | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| about it, but I didn't deal with them | | | | | |
| My feelings about it were kind of numb | | | | | |
| I tried to remove it from my memory | | | | | |
| I tried not to talk about it | | | | | |

GAD-7 Anxiety

Over the last two weeks, how often have you been bothered by the following problems?

| | Not at all | Several days | More than half the days | Nearly every day |
|---|---|---|---|---|
| 1. Feeling nervous, anxious, or on edge | | | | |
| 2. Not being able to stop or control worrying | | | | |
| 3. Worrying too much about different things | | | | |
| 4. Trouble relaxing | | | | |
| 5. Being so restless that it is hard to sit still | | | | |
| 6. Becoming easily annoyed or irritable | | | | |
| 7. Feeling afraid, as if something awful might happen | | | | |

Affiliate Stigma Scale

Below are a list of statements that are related to your feeeling. Your may choose among "strongly agree", "agree", "disagree", "strongly disagree". Please do not skip any questions. Should there is any question not apply to you, please make an“X” under “never” in these cases.

| | Strongly agree | Agree | Disagree | Strongly disagree |
|---|---|---|---|---|
| 1.I avoid talking too much with others about my family's breast cancer | | | | |
| 2.When I am with family member who is diagnosed with breast cancer, I would keep silent | | | | |
| 3.Given that I have a family member with breast cancer, I’ve cut down the contacts with my relatives | | | | |
| 4.I care more about what other others think after my family member was diagnosed with breast cancer | | | | |

| | | | | |
|---|---|---|---|---|
| 5.After my family member was diagnosed with breast cancer, I was afraid to participate in social activities because I fear others asking about my family's breast cancer | | | | |
| 6.I was reluctant to let my family participate in social activities because I was afraid others would find out she was diagnosed with breast cancer | | | | |
| 7.I dare not to participate in activities related to breast cancer, lest other people would suspect that I have a family member with breast cancer | | | | |
| 8.I get nervous or embarrassed when my family member needs to talk about her breast cancer in public | | | | |
| 9.After my family member diagnosed with breast cancer, I was afraid of others paying attention or judging her sex life | | | | |
| 10.I didn't want others to know my family member was diagnosed with breast cancer | | | | |
| 11.I feel embarrassed when others talk with me that my family member was diagnosed with breast cancer | | | | |
| 12.I felt shame and remorse for not being able to afford the expensive treatment fee | | | | |
| 13.After my family taking the treatment for breast cancer, I felt uncomfortable when people stared at her chest or head | | | | |
| 14.I didn't want others to see my family member being emaciated after being diagnosed with breast cancer | | | | |
| 15.I advised family members not to tell others that someone in our family was diagnosed with breast cancer | | | | |
| 16.I was worried that others thought there was a hereditary risk of breast cancer in my family | | | | |
| 17.After my family member was diagnosed with breast cancer, I felt the strange vision from others | | | | |
| 18.After my family member was diagnosed with breast cancer, I felt someone was talking about our family or about her disease | | | | |
| 19.After my family member was diagnosed | | | | |

| | | | | |
|---|---|---|---|---|
| with breast cancer, I often felt someone was staring at her chest or head | | | | |
| 20.When my family member was diagnosed with breast cancer, others didn't want to contact our family | | | | |
| 21.My family members and I were excluded from social activities (e.g., eatting, gatherings) | | | | |
| 22.After my family member diagnosed breast cancer, I avoided communicating with her | | | | |
| 23.After family member was diagnosed with breast cancer, I wanted to distance myself from her | | | | |
| 24.After my family taking the treatment for breast cancer, I felt humiliated or ashamed of her appearance (e.g., the loss of breasts and hair, hyperpigmentation, weight change, etc.) | | | | |

Appendix 8 Information sheet for the pilot study - Chinese version

**研究项目：一项基于理论和自我表露的家庭支持项目对中国大陆乳腺癌夫妇应对癌症复发恐惧的效果研究：预实验**

诚邀您参加由香港理工大学的梁燕萍博士（副教授），刘翔宇博士（教授），蒋玲（教授）负责监督，卜晓繁（博士生研究生）负责执行的研究计划。这项研究由香港理工大学校机构审查委员会（或其代表）审核批准（参考编号：HSEARSXXXXXXXXXXXX）。在决定是否参与本研究前，请仔细阅读以下资料。如有任何疑问或想获得更多相关资料，请向研究员查询。

**研究目的是什么？**

本研究旨在建立一个基于理论和自我表露的家庭支持项目，并探讨该项目的可行性、可接受性及初步成效。这项研究第一阶段的目的是: 评估制定的基于理论和自我表露的家庭支持项目的可行性和可接受性.

