BEHAVIORAL ACTIVATION FOR IMPROVING SLEEP QUALITY IN FAMILY CAREGIVERS OF PEOPLE WITH DEMENTIA: A PILOT RANDOMIZED CONTROLLED TRIAL

XU XIN YI

PhD
The Hong Kong Polytechnic University
2020

The Hong Kong Polytechnic University
School of Nursing

Behavioral Activation for improving sleep quality in family caregivers of people with dementia: A pilot randomized controlled trial

Xu Xin Yi

A thesis submitted in partial fulfilment of the requirements for the degree of
Doctor of Philosophy
July 2020

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.

__________________ (Signed)

Xu Xin Yi (Name of student)

Abstract

Background: Sleep disturbance is a common phenomenon in family caregivers of people with dementia (PWD). It has a negative impact on caregivers themselves, care recipients, and society as a whole. Different non-pharmacological treatments, therefore, have been utilized to improve sleep quality and psychological health in family members who are caregivers of PWD. Among these treatments, behavioral activation (BA) shows promising potential in improving sleep quality; however, by now, evidence for the feasibility and efficacy of this treatment on sleep quality in family caregivers of PWD is limited.

Aims and objectives: This study aims to develop and pilot test an evidence-based BA protocol for improving sleep quality in Chinese family caregivers of PWD. The objectives of this study are to (1) develop an evidence-based standard protocol for using BA to improve sleep quality for Chinese family caregivers of PWD; (2) determine the feasibility and acceptability of the newly developed BA protocol in Chinese family caregivers of PWD; and (3) preliminarily examine the effects of BA on sleep quality and psychological health in family caregivers of PWD.

Methods: This study compromises two phases: 1) phase 1: development and refinement of the BA protocol, and 2) phase 2: feasibility assessment and preliminary examination of BA. For phase 1, a comprehensive literature review was conducted to identify relevant BA theories, principles, and related manuals to develop BA protocol. Semi-structured interviews were conducted to explore and understand Chinese family caregivers of PWD's perceptions and expectations of pleasant leisure activities and BA protocol. A draft BA protocol was also shown to the interviewers to comment. The BA protocol was revised based on the results of the interviews. For phase 2, a pilot 2-arm randomized controlled trial (RCT) was carried out to examine the feasibility, acceptability, and potential efficacy of the BA on sleep quality. The BA intervention involved eight weekly individual telephone-based sessions designed to teach caregivers specific BA techniques. Participants in the control group received usual care from communities, hospitals and clinics. Sleep quality, depression, leisure activity, relationship satisfaction, self-rated health, positive aspect of caregiving, and caregiving burden were assessed at baseline and post-intervention by blinded interviewers. Data were analyzed with Repeated Measures of ANOVA based on the intention-to-treat principle of all available data. After completing the pilot RCT, semi-structured interviews were conducted to explore the participants' experiences of participating in the BA intervention.

Result: In phase 1 of this study, 20 family caregivers participated in the semi-structured interviews, and the BA intervention protocol was revised according to their comments. A total of 71 family caregivers of PWD (35 for the intervention group, and 36 for the control group) were recruited, and 59 participants (83.10%) completed the post-intervention outcome assessments. Compared with caregivers in the control group, caregivers in the intervention group displayed significantly greater improvement in sleep quality ($F(1,69) = 6.32$, $p=0.014$, Partial $\eta 2 = 0.084$), leisure activities ($F(1,69) = 15.89$, $p<0.001$, Partial $\eta 2 = 0.218$), as well as positive aspect of caregiving ($F(1,69) = 6.53$, $p=0.013$, Partial $\eta 2 = 0.086$), and greater reduction in depression ($F(1,69) = 7.53$, $p=0.008$, Partial $\eta 2 = 0.098$) and caregiving burden ($F(1,69) = 6.93$, $p=0.010$, Partial $\eta 2 = 0.091$). The BA intervention protocol was found to be feasible for use, as the majority of participants (85.71%) from the intervention group followed the study protocol to complete the eight-week BA intervention. Nineteen participants took part in the post-intervention semi-structured interviews. Most of the interviewed participants were very satisfied with the intervention, and they could improve their sleep and psychological health by adopting BA intervention techniques.

Conclusion: The current findings suggest that individual telephone-based BA intervention is feasible, acceptable, and effective for improving sleep quality as well as psychological health in family caregivers of PWD. Results contribute to the current literature by providing evidence for developing effective, accessible, sustainable BA intervention for family caregivers of PWD.

Publications and Awards

Journal papers

Xu, X. Y., Leung, A. Y. M., Smith, R., Wong, J. Y. H., Chau, P. H., Fong, D.Y.T. (2020). The Relative Risk of Developing Type 2 Diabetes among Individuals with Prediabetes Compared to Individuals with Normoglycaemia: Meta-analysis and Meta-regression. Journal of Advanced Nursing, accepted.

Xu, X. Y., Kwan, R. Y. C., & Leung, A. Y. M. (2020). Behavioural activation for family dementia caregivers: A systematic review and meta-analysis. Geriatric Nursing, in press. doi: https://doi.org/10.1016/j.gerinurse.2020.02.003

Xu, X. Y., Kwan, R. Y. C., & Leung, A. Y. M. (2020). Factors associated with the risk of cardiovascular disease in family caregivers of people with dementia: a systematic review. Journal of International Medical Research, 48(1). doi: https://doi.org/10.1177/0300060519845472

Kwan, R. Y. C., Leung, A. Y. M., Yee, A., Lau, L. T., Xu, X. Y., & Dai, D. L. (2019). Cognitive frailty and its association with nutrition and depression in community-dwelling older people. The Journal of Nutrition, Health & Aging, 23(10), 943-948. doi: https://doi.org/10.1089/rej.2017.2038

Leung, A. Y., Xu, X. Y., Chau, P. H., Yu, Y. T. E., Cheung, M. K., Wong, C. K., ... & Lam, C. L. (2018). A Mobile App for Identifying Individuals With Undiagnosed Diabetes and Prediabetes and for Promoting Behavior Change: 2-Year Prospective Study. JMIR mHealth and uHealth, 6(5). doi: 10.2196/10662

Xu, X. Y., Leung, A. Y. M., & Chau, P. H. (2018). Health Literacy, Self-Efficacy, and Associated Factors Among Patients with Diabetes. HLRP: Health Literacy Research and Practice, 2(2), e67-e77. doi: https://doi.org/10.3928/24748307-20180313-01

Book chapters

Leung, A. Y. M., & Xu, X. Y. (2019). Gerontechnology. Encyclopedia of Gerontology and Population Aging: Springer. Retrieved from https://link.springer.com/content/pdf/10.1007%2F978-3-319-69892-2_1087-1.pdf

Leung, A. Y. M., Xu, X. Y. &Wong, E.M. (2019). Home health technologies. Encyclopedia of Gerontology and Population Aging: Springer. Retrieved from https://link.springer.com/content/pdf/10.1007%2F978-3-319-69892-2_1086-1.pdf

Presentations

Xu, X. Y., Leung, A. Y. M., Kwan, R. Y. C., Liang. T. N. & Chai. A. J. 'Is leisure a Right for Me?': Family Dementia Caregivers' Perceptions of Leisure Activities. Poster presented at the 23rd East Asian Forum of Nursing Scholars (EAFONS) 2020, Chiang Mai, Thailand. 10-11 January 2020.

Xu, X. Y. Becoming a Scholar Doctoral Students' Pathway to Success. Invited oral presentation at the 23rd East Asian Forum of Nursing Scholars (EAFONS) 2020, Chiang Mai, Thailand. 10-11 January 2020.

Xu, X. Y., Kwan, R. Y. C., & Leung, A. Y. M. Behavioural Activation for Depression of Family Dementia Caregivers: A Systematic Review and Meta-analysis. Poster presented at the Gerontological Society of America 2019 Annual Scientific Meeting, Austin, U.S.. 13-17 November 2019.

Honors and Awards

23rd East Asian Forum of Nursing Scholars (EAFONS) 2020: Best Poster Presentation Award: 1st place 01/2020

Geological Society of America (GSA) 2019 Annual meeting: Health Sciences Travel Student Travel and Engagement Stipend 11/2019

Research Student Attachment Programme for Visiting scholar of University Technology Sydney 2019/20 (Outgoing PolyU Students: 1st Round) 10/2019

Acknowledgment

My three year Ph.D. journey is finally reaching the terminal. I have gained a lot through this beautiful, lovely, challenging, and tough journey. It will be a treasure for my whole life, and I have never regretted choosing this journey.

I would like to express my sincere appreciation to my supervisors, Dr Angela Leung and Dr Rick Kwan. For their intelligence and the great responsibility that guides me on the right track of the study. My special thanks to Dr Leung. From 2015 to 2020, she witnessed me grew from a fresh-faced undergraduate student to a mature Ph.D. candidate. She guided me a lot, whether in research or life, to promote my academic and spiritual growth. I could not complete this journey without her encouragement and expert guidance. I have never met a supervisor like her that was so considerate of the students. Dr Angela Leung is my role model, and I wish to become a supervisor like her in the future.

I’m grateful to the fellow students and friends in the Hong Kong Polytechnic University. Thank you for your peer support for encouraging me to resolve difficulties in research. Thank you for your selfless sharing for guiding me to solve puzzles in life. It is you who have made my three years unforgettable, meaningful, and joyful.

Finally, I would like to extend my profound appreciation and gratitude to my parents, who has encouraged me to dream bigger and to realize my potential, who has provided tremendous support. Their great love supported me to get where I am today.

Table of contents

List of Tables

List of Figures

Abbreviations

BA: Behavioral Activation

BATD: Behavioral Activation Treatment for Depression

BATD-R: revised version of Behavioral Activation Program

BPSD: behavioral and psychological symptoms of dementia

BOCF: baseline observation carried forward

CBT: cognitive behavioral therapy

CCES-D: Chinese version of Center for Epidemiologic Studies Depression Scale

CONSORT: Consolidated Standards of Reporting Trials

COREQ: Consolidated Criteria for Reporting Qualitative Studies

C-PAC: Chinese version of the positive aspect of caregiving scale

CPSQI: Chinese version of the Pittsburgh Sleep Quality Index

CRP: C-creative protein

CTS-R: Cognitive Therapy Scale Revised

CVD: cardiovascular disease

CWC: Coping with Caregiving

C-ZBI: Chinese version of Zarit Burden Interview

DIMS: disorders of initiating and maintaining sleep

DOES: disorders of excessive somnolence

HPLR: High Pleasant Events + Low Activity Restriction

HPHR: Either High Pleasant Events + High Activity Restriction or

IL-6: interleukin-6

ITT: intention to treat

LOCF: last observation carried forward

LPHR: Low Pleasant Events + High Activity Restriction

LPLR: Low Pleasant Events + Low Activity Restriction

MRC: Medical Research Council

PEAR: Pleasant Events and Activity Restriction

PES: pleasant event scheduling

PSQI: Pittsburgh Sleep Quality Index

PWD: people with dementia

QoL: quality of life

RCT: randomized controlled trial

REACH: Resources for Enhancing Alzheimer's Caregiver Health

RM-ANOVA: repeated measures of Analysis of Variance

SD: standard deviation

SE: standard error

SRH: Self-rated Health

VHN: Virtual Healthcare Neighborhood

VWF: von Willerbrand

Chapter One: Introduction

1.1 Introduction

The first chapter of this thesis constitutes a general introduction, which includes the background and study procedure of the research project, and introduces the organization of this thesis.

1.2 Background

The issue and current situation

"Dementia is a syndrome – usually of a chronic or progressive nature – in which there is deterioration in cognitive function (i.e., the ability to process thought) beyond what might be expected from normal aging" (World Health Organization, 2017). Dementia is one of the major causes of disability and dependency amongst the elderly, and it is now the 7th leading cause of death in the world (World Health Organization, 2017). According to the World Health Organization , nearly 50 million people had dementia (World Health Organization, 2019), and this number is expected to reach 131.5 million in 2050 (Alzheimer's Disease International, 2019). China has the largest population of people with dementia (PWD), the overall prevalence of dementia in Chinese people aged 60 years and older was 5.30% (Jia et al., 2020).

Dementia affects memory, thinking, orientation, comprehension, calculation, learning capacity, language, and judgement (World Health Organization, 2017). Dementia may affect people in different ways. PWD in the early stage may have the symptoms include forgetfulness, losing track of the time, becoming lost in familiar places. When dementia progresses to the middle stage, the signs and symptoms become clearer and more restricting. PWD will be easily forgetful of recent events and people's names, and will get lost at home (Alzheimer's Disease International, 2019). They will also have increased difficulty in communication, and will experience behavior changes, including wandering and repeated questioning. PWD in the late stage will loss dependence and become inactivity. Their memory disturbances are serious and the physical signs and symptoms become more obvious. They will finally become unaware of the time and place, have difficulty recognizing relatives and friends, have an increasing need for assisted self-care, have difficulty walking, and experience behavior changes that may escalate and include aggression (World Health Organization, 2017). Therefore, PWD have to be cared by other people in the progression of dementia.

Family caregivers play a vital role in taking care of PWD, with most PWD receiving care at home (World Health Organization, 2014). The term ‘family caregivers’ therefore refers to non-professionals who provide unpaid care for others in the home. In China, as a result of cultural traditions, the level of economic development, and the medical care system, family members provide a large amount of care and support to PWD (J. Wang, Xiao, He, & De Bellis, 2014). The burden for caring older adults in China has been multiplied because of the ‘one-child policy’ and a ‘4-2-1’ family structure (e.g., four grandparents, two parents, and one child). Nearly all PWD are taken care of at home. Family care is estimated to account for more than 80% of the total cost of dementia care, and the total cost of dementia *per se* has increased from 9 billion US$ in 1990 to 472 billion US$ in 2010. Based on these figures, the cost will rise to 1142 billion US$ in China in 2030 (J. Xu, Wang, Wimo, Fratiglioni, & Qiu, 2017).

Family caregivers face many challenges in taking care of their relatives with dementia. The amount of time that family caregivers sacrifice for the care of their relatives is one of the most significant challenges. Since PWD are highly dependent on the help of others, their family caregivers are responsible for most of the daily routines of PWD, including eating, dressing, bathing, toileting, etc. (Brodaty & Donkin, 2009; Win, Chong, Ali, Chan, & Lim, 2017). Besides, caregivers have to manage a variety of personal demands and unexpected behaviors that result from the relentless cognitive deterioration of PWD (McCabe, You, & Tatangelo, 2016; Tremont, 2011). Family caregivers sacrifice most of their leisure time to look after their relatives with dementia. They spend about 9 hours per day spent on their caregiving duties (Family Caregiver Alliance, 2019a; Wimo, von Strauss, Nordberg, Sassi, & Johansson, 2002).

Given that the average life expectancy of PWD after diagnosis is 7 to 10 years, family caregivers are likely to spend five years or longer in taking care of their family members with dementia (Brookmeyer, Corrada, Curriero, & Kawas, 2002; Family Caregiver Alliance, 2019a; Zanetti, Solerte, & Cantoni, 2009). Family caregivers usually have limited leisure time for themselves. In these circumstances, caregiving has a profound influence on the psychological and physical well-being of family caregivers of PWD (Abreu, Tolson, Jackson, & Costa, 2020; Bedini, Labban, Gladwell, & Dudley, 2018; Dassel & Carr, 2016; Dassel, Carr, & Vitaliano, 2017). Additionally, family caregivers of PWD face a higher risk of psychological morbidity and physical problems than caregivers of patients with other chronic diseases (e.g., diabetes, cancer, stroke). These psychological and physical negative impacts may further disrupt the sleep patterns of family caregivers of PWD (Chiu et al., 2014; S. M. McCurry, Pike, Vitiello, Logsdon, & Teri, 2008).

Sleep disturbance is prevalent among family caregivers of PWD, with two-thirds of all family caregivers being negatively affected by the consequences of sleep disturbance (H.-L. Peng, Lorenz, & Chang, 2019). Numerous studies have reported that the problem is more significant amongst family caregivers of PWD than in the general population (Fonareva, Amen, Zajdel, Ellingson, & Oken, 2011). People spend nearly one-third of their life span to sleep, and adequate sleep is essential in keeping physical and psychological health. Inadequate sleep can have a deleterious effect on the immune system, daily function, and psychological and physical health, as mentioned above (Kryger, Roth, Eloni, & Dement, 2005; Medic, Wille, & Hemels, 2017). Some studies suggest that sleep disturbance of family caregivers of PWD is associated with complaints of impaired daytime and social functioning, decreased concentration and memory, and excessive daytime sleepiness (Medic et al., 2017; Riedel & Lichstein, 2000; Semler & Harvey, 2005). Sleepiness is also a common physical problem in Chinese family caregivers of PWD (Liu et al., 2017). Family caregivers of PWD also reported experiencing more frequent episodes of depression, weariness, stress and cardiovascular disease (CVD) as a result of sleep disturbance (Brent T Mausbach et al., 2006; von Känel et al., 2006; X. Y. Xu, Kwan, & Leung, 2020b). Sleep disturbance may also contribute to a lower quality of caregiving, as well as an early placement in a long-term care center (H. L. Peng & Chang, 2013). Therefore, maintaining enough sleep is important for family caregivers to perform their caregiving roles. It is essential to offer suitable interventions to improve sleep quality in family caregivers, and therefore improve their physical and psychological health. While sleep disturbance is still an under-recognized and undertreated problem in family caregivers of PWD.

“BA is a brief structured psychotherapeutic treatment for depression that aims to activate clients in specific ways that will increase rewarding experiences in their lives” (Martell, Dimidjian, & Herman-Dunn, 2013). BA aims to increase positive response-contingent environmental reinforcement and help clients to engage in pleasant and constructive activities and therefore make them reconnected with positive and enjoyable aspects of their lives (Martell et al., 2013). It is a well-designed psychotherapeutic intervention that might have the potential in the future to provide a cost-effective way of improving overall sleep quality in Chinese family caregivers of PWD. Since BA could increase positive response-contingent environmental reinforcement and the engagement in pleasant and constructive activities among clients, so it can effectively reduce psychological burden, especially depression, and improve sleep quality consequently. However, there is very little research evidence to support this view. No study has investigated the feasibility, acceptability, and efficacy of BA on improving sleep quality in family caregivers of PWD.

The present study

The overall aim of this research project is to test the feasibility and acceptability of a BA protocol for improving sleep quality in family caregivers of PWD and to explore the preliminary effects of BA on sleep through a two-parallel-arm usual care-controlled randomized pilot trial. The Medical Research Council (MRC) Framework for Developing and Evaluating Complex Interventions was applied to guide the study design to achieve the study’s aim. An evidence-based BA protocol was revised, based on relevant BA theories and the BA manual. Then, semi-structured interviews were selected from a group of Chinese family caregivers of PWD to determine and evaluate the appropriateness of the contents. After that, a pilot randomized controlled trial (RCT) and a nested post-intervention semi-structured interviews were set up to examine the feasibility of the BA protocol; to pilot the methodological procedures of the RCT; and, preliminarily, to examine the effects of BA on family caregivers’ sleep quality.

1.3 Organization of the thesis

The overall theme that links all studies is to applying a revised BA protocol to improve sleep quality in Chinese family caregivers of PWD. This thesis consists of eight chapters. This first chapter provides an overview of the study. The second chapter provides a detailed and comprehensive review of the literature on sleep and BA in family caregivers of PWD. Besides, it identifies gaps in the research that has not been done. The third chapter provides details of the research methodology, including the research aim and objectives, the research questions and hypotheses, and the research design for different stages of the study. The fourth chapter presents the development and refinement of BA protocol in this study. The fifth chapter provides the feasibility and acceptability assessments of BA from both quantitative and qualitative analysis aspects. The sixth chapter shows the results of pilot RCT, as well as the nested post-intervention semi-structured interviews. The seventh chapter presents the discussion about family caregivers' perceptions of leisure activity, refinement of BA, the efficacy, and the feasibility of BA. The seventh chapter also discusses the strengths and limitations, implications for future study, and clinical practice. The last chapter summarized the conclusion of the entire study.

Chapter Two: Literature Review

2.1 Introduction

This chapter focuses on reviewing literature related to the use of BA in improving sleep quality in family caregivers of PWD. Firstly, this chapter discusses definitions of sleep quality and sleep disturbance and the significance of sleep in family caregivers of PWD. Secondly, it discusses the causes of sleep disturbance in family caregivers of PWD and presents possible interventions to improve sleep quality by alleviating those contributing factors. Thirdly, a systematic review and meta-analysis of BA in family caregivers of PWD is shown. Fourthly, this chapter closes with a discussion about why BA is potentially useful in managing sleep disturbance in family caregivers of PWD and points to gaps in current knowledge about this topic. Finally, a conceptual framework of BA is presented to guide the whole study.

2.2 Sleep in family caregivers of PWD

2.2.1 Sleep quality

Sleep occupies one-third of the human life span, and good sleep is critical for maintaining physical and psychological health (Aminoff, Boller, & Swaab, 2011). Carskadon and Dement (2005) have defined sleep as: “a recurring, reversible neurobehavioral state of relative perceptual disengagement from and unresponsiveness to the environment.” Good sleep quality helps a person to keep healthy brain function and emotional well-being, for example, enhancing learning and problem-solving skills, being creative and learning, and remembering information efficiently (National Institute of Health, 2020). Sleep also plays a vital role in keeping physical health, and the ongoing sleep deficiency is associated with the increased risk of diabetes, high blood pressure, obesity, heart disease, kidney disease, and stroke (National Institute of Health, 2020). Additionally, getting enough quality of sleep is beneficial for daytime performance and safety throughout the day. People with sleep deficiency are less productive in school and work since they will have slower reaction times and make more mistakes (National Institute of Health, 2020).

Sleep quality is defined as “one’s satisfaction with the sleep experience, integrating aspects of sleep initiation, sleep maintenance, sleep quantity, and refreshment upon awakening” (Kline, 2013). In this study, the sleep quality was reported by the global score of PSQI through summing up seven subscales’ scores (overall subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction).

The Pittsburgh Sleep Quality Index (PSQI) (Buysse, Reynolds III, Monk, Berman, & Kupfer, 1989) was developed in 1989, which is a reliable and simple index of discriminating “good” from “poor” sleepers. It is one of the most widely used instruments to measure sleep quality in family caregivers of PWD subjectively. The PSQI is a 19-item self-rated questionnaire for evaluating subjective sleep quality over the previous month. The 19 items include seven clinical components, each weighted equally from 0–3, and the global score ranging from 0–21, with higher scores indicating worse sleep quality. The PSQI consists of seven subscales, including the overall subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances (wake up at night), use of sleeping medication, and daytime dysfunction (difficulty in staying awake during the day). These seven subscales can be measure by 19 questions. The first four questions focus on the usual bedtime, how long it takes to fall asleep, rising time, as well as the duration of the true sleep of the patients. Next, the questions address specific physical and psychological events at night, such as having difficulty falling asleep, waking during the night, going to the toilet, breathing with disturbance, coughing or snoring, feeling too cold or hot, having nightmares, and feeling pain. The questions also asked about the uses of sleep-promoting drugs, daytime sleepiness, and enthusiasm for doing things. Last, the question is the overall sleep quality on a semantic scale ranging from “very good” to “very bad” (Buysse et al., 1989). It has good reliability and validity in measuring sleep (Buysse et al., 1989). The PSQI has been translated into 48 languages and has been used in a wide range of population-based and clinical studies (Buysse et al., 2008).

Sleep latency is one of the most critical parameters in measuring sleep quality. It is the duration of time between lights out when a person attempts to sleep until he/she finally fall asleep (Shrivastava, Jung, Saadat, Sirohi, & Crewson, 2014). Sleep latency indicates conscious attention was paid to the person’s sleep diary, and ‘light out’ time was close to a person’s routine bedtime at home. The sleep latency would be long if a person turns off the lights earlier than his/her usual bedtime, and that person may not fall asleep until his/her bedtime is reached. Similarly, the sleep latency would be short if a person turns off the lights later than his/her usual bedtime, and that person would be sleepy and would fall asleep very quickly (Shrivastava et al., 2014). The sleep latency in family caregivers of PWD is slightly lower than the normal range (H. L. Peng & Chang, 2013).

Sleep efficiency is another essential parameter in measuring sleep quality. It refers to the percentage of total time in bed actually spent in sleep. Sleep efficiency refers to the ratio of total sleep time relative to the time span that *begins* when the person participates in behaviors that are intended to induce sleep (e.g., lying still, eyes closed) and *ends* when the person finally wakes *and* ceases all further attempts to sleep even if they remain in bed (Reed & Sacco, 2016). Sleep efficiency provides an overall sense of how well a person slept (Shrivastava et al., 2014). Poor sleep efficiency, characterized by prolonged sleep latency and/or fragmented sleep, is one of the most common sleep complaints among family caregivers (McKibbin et al., 2005; Wilcox & King, 1999).

2.2.2 Sleep disturbance

Sleep disturbance comprises of a broad range of sleep and arousal disorders. It encompasses disorders of initiating and maintaining sleep (DIMS, insomnias), disorders of excessive somnolence (DOES), disorders of sleep–wake schedule, and dysfunctions associated with sleep, sleep stages, or partial arousals (parasomnias) (Cormier, 1990). The DIMS include having difficulty in getting sleep, frequently waking during the night, waking early in the morning, and experiencing nonrestorative sleep. The primary complaint in DIMS is insomnia. The prevalence of insomnia was high in family caregivers of PWD, and caregivers with older age and longer caregiving duration had a higher risk of developing insomnia (Simón, Bueno, Otero, Blanco, & Vázquez, 2019). DOES are a diverse group of conditions that share a common complaint of excessive daytime sleepiness. It is often characterized as a psychiatric disorder. People with depression frequently report that they do not feel refreshed in the morning, although the objective sleeping measurement reported that their sleep efficiency exceeded 95% (Cormier, 1990). Family caregivers of PWD are usually have a high level of depression, and they also experienced more daytime sleepiness than non-caregivers (Dongwhane Lee et al., 2014). Disorders of the sleep-wake schedule are a group of clinical syndromes that include misaligned and disorganized ultradian rhythms or endogenous circadian controlling sleep-wake schedule. This category of disorders includes circadian disorders related to work shift changes, rapid time-zone change (jet lag) syndrome, and frequent change of sleep-wake schedules (Cormier, 1990). Since sleep-wake disturbances are common and often a debilitating feature of dementia (M. M. Lim, Gerstner, & Holtzman, 2014). Family caregivers often need to adjust their sleep-wake schedule to that of the care-recipients (S. M. McCurry, Logsdon, Teri, & Vitiello, 2007). The primary complaint of dysfunctions associated with sleep, sleep stages, or partial arousals (parasomnias) is not only about sleep or wake process.

Sleep disturbance in family caregivers of PWD related to changes or variations in normal sleep and waking patterns in family caregivers while taking care of PWD (H. L. Peng & Chang, 2013). These changes include one or more of the following features: (a) difficulty in falling asleep; (b) fragmented sleep or difficulty in maintaining sleep; (c) excessive daily sleepiness or difficulty in functioning caregiving role; (d) early morning awake (Castro et al., 2009; Flaskerud, Carter, & Lee, 2000; Wilcox & King, 1999).

2.2.3 Sleep disturbance in family caregivers

Sleep disturbance is prevalent in family caregivers of PWD. Studies have reported nearly two-thirds of family caregivers to suffer from various forms of sleep disturbance, and it has increasingly become a public issue (H. L. Peng & Chang, 2013). Several studies have found family caregivers of PWD experienced difficulty with sleep such as impaired quality of sleep, sleep difficulties, and daytime sleepiness more frequently than members of the general population (Castro et al., 2009; Dongwhane Lee et al., 2014; McKibbin et al., 2005; Rowe, McCrae, Campbell, Benito, & Cheng, 2008). The sleep disturbance in family caregivers of PWD requires greater attention from society.

Sleep disturbance has a negative impact on family caregivers of PWD themselves, care recipients, and society as a whole. Evidence has shown that sleep disturbance has a particularly negative impact on psychological and physical health in family caregivers of PWD. For the psychological health, recent studies have suggested that caregivers with poor sleep have a higher risk of becoming depressed than caregivers with good sleep quality (Creese, Bédard, Brazil, & Chambers, 2008; Cupidi et al., 2012; David Lee, 2008). Sleep deficiency is also associated with indicators of an increased level of psychological stress (Chiu et al., 2014). Also, frequent sleep disturbance is frequently and significantly related to poor perceptions about the quality of life (QoL) in caregivers (Cupidi et al., 2012). For physical health, shorter sleep time in total was associated with poorer subjective physical health (Spira et al., 2010). Sleep disorders in family caregivers of PWD were also associated with an increased risk of CVD (Brent T Mausbach et al., 2006; P. J. Mills et al., 2009; von Känel et al., 2006). Caregivers' sleep quality is related to levels of biomarkers of atherosclerosis, including interleukin-6 (IL-6; inflammatory marker), D-dimer (coagulant marker), von Willerbrand factor (VWF; endothelial function marker), and C-creative protein (CRP; inflammatory marker). Caregivers who wake up more frequently after the onset of sleep will have higher levels of D-dimer (P. J. Mills et al., 2009). Von Känel et al. (2010) also found that subjectively impaired sleep quality predicted elevated levels of D-dimer and VWF, and objectively reduced sleep quality predicted elevated inflammation activity, including elevated levels of IL-6 and CRP. The increased level of IL-6 and CRP is associated with a higher incidence of diabetes, CVD, frailty, and mortality (Maggio, Guralnik, Longo, & Ferrucci, 2006). VWF is a marker for endothelial cell activation and damage, and can predict incidents of coronary artery disease (Lip & Blann, 1997). Therefore, family caregivers with higher sleep disturbance will have a greater risk of developing chronic diseases.

The sleep disturbances in family caregivers not only have a negative impact on family caregiver themselves but also influence their care recipients. Family caregivers with poor sleep quality may decrease their caregiving quality, and bring adverse effects for care recipients consequently (H. L. Peng & Chang, 2013). For example, caregivers who have daytime sleepiness during a long period are likely to be more irritable with their care recipients. They will be more probably to have home or traffic accidents, and more likely to have difficulty in solving rapid or complex problems under the behavioral and psychological symptoms of dementia (BPSD) of care recipients (S. M. McCurry et al., 2007). Meanwhile, sleep disturbance in family caregivers of PWD is one of the major causes of early admission to nursing homes or related institutions for the patients (H. Kim & Rose, 2011). The nocturnal behaviors and excessive night-time activities of PWD, which can be indicative of sleep disturbance in family caregivers of PWD, is one of the main predictive factors of care recipients' institutionalization (H. Kim & Rose, 2011). However, the early institutionalization of PWD may have a negative impact on PWD's psychological and physical health, and even increase their mortality rates (Leung & Rao, 2009). A meta-analysis reported that the institutionalization of elders reduced their quality of life, including the decreased physical and social activities, increased depression, as well as decreased functional capability (de Medeiros et al., 2020). Furthermore, the institutionalization of PWD is costly and therefore bring a greater burden to the national budget and the whole society.

The evidence provided by all these research points to the conclusion that sleep disturbance in family caregivers of PWD is a clinical problem which negatively impacts on family caregivers of PWD, care recipients, and society as a whole. Sleep disturbance in family caregivers of PWD merits being thoroughly researched, and to find more effective ways of treating it.

2.3 Contributing factors for sleep disturbance in family caregivers of PWD

There are many contributing factors for sleep disturbance in family caregivers. These factors can be classified into three categories: care recipient factors, demographic factors of caregivers, and psychosocial factors of caregivers.

2.3.1 Care recipients' behavior affects the sleep of caregivers

The first contributor to sleep disturbance in family caregivers is the nocturnal behavior of PWD. BPSD, including hallucination, delusion, agitation, depression, anxiety, apathy, irritability, aberrant motor behavior, sleep disturbances, and disinhibition, are prevalent among PWD

(Cerejeira, Lagarto, & Mukaetova-Ladinska, 2012). PWD also suffer from sleep disturbance, and various sleep disturbances of PWD are frequently derived from these symptoms. Many family caregivers of PWD experience sleep disturbance because of the nocturnal awaking and problems of PWD. The sleep of family caregivers can be easily affected if a person with dementia is awake and roaming around the house at night. The sleep disturbance will occur when a person needs to face some events that precipitate nighttime wakefulness (Kryger et al., 2005). The precipitating events often differ from night to night for family caregivers. For a vulnerable family caregiver, it is even harder to go back to sleep after dealing with the nocturnal behavior (e.g., assistance with toileting, redirection to the bed, emotional reassurance) of a person with dementia.

Besides, caregivers' sleep can also be affected by their anxiety about the PWD's activities, which can be defined as a caregiver's vigilance (Liu et al., 2017). Vigilance in dementia is defined as "the caregiver continually overseeing the care recipient's activities" (Mahoney, 2003). It is an "on duty" condition even though caregivers are doing nothing (Mahoney, 2003). The sleep quantity and quality of family caregivers can subsequently further deteriorated by frequent awakening because of the vigilance in dementia. The disturbed sleep pattern will be further perpetuated because of inadequate sleep hygiene even after the absence of patients' disruptive nocturnal behavior (Stepanski & Wyatt, 2003).

2.3.2 Demographic factors of caregivers: the impact

Sleep disturbance arises from the combination of predisposing, precipitating, and perpetuating factors, and this is what called the 3P model (Spielman, 1986). For family caregivers of PWD, these factors can exist independently in a caregiving situation, and can directly influence the care recipients themselves as well. Predisposing factors related to the risk factor of variation in the standard sleep patterns in older and female caregivers, both of whom experience a higher prevalence of sleep problems. Most family caregivers are older women (either spouses or adult children). The age-related changes contribute to increased difficulty in falling asleep and maintaining sleep (Beaudreau et al., 2008; Castro et al., 2009; von Känel et al., 2012). Elderly caregivers of PWD have less sleep efficiency, more stages of sleep (the lightest level of sleep: defined by the presence of slow eye movements, this drowsy sleep stage can be easily disrupted, causing awakenings or arousals), and less slow-wave sleep (deep sleep) than younger caregivers. Besides, compared to younger caregivers, the condition of sleep disturbance in elderly caregivers are more persistent and more likely to relapse (S. M. McCurry et al., 2007).

2.3.3 Psychosocial factors of caregivers: the impact

One of the major contributors to sleep disturbance in family caregivers of PWD is the “subjective burden” in caregivers. The “subjective burden” is the response of caregivers to the behavior of their patients’. These responses include feelings of depression, stress, and anxiety, feelings of being isolated from other family members, friends, and society, having difficulty in coping with stress, and being unsatisfied with his or her relationship with the care recipient. Caregivers’ appraisals of the objective and subjective burden affect their physical and psychological responses to the stressors and ultimately affect their morbidity and mortality risk (M.-D. Kim et al., 2009; Liu et al., 2017).

Even though nocturnal behaviors of care recipients are the source of sleep disturbance in family caregivers of PWD, sleep disturbance can still exist in the absence of patient awakenings. Pollak and Stokes (1997) reported that older people with dementia were not significantly more active at night than their family caregivers. Similarly, S. M. McCurry et al. (2008) found that some family caregivers experienced good sleep despite their family members suffering from poor sleep during the same period. In the study reported by Simpson and Carter (2013), the relationship between the caregiver’s subjective sleep and the frequency of BPSD of care recipients was not statistically significant. von Känel et al. (2012) found that after followed 109 spousal dementia caregivers and 48 age- and gender-matched non-caregiving spouses for three years, the spousal caregivers and non-caregiving spouses had similar sleep patterns. Thus some subgroups of family caregivers of PWD may be more vulnerable to develop sleep disturbance than others. The sleep problems of caregivers often continue when the sleep of their care recipients improves. This phenomenon upholds the finding that subjective factors of caregivers are crucial for understanding sleep disturbance in this population.

In some studies, poor sleep was attributed to caregiver burden and depression rather than caregiver status (Kochar, Fredman, Stone, Cauley, & Fractures, 2007; S. M. McCurry et al., 2007). Depression is a well-known risk factor for sleep disturbance, and the prevalence of depression is significantly higher in family caregivers of PWD compared to non-caregivers. The prevalence of depression in family caregivers of PWD was estimated to be more than 50% (García-Alberca, Lara, & Berthier, 2011). Depression is strongly associated with disturbances to sleep and 24-hour sleep-wake patterns (Hori et al., 2016; Luik et al., 2015; Maglione et al., 2014). Castro et al. (2009) found that objective sleep measures seemed to be less influenced by depression, while subjective sleep measures were significantly affected by depression. Similarly, von Känel et al. (2012) also reported that a high level of depression significantly contributed to more subjective sleep disturbances in spousal caregivers of PWD. However, depression contributed comparatively less to objective sleep measures. Caregivers with more depressive symptoms take more time to fall asleep than non-depressed caregivers (Castro et al., 2009).