**为何你被邀请？**

总共 15 对患有乳腺癌的女性和她们的男性伴侣将被纳入这项研究。

纳入标准：

1）二人组(即已婚、订婚或其他恋爱关系的夫妇）涉及被诊断患有乳腺癌的女性，处于 I-IV 期，正在接受治疗或完成治疗，并且男性伴侣被女性乳腺癌患者确定为其照顾者；

2）每一对都住在同一个家庭；

3）年满 18 岁；

4）二组中至少有一名成员的 FCR 水平具有临床显著性(即进展恐惧量表(FoP-Q-SF)评分≥34）；

5）两组成员均签署书面知情同意书参加本研究。

排除标准：

1）其中至少一人有失明、瘫痪等身体缺陷；

2）两人均不会说或听不懂普通话。由于干预会以普通话进行，不懂或不能说普通话的参加者可能难以继续所有的课程；

3）其中至少一人有精神病史，或

4）乳腺中的癌细胞来自其他器官，而不是乳腺癌本身。

**我必需同意参加这项研究吗？**

参与本项研究全属自愿。如您决定参加，您会保留此“研究资料”，并签署同意书。您可以在任何时候停止参加研究而不需交待原因，而且不会有任何后果。

**如我参加这项研究，有什么事情要做？**

在您住院期间，我们将评估您或您的伴侣是否有资格参加本次研究。如果您和您的伴侣符合条件，我们将获得您的书面同意，并收集您的联系方式，以便将来联系。在完成书面知情同意书后，您将被邀请完成基线评估(一套问卷和测量，详细信息稍后介绍)。

您和您的伴侣将从医院获得常规护理，以及每周 40 分钟，共 6 次的基于微信的支持项目。如果您和您的伴侣同意参加这项研究，您和您的伴侣将接受每周 40 分钟，共 6 次的干预项目。该项目将提供两次运动和健康饮食的教育。此外，在剩下的 4 次干预中，夫妻双方将被要求在研究者的指导下相互表露。

你需要在两个不同的时间点：在干预前和 6 周后，完成一组问卷和测量，包括对癌症复发的恐惧，社会约束，焦虑，病耻感，侵入性想法和回避。每套问卷和测量将花费您大约 30 分钟的时间。您将被要求在双方约定的时间通过微信完成问卷。此外，您将被邀请在干预后 6 周进行访谈。关于对干预内容的整体感受的开放式问题，如会议的顺序，干预的剂量，以及对内容的建议。访谈时间为 15 分钟至 30 分钟，访谈对话将使用录音笔记录。

**参加这项研究有什么利益？**

你可以了解更多关于乳腺癌和癌症复发的知识。

**参加这项研究有什么潜在的风险和坏处？**

参与者可能会有情绪问题。如果造成情绪问题，将立即停止初步测试。若需要，夫妻将被转介到心理护理部门或医院的心理学家处。

**如果有新的信息，会发生什么事？**

研究人员将通知您与本研究相关的新信息。您可以决定是否继续参与研究。如果你决定继续，你需要签署一份最新的同意书。但是，如果您选择退出，研究人员将不会为您安排任何进一步的评估/随访。

**参加这项研究后我所提供的所有资料会否保密？**

所有与您有关的信息都将保密，并将通过只有研究人员知道的代码来识别。收集的资料将于项目完成后保存 5 年。香港理工大学会采取合理的预防措施，防止您所提供的资料遗失、被盗用、未经授权查阅或损毁。受试者的个人资料不会被转移，只有理大的研究团队才有权查阅有关资料。

**研究成果将如何处理？**

研究结果将在完成研究后予以公布，您可向我们的研究团队要求获得研究报告一份。

**哪个机构主办这项研究？**

本研究由香港理工大学护理学院主办。本研究已得到中南大学湘雅医学院附属肿瘤医院，南京医科大学附属苏州医院的同意及支持。

**谁审查研究？**

这项研究由香港理工大学校机构审查委员会审核批准（参考编号：HSEARSXXXXXXXXXXXX）。

如果您有任何问题，您可以现在或在研究开始后，向我们的助手询问。如果您对本研究的进行有任何投诉，您可以电邮联系香港理工大学机构审查委员会（institutional.review.board@polyu.edu.hk），并列明本研究的负责人、部门和参考编号。

如果您有以下任何情况，你可以联系卜晓繁（电话：1836034 /email: xiaofan123.bu@ ）：

a.如果你有任何其他与研究有关的问题；

b.在非常罕见的情况下，假如你因参与这项研究而受伤果；或

c.如果你想在（有效期限）前查阅或更改你的个人资料。

如发生严重不良事件[1]，请立即向首席调查主任/总调查主任报告，而首席调查主任/总调查主任须在收到报告后 48 小时内向理大审计局报告。

感谢您有兴趣参与这项研究。

主要研究人员：

梁燕萍博士(Email: doris.yp.leung@ )

卜晓繁博士研究生

电话：1836034

电邮：xiaofan123.bu@

[1] 严重不良事件是以下任何不良事件：
导致死亡
危及生命，或使参与者在事件发生时面临死亡的直接风险
需要或延长住院时间
导致持续或严重的残疾或丧失能力
导致先天性异常或出生缺陷
调查人员判断是重大危险的情况

Appendix 9 Consent form to participate in the pilot study - Chinese version

# 参与研究同意书

## 研究项目：一项基于理论和自我表露的家庭支持项目对中国大陆乳腺癌夫妇应对癌症复发恐惧的效果研究：预实验

由香港理工大学的梁燕萍博士（副教授），刘翔宇博士（教授），蒋玲（教授）负责监督，卜晓繁（博士生研究生）负责执行的研究。

我理解此研究所获得的资料可用于未来的研究和论文发表。 然而我有权保护自己的隐私，我的个人资料将不能泄露。我对所附资料的有关步骤已经得到充分的解释。我理解可能会出现的风险。 我是自愿参与这项研究。我理解我有权在研究过程中提出问题，并在任何时候决定退出研究而不会受到任何不正常的待遇或被追究责任。本人明白于是次研究中所提供的任何个人资料会被严格保密，除非本人明确同意相关资料被发布。另外，由研究中获取的资料将于完成研究后 5 年内销毁。

_____（研究员姓名）已向本人解释是次研究的细节，已就本人对于此次研究的问题作出解答。本人明白香港理工大学机构审查委员会（参考编号：HSEARS20230223005）已被授权存取本人有关此项目的资料，以做伦理审核用途。

如本人想获得更多关于是次研究的信息，可联络研究人员：

卜晓繁

香港理工大学

电话：1836034

电邮：xiaofan123.bu@

参加者姓名:

参加者签名:

研究人员姓名:

研究人员签名:

日期:

Appendix 10 Information sheet for the RCT - Chinese version

**研究项目：一项基于理论和自我表露的家庭支持项目对中国大陆乳腺癌夫妇应对癌症复发恐惧的效果研究：一项随机对照试验**

诚邀您参加由香港理工大学梁燕萍博士（副教授），刘翔宇博士（教授），蒋玲（教授）负责监督，卜晓繁（博士生研究生）负责执行的研究计划。这项研究由香港理工大学校机构审查委员会（或其代表）审核批准（参考编号：HSEARSXXXXXXXXXXXX）。在决定是否参与本研究前，请仔细阅读以下资料。如有任何疑问或想获得更多相关资料，请向研究员查询。

**研究目的是什么？**

本研究旨在建立一个基于理论和自我表露的家庭支持项目，并探讨该项目的可行性、可接受性及初步成效。这项研究第二阶段的目的是:

(1)探讨该项目在缓解中国乳腺癌女性及其伴侣的复发恐惧、社会约束、病耻感、焦虑、侵入性思维和回避等方面的效果。

(2)确定乳腺癌女性及其伴侣的符合率、招募率、参与率和量表缺失条目缺失率。

(3)评估干预组夫妻对该支持项目的可接受性。

**为何你被邀请？**

共有 90 对患有乳腺癌的女性和她们的男性伴侣将被纳入这项研究。

纳入标准：

1）二人组(即已婚、订婚或其他恋爱关系的夫妇）涉及被诊断患有乳腺癌的女性，处于 I-IV 期，正在接受治疗或已完成治疗，并且男性伴侣被女性乳腺癌患者确定为其照顾者；

2）每一对都住在同一个家庭；

3）年满 18 岁；

4）二组中至少有一名成员的 FCR 水平具有临床显著性(即进展恐惧量表(FoP-Q-SF)评分≥34）；

5）两组成员均签署书面知情同意书参加本研究。

排除标准：

1）其中至少一人有失明、瘫痪等身体缺陷；

2）两人均不会说或听不懂普通话。由于干预会以普通话进行，不懂或不能说普通话的参加者可能难以继续所有的课程；

3）其中至少一人有精神病史；或

4）乳腺中的癌细胞来自其他器官，而不是乳腺癌本身。

**我必需同意参加这项研究吗？**

参与本项研究全属自愿。如您决定参加，您会保留此“研究资料”，并签署同意书。您可以在任何时候停止参加研究而不需交待原因，而且不会有任何后果。

**如我参加这项研究，有什么事情要做？**

在您住院期间，我们将评估您或您的伴侣是否有资格参加本次研究。如果您或您的伴侣符合条件，我们将获得您的书面同意，并收集您的联系方式以供将来联系。在完成书面知情同意书后，您将被邀请完成基线评估(一套问卷和测量，详细信息稍后介绍)。然后，研究人员会将您按 1:1 的比例随机分为干预组或对照组，研究组不能随意改变。