Among the articles reviewed for this study project, depression was found to be the most frequently studied factor for sleep disturbance in family caregivers of PWD. Depression is more highly correlated with sleep disturbance in family caregivers of PWD than other caregivers or patient variables (S. M. McCurry & Teri, 1996). In many cross-sectional studies, family caregivers with higher levels of depression have higher levels of sleep disturbance (Beaudreau et al., 2008; Brummett et al., 2006; Castro et al., 2009; Chiu et al., 2014; Cupidi et al., 2012; S. M. McCurry et al., 2008). The study which was done by Simpson and Carter (2013) reported that depressive symptoms made the most significant contribution to the sleep disturbance in family caregivers of PWD compared with other variances such as caregivers' age and gender, and the severity of care recipients' BPSD. In a longitudinal study that followed 231 family caregivers of PWD for five years, depression was found to be the most influential predictor of the development of sleep disturbance among caregivers (S. McCurry, Gibbons, Logsdon, & Teri, 2004). Therefore, interventions targeting a reduction in depression also have the potential to manage sleep disturbance in family caregivers of PWD.

2.4 Interventions for improving sleep quality in family caregivers of PWD

According to the previous reviews of the contributing factors of sleep disturbance in family caregivers of PWD. The non-pharmacological interventions for improving sleep quality in family caregivers were divided into two types: 1) interventions in reducing the effects of care recipients' behaviors on family caregivers' sleep quality, 2) interventions in treating psychosocial problems of family caregivers

2.4.1 Interventions in reducing the effects of care recipients' behaviors on family caregivers' sleep quality

1. Nighttime monitoring of PWD

Nearly 60% of family caregivers of PWD reported their care recipients regularly wake up at night (Creese et al., 2008). As a result, caregivers are compelled to provide supervision during the night. To decrease the “vigilance” in family caregivers of PWD, Rowe, Kairalla, and McCrae (2010) developed a Nighttime Monitoring System, which aimed at tracking the movements of care recipients at night, and consequently relieved the worry and improved the sleep of family caregivers. This system consisted of a home security sensor to provide information about the movements of PWD when they arise from their beds. Although family caregivers subjectively reported that this system significantly relieved their anxiety about their care recipient’s nighttime awakenings, no group difference was found regarding time awake after sleep onset, sleep quality, and total sleep time.

2. Respite care

Respite care is one of the approaches for researchers to improve sleep for family caregivers of PWD. Providing respite care is critical in supporting family caregivers of PWD. Studies conducted in many countries have shown that respite care can improve sleep quality for the majority of caregivers (Larkin & Hopcroft, 1993; Pearson, 1988; Perry & Bontinen, 2001; Watkins & Redfern, 1997). David Lee, Morgan, and Lindesay (2007) examined the effectiveness of institutional respite care on improving sleep in family caregivers of PWD. This intervention included two weeks of institutional short-term respite care during which patients were admitted to community hospitals while caregivers were at home. Caregivers in the respite periods had a significant improvement in subjective sleep quality and total sleep time per night.

Compared to short-term respite care, the placement of PWD in a long-term care center did not significantly affect the sleep of the family caregivers. It may be because the long term placement of PWD is not specifically able to completely relieve distress in caregivers (R. Schulz et al., 2004; von Känel et al., 2012). Some burdens may be released when a family member with dementia is placed in a care center. Still, others may persist or even increase. For example, the worries of financial hardship or the appropriateness of the placement of the loved one. Therefore, long term placement of PWD should not be regarded as having the same capacity to improve sleep the sleep of family caregivers as short term respite care (David Lee et al., 2007).

2.4.2 Interventions for treating psychosocial problems of family caregivers

1. Caregiver support

It is critical to provide support to caregivers, especially family caregivers. Since family caregivers are often socially isolated and have little time to care about their personal needs and health. Fowler, Kott, Wicks, and Rutledge (2016) developed an Interprofessional Virtual Healthcare Neighborhood (VHN) system to deliver information, peer support, and professional guidance to family caregivers of PWD. However, the VHN support system did not significantly improve sleep quality and quantity in family caregivers of PWD. Therefore, providing general supportive information may not be enough to improve caregivers' sleep quality significantly. Caregiver support that targets psychological distress and sleep may be more effective in improving sleep quality in family caregivers of PWD.

2. Physical activity programs

Some researchers also employed physical activity programs to improve sleep in family caregivers of PWD. In one relevant study, King, Baumann, O'Sullivan, Wilcox, and Castro (2002) randomly assigned 100 female caregivers of PWD to either a moderate-intensity physical activity program (such as brisk walking) or a nutrition education control condition. Among participants in the physical activity group, the improvement in sleep quality also subsequently led to a reduction in perceived stress and subjective perceptions about the burden of caring for the PWD. Even though sleep was not the specific target of this study, it augmented the hypothesized positive relationship between physical activity and sleep. Hirano et al. (2011) have also corroborated this finding. Caregivers who were prescribed regular physical activity with moderate-intensity (i.e., three metabolic equivalents three times per week for 12 weeks) experienced a significant improvement in the quality of their sleep as a result of the intervention compared to caregivers who did not receive any prescription.

3. Cognitive behavioral strategy

Cognitive behavioral strategies are effective in improving sleep quality in family caregivers of PWD, especially for caregivers whose care recipients are no longer staying in homes but still experience chronic insomnia (Gao, Chapagain, & Scullin, 2019; Irwin, Cole, & Nicassio, 2006). The literature review revealed a large number of studies that had evaluated the efficacy of cognitive behavioral strategies, including stimulus control, sleep hygiene, sleep compression and relaxation training for managing sleep disturbance in older adults (Irwin et al., 2006; McCall, 2005; Montgomery & Dennis, 2004). Simpson and Carter (2010) conducted a behavioral sleep intervention, and the sleep quality and depression tended to improve in caregivers in the intervention group.

2.5 Discussions on selecting an appropriate non-pharmacological intervention for improving sleep quality in family caregivers of PWD

Although several interventions have demonstrated favorable effects on improving sleep quality in family caregivers of PWD, many factors other than the effectiveness of the intervention itself also need to be taken into consideration when selecting the optimal intervention. After analyzing such factors, further studies could focus on studying the most suitable and effective interventions to improve sleep quality in family caregivers of PWD. The balance between benefit and harm should be considered when selecting the most appropriate treatment (Glasziou & Irwig, 1995). However, this principle is overly simplistic, ignoring the preferences of family caregivers

(DaCruz, 2002). The potential benefits of the intervention, the possible side effects of the intervention, personal interest, and cost should be considered when deciding the appropriate intervention (Haynes, Devereaux, & Guyatt, 2002).

The review of non-pharmacological interventions on sleep in family caregivers of PWD showed that treatments could improve sleep in family caregivers of PWD. Behavioral therapy for insomnia will improve both sleep and psychological health. S. M. McCurry et al. (2007) suggested: "behavioral strategies should always be considered in treating sleep disturbance in elderly caregivers, either separately or in conjunction with pharmacological interventions." A range of behavioral interventions, including relaxation, physical activities, stimulus control, and sleep restriction techniques, are shown to be effective in managing sleep disturbance in non-caregiving older adults. However, it may be difficult for family caregivers of PWD to comply with such treatment because of the complex environment that they experience. For example, they may have difficulty in finding a quiet place to do the relaxing physical activities, or they may have problems in establishing a consistent nighttime routine. Meanwhile, the cognitive behavioral strategy should be delivered by professional experts, which may limit its generalizability.

The moderate-intensity physical activity program can also improve sleep in caregivers. Even though physical activity can be treated as one of the leisure activities, not all caregivers are in favor of doing physical activity during their spare time. Meanwhile, all the above treatments do not include all the components that may be important, given what is known about the correlates of sleep disturbance in family caregivers of PWD, such as psychological distress and depression. Therefore, it is critical to find or develop an intervention that is not only preferable to caregivers but is also easy to implement and cost-effective in improving sleep among the caregivers.

For interventions focusing on alleviating the impacts of care recipients' behaviors on family caregivers' sleep, only the short-term respite care is shown to be effective in improving sleep in family caregivers of PWD. However, respite care requires a great deal of funding and resources from society. As there are a limited number of respite care centers and professional nurses, not all patients will be able to receive respite care. Neither night time monitoring of PWD nor long-term respite care could significantly improve sleep in family caregivers of PWD.

Interventions that focus on increasing and maintaining pleasant leisure activities in family caregivers' daily lives may have distinct value when alleviating psychological distress and improving sleep quality. Depression is a well-known risk factor for sleep disturbance. However, there are very few particular interventions improving sleep quality by reducing depression levels in family caregivers of PWD. A national survey of 1500 family caregivers found dementia caregivers gave up more hobbies and vacations and had less time for other family relationships than any other types of caregivers (Ory, Hoffman III, Yee, Tennstedt, & Schulz, 1999). The inverse relationship between pleasant events and depression is consistently reported in studies (B. T. Mausbach et al., 2012; B. T. Mausbach et al., 2008; Romero-Moreno, Ḿrquez-Gonźlez, Mausbach, & Losada, 2012; L. W. Thompson et al., 2002). Helping family caregivers to establish and maintain a healthy balance between caregiving and pleasurable activities may be both important for reducing depression and sleep disturbance among them. BA has been proved to be effective in improving pleasant leisure activities and reducing depression among clients. Caregivers can freely choose activities in their leisure time. Meanwhile, BA may be more cost-effective and easy to be delivered in community settings for improving sleep quality in family caregivers of PWD since it does not require extensive training for interventionists to implement the intervention. Therefore, BA is likely to be effective in improving sleep and reducing depression in family caregivers of PWD.

2.6 Behavioral Activation and sleep quality in family caregivers of PWD

This section focuses on discussing the use of BA as a treatment in improving sleep quality in family caregivers of PWD. Theories of BA are firstly explained. Then, evidence from clinical research on examining the effect of BA in family caregivers of PWD is presented, followed by a discussion of the clinical research examining the relationship between pleasant events with depression and sleep quality in family caregivers of PWD. After that, the implications for BA on sleep are presented. Finally, the knowledge gap in the use of BA for sleep in family caregivers of PWD is discussed.

2.6.1 Theory of BA

“BA is a brief structured psychotherapeutic treatment for depression that aims to activate clients in specific ways that will increase rewarding experiences in their lives” (Martell et al., 2013). It aims to 1) increase participation in adaptive activities that related to the experience of pleasure and mastery, 2) decrease participation in activities that relate to the experience of depression, 3) solve problems that limit access to rewarding and pleasant experience (Dimidjian, Barrera Jr, Martell, Muñoz, & Lewinsohn, 2011). BA interventionists should apply a variety of strategies such as activity scheduling, activity structuring, self-monitoring of mood, social skill training, and problem-solving to achieve the aims of BA. BA assumes clients should be assisted with the ability to engage in behaviors that they find pleasurable or fulfilling. BA is rooted in the biological basis of behavior. Beginning with the pioneer work of Peter Lewinsohn and colleagues (Lewinsohn, 1974; Lewinsohn & Graf, 1973; Lewinsohn, Sullivan, & Grosscup, 1980), several researchers reinvigorated the contents of cognitive behavioral therapy (CBT) (Jacobson et al., 1996;

J.W. Kanter, Busch, & Rusch, 2009), and made BA achieve the outstanding status over a range of clinical settings (Cuijpers, Van Straten, & Warmerdam, 2007; Mazzucchelli, Kane, & Rees, 2009, 2010),

The basic foundation of BA can be traced back to the original behavior model for depression, which aimed to improve response-contingent reinforcement for non-depressive behaviors and thus waken the depressive impact (Lewinsohn, 1974; Lewinsohn & Graf, 1973). Peter Lewinsohn's work was deeply influenced by B. F. Skinner, who initially proposed that “depression was associated with interruption of healthy behaviors which had been positively reinforced by the social environment” (Skinner, 1953). The conventional behavioral therapy for depression aimed at increasing the frequency and intensity of pleasant and positive events as well as decrease the revoltive activities and consequences (Lewinsohn & Graf, 1973; Lewinsohn et al., 1980). Many pioneer works have proved that depression levels can be reduced through daily pleasant events scheduling and corresponding mood monitoring, as well as social skills development and time management training (Ekers et al., 2014; Orgeta, Brede, & Livingston, 2017).

Now, BA has been revitalized to encompass two central interventions: Behavioral Activation (Markowitz, 2003) and the Behavioral Activation Treatment for Depression (BATD) (C. Lejuez, Hopko, Acierno, Daughters, & Pagoto, 2011; C. W. Lejuez, Hopko, & Hopko, 2001). Although these protocols apply somewhat different strategies, both of them are based on traditional behavioral treatment and aim to increase response-contingent positive reinforcement. Other versions of BA have been developed over the past years, with overlapping or different techniques and treatment mechanisms. Jonathan W Kanter et al. (2010) reviewed all the techniques and treatment mechanisms to identify the common core elements of BA. Activity scheduling to contact with positive reinforcement emerged as the core element across all forms of BA. Therefore, the goal of BA should be to help clients to become involved in diverse pleasurable, personally meaningful, rewarding, and stable positive reinforcement (Jonathan W. Kanter & Puspitasari, 2012).

2.6.2 BA for depression in family caregivers of PWD: A systematic review and meta-analysis

We did a systematic review and a meta-analysis on BA and to examine the efficacy of BA in family caregivers of PWD (X. Y. XU, KWAN, & LEUNG, 2020a). This review was published with full paper in **Appendix A**. Below is the highlighted key parts of this review.

2.6.2.1 Search strategy

This review was conducted in line with the PRISMA guidelines for reporting systematic reviews (Moher et al., 2015).

This review exclusively included randomized controlled trials (RCTs) that applied BA theories to family dementia caregivers. No restrictions were applied to the intervention delivery format or the duration or frequency of intervention sessions. There was also no restriction on sample size, since the exclusion of studies with a small sample size would have contributed to publication bias. Studies that were not primary studies, including systematic reviews, editorials and ‘letters to the editor’, were excluded from this review. Practice guidelines and study protocols were also excluded.

Participants were family dementia caregivers. Studies were excluded if the participants were employees caring for PWD. There was no limitation on gender or age or on the length of time over which caregivers provided care. However, participants had to be the primary caregiver of a patient. Participants did not need to have a clinical diagnosis of a depression disorder.

This study applied a systematic review and meta-analysis to determine how BA affects depression and other areas of the psychological and physical health of family caregivers of PWD. This review included RCTs that did BA in family caregivers of PWD. An electronic database search of PubMed, Medline, CINAHL, Cochrane, Embase, and PsycINFO was done using the following keyword search terms: dementia OR Alzheimer OR "cognitive impairment" AND caregiv* AND "behavioral therapy" OR "behavioral activation" OR "activity scheduling" OR "activity restriction" OR "leisure activities" OR "pleasurable activities". All the titles and abstracts were reviewed; full texts were retrieved when potential eligible studies were identified from the review of the titles and abstracts.

2.6.2.2 Search results

Study selection began with the 797 references that were initially obtained. Two studies were identified from other systematic reviews. Of these, 405 were duplicates, so these were removed from the sample. Then, 394 studies remained for further analysis, of which 381 were found to be not relevant to the study objectives. This left 13 references, of which three were eliminated after their full text was read; this was because one was a study protocol, one did not investigate the effect of BA on family dementia caregivers, and one did not apply the BA principle. Ten studies therefore remained for systematic review. The data selection process is shown in Figure 1 as a PRISMA flow diagram. Table 1 shows the participants’ characteristics in the included studies.

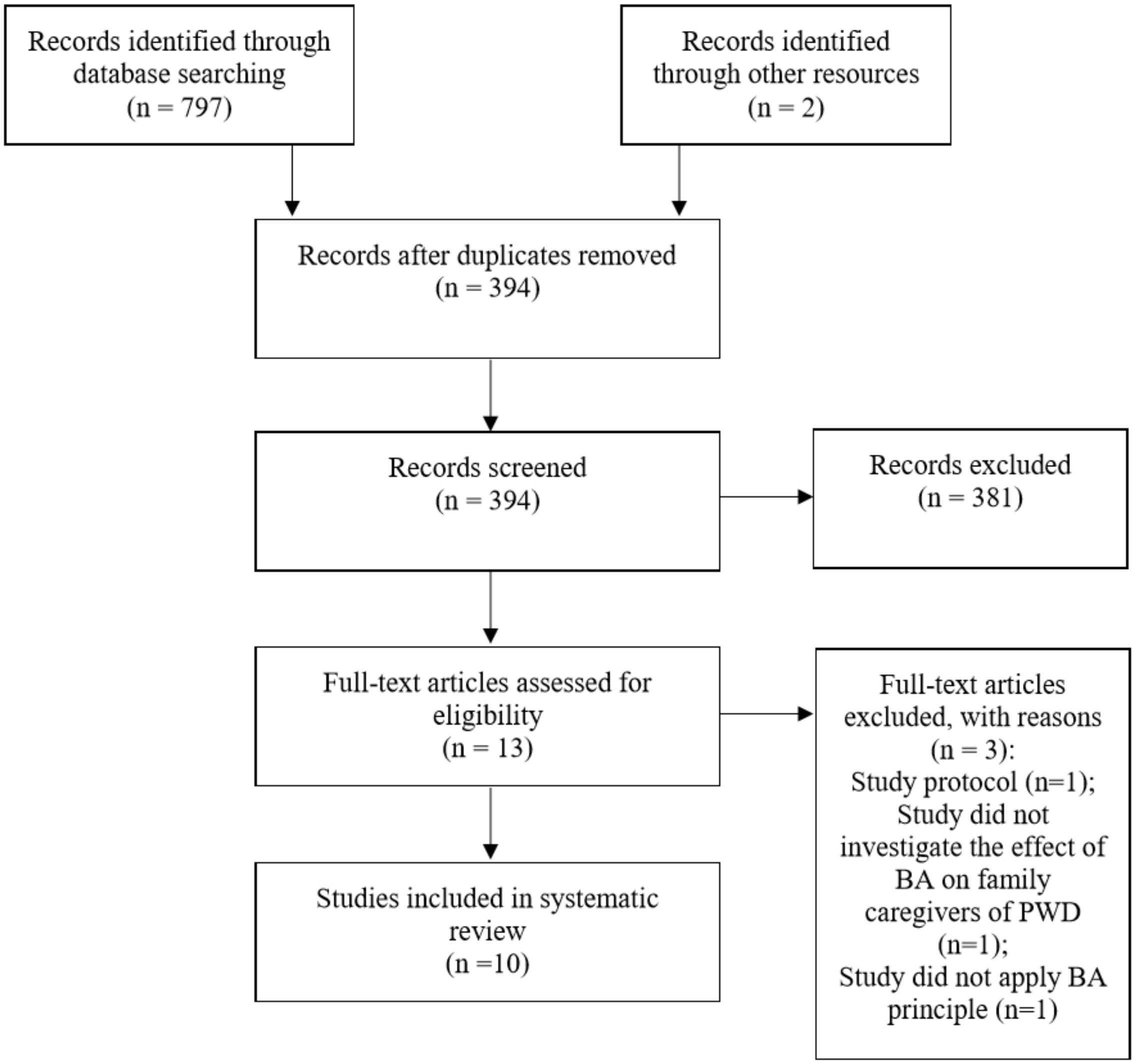


Figure 1. PRSIMA flow diagram (extracted from X. Y. XU et al. (2020a))

Table 1. Characteristics of the reviewed studies (extracted from X. Y. XU et al. (2020a))

Author, year	Number of participants (intervention/control)	Intervention		Comparison		Post-intervention outcomes		Follow-up findings
		Dosage	Component	Dosage	Component	Outcomes with significant results	Outcomes with non-significant results	
Au et al. 2019	56/55	•20 weeks •12 sessions (4 weekly sessions + 8 biweekly sessions) •20 minutes/ session	•Psychoeducation •Behavioral activation •Telephone based	•20 weeks •12 sessions (4 weekly sessions + 8 biweekly sessions) •20 minutes/ session	•Caregiver's health •Care recipient's needs •Caregiver's routines •Social support •Telephone based	Depression; Burden; Self-efficacy; Relationship satisfaction	NI	NI
Steffen et al. 2016	33/41	•16 weeks •12 sessions (10 weekly sessions+ 2 biweekly maintenance calls) •30-50 minutes/ session	•Behavioral activation for both carer and care recipient •Relaxation •Caregiving self-efficacy •Telephone based •Video + workbook	•14 weeks •1 session/ two weeks •20 minutes/ session	•Basic care guide •Telephone based	Depressive symptomatology; Negative mood; Anxiety; Caregiving self-efficacy	Hostility	6 months: NS
Au et al. 2015	29/30	•16 weeks •1-2 sessions /two weeks	•Pleasant event scheduling •Effect communication training	•16 weeks •1-2 sessions /two weeks	•Psychoeducation •Information support	Depression; Relationship Satisfaction	NI	NI

		•15-20 minutes /session	•Telephone based	•15-20 minutes /session	•Telephone based			
Au. 2015	49/44	•16 weeks •1-2 sessions /two weeks •15-20 minutes /session	•Pleasant event scheduling •Effect communication training •Telephone based	•16 weeks •1-2 sessions /two weeks •15-20 minutes /session	•Psychoeducation •Information support •Telephone based	Depression	NI	NI
Prick et al. 2015	57/54	•16 weeks •1-2 session /two weeks •60 minutes / session	•Psychoeducation •Communication skills training •Pleasant activity training •Dyadic intervention •Home visits	•16 weeks •1 session /month •10 minutes /session	•Usual care •Information support •Car driving •General health in dementia •Phone calls	NI	Depression; Feelings of role-overload; General health; Observable behavioral problems in PWD	6 months: NS
Moore et al. 2013	49/51	•6 weeks •6 sessions (4 in-home sessions + 2 weekly telephone based sessions) •15-60 minutes /session	•Monitoring time •Identifying leisure activities •Developing activity hierarchy •Scheduling/participating leisure activities and tracking moods	•6 weeks •6 sessions (4 in-home sessions + 2 weekly telephone based sessions) •15-60 minutes /session	•Information support	Depression; Negative affect; IL-6	Positive affect; D-dimer	1 year: NS

Losada et al. 2011	68/50	•12 weeks •1 session /week •1.5-2 hours /session	•Acknowledge, analyze, and flexibilize dysfunctional thoughts •Analysis of cognitive barriers to do pleasant activities •Analyze and discuss of homework •Group education	•NI	•Usual care	Depression; Dysfunctional thoughts; Frequency of leisure activities	NI	NI
Gonyea et al. 2006	40/40	•5 weeks •1 session /week •90 minutes /session	•Pleasant events and improving communication •Pleasant events and understanding behavior •Understanding and changing difficult behaviors •Group meeting	•5 weeks •1 session /week •90 minutes /session	•General information on ageing and Alzheimer's disease •Home safety tips •Techniques for improved communication •Support •Group meeting	Caregiver distress related to neuropsychiatric symptoms	Burden; Frequency and severity of neuropsychiatric symptoms of PWD	NI

Coon et al. 2003	64/52	•16 weeks •10 sessions (8 weekly teaching sessions + 2 monthly skill reinforcement sessions) •2 hours /week	•Problem solving •Pleasant event scheduling •Mood controlling •Group meeting	•NI	•Wait-list	Anger and hostility; Depressed mood; Self-efficacy	Coping	NI
Bourgeois et al. 2002	21/20	•12 weeks •1 session / week •1 hour / week	•Increasing pleasant events •Problem solving •Relaxation techniques •Group workshop	•12 weeks •1 session / week •1 hour / week	•Medication change •Mood rating •Caregiving issue	Mood; Patient problem behaviors; Depression; Caregiver strain	Anger; Anxiety; Self-efficacy; Perceived stress; Perceived health	3 months: mood, patient problem behaviors, caregiver strain; 6 months: mood, patient problem behaviors, caregiver strain

BA: behavioral activation
CES-D: Center for Epidemiologic Studies-Depression Scale
CVD: cardiovascular disease
IL-6: interlukin-6
NA: not applicable

NM: not mention
NS: not significant
PANAS: Positive and Negative Affect Schedule

2.6.2.3 Intervention and control group characteristics

Interventions

The length of the interventions varied from five to twenty weeks, with sessions lasting between fifteen to ninety minutes. Four of the included interventions were conducted over the telephone (A Au, 2015; A Au et al., 2015; Alma Au et al., 2019; Steffen & Gant, 2016), whereas six others were conducted through face to face. Although in one study (R. C. Moore et al., 2013), participants were followed for a year after treatment, three were only continued for six months after baseline (Bourgeois, Schulz, Burgio, & Beach, 2002; Prick, de Lange, Twisk, & Pot, 2015; Steffen & Gant, 2016).

Losada, Márquez-González, and Romero-Moreno (2011) modified the findings in Márquez-González, Losada, Izal, Pérez-Rojo, and Montorio (2007); more precisely, a procedure to enable those administering care to recognize and evaluate cognitive barriers to support and joining in pleasant activities. An intervention based on Lewinson's BA model undertaken by Au (A Au, 2015; A Au et al., 2015; Alma Au et al., 2019; Steffen & Gant, 2016) concentrated on raising the number and length of involvement in pleasant activities. Lewinsohn's theories were employed by Bourgeois et al. (2002) to produce a workshop. The published treatment manual provided by Lejuez (C. W. Lejuez et al., 2001), encouraging participants to choose and get involved in leisure activities, was further developed by R. C. Moore et al. (2013). Gonyea, O'Connor, and Boyle (2006) used behavior therapy and BA as the basis for their interventions. The interventions developed by Prick et al. (2015) and Steffen and Gant (2016) were for dementia dyads. Prick et al. based their work on the dyadic intervention of Teri et al. (2003), producing a version of pleasant activity training involving three sessions for both caregivers and care recipients. The Depression Management Class developed by Coon, Thompson, Steffen, Sorocco, and Gallagher-Thompson

(2003) used cognitive-behavioral components alongside behavioral components. Although nearly all of the studies included homework in their BA interventions, (A Au, 2015; A Au et al., 2015; Gonyea et al., 2006; Losada et al., 2011; R. C. Moore et al., 2013; Prick et al., 2015; Steffen & Gant, 2016), this was only raised and discussed in one set of training sessions Losada et al. (2011).

The attrition rate ranged from 3.1% to 23.3%. Losada et al. (2011) measured treatment completion rates and participants' adherence to the program by evaluating their understanding regarding the contents and skills of the program. In Losada et al. (2011)'s study, the attendance rate for sessions was 9 out of 12 (76%), and caregivers' knowledge about the contents of BA increased considerably after the intervention. Adherence to the program was also calculated by Bourgeois et al. (2002), who evaluated the delivery, receipt, enactment, and satisfaction of participants to the treatment. All of the caregivers attended the training, and 89% of the questionnaires reported a high level of satisfaction. Alma Au et al. (2019) measured adherence to the scheme using a rating system, whereby participants' ability to follow the intervention protocol was assessed. Over 60% of the participants in the intervention group were willing to share their experiences. A study by R. C. Moore et al. (2013) found that participants in the intervention group were slightly, but not significantly less happy with the quantity of sessions than caregivers in the control group who did not receive the intervention. It was also identified that participants who failed to complete the program were less well educated than those who completed the program Prick et al. (2015) and that 75.4% of participants felt that they were moderately compliant with the procedure. In the study by Gonyea et al. (2006), nearly 88% of the participants attended more than 80% of the weekly sessions and the follow-up assessments.

Controls

Comparing to the interventions in each study, the length and dosage of controls were comparable. BA intervention was not given to any members of the control group. However, there were differences in the nature of the control groups in various studies. For example, in the studies by Losada et al. (2011) and Akemi Hirano, Hiroyuki Umegaki, Yusuke Suzuki, Toshio Hayashi, and Masafumi Kuzuya (2016), participants in the control group received the usual treatment provided by care centers. However, this was not identified in the studies. As revealed by R. C. Moore et al. (2013), the information usually provided by community agencies. R. C. Moore et al. (2013) provided the control group with the information, including details of the topics commonly included in information packages offered by community agencies. Similarly, the information had been released to control groups in the studies by Prick et al. (2015) and Gonyea et al. (2006). In the studies by Au et al.(A Au, 2015; A Au et al., 2015; Alma Au et al., 2019; Steffen & Gant, 2016), the control group was provided with materials, information packages, and psychoeducation. Bourgeois et al. (2002) supported the control group with home visits but withheld the information and skills training provided for the treatment group.

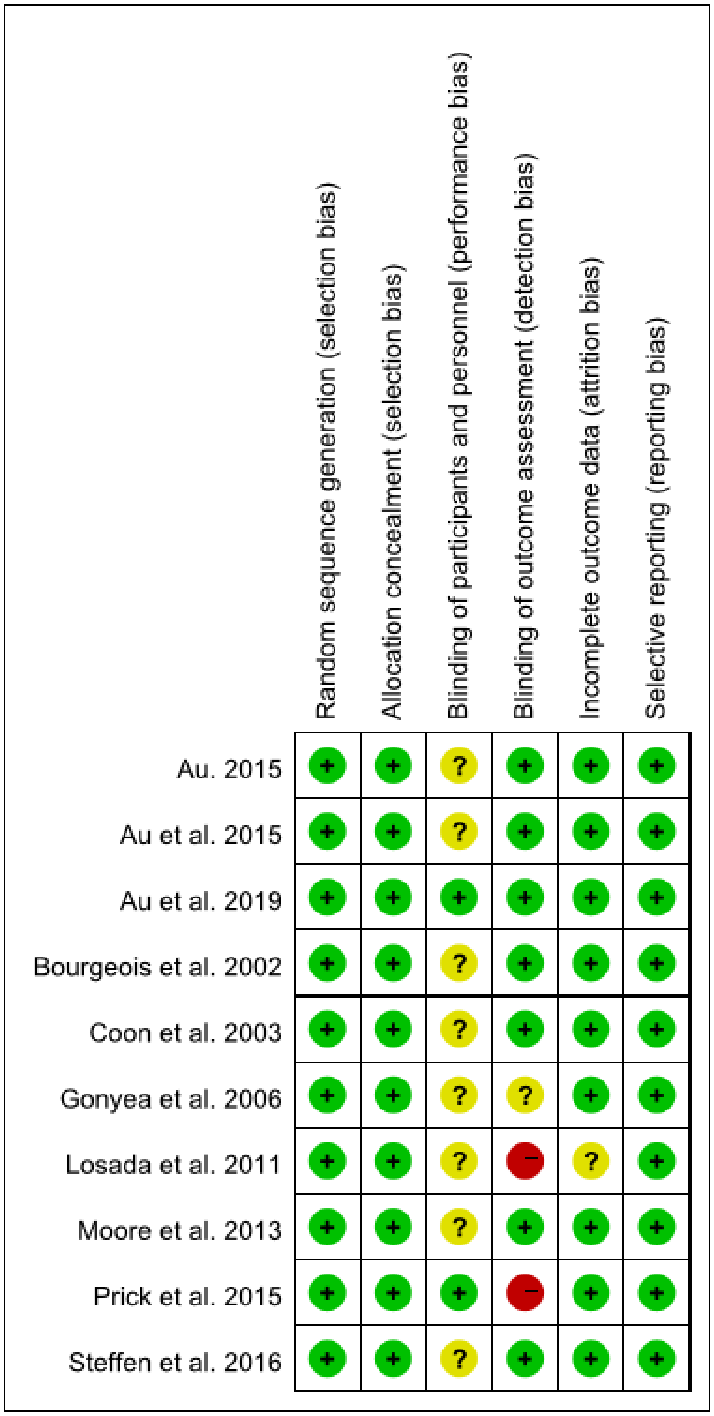
2.6.2.4 Results of individual studies

The results from these studies are summarized in Table 1. Depression or depressive symptoms were significantly lower after BA in the eight studies (A Au, 2015; A Au et al., 2015; Alma Au et al., 2019; Bourgeois et al., 2002; Coon et al., 2003; Losada et al., 2011; R. C. Moore et al., 2013; Steffen & Gant, 2016). Caregivers demonstrated increased self-efficacy following the BA intervention in three studies (Alma Au et al., 2019; Coon et al., 2003; Steffen & Gant, 2016). Coon et al. (2003) did not identify a significant reduction in strain, unlike the findings of Au et al. (2019). BA also significantly reduced the negative aspects of caregiving (R. C. Moore et al., 2013), such as anxiety (Steffen & Gant, 2016), anger and hostility (Coon et al., 2003) and caregiver strain

(Bourgeois et al., 2002) among family dementia caregivers. The only study which identified both increased involvement in leisure activities and a lower incidence of dysfunctional thinking among caregivers was Losada et al. (2011). In terms of physical health, the level of IL-6 (R. C. Moore et al., 2013) was lowered following BA intervention in family dementia caregivers in comparison to members of the control group. Reports by (Gonyea et al., 2006; Akemi Hirano et al., 2016), found that the number and frequency of neuropsychiatric symptoms in PWD were not reduced after BA intervention. However, the concerns of family caregivers with regards to neuropsychiatric symptoms were significantly reduced (Gonyea et al., 2006).

2.6.2.5 Risk of bias across the included studies

The assessment of the bias in individual studies is given in Figure 2. All of the studies were considered to be at low risk of selection bias in terms of ‘random sequence generation’ and ‘allocation concealment’. This is because in all reviewed studies, the randomization procedure and allocation concealment method were well reported. Only Prick et al. (2015) and Alma Au et al. (2019) specified whether study participants were ‘blind’ to the intervention; therefore, a high risk of performance bias was associated with almost all of the studies. However, BA is an interventional study, so it is difficult for participants to be ‘blind’ to receiving BA. The studies of Losada et al. (2011) and Prick et al. (2015) were considered to be at high risk of detection bias because they did not use ‘blind’ assessors. No study received a high-risk rating for attrition bias, reporting bias or any other bias.

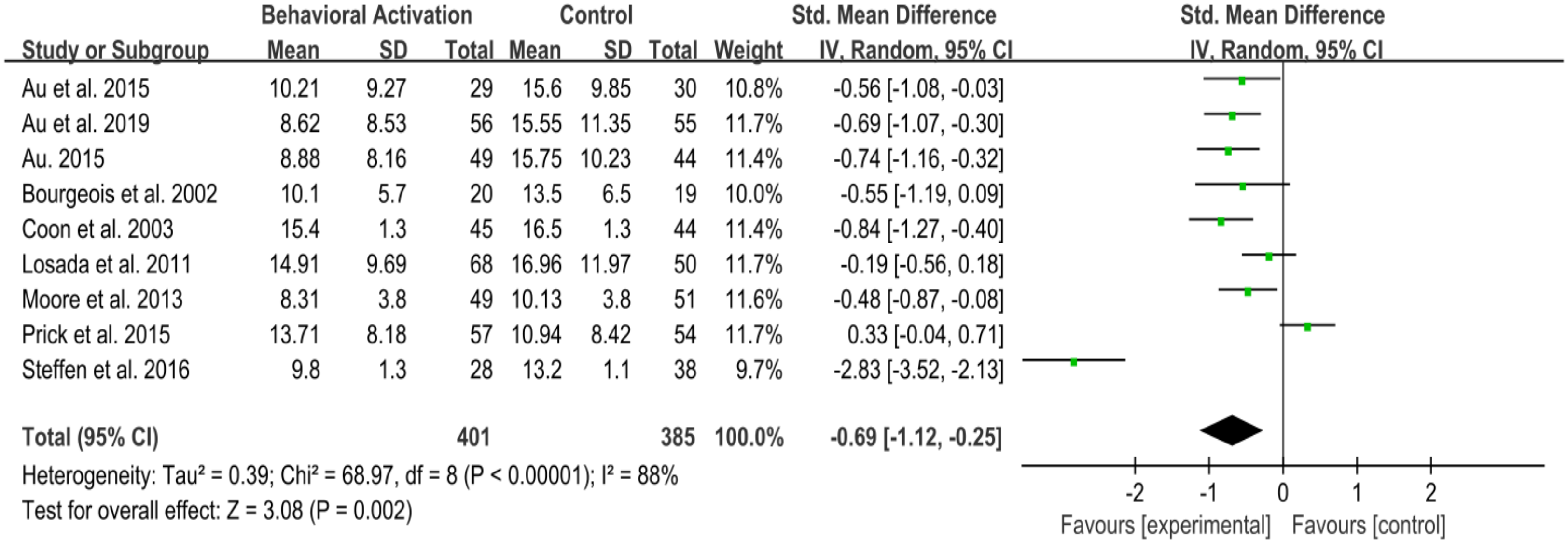


	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)
Au. 2015	+	+	?	+	+	+
Au et al. 2015	+	+	?	+	+	+
Au et al. 2019	+	+	+	+	+	+
Bourgeois et al. 2002	+	+	?	+	+	+
Coon et al. 2003	+	+	?	+	+	+
Gonyea et al. 2006	+	+	?	?	+	+
Losada et al. 2011	+	+	?	−	?	+
Moore et al. 2013	+	+	?	+	+	+
Prick et al. 2015	+	+	+	−	+	+
Steffen et al. 2016	+	+	?	+	+	+

Figure 2. Risk of bias across the included studies (extracted from X. Y. XU et al. (2020a))

2.6.2.6 Overall effect of BA on the reduction of depressive symptoms

Meta-analysis was undertaken to compare the effects of BA on depression in the sample in intervention and control groups. One study (Gonyea et al. (2006) were not included, as there was not enough data on the effects of depression. The combined results of BA on depression across the studies are summarized in Figure 3, contrasting the BA groups with the control groups following the test. Family dementia caregivers who had BA showed a statistically significant reduction in depressive symptoms (n=9; 786 participants; SMD = -0.69; 95% CI: -1.12 to -0.25; p=0.002)(A Au, 2015; A Au et al., 2015; Alma Au et al., 2019; Bourgeois et al., 2002; Coon et al., 2003; Losada et al., 2011; R. C. Moore et al., 2013; Prick et al., 2015; Steffen & Gant, 2016). There was significant heterogeneity in the studies (I^2=88%, p<0.001).