如果您被分配到干预组，您和您的伴侣将从医院接受常规护理，外加基于微信的为期 6 周每周 40 分钟的支持项目。如果您被安排为对照组，您将接受医院的常规护理和每周 6 次随访微信电话。12 周后，对于对照组的人，研究人员将免费为他们提供与干预组相同的教育手册。

无论你是在干预组还是对照组，你都需要在三个不同的时间点：随机化前，6 周和 12 周，完成一套调查问卷和测量，包括对癌症复发的恐惧，社会约束，焦虑，病耻感，侵入性想法和回避。每套问卷和测量将花费您大约 30 分钟的时间。测量结果将在双方约定的时间通过微信完成自我报告。**此外，您将被邀请在干预后 12 周进行访谈。关于对干预可接受性的看法的开放式问题。访谈时间为 20 分钟左右，访谈对话将使用录音笔记录。**

**参加这项研究有什么利益？**

您提供的信息将有助于提高乳腺癌患者及其护理人员的护理水平。。

**参加这项研究有什么潜在的风险和坏处？**

参与者可能会有情绪问题。如果造成情绪问题，将立即停止初步测试。若需要，夫妻将被转介到心理护理部门或医院的心理学家处。

**如果有新的信息，会发生什么事？**

研究人员将通知您与本研究相关的新信息。您可以决定是否继续参与研究。如果你决定继续，你需要签署一份最新的同意书。但是，如果您选择退出，研究人员将不会为您安排任何进一步的评估/随访。

**参加这项研究后我所提供的所有资料会否保密？**

所有与您有关的信息都将保密，并将通过只有研究人员知道的代码来识别。收集的资料将于项目完成后保存 5 年。香港理工大学会采取合理的预防措施，防止您所提供的资料遗失、被盗用、未经授权查阅或损毁。受试者的个人资料不会被转移，只有理大的研究团队才有权查阅有关资料。

**研究成果将如何处理？**

研究结果将在完成研究后予以公布，您可向我们的研究团队要求获得研究报告一份。

**哪个机构主办这项研究？**

本研究由香港理工大学护理学院主办。本研究已得到中南大学湘雅医学院附属肿瘤医院，南京医科大学附属苏州医院的同意及支持。

**谁审查研究？**

这项研究由香港理工大学校机构审查委员会审核批准（参考編號：HSEARSXXXXXXXXXXXX）。

如果您有任何问题，您可以现在或在研究开始后，向我们的助手询问。如果您对本研究的进行有任何投诉，您可以电邮联系香港理工大学机构审查委员会（institutional.review.board@polyu.edu.hk），并列明本研究的负责人、部门和参考编号。

如果您有以下任何情况，你可以联系卜晓繁（电话：1836034　　/email:

xiaofan123.bu@

a.如果你有任何其他与研究有关的问题；

b.在非常罕见的情况下，假如你因参与这项研究而受伤果；或

c.如果你想在（有效期限）前查阅或更改你的个人资料。

如发生严重不良事件 [1]，请立即向首席调查主任/总调查主任报告，而首席调查主任/总调查主任须在收到报告后 48 小时内向理大审计局报告。

感谢您有兴趣参与这项研究。

主要研究人员：

梁燕萍博士(Email: doris.yp.leung@　　)

卜晓繁博士生

电话：1836034

电邮：xiaofan123.bu@

[1] 严重不良事件是以下任何不良事件：
导致死亡
危及生命，或使参与者在事件发生时面临死亡的直接风险
需要或延长住院时间
导致持续或严重的残疾或丧失能力
导致先天性异常或出生缺陷
调查人员判断是重大危险的情况