	Behavioral Activation			Control				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Au et al. 2015	10.21	9.27	29	15.6	9.85	30	10.8%	-0.56 [-1.08, -0.03]
Au et al. 2019	8.62	8.53	56	15.55	11.35	55	11.7%	-0.69 [-1.07, -0.30]
Au. 2015	8.88	8.16	49	15.75	10.23	44	11.4%	-0.74 [-1.16, -0.32]
Bourgeois et al. 2002	10.1	5.7	20	13.5	6.5	19	10.0%	-0.55 [-1.19, 0.09]
Coon et al. 2003	15.4	1.3	45	16.5	1.3	44	11.4%	-0.84 [-1.27, -0.40]
Losada et al. 2011	14.91	9.69	68	16.96	11.97	50	11.7%	-0.19 [-0.56, 0.18]
Moore et al. 2013	8.31	3.8	49	10.13	3.8	51	11.6%	-0.48 [-0.87, -0.08]
Prick et al. 2015	13.71	8.18	57	10.94	8.42	54	11.7%	0.33 [-0.04, 0.71]
Steffen et al. 2016	9.8	1.3	28	13.2	1.1	38	9.7%	-2.83 [-3.52, -2.13]
Total (95% CI)			**401**			**385**	**100.0%**	**-0.69 [-1.12, -0.25]**

Heterogeneity: Tau² = 0.39; Chi² = 68.97, df = 8 (P < 0.00001); I² = 88%

Test for overall effect: Z = 3.08 (P = 0.002)

Figure 3. Forest plot of meta-analysis. The effect sizes and meta-analyzed overall effect for decreasing depression in family dementia caregivers are shown. (extracted from X. Y. XU et al. (2020a))

2.6.2.7 Discussion

This systematic review and meta-analysis reveals that BA has both psychological and physical benefits for family caregivers of PWD. BA did have a moderate effect in reducing depression for caregivers compared with control groups who had only been given psychoeducation or information. The results of this study show that BA could have a favorable effect on reducing depression. Former meta-analysis showed that programs aimed at psychological morbidity in family dementia caregivers had an effect size range from 0.24 (M. Pinquart, Sörensen, Pinquart, & Sörensen, 2006) to 0.31 (Brodaty, Green, & Koschera, 2003). According to M. Pinquart et al. (2006), the effect sizes for interventions targeting depression in family dementia caregivers ranged from 0.01 to 0.36, and the interventions including psychoeducation, counseling/case management, support, training of care recipients, respite care, and multicomponent interventions.

Although BA was developed to reduce depression, it also has the potential for alleviating other types of psychological health issues and for physical health among caregivers. It has been evidenced by Moore et al. (2013), who found that BA had a positive effect on reducing negative thoughts, including IL-6, which was treated as the indicator for CVD risk in family caregivers. This study also uncovered a pattern of reduction in the caregiving burden carried by family dementia caregivers following BA intervention (Alma Au et al., 2019; Gonyea et al., 2006). Observational studies have revealed a positive relationship between involvement in pleasant leisure activities and lower psychological morbidity and CVD risk (Chattillion et al., 2013; Ho, 2017; Brent T. Mausbach et al., 2017). Further interventional studies would be required to analyze the impact of BA intervention on other psychological and physical aspects in family dementia caregivers.

None of the reviewed studies has investigated the effects of BA on sleep quality in family caregivers of PWD. As discussed previously, depression is the primary psychological risk factor of sleep disturbance, and BA could significantly reduce depression level in family caregivers of PWD. Theoretically, BA has the probability of improving sleep quality by reducing depression levels among family caregivers of PWD.

2.6.3 The potential of BA on improving sleep among family caregivers of PWD

2.6.3.1 Pleasant event scheduling in BA

In the previous meta-analysis, pleasant event scheduling (PES) was a core component in BA across all the reviewed studies. Historically, research on BA models has relied on PES. PES is a kind of activity scheduling in BA that was developed as a measure of positive reinforcement obtained over time (MacPhillamy & Lewinsohn, 1974, 1982). Research applying PES is mostly consistent with the BA model. In many studies, participants who were instructed to increase pleasurable activities showed increased healthy behaviors and decreased depressed mood. PES not only can reduce depression, but it is also able to improve other aspects of psychological health (e.g., anxiety, stress, subjectively perceived burden).

Many observational studies have also shown that the engagement in pleasant leisure activity and leisure satisfaction is positively related with psychological and physical well-being in family caregivers of PWD (Chattillion et al., 2013; Del-Pino-Casado & Ordóñez-Urbano, 2016; Brent T. Mausbach et al., 2017; L. W. Thompson et al., 2002; von Kanel et al., 2014). Meanwhile, PES is easier for family caregivers of PWD to understand and practice compared to BA as a whole. Therefore, the future study should focus on PES to decrease depression and other physical and psychological burdens amongst family caregivers of PWD.

2.6.3.2 The relationship between pleasant leisure activity and sleep

Cross-sectional studies have reported that a pleasant leisure activity, which is the core element of the BA model, is positively associated with sleep quality in family caregivers of PWD. A survey was conducted to examine the relationship between the Pleasant Events and Activity Restriction (PEAR) model with multiple domains of sleep (Raeanne C Moore et al., 2011). In this study, spousal caregivers were classified into one of three groups: HPLR = High Pleasant Events + Low Activity Restriction; HPHR/LPLR = Either High Pleasant Events + High Activity Restriction or Low Pleasant Events + Low Activity Restriction; and LPHR: Low Pleasant Events + High Activity Restriction. Participants with LPHR experienced significantly poorer sleep quality, sleep latency, sleep efficiency, and daytime dysfunction compared to participants with HPLR. Similarly, in another study conducted by Brent T Mausbach et al. (2011), family caregivers of PWD reporting LPHR had a higher number of subjective sleep disturbance than those with HPHR/LPLR and HPLR. Hawkley, Preacher, and Cacioppo (2010) reported that loneliness (as defined as perceived social isolation), sleep disturbance, and daytime dysfunction were positively related to each other. Tighe, Shoji, Dautovich, Lichstein, and Scogin (2016) also found that engagement in pleasant events was indirectly associated with subjective sleep quality via depressive symptoms.

These findings have significant implications for choosing interventions to improve sleep quality in family caregivers of PWD. BA that is aimed at increasing engagement in pleasant events and decreasing perceived activity restrictions may have a significant effect on reducing sleep disturbance, and BA may also reduce sleep disturbance via reducing depression in family caregivers of PWD.

2.6.3.3 BA and sleep

As discussed previously, depression is the primary psychological risk factor of sleep disturbance in family caregivers of PWD. BA can significantly reduce depression levels in family caregivers of PWD. Meanwhile, cross-sectional studies have also reported that engagement in pleasant events (the core element of BA) is positively associated with reduced depression levels and improved sleep quality in family caregivers of PWD. Therefore, we can hypothesize that BA has the potential to reduce sleep disturbance in family caregivers of PWD. Previous studies have also suggested that BA, such as engagement in pleasant events, may both improve problems with mood and sleep simultaneously (S. M. McCurry et al., 2007). Indeed, S. M. McCurry et al. (2007) have suggested BA theories could not only be applied to explain the occurrence of depression but also could be useful for explaining the changes in sleep in caregivers. Particularly, the engagement in daytime recreational activities could help to maintain regular sleep patterns and circadian rhythms, and the disengagement in pleasant and social activities may result in the development of depression and sleep disturbance in family caregivers of PWD (S. M. McCurry et al., 2007). Meanwhile, two interventional studies that applied moderate-intensity physical activity have been reported to be effective in improving sleep quality in family caregivers of PWD (Hirano et al., 2011; King et al., 2002). Moderate-intensity physical activity can be considered to be a category of leisure activities. Thus, this evidence further supports the idea of using BA in improving sleep quality in family caregivers of PWD.

Many studies have found positive affect, which was the core element of BA (Markarian, Pickett, Deveson, & Kanona, 2013), positively contributed to sleep quality (Norlander, Johansson, & Bood, 2005). BA could respond to appetitive and rewarding stimuli, which is experienced as positive affect by approaching pleasant and rewarding behaviors (Markarian et al., 2013). R. C.

Moore et al. (2013) also demonstrated BA was able to improve positive affect in family caregivers of PWD. Positive affectivity is characterized by enjoyment, satisfaction, high self-report energy, and happiness across different situations, activities, and involvement over a long period (Melvin & Molloy, 2000). In Norlander et al. (2005)' study, individuals with high positive affect and low negative affect were reported to have the best sleep quality, particularly in comparison to individuals with little positive affect and high negative affect. A systematic review conducted by Ong, Kim, Young, and Steptoe (2017) provided the most consistent evidence of an association between positive affect and sleep quality in the healthy population from cross-sectional, longitudinal, ambulatory, and experimental studies. This evidences further proved that BA is promising in improving sleep quality among family caregivers of PWD.

As stated in the above section, the behavioral therapy should be delivered by professional experts, which may limit its generalizability, and it might be difficult for family caregivers of PWD to comply with such treatment because of the complex environment that they experienced. Therefore, BA could be more useful for improving sleep among family caregivers of PWD, since it did not require extensive training to be delivered by interventionists, and was easier to be implemented in community settings.

2.6.4 The knowledge gap on the use of BA for improving sleep quality in family caregivers of PWD

In the systematic search, no study has reported the pattern of use of BA in improving sleep quality in family caregivers of PWD. Besides, no study has reported the pattern of improving sleep by reducing depression in family caregivers of PWD. Preliminary evidence has shown that BA has the potential to enhance the quality of sleep in family caregivers of PWD. However, the utilization of BA in community settings, the possible risks, the effectiveness and efficacy, the principal efficacy component, the functional mechanisms are still unknown. Further studies are needed to understand these hidden areas related to the use of BA in improving sleep quality in family caregivers of PWD.

2.7 The conceptual framework of this study

The conceptual framework in an experimental study is a series of hypothetical relationships among concepts and variables to map out the possible actions in the course of research (Eldridge et al., 2016). From the literature review, there are three key concepts or variables involved in this study: BA, depression, and sleep. It can be hypothesized that family caregiving is a major cause of depression, and depression is the main predictor of poor sleep quality in family caregivers of PWD. According to the previous meta-analysis, BA could significantly reduce depression levels in family caregivers of PWD. When depression level is reduced, the sleep quality can be improved consequently. Besides, BA has the potential to improve sleep quality directly by improving positive affect. It is conceptualized that BA can partially exert a direct effect on improving sleep quality in family caregivers of PWD, and partially exert an indirect effect on improving sleep quality by mediating the depression level. The conceptual framework of this study is shown in Figure 4.

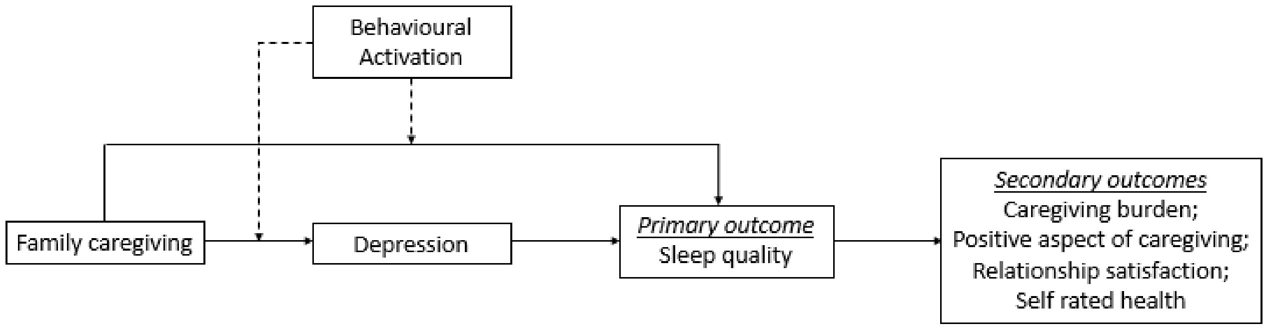


Figure 4. Conceptual framework of Behavioral Activation program

2.8 Summary of this chapter

This chapter presented a comprehensive review of sleep disturbance and its risk factors as well as related interventions in family caregivers of PWD. Sleep disturbance, which has many negative impacts, is a common problem in family caregivers of PWD. Depression is the main psychological risk factor for sleep disturbance in family caregivers of PWD.

This chapter reported the findings of a systematic review and meta-analysis of BA in family caregivers of PWD, and BA yielded a favorable result in reducing depression. This chapter's findings supported the view that BA has the potential to improve sleep quality in family caregivers of PWD, but the evidence is scarce. Therefore, we should develop a BA intervention to improve sleep quality in family caregivers of PWD. The next chapter will present the research methodology of this proposed study.

Chapter Three: Methods

3.1 Introduction

This chapter describes the research methodology to be used in the study. Section 3.1 of this chapter comprises a general introduction to this chapter, and Section 3.2 describes the research aim of the study, its objectives, questions, and hypotheses. Section 3.3 introduces the MRC Framework for Developing and Evaluating Complex Interventions and then presents a summary of the study design that complies with the MRC framework. Section 3.4 presents the methods of developing and refining the BA protocol. The BA protocol was developed under the mechanism, BA principles, and existing BA manuals. Deals with the qualitative study that was used to assess individuals' perceptions of, refinements for, changes to the structure, content, and utility of the BA. Section 3.5 describes methods of the pilot RCT, which aims to examine the feasibility of applying the BA protocol, and to explore the efficacy of the BA on sleep quality preliminarily. Section 3.6 and Section 3.7 deal with the principle of confidentiality and ethical considerations of this research project. Section 3.8 provides a summary of this chapter.

3.2 Research aims, objectives, and hypotheses

This section deals with the specific research aim, objectives, questions, and null hypotheses of the study, which was a pilot RCT design with two parallel arms (BA arm, using BA techniques; and the control arm, using usual care).

3.2.1 Aim of the study

The study aimed to develop an evidence-based BA protocol for improving sleep in family caregivers of PWD, and to assess its feasibility and acceptability in the Chinese population and preliminarily assess its efficacy.

3.2.2 Objectives of the study

The objectives of this study were:

(1) to identify the key components that should be included in the BA intervention for sleep improvement in family caregivers of PWD;

(2) to determine the feasibility and acceptability of the BA protocol for family caregivers of PWD;

(3) to preliminarily examine the efficacy of BA on sleep quality, leisure activity, depression, relationship satisfaction, self-rated health (SRH), positive aspect of caregiving (PAC), and caregiving burden in family caregivers of PWD

3.2.3 Research questions

Specific research questions for the focus group and pilot RCT were as follows:

(1) What are the key contents in BA to improve sleep quality in family caregivers of PWD in China?

(2) What are the feasibility and acceptability of BA protocols in family caregivers of PWD in China?

(3) Are there any changes in sleep quality, leisure activity, depression, relationship satisfaction, SRH, PAC, and caregiving burden in the BA intervention group compare to the control group?

3.2.4 Hypotheses

The related hypotheses were as follows:

(1) The key contents of a scientific-based, culturally sensitive, and well-organized BA protocol are identified.

(2) The BA protocol is feasible to be implemented and acceptable by family caregivers of PWD.

(3) Compare to the control group, sleep quality, leisure activity, depression, relationship satisfaction, SRH, PAC, and caregiving burden are improved after receiving BA among the participants in the intervention group.

3.3 The MRC framework for developing and evaluating this proposed BA study

The MRC Framework for Developing and Evaluating Complex Interventions was applied to guide the study design of this study. The MRC framework guided us to develop, evaluate, and implement a complex intervention to improve health (Craig et al., 2008). Complex interventions usually include several interacting components within the interventional and control groups, consisting of a variety of outcomes, and require several behaviors for delivering and receiving interventions (Craig et al., 2008). There are usually four stages in the process of developing and implementing a complex intervention, including the development of an evidence-based complex intervention; assessment of the feasibility and pilot testing of the effectiveness of the intervention; evaluation of the complex intervention; and implementation and dissemination of the intervention (Craig et al., 2008). The development and evaluation of an intervention may not follow a linear sequence or even a cyclical sequence. Still, each phase should be considered interactively when developing a complex intervention (Craig et al., 2008).

In the development stage of a complex intervention, existing evidence and appropriate theory should be systematically reviewed to provide evidence and theory bases for developing an intervention. Before formally evaluating a complex intervention, preliminary studies are needed to evaluate the feasibility, accessibility, compliance, and recruitment rate, and the condition of delivering the intervention (Craig et al., 2008). Pilot study results should be interpreted to make assumptions for the required sample size for the main intervention. Meanwhile, a pilot study should address the main uncertainties which have been identified during the development of a complex intervention. A mixture of qualitative and quantitative approaches can be used to capture a complete picture of the potential benefits and barriers to guide the future implementation of an intervention. In the evaluation and implementation stage of a complex intervention, effectiveness, change patterns, and cost-effectiveness should be assessed. The reliable research evidence needs to be summarized to support the implementation and dissemination of the intervention to clinical practice settings (Craig et al., 2008).

In this study, we followed the MRC framework (Figure 5) to develop an evidence-based BA protocol for improving sleep in Chinese family caregivers of PWD. The two stages, including "Development" and "Feasibility and Piloting," were adopted in this study. The development of BA was based on several recent systematic reviews, related BA theories, and manuals. After developing the BA protocol, semi-structured interviews were organized to assess Chinese family caregivers' perceptions of, and refinements for, changes to the structure, content, and utility of BA interventions to improve sleep quality among the caregivers. To comprehensively evaluate the feasibility and acceptability of the BA protocol, a pilot study was designed under the second stage of the MRC framework. As this pilot study was designed as an RCT, the efficacy of BA in improving in Chinese family caregivers of PWD was also tested. This pilot study focused on two stages of the MRC framework, which were the development and, secondly, the evaluation of the BA protocol for sleep improvement (Figure 6). This pilot study informed the future main study for the formal implementation of the BA protocol.

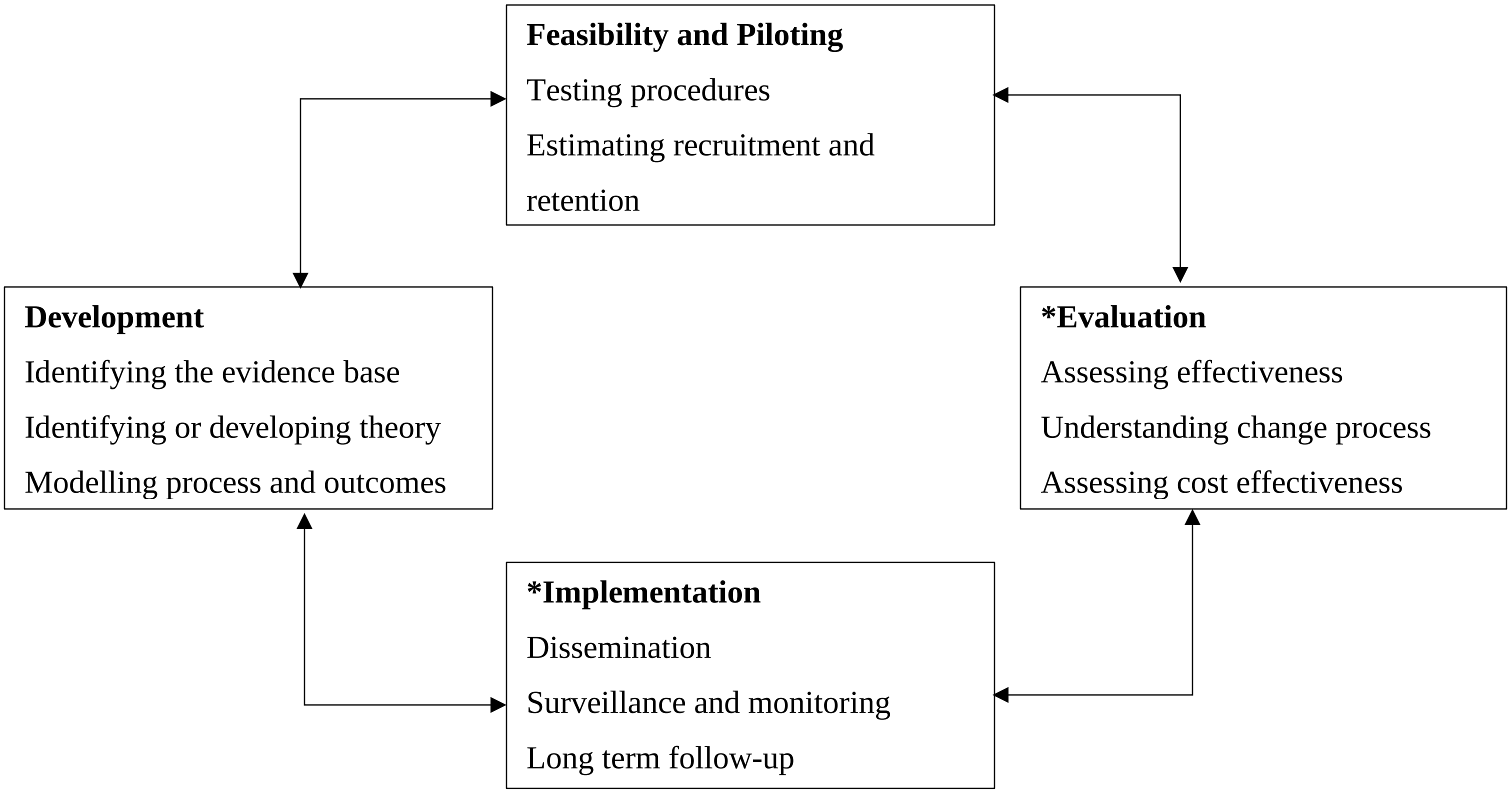


Figure 5. The MRC Framework for Developing and Evaluating Complex Interventions

* These domains are included in the MRC framework but these are not included in the current study

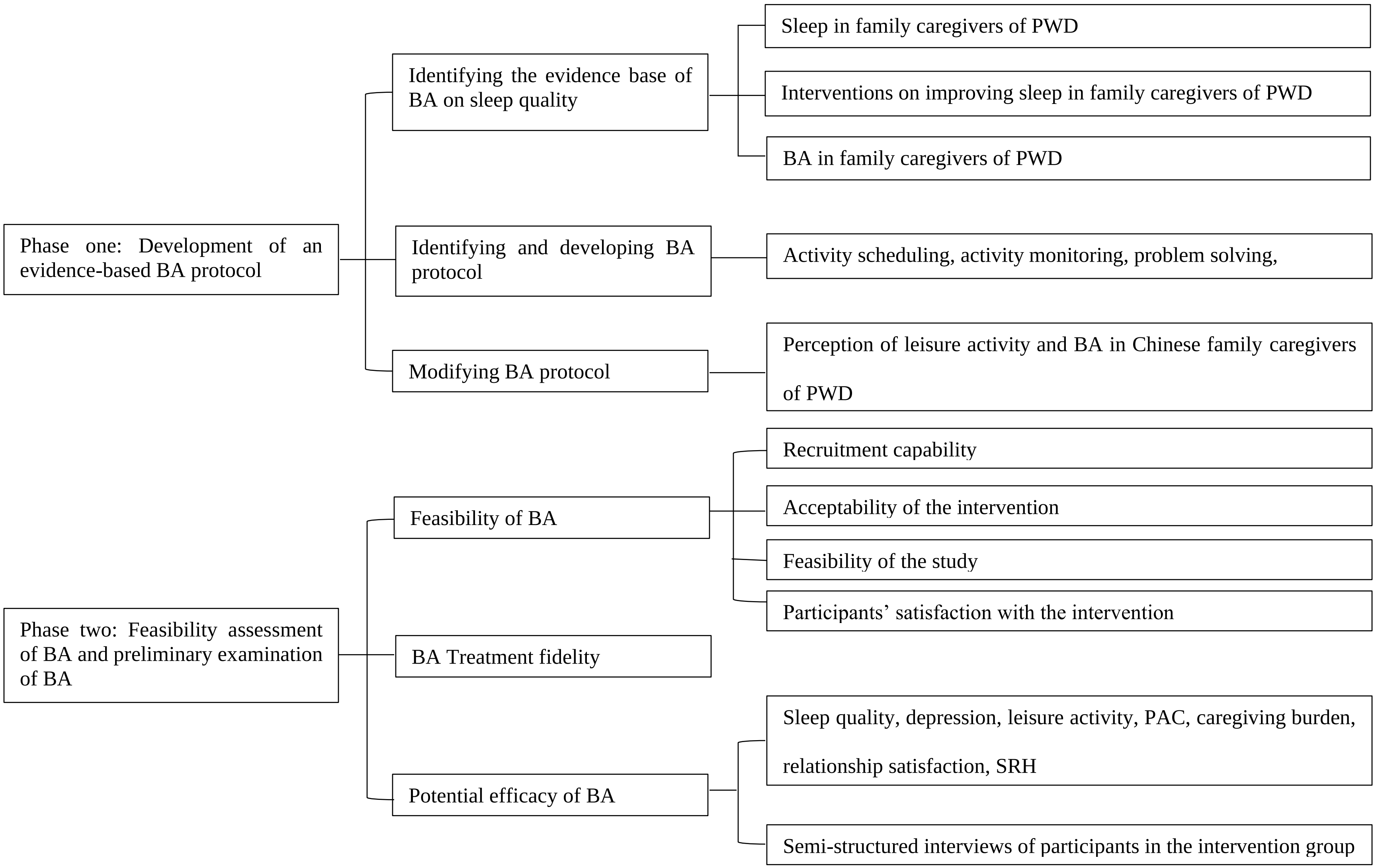


Figure 6. Process of the study design following the MRC Framework for Developing and Evaluating Complex Interventions

BA: behavioral activation
PAC: positive aspect of caregiving
PWD: people with dementia
SRH: self-rated health

3.4 Phase 1: Development and Refinement of BA intervention

3.4.1 Phase 1a: Development of an evidence-based BA protocol for sleep improvement

Phase 1a of the research project comprised the development of the BA protocol for sleep disturbance management. BA protocol was developed according to several reviews dealing with BA research, principles, theories, and existing manuals related to BA and sleep disturbance in family caregivers of PWD.

3.4.2 Phase 1b: Refinement of the BA protocol via semi-structured interviews

Qualitative interviews were needed to explore and understand the context of sleep disturbance, and the perceptions of the proposed BA in Chinese family caregivers of PWD to develop a culturally sensitive BA protocol. Since BA is a treatment aims to help participants to schedule activities they feel pleasant or fulfilled in their daily lives, and pleasant leisure activity scheduling plays a core element in BA in the previous systematic review. Therefore, this qualitative study aimed to explore family caregivers' perceptions and experience of doing leisure activities. The modification of the BA was conducted based on the data collected from the semi-structured interviews. Additionally, the BA intervention protocol was also refined by suggestions from clinicians.

3.4.2.1 Reasons for choosing the semi-structured interview

The structured interview allows researchers to collect data of a particular research domain in a relatively short period, or to collect data of participants with difficulty in reading and writing. However, the structured interview cannot be used to explore a particular research question in an in-depth way (Gill, Stewart, Treasure, & Chadwick, 2008). On the contrary, unstructured interviews do not include any predefined questions and could deeply explore a particular research concern. However, the whole interview process could be weakly managed and organized and will take a lot of time and energy for both participants and researchers (Gill et al., 2008). Nowadays, the semi-structured interview is the most popular and commonly used qualitative interview approach in healthcare research (Gill et al., 2008), since semi-structured interview combines the strengths and eliminate the weaknesses of both structured interviews and unstructured interviews. The semi-structured interviews enable researchers to have an in-depth understanding of the perceptions and experiences of participants on a focused research topic. The semi-structured interviews allow researchers to ask a few leading questions that are regarded as essential questions for a certain research topic, and leave some space for researchers to further explore some specific research areas (Pope & Mays, 1999). According to the discussions above, the semi-structured interview seemed to be the most appropriate interview approach to explore family caregivers' perceptions of pleasant leisure activities and BA intervention, as well as participants' experiences of participating in the pilot RCT and receiving the BA intervention. Therefore, the semi-structured interview approach was utilized both in the pre-intervention qualitative study and the qualitative study nested within the pilot RCT, and the study design is described in the following sections.

3.4.2.2 Study design

A semi-structured interview design for family caregivers of PWD was used. A purposive sampling method was adopted to recruit participants until data saturation was reached. Family caregivers of PWD were recruited from hospitals and communities. Two clinicians from the memory clinics helped to recruit participants. Family caregivers who agreed to participate in this qualitative study were asked to come to the hospital. The interviews took place in an interview room, demonstration room, or other places convenient for the interviewees at the study hospital to ensure the participants' privacy.

3.4.2.3 Sample and recruitment

The sample size comprised of participants who were recruited from The First Hospital of Shijiazhuang. The caregivers were invited by telephone. The following inclusion criteria were applied:

- Was a relative of the person diagnosed with dementia.
- Provided for the person with dementia for more than one hour per day and had provided care for a longer period than three months.
- Lived with the person with dementia in the same household.
- Was at least 18 years old.

Family caregivers who had diagnosed psychiatric disorders or other serious functional problems were excluded from the study.

3.4.2.4 Procedure

The semi-structured interviews were conducted between October 2018 and December 2018. Two researchers facilitated semi-structured interviews. One facilitator led the interview and ask questions; another facilitator actively listened to the discussion, seeking clarification, handling logistics, and taking careful notes (R. A. Krueger & Casey, 2002). A brief introduction, including the reasons for being present, was discussed was given at the beginning of each interview. This allowed participants to ask questions before the audio recording is switched on. Participants were allowed to refuse to answer particular questions, to leave the discussion at any time, or to withdraw their consent at any time. Written consent was given to the participants prior to the discussion. All participants were encouraged to contribute by answering each question. The semi-structured interviews were audio-recorded with the permission of the participants and were transcribed verbatim. After the interview, each participant received 100 RMB coupon for the compensation of their time.

Participants were provided with visual materials about the outline of the BA protocol, especially for pleasant leisure activity. The following guiding questions were used in the interviews:

- How do you describe your daily life after taking care of patients?
- What does "pleasant leisure activity" mean to you?
- When will you do a pleasant leisure activity?
- Do you think that doing pleasant leisure activity influences your feelings? How?
- If you are asked to do pleasant leisure activity, what would you do? Do you think these pleasant leisure activities are likely to improve your sleep?
- SHOW THE PROPOSED CONTENTS OF BA PROGRAMME: What do you think about these contents? Which one do you like? Which one do you dislike?

3.4.2.5 Data analysis

The data collection and analysis was an interactive process. A content analysis principle was followed, which was data-driven and allow themes to originate from the transcript (Braun & Clarke, 2006), and finally, achieve data saturation. Two researchers read and re-read the transcripts of interviews independently to be familiar with data. Then, two researchers coded the transcripts independently with reference to the audio recordings and researchers' notes. Keywords were chosen based on their proximity to the wording that was used by participants, and then the related codes were grouped to identify themes. Basic themes were identified, and illustrative quotes were noted. These were then reviewed and compared to work out broader patterns. They were then rearranged into main themes. After that, themes were named, and relationships between themes were analyzed (Braun & Clarke, 2006). The interpretations of the codes were discussed by two researchers to deepen the analysis and find a consensus between the main themes.

The qualitative methods and reporting of results followed the Consolidated Criteria for Reporting Qualitative Studies (COREQ) guidelines (Tong, Sainsbury, & Craig, 2007). This checklist was developed to improve the comprehensive and transparent reporting of interviews and focus groups. It consists of 32 criteria in three domains, including research team and reflexivity, study design, and analysis and findings. A complete COREQ checklist has been uploaded in **Appendix B**. NVivo™ (QSR International's NVivo 10 qualitative data analysis software) was used to help to code the transcripts.

3.5 Phase 2: Feasibility assessment of BA and preliminary examination of BA

The pilot RCT and a nested qualitative study were conducted to examine the feasibility and accessibility of the BA, and also to preliminarily investigate the potential efficacy of BA on improving sleep quality in family caregivers of PWD.

3.5.1 Phase 2a: The Pilot RCT

3.5.1.1 Study design

The study design was a pilot two-arm RCT. Feasibility results, including subject recruitment, completion of questionnaires, adherence rate to the intervention, treatment fidelity of the intervention were assessed. Besides, the effects of BA on improving sleep quality and psychological health were subjected to a preliminary investigation in this pilot RCT.

The cause-and-effect relationship between BA and sleep quality in family caregivers of PWD was the focus of the preliminary test in this pilot phase. Therefore, an RCT design was the best approach for this context. RCTs are the gold standard as far as the examination of the efficacy of an intervention is concerned (Byar et al., 1976; Concato, Shah, & Horwitz, 2000; Kabisch, Ruckes, Seibert-Grafe, & Blettner, 2011). RCTs can demonstrate the superiority of a new treatment over an existing treatment or a placebo. By adopting the RCT design, this study was equipped to examine the superiority of BA over usual care. An RCT is a real experiment that randomly allocates participants into different groups to receive an intervention, conventional intervention, or no intervention at all (Roberts & Dicenso, 1999). Therefore, it was able to ensure that characteristics that might affect the relationship between the intervention and the outcome would be roughly equal across all arms, thus minimizing any potential bias (Levin, 2007).

However, a rigorously designed RCT requires a large amount of funding, time, and human resources (Thabane et al., 2010). The preparatory work is necessary to determine the recruitment rate, retention rate, time and budget problems, personnel and data management issues, treatment safety, dose level, and response, and the estimation of the treatment effect to ensure the smooth progress of the formal RCT (Thabane et al., 2010). As defined by epidemiology and statistics dictionaries, a pilot study is an “investigation designed to test the feasibility of methods and procedures for later use on a large scale or to search for possible effects and associations that may be worth following up in a subsequent larger study” (Everitt, 2006). Therefore, before a formal evaluation of a large scale RCT can be conducted, it is necessary to test the feasibility and acceptability of the intervention procedure in advance to ensure that the RCT is feasible and acceptable for application to the target population. Thabane et al. (2010) also stressed, “the main goal of pilot studies is to assess the feasibility to avoid potentially disastrous consequences of embarking on a large study - which could potentially ‘drown’ the whole research effort.” The preliminary RCT proposed in this research project is, therefore, a pilot trial design to assess the feasibility and acceptability of the BA protocol and the methodology to be used, as well as a preliminary examination of the potential efficacy of BA on improving sleep in family caregivers of PWD. By assessing feasibility and acceptability, researchers can determine whether an intervention should be tested further, and also assess whether the ideas or findings can be shaped to be relevant and sustainable (Bowen et al., 2009). Besides, researchers can apply the results of the pilot study to determine the sample size of the main RCT, with which to test for the accurate effects of an intervention.

3.5.1.2 Study participants and sample size

Family caregivers of PWD were selected as the target study population of this research project. The inclusion criteria, exclusion criteria, and sample size estimation are presented in the following sections.

1. Inclusion criteria

Eligible participants were recruited to the trial according to the following inclusion criteria:

(1) Adult caregivers were aged 18 or above.
(2) Caregivers who were spouses, kin (e.g., daughters/sons or daughters/sons in law), or siblings of PWD
(3) Caregivers who provided care for a care recipient.
(4) Caregivers who devoted more than one hour per day to take care of a care recipient, and have provided care for longer than three months.
(5) Care recipients had a physician-diagnosis of dementia.
(6) Caregivers who were able to communicate (both verbally and in writing) in Mandarin Chinese.
(7) Caregivers who agreed to participate in the research project.

2. Exclusion criteria

Caregivers were determined ineligible for participating in the study if they met at least one of the following exclusion criteria:

(1) Caregivers who showed signs of severe intellectual deficit.

(2) Caregivers who had a history of severe disorder (e.g., sleep apnea) or other major medical illness known to contribute to their sleep problems.

(3) Caregivers who had been diagnosed with a terminal illness with a life expectancy less than six months.

(4) Caregivers who took part in other clinical trials for the control of sleep disturbance, or other studies that might have generated some interaction with the current pilot RCT.

(5) Caregivers who were unable to follow study instructions and cooperate with the intervention.

3. Sample size estimation

As explained previously, a pilot study is usually primarily focusing on assessing the feasibility and acceptability as well as the study methodology procedure of intervention (Leon, Davis, & Kraemer, 2011; Thabane et al., 2010). The focus of a pilot study is usually not on the efficacy of the intervention. Therefore, inferential statistical tests were not necessary for this pilot RCT design. The sample size for a pilot study instead should be based on the pragmatics of recruitment and the necessity for examining feasibility (Leon et al., 2011). Because the secondary focus of a pilot study was a preliminary examination of the effects of BA, a variance estimate could be further applied to guide the design of the future main study. The National Institute for Health Research and The National Research Ethics Service stated that not all studies need a power-based sample size calculation, but they need to justify the selected sample size. The sample size estimation of this current pilot study should be reasonable enough to provide evidence for further calculation of the main study sample size.

Many researchers suggested recruiting 30 participants per arm in the pilot RCT. Browne (1995) provided a general rule for using at least 30 people to estimate parameters. Billingham, Whitehead, and Julious (2013) found that the median sample size was 30 per arm among reviewed pilot trials. Chief Scientist Office of the Scottish Government Health Directorates recommended that a minimum of 30 participants per arm is sufficient for parameter estimation in the future main study. Hertzog (2008) also suggested that a minimum of 30 participants per arm was necessary for a pilot trial to estimate effect size and confidence interval for the future main study. Given an attrition rate of 20% of the whole pilot study, the total sample size of this study was 72, with 36 participants in each group.

3.5.1.3 Study settings

This study was conducted in Shijiazhuang, the capital city of Hebei Province in Mainland China. A convenient sampling approach was utilized to select the study hospitals, as a random sampling approach was very difficult to conduct in this study. The study participants were recruited from one city hospital, namely, The First Hospital of Shijiazhuang. The First Hospital of Shijiazhuang is a grade iii-a general hospital in northern China. It is also a large teaching hospital affiliated with Hebei Medical University. It has 76 clinical departments and 2127 beds. The participants were recruited from the Memory Clinic, which covers the screening, evaluation, diagnosis, and treatment of dementia. The participants were also recruited from the department of geriatrics, psychiatry, and neurology.

3.5.1.4 Trial arms

Two study arms were designed for this pilot RCT, including an intervention group and a control group.

1. BA intervention group

Participants who were allocated to the BA group (i.e., the intervention group) received a protocol that lasts for about eight weeks. The BA manual was utilized to help them follow the instructions. Participants received BA intervention via phone calls every week BA intervention. Participants were asked to finish homework after each session. Daily logs were needed to record their daily activities.

2. Usual care control group

Usual care refers to the regular care that participants received from the health care system to prevent or treat disease (B. T. Thompson & Schoenfeld, 2007). Participants in the control group received usual care from communities, hospitals, and clinics. The usual care received by the control group in this study is supposed to reflect the care that they usually received in their daily practice (Roland & Torgerson, 1998). In China, there is no service for family caregivers of PWD.

3.5.1.5 Randomization and Blinding

A well-designed trial is able to minimize the variability of the evaluation and provides an unbiased evaluation of the intervention by avoiding confounders of other known and unknown variables. The influence of the imbalance of covariates is indistinguishable from the treatment effects. Randomization provides participants with equal opportunities to receive any treatments under the study, and thus generate comparable groups (Suresh, 2011). Randomization includes generating random numbers and randomly assigning random numbers to each participant. Random numbers can be generated from computers or random number tables from statistical books. R (version 3.5.1) was used to generate a randomization table.

Allocation concealment was applied to ensure no prior knowledge of group assignment and was thus minimize the potential for selection bias (Suresh, 2011). The randomization table was generated and kept by a person (a Ph.D. student) who was not involved in any part of this study and did not know the study process. After potential participants agreed to participate in this study and signed the consent form, the researcher contacted the person who was in charge of randomization to generate random numbers by R and determine the group assignment for the participant.

Even though randomization minimizes selection bias and confounding, and thus minimizes the prognostic differences between treatment groups, it does not prevent the subsequent biased assessment of outcomes. Blinding was, therefore, necessary to minimize performance and ascertainment bias after randomization (Karanicolas, Farrokhyar, & Bhandari, 2010). Prior knowledge of group assignment will influence participants' behaviors in the intervention and their response to outcome measures. For example, a participant who is aware that he/she is not in the intervention group will be more likely not to seek additional assistance and leave the study earlier. A researcher who is aware of the group assignment will be more likely to change his/her attitude towards participants and provide different treatment.

Meanwhile, the researcher may be more eager to seek positive results. Therefore, the blinding of data collectors and data analysts is essential for receiving unbiased outcomes (Karanicolas et al., 2010). Even though a complete blinding design was necessary to limit bias in this research project as much as possible, it was not possible for this pilot trial, because participants were informed of the details of the intervention before participated in the intervention, and the interventionist was aware of the group allocation. To further ensure the successful design and minimize the bias in this research project, a data collector was included. Blinding of data collectors is critical in ensuring unbiased ascertainment of outcomes (Karanicolas et al., 2010).

3.5.1.6 Study procedure

Before the implementation of the pilot study, a group meeting was held among researchers (the doctoral researcher and two clinical workers who assisted with the recruitment of participants and the implementation of intervention). The clinical worker assisted with the identification of potential eligible caregivers according to the inclusion and exclusion criteria. Family caregivers of PWD were recruited from one hospital and several communities. Caregivers who had been identified as eligible participants were invited to participate. Potential participants were provided with further details, such as the aim of the study aim and the procedures involved. Potential participants were well informed that participation in this research was done voluntarily, and they had the right to withdraw from the study at any time. Those who agreed to participate in this study were invited to sign consent forms. The baseline demographic data, as well as sleep, leisure activity, and psychological conditions, were then collected. Following the completion of the baseline assessment, the participants were randomly assigned to one of the two study groups: the BA intervention group or the usual care control group. The addresses of recruited family caregivers were checked to prevent the contamination between intervention and control groups.

All the treatment sessions were provided by one doctoral researcher. Participants in the intervention groups received eight weekly individual telephone-based sessions. The first five sessions lasted approximately 30-45 minutes. The duration of the last three phone calls was decided by the participants and was varied from 15 to 30 minutes. Participants in the intervention group were provided with the BA manual, including chapter information and various worksheets to complete during the intervention. A participant who had completed 80% of all the sessions (seven out of eight sessions) was treated as the person who has completed the intervention. Participants in the control group received care as usual. After the intervention, all of the participants were asked to complete the post intervention assessment by paper.

3.5.1.7 Study outcome measures

The main outcomes for this pilot RCT was a series of feasibility outcomes related to subject recruitment and the follow-up process. In addition, several outcomes in terms of the effects of BA on sleep quality and psychological health were measured.

3.5.1.7.1 Baseline assessment

The participants' demographic data, health status, caregiving conditions, and quality of the caregivers' relationships with PWD were collected via a specifically-designed baseline assessment questionnaire. The demographic data included the participants' ages, sex, marital statuses, educational levels, smoking and drinking conditions, employment statuses, religious beliefs, and monthly household incomes. The caregiving condition included years involved in providing care, hours of care provided per day and relationship with care recipients.

3.5.1.7.2 Feasibility and acceptability of BA intervention in family caregivers of PWD

Feasibility and acceptability of BA intervention were included as the primary outcomes in this pilot RCT. The feasibility and acceptability assessments include the recruitment capability, the feasibility of study questionnaires, the acceptability of the intervention, and the patients' satisfaction with the study. Semi-structured interviews were conducted to let participants talk about their experiences and feelings of participating in this study.

(1) Recruitment capability

The feasibility in terms of subject recruitment was included: (1) the time taken to complete the entire subject recruitment; (2) the eligibility rate of the screened patients (the number of subjects eligible for participation divided by the number of subjects screened for eligibility); (3) the recruitment rate (the number of subjects who participated in the study divided by the number of subjects eligible for participation); (4) the retention rate (the number of subjects who completed the study divided by the number of subjects who participated in the study); (5) the attrition rate (the number of subjects who dropped out after randomization divided by the number of subjects who participated in the study); and (6) the patients' reasons for discontinuing the study after participation.

(2) Feasibility of the study questionnaires

The feasibility of the study questionnaires was measured by calculating the proportion of missing values at both item-level and scale-level for each study questionnaires. Item-level missing values were determined as the percentage of participants who do not respond to every single item, and scale-level missing values were identified as the percentage of participants who did not respond to at least one item in the whole questionnaire.

(3) Acceptability of the intervention

The acceptability of the intervention was assessed by (1) the total number of participants in each session; (2) the mean length of contact (minutes) for each participant, (3) and the mean number of contacts.

(4) Participants' satisfaction with the intervention

Patient satisfaction scores in terms of "satisfaction with BA intervention" were presented as mean and standard deviation (SD).

3.5.1.7.3 Intervention fidelity

Intervention fidelity can help to increase the scientific confidence of an intervention. Intervention fidelity includes two components: 1) intervention integrity, the degree to which intervention is implemented as intended, and 2) intervention differentiation, the degree to which two or more study arms are different in the major elements (Borrelli, 2011; Moncher & Prinz, 1991; Yeaton & Sechrest, 1981). Significant results may result from an effective intervention or the inclusion of other unknown factors or the omission of inactive components of the intervention if researchers have not measured intervention fidelity (Borrelli, 2011). Thus the assessment of intervention fidelity can enhance both the internal validity (the treatment is delivered as intended) and external validity (the treatment can be replicated and applied in real-world settings). A checklist (**Appendix C**) developed by Borrelli et al. (2005) was applied to measure the intervention fidelity, including treatment design, training providers, delivery of the intervention, receipt of intervention, and enactment of intervention skills through the whole pilot intervention. All items were rated as “Present,” “Absent, but should be present,” or “Not Applicable.” All sessions were videotaped and rated independently by a researcher.

Cognitive Therapy Rating Scale (CTRS) was used to assess the provider’s adherence (**Appendix D**) (Young & Beck, 1980). CTRS is a widely used tool with satisfactory validity and reliability to measure the competence of interventionists in CBT. The CTRS showed high internal consistency and adequate average interrater reliability (Affrunti & Creed, 2019). It contains two theorized factors: ‘general therapeutic skills’ and ‘cognitive-behavioral skill’ (Young & Beck, 1980), which are generated into two theory-driven subscales: General Therapeutic skills and Cognitive-Behavioral Therapy skills. General Therapeutic skills consist of the items: Agenda, Feedback, Understanding, Interpersonal Effectiveness, Collaboration, and Pacing. Cognitive-Behavioral Therapy skill consists of the items: Guided Discovery, Focusing on Key Cognitions and Behaviors, Strategy for Change, Application of CBT Techniques, and Homework. The CTRS consists of 11 items that are rated by a 0 to 6 Likert scale, with a total score ranges from 0 to 66, and cut-off for competence is 40 (Shaw et al., 1999). Since BA can be treated as a major component of CBT, CTRS can be applied to assess the BA interventionist’ adherence, and higher score indicated higher competence of the interventionist.

3.5.1.7.4 Outcome measurements

The outcomes regarding the effects of BA included sleep and psychological health. The CPSQI was employed to measure sleep quality. The Chinese version of the Center for Epidemiologic Studies Depression Scale (CCES-D) was used to measure depression in family caregivers. The Chinese version of the positive aspect of caregiving scale (C-PAC) was applied to measure PAC. The Chinese version of Zarit Burden Interview (C-ZBI) was used to assess the caregiving burden. The leisure activity scale was adopted to measure leisure activities. The health status was measured by Self-rated Health (SRH). And the relationship satisfaction with PWD was captured by a scale from 1 (conflict-ridden) to 5 (harmonious) (**Appendix E**).

(1) Sleep quality

The PSQI is a self-reported questionnaire that assesses sleep quality over a 1-month time interval (Buysse et al., 1989). PSQI has been widely used in different populations with preferable internal homogeneity, consistency (test-retest reliability), and validity (Buysse et al., 1989). CPSQI is the Chinese version of PSQI, and it also has acceptable psychometric properties, with an overall reliability coefficient of 0.82-0.83 and a test-retest reliability over a 14- to 21- day interval of 0.85 (Tsai et al., 2005). Nineteen individual items are used to generate seven "component" scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. A global score ranges from 0 to 21 by summing the seven component scores. Higher scores indicate more inferior sleep quality. The optimal PSQI for distinguishing sleep disturbance is 5, with a sensitivity of 89.6% and specificity of 86.5% (kappa = 0.75, $p \leqslant 0.001$) (Buysse et al., 1989).

(2) Depression

The Center for Epidemiologic Studies Depression Scale (CES-D) has been widely used as a self-report measure of depression, and it is a balanced and comprehensive instrument (Shafer, 2006), which assesses interpersonal aspects. The CES-D, which was developed by Radloff (Radloff, 1977), has been extensively used in different age groups, including adolescents, adults, and the elderly (Shafer, 2006). CCES-D has an acceptable internal consistency of 0.855, and an excellent two-week test-retest reliability of 0.91 (Chin, Choi, Chan, & Wong, 2015). The CCES-D consists of 20 questions, which are four-point Likert scales range from 0 to 3, and they measure depressive symptomatology during the past week. The total score ranges from 0 to 60, with higher scores indicating more severe depression. Patients with scores of 16 to 26 can be categorized as having mild depression, and patients with scores of 27 to 60 can be categorized as having major depression (Radloff, 1977).

(3) Leisure activity

The leisure activities were measured by the frequency of leisure activities, which includes 14 items of leisure activities that Chinese older adults usually do in their leisure time. These 14 leisure activities were extracted and concluded from other studies which investigated leisure activities in family caregivers of PWD, and were also extracted from the pre-intervention qualitative study. Each item ranged from 0 (Never) to 3 (Often). Higher scores indicate a higher frequency of doing leisure activities. It was a self-developed scale.

(4) Positive aspect of caregiving

The positive aspect of caregiving (PAC) was measured by the Chinese version of PAC (C-PAC). The PAC scale was developed by Tarlow et al. (2004), and it was adopted in the Resources for Enhancing Alzheimer's Caregiver Health (REACH) I and II interventions to measure caregivers’ positive role appraisals. PAC is an instrument composed of nine items; each item ranges from 0-4, with a higher score indicating better PAC. The reliability of C-PAC was confirmed by Cronbach's α for internal consistency ranged from 0.72 to 0.82; the CVI for item content validity ranged from 0.8 to 1.0. The construct validity was also confirmed by factor analysis with a 55.08% variance by two factors (Self Affirmation and Outlook on Life) (Li & Zhang, 2007). The criteria-related validity of C-PAC is proved by significant associations with CES-D, caregiver confidence, the occurrence of problem behaviors, SRH, and caregiver bother (Lou, Lau, & Cheung, 2015).

(5) Caregiving burden

The Chinese version of the Zarit Burden Inventory (CZBI) was used to measure the caregiving burden in this study (Ko, Yip, Liu, & Huang, 2008). Zarit Burden Inventory (ZBI) is a caregiver self-report scale and has been commonly used to assess caregiving burden in caregivers of PWD (American Psychological Association, 2011). The revised ZBI, which contains 22 items, is originated from as a 29-item questionnaire (Zarit, Reever, & Bach-Peterson, 1980). The CZBI is a 5-point Likert-type scale consists of 22 items with a response of, each item ranging from 0 (never) to 4 (nearly always), and the total score ranging from 0 to 88. For ZBI, a higher score indicates a greater caregiving burden. In CZBI, the test-retest reliability of the total scores was 0.88, indicating little variability between the 2-week time points. The CZBI also had a good concurrent validity, and it was positively correlated with the 12-item Chinese Health Questionnaire (Spearman's r = 0.54) and the Caregiver Activity Survey (Spearman's r = 0.47). The CZBI is feasible for measuring the caregiving burden of Chinese caregivers for PWD.

(6) Health status

The health status of overall health ratings was measured by Self-rated Health (SRH), in which participants were asked to rate their health status on a scale of 1 = excellent to 5 = very poor. This measurement is highly correlated with physical ratings of health (LaRue, Bank, Jarvik, & Hetland, 1979) and to be sensitive to health changes over time (Rakowski, Fleishman, Mor, & Bryant, 1993).

(7) Relationship satisfaction with PWD

The relationship satisfaction with PWD (past and present) was captured by asking caregivers to describe the relationship on a scale from 1 (conflict-ridden) to 5 (harmonious). It was a self-developed scale.

3.5.1.8 Data analysis

Data were entered into statistical software to create datasets for statistical analysis. Both descriptive statistics and inferential statistics were utilized for data analysis using the IBM SPSS Statistics for Windows, version 25.0 (IBM Corp., Armonk, NY, USA). Data cleaning was conducted before data analysis. The analysis of the pilot study clinical outcomes was based on the principle of intention to treat (ITT) analysis, and missing data were managed using the last observation carried forward (LOCF) approach. Details of the approaches to data analysis are described below.

3.5.1.8.1 Data cleaning

Data cleaning is a critical procedure in maintaining the validity of the statistical analysis. The datasets were double-checked according to the raw data to ensure the correct data coding. Categorical data was checked by generating frequency counts to identify the frequency of codes as well as possible missing values for each outcome variable (Portney & Watkins, 2000). Continuous data were checked by generating the descriptive statistics, such as the mean score, minimum value, and maximum value, and to see whether the score ranges fall within the normal scope (Portney & Watkins, 2000).

3.5.1.8.2 Management of missing data

LOCF is the simplest and the most popular method to manage missing data of repeated measures over different time points of data collection (Lachin, 2016). This method assumes that the missing data are missing completely at random and the participants' responses are constant from the last observed value to the endpoint of the study, which means "treating carried-forward data as observed data at the last time point" (Mallinckrodt et al., 2003; Shao & Zhong, 2003). In this study, LOCF was used for the CPSQI, CCES-D, leisure activities, C-PAC, C-ZBI, SRH, and Relationship satisfaction with PWD questionnaires. Since participants were measured before and after the intervention, baseline data of outcome measures were therefore carried forward to the post-intervention assessment, which called baseline observation carried forward (BOCF). The BOCF can be treated as a relatively conservative approach as it may potentially minimize false-positive interpretation of the interventional effects when an intervention is claimed to be more effective than a comparison (Barnes, Mallinckrodt, Lindborg, & Carter, 2008).

3.5.1.8.3 Statistical analysis

The statistical analysis planned for the pilot RCT included both descriptive statistics and inferential statistics. The significance level was determined to be $p<0.05$ for a two-tailed test. Statistical analysis of the demographic data, the pilot outcomes, feasibility outcomes, and the treatment fidelity were described separately in the following sections.

1. Demographic data

For the nominal and ordinal data of the demographic characteristics, including sex, marital status, educational levels, smoking and drinking conditions, employment status, religious beliefs, monthly household income, and caregiving condition, the Chi-square test or Fisher's exact test were utilized to perform baseline comparisons between intervention and control groups. An independent t-test was considered to begin with for the interval data of the demographic characteristics, including patients' age, years providing care, hours of care provided per day, and caregiving condition. The assumption of normality was checked by the Shapiro-Wilk test, and the assumption of homogeneity of variance was measured by Levene's test. If all of these assumptions were not violated, an independent t-test was conducted; if these assumptions were significantly violated, the Mann-Whitney test was utilized for the analysis. Comparisons of the demographic variables between the participants in the intervention group who were compliant to the study protocol and who dropped out the intervention were also conducted.

2. Outcomes measures

(1) Statistical analysis of outcome measures

The statistical analysis of this pilot study was conducted based on the principle of an ITT analysis approach. ITT is an analytic strategy aimed at reducing potential bias arising from missing data in RCTs (Gupta, 2011). ITT helps to keep the integrity of the randomization process (i.e., groups are expected to be similar) and to provide a more realistic estimate for the treatment because in the "real world," it is normal for some patients to drop out from the treatment (Gupta, 2011). The more realistic estimate of the treatment effect can be derived from ITT.

Continuous data were presented as mean, SD, standard error (SE), and median, while nominal and ordinal data were presented as absolute numbers and percentages. The baseline differences in these two outcome variables between intervention and control groups were adjusted during the subsequent analysis of the effects of the BA.

Internal consistency of the instruments which were used in this study was examined, Cronbach's alpha was calculated based on the baseline data. Each outcome (CPSQI, CCES-D, leisure activity, C-PAC, C-ZBI, SRH, and relationship satisfaction with PWD) was summed up by items. To compare the baseline difference on outcomes between the intervention group and the control group at baseline, independent t-test or Mann-Whitney tests were conducted. Shapiro-Wilk test and Levene's test was applied to examine the assumptions of normality and the assumptions of homogeneity of variance, respectively. If all these assumptions were not violated, an independent t-test was conducted; alternatively, if these assumptions were significantly repudiated, a Mann-Whitney test was utilized instead.

(2) Effect size estimations

The effectiveness of the BA was evaluated by comparing the changes in the mean scores of the outcome measures (sleep quality, depression level, PAC, caregiving burden, relationship satisfaction, self-rated health) between the intervention and control groups immediately after the intervention. The paired t-test was used to compare the changes in outcomes in both intervention and control groups. The repeated measures of Analysis of Variance (RM-ANOVA) test was used for outcome analysis in this study, as most of the assumptions for using RM-ANOVA were not violated. The RM-ANOVA is applied to compare group means across repeated measures of time on a dependent variable. In the RM-ANOVA, a fixed variable (e.g., intervention and control groups) is usually regarded as between-subjects factors, and time is usually regarded as a within-subject factor (C. Krueger & Tian, 2004). RM-ANOVA requires the outcome variable to be quantitative (i.e., a continuous variable) and normally distributed (Ma, Mazumdar, & Memtsoudis, 2012). RM-ANOVA is a popular approach to dealing with intervention effects (Stevens, 2012). Partial eta-squared (ηp^2) was used as an indicator of the effective size of the time by intervention condition effect (interaction effect), following conventional guidelines for its interpretation (small = 0.01, medium = 0.06, and large = 0.14) (Ferguson, 2009). Demographic factors with baseline differences were adjusted in the RM-ANOVA model.

(3) Sensitivity analysis

The sensitivity analysis was performed by comparing the results of per protocol analysis with the results of ITT analysis. In per protocol analysis approach, participants who violated the intervention protocol were excluded from the analysis (Gupta, 2011). In this study, participants who did not complete the intervention and post-intervention assessment were excluded from per protocol analysis. The primary analysis for this pilot RCTs was based on the ITT principle, in which participants were analyzed based on the arm they were randomized, instead of whether they received true treatment or completed a prescribed regimen (Thabane et al., 2013).

The purpose of this sensitivity analysis is to examine the effects of non-compliance with study outcomes (Thabane et al., 2013). Sensitivity analysis plays a critical role in evaluating the robustness of the findings and conclusions in clinical trials. It is “a method to determine the robustness of an assessment by examining the extent to which results are affected by changes in methods, models, values of unmeasured variables, or assumptions” to identify “results that are most dependent on questionable or unsupported assumptions” (Schneeweiss, 2006). The study design and analysis of clinical trials usually based on the assumption of some effects or impacts on conclusions. The study needs to conduct a sensitivity analysis to assess these effects. Consistency between the results of the primary analysis and the results of sensitivity analysis could strengthen the credibility of the findings (Thabane et al., 2013).

3. Statistical analysis of feasibility outcomes

(1) Feasibility of subject recruitment

Descriptive statistics (absolute number of caregivers and related percentage) were used to describe the eligibility and recruitment rate during subject recruitment, and descriptive statistics were applied to present the retention and attrition rates of the study.

(2) Feasibility of the study questionnaires

Descriptive statistics were used to report the completion rate of the study questionnaires. To assess the feasibility of the study questionnaires, the percentage of missing values for every single item, as well as the whole scale, was computed respectively.

(3) Acceptability of the intervention

Descriptive statistics were used to report the acceptability of the intervention. Means and standard deviations were used to report the number of participants in each session and the duration of each session.

(4) Participants' satisfaction with the study intervention

Patient satisfaction scores in terms of "satisfaction with BA" were presented as means and standard deviations. The experience of participating in this study was collected by the researchers.

4. Treatment fidelity

Means and standard deviations were used to report the interventionist's competency.

All of the data analysis approaches were summarized in Table 2.

Table 2. Data analysis approaches utilized in this study

Outcomes	Data Analysis Approaches		
	Statistical Approach	Post-hoc Analysis	Effect Size
Baseline characteristics			
Nominal and ordinal data	Chi-square test (or Fisher's exact test)	NA	NA
interval data	Independent t-test (or Mann-Whitney test)	NA	NA
Feasibility outcomes			
Eligibility and recruitment rate	Descriptive statistics	NA	NA
Retention and attrition rates	Descriptive statistics	NA	NA
Missing values for every single item, and whole scale	Descriptive statistics	NA	NA
Patients' satisfaction with the study	Descriptive statistics	NA	NA
Number of participants in each session.	Descriptive statistics	NA	NA
Duration of each session	Descriptive statistics	NA	NA
Patient satisfaction scores	Descriptive statistics	NA	NA
Treatment fidelity			
Interventionist's competency	Descriptive statistics	NA	NA
Pilot study clinical outcomes			
CPSQI	Independent t-test (or Mann-Whitney test)	RM-ANOVA	ηp^2
CCES-D	Independent t-test (or Mann-Whitney test)	RM-ANOVA	ηp^2
C-PAC	Independent t-test (or Mann-Whitney test)	RM-ANOVA	ηp^2
C-ZBI	Independent t-test (or Mann-Whitney test)	RM-ANOVA	ηp^2
Leisure activity scale	Independent t-test (or Mann-Whitney test)	RM-ANOVA	ηp^2
SRH	Independent t-test (or Mann-Whitney test)	RM-ANOVA	ηp^2
Relationship satisfaction with PWD	Independent t-test (or Mann-Whitney test)	RM-ANOVA	ηp^2
Sensitivity analysis	Comparing the results of per protocol analysis with the results of ITT analysis		

C-PAC: Chinese version of positive aspect of caregiving

CPSQI: Chinese version of Pittsburgh Sleep Quality Index

C-ZBI: Chinese version of Zarit Burden Interview
ITT: intention to treat
NA: not applicable
PWD: People with dementia
RM-ANOVA: repeated measures of Analysis of Variance
SRH: self-rated health
ηp^2: partial eta-squared

3.5.2 Phase 2b: The qualitative study nested within the pilot trial

3.5.2.1 Study sample and setting

A purposive sampling method was adopted to recruit participants until data saturation was reached. Family caregivers of PWD who had participated in the pilot RCT were recruited. The interviews took place in an interview room, demonstration room, or other places convenient for the interviewees at the study hospital to ensure the participants' privacy.

3.5.2.2 Study procedure

As the qualitative study was part of the research design nested within the pilot RCT, information in terms of the semi-structured interview was included in the pilot RCT information sheet and consent form. All family caregivers of PWD who agreed to participate in the pilot trial were also informed in advance about the aims and procedures of the nested semi-structured interview when they met with the researchers the first time. The potential eligible participants were included in the interviews if they felt comfortable with the individual interviews and were willing to share their views and experiences with the doctoral researcher. The doctoral researcher then negotiated with each participant to arrange the most appropriate time and location to conduct the interview.

The interviews were performed within two months after the study participants had completed the pilot trial. All of the interviews were conducted by the doctoral researcher. A brief introduction was given and was discussed at the beginning of each interview. It allowed participants to ask questions before the audio recording is switched on. Participants were allowed to refuse to answer particular questions, to leave the discussion at any time, or to withdraw their consent at any time.

The following guiding questions were used to guide interviews:

- What was your overall experience of participating in the pilot RCT?

- How would you evaluate the instruments/questionnaires that you completed during the study periods?
- How would you evaluate the daily activity log that you were asked to complete daily during the BA intervention period?
- To what degree do you believe that the BA intervention improved sleep during caregiving?
- What changes did you experience after receiving the BA intervention?
- What kinds of burdens or difficulties did you encounter related to the BA intervention?
- How satisfied are you with the BA intervention?
- What are your recommendations/suggestions to help us improve the study design (and the BA intervention arrangement in the future)?
- Is there anything else related to the study that has not been discussed?

3.5.2.3 Data analysis

The data collection and analysis was an interactive process. A content analysis principle was followed, which was data-driven and allowed themes to emerge from the transcript (Braun & Clarke, 2006), and finally, achieve data saturation. Two Ph.D. students read and re-read the transcripts of interviews independently to be familiar with data. Then, they coded the transcripts independently with reference to the audio recordings and researchers' notes. Keywords were chosen based on their proximity to the wording that was used by participants, and then the related codes were grouped to identify themes. Basic themes were identified, and illustrative quotes were noted. These were then reviewed and compared to work out broader patterns. They were then rearranged into main themes. After that, themes were named, and relationships between themes were analyzed (Braun & Clarke, 2006). The interpretation of the codes was discussed by the same two Ph.D. students to deepen the analysis and find consensus between the main themes.

3.6 The principle of confidentiality

Participants' information collected for a research project must not be used or disclosed for any purpose without their permission and authorization. Only core members of the research team in this doctoral research project were allowed to access the participants' research records, documents, and any other types of files that had identifiers of the study participants. Several strategies were utilized in this study to secure the confidentiality and anonymity of the participants' research materials. A unique code with a name acronym was assigned to each of the study participants to replace their names and other essential identifiers, such as their ID card number and social security card number. All hard copies of the research materials, including the participants' questionnaires, daily logs, and relevant forms, were locked in a cabinet, and all electronic files were saved in a compressed file that could only be accessed by the doctoral researcher via passwords.

3.7 Ethical consideration

The ethical approval of this research project was obtained from the Research Committees of The Hong Kong Polytechnic University and the study hospitals themselves (**Appendix F**). At the time when the potential participants were invited to take part in the study, they were provided with information regarding the study's aims and objectives and its procedures. In addition, the researchers explained the potential risks associated with different intervention approaches in detail. All the relevant information was included in an information sheet to be handed to the participants. In this way, the potential participants had the chance to carefully read the information sheet (**Appendix G**) and ask any questions regarding the study before making a final decision about whether to participate in the study or not. For those who decided to participate in the study, written informed consent forms (**Appendix H**) were circulated for them to certify their willingness to participate.

3.8 Summary of the chapter

This chapter described the research methodology to be used in this research project. The study design followed the *MRC Framework for Developing and Evaluating Complex Interventions*, which includes three study phases: the development of an evidence-based BA protocol, the focus group, and the pilot RCT. The development of the BA protocol was based on related theories, principles, and manuals, and it then was modified to be culturally sensitive by using semi-structured interviews made up of Chinese family caregivers of PWD. After that, a pilot RCT and a nested qualitative study were conducted to investigate the feasibility and accessibility of the BA protocol to family caregivers of PWD in China. In addition, there was a preliminary examination of the potential efficacy of BA in improving sleep quality in family caregivers of PWD.

The whole study procedure and timeline was shown in Figure 7.

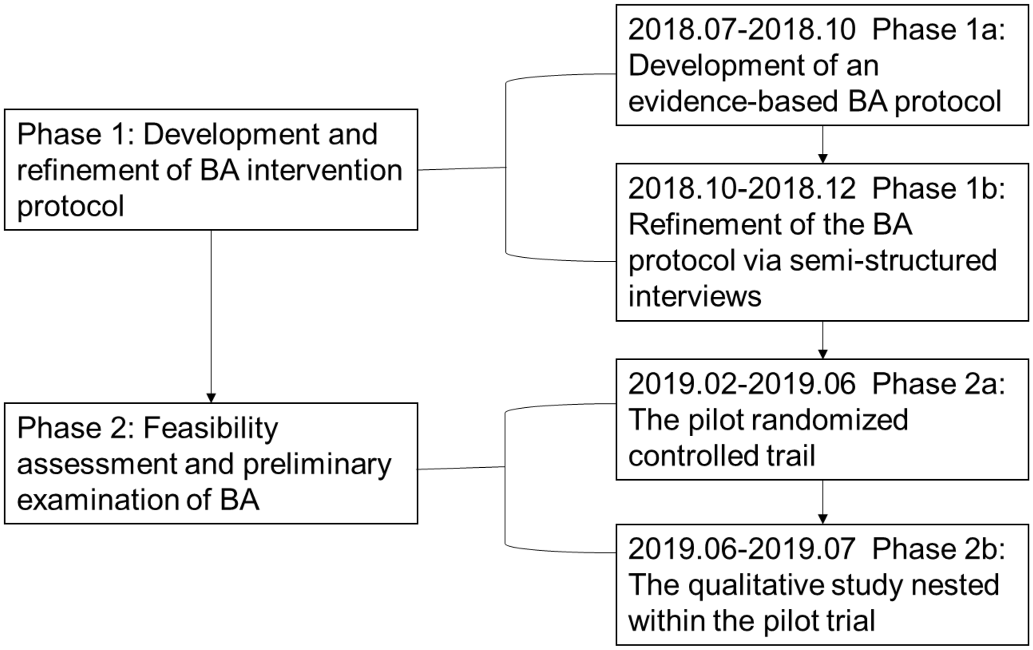


Figure 7. Study procedure and timeline

Chapter Four: Development and Refinement of Behavioral Activation Protocol

4.1 Introduction

This chapter consists of four parts, which presents the results of the development and refinement of BA protocol. Section 4.1 (this section) presents an introduction to this chapter. Section 4.2 presents the process of the development of the BA protocol. Section 4.3 shows the qualitative results and the discussion of the pre-intervention semi-structured interviews for perceptions of doing pleasant leisure activity in family caregivers of PWD. Section 4.4 shows the discussion on the refinement of BA protocol. Section 4.5 presents the revised contents of BA intervention. Section 4.6 presents a summary of this chapter.

4.2 Development of BA protocol

4.2.1 Treatment mechanism of BA

The mechanism of BA in this study was adopted from the BA's Model of Treatment by O'Donohue and Fisher (2012) (shown in Figure 8). By providing BA techniques, for example, activity scheduling and monitoring, self-monitoring of activities and mood, problem-solving, social skill training, and hierarchy construction, new activation behaviors can be motivated directly (depicted as "↑ activation). Some secondary techniques are intended to reduce avoidance and depressed behaviors (depicted as "↓ avoidance and depressed behaviors"), which makes T (treatment) to B (behavior). Meanwhile, some BA techniques, like contingency management, which is a function of changing the environment directly rather than changing the participants' behaviors, can directly provide positive environmental reinforcement for healthy behaviors, and that leads T to R (reinforcement). Lewinsohn (1974) stated that positive reinforcers could be found in a personal environment, but an untrained person might not have the ability to find and keep the positive reinforcers. Therefore, it is critical to provide clients with BA techniques. The changes of environmental reinforcement that result from the provision of BA techniques and the occurrence of behavior activation could break the depressive cycle and produce a healthier cycle in which the positive reinforcement also strengthens activation behaviors, and is represented by an arrow back from R to B. According to BA, the environment will be changed after the occurrence of the initial changes in behaviors, which is B to R. For example, if one person stopped socializing because of the avoidance, this will, in turn, increase depressed mood and reduce behavior even further. As positive reinforcement can improve the mood in participants, there is an arrow from R to M (mood). The reinforcement and mood are grouped in a larger box indicate that reinforcement and mood can be covaried together. As a result of the change in contingencies, the mood reacts when reinforcement occurs (J.W. Kanter et al., 2009; Lewinsohn, 1974), which means people feel bad when reinforcers lost. The level of depressive symptoms (D) could finally be reduced by this cycle over time. Therefore, BA aims to help clients contact stable, varied, and personally meaningful positive reinforcement. The improved positive reinforcement should finally decrease depressive symptoms and create a meaningful, purposive, and valuable life.

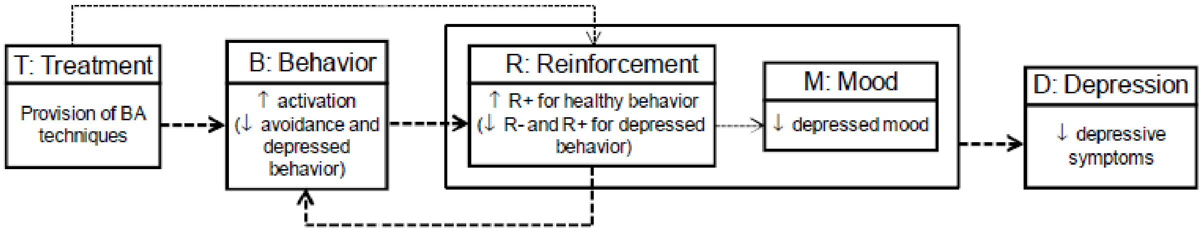


Figure 8. Treatment model of Behavioral Activation

4.2.2 The 10 core principles of BA

The reviewed BA literature consistently focused on getting participants to be active and engage in the lives of their own. This kind of treatment focuses on what areas of change are likely to improve participants' moods, and then repeatedly and persistently to make changes that modify their behavior and improve their physical and psychological health. Table 3 describes the ten principles to guide BA interventionists when they conduct BA with their clients. The ten principles also guided us in developing the BA intervention in this proposed study.

Table 3. The 10 core principles of Behavioral Activation

Principle 1	The key to changing how people feel is helping them change what they do.
Principle 2	Changes in life can lead to depression, and short-term coping strategies may keep people stuck over time
Principle 3	The clues to figuring out what will be antidepressant for a particular client lie in what precedes and follows the client important behavior.
Principle 4	Structure and schedule activities that follow a plan, not a mood.
Principle 5	Change will be easier when starting small.
Principle 6	Emphasize activities that are naturally reinforcing.
Principle 7	Act as a coach.
Principle 8	Emphasize a problem-solving empirical approach, and recognize that all results are useful.
Principle 9	Don't just talk, do!
Principle 10	Troubleshoot possible and actual barriers to activation.

From Behavioral Activation for Depression: A Clinician's Guide by Christopher r. Martell, Sona Dimidjian, and Ruth Herman-Dunn. Copyright 2010 by the Guilford Press.