Appendix 11 Consent form for the RCT - Chinese version

**参与研究同意书**

项目名称: 一项基于理论和自我表露的家庭支持项目对中国大陆乳腺癌夫妇应对癌症复发恐惧的效果研究：随机对照试验

由香港理工大学的梁燕萍博士（副教授），刘翔宇博士（教授），蒋玲（教授）负责监督,卜晓繁（博士生研究生）负责执行的研究。

我理解此研究所获得的资料可用于未来的研究和论文发表。 然而我有权保护自己的隐私，我的个人资料将不能泄露。我对所附资料的有关步骤已经得到充分的解释。我理解可能会出现的风险。 我是自愿参与这项研究。我理解我有权在研究过程中提出问题，并在任何时候决定退出研究而不会受到任何不正常的待遇或被追究责任。本人明白此次研究中所提供的任何个人资料会被严格保密，除非本人明确同意相关资料被发布。另外，由研究中获取的资料将于完成研究后5 年内销毁。

_____（研究员姓名）已向本人解释是次研究的细节，已就本人对于此次研究的问题作出解答。本人明白香港理工大学机构审查委员会（参考编号：HSEARS20230223005）已被授权存取本人有关此项目的资料，以做伦理审核用途。

如本人想获得更多关于是次研究的信息，可联络研究人员：

卜晓繁

香港理工大学

电话：1836034

电邮：xiaofan123.bu@

参加者姓名:

参加者签名:

研究人员姓名:

研究人员签名:

日期:

Appendix 12 Questionnaire for pilot study and RCT for women with breast cancer - Chinese version

**Chinese version-scales for women with breast cancer**

**疾病进展恐惧量表(FoP-Q-SF)**

下列是您可能担心和关注的问题，请您依照您的感受，勾选（“√”）最适合的程度：分别有“从不”、“很少”、“有时”、“经常”及“总是”五种，请您每一题都作答。如果有些不符合您现在的状况，就请勾选“从不”，例如：如果已经退休，则有关工作的相关描述就请勾“从不”。感谢您的配合！

| | 从不 | 很少 | 有时 | 经常 | 总是 |
|---|---|---|---|---|---|
| 1.担心疾病会进展 | | | | | |
| 2.在医生检查和一些定期体检前我感到紧张 | | | | | |
| 3.害怕疼痛 | | | | | |
| 4.担心可能影响今后的工作 | | | | | |
| 5.担心有一些症状（如疼痛、焦虑、淋巴水肿等） | | | | | |
| 6.我担心我的孩子会得这个疾病 | | | | | |
| 7.担心今后的活动和日常生活要依靠别人 | | | | | |
| 8.担心以后不能追求我的爱好 | | | | | |
| 9.担心疾病过程中会有一些大的治疗 | | | | | |
| 10.担心治疗和药物会损害我的身体 | | | | | |
| 11.我担心如果我发生什么家庭会发生变化 | | | | | |
| 12.担心今后不能再继续工作了 | | | | | |

**社会约束量表**

有时，即使您的配偶或伴侣没有恶意，他可能会说了或是做了一些令您不愉快的事情。请回想过去一个月，并指出您的配偶或伴侣有多少次曾对您做过以下的事情。

| 内容 | 从不 | 甚少 | 有时 | 经常 |
|---|---|---|---|---|
| 1.当您尝试讨论您的疾病时改变话题？ | | | | |
| 2.好像不理解您的情况？ | | | | |

| | | | | |
|---|---|---|---|---|
| 3.逃避您？ | | | | |
| 4.忽略/低估您的问题？ | | | | |
| 5.他好像在隐藏自己的感觉？ | | | | |
| 6.当您提到您的病时显得不自在？ | | | | |
| 7.令您觉得您的问题不重要？ | | | | |
| 8.当您想找他倾谈时，他却只在抱怨自己的问题？ | | | | |
| 9.他在您面前显得高兴，来隐藏他对您真正的感受或担心？ | | | | |
| 10.让您不要太担心您的健康？ | | | | |
| 11.让您不要为您的疾病想得太多？ | | | | |
| 12.令您觉得他不想听到您的疾病？ | | | | |
| 13.令您觉得应该隐藏您对癌症的感受，因为您的感受令他觉得很不自在？ | | | | |
| 14.令您觉得应该隐藏您对癌症的感受，因为您的感受令他感到不愉快？ | | | | |
| 15.他让您不开心，因为他没有像您希望中的那般爱和关怀您？ | | | | |

**事件影响量表修订版(IES-R)**

以下陈述想知道您对此事（患乳腺癌）的感受，请您根据自己的情况在相应选项下打“√”。

| | 从没 | 很少 | 有时 | 常常 | 总是 |
|---|---|---|---|---|---|
| 侵袭性思维 | | | | | |
| 1.我常因为其他事想起此事 | | | | | |
| 2.关于此事的画面或者形象常在脑海闪现 | | | | | |
| 3.关于此事常有强烈的情感波澜袭扰我 | | | | | |
| 4.想起此事导致我有生理反应，如出汗、呼吸困难、恶心或心跳加速 | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| 5.我觉得容易愤怒或生气 | | | | | |
| 6.我尽量不谈论此事 | | | | | |
| 7.我试图把此事从记忆中抹去 | | | | | |
| 回避 | | | | | |
| 1 我发现我的所作所想好像又回到了那时 | | | | | |
| 2 我难以保持熟睡 | | | | | |
| 3.我难以入数 | | | | | |
| 4.我很敏感且容易受到惊吓 | | | | | |
| 5.我充满警惕性或处于警觉状态 | | | | | |
| 6.我难以集中注意力 | | | | | |
| 7.我对此事的感触有些麻木 | | | | | |

**GAD-7 焦虑自评量表**

说明：在过去的两周里，你生活中以下症状出现的频率有多少？

| | 没有 | 有几天 | 一半时间以上 | 几乎天天 |
|---|---|---|---|---|
| 1.感觉紧张，焦虑或急切 | | | | |
| 2.不能够停止或控制担忧 | | | | |
| 3.对各种各样的事情担忧过多 | | | | |
| 4.很难放松下来 | | | | |
| 5.由于不安而无法静坐 | | | | |
| 6.变得容易烦恼或急躁 | | | | |
| 7.感到似乎将有可怕的事情发生而害怕 | | | | |

**乳腺癌患者病耻感量表**

填表说明：表格中共有 15 句话，是想了解您对患病的真实想法，请您仔细阅读，根据是否同意每句话的说法，分别在“非常同意”、“同意”、“不同意”、“非常不同意”下划“√”。

| 内容 | 非常 | 同意 | 不同意 | 非常不 |
|---|---|---|---|---|

| | 同意 | | | 同意 |
|---|---|---|---|---|
| 1.我在意自己乳房的变化 | | | | |
| 2.我觉得乳房做了手术，自身就不完美了 | | | | |
| 3.手术后，我不愿意看或触摸乳房手术留下的伤疤 | | | | |
| 4.手术后，我比（手术）以前对自己的外在形象更焦虑无自信 | | | | |
| 5.我觉得治疗让我外表吸引力减少了，不再那么女性化了 | | | | |
| 6.我觉得自己不是一个健康人 | | | | |
| 7.在与伴侣亲密时，我会遮住胸部 | | | | |
| 8.我害怕亲密的身体接触：如拥抱等 | | | | |
| 9.因为患病，人们通常会同情我 | | | | |
| 10.患病后，我常常感觉有人盯着我看 | | | | |
| 11.患病后，我常常听到有人背后偷偷议论我 | | | | |
| 12.因为化疗所致脱发而带帽子后被嘲笑 | | | | |
| 13.我不想让除了亲近之外的人知道我患有乳腺癌 | | | | |
| 14.当别人看我胸部时，我感觉不自然 | | | | |
| 15.我不想让别人看到我患病后的样子 | | | | |

Appendix 13 Questionnaire for pilot study and RCT for partners

Chinese version-scales for partners

疾病进展恐惧简化量表-配偶

下列是您可能担心和关注的问题，请您依照您的感受，勾选（“√”）最适合的程度：分别有“从不”、“很少”、“有时”、“经常”及“总是”五种，请您每一题都作答。如果有些不符合您现在的状况，就请勾选“从不”，例如：如果已经退休，则有关工作的相关描述就请勾“从不”。

感谢您的配合！

| 条目 | 从不 | 很少 | 有时 | 经常 | 总是 |
|---|---|---|---|---|---|
| 1.想起爱人病情也许会进展时我感到焦虑 | | | | | |
| 2.在医生预约和定期检查之前我感到紧张 | | | | | |
| 3.我害怕我爱人会疼痛 | | | | | |
| 4.我担心爱人因为生病而无法达到她的职业目标 | | | | | |
| 5.每当我担心时会有一些症状（如心跳加快，胃痛，紧张等） | | | | | |
| 6.我担心我的孩子会传到爱人的疾病 | | | | | |
| 7.我爱人的日常生活活动可能不得不依靠陌生人，这使我困扰 | | | | | |
| 8.我担心在某些时候因为我爱人的疾病，我不能再继续自己的爱好 | | | | | |
| 9.我担心疾病过程中会有一些重大的治疗 | | | | | |
| 10.我害怕药物会损害我爱人的身体 | | | | | |
| 11.我担心如果爱人发生什么家庭会怎么样 | | | | | |
| 12.我爱人因为生病无法工作的想法困扰着我 | | | | | |