Principle 1 is "The key to changing what people feel is helping them change what they do". Usually, people will act when their inner feeling tells them to do so. A woman will go to a movie on the weekend because she feels like it; she will also go climbing a mountain because she feels adventurous. It can be regarded as acting from the "inside out", since the motivation for engaging in these activities originates from inside. Family caregivers of PWD usually have a minimal choice in their daily routines because they need to undertake caregiving tasks. Therefore, they will be less motivated to do other leisure activities. However, when they experience a sense of accomplishment and interest after doing a particular kind of activity, they will continue to do that. This action is regarded as acting from the “outside-in”: engaging in an activity because of the feelings (Markowitz, 2003). *In this BA protocol, participants will be guided to choose activities that make them feel pleasant and rewarded and to continue engaging in those kinds of activities.*

Principle 2 and Principle 3 focus on explaining the causes of depression and the procedures for combating depression. *However, this research project is not only focused on reducing depression among family caregivers of PWD. These two principles can be modified to explore the causes of depression and sleep disturbance.* The BA acknowledges that family interaction may increase vulnerability to psychological burdens. Life events such as taking care of a family member with dementia may lead to a decrease in positive reinforcement and result in withdrawal from normal activities. If an individual stops doing pleasant and rewarding activities because of the major life change, it will be easy for him or her to get caught in a continual cycle of feeling down, getting away from one’s world and doing less, and as a consequence, feeling more down (Jacobson, Martell, & Dimidjian, 2001). *In this study, the interventionists need to help participants to carefully examine what kind of adaptable behaviors are associated with psychological distress and what happens before and after such behavior occurs. After that, interventionists should use activity monitoring charts to understand participants’ behavior and the connections between their behavior and mood. In the early sessions of BA, interventionists should present the concepts of why changes in life can lead to psychological distress and how to cope with the changes and distress.*

Principle 4 stresses that a core part of BA is to begin to act, even when motivation is low, rather than waiting for a mood to motivate the participant. Some forms of activity structuring and scheduling will be applied to support participants to act from “outside-in.” Activity structuring and scheduling are the backbones of BA, and all other strategies are stick to these essential basics. However, many participants may take on too much and too soon when they start activity structuring and scheduling. *According to Principle 5, the interventionists in the BA intervention should help participants to break down a behavior into small elements; things can be easily changed by a stepwise approach.*

Principle 6 emphasizes that the ultimate aim of BA is to help participants engage in life so that it increases the likelihood that pleasurable and rewarding behaviors will be reinforced naturally by the world around them. For example, a person who has avoided social contact when taking care of a family member with dementia could begin to practice re-engaging in conversation with neighbors. When this person feels pleasant and expresses interest in communication, he or she will continue the conversation. This kind of behavior is a natural re-enforcer that links to the immediate environmental reward. *However, BA interventionists should inform participants that not all behaviors will be reinforced immediately; therefore, participants should have mental preparation not to give up halfway. In this study, participants need to be asked to complete an activity recording form when they are back home and discuss the feelings and problems of doing pleasant leisure activity during the last four sessions.*

The BA interventionist should act as a coach (Principle 7). The BA interventionists’ job is to help participants to solve problems and encourage them to take actions that connect with rewards. A good BA therapist maintains a coaching position and supports the clients to become more confident about their games. *Therefore, to make participants become actively involved in each session, every session should include a discussion of the previous session’s homework as well as the assignment of new homework for the following session.* Principle 9 also emphasizes the importance of the homework. The task in homework should be realistic. The interventionists should discuss the plan of implementation with participants, the more detailed and specific the plan, the better.

When implementing BA, participants may face a lot of challenges and barriers. The effect therapy should develop, evaluate, and try out possible solutions. Therefore, BA intervention requires a continuous problem-solving approach from the interventionists (Principle 8). *While participants may be discouraged when they do not feel better, interventionists need to remain hopeful and positive. The interventionists in this study should keep intervention moving forward and cause participants to be hopeful about making changes in their lives (Principle 10).* Although it would be a great achievement to motivate all participants to complete their homework, and fully engage in the therapy, there is no magic formula for each participant. BA, like other therapies, requires persistence and creativity on the part of the interventionist and the participant.

4.2.3 BA manuals for reference

There are a few manuals that have adopted the BA concept and have been used in family caregivers of PWD. We referred to these manuals to develop BA protocols in this proposed study. The commonly used BA approaches were usually developed and revised based on the Brief BATD (C. W. Lejuez et al., 2001), the revised version of Behavioral Activation Program (BATD-R) (C. Lejuez et al., 2011), and the selected sessions of Coping with Caregiving (CWC) (Gallagher-Thompson et al., 2002). Therefore, our study was developed by referring to these manuals. The main contents of these three manuals are discussed below.

(1) BATD

In BATD (C. W. Lejuez et al., 2001), the first three sessions include an explanation of the treatment rationale, attaining environment support, and activity and goal session. Following the introduction of the treatment rationale, session four guides participants to collect the baseline activity level and depressive symptom severity. In session five, patients are directed toward the identification of contextual factors that may influence the occurrence of depressed behaviors, and they select and place activities that they have identified to be re-enforcers for depressed and non-depressed behaviors. After that, participants receive weekly assessment, planning, and adjustment for selected activities in the six sessions. Finally, participants are encouraged to keep doing selected activities for the next four to six weeks.

(2) BATD-R

BATD-R (C. Lejuez et al., 2011) focuses more on activity scheduling. It provides treatment in five unique sessions including discussion of depression, introduction to treatment rationale and daily monitoring in session one; identification of complete life areas, values, and activities in session two; selection and ranking of activities in session three; plan of daily monitoring in session four; introduction of contracts (for obtaining help to support activities) in session five. In the last five sessions, the participants are guided to review the concept and plan termination/post-treatment. Interventionists guide participants to review former skills in each session.

(3) CWC

CWC (Gallagher-Thompson et al., 2002) included ten sessions. The first five sessions introduce Action (a situation that causes me frustration), Belief (thoughts/beliefs about the situation that are making me upset), Consequences (feelings about the situation that are making me upset) model. The last five sessions are about BA focusing on PES, and the first session is about the introduction to pleasant events and mood monitoring; the second session helps participants to identify potential pleasant activities that affect everyday mood and learn to monitor the activities daily in order to improve feelings of well-being; the third session helps participants to understand and overcome personal barriers to increasing everyday pleasant activities; the fourth session teaches them how to increase everyday pleasant activities; and the last session reviews all the major skills that have been taught in the treatment. Also, interventionists will guide participants to review former skills in each session.

Even though all three manuals are well designed and have been applied in many projects, none of them is suitable for this proposed study. BATD and BATD-R focused too much on depression, but this proposed study is aimed at improving sleep quality. The target population of BATD and BATD-R are not family caregivers of PWD. CWC is specific for family caregivers of PWD; however, this manual, which includes BA, also introduces other aspects of coping with caregiving. Therefore, to maintain the integrity of the CWC manual, we cannot simply extract certain BA sections. The development of this BA intervention protocol needs to be based on the key elements of these widely used and well-organized manuals.

All of the three manuals begin by introducing the rationale for the BA protocol. The introduction of the rationale helps participants to understand the entire treatment. All the manuals help participants to identify and arrange activities that make them feel fulfilled and pleasant. The identification of potential support and barriers to doing selected activities also plays a critical role in the treatment. All three manuals provide daily logs to help participants to keep doing activities in their daily lives. Therefore, we can develop the BA by referring to these standard components. The next two sessions present and discuss the dosage and key elements that are included in the BA protocol of this study.

4.2.4 Dosage of treatment

The number of sessions varies across studies, and the entire manual suggests participants receive treatment every week. However, Lejuez also explained that the number of sessions could be modified to include fewer sessions when needed (C. Lejuez et al., 2011). Because some BA interventions have shown the depression level could significantly be reduced from six to eight sessions (Daughters et al., 2008; MacPherson et al., 2010), and one study even showed some benefits of BATD-R with a single session (Gawrysiak, Nicholas, & Hopko, 2009). Although the research protocol usually requires a certain number of sessions, BA can be used flexibly in clinical settings depending on the characteristics of participants and settings.

From the literature review, it was found that the number of sessions ranged from 5-20 weeks. Each session ranged from 15 minutes to 90 minutes. All of the included studies except Prick et al. (2015) significantly reduced depression in family caregivers of PWD. Previous meta-analyses have also shown that interventions of longer duration have had a greater effect in reducing psychological distress (M. Pinquart et al., 2006). Therefore, the duration of BA intervention is critical for the experimental design.

Family caregivers of PWD are busy at caring for their family members, and they may not have enough time to participate in studies even though these may be a benefit for their physical and psychological health. Therefore, to increase the adherence rate of participants, the number of sessions, and duration of the whole treatment was adjusted in a reasonable range. The number of sessions that provide treatments ranges from four to six across the three manuals, and the number of sessions that designed for continuing and maintaining BA progress ranges from one to five sessions (Gallagher-Thompson et al., 2002; C. Lejuez et al., 2011; C. W. Lejuez et al., 2001). However, the BA protocol for this study is not focused on depression in family caregivers of PWD. Therefore, some sessions that are related to depression in BATD and BATD-R were cut off. R. C. Moore et al. (2013) and A Au et al. (2015) have reported that the BA intervention can be provided in four sessions. Therefore, the sessions for treatment could be arranged as four. Meanwhile, the sessions to continue and maintain BA is also critical in the whole treatment, and two sessions for review have been reported to be effective in R. C. Moore et al. (2013)’s study. To have a better effect of BA and keep a high adherence rate of participants, four sessions for review and continue BA were chosen.

The duration of each session is also critical in the protocol design. Lejuez has suggested that the treatment sessions should take as long as one hour, and the duration for the following sessions should range from 15 to 30 minutes (C. W. Lejuez et al., 2001). The last four sessions cand be conducted by phone because R. C. Moore et al. (2013) and A Au et al. (2015) have already applied telephone-based interventions in their studies, and these have been reported to be effective in reducing depression in family caregivers of PWD. The telephone-based intervention has been demonstrated to enhance the physical and mental health of family caregivers of PWD (Steffen, 2000; Tremont, Duncan Davis, Bishop, & Fortinsky, 2008; Winter & Gitlin, 2007). Family caregivers would be overscheduled to participate in prolonged intervention periods, which can make it difficult for them to leave their homes to seek support through traditional face-to-face intervention. Consideration is made to develop the protocol with telephone-based support to overcome the obstacles to obtaining support from caregivers.

There will be eight sessions in this research project, including four main treatment sessions and four reviews and continued BA sessions, and participants will receive sessions every week. Each session for the first four sessions will last for about one hour face-to-face in a group, and for the last four sessions by telephone will last for about 15 to 30 minutes.

4.2.5 Key elements of eight sessions in the proposed BA

The review of the literature revealed that family caregivers of PWD found it burdensome to take care of their family members with dementia, and they had very little leisure time over after undertaking caregiving tasks (von Kanel et al., 2014). Therefore, it is recommended that the proposed non-pharmacological intervention should not increase the burden on family caregivers or let them be exposed to the side- effects associated with the intervention. In other words, the BA techniques applied in this study should be associated with the lowering of costs and harm.

The development of the BA manual is based on theories, principles, and commonly used BA approaches. As discussed before, firstly, the introduction of the BA and the rationale for intervention is critical for the whole intervention; secondly, interventionists should act as coaches to help participants to select, revise and plan activities; thirdly, barriers to intervention need to be identified, and solutions that could help participants better comply with the BA need to be found; fourthly, homework should be reviewed in each session; fifthly, the BA intervention needs to be continued after the main classes. The main topics and key contents of each session are presented in Table 4.

Table 4. Session orders and contents of the proposed BA manual in this study

Session no.	Session title	Summary contents	Homework	Related principles	Related manuals
1	Introduction of BA	(1) Overview of BA; (2) Recognizing common signs of depression; (3) Understanding mood; (4) How life events affect your mood.	Find at least one event you do this week that make you feel better	Principle 1, Principle 2, Principle 5,	BATD: Unit 1: Introduction; Unit 2: Recognizing depression; Unit 3: The rationale for the BATD. BATD-R: Session 1: Discussion of depression; introduction to daily monitoring; CWC: Class 6: Introduction to Pleasant Events and Mood Monitoring
2	Identification of potential pleasant events and monitor them daily	(1) Review: BA, depression, and mood (2) Thinking most important life areas, values , and activities of your life; (3) Identifying potential pleasant activities that affect mood;	Complete daily pleasant activity log	Principle 3	BATD: Unit 3: The rationale for the BATD; Unit 4: Preparing for treatment; Unit 5: Getting started. BATD-R: Session 2: Complete life areas, values, and activities inventory; Session 3: Activity selection and ranking. CWC: Class 7: Identifying potential pleasant events and activities that affect everyday mood and

		(4) Selecting and ranking activities that make you feel fulfill and pleasant.			learning to monitor them daily in order to improve feelings of well-being
3	Understanding and overcoming personal barriers	(1) Review: Pleasant activities (2) Findings obstacles when doing activities you chose; (3) Creating a healthy environment; (4) Problem-solving to overcome barriers, and to accomplishing goals	Complete activity difficulty assessment Complete daily pleasant activity log	Principle 8, Principle 10	BATD: Unit 6: Charting progress; Unit 4: Preparing for treatment. CWC: Class 8: Understanding and overcoming personal barriers to increasing everyday pleasant events and activities.
4	Reinforcing and modifying the pleasant events	(1) Review: Barriers (2) Modifying previous goals; (3) Identifying new goals	Complete revised daily pleasant activity log	Principle 4, Principle 6,	BATD: Unit 6: Charting progress, rewarding progress. BATD-R: Session 4: Daily monitoring with activity planning; Session 5: Daily monitoring with activity planning for the upcoming week. CWC: Class 9: Practicing how to increase everyday pleasant events and activities (including some with the

					demented relative). begin review of skills taught in the class
5-8	Continuing BA and maintaining progress	(1) Planning long-term continued BA; (2) Problem-solving	Complete daily pleasant activity log	Principle 7, Principle 9	BATD-R: Session 6-10: Daily monitoring with activity planning: review assignment; Daily monitoring with activity planning for the upcoming week.

4.3 Results of pre-intervention qualitative interviews

Before the implementation of the protocol in family caregivers of PWD in community, semi-structured interviews were conducted.

4.3.1 Demographics of family caregivers

A total of 20 family caregivers (5 males and 15 females) agreed to participate in the interviews. The demographic characteristics of the informants are shown in Table 5. Most caregivers were retired, and the mean age of caregivers was 55.6±12.7. These caregivers had different relationships with persons with dementia, including wives, husbands, daughters, sons, and daughter-in-law. The mean duration of caring for PWD was 4.4±4.0 years. The mean age for the PWD was living at home and cared for by their family caregivers.

Table 5. Characteristics of family caregivers and PWD

Participant no.	Gender	Occupation	Caregiver age (year)	Patient's age (year)	Years of caring for the PWD	Relation with the PWD	Diagnosis of PWD
1	Female	Retired	68	95	16	Daughter	Alzheimer
2	Male	Retired	63	61	2	Husband	Vascular dementia
3	Male	Unemployed	48	73	3	Son	Alzheimer
4	Female	Retired	60	90	5	Daughter	Alzheimer
5	Female	Retired	80	82	6	Wife	Alzheimer
6	Female	Doctor	45	71	2	Daughter	Alzheimer
7	Male	Enterprise staff	53	82	8	Son	Alzheimer
8	Female	Retired	62	85	2	Daughter	Alzheimer
9	Female	Nurse	54	87	4	Daughter	Alzheimer
10	Male	Bus driver	42	64	0.5	Son	Vascular dementia
11	Female	Enterprise staff	34	59	0.5	Daughter	Vascular dementia
12	Male	Businessman	58	89	6	Son	Alzheimer
13	Female	Housewife	83	85	13	Wife	Alzheimer
14	Female	Doctor	45	70	1.5	Daughter	Alzheimer
15	Female	Retired	55	55	3	Wife	Vascular dementia
16	Female	Builder	44	47	1	Wife	Cerebral traumatic dementia
17	Female	Retired	55	56	2	Wife	Alzheimer
18	Female	Retired	75	75	5	Wife	Alzheimer
19	Female	Doctor	52	80	3	Daughter in law	Alzheimer
20	Female	Retired	56	87	5	Daughter	Alzheimer

Categories were derived from the data, which reflected the perceptions of leisure activities in family dementia caregivers. Four main themes and eleven sub-themes were extracted from the data analysis (Table 6). The critical aspects of this qualitative study were reported, according to COREQ (**Appendix I**).

Table 6. The overall theme and subthemes that emerged from the post-intervention semi-structured interviews

Themes	Subthemes
1. The condition of leisure life	Without self
	Loss of leisure time
	Simple leisure activities
2. Needs for leisure activities	Adjust negative feelings
	Keep personal life
3. Why don't family caregivers do leisure activities?	Accepting destiny and losing the impetus to make the changes
	Feeling guilty for sparing time in leisure activities
	Lack of instructions and social support
4. What can be done to pursuit leisure activities?	The presence of family support
	Having good relationships with friends
	Doing exercise together with PWD

4.3.2 Themes and sub-themes

4.3.2.1 Theme one: The condition of leisure life

In response to open-ended questions regarding daily life when taking care of patients, family dementia caregivers spontaneously talked about their leisure lives. Three sub-themes were identified to explain the condition of leisure life among Chinese family dementia caregivers, and they were "without self," "loss of leisure time," and "simple leisure activities."

***Without self*:** In general, family caregivers experienced a significant modification of their lives in caring PWD. *"Without self"* emerged as a common situation after caregiving tasks onset. Many family caregivers described their lives as being centered on the PWD.

> *"My life is completely here with her." (P. 2)*
>
> *"Anyway, we are together for 24 hours every day." (P.17)*

Meanwhile, most of the family dementia caregivers considered their lives as lack of personal freedom. Because of the characteristics of dementia, family caregivers could not leave PWD alone, which limited the scope of their activities.

> *"My life is not that free now. Before he became sick, I could go anywhere I wanted, but after he got sick, I stopped having time to go out, and I cannot leave him alone." (P.17)*
>
> *"Absolutely, definitely, I cannot [go outside], and I haven't left Shijiazhuang for five years." (P.12)*

***Loss of leisure time*:** Family caregivers had to sideline or interrupt their own leisure lives to take care of their relatives with dementia. "Don't have (leisure) time" was the most frequently used phrase among the family caregivers. Therefore, their leisure time was generally reduced after they started to take up the caregiving role.

"Basically, I don't have any leisure time. When my father was still okay, I could go out to play the mah-jong [tile-based game that was developed by Chinese in Qing Dynasty] with my friends. But since my father became seriously ill, he could not take care of himself, not to mention take care of my mother. So I didn't go out, and even when I went out to buy food, I still worried my father would have a fall." (P.12)

"I don't have time for myself [to do leisure activities]." (P. 4)

Many family caregivers participated in leisure activities before taking care of their patients, but after their loved ones become sick, their leisure time could no longer be the same as before.

"In the past, my husband and I could travel, go out for fun, and go to parties, but now, I can hardly go anywhere without him." (P.15)

"*I could do whatever I wanted before he became sick, but after he got sick, I couldn't do anything. My life revolves around him." (P.5)*

Some individuals with dementia still could exercise, but they had already lost their memory and become easily confused. Therefore, family dementia caregivers need to sacrifice more personal time to care for their relatives, compared to family caregivers of other diseases (e.g., cancer, stroke, diabetes).

"Can you imagine? I have to take the bus with my father every day because he likes to go outside and travel by bus before he becomes ill. My sister and I have to take a bus with him in the morning, afternoon, and even evening, otherwise he becomes very upset."(P.8)

Simple leisure activities**:** Because of the limitation of family caregivers' leisure time, most of them chose to do some simple and time-saving leisure activities at home. Watching television was the most reported leisure activity among the informants.

"After I finish my housework, I watch TV, just watch TV." (P.1)

"…. there's nothing I can do but watch TV." (P.13)

With the advancement of technology, electronic products gradually integrated into people's lives. Some family caregivers also chose to play with their mobile phones or tablet devices when they were free at home.

"When I finish my housework, I use my phone to read novels and surf the Internet. Mobile phones are now more common than TV, and you can just lie on the sofa or bed and play with your phone." (P.20)

"*I also play with my iPad when I am free. I will watch TV if there are any good programs on, but if the shows are not good, I will play on the iPad." (P.5)*

4.3.2.2 Theme two: Needs for leisure activities

Adjust negative feelings: Family dementia caregivers expressed that they need leisure activities. It seemed that they understand the benefits of leisure activities. Some family dementia caregivers shared their experiences and feelings about doing leisure activities.

"Sometimes, I really need these kinds of activities [leisure activities] to adjust my negative feelings." (P.14)

"I feel a bit tired if I haven't walked for a week. Walking makes me feel energetic." (P.7)

"*I don't feel tired 'in my heart' after I play cards with others. I'm very happy when I'm playing cards." (P.17)*

***Keep personal life*:** Some family caregivers thought of their personal lives, they wish to plan for the future. They imagined what would happen in the future and wondered how they devoted their time to their activities.

"… I can't totally devote myself to caregiving. In the future, I will still have my own life to live. I need to think about my future, too." (P.12)

4.3.2.3 Theme three: Why don't they do leisure activities?

Some family dementia caregivers expressed that they did not do leisure activities for many good reasons. This theme concludes these reasons: "Accepting destiny and losing the impetus to make changes," "feeling of guilty for sparing time in leisure activities," and "lack of instructions and social support."

***Accepting destiny and losing the impetus to make changes*:** As the time of caregiving increased, many family caregivers gradually became accustomed to taking care of the PWD, and they did not wish to change their current status.

> "*I feel that nothing I do is 'interesting', and it's better for me to stay at home. Two hours is not enough for me to go out and enjoy a family party, and I gradually lose my mood to do so." (P.3)*

The term *"accept destiny"* further explained why family caregivers did not want to make any changes to their current status.

> *"What else can I do? This is my life. This is my destiny [to contribute myself to caregiving]. What else can I do?" (P.13)*

Although some family caregivers thought about doing leisure activities, they did not dare to do so.

> *"I can only look at those old men, and old women perform square dancing; I did not dare to think about it." (P.8)*

Feeling guilty for sparing time in leisure activities: Furthermore, family caregivers experienced misunderstanding concerning their situations. Some of them considered doing leisure activities as irresponsible behavior towards their PWD, and some even felt guilty after doing leisure activities.

> *"Yeah, I feel guilty if I do something I like because I think I haven't taken good care of my mother, and I haven't done 'my job' properly." (P.9)*

Chinese family caregivers were restricted by the traditional Chinese belief, which prevents them from participating in leisure activities. When the interviewer asked the adult child caregivers whether they would feel more relaxed if they engaged in leisure activities, one of them replied as follows.

> *"No! No! On the contrary, I would feel a bit guilty. I would ask myself: Why am I not taking time to care for my parents during this period? I'm an unfilial son." (P.10)*

Lack of instruction and social support**:** Although some family caregivers realized that they could benefit from leisure activities and they were willing to participate in these activities, not all of them understood how to work out a time for leisure activities. Lack of instructions from professionals impedes their pursuits of doing leisure activities.

> *"I understand everything, and I know the truth; however, I don't know what I can do and how I can change." (P.3)*
>
> "*The problem is that, while I know I should change, it's difficult for me, and I need help." (P.14)*

Social support for family dementia caregivers was not enough, so they had to sacrifice most of their leisure time to take care of their PWD.

> *"Is there any way for us [to increase our leisure time]? No way. No way. Unless I make him stay in a hospital, but even then, I still have to accompany him. I don't know what to do." (P.13)*
>
> *"I cannot get any support from my community, and I even don't have enough time to take care of my husband, let alone leisure activities." (P.15)*

4.3.2.4 Theme four: What can be done to pursue leisure activities?

Some phenomena were described by the informants as the situation where they could enjoy leisure activities: the presence of family support, having good relationships with friends, and doing exercise together with PWD.

The presence of family support: Family support was a core element in supporting family caregivers to participate in leisure activities. Some family members took turns to take care of the PWD, and this shared the caregiving burden between family caregivers and other family members.

> *"I have a very good relationship with my sister. We take turns to take care of our father: each of us takes care of him for one whole week. When my sister is taking care of our father, I can spare time to do some leisure activities. Support from other family members is very important to me." (P.8)*

However, not all family caregivers were lucky enough to have strong family support. Some family caregivers expressed their needs for family support, but their family members seemed not to understand their needs and did not offer help. Under this circumstance, these family caregivers would feel deeper helpless and hopeless.

> *"I understand that my son doesn't have time to help me, as he needs to work. But when he is free, he still can't understand how tired I am. I feel better when he helps me with the housework, but he still hasn't grown up (mind mature)……Sometimes I feel it's really boring to be alive." [cries] (P.15)*

Communication was essential in seeking assistance from other family members. Family caregivers might miss possible support and help if they did not know how to share their burden with others.

> *"My brother and sister still haven't retired, so I have to take care of my father most of the time. Sometimes I really feel very tired and helpless, and my in-laws cannot give me a hand to take care of our grandchild, even when they know I am busy. I really want them to give me hand, but I don't know how to tell them my difficulties." (P.8)*

***Having good relationships with friends*:** The strength of friendship should not be neglected in family caregivers' engagement in leisure activities. Regular gathering with friends motivated family caregivers to participate in leisure activities, even though sometimes they did not intend to relieve psychological stress through these activities.

> *"We usually don't go for a gathering because we are in a bad mood, it's not like that……usually me and my friends have gathering regularly." (P.9)*
>
> *"Whether I'm happy or not, I go to play mah-jong with my friends when they are missing one player." (P.1)*

Family caregivers indeed release pressure through getting together with friends. Meanwhile, developing powerful, supportive, and active friendships is critical in encouraging family caregivers to participate in leisure activities.

> *"I have many friends. If I say 'let's go for singing,' they will say 'yes.' If I say 'let's go for playing cards,' they will say 'let's go!'. Even though I still need to face those difficulties, my mood is different [be more positive]." (P.11)*

Doing exercise together with PWD: However, some family caregivers did not do leisure activities for their benefits. They chose to participate in leisure activities together with the PWD, to train PWD's physical and mental functions.

> *"I always take him out to exercise together. We walk down from the fourth floor to the first floor. We usually walk in the public area of our district for four rounds: two rounds in the morning and two rounds in the afternoon……I know he has to exercise, otherwise, he will get worse" (P.11)*
>
> *"We also play mah-jong together when it rains. Even though he plays very slowly now, playing mah-jong can train his reaction functions. (P.13)*

Even though some family caregivers chose to do leisure activities for training PWD, they could still experience a sense of achievement, happiness, and relaxation during this process.

> *"I still feel happy and relax when playing [mah-jong] with him; some of his reactions were really funny." (P.13)*
>
> *"Sometimes, we will read newspapers together with our father, and we will let him read out those words. When he can read them correctly, we will be very happy." (P.9)*

4.3.3 Discussion of the pre-intervention semi-structured interviews

4.3.3.1 Family caregivers did not reserve enough time for leisure activities

From the interviews before the intervention, it was noted that Chinese family dementia caregivers did not reserve enough time for themselves to participate in leisure activities. Although they knew the benefits of doing leisure activities, inadequate impetus, and support impeded their pursuit of these activities. Many family dementia caregivers described their lives as "patient-centered" lives. Individuals with dementia are different from individuals with cancer, stroke complications, or diabetes. PWD need caregivers' assistance to perform self-care and daily activities (walking, eating, bladder control). On some occasions, caregivers had to deal with PWD's behavior due to hallucinations, memory loss, and confusion (Etters, Goodall, & Harrison, 2008). However, family caregivers of individuals with cancer, stroke complications, or diabetes do not need to deal with such behavioral symptoms. Because of the characteristics of dementia, family caregivers cannot leave PWD unsupervised; otherwise, PWD will be in danger of getting lost or hurt (Rowe et al., 2011). Also, many PWD still maintains their capacity for exercise after the onset of dementia. The example of "taking buses with patients" further explained why the leisure time of dementia caregivers decreased sharply. Family dementia caregivers experienced higher psychological distress than other caregivers under this circumstance.

4.3.3.2 Address leisure activities to family caregivers

As expressed by many family caregivers in the interviews, doing leisure activities could alleviate caregivers' negative feelings on providing care and allowed caregivers to maintain their own lives. Many quantitative studies also showed that increasing the frequency of leisure activities was beneficial for both psychological and physical health of family dementia caregivers (Chattillion et al., 2013; Chattillion et al., 2012; A Hirano, H Umegaki, Y Suzuki, T Hayashi, & M Kuzuya, 2016; B. T. Mausbach et al., 2012). Furthermore, family caregivers expressed their needs for leisure activities in this study. However, some of them indicated that they were not aware of how to increase their leisure activities in their current circumstances in which they experienced a huge caregiving workload. Besides, they had no idea of finding support and guidance from society. Therefore, health professionals should work with caregivers, as well as their family members and friends, and discuss the best ways to cope with the situations. Strategies to help family dementia caregivers could be individualized, as we noted that different family dementia caregivers had different resources and challenges. Simply highlighting the importance of maintaining a balance between caregiving and leisure time may not be good enough to resolve the problems because caregivers are facing individualized challenges. BA, which allows caregivers to choose activities in their leisure time freely, could provide a good solution to balance caregiving and leisure activities.

4.3.3.3 "Filial piety" and 'fatalistic voluntarism' stops family caregivers from doing leisure activities

Traditional Chinese culture also contributes to the hesitation of Chinese family dementia caregivers to engage in leisure activities. This study verified that a strong sense of responsibility and filial commitment had been exerting a far-reaching influence on the implementation of leisure activities among Chinese family caregivers. Filial piety influences children’s loyalty, obedience, respect, and physical care of their parents (Lai, 2010). For the sake of maintaining family harmony and reaching the demand for internal supports within the family, children and spouses are obliged to sacrifice themselves (including their own time and energy). Yeung et al. (2015) indicated that Chinese-American family caregivers paid particular attention to filial piety, which required Chinese families to take significant responsibility when taking care of other family members. Meanwhile, this sense of obligation or reciprocity might put some Asian caregivers at risk of caregiver burden, stress, and depression (D. S. Wang, 2012). It may not be correct to take filial piety or obligations for granted.

Being too devoted to caregiving tasks seemed to prevent family caregivers from participating in leisure activities. Many family caregivers gradually compromised with their current situation and had no idea about how to change. Some informants believed in fate, which was to care for their patients and forgo any personal leisure time. This condition could be described as fatalism, a belief system involving fate (‘Ming’ in Chinese), which helped people to adapt to the reality of caregiving (Yen, Huang, Ma, Lee, & Lee, 2009). 'Fatalistic voluntarism' is one of the major concepts in Chinese culture and represents a unique coping strategy among Chinese family caregivers (H. Y. Chan, 2008). This finding is also consistent with another study that explored the responsibility and burden from the perspective of seniors’ family caregivers in China (Zeng et al., 2014). Health professionals and other health professionals should understand the possible influence of culture on caregivers’ decisions and behaviors when they promote the importance of leisure time in family caregivers. For instance, community education programs that improve community caring values and housing policies should provide to family caregivers of PWD. Behavioral activation treatment, which aims to increase positive response-contingent environmental reinforcement and make them reconnected with positive and enjoyable aspects of their lives, could be a useful solution to change family caregivers’ minds.

4.3.3.4 Strategies for promoting leisure activities

1. Family support

This study showed the importance of family support to caregivers in their engagement in leisure activities. Taking turns to take care of PWD enable family caregivers to engage in leisure activities. However, inadequate support from other family members made family caregivers stressed, tired, anxious, and even depressed (North, Holahan, Moos, & Cronkite, 2008). In this study, some family caregivers were found to be unskilful in communicating with others, yet communication is indispensable when seeking help from other family members. Family caregivers should recognize the limits of their endurance and strength (Oregon Department of Human Services (DHS), 2013) and communicate with other family members timely. Siemens and Hazelton (2011) suggested that family caregivers recruited other family members to share the burden of care, inquiring about caregivers' health, and inquiring about patients’ behavioral problems and their adverse physical and psychological effects on the caregiver. Therefore, regular family meetings were needed to make essential decisions for PWD, such as financial or caring plan. Meanwhile, family meetings could also increase family cohesion, and therefore make other family members participate in caregiving tasks gradually.

2. Friends support

Meanwhile, friend support encourages family dementia caregivers to pursue leisure activities. Friend support is the support that caregivers received from non-family members, such as close friends, fellow church members, and co-workers. Wilks and Croom (2008) demonstrated that friends support moderating perceived stress and resilience in family dementia caregivers. Research on friendship relationships suggests friendships are voluntarily developed on life experience, mutual interest, and personal similarities (Taylor, Chatters, Woodward, & Brown, 2013). Therefore, friends provide different forms of support and interactions (e.g., confidant) than do family members. The qualitative study of Lilly, Richards, and Buckwalter (2003) also indicated that friends are critical providers of emotional support and social integration. It is vital for family dementia caregivers to maintain social interactions with friends and peers, and thus alleviate their psychological distress.

3. Exercising PWD

Exercising PWD was one of the motivations for family caregivers to spend time on leisure activities. Some studies also encouraged family dementia caregivers to do leisure activities together with the care recipients to exercise both physical and cognitive functions of the patients (Prick et al., 2015). Health professionals could encourage dementia patients and caregivers to do leisure activities together. Doing leisure activities together could not only increase leisure activities in family caregivers but also exercise the function in patients, representing a win-win solution for both family caregivers and PWD.

4.4 Refinement of BA protocol

Since BA aims to assist clients in possessing the ability to engage in behaviors that they find pleasurable or fulfilled, this qualitative study explored family caregivers' perception of leisure activities. These findings support the revision of BA for family caregivers of PWD.

According to Chinese family caregivers' perception of leisure activities, it is necessary to give them support and guidance to help them increase their leisure activities in their caregiving lives. ***Firstly***, the findings from the interviews before the intervention inspire us to reconsider the influence of culture in caregivers' health. The Family Caregiver Alliance lists ten caregiver's rights, which include protecting individuality and the right of caregivers to make a life for themselves (Family Caregiver Alliance, 2019c). Chinese family caregivers should be educated that keeping personal time and doing leisure activities are not irresponsible and unfilial to their patients; on the contrary, they have the right to retain their personal lives. ***Secondly***, professionals should assist Chinese family caregivers in staying positive and not to jump to negative conclusions without having all the facts about a situation (e.g., accept their fate that they cannot make any change of their caregiving situation). The CWC program addressed that family caregivers should be educated to understand unhelpful ways of thinking when taking care of PWD, and they should not exaggerate their negative qualities and discount positive qualities during caregiving (Stanford Medicine, 2017). ***Thirdly***, examples of leisure activities should accord with the Chinese culture, like playing Mahjong and planting vegetables. In addition, the examples should be realistic and easy to complete; otherwise, family caregivers will not have enough time, energy, and interest to do leisure activities. Additionally, family caregivers could also be advised to do leisure activities with their care recipients to reduce the feelings of guilt as well as to exercise patients' function. Some BA for family caregivers also suggested to implement dyadic interventions for both caregivers and care recipients (Prick et al., 2015; Steffen & Gant, 2016). Meanwhile, according to some clinician's suggestions, the tracking form of pleasant events should not be too difficult and complicated for family caregivers to complete. ***Fourthly***, according to the Chinese family caregiving condition, many family caregivers were not able to get enough support from other family members and communities, so they did not have enough time to go out to participate in group courses. In-home programs are essential and can affect several caregiving outcomes (Kuo et al., 2013), but they also induce some cost of staff travel and individualized services. Therefore, telephone-based BA stands out because its easy accessibility, convenience, and cost-effectiveness, and it has been proved to be efficient in improving psychological health and QoL in family caregivers of PWD in some studies (Alma Au et al., 2019; Steffen & Gant, 2016). ***Fifthly***, the interviewed family caregivers expressed they won't have enough time to complete complicated homework. The homework should be simplified according to the busy schedule of family caregivers. However, daily activity monitoring is necessary for BA (C. Lejuez et al., 2011). Therefore, in the revised BA protocol, participants were asked to record the number of pleasant leisure activities they did each day. ***Sixthly***, to help family caregivers to find support from other family members and friends, and to have more time to do leisure activities, it is critical to teach caregivers some kinds of communications skills. Many researchers also treated communication skills as indispensable contents in BA intervention (A Au et al., 2015; Gonyea et al., 2006; Prick et al., 2015). Therefore, another communication skill session was added to the treatment sessions.

Different from the originally developed BA protocol in Section 4.2. All of the BA sessions in this study were individual telephone-based. Besides, there were five treatment sessions and three continued sessions, since the communication skills are also very critical for family caregivers to increase pleasant leisure activity, and has been added as the main treatment session.

4.5 Revised BA protocol

The BA protocol was revised according to pre-intervention qualitative interviews, clinicians' suggestions, BA intervention protocols, and former BA studies for family caregivers of PWD.

4.5.1 Logistics and processes of the BA

The BA in this study includes an educational approach for teaching relevant content, including changing unhelpful thoughts, PES and mood tracking, effect communication training, caregiving skills training. The BA intervention in this study was individual telephone-based. Participants received courses once per week for eight weeks. The first five courses lasted about 30 to 45 minutes, and the last three courses lasted about 15 to 20 minutes. All sessions followed the treatment manual, and sessions began with a review of learned materials during the last meeting, and the homework was also performed and analyzed. Homework was assigned to all the participants to ensure they have practiced the content delivered in the sessions in their daily lives. Participants' completion of their homework was reviewed at the beginning of the next session.