社会约束量表

有时，即使您的配偶或伴侣没有恶意，他可能会说了或是做了一些令您不愉快的事情。请回想过去一个月，并指出您的配偶或伴侣有多少次曾对您做过以下的事情。

| 内容 | 从不 | 甚少 | 有时 | 经常 |
|---|---|---|---|---|
| 1.当您尝试讨论您的疾病时，您的爱人会改变话题吗？ | | | | |
| 2.您的爱人好像不理解您的情况？ | | | | |
| 3.您会觉得您的爱人逃避您？ | | | | |
| 4.当您提出有关健康的问题或想法是，会被您的爱人 | | | | |

| | | | | |
|---|---|---|---|---|
| 忽略或低估吗？ | | | | |
| 5.您觉得您的爱人好像在隐藏自己的情绪或感觉？ | | | | |
| 6.当您提到您的病时，您的爱人会显得不自在？ | | | | |
| 7.您的爱人会令您觉得您的问题不重要？ | | | | |
| 8.当您想找您的爱人倾谈时，您的爱人却只在抱怨自己的问题？ | | | | |
| 9.您的爱人在您面前显得高兴，来隐藏他对您真正的感受或担心？ | | | | |
| 10.您的爱人让您不要太担心您的健康？ | | | | |
| 11.您的爱人让您不要为您的疾病想得太多？ | | | | |
| 12.令您觉得您的爱人不想听到您的疾病？ | | | | |
| 13.令您觉得应该隐藏您对癌症的感受，因为您的感受令您的爱人觉得很不自在？ | | | | |
| 14.令您觉得应该隐藏您对癌症的感受，因为您的感受令您的爱人感到不愉快？ | | | | |
| 15.您的爱人让您不开心，因为他没有像您希望中的那般爱和关怀您？ | | | | |

事件影响量表修订版

以下陈述想知道您对此事（妻子患乳腺癌）的感受，请您根据自己的情况在相应选项下打“√”。

| | 从没 | 很少 | 有时 | 常常 | 总是 |
|---|---|---|---|---|---|
| 侵袭性思维 | | | | | |
| 1.我常因为其他事想起此事 | | | | | |
| 2.关于此事的画面或者形象常在脑海闪现 | | | | | |
| 3.关于此事常有强烈的情感波澜袭扰我 | | | | | |
| 4.想起此事导致我有生理反应，如出汗、呼吸困难、恶心或心跳加速 | | | | | |
| 5.我觉得容易愤怒或生气 | | | | | |
| 6.我尽量不谈论此事 | | | | | |
| 7.我试图把此事从记忆中抹去 | | | | | |
| 回避 | | | | | |
| 1 我发现我的所作所想好像又回到了那时 | | | | | |
| 2 我难以保持熟睡 | | | | | |
| 3.我难以入数 | | | | | |
| 4.我很敏感且容易受到惊吓 | | | | | |
| 5.我充满警惕性或处于警觉状态 | | | | | |
| 6.我难以集中注意力 | | | | | |
| 7.我对此事的感触有些麻木 | | | | | |

乳腺癌照护者连带病耻感量表

填表说明：回想您对家人患乳腺癌疾病后的真实想法，请您仔细阅读，根据是否同意每句话的说法，分别在“非常同意”、“同意”、“不同意”、“非常不同意”下划“√”。

| 内容 | 非常同意 | 同意 | 不同意 | 非常不同意 |
|---|---|---|---|---|
| 1.我会避免与其他人过多谈及家人的乳腺癌疾病 | | | | |
| 2.当我与患乳腺癌的家人在一起时，我有时会比较沉默 | | | | |
| 3.我的家人患乳腺癌后，我有减少与亲戚朋友的联络 | | | | |
| 4.家人得乳腺癌后，我会更在意别人的看法 | | | | |
| 5.家人患乳腺癌后，我害怕参与社交活动，因为我害怕别人问起我家人的乳腺癌情况 | | | | |
| 6.我不愿意让我的家人参加社交活动，因为我担心别人会发现她患有乳腺癌。 | | | | |
| 7.我不敢参加与乳腺癌相关的活动，免得别人怀疑我的家人患有乳腺癌 | | | | |
| 8.当我的家人需要在公共场合谈论她患乳腺癌时，我会感到紧张或尴尬 | | | | |
| 9.在家人患有乳腺癌后，我害怕别人关注或评价她的性生活 | | | | |
| 10.我不想让别人知道我的家人患有乳腺癌 | | | | |
| 11.当别人和我谈起我家人得了乳腺癌时我会感到尴尬 | | | | |
| 12.我因无力承担昂贵的治疗费用而感到羞愧与自责 | | | | |
| 13.我的家人经过乳腺癌的治疗后，别人盯着她的胸部或头部看时令我感觉不舒服 | | | | |
| 14.我不想让别人看到我的家人患乳腺癌后憔悴的样子 | | | | |
| 15.我曾劝告家庭成员不要告诉别人我们家里有人患乳腺癌 | | | | |
| 16.我担心别人会认为我家族有遗传性乳腺癌的风险。 | | | | |
| 17.家人患乳腺癌后，我感受到了别人的异样眼光 | | | | |

| | | | | |
|---|---|---|---|---|
| 18.我的家人患乳腺癌后，我感觉有人在议论我们家或议论她的疾病 | | | | |
| 19.我的家人患乳腺癌后，我常感觉有人盯着她的胸部或者头部看 | | | | |
| 20.我的家人患乳腺癌后，别人不愿意和我们家庭接触 | | | | |
| 21.我的家人患乳腺癌后，我和我的家人被外界歧视或排斥在社交活动之外（如吃饭、聚会等） | | | | |
| 22.我的家人患乳腺癌后，我曾避免与她沟通 | | | | |
| 23.我的家人患有乳腺癌后，我曾想疏远她 | | | | |
| 24.家人接受乳腺癌的相关治疗后，我对她的外在形象（乳房缺失、脱发、色素沉着、体重改变等）感到到丢脸或羞耻 | | | | |
| 25.我害怕别人觉得是我祖上做了不好的事才导致家人得到了乳腺癌的报应 | | | | |

GAD-7 焦虑自评量表

说明：在过去的两周里，你生活中以下症状出现的频率有多少？

| | 没有 | 有几天 | 一半时间以上 | 几乎天天 |
|---|---|---|---|---|
| 1.感觉紧张，焦虑或急切 | | | | |
| 2.不能够停止或控制担忧 | | | | |
| 3.对各种各样的事情担忧过多 | | | | |
| 4.很难放松下来 | | | | |
| 5.由于不安而无法静坐 | | | | |
| 6.变得容易烦恼或急躁 | | | | |
| 7.感到似乎将有可怕的事情发生而害怕 | | | | |

Appendix 14 Details of the changed content of affiliate stigma scale in the two Delphi rounds

For the first round of Delphi study, a scale comprising four domains and 38 items was distributed for expert review. Based on their feedback, seven items were deleted due to irrelevance to stigma, for instance, “I feel helpless after my family member diagnosed with breast cancer”, “Breast cancer in my family took a toll on my reputation”, and “I felt stressed after my family member diagnosed with breast cancer”. Four items were merged due to redundancy. For instance, two items of “I avoid talking to others about my family's illness” and “I don't like to talk to others about my family's disease too much” were combined into one item of “I would avoid talking too much about my family member’s breast cancer disease with others”; items of “I care about the changes in appearance of my family member after treatment, such as hair loss/breast loss/weight loss, etc.” and “I feel the appearance of my family member is not perfect any more after surgery and chemotherapy” were merged to “After my family received treatment for breast cancer, I felt humiliated or ashamed about her appearance (e.g., missing breasts, hair loss, hyperpigmentation, and weight change).” The wording of eight items was revised for clarity and appropriateness. For example, phrase of “discriminate against me” was changed to “strange looks from others”; “low key” was revised to “reticent”, “uncomfortable was changed to “embarrassed”. Additionally, three items were added based on expert suggestions. For example, “I was worried that others would think there was a hereditary risk of breast cancer in my family.”; “After my family member was diagnosed with breast cancer, I was afraid of others paying attention or judging her sex life.”

In the second round of Delphi study, a revised-version of the scale comprising four domains and 28 items was sent for expert review. Based on the feedback, two items were deleted as they were either unrelated to stigma or considered redundant and two items were revised due to expression issue. As a result, the initial 26-item scale was finalized, which was deemed more applicable and appropriate for measuring affiliate

stigma in caregivers of women with breast cancer. The I-CVI was calculated for each item, with values ranging from 0.8 to 1.0. In the subsequent pilot testing phase, 10 caregivers indicated that the wording of the scale was easy to understand and the time required for completion was acceptable. Hence, no further modification was made to this version of the scale.

Appendix 15 Intervention fidelity checklist

Intervention fidelity was assessed using a self-developed checklist addressing the distribution of electronic handbook materials, duration of intervention delivery, delivery of all contents in each session according to the session plan, delivery mode and implementation of disclosure between couples. Three possible responses were given (Yes/No/Not applicable).

| Couples ID | Distribution of electronic handbook materials | Duration of intervention delivery | Delivery of all contents | Delivery mode | Implementation of disclosure |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

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