4.5.2 Contents of the BA

There are in total of eight sessions of the BA intervention. The outline of the program content is described in Table 7. Participants were expected to understand how to stay positive in caregiving and how to balance caregiving and leisure life over the eight sessions. There was six homework in total.

In the first session, we provided an overview of the program, gave basic information about each meeting, provided a basic knowledge of BA, and facilitated role models for family caregivers of BA. At the beginning of the session, to let participants have a general impression of dementia and to make them be better prepared for the possible upcoming conditions of the persons with dementia, the participants were taught about the progression of dementia. Additionally, participants were encouraged to stay positive and to treat leisure activities properly; thus, they were facilitated to be aware of their bill of rights and the unhelpful thoughts of caregiving. Although the interventionist was regarded as the 'expert' facilitator during the intervention process, the participants were also regarded as the 'experts' in their lives. Participants can consider and address their own life problems with the support from the facilitator, as well as other health professionals.

The second session was about communication skills. Firstly, the introduction of communication styles would provide participants a general impression of boundaries of communication and let them think about their communication style. Secondly, participants were asked to practice assertive communication since the assertive style of communication was the most effective method of communicating. Communicating assertively involved standing up for one's rights and expressing thoughts directly and honestly. This way, people do not violate another person's rights. Thirdly, participants were educated on how to communicate with and seek help from other family members. Since inadequate support from other family members made family caregivers stressed, tired, anxious, and even depressed.

The third session started with an introduction of depression and sleep disturbance, which could guide them to identify their current psychological and sleep condition. Participants were asked to recapture those depressed and sleep disturbed situations experienced before. After that, participants were guided to learn how life events affect their mood, which illustrates the way of thinking about depression. Learning this technique and how events affect mood will increase their understanding of the possible effect of depression on their health. Besides, they could be aware that small life events could affect their mood, and thus they should adjust their daily activities. Then, participants were encouraged to increase their pleasant leisure activities in their daily lives. Participants were asked to pay attention to their activities in the next week, and they were asked to record four activities that make them feel good.

The fourth session started with sharing four pleasant activities that participants did last week and the feelings when doing those activities. In this session, the rules of how to identify potential pleasant events in daily lives were introduced. Participants were then encouraged to choose the top ten favorable activities from the pleasant activity list, and they could also choose favorable activities that were not on the list (**Appendix J**). Meanwhile, to make family caregivers do more leisure activities without a feeling of guilt, participants were also encouraged to do leisure activities together with persons with dementia (**Appendix K**). To better communicate with PWD, communication skills with PWD were also provided to the participants. For the homework, participants were asked to fill in the top ten favorable activities list and to try to do some pleasant leisure activities in the next week.

In the fifth session, participants were asked to revise the top ten favorable activities list firstly. The relationship between mood and activities was illustrated to participants secondly, and to make them understand how could they control their mood. Increasing pleasant events is a guaranteed way to improve mood, and it makes the more unpleasant events in caregivers' life easier to handle. The participants were also taught to record their mood daily. Therefore, through the daily tracking, participants would practically understand how daily activities would influence their mood. The homework was given to each participant to record the number of pleasant activities and moods daily.

In the sixth to eighth sessions, participants were asked to share their experience of doing pleasant activities and feeling of filling in the "Daily pleasant events tracking and mood rating form" (**Appendix L**). The tracking forms were shared with the interventionist in each session. Participants were asked to talk about the feeling when doing leisure activities, and their plans to do leisure activities in the next week. The interventionist would provide suggestions to help participants to overcome the barriers when doing leisure activities.

Table 7. Contents in each session of Behavioral Activation Intervention

Session number	Topic	Contents	Related outcomes of semi-structured interviews	Related principles	Related manuals
1	Introduction of BA	1. Introduction of progression of dementia 2. Caregivers' bill of rights 3. Unhelpful thoughts of caregiving 4. Introduction of BA	"Filial piety" and 'fatalistic voluntarism' stops family caregivers from doing leisure activities	Principle 1, Principle 2	BATD: Unit 1: Introduction; Unit 3: The rationale for the BATD. BATD-R: Session 1: Introduction to Treatment rationale. CWC: Class 1: Goals of class, overview of dementia, understanding frustration, bill of rights, and practicing how to relax.
2	Understanding Various Types of Communication	1. Introduction of communication styles 2. Practicing assertive communication 3. How to communicate with, and seek help from other family members	Family and friends support	Principle 8	CWC: Class 5: Understanding various types of communication

3	Depression, sleep and life events	1. Introduction of depression and sleep 2. How life events affect mood 3. Increase pleasant leisure activities in daily lives Homework: Paying attention to daily activities in the next week, and recording four pleasant activities		Principle 2, Principle 3	BATD: Unit 2: Recognizing depression; Unit 4: Preparing for treatment; Unit 6: Charting progress. BATD-R: Session 1: Discussion of depression; Introduction to daily monitoring; Session 2: Complete life areas, values, and activities inventory. CWC: Class 7: Identifying potential pleasant events and activities that affect everyday mood and learning to monitor them daily in order to improve feelings of well-being.
4	Identification of potential pleasant leisure actvities	Review: Sharing four pleasant activities and feelings when doing activities 1. Rules of identifying potential pleasant events in daily lives	Exercising PWD; Examples of leisure activities should	Principle 4, Principle 5, Principle 7,	BATD: Unit 6: Charting progress, rewarding progress. BATD-R: Session 3: Activity selection and ranking.

		2. Fill in top ten favorable activities list 3. Fill in top five favorable activities doing with patients list 4. Communication skills with PWD Homework: Doing some pleasant leisure activities and revising favorable activity list	accord with the Chinese culture		CWC: Class 7: Identifying potential pleasant events and activities that affect everyday mood and learning to monitor them daily in order to improve feelings of well-being.
5	Pleasant leisure activities and mood	Review: Revising favorable activity lists 1. The relationship between mood and activities 2. Daily pleasant events tracking and mood rating form Homework: Doing pleasant leisure activities daily and filling in daily pleasant events tracking and mood rating form		Principle 4, Principle 5, Principle 6, Principle 7	BATD-R: Session 4: Daily monitoring with activity planning; Session 5: Daily monitoring with activity planning for the upcoming week. CWC: Class 7: Identifying potential pleasant events and activities that affect everyday mood and learning to monitor them daily in order to improve feelings of well-being;

					Class 9: Practicing how to increase everyday pleasant events and activities (including some with the demented relative). begin review of skills taught in the class
6	Continuing BA and maintaining progress	1. Reviewing and discussing daily pleasant events tracking and mood rating form: How enjoyable and important did you find for doing those activities? 2. Problem solving: What difficulties have you met on doing daily pleasant activities? How did you overcome these difficulties.	Simplified tracking forms are more easily for caregivers to complete.	Principle 6, Principle 8, Principle 9, Principle 10	BATD-R: Session 6-10: Daily monitoring with activity planning: review assignment; Daily monitoring with activity planning for the upcoming week. CWC: Class 8: Understanding and overcoming personal barriers to increasing everyday pleasant events and activities.
7	Continuing BA and maintaining progress	1. Reviewing and discussing daily pleasant events tracking and mood rating form: How enjoyable and important did you find for doing those activities? 2. Problem solving: What difficulties have you met on		Principle 6, Principle 8, Principle 9, Principle 10	BATD-R: Session 6-10: Daily monitoring with activity planning: review assignment; Daily monitoring with activity planning for the upcoming week. CWC: Class 8: Understanding and overcoming personal barriers

		doing daily pleasant activities? How did you overcome these difficulties.			to increasing everyday pleasant events and activities.
8	Continuing BA and maintaining progress	1. Reviewing and discussing daily pleasant events tracking and mood rating form: How enjoyable and important did you find for doing those activities? 2. Problem solving: What difficulties have you met on doing daily pleasant activities? How did you overcome these difficulties.		Principle 6, Principle 8, Principle 9, Principle 10	BATD-R: Session 6-10: Daily monitoring with activity planning: review assignment; Daily monitoring with activity planning for the upcoming week. CWC: Class 8: Understanding and overcoming personal barriers to increasing everyday pleasant events and activities.

4.6 Summary of the chapter

This chapter presents the intervention protocol that guides the interventionist to deliver individual telephone-based BA for family caregivers of PWD to improve sleep quality and psychological health. The intervention protocol was developed and refined based on a series of BA theories and principles, BA literature, BA manuals, and findings of a qualitative interview of twenty Chinese family caregivers of PWD.

This BA intervention aimed to help family caregivers of PWD to engage in pleasant and constructive activities and therefore make them reconnected with positive and enjoyable aspects of their caregiving lives. The BA intervention was structured in eight weekly, telephone-based individual sessions for the consecutive eight weeks. The teaching contents included changing unhelpful thoughts, PES and mood tracking, effect communication training, caregiving skills training. All the BA sessions were delivered by a trained research investigator (Ms. Xin Yi XU, Ph. D candidate)

Chapter Five: Feasibility and Acceptability of BA

5.1 Introduction

This chapter presents the feasibility and acceptability of this study in both quantitative and qualitative approaches.

5.2 Feasibility assessments from quantitative analysis aspects

5.2.1 Recruitment capability

In the 3-month recruitment period, 98 family caregivers of PWD were assessed for eligibility, 12 did not meet the inclusion criteria. Among the 12 ineligible family caregivers, seven care recipients did not have physician-diagnosis of dementia, three caregivers did not provide care for more than one hour per day, and two caregivers were paid caregivers. Therefore, the 86 eligible family caregivers were approached to participate in the study. However, a total of 15 family caregivers declined to take part in the study. The reasons were that they did not need the BA intervention (n = 2), or that they did not want to complete the questionnaire (n = 5), or that they did not have time (n = 8). Then 71 out of the 86 eligible patients were randomly selected into intervention and control groups using the random numbers generated from the online randomizer (www.randomiser.org). There were no reported or observed adverse effects (e.g., mortality, severe mental illness, or other medical complications) caused by the interventions over the intervention period.

For the intervention group, 28 of 35 participants (80%) completed the post-intervention outcome assessments. Five of them dropped out due to their time inconvenience to attend the sessions, and two of them refused to complete the post-intervention assessments. For the control group, 31 of 36 participants (86%) completed the post-intervention outcome assessments. Five of them dropped out due to their time inconvenience to attend the post-intervention assessments. Around 17% attrition rate in this study was noticed.

(1) Time taken to complete the entire subject recruitment: three months;

(2) Eligibility rate of the screened patients: 87.76%;

(3) Recruitment rate: 83.72%;

(4) Retention rate: 82.56%;

(5) Attrition rate: 16.90%;

(6) Subjects' reasons for discontinuing the study after participation: Ten of them dropped out due to their time inconvenience to attend the sessions, and two of them refused to complete the post-intervention assessments.

5.2.2 Feasibility of the study questionnaires

There was no missing value in CPSQI, CCSE-D, leisure activity at either baseline (n=71) and post-intervention assessment (n=59). For the C-PAC and C-ZBI, several missing values were identified. For the baseline assessment, three missing values (4.23%) was found in item 9 in C-PAC; two missing values (2.82%) were found in item 15, three missing values (4.23%) were found in item 19, and five missing values (7.04%) was found in item 22 in C-ZBI. For the post-intervention assessment, only three missing values (5.08%) were found in item 22 in C-ZBI.

5.2.3 Acceptability of the intervention

(1) Attendance rate of each session: 35 (100%) in the first session, 35 (100%) in the second session, 33 (94.29%) in the third session, 32 (91.43%) in the fourth session, 32 (91.43%) in the fifth session, 30 (85.71%) in the sixth session, 28 (80.00%) in the seventh session, 28 (80.00%) in the eighth session; the average attendance rate through the whole study was 88.41%.

(2) In the intervention group, the mean length of contact (minutes) for each participant was 132.86 (SD=19.138) (intended was 140 minutes), and the mean number of contacts was 7.54 (SD=0.693) (intended was 8).

5.2.4 Participants' satisfaction with the intervention

25 (89.28%) participants were very satisfied with the BA intervention, 5 (10.72%) participants were satisfied with the intervention.

5.3 Feasibility assessments from qualitative analysis aspects

5.3.1 Characteristics of the participants in the post-intervention semi-structured interviews

The semi-structured interviews were conducted within one month after the family caregivers of PWD completed the BA interventions. Nineteen interviewees from the intervention group participated in the interviews. Table 8 shows the profile of all the participants in the post-intervention interviews.

A majority of the participants were female (n=14). Most of them were middle-aged, and nearly half of them had tertiary education. Only one interviewee had a religious belief (Buddhism), and more than half of them were retired (n=10). Nearly 50% of them had an average household (monthly) income of 5,000-10,000 RMB. More than half of the family caregivers were children (n=14). Most of them provided care for more than five days per week. Besides, more than half of the caregivers appraised their relations with PWDs as good or higher (n=14). The majority of the family caregivers did not smoke (n=16) and drinking (n=11).

Table 8. Characteristics of interviewed participants

Participant no.	Age (year)	Gender	Occupation	Educational level	Religious Belief	Family monthly income (RMB)	Relation with the PWD	Duration of caring for the PWD (months)	Days per week for caring PWD	Hours per day for caring PWD
1	69	Male	Retire	Bachelor	No	<5000	Husband	36	7	24
2	62	Female	Retire	Middle	No	<5000	Daughter	228	7	24
3	60	Female	Retire	Middle	No	5000-10000	Daughter	24	2	24
4	50	Female	Full time	Middle	Buddhism	<5000	Daughter	120	3	5
5	44	Female	Housewife	Bachelor	No	5000-10000	Daughter	15	5	4
6	46	Male	Full time	Middle	No	<5000	Son	86	7	24
7	56	Female	Full time	Bachelor	No	5000-10000	Daughter	24	7	2
8	59	Female	Retire	Bachelor	No	5000-10000	Daughter	180	3.5	24
9	61	Female	Retire	Middle	No	5000-10000	Daughter	180	3.5	24
10	68	Female	Retire	Middle	No	<5000	Wife	8	7	12
11	54	Female	Retire	Bachelor	No	5000-10000	Daughter in law	45	3.5	6
12	40	Male	Full time	Middle	No	5000-10000	Son	9	4	24
13	37	Female	Full time	Bachelor	No	5000-10000	Daughter in law	18	3	8
14	66	Female	Retire	Middle	No	10000-15000	Wife	36	7	24
15	32	Male	Part time	Bachelor	No	10000-15000	Son	6	5	4

16	58	Female	Retire	Middle	No	<5000	Wife	60	7	24
17	55	Female	Retire	Bachelor	No	>15000	Daughter	3	7	18
18	57	Female	Retire	Middle	No	10000-15000	Daughter	18	3.5	24
19	65	Male	Retire	Bachelor	No	10000-15000	Son	18	7	24

5.3.2 Themes and sub-themes

Three themes were identified in the post-intervention interviews describing the participants' experiences of receiving the BA intervention: (1) overall experience of the BA intervention; (2) evaluation of the "Daily pleasant events tracking and mood rating form"; (3) recommendations for BA intervention in the future study. Each main theme included four sub-themes. The main themes and sub-themes generated from the interview data are presented below in Table 9. The important aspects of this qualitative study were reported, according to COREQ (**Appendix M**).

Table 9. The overall theme and subthemes that emerged from the interview

Themes	Subthemes
1. The overall experience of the BA intervention	1. A future development direction for Chinese society 2. A desire to receive BA intervention in the earlier stage 3. This course taught me the things what I wanted to do but did not dare to do before 4. Started to put those views in my heart until I learned this course
2. Evaluation of the "Daily pleasant events tracking and mood rating form."	1. Let me see the good things in life 2. Remind me to adjust negative feelings 3. Difficult to change fixed lifestyle and mood 4. Change this recording mode to a diary
3. Recommendations for the BA intervention in future study	1. Follow-up guidance is necessary 2. More contents should be added 3. Views on changing course format to small lectures 4. Views on changing course format to a video course

5.3.2.1 Theme1: Overall experience of the BA intervention

In response to open-ended questions regarding the overall experience after receiving BA intervention, most family caregivers appraised positively. Four sub-themes were identified to explain the overall experience of the BA intervention among family dementia caregivers who participated in the intervention group. They were “a future development direction for Chinese society,” “a desire to receive BA intervention in the earlier stage,” “this course taught me the things what I wanted to do but did not dare to do before,” and “start to put the points into my heart that I knew before.”

Sub-theme 1. A future development direction for Chinese society

Since the supportive system for dementia in China was still under development, hospitals and communities were lack of psychological counseling and caregiving skill training courses for family caregivers. Most of the interviewees stated that they hadn’t heard or thought about there were courses like BA intervention for family caregivers before.

“I haven’t heard about this kind of course before, or even thought about it.” (P3)

“I didn’t know there were courses for family caregivers before, I just knew there were some courses for patients.” (P6)

“How would I knew such a good course if I hadn’t met you?” (P7)

Many family caregivers thought providing BA courses was a future development direction for Chinese society.

“There will be a lot of people getting older like us. If we don’t have a professional or an organization to guide our children how to do, they will gonna crazy” (P7)

“This is a future development direction, especially for the generations after 80s and 90s, most of them are “the only child.” Like me, I’m already 60 years old, and it will be a big problem for me to care for myself in the future. I have to think about this thing.” (P2)

“This is a big social issue. The “only child” should take care of four elders in their future. You have no choice; it’s really a big burden for you.” (P8)

Sub-theme 2. A desire to receive BA intervention in the earlier stage

Due to the shortage of support in China, family caregivers were lack of caregiving skills as well as self-regulating capacity at the early caregiving stage. Therefore, they suffered a lot in their early caregiving stage. Some family caregivers thought it was a pity that they didn't know this course earlier, and they had a desire to receive BA intervention in their earlier caregiving stage.

> *"My first impression when I knew you were 'How I wish I could meet you earlier'. If I met you earlier, I could avoid the negative feelings like pain, anxiety, and depression that I had before. I could also learn how to love myself, have my own life, take good care of my mother, and also deal with my negative feelings." (P7)*
>
> *"I should know you earlier. It would be better if I had this course when I began to take care of my mother. It's a bit late for me to know you. I was really confused when I began to take care of my mother. At the same time, my husband had to take care of my father in law. I felt it was really difficult for me to pass through that tough time." (P11)*

Sub-theme 3. This course taught me the things what I wanted to do but did not dare to do before

As some family caregivers expressed, this BA intervention gave them the courage to do the things (e.g., doing leisure activities, having a personal life) they wanted to do but did not dare to do before.

> *"I think the course is really helpful, and the things you taught me are what I wanted to do but did not dare to do before." (P14)*
>
> *"Is that because you don't know whether the things you wanted to do before are right or not?" (Interviewer)*

"Yes, this is it. But after you told me, I thought I should follow you to do those things, like don't put 100 percent of myself into taking care of him, and I should take good care of myself and do leisure activities I like." (P14)

Sub-theme 4. Started to put those views in my heart until I learned this course

In reality, family caregivers knew some common views which were also included in BA intervention, like "to take care of myself, this is not an act of selfishness, and it will give me the capacity to take better care of my relative," and "I know that I do everything that I reasonably can for this person, and I have the rights to do some things just for myself." However, they did not apply them in their daily lives until they learned this course. Besides, their friends and relatives have used these views to comfort them, but they did not work either. Some family caregivers thought their relatives comforted them with ulterior motives.

"Firstly, they want to comfort you. Secondly, they just want you to undertake those caregiving tasks by yourself, and don't use them." (P2)

Furthermore, some family caregivers thought other people could not understand their situation, and they would feel "it is easier said than done" when other people tried to comfort them. Besides, family caregivers also reckoned that their friends or relatives comforted them just for the sake of comforting them, not for solving practical problems for them. Therefore, some family caregivers would be resistant to comfort from friends or relatives.

"For example, I was lived on the fourth floor, and my mom lived on the first floor before. When I talked to my mother loudly, my neighbor would say I should be patient with my mom. My mom couldn't hear me if I didn't speak loudly. My neighbors couldn't understand my situation, and I think when they tried to comfort me, they were insincere. It's always easier said than done" (P8)

"They couldn't understand you if they didn't have these kinds of patients in their families. They couldn't understand the mood of taking care of the patients for such a long time." (P18)

"When my sister talked with me, I just thought that she was saying some empty words. And she just wants to comfort me without any practical action."(P11)

Therefore, many family caregivers trusted professionals instead of listening to their friends and relatives. They thought professionals were more convincing, and professionals came to solve their problems. On the other hand, the formal course format made them pay more attention to the contents.

"When you talked with me, I thought that's the way it should be. You taught me I should have my own life and think positively, and then I followed your instruction." (P16)

"You are the professional, and I think you are different from others. I felt different when you talked with me. I couldn't have the same feeling whatever other people talked with me" (P19)

"Yes, because you are the professional, whatever you said should be right. " (P14)

"Because we were talking formally, so I put your words into my heart." (P12)

5.3.2.2 Theme 2. Evaluation of the "Daily pleasant events tracking and mood rating form"

As the "Daily pleasant events tracking and mood rating form" was a major component of this BA intervention, and participants spent nearly one-third of the time to complete this tracking form. When interviewees were asked the most impressive part in the booklet, they spontaneously talked about the "Daily pleasant events tracking and mood rating form." Four sub-themes were identified: "let me see the good things in life," "remind me to adjust negative feelings," "difficult to change fixed lifestyle and mood," and "change this recording mode to a diary."

Sub-theme 1. Let me see the good things in life

Most of the family caregivers were enthusiastic about the tracking forms, expressing not only pleasure in engaging the recording process but a deep sense of delight since the records reminded them that they still owned a colorful life. Besides, because of the heavy caregiving workload, family caregivers would ignore the good things in their lives. This tracking form lets family caregivers remember that they still preserve "little happiness."

> *"It is necessary for me to do the recording. I used to think about how unlucky I was in the past. But when I started to record, I knew that I have so many things to do, and my life could also be quite good. I think it's stimulation for me, and I would grasp every minute to do leisure activities when I didn't have to take care of my mother. Sometimes when I talked with others, they would say 'Wow, you can do so many things, all we do is just take care of our elderly and lie on the bed'" (P8)*
>
> *"I would feel my life was so boring before I do the recording. But when I recorded activities I did, I would feel that I had so much fun." (P9)*
>
> *"I didn't summarize my activities in the past. But now, after I recorded my activities for a few days, I started to feel that my life was still colorful instead of doing nothing." (P11)*

Sub-theme 2. Remind me to adjust negative feelings

The tracking forms also reminded family caregivers to adjust their negative feeling and stay positive. Family caregivers needed to manage their anxious, depressed, stressed, and sad feelings, as these feelings would have negative impacts on their physical health. Tracking forms set as homework format encouraged family caregivers to achieve a better score on leisure activities and mood, which consequently reminded them to adjust their negative feelings.

"It's really necessary for me to do this recording. If I didn't do the recording, I would totally forget the activities I had done. I could track my daily mood through the tracking forms. And when I didn't feel well, I would remind myself to adjust it." (P1)

"Like doing homework. If I felt depressed today, I would think I should adjust my feelings because I have this homework." (P4)

"I wanted to make my score to be higher, so it reminded me to do more leisure activities and have a better mood." (P12)

Sub-theme 3. Difficult to change fixed lifestyle and mood

Even though the tracking forms positively affected family caregivers' lives and moods, due to the caregiving situation, it was still difficult for them to change their fixed lifestyle and mood. Under this condition, it was also hard for family caregivers to do the recording.

"Like us, our lives are usually more fixed and closed. So it's difficult for me to make a change." (P6)

"Because caregiving life is similar every day, and it's relatively simple. So it's still hard for me to fill in this form." (P17)

"I will put what you taught me into daily caregiving tasks, so I don't need to do the record." (P15)

Sub-theme 4. Change this recording mode to a diary

Therefore, to make family caregivers record their daily activities and mood more freely, some family caregivers suggested changing "Daily pleasant events tracking and mood rating form" to a small diary. On the other hand, a small diary enabled family caregivers to record specific activities and the reasons behind different moods.

> *"I should add explanations for my happy and unhappy, instead of just recording how many leisure activities I did. Otherwise, I would forget why I felt happy or unhappy that day." (P1)*
>
> *"I think it would be better if I write daily logs. Because when I looked back at my previous records, I couldn't remember which activity made me happy or which activity made me depressed." (P4)*
>
> *"I would like to write two or three sentences to record what made me happy and unhappy today, like a small diary." (P8)*

5.3.2.3 Theme 3. Recommendations for future BA intervention

Even though most of the family caregivers were satisfied with the BA intervention, and they have improved a lot on their caregiving and psychological health. Interviewees still found some deficiencies in this course, and they have raised some recommendations to improve future BA studies. Their recommendations have been summarized into four sub-themes: "follow-up courses is necessary," "more contents need to be added," "views on changing course format to small lectures," "views on changing course format to video courses."

Sub-theme 1. Follow-up guidance is necessary

The length of this BA intervention was eight weeks, and each session lasted about 30 to 40 minutes. However, some of the participants considered the number of courses was still insufficient. They would like to have long-term guidance from professionals after the intervention.

> *"I would like to have a follow-up after this course. For example, we have different conditions in different families, with patients developed in different stages. I want to have more people to help us, to teach us how to deal with different problems in different stages. We can't solve some problems just by taking medicine. It would be better is you can contact with hospitals to continue this research project." (P5)*

"Yes, it will be much better if you can have follow-up courses, like an advanced course. But I understand it is really difficult." (P12)

Sub-theme 2. More contents need to be added

In addition to adding follow-up sessions, more content were suggested to be added to BA intervention by interviewed family caregivers. For example, more examples of leisure activities, communication skills with patients, caregiving and training skills, and healthy lifestyle of caregivers. Because of the limited scope and leisure time, family caregivers would like to have more choices of accessible leisure activities.

"The leisure activity part is really good, but it will be much better is you can enrich that part by adding more examples of daily leisure activities. Then we can have more choices and follow those examples to do our leisure activities." (P7)

"Some people will forget themselves when taking care of patients. You can list more leisure activities to remind them to follow your instructions." (P9)

Besides, family caregivers were also interested in a healthy lifestyle.

"I think you can teach more about a healthy lifestyle among family caregivers of PWD. Like healthy eating habits. I think caregivers will definitely follow your instruction." (P4)

Some family caregivers had difficulty communicating with their patients; therefore, they would like to learn more communication skills to take better care of their patients. Meanwhile, they were lack of caregiving skills, which made them waste more time and energy on caregiving. In consequence, they had little time to do leisure activities. Therefore, they suggested adding more caregiving skills in the courses.

"Can you teach us how to communicate with the patients? Like how to make them listen to you and follow your instruction." (P5)

"You can teach us how to exercise patients. We want to have more real samples that are closely related to our lives." (P15)

"Because you definitely know more than us, but I only know my mother. You can list some good caregiving examples for us. Maybe we can find something useful in your examples. Like the patients often curse, how can we deal with it?" (P13)

"The contents of caregiving skills are still insufficient, like how to make them happy and how to better serve them. Because actually, we don't know how to deal with them at the very beginning." (P11)

Sub-theme 3. Views on changing course format to small lectures

The BA intervention in this study was individual telephoned based, which kept family caregivers from communicating with others. However, some interviewees expected to share caregiving experience and feelings with other family caregivers. Small lectures would allow family caregivers to stay together and remedy the limitation of telephone-based courses.

"We can raise questions in your class. Sometimes other people will think of the things that you haven't think of. It's good for me to improve." (P4)

"Maybe what happens to you also happens to others, so you can talk with that person and know how to do." (P3)

"Like me, sometimes I talked with my neighbor because her father's condition is similar to my father. We can release ourselves by communicating with each other. If I sit with other family caregivers, I would think not only I feel so bad, other people also feel bad." (P17)

However, because of the characteristics of dementia, family caregivers could not leave PWD alone. It was difficult for family caregivers who take care of their patients alone to go out to have classes. Time became the biggest problem for family caregivers to gather outside of their homes.

"I had to find someone to replace me when I went out. I won't have time to go out to listen to your class." (P2)

"I can go out because I can take turns with my sister. But it is unrealistic for those people who have to stay at home for 24 hours." (P8)

"Maybe you can save time if you gather all family caregivers. However, because we have to take care of the patients, it is difficult for us to unify time." (P10)

Sub-theme 4. Views on changing course format to video courses.

Furthermore, with the innovation of technology, even the elderly could easily get access to cellphones and computers. Video course is very popular now because it's time-saving, convenient and economic characteristics. Many family caregivers also kept a positive attitude towards video course. Some of them believed the video-based course was time-saving.

"I think it's good if we can have video courses at home. We can learn these skills without going outside." (P2)

Meanwhile, the video course could present content more intuitively and interestingly.

"It will be more straight forward for me to watch videos than to read books." (P17)

"I will be more interested in watching videos because it saves a lot of brainpower and vision. I can watch videos whenever I want." (P8)

Moreover, the video course enabled family caregivers to learn one course over and over again.

"I can watch the video again and again, and finally, I can remember something. But if I just listen to the course once a week, it's easy for me to forget the content." (P1)

Above all, the video course was able to maximize the influence of BA intervention since professionals couldn't distribute the course one by one.

"There will be more people to be beneficial from your video, and your research will become much more influential." (P3)

"It is not realist for you to teach one by one, the video course will save you a lot of energy." (P10).

Even though many family caregivers supported to have video-based BA intervention, some of them still doubted whether this format could properly deliver information or not.

"I think it won't work. People don't like to watch those online courses, and they won't put the contents into their hearts. I could concentrate on you because I was talking with you. But I will be distracted if I watched the video." (P4)

"It's a kind of formalism, and it won't be that effective. I have watched videos before, but those things couldn't go into my heart." (P11)

For the sake of increasing learning interest and enhancing the teaching effect of video courses, some strategies, like earlier period propaganda and post-follow-up, should be added to the treatment.

"You should strengthen advocation at first. You can develop a small video to promote it and let people know that you have this. Maybe people will find you rather than you find them." (P13)

"I want to have professionals to do the follow-up. I can get counseling with the professional when I have questions after the video." (P5)

"I think learners could leave messages on the video, and you can answer it when you see it. It will be more efficient" (P10)

5.4 Summary of the chapter

This chapter reported the feasibility and acceptability of BA intervention through quantitative results and the post-intervention semi-structured interviews. The BA intervention provided reliable evidence in terms of the feasibility and accessibility of applying an eight-week individual telephone-based BA intervention in family caregivers of PWD. The semi-structured interviews explored the experience of participating in BA intervention among family caregivers of PWD, which further extend our understanding of the feasibility and accessibility of the BA intervention from family caregivers' perspective. The results guided the further refinement of the study protocol.

Chapter Six: Preliminary Examination of the Efficacy of BA

6.1 Introduction

This chapter consists of six parts, which present pilot RCT and post-intervention semi-structured interviews. Section 6.1 (this section) presents an introduction to this chapter. Section 6.2 shows the results of the pilot RCT in two parts, including the recruitment and dropouts of the study participants and the baseline comparison of the participants' characteristics. Section 6.3 presents the preliminary analysis of the hypothesis testing for the pilot study outcomes by showing the preliminary effectiveness of BA on sleep quality, depression, leisure activities, relationship satisfaction, SRH, PAC, and caregiving burden in ITT, per protocol, as well as qualitative analysis approach. The intervention fidelity is presented in 6.4. Section 6.5 presents the summary of this chapter.

6.2 Results of the pilot randomized controlled trial

6.2.1 Recruitment and dropouts of the study participants

In the 3-month recruitment period, 98 family caregivers of PWD were assessed for eligibility, 12 did not meet the inclusion criteria. Among the 12 ineligible family caregivers, seven care recipients did not have physician-diagnosis of dementia, three caregivers did not provide care for more than one hour per day, and two caregivers were paid caregivers. Therefore, the 86 eligible family caregivers were approached to participate in the study. However, a total of 15 family caregivers declined to take part in the study. The reasons were that they did not need the BA intervention (n = 2), or that they did not want to complete the questionnaire (n = 5), or that they did not have time (n = 8). Then 71 out of the 86 eligible patients were randomly selected into intervention and control groups using the random numbers generated from the online randomizer (www.randomiser.org). There were no reported or observed adverse effects (e.g., mortality, severe mental illness, or other medical complications) caused by the interventions over the intervention period.

A total of 71 family caregivers of PWD (35 for the intervention group, and 36 for the control group) were recruited between February 2019 and April 2019. Flowchart of the study procedure is presented in Figure 9, as recommended by the latest Consolidated Standards of Reporting Trials (CONSORT) statement (Schulz et al., 2010).

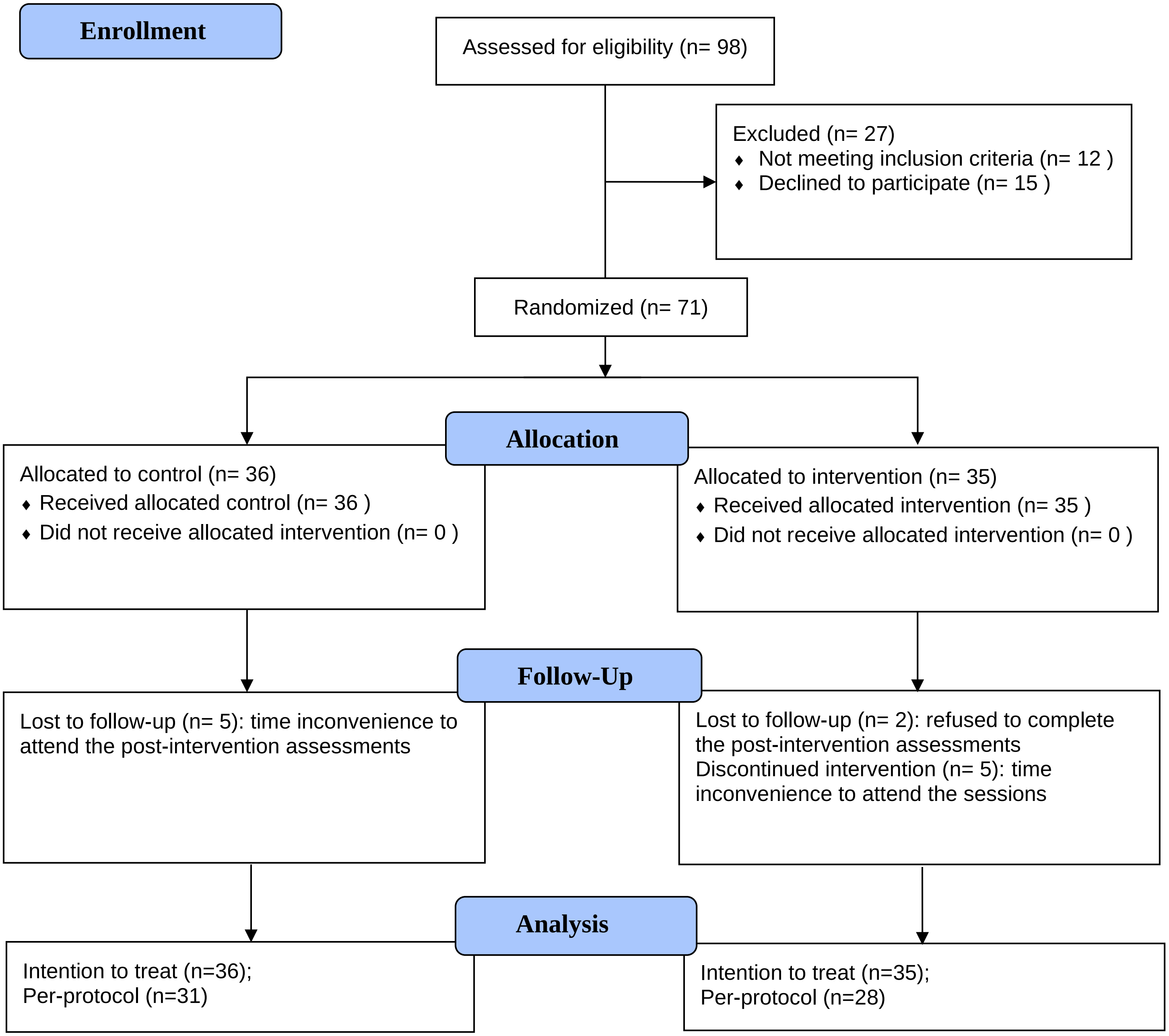


Figure 9. CONSORT flow diagram

For the intervention group, 28 of 35 participants (80%) completed the post-intervention outcome assessments. Five of them dropped out due to their time inconvenience to attend the sessions, and two of them refused to complete the post-intervention assessments. For the control group, 31 of 36 participants (86%) completed the post-intervention outcome assessments. Five of them dropped out due to their time inconvenience to attend the post-intervention assessments.

Around 17% attrition rate in this study was noticed. There were also no significant differences in participants' attrition rates (χ^2= 0.472, p= 0.541) between the two groups. Both ITT and per-protocol analyses were thus used for outcome analysis to examine whether the dropouts have any influence on the study results.

6.2.2 Demographic and outcome variables and baseline data

A comparison of the socio-demographic and outcome variables of the participants between intervention and control groups were conducted at baseline.

6.2.2.1 Socio-demographic of participants at baseline

Table 10 shows the socio-demographic of all participants. A majority of the participants were female (n=53, 74.65%). Their mean age was 54.07 years (SD=10.95), and over half (n=37, 52.11%) of them had tertiary education or higher. Most of the participants (n=62, 87.32%) did not have any religious beliefs, and nearly half of them were retired (n=33, 46.48%). Nearly 40% of them had an average household (monthly) income of 5,000-10,000 RMB. More than half of the family caregivers were children (n=39, 54.93%), and one-third of them were spousal caregivers (n=24, 33.80%). The average duration of caregiving was 44.12 months (SD=53.61), with 14.77 hours (SD=8.48) for providing care per day, and 5.7 days (SD=1.52) per week. Besides, more than half of the caregivers appraised their relations with PWD as good (n=39, 54.93%), and more than one-third of the caregivers appraised their relations with PWDs as very good (n=24, 33.80%). The majority of the family caregivers did not smoke (n=58, 81.69%) or drink (n=50, 70.42%). The mean score of the participants' self-health rating was 6.91 (out of 10) (SD=1.83).

There was no statistically significant difference in all demographic variables between the intervention and control groups. Therefore, no demographic variable was included for adjustment in the analyses of treatment effects. There was no statistically significant difference between the compliant group and the drop-out group in socio-demographic and caregiving conditions (Table 11).

Table 10. Baseline characteristics of participants between the intervention and control groups

	Total (n=71)	IG (n=36)	CG (n=36)	X^2	t-score	p-value
Age (years), mean (SD)	54.07 (10.95)	54.71 (11.19)	53.44 (10.83)		-0.48	0.63
Sex (female), n (%)	53 (74.65)	27 (77.14)	26 (72.22)	0.23		0.79
Education, n (%)						
Primary or below	4 (5.63)	0 (0.00)	4 (11.11)	Fisher=4.26		0.15
Secondary	30 (42.25)	17 (48.57)	13 (36.11)			
Tertiary or higher	37 (52.11)	18 (51.43)	19 (52.78)			
Religious belief, n (%)						
None	62 (87.32)	30 (85.71)	32 (88.89)	Fisher=1.31		0.92
Buddhism	6 (8.45)	3 (8.57)	3 (8.33)			
Christianism	2 (2.82)	1 (2.86)	1 (2.78)			
Taoism	0 (0.00)	0 (0.00)	0 (0.00)			
Others	1 (1.41)	1 (2.86)	0 (0.00)			
Job, n (%)						
Full-time	28 (39.44)	13 (37.14)	15 (41.67)	Fisher=5.43		0.11
Part-time	3 (4.23)	1 (2.86)	2 (5.56)			
Retired	33 (46.48)	20 (57.14)	13 (36.11)			
Others (housewife, farmer)	7 (9.86)	1 (2.86)	6 (16.67)			
Household monthly income, n (%)						
<RMB 5000	27 (38.03)	15 (42.86)	12 (33.33)	Fisher=2.93		0.40
RMB 5000-10000	30 (42.25)	16 (45.71)	14 (38.89)			
RMB 10000-15000	10 (14.08)	3 (8.57)	7 (19.44)			
>RMB 15000	4 (5.63)	1 (2.86)	3 (8.33)			
Relationship with PWD, n (%)						
Spouse	24 (33.80)	10 (28.57)	14 (38.89)	Fisher=5.14		0.15
Child	39 (54.93)	21 (60.00)	18 (50.00)			
Sibling	0 (0.00)	0 (0.00)	0 (0.00)			
Parent	5 (7.04)	4 (11.43)	1 (2.78)			

Others	3 (4.23)	0 (0)	3 (8.33)			
Duration of caregiving, in months mean (SD)	44.12 (53.61)	44.83 (57.74)	43.43 (50.08)		-0.11	0.91
Hours providing care per day, mean (SD)	14.77 (8.48)	14.66 (8.96)	14.88 (8.12)		0.11	0.92
Days providing care per week, mean (SD)	5.70 (1.52)	5.73 (1.63)	5.65 (1.41)		-0.21	0.84
Smoking, n (%)						
No	58 (81.69)	30 (85.71)	28 (77.78)	Fisher=2.84		0.42
Quitted	7 (9.86)	3 (8.57)	4 (11.11)			
< 1 pack/day	5 (7.04)	1 (2.86)	4 (11.11)			
1-2 pack/day	1 (1.41)	1 (2.86)	0 (0.00)			
>= 2 packs/day	0 (0.00)	0 (0.00)	0 (0.00)			
Drinking, n (%)						
Never	50 (70.42)	21 (60.00)	29 (80.56)	Fisher=4.71		0.32
Once/month	9 (12.68)	7 (20.00)	2 (5.56)			
2-4 times/month	3 (4.23)	2 (5.71)	1 (2.78)			
2-3 times/week	4 (5.63)	2 (5.71)	2 (5.56)			
>= 4 times/week	5 (7.04)	3 (8.57)	2 (5.56)			

PWD: People with dementia

IG: intervention group

CG: control group

***$p<0.05$, **$p<0.015$, ***$p<0.0001$**

Table 11. Baseline characteristics of participants between who completed intervention and drop-out in the intervention group

	Loss of follow up (n=7)	Completed intervention (n=28)	X^2	t-score	p-value
Age (years), mean (SD)	51.14 (13.03)	55.61 (10.77)		-0.94	0.35
Sex (female), n (%)	5 (71.43)	22 (78.57)	0.16		0.65
Education, n (%)					
Primary or below	0 (0.00)	0 (0.00)	0.26		0.69
Secondary	4 (57.14)	13 (46.43)			
Tertiary or higher	3 (42.86)	15 (53.57)			
Religious belief, n (%)					
None	6 (85.71)	24 (85.71)	0.83		0.84
Buddhism	1 (14.29)	2 (7.14)			
Christianism	0 (0.00)	1 (3.57)			
Taoism	0 (0.00)	1 (3.57)			
Others	0 (0.00)	0 (0.00)			
Job, n (%)					
Full-time	3 (42.86)	10 (35.71)	0.58		0.75
Part-time	0 (0.00)	0 (0.00)			
Retired	4 (57.14)	16 (57.14)			
Others (housewife, farmer)	0 (0.00)	2 (7.14)			
Household monthly income, n (%)					
<RMB 5000	4 (57.14)	11 (39.29)	1.43		0.70
RMB 5000-10000	3 (42.86)	13 (46.43)			
RMB 10000-15000	0 (0.00)	3(10.71)			
>RMB 15000	0 (0.00)	1 (3.57)			
Relationship with PWD, n (%)					
Spouse	2 (28.57)	8 (28.57)	0.074		0.96
Child	4 (57.14)	17 (60.71)			
Sibling	0 (0.00)	0 (0.00)			

Parent	1 (14.28)	4 (14.28)			
Others	0 (0.00)	0 (0.00)			
Duration of caregiving, in months mean (SD)	32.14 (46.35)	48.00 (60.57)		-0.64	0.52
Hours providing care per day, mean (SD)	17.00 (6.86)	14.07 (9.42)		0.77	0.45
Days providing care per week, mean (SD)	6.50 (0.87)	5.54 (1.73)		1.42	0.17
Smoking, n (%)					
No	5(71.43)	25 (89.29)	4.79		0.19
Quitted	2 (28.57)	1 (3.57)			
< 1 pack/day	0 (0.00)	1 (3.57)			
1-2 pack/day	0 (0.00)	1 (3.57)			
>= 2 packs/day	0 (0.00)	0 (0.00)			
Drinking, n (%)					
Never	3 (42.86)	18 (64.29)	5.09		0.28
Once/month	3 (42.86)	4 (14.29)			
2-4 times/month	0 (0.00)	2 (7.14)			
2-3 times/week	1 (14.28)	1 (3.57)			
>= 4 times/week	0 (0.00)	3 (10.71)			

PWD: People with dementia

$p<0.05$, **$p<0.015$, ***$p<0.0001$

6.2.2.2 Outcome measures at baseline

Table 12 shows the comparison of mean scores of outcome measures between the intervention group and the control group at baseline. There was no statistically significant difference in most of the outcome variables between the intervention and control groups. Only sleep latency (t=2.96, p=0.004) and sleep disturbance (t=2.09, p=0.041), the subscales of CPSQI were significantly different between the intervention group and the control group.

The internal consistency of all the outcome measures is good and adequate. Cronbach's alpha: 0.743 for leisure activities, 0.907 for CCES-D 0.800 for PAC, 0.889 for C-ZBI, and 0.816 for CPSQI.

Table 12. Comparison of CPSQI, CCSE-D, leisure activity, relationship satisfaction, SRH, C-PAC, and C-ZBI at baseline

	Total (n=71)	IG (n=35)	CG (n=36)	X^2	t-score	p-value
CPSQI, mean (SD)	8.21 (4.58)	9.03 (5.08)	7.42 (3.95)		1.50	0.14
Quality, mean (SD)	1.37 (0.87)	1.37 (0.84)	1.36 (0.90)		0.05	0.96
Latency, mean (SD)	1.13 (0.89)	1.43 (0.88)	0.83 (0.81)		2.96	0.004**
Duration, mean (SD)	1.68 (1.01)	1.71 (1.13)	1.64 (0.90)		0.312	0.756
Efficiency, mean (SD)	0.66 (0.96)	0.74 (1.07)	0.58 (0.84)		0.701	0.49
Disturbance, mean (SD)	1.21 (0.65)	1.37 (0.65)	1.06 (0.63)		2.09	0.04*
Medications, mean (SD)	0.52 (1.05)	0.66 (1.19)	0.39 (0.90)		1.07	0.29
Dysfunction, mean (SD)	1.65 (1.14)	1.74 (1.20)	1.56 (1.08)		0.69	0.49
PSQI Global Score >5, n (%)	47 (66.20)	24 (68.57)	23 (63.89)	0.17		0.80
CCES-D, mean (SD)	17.27 (11.46)	18.49 (11.68)	16.08 (11.27)		-0.88	0.38
Depressed affect, mean (SD)	5.72 (5.44)	6.26 (6.06)	5.19 (4.79)		-0.82	0.41
Positive affect, mean (SD)	4.46 (2.92)	4.40 (2.80)	4.53 (3.08)		0.18	0.86
Somatic complaints, mean (SD)	6.56 (4.37)	7.26 (4.14)	5.89 (4.54)		-0.13	0.19
Interpersonal problems, mean (SD)	0.52 (0.91)	0.57 (0.88)	0.47 (0.94)		-0.46	0.65
Clinical depression (CES-D⩾16, n (%)	41 (57.75)	21 (60.00)	20 (55.55)	0.14		0.81
Leisure activity, mean (SD)	16.30 (6.47)	17.43 (6.82)	15.19 (6.00)		-1.47	0.15
Relationship with PWD, mean (SD)	4.08 (0.98)	4.00 (0.97)	4.17 (1.00)		0.71	0.48
SRH, mean (SD)	6.91 (1.83)	6.50 (1.70)	7.31 (1.89)		1.88	0.06
C-PAC, mean (SD)	28.20 (6.17)	26.89 (6.04)	29.47 (6.11)		1.79	0.77
C-ZBI, mean (SD)	35.11 (16.52)	37.17 (17.26)	33.11 (15.74)		-1.04	0.30

IG: intervention group; CG: control group C-PAC: Chinese version of positive aspect of caregiving; CPSQI: Chinese version of Pittsburgh Sleep Quality Index; C-ZBI: Chinese version of Zarit Burden Interview; PWD: People with dementia; SRH: self-rated health PSQI Global Score>5 is the cut-off for identifying cases with sleep disorder

p<0.05, **p<0.015, ***p<0.0001

6.3 Preliminary examination of the efficacy of BA in sleep and secondary outcomes

6.3.1 Results of ITT analysis

6.3.1.1 Testing the statistical assumptions of RM-ANOVA

The data were tested to examine the eligibility for using the RM-ANOVA. The continuous outcome variables, including CPSQI, CCES-D, leisure activities, relationship satisfaction, SRH, C-PAC, and C-ZBI, were all normally distributed. No outliner was identified according to the Mahalanobis distance. Besides, the missing data was inputted by LOCF. Therefore, the RM-ANOVA was performed.

6.3.1.2 BA effects on overall sleep quality

Table 13 shows the comparison of mean scores of CPSQI between the intervention group and the control group using ITT analysis. A Higher CPSQI score indicates a more reduced sleep quality. In the intervention group, CPSQI global score (post-pre: mean ± SD = -0.97 ± 2.36, p=0.020) was significantly reduced after the BA intervention. There was no significant change in CPSQI global score in the control group. A similar observation was noted in perceived sleep quality (a subscale of PSQI). There was a significant decrease in the mean score in perceived sleep quality (post-pre: mean ± SD = -0.23 ± 0.03, p=0.030) in the intervention group, but this did not happen in the control group.

At the baseline, 24 (68.57%) participants in the intervention group and 23 (63.89%) participants in the control group were considered as poor sleepers (PSQI global score of >5), and there was no difference between these two groups. After the intervention, although more participants in the intervention group became poor sleepers, the growth trend of poor sleepers in the intervention group (25, 71.43%) still lower than the control group (27, 75.00%). The change of the percentage of poor sleepers in the intervention group after BA intervention was not significantly different from the change in the control group (2.96% vs. 11.11%, p=0.316).

Table 14 shows the interaction effects of BA intervention and time. BA intervention had statistically significant effects on participants' CPSQI global score (F(1,69) = 6.32, p=0.014, Partial η2 = 0.084) and sleep efficiency (F(1,69) = 5.50, p=0.022, Partial η2 = 0.074) by the group-by-time interaction effects. For the between-group effects, the BA only indicated statistically significant difference on sleep latency (F(1,69) = 8.02, p=0.006, Partial η2 = 0.104) between intervention and control groups.

Table 13. Comparison of mean scores of sleep quality after Behavioral Activation intervention in the intervention group and control group using ITT analysis

Measure	Group	Measurement occasion				Mean difference (post-pre)	p-value
		Pre-intervention		Post-intervention			
		n	Mean (SD)/ n (%)	n	Mean (SD)/ n (%)	Mean (SD)	
CPSQI > 5 (Yes)	IG		24 (68.57%)		25 (71.43%)		0.316
	CG		23 (63.89%)		27 (75.00%)		
CPSQI global score	IG	35	9.03 (5.08)	35	8.06 (4.06)	-0.97 (2.36)	0.020*****
	CG	36	7.42 (3.95)	36	7.69 (3.42)	0.28 (1.80)	0.360
Sleep Quality	IG	35	1.37 (0.84)	35	1.14 (0.81)	-0.23 (0.60)	0.030*****
	CG	36	1.36 (0.90)	36	1.36 (0.80)	0.00 (0.63)	1.000
Sleep Latency	IG	28	1.43 (0.88)	35	1.40 (0.91)	-0.03 (0.51)	0.744
	CG	31	0.83 (0.81)	36	0.92 (0.81)	0.08 (0.65)	0.446
Sleep Duration	IG	35	1.71 (1.13)	35	1.63 (0.84)	-0.09 (0.66)	0.447
	CG	36	1.64 (0.90)	36	1.58 (1.00)	-0.06 (0.63)	0.600
Sleep Efficiency	IG	35	0.74 (1.07)	35	0.51 (0.85)	-0.23 (0.84)	0.118
	CG	36	0.58 (0.84)	36	0.78 (0.87)	0.19 (0.67)	0.090
Sleep Disturbance	IG	35	1.37 (0.65)	35	1.29 (0.67)	-0.09 (0.45)	0.263
	CG	36	1.06 (0.63)	36	1.08 (0.77)	0.03 (0.65)	0.800
Medications	IG	35	0.66 (1.19)	35	0.51 (1.04)	-0.14 (0.65)	0.201
	CG	36	0.39 (0.90)	36	0.42 (0.94)	0.03 (0.29)	0.571
Dysfunction	IG	35	1.74 (1.20)	35	1.57 (1.09)	-0.17 (0.62)	0.110
	CG	36	1.56 (1.08)	36	1.56 (0.94)	0.00 (0.54)	1.000

IG: Intervention group; CG: Control group; CPSQI: Chinese version of Pittsburgh Sleep Quality Index

p<0.05, **p<0.015, ***p<0.0001

Table 14 Intention-to-treat analysis of BA intervention effects on sleep quality (n=71)

	Group effect			Time effect			Interaction effect		
Variables	F (1,69)	Partial η^2	p-value	F (1,69)	Partial η^2	p-value	F (1,69)	Partial η^2	p-value
CPSQI global score	1.07	0.015	0.306	1.95	0.027	0.167	6.32	0.084	0.014**
Sleep Quality	0.32	0.005	0.576	2.44	0.034	0.123	2.44	0.034	0.123
Sleep Latency	8.02	0.104	0.006**	0.16	0.002	0.695	0.65	0.009	0.424
Sleep Duration	0.08	0.001	0.783	0.86	0.012	0.359	0.04	0.001	0.844
Sleep Efficiency	0.07	0.001	0.792	0.04	0.001	0.850	5.50	0.074	0.022*
Sleep Disturbance	3.10	0.043	0.083	0.19	0.003	0.665	0.73	0.010	0.397
Medications	0.61	0.009	0.439	0.94	0.013	0.336	2.07	0.029	0.155
Dysfunction	0.17	0.002	0.682	1.57	0.022	0.215	1.57	0.022	0.215

CPSQI: Chinese version of Pittsburgh Sleep Quality Index; RR=relative risk
*p<0.05, **p<0.015, ***p<0.0001

6.3.1.3 BA effects on secondary outcome variables including depression, leisure activity, relationship satisfaction, health, PAC, and caregiving burden

Table 15 shows the comparison of mean scores of CCES-D, leisure activity, relationship satisfaction, SRH, C-PAC, and C-ZBI between the intervention group and control group using ITT analysis. In the intervention group, CCES-D (post-pre: mean ± SD = -2.77 ± 8.06, p=0.0495), leisure activity (post-pre: mean ± SD = 2.79 ± 4.13, p=0.001), C-PAC (post-pre: mean ± SD = 1.63 ± 4.17, p=0.027), C-ZBI (post-pre: mean ± SD = -4.54 ± 9.41, p=0.007) was significantly reduced after the BA intervention. There was no significant change in CCES-D, leisure activities, relationship satisfaction, SRH, C-PAC, and C-ZBI in the control group. There was also no significant change in relationship satisfaction and SRH in both the intervention group and the control group.

BA intervention had statistically significant effects on participants' CCES-D (F(1,69) = 7.53, p=0.008, Partial η2 = 0.098), leisure activity (F(1,69) = 15.89, p<0.001, Partial η2 = 0.218), C-PAC (F(1,69) = 6.53, p=0.013, Partial η2 = 0.086), C-ZBI (F(1,69) = 6.93, p=0.010, Partial η2 = 0.091) by the group-by-time interaction effects (Table 16). BA did not significantly improve relationship satisfaction and SRH for participants in the intervention group compared to those in the control group. For the time effects, the BA only indicated statistically significant improvements in the participants' leisure activities (F(1,69) = 5.33, p=0.039, Partial η2 = 0.086), and C-ZBI (F(1,69) = 6.13, p=0.016, Partial η2 = 0.082). For the between-group effects, the BA only indicated statistically significant difference on leisure activities (F(1,69) = 6.68, p=0.015, Partial η2 = 0.105) between intervention and control groups.

Table 15. Comparison of mean scores of CCSE-D, leisure activity, relationship satisfaction, SRH, C-PAC, and C-ZBI after Behavioral Activation intervention in the intervention group and control group using ITT analysis

Measure	Condition	Measurement occasion				Mean difference (post-pre)	p-value
		Pre-intervention		Post-intervention			
		n	Mean (SD)	n	Mean (SD)	Mean (SD)	
CCES-D	IG	35	18.49 (11.68)	35	15.71 (10.44)	-2.77 (8.06)	0.0496*
	CG	36	17.39 (10.76)	36	18.89 (11.08)	1.50 (4.05)	0.066
Leisure activity	IG	28	17.79 (7.05)	28	20.57 (6.36)	2.79 (4.13)	0.001**
	CG	31	15.58 (5.32)	31	14.84 (5.77)	-0.74 (2.56)	0.116
Relationship satisfaction	IG	35	4.00 (0.97)	35	3.86 (0.91)	-0.14 (0.70)	0.230
	CG	36	4.17 (1.00)	36	4.14 (1.05)	-0.28 (0.51)	0.744
SRH	IG	35	6.50 (1.70)	35	6.61 (1.53)	0.11 (1.18)	0.571
	CG	36	7.31 (1.89)	36	7.25 (1.78)	-0.06 (1.01)	0.744
C-PAC	IG	35	26.89 (6.04)	35	28.51 (6.01)	1.63 (4.17)	0.027*
	CG	36	29.47 (6.11)	36	29.11 (6.96)	-0.36 (2.07)	0.303
C-ZBI	IG	35	37.17 (17.26)	35	32.63 (13.24)	-4.54 (9.41)	0.007**
	CG	36	29.47 (6.11)	36	29.11 (6.96)	0.22 (5.43)	0.868

IG: intervention group; CG: control group; C-PAC: Chinese version of positive aspect of caregiving; C-ZBI: Chinese version of Zarit Burden Interview; PWD: People with dementia; SRH: self-rated health

*p<0.05, **p<0.015, ***p<0.0001

Table 16. Intention-to-treat analysis of BA intervention effects for CCSE-D, leisure activity, relationship satisfaction, SRH, C-PAC, and C-ZBI (n=71)

	Group effect			Time effect			Interaction effect		
Variables	F (1,69)	Partial η^2	p-value	F (1,69)	Partial η^2	p-value	F (1,69)	Partial η^2	p-value
CES-D	0.01	0.000	0.930	0.56	0.008	0.457	7.53	0.098	0.008**
Leisure activity	6.68	0.105	0.015*	5.33	0.086	0.039*	15.89	0.218	<0.001***
Relationship satisfaction	1.02	0.015	0.317	1.41	0.020	0.239	0.64	0.009	0.426
SRH	3.41	0.047	0.069	0.05	0.001	0.823	0.42	0.006	0.517
C-PAC	1.22	0.017	0.274	2.65	0.037	0.108	6.53	0.086	0.013**
C-ZBI	0.23	0.003	0.633	6.13	0.082	0.016*	6.93	0.091	0.010**

C-PAC: Chinese version of positive aspect of caregiving; C-ZBI: Chinese version of Zarit Burden Interview; PWD: People with dementia; SRH: self-rated health

p<0.05, **p<0.015, ***p<0.0001

6.3.2 Sensitivity analysis

Per protocol analysis was also performed to assess the preliminary efficacy of BA on caregivers' sleep, depression, leisure activity, relationship satisfaction, health, PAC, and caregiving burden. Results of per protocol analysis are shown in table 17 and 18. Comparisons of the ITT analysis and per protocol analysis were made. It was found that there was no significant difference between ITT results and per protocol results in caregivers' sleep, depression, leisure activity, relationship satisfaction, health, PAC, and caregiving burden.

Table 17. Comparison of BA intervention effects for CPSQI between per protocol and ITT analysis approach

Measure	Condition	Per protocol					ITT				
		Mean difference (post-pre)		Interaction effect			Mean difference (post-pre)		Interaction effect		
		Mean (SD)	p-value	F (1,57)	Partial η^2	p-value	Mean (SD)	p-value	F (1,69)	Partial η^2	p-value
CPSQI global score	IG	-1.21 (2.59)	0.020*	2.72	0.038	0.012**	-0.97 (2.36)	0.020*	6.32	0.084	0.014**
	CG	0.32 (1.94)	0.362				0.28 (1.80)	0.360			
Sleep Quality	IG	-0.29 (0.66)	0.030*	2.66	0.045	0.108	-0.23 (0.60)	0.030*	2.44	0.034	0.123
	CG	0.00 (0.68)	1.000				0.00 (0.63)	1.000			
Sleep Latency	IG	-0.04 (0.58)	0.745	0.13	0.002	0.434	-0.03 (0.51)	0.744	0.65	0.009	0.424
	CG	0.97 (0.70)	0.448				0.08 (0.65)	0.446			
Sleep Duration	IG	-0.11 (0.74)	0.449	0.87	0.015	0.818	-0.09 (0.66)	0.447	0.04	0.001	0.844
	CG	-0.06 (0.68)	0.601				-0.06 (0.63)	0.600			
Sleep Efficiency	IG	-0.29 (0.94)	0.118	0.08	0.001	0.021*	-0.23 (0.84)	0.118	5.50	0.074	0.022*
	CG	0.23 (0.72)	0.090				0.19 (0.67)	0.090			
Sleep Disturbance	IG	-0.11 (0.50)	0.264	0.22	0.004	0.389	-0.09 (0.45)	0.263	0.73	0.010	0.397
	CG	0.03 (0.71)	0.801				0.03 (0.65)	0.800			
Medications	IG	-0.18 (0.72)	0.202	1.05	0.018	0.145	-0.14 (0.65)	0.201	2.07	0.029	0.155
	CG	0.03 (0.32)	0.572				0.03 (0.29)	0.571			
Daytime Dysfunction	IG	-0.21 (0.69)	0.110	1.70	0.029	0.198	-0.17 (0.62)	0.110	1.57	0.022	0.215
	CG	0.00 (0.58)	1.000				0.00 (0.54)	1.000			

IG: Intervention group; ITT: Intention to treat; CG: Control group; CPSQI: Chinese version of Pittsburgh Sleep Quality Index

p<0.05, **p<0.015, ***p<0.0001

Table 18. Comparison of BA intervention effects for CCSE-D, leisure activity, relationship satisfaction, SRH, C-PAC, and C-ZBI between per protocol and ITT analysis approach

		Per protocol					ITT				
Measure	Condition	Mean difference (post-pre)		Interaction effect			Mean difference (post-pre)		Interaction effect		
		Mean (SD)	p-value	F (1,69)	Partial η^2	p-value	Mean (SD)	p-value	F (1,69)	Partial η^2	p-value
CCES-D	IG	-3.70 (8.79)	0.035*	8.27	0.127	0.006**	-2.77 (8.06)	0.0496*	7.53	0.098	0.008**
	CG	1.71 (5.36)	0.086				1.50 (4.05)	0.066			
Leisure activity	IG	2.79 (4.13)	0.001**	15.89	0.218	<0.001***	2.79 (4.13)	0.001**	15.89	0.218	<0.001***
	CG	-0.74 (2.56)	0.116				-0.74 (2.56)	0.116			
Relationship satisfaction	IG	-0.18 (1.33)	0.232	0.72	0.012	0.401	-0.14 (0.70)	0.230	0.64	0.009	0.426
	CG	-0.03 (0.55)	0.745				-0.28 (0.51)	0.744			
SRH	IG	0.14 (0.77)	0.573	0.43	0.008	0.513	0.11 (1.18)	0.571	0.42	0.006	0.517
	CG	-0.06 (1.09)	0.745				-0.06 (1.01)	0.744			
C-PAC	IG	2.03 (4.59)	0.027*	7.04	0.110	0.010**	1.63 (4.17)	0.027*	6.53	0.086	0.013**
	CG	-0.42 (2.23)	0.304				-0.36 (2.07)	0.303			
C-ZBI	IG	-5.54 (10.31)	0.008**	7.47	0.116	0.009**	-4.54 (9.41)	0.007**	6.93	0.091	0.010**
	CG	0.23 (5.35)	0.816				0.22 (5.43)	0.868			

IG: intervention group; CG: control group; C-PAC: Chinese version of positive aspect of caregiving; C-ZBI: Chinese version of Zarit Burden Interview; PWD: People with dementia; SRH: self-rated health

*$p<0.05$, **$p<0.015$, ***$p<0.0001$

6.3.3 Changes after BA intervention from the post-intervention semi-structured interviews

In the post-intervention semi-structured interviews, family caregivers in the intervention group reported they changed a lot after the BA intervention. Their changes could be summarized into six categories: "accept the fact that the patient is sick," "understand positive aspects of caregiving," "realize health, especially psychological health is very important," "want to have a personal life," "be in a better mood," "fall asleep easily." Demographic conditions were already shown in Table 8.

Sub-theme 1. Accept the fact that the patient is sick

Because of the particularity of dementia, some PWD who got clinical diagnosis were still able to carry out daily routines, like eating, drinking, exercising, etc. For this reason, some family caregivers were not unable to accept the fact that their loved ones were sick. They would be more depressed when patients displayed abnormal behaviors. After BA intervention, most of them began to accept the fact that their patients were sick, which made them feel released.

> *"There is something that needs to be inspired by other people. After you talked with me, when we quarreled because of some tiny things again, I would just remind myself that he was a patient. Then I would not feel that unhappy." (P3)*
>
> *"There's something you can't change, and I tried to accept her condition now. And I feel there are something changes slowly in my heart. Sometimes I could restrain my anxious and depressed emotion." (P5)*
>
> *"Now I think he is really sick. I knew he had this disease before, but I still couldn't accept his sudden changes. I was very angry with him, and I thought I couldn't live anymore. But now I know he is a patient." (P14)*

> *"At the beginning, I thought he made me angry intentionally. But now I accept his behaviors." (P17)*

Therefore, family caregivers would treat their patients more calmly when PWD had abnormal behaviors again.

> *"Recently, I think she already has this disease, so I don't need to be angry with her." (P5)*
>
> *"I won't fight with him anymore if he didn't listen to me. But I will tell him what is good for him and what is bad for him." (P10)*
>
> *"What you said were right, I don't fuss about her words anymore. She could say whatever she wanted, and I would not bother about it" (P2)*

Sub-theme 2. Understand the positive aspect of caregiving

Since family caregivers stopped struggling against their patients after the BA intervention, they gradually pay attention to the positive experience of caregiving. PAC refers to the inspiring and rewarding experience that derived from the caregiving process.

> *"I think through this caregiving journey, I became more positive, and I understand how to treasure every moment with my family. I really appreciate that I still have my father with me." (P17)*
>
> *"After this course, I learned how to treat my patients. Now we have a closer relationship with each other." (P11)*
>
> *"Sometimes, I could feel that my mother really needs me, and she could not live without me." (P2)*

Sub-theme 3. Realize self-health, especially psychological health is also very important

Originally, family caregivers described their lives as being centered on the PWD. They would devote themselves to caregiving tasks and ignored their own physical and psychological health.

"I totally devoted myself to taking care of my mother and put myself aside in the past. It's my responsibility to take good care of my parents. Sometimes I think I just live for my parents." (P2)

"I had to take good care of my parents and gave up all my personal life in the past. I really put my parents first, and I felt I was unfilial if I didn't live for my parents. I locked myself in taking care of them." (P11)

"Always give priority to taking care of my patients and making them be happy and comfortable. But I would forget my own discomfort." (P13)

"Totally forgot myself, totally forgot to do something for my own. Sometimes I really felt painful after finishing one-day caregiving work, but I didn't have more energy to deal with it." (P15)

After BA intervention, most of the family caregivers changed their minds. In the past, they only considered their physical health. Now, they started to realize that their own health, especially psychological health, was also very important.

"Yes, it's really important, and I know psychological health is more important than my physical health. If you don't have a good mood, you won't have good health. So I should put my mood at the first place" (P7)

"I realized my psychological health was very important after you talked with me. I thought it was normal for me to feel upset and unhappy before this course." (P15)

"People always say that we should have a good body, and never think about mood. Actually, only have good physical health doesn't mean you are healthy. If you are unhappy and upset every day, you are still unhealthy." (P18)

Sub-theme 4. Want to have a personal life

It is crucial for family caregivers to have personal life instead of fully devoted themselves to caregiving tasks to have good physical and psychological health. Many family caregivers were willing to keep their personal lives as well as to do some pleasant leisure activities after received BA intervention.

> *"I still have my own life. I still have some time to do something I like after taking care of my parents-in-law. I can still draw pictures, wear beautiful clothes, and do beauty." (P11)*

> *"I think I should have my own life now. Even though I still have to take care of my old mother, I can take some leisure time to enjoy my retired life." (P8)*

Moreover, since family caregivers understood that doing leisure activities were beneficial for their psychological health, they would do leisure activities intentionally to keep a good mood.

> *"When I had time, I would gather with my old colleagues and schoolmates to have fun to improve my mood." (P3)*

> *"My mood would definitely improve after I did something I like. For example, I planted flowers and tidied up the balcony this morning, and it enriched me the whole morning." (P19)*

> *"Much better, much better. After I went for a walk, I felt much better." (P16)*

Sub-theme 5. Be in a good mood

Since most of the participated family caregivers mastered the relaxation skills in BA intervention, they learned how to adjust their negative feelings as well as release stress and pressure. Therefore, their depression, anxiety, and caregiving burden level reduced significantly.

> *"I think it's really helpful to learn with you. You opened the knot in my heart. I didn't feel so depressed when I took care of him." (P10)*

> *"After listened to your course, I felt released and didn't feel that anxious and depressed all day. Really thank you. I can't do it by myself without your help." (P14)*

"Now I make every day to be my best day. If I haven't learned this course, I will feel I didn't do well here and there." (P19)

"Before I know you, I was so depressed, angry, unhappy, and anxious, and it became a negative cycle. But after you guided me, I didn't think a lot and didn't have so much pressure." (P12)

Sub-theme 6. Fall asleep easily

There was a close relationship between psychological health and sleep quality, and depression is a well-known risk factor for sleep disturbance. Before the BA intervention, many family caregivers mentioned that they have difficulty in falling asleep even though they were exhausted after caregiving. They described they thought a lot when lying on the bed, and it was just like a "train" running in their heads. However, after the BA intervention, some family caregivers felt they fall asleep easier than before.

"I didn't pay attention to my sleep, and it became better spontaneously." (P1)

"I thought fewer when I was lying on the bed. Maybe this is the reason why I fall asleep easily now." (P19)

"When I felt good, I would sleep well. The activities I did in the day time made me feel relaxed and let me forget the things that were bothering me. Thinking less naturally makes me sleep better." (P11)

6.4 Intervention fidelity

The intervention fidelity was assessed by the fidelity checklist. The interventionist was trained through online "Behavioral Activation for Medical Personnel" and "Behavioral Activation for Mental Health Professionals" presented by Stanford Geriatric Education Center (Stanford Geriatric Education Center, 2020). Table 19 summarizes the intervention fidelity results.

In the treatment delivery part, with the participants' consents, all sessions were audio-taped, and ten participants' records were randomly selected to be measured and scored. Cognitive Therapy Rating Scale (CTRS) scores ranged from 35-57, with a mean score was 48.76 (SD=8.28). The BATD manual was used at all times to ensure the standardization of treatment and consistency of delivery. All of the active ingredients, including caregivers' rights, caregiving skills, depression, treatment rationale, daily monitoring, activity selection, activity planning, mood, and activity, were presented in the intervention sessions. Family caregivers were lived in different communities to prevent contamination between intervention and control groups.

For the treatment receipt, family caregivers were asked whether they understood the intervention contents in qualitative interviews after the intervention. Most of the interviewed family caregivers reported they understood the intervention. Interventionist used simple words and examples to improve participant comprehension of the intervention. The courses were delivered in Mandarin, and a qualitative study was implemented before revising the BA intervention protocol to suits the values of Chinese family caregivers of PWD. Family caregivers in the intervention group were asked to complete homework to improve participants' performance of intervention skills during the intervention period. For the completion rate of homework. 19 (54.28%) participants completed all required six homework for eight weeks, and 25 (71.43%) participants completed more than five out of six homework in the intervention group.

In the enactment of the treatment skills domain, the BA indicated statistically significant effects on participants' leisure activities for the group-by-time interaction effects (F (1, 69) = 14.33, $p<0.001$, Partial $\eta 2 =0.172$).

Table 19. Summary of intervention fidelity data

Manner of evaluation	Outcomes
Delivery of Intervention	
1. Method to ensure that the content of the intervention is delivered as specified.	With the participants' consent, all workshops were audio-taped, and ten participants' records were randomly selected to be scored by CTRS.
2. Method to ensure that the dose of the intervention is delivered as specified.	With the participants' consent, all workshops were audio-taped, and ten participants' records were randomly selected to be measured.
3. Mechanism to assess if the provider actually adhered to the intervention plan or in the case of computer delivered interventions, method to assess participants' contact with the information.	CTRS scores ranged from 35-57, with a mean score was 48.76 (SD=8.28).
4. Assessment of non-specific treatment effects.	Not applicable
5. Use of treatment manual.	The BATD manual was used at all times to ensure the standardization of treatment and consistency of delivery.
6. There is a plan for the assessment of whether or not the active ingredients were delivered.	It was assessed by the presence or absence of each treatment component, including caregivers' rights, caregiving skills, depression, treatment rationale, daily monitoring, activity selection, activity planning, mood, and activity. All of the active ingredients were presented in the intervention sessions.
7. There is a plan for the assessment of whether or not planned components were	With the participants' consent, all workshops were audio-taped, and ten participants' records were randomly selected to be scored by CTRS.

delivered. (e.g., components that are unnecessary or unhelpful)	
8. There is a plan for how contamination between intervention and control groups be prevented.	Family caregivers in the intervention group and control group were living in the different districts.
9. There is an a priori specification of treatment fidelity	A checklist (Appendix C) was applied to measure the intervention fidelity, including treatment design, training providers, delivery of the intervention, receipt of intervention, and enactment of intervention skills through the whole pilot intervention. All items were rated as "Present," "Absent, but should be present," or "Not Applicable." All sessions were videotaped and rated independently by a researcher.
Receipt of Intervention	
1. There is an assessment of the degree to which participants understood the intervention.	Family caregivers were asked whether they understood the intervention contents in qualitative interviews after the intervention face to face. Most of the interviewed family caregivers reported they understood the intervention.
2. There are specification of strategies that will be used to improve participants' comprehension of the intervention.	Interventionist used simple words and examples to improve participant comprehension of the intervention.
3. The participants' ability to perform the intervention skills will be assessed during the intervention period.	Family caregivers in the intervention group were asked to complete "Daily pleasant events tracking and mood rating form."
4. A strategy will be used to improve participants' performance of intervention skills during the intervention period.	Family caregivers in the intervention group were asked to complete homework.

5. Cultural factors are considered in the development and delivery of the intervention (e.g., provided in native language; protocol is consistent with the values of the target group).	The courses were delivered in Mandarin. A qualitative study was implemented before revising the BA intervention protocol to suits the values of Chinese family caregivers of PWD.
Enactment of Intervention Skills	
1. Participants' performance of the intervention skills will be assessed in settings in which the intervention might be applied.	Participants in the intervention group were asked to do pleasant leisure activities in their living settings during the intervention by themselves. The BA indicated statistically significant effects on participants' leisure activities for the group-by-time interaction effects (F (1, 69) = 14.33, p<0.001, Partial η2 =0.084).
2. A strategy will be used to assess performance of the intervention skills in settings in which the intervention might be applied.	Interventionist was trained online, and return demonstrated what was trained. All of the classes have been audiotaped. They were listened to by the interventionist and another researcher right after the intervention. Recommendations for the intervention were made by them.

6.5 Summary of the chapter

This chapter reported the results of pilot RCT and the nested post-intervention semi-structured interviews. The pilot RCT provided preliminary evidence on the effects of BA on sleep quality, depression, leisure activity, relationship satisfaction, SRH, PAC, and caregiving burden. BA could significantly improve sleep quality, depression, leisure activity, PAC, and caregiving burden in family caregivers of PWD. Details of the study’s findings and limitations, as well as implications for future research and practice, will be discussed in the next chapter.

Chapter Seven: Discussion

7.1 Introduction

This chapter consists of five parts, which presents the discussions of the pre-intervention semi-structured interviews, BA intervention contents, BA effects on study outcomes, the feasibility of BA, strengths, and limitations, and implications. Section 7.1 (this section) presents an introduction to this chapter. Section 7.2 shows the effects of the BA on sleep quality, depression, leisure activities, PAC, and caregiving burden. Section 7.3 presents the feasibility issues of implementing BA, including subject recruitment, BA intervention protocol, and participants' satisfaction. Section 7.4 discusses the generalizability of the study outcomes. Section 7.5 stresses the contributions to the body of knowledge of this study. Section 7.6 presents the strengths and limitations of BA. Section 7.7 discusses the implication for future study and clinical practice.

7.2 BA effects on study outcomes

7.2.1 Improve overall sleep quality and sleep efficiency

To the best of my knowledge, this is the first study applied BA to improve sleep among family caregivers of PWD. Besides, little evidence of the effectiveness of BA on sleep in the general population has been found. This current study contributed new evidence to the effect of BA intervention on sleep quality. In this study, no discomfort or adverse effects related to the BA intervention were reported. The findings of this study indicated that BA intervention was safe and effective in improving sleep quality among family caregivers of PWD.

The intervention group demonstrated that BA significantly improved overall sleep quality among family caregivers of PWD with a moderate effect compared with the control group. The beneficial effects of BA on sleep were consistent with the previous view of the Global Council on

Brain Health (Global Council on Brain Health, 2016), who believes most adults could improve their sleep quality by changing behaviors and thoughts. The findings of this study proved that family caregivers of PWD's sleep could get benefits from improving psychological and behavioral aspects. Under the stressful and unpredictable caregiving condition, family caregivers of PWD are still able to improve sleep quality by responding positively to caregiving stress.

BA stands out in improving sleep quality for family caregivers because of its larger effect size and higher flexibility compared to other behavioral or pharmacological treatments for sleep. According to Gao et al. (2019), behavioral interventions and pharmacological treatments are two major types of interventions to improve sleep for family caregivers of PWD. Gao et al. (2019) conducted a systematic review and meta-analysis to compare the effects of sleep interventions on caregivers of PWD. In this review, behavioral interventions, including light chronotherapy, sleep hygiene education, and stimulus control, significantly improved sleep quality with a small effect. The pharmacological and neurostimulation interventions did not significantly improve sleep. Therefore, BA has a larger effect on improving sleep quality compare behavioral and pharmacological interventions (Gao et al., 2019).

It is critical to note that diverse sleep interventions are able to benefit sleep for family caregivers through multiple mechanisms. Sleep hygiene education could improve nighttime routine, light chronotherapy treatments are beneficial for regulating circadian rhythms, daytime exercise can relieve caregivers' subjective sense of fatigue and burden, and managing stress may decrease depressive symptoms (Gao et al., 2019). BA could reduce caregiving burden and depression, and thus improve sleep quality through increasing daytime exercise (e.g. pleasant leisure activities) and managing stress (e.g. coping with caregiving) (S. M. McCurry et al., 2007). Besides, there is a strong relationship between pleasant leisure activities and sleep. As stated in

PEAR model by Raeanne C Moore et al. (2011), family caregivers with high pleasant events and low activity restriction had better subjective sleep quality, sleep latency, and habitual sleep efficiency compared to family caregivers with low pleasant events and high activity restriction. In the qualitative study, participants also reported they have better sleep latency after doing more pleasant events. Therefore, this study supported the importance of developing and evaluating caregiver interventions that aim to increase leisure activities for family caregivers of PWD.

Most of the previous studies focused on the global PSQI score (Korn et al., 2009), few studies reported the effects of interventions on individual aspects of sleep quality (King et al., 2002). In this current study, the BA intervention only revealed significant positive effects on sleep efficiency. While perceived sleep quality, duration, disturbance, and daytime dysfunction, as well as medication use, did not significantly improve after the intervention. The findings of individual aspects could provide deeper insights into understanding BA intervention.

According to previous studies, there was a strong correlation between poor sleep efficiency and psychosocial stress (E.-J. Kim & Dimsdale, 2007). Meanwhile, both Beaudreau et al. (2008) and Dongwhane Lee et al. (2014) found that family caregivers of PWD with greater depressive symptoms have lower sleep efficiency. The current study significantly reduced depressive symptoms and caregiving burden among family caregivers in the BA intervention group compared to those in the control group, which partially supported that BA could improve sleep efficiency by lowering psychological distress. Poor sleep efficiency is usually affected by prolonged sleep latency and/or fragmented sleep, and it is the most common complaint among family caregivers (McKibbin et al., 2005). However, sleep latency did not significantly improve after the intervention. Therefore, in this current study, sleep efficiency may be improved by the fragmented ameliorative sleep among family caregivers of PWD. Even though fragmented sleep was reported to attribute to nocturnal behaviors of PWD, some studies argued that awakenings of PWD were insufficient to explain sleep efficiency in family caregivers (S. M. McCurry et al., 2008). According to the previous studies, BA cannot reduce the BPSD of the care recipients. Prick et al. (2015) reported that BA was not able to alleviate observable behavioral problems in PWD significantly. Similarly, Gonyea et al. (2006) also found that BA could not significantly reduce the severity of neuropsychiatric symptoms of PWD. Alternatively, because of the psychological burden that family caregivers experience, poor sleep quality could still exist without the nocturnal behaviors of PWD. Therefore, this current study demonstrated that the fragmented sleep of family caregivers could be improved by psychotherapeutic interventions.

However, sleep latency did not significantly improve by BA intervention in the quantitative analysis aspect. Similar findings were also reported in King et al. (2002)'s study. They investigated the effectiveness of a moderate-intensity physical activity intervention on sleep in 100 female family caregivers of PWD, and caregivers in the 12-month endurance exercise training program did not significantly improve sleep latency compared to caregivers in the 12-month nutrition education condition. However, in the qualitative analysis part in this study, the interviewed family caregivers reported that they were more easily to fall asleep after the BA intervention. They felt they thought less when they were lying on beds, which assisted them to fall asleep quickly. Even though Castro et al. (2009) reported caregivers with more depressive symptoms would take more time to fall asleep than non-depressed caregivers, the current study just supported this idea in the qualitative part. Even though significant improvements in sleep latency was not observed, the improvement trend with a small effect size of sleep latency was shown. Larger sample size is needed to detect the statistical significance. Additionally, family caregivers with older age would have some memory deficiencies in recording time to go to bed and time to fall asleep (Harkins, Chapman, & Eisdorfer, 1979). It is also known that patients with insomnia tend to overestimate sleep latency and underestimate sleep time (Harvey & Tang, 2012). Therefore, further study should apply objective measures (e.g., ActiGraph) of sleep to examine the effects of BA on sleep efficiency among family caregivers of PWD.

The sleep duration and sleep disturbance were not significantly improved after the BA intervention, either. According to some interviewed family caregivers, even though they fell asleep quickly, their sleep would still be disturbed by their care recipients. In the CPSQI post-intervention assessments, some participants also reported that their sleep would be interrupted by the nocturnal behaviors of patients. Family caregivers' sleep duration and disturbance were more likely to be influenced by the nocturnal behaviors of the care recipients. The sleep disturbance will occur when a person needs to face some events that precipitate nighttime wakefulness (Kryger et al., 2005). However, BA cannot reduce the BPSD of the care recipients. Prick et al. (2015) reported that BA was not able to alleviate observable behavioral problems in PWD significantly. Similarly, Gonyea et al. (2006) also found that BA could not significantly reduce the severity of neuropsychiatric symptoms of PWD. Therefore, future studies should also consider improving family caregivers' sleep by reducing BPSD in PWD. In Gibson, Gander, Dowell, and Jones (2017)' interventional study, family caregivers have less sleep disturbance, and better sleep latency after care recipients' sleep became more organized and predictable.

7.2.2 Reduce depression

As compared to the usual care group, the BA intervention group significantly reduced depression on CCES-D with a moderate effect (partial eta squared= 0.098). The study result was consistent with the meta-analysis in Chapter 2, in which BA has a moderate effect on reducing depression levels among family caregivers of PWD.

Depression is one of the most significant problems facing by caregivers. BA, as a psychotherapeutic approach, is rooted in the theoretical conceptualization of depression (Dimidjian et al., 2011). It is noteworthy that BA aims to increase positive response reinforcement for awakening the non-depressive impact (Lewinsohn, 1974; Lewinsohn & Graf, 1973). Depression, as the core concept of Lewinsohn's behavioral model, is the most critical target of the BA intervention (Dimidjian et al., 2011). The BA intervention provides family caregivers with activity scheduling and problem-solving techniques to achieve the goal of reducing depression levels (Jonathan W Kanter et al., 2010). The American Psychological Association (American Psychology Association, 2016) also reported BA had strong evidence of effectiveness in treating depression according to the criteria for evidence-based psychotherapies originally formulated by Chambless and Hollon (1998).

Interventions for reducing depression in family caregivers of PWD usually include CBT, psychoeducational programs, emotional support, cognitive rehabilitation therapy, and multicomponent interventions (Waller, Dilworth, Mansfield, & Sanson-Fisher, 2017). According to a meta-analysis for investigating the efficacy of interventions for managing depressive symptoms among caregivers of PWD, CBT showed a significant, large effect, and mindfulness interventions showed significant, moderate effects on decreasing depressive symptoms for caregivers, while psychoeducational interventions only showed small but significant effects (M. Lee et al., 2019). However, among the included CBT interventions, some uniformly implemented BA as a stand-alone intervention to treat depressive symptoms. Combine the evidence of the meta-analysis in Chapter 2. BA is a promising treatment for decreasing depressive symptoms for family caregivers of PWD. Additionally, BA is easy to conduct according to individual preference, and it only requires minimal time investment from interventionists. For these reasons, BA can be easily disseminate to a larger community.

7.2.3 Improve leisure activities

This current study demonstrated that BA had a large effect on improving leisure activities among family caregivers of PWD. Even though increasing pleasant leisure activities was one of the techniques of BA, few studies investigated the effectiveness of BA on leisure activities among family caregivers of PWD. In the systematic review of BA in Chapter 2, only Losada et al. (2011) assessed the frequency of leisure activities after the study. However, BA only had a small effect (η^2=0.07) on improving the frequency of leisure activities in their study. The forms of intervention might be contributed to the difference in the degree of BA effectiveness on leisure activities between this pilot study and Losada et al. (2011)'s study. Our study consisted of eight weekly individual telephone-based BA sessions, while Losada et al. (2011)'s study consisted of 12 weekly group-based BA sessions. Even though the session amount in our study is lower than Losada et al. (2011)'s study, our study adopted individual-based sessions. A meta-analysis compared the effectiveness of individual and group interventions for depression in adults, and individual interventions were more effective in reducing depression compared to group interventions in the short term (Cuijpers, van Straten, & Warmerdam, 2008). However, group interventions might be more cost-effective than individual interventions.

In the post-intervention qualitative interviews, family caregivers also reported doing more leisure activities after BA intervention. They realized that doing leisure activities were beneficial for their psychological health, and they would do leisure activities intentionally to keep psychologically healthy. Initially, family caregivers did not become aware of the importance of psychological health, and they thought it was normal for them to feel unhappy, depressed, and stressed. Similarly, researchers from the Dana-Farber Cancer Institute and the Yale University School of Medicine found that nearly half of the cancer caregivers who met diagnostic criteria for a psychiatric disorder did not seek treatment for it (Vanderwerker, Laff, Kadan-Lottick, McColl, & Prigerson, 2005). Similarly, family caregivers of PWD indicated that they were not aware of how to increase their leisure activities in their current circumstances in which they experienced a huge caregiving workload. In addition, they had no idea of finding support and guidance from society. Bedini and Gladwell (2014) also reported that recreation programs explicitly targeted at caregivers are rare. This current study provided family caregivers supports and guidance for doing leisure activities under a huge caregiving workload. After the BA intervention, the interviewed caregivers understood how to incorporate leisure activities into their caregiving lives. They started to break their stereotype (e.g., guilty, unfilial, irresponsible) of doing leisure activities and preserved some personal life for themselves to do leisure activities without any psychological burden. Family Caregiver Alliance (2019c) also suggested to include the ten caregiver's rights, which include protecting individuality and the right of caregivers to make a life for themselves to the treatment manual. This BA intervention educated Chinese family caregivers that keeping personal time and doing leisure activities are not irresponsible and unfilial behaviors to their patients; on the contrary, they have the right to retain their personal lives.

7.2.4 Improve PAC but not relationship satisfaction

In this study, BA significantly improved PAC among family caregivers of PWD with a moderate effect. Meanwhile, this is the first study to investigate the effectiveness of BA on PAC among family caregivers of PWD. Previous studies had investigated the negative impacts of caregiving on family caregivers of PWD; however, little attention has been paid to PAC. Increasing evidence suggested that the adaptation process of caregiving coexisted with a negative and positive experience (Andrén & Elmståhl, 2005). PAC refers to the inspiring and rewarding experience that derived from the caregiving process and has positive consequences on one’s life experience (Williams, 2005). This concept includes gratification, uplift, growth, reward, and satisfaction (Duggleby, Williams, Wright, & Bollinger, 2009). PAC has been reported to be associated with reduced depression and anxiety (Williams, 2005), better subjective health (Gold et al., 1995), and a sense of role fulfillment (Brent T Mausbach et al., 2004). It also decreases the rate of institutionalization of PWD (Brent T Mausbach et al., 2004). Promoting PAC, therefore, has a promising future in both family caregivers and care recipients.

PAC can be reinforced by the enrichment events. As stated in Chapter 2, performing daily pleasant events could balance the caregiving tasks and positive experience in family caregivers. Many researchers also suggested that to improve the positive experience and wellbeing of the caregivers, and studies should focus on enhancing positive events in daily caregiving experience (A Au et al., 2015; Noonan, Tennstedt, & Rebelsky, 1996; Martin Pinquart & Sörensen, 2003). A strong relationship (r=0.71) between the number of joyful and satisfying activities and caregiver uplifts and satisfaction was also shown in Jensen, Ferrari, and Cavanaugh (2004)’s study. Hilgeman, Allen, DeCoster, and Burgio (2007) also found that positive events could improve PAC in family caregivers of PWD.

However, according to the qualitative study before the intervention, family caregivers were too overwhelmed to perform pleasant leisure activities. Therefore, in this pilot intervention, family caregivers were suggested to do leisure activities together with the PWD. The positive shared times could improve the reciprocity of the relationship between caregivers and care recipients, and thus maintain care recipients’ senses of identity (Hellström, Nolan, & Lundh, 2005). Cartwright, Archbold, Stewart, and Limandri (1994) developed a model of the process of enriching the caregiving pleasurable or meaningful experiences, in which the core component is the enriching events include acquiring symbolic meaning, performing the activity, and fine-tuning. They observed that such events facilitate the caregiver/care recipient dyads' relationship as well as the feeling of accomplishment for caregivers. Doing shared leisure activities have many positive outcomes for caregivers and PWD: firstly, exercising the cognitive and physical function of PWD; secondly, improving the relationship between family caregivers and care recipients; and lastly, enhancing the positive experience in daily caregiving routines for family caregivers. In the post-intervention interviews, family caregivers also reported that they stopped struggling against their patients after the BA intervention, and understood how to treasure every moment with their families. Overall, BA is an effective intervention to improve PAC for family caregivers of PWD.

Cultural values are also related to PAC. Morano (2000) found that mastery, satisfaction, and personal gain was significantly associated with the level of acculturation in caregivers. Even though African Americans face difficulties and sacrifice, they often treat caregiving as an obligation and a rewarding experience rather than a burden (White, Townsend, & Stephens, 2000). On the contrary, Asian population usually place family over the individual and share a family-centered culture which stresses the interdependence (Gelfand, 2001). They are subject to Confucian ethics, including respect for older persons, obedience to parents, and filial obligations to aging parents. According to the qualitative interviews prior to the pilot intervention, traditional Chinese beliefs, including filial commitment and "fatalistic voluntarism," stop Chinese family caregivers from doing leisure activities. Therefore, it is more critical to implement BA intervention in Chinese family caregivers of PWD to improve their PAC, and thus to improve the physical and psychological health for both family caregivers and care recipients.

However, BA did not significantly influence the relationship satisfaction between family caregivers and care recipients in this study. Theoretically, the shared activities for family caregiver/care recipient dyads are associated with their relationships (Hellström et al., 2005). Schneider, Murray, Banerjee, and Mann (1999) also found that sharing pleasant leisure activities helps to maintain companionship. The relationship satisfaction significantly improved in Alma Au et al. (2019)' study, which supported that training in communications with other family members to seek support could help enhance the relationship with the care recipient. The increased resourcefulness experienced by caregivers could facilitate them to better communicate with the care recipient. It is important to understand what factors contribute to intimacy loss to attain better theoretical understanding of the relationship between dementia onset and intimacy in the caregiver/care recipient relationship. Unfortunately, researchers have gathered little quantitative data addressing factors contributing to the loss of intimacy in the context of dementia. More studies are needed to explore the predictors of relationship satisfaction of family caregivers of PWD.

7.2.5 Reduce caregiving burden

As compared to the control group, the BA group significantly lowered levels of caregiving burden. Caregiving burden refers to anxiety, stress, and tension when facing caregiving challenges (Donnellan, Bennett, & Soulsby, 2017). It is a general construct that could be affected by many factors, including emotional, financial, and social stressors. Caregiving burden has negative impacts on physical, psychological, and emotional wellbeing, and negatively affect their functioning in daily life (Zwaanswijk, Peeters, Van Beek, Meerveld, & Francke, 2013). Therefore, health professionals should help family caregivers to reduce caregiving burden. Caregiving burden is usually related to living with PWD (Conde-Sala, Garre-Olmo, Turró-Garriga, Vilalta-Franch, & López-Pousa, 2010), being a child of PWD (M.-D. Kim et al., 2009), being a female (M.-D. Kim et al., 2009), having depressive symptoms (Springate & Tremont, 2014), adopting criticism and disengagement as coping strategies (J. Lim, Griva, Goh, Chionh, & Yap, 2011), and having a high social restrictiveness score (Zawadzki et al., 2011). BA could reduce depressive symptoms, increase social interaction for family caregivers, and make family caregivers better cope with caregiving.

Two studies (Alma Au et al., 2019; Gonyea et al., 2006) in the previous systematic review of BA investigated the effectiveness of BA on caregiver burden. Only Alma Au et al. (2019)'s study revealed a trend in reducing burden among family caregivers of PWD after BA. In Gonyea et al. (2006)'s study, the overall level of burden was not significantly reduced in either the intervention or control group. There was only five sessions in Gonyea et al. (2006)'s study. Even though the intervention has covered the main contents of BA, the dosage of the intervention may not be sufficient to impact caregiving burden effectively. Therefore, researchers should implement BA intervention with a sufficient dosage to make BA more effective.

Although BA was initially being designed to reduce depression, it can also be used to try to alleviate other forms of mental health issues among caregivers. For instance, R. C. Moore et al. (2013) reported on BA having a positive impact in reducing negative feelings relating to shame, distress, and unhappiness, etc., among recipients of an intervention, as well as alleviating symptoms of depression. There is a tight association between depression and other psychological distress related to the caregiving burden, stress, anxiety, and strain, according to Beekman et al. (2000)'s study. However, more studies are still needed to examine the effect of BA on other psychological aspects in family caregivers of PWD.

7.3 Feasibility for implementing BA in community

7.3.1 Feasibility of subject recruitment and follow-up process

The recruitment rate of this pilot study was 73.47%, which was relatively high among BA interventions for family caregivers of PWD (29.25% to 98.23%). The adequate sample size is one of the key determinants for successful clinical trials. Low recruitment rate may lead to several negative implications, for example, less statistical power, longer duration of clinical trials, and extra recruitment effort (Ruckmani & Vishaly, 2012; Yelland, Makrides, McPhee, Quinlivan, & Gibson, 2016). Recruitment of participants may be one of the most challenging part in clinical trials. According to the literature, the barriers to recruitment may be classified into three groups: 1) subject-related barriers, 2) investigator-related barriers, and 3) protocol-related barriers (Kadam, Borde, Madas, Salvi, & Limaye, 2016; Pribulick, Willams, & Fahs, 2010).

For subject-related barriers, it is indicated that participants often fail to accept or complete interventions since they dislike the uncertainty of the potential treatment effects of the interventions (Kadam et al., 2016; Pribulick et al., 2010). Meanwhile, participants who refuse to participate in interventions will consider more on the side effects of the intervention, as well as the time and costs associated with participating interventions (Adams, Caffrey, & McKevitt, 2015; Hewison & Haines, 2006). In this pilot RCT, although the effects of BA on sleep quality were not conclusive, the BA theories and current literature still supported its promising role in the improvement of sleep. Besides, BA was shown to be a safe and convenient treatment approach in many studies (Alma Au et al., 2019; R. C. Moore et al., 2013; X. Y. XU et al., 2020a). The information of BA was included in the information sheet and was explained by researchers when recruiting the participants to eliminate participants' uncertainty and worry about BA, (Huang et al., 2018). Moreover, the BA intervention was conducted through the telephone, and participants could choose time to have individual sessions when they were convenient. The telephone-based approach saved more participants' energy, time, and costs during their frequent study participation compare to other studies applying face to face BA interventions. Alma Au et al. (2019) also applied telephone-based BA intervention, and the recruitment rate was 86.05%, which was also relatively higher than other studies. The potential benefits, safety study protocol, brief and clear information sheet, as well as convenient study format all partially helped to improve the recruitment rate of this pilot RCT.

The second barrier was investigator-related barriers. The good relationship between researchers and participants is a critical factor for improving study recruitment. Participants who receive study information from their trusted ones are more likely to take part in the study (Newington & Metcalfe, 2014). In this pilot RCT, most of the participants were invited by doctors, nurses, friends, and relatives, which made them trusted the researchers and thus increased their participation in the intervention. Besides, the researchers were all qualified health professionals, which positively associated with relatively high recruitment and participation rate in this study. According to the post-intervention qualitative interviews, it was more easily for family caregivers to accept points of view from health professionals. Even though some of the caregivers have learned several ideas of BA intervention from their relatives or friends before, they still have difficulties in changing. Various studies have stated the importance of family and friend support for family caregivers of PWD (Taylor et al., 2013; Wilks & Croom, 2008). However, on the contrary, in this qualitative study, some family caregivers expressed they were not willing to receive comfort from their friends or relatives. Similar findings were also reported in Mandani, Hosseini, Hosseini, Noori, and Ardakani (2018)'s study, family caregivers of individuals with chronic psychiatric disorders were not willing to talk about their feelings with relatives and friends, because they felt the sympathy and pity from their relatives. They were more easily to be convinced by health professionals and got more information through the formal learning process. Therefore, to get better effects of interventions on family caregivers, more health professionals should join in the delivery of interventions.

In terms of the protocol-related barriers, a study protocol with research procedures that are too complicated, insufficient/unclear study information, and an intervention protocol with potential adverse reactions can be barriers to subject recruitment (E. J. Mills et al., 2006). The BA intervention protocol was selected and revised based on a comprehensive analysis of convenience, effectiveness, and safety. The conduction of daily leisure activities was designed not to disturb caregiving duty and the normal life of the participants. This information was presented in writing and verbally, all of which could be viewed as definite protocol related factors in facilitating subject recruitment and participation.

The attrition rate in this study was reasonable and acceptable for this vulnerable target group (20% participants dropped out), and previous studies included in the systematic review (BA for family caregivers of PWD) in Chapter 2 having attrition rates from 3.1% to 23.3% (Bell, Kenward, Fairclough, & Horton, 2013). Waller et al. (2017) did a systematic review of computer and telephone-based interventions for family caregivers of PWD, in which the mean attrition rate was 23%, and this was also similar to our study. The study attrition was mainly due to their time inconvenience and/or loss contact, and they were consistent with the previous studies (Gonyea et al., 2006; Losada et al., 2011; Prick et al., 2015). In addition, death or significant health changes of PWD also contributed to the loss of follow-up (Waller et al., 2017). There were no significant differences between caregiver completers and caregiver dropouts in this pilot study. However, in Prick et al. (2015)' study, caregiver dropouts had a significantly lower educational level than caregiver completers. Due to the heavy caregiving workload and time inconvenience to adhere a structured multiple-session intervention for family caregivers (especially those who taking care of their patients alone), we considered the attrition rate of our study as acceptable. Therefore, in order to improve the retention rate of the intervention, researchers would better apply modern technology to alleviate the time burden for participating in the supportive interventions for family caregivers of PWD.

7.3.2 Feasibility of the BA intervention protocol

The feasibility of the BA intervention protocol was examined by assessing the participants' adherence to the BA intervention. The completion rate of BA intervention was used to assess the participants' adherence to the BA intervention in the intervention group. This study demonstrated a relatively high completion rate (86%) in the intervention group. The completion rate was similar to Gonyea et al. (2006)'s study, which is an RCT of a BA for family caregivers of Alzheimer's disease. In this study, nearly 88% of the participants attended at least four out of five weekly sessions. When compared with Prick et al. (2015)'s study on a dyadic BA intervention to manage the psychological distress of family caregivers of PWD that adopted similar methods in calculating the intervention completion rate, the completion rate (77%) was also similar to this study. The strategies mentioned in Section 2.1 may partially contribute to the relatively high adherence to BA intervention in this study. Due to the heavy caregiving workload, it is more difficult for family caregivers of PWD to follow the intervention protocol. However, because of the safe and clear intervention protocol, the time- and energy-saving treatment delivery method, the mutual trusted relationships between researchers and participants, and the remarkable positive effects on participants during the intervention, most of the participants could follow the treatment protocol to complete the intervention.

The “Daily pleasant events tracking and mood rating form” was a significant component of this BA intervention protocol. Chapter 2 has shown that PES is a core component of BA. PES is a kind of activity scheduling in BA that was developed as a measure of positive reinforcement obtained over time (MacPhillamy & Lewinsohn, 1974, 1982). Different BA interventions apply various daily activity logs. In this pilot study, to alleviate the burden when taking part in this intervention, family caregivers were just asked to record how many leisure activities they did, and how about their moods everyday. However, some family caregivers suggested to record what kind of leisure activities they did every day, or change the tracking forms to small diaries, since they wanted to recall what activities made them feel better. In Brief BATD (C. W. Lejuez et al., 2001), the revised version of BATD-R (C. Lejuez et al., 2011), and the selected sessions of CWC (Gallagher-Thompson et al., 2002), activities were recorded in a detailed way. Some family caregivers also expressed that if they chose to join an intervention or learn a course, they would be willing to spend time and effort to complete it. Future studies could ask participants to record their activities in a more detailed way to improve the efficiency of the BA intervention.

Even though the tracking form was not perfect enough, it still had many positive impacts on family caregivers of PWD. Through completing the tracking forms, family caregivers not only felt pleasure in engaging the recording process but also a deep sense of delight, since the records reminded them that they still owned a colorful life. In addition, the tacking forms motivated family caregivers to have a better score, which means doing more leisure activities and keeping a better mood. These results are consistent with the BA theory; BA aims to increase positive response-contingent environmental reinforcement and help clients to engage in pleasant and constructive activities and therefore make them reconnected with positive and enjoyable aspects of their lives (Martell et al., 2013). In this pilot study, family caregivers reconnected with positive aspects of their lives through completing activity tracking forms. BA, which started from being a self-monitoring exercise, could be easily tailored to meet the needs of family dementia caregivers (C. W. Lejuez et al., 2001). Still, its positive impacts could only be sustained if participants implement what they learn from training sessions into their daily lives. Therefore, this is the reason why there is 'homework' (e.g., daily activity logs of BA activities) for participants to complete after each session (C. W. Lejuez et al., 2001) in most of the included studies.

7.3.3 Participants' satisfaction with BA

The participants' satisfaction with the BA intervention was deemed good in this pilot study, and nearly 90% of participants were very satisfied with the BA intervention. The data analysis results indicated that BA intervention produced favorable effects in improving sleep and other psychological health compared with the usual care group. The positive effects of BA might partially contribute to the high level of satisfaction with BA. Furthermore, according to the post-intervention qualitative study, the professionalism of the interventionist, and the easily understandable intervention contents improved participants' satisfaction with BA.

In the post-intervention qualitative interviews, the interviewed family caregivers generally held a positive attitude towards BA intervention. Nearly all of the interviewed family caregivers have not heard about thought about there were courses like BA intervention for family caregivers before. Most caregiving interventions were conducted in western countries (e.g., Australia, the United Kingdom, Canada, and the United States). Few interventions were conducted in the mainland of China (Wu et al., 2019). In developed countries, general practitioners and community nurses are usually responsible for the provision of dementia care in a primary care context, with emphasis on diagnosing and managing the disease as early as possible and on offering assistance to caregivers. (Brodaty & Cumming, 2010; L. Lee et al., 2010). By contrast, in China, community care centers have little capacity for preventing diseases, managing chronic conditions, and providing living support for the elderly, because they serve as small-scale acute hospitals. (Ministry of Health, 2012). Furthermore, the pharmaceutical benefit policy implemented by the state excludes dementia as a chronic disease, placing significant financial strain on patients and their families. (Ministry of Human Resources and Social Security, 2009). More affluent families frequently hire caregivers to provide care to dementia patients in their stead. (Prince et al., 2012). But most PWD were staying at home and cared for by their family members. Therefore, most of the interviewed family caregivers regard providing BA or psychological interventions for family caregivers as a future development direction in China.

The interviewed family caregivers were more willing to have BA intervention at an early stage of caregiving. Since some family caregivers felt more depressed and emotional distress, as well as had more uncertainty in their early-stage compare to their later stages of caregiving. Van Wijngaarden, Van der Wedden, Henning, Komen, and The (2018) reported family caregivers of PWD in the early stage of caregiving had an indefinite feeling that something was amiss. According to Signe and Elmståhl (2008)'s study, the best effects of the intervention were found in family caregivers who care for individuals with early-stage of dementia. In the early stage diagnosis of dementia, both family caregivers and care receivers could make plans for arranging the future (Whitlatch, Judge, Zarit, & Femia, 2006), which alleviates the psychological burden of family caregivers. Furthermore, family caregivers who receive early interventions may reduce their risk for psychological distress, and this may help to reduce the risk of developing CVD or other physical diseases (X. Y. Xu et al., 2020b). The early detection and prevention of depression or other psychological distress may prevent family caregivers from higher risk for early mortality. Therefore, to better promote psychological and physical health for family caregivers, it is critical for health professionals to provide psychological treatment for family caregivers at their early stages of caregiving.

7.4 Generalization of the study outcome

The participants' characteristics were analyzed to measure the external validity of this current study and present the comparability between intervention and control groups (Khorsan & Crawford, 2014). According to Cook and Campbell, external validity explains the generalizability of this study results in similar populations (i.e., family caregivers of PWD) (Cook & Campbell, 1979).

In this study, the mean age of the participated family caregivers was 54years old, and the majority of the participants were female (75%). The age and gender distribution for the participants in this study were comparable with the general population of family caregivers of PWD. According to Alzheimer Association, the majority of the family caregivers are middle-aged adults (under 35: 16%, 35-49: 17%, 50-64: 41%, 65 and older: 26%) (Alzheimer Association, 2020). Family Caregiver Alliance (2019b) reports that 75% of all family caregivers of PWD are female in the United States. There is less investigation of family caregivers of PWD in China. In Ding, Liu, Tang, and Zeng (2014)'s study in Chinese family caregivers of PWD, the mean age is 62 years old, and 66% of the family caregivers are female. Therefore, the age and gender of the family caregivers in this study were more or less comparable with family caregivers in different regions.

For the caregiving condition, according to Family Caregiver Alliance (2019b), family caregivers in the United States spend an average of 24.4 hours per week providing care, and the average duration of a caregiver's role is four years. In this study, the average duration of caregiving was 44 months (3.7 years), with 14.8 hours for providing care per day, and 5.7 days per week, which means family caregivers spend nearly 84.36 hours per week to take care of their patients.

The average duration of providing care for family caregivers in this study is higher than family caregivers in the United States. In the systematic review of BA in family caregivers in Chapter 2 (X. Y. Xu et al., 2020b), the average hours that family caregivers spend for taking PWD ranges from 4 to 11.5 hours, which is also a bit lower than the caregiving time in this study. However, in some studies which did interventions for Chinese family caregivers of PWD, the mean caregiving hours per week are similar to our study. For example, the mean caregiving hours per week is 86 in Cheng, Fung, Chan, and Lam (2016)'s study. From these findings, it can be concluded that geographical factors play a significant role in hours of care per caregiver per week among family caregivers of PWD. Chinese family caregivers generally have long hours of care per week. The comparison between demonstrated that this study result might be more suitable to be generated to the Chinese population.

Additionally, for the depression condition, since a cut-off score of ⩾16 for CCES-D was used to define clinical depression, and nearly 58% of the participants were screened with clinical depression. The prevalence of depression in this study is similar to other studies applied CES-D ⩾ 16 to define depression. For example, in Holland, Thompson, Tzuang, and Gallagher-Thompson (2010)'s study, the prevalence of depression is 46.8%. Similarly, there were 59.5% of participants had depression in McConaghy and Caltabiano (2005)'s study. Alzheimer Association (2019) reported that approximately 30 to 40 percent of family caregivers of PWD suffer from depression. Also, of clients (family caregivers of PWD) of California's Caregiver Resource Centers, nearly 60% show clinical signs of depression (Family Caregiver Alliance, 2020). There were few studies investigated the prevalence of depression among family caregivers of PWD in China. According to Zhong, Wang, and Nicholas (2020)' study, the prevalence of depressive symptoms among family caregivers of older people with disabilities (e.g., stroke, dementia) was

37.7% in urban China, and the prevalence was lower than our study. It might be because our study just included family caregivers of PWD. By comparing it with different studies and regions, the prevalence of depression in this study was similarly common.

Similarly, for the sleep condition, as poor sleeper was defined by a CPSQI global score of >5, in the baseline, there were 66% of participants defined as poor sleepers. Liu et al. (2017) investigated the prevalence of sleep disturbances in Alzheimer's disease family caregivers in China. Among 309 caregivers, 84.5% of them had sleep problems (CPSQI global score ⩾ 5), which is a bit higher than our study. According to H. L. Peng and Chang (2013)’s review, nearly 50% to 74% of family caregivers of PWD suffer from sleep disturbance. It can be concluded that there are no apparent differences in the prevalence of sleep disturbance of the participants in this study compared with general family caregivers of PWD in different countries.

7.5 Contributions to the body of knowledge

This study extends the investigations of BA to sleep in family caregivers of PWD. The systematic review and meta-analysis of BA in Chapter Two has demonstrated BA could significantly reduce depression level in family caregivers of PWD. However, none of the reviewed studies has investigated the efficacy of BA on sleep in family caregivers. Preliminary evidence has shown that BA has the potential to improve sleep quality in family caregivers of PWD. However, little evidence of the effectiveness of BA on sleep in the general population has been found. This BA protocol was found to be feasible and acceptable in Chinese family caregivers of PWD, which could give researchers new insights into the application of BA in family caregivers of PWD.

This study also extends the understanding of BA to other psychological aspects in family caregivers. For example, BA could significantly improve PAC in family caregivers. Even though keeping a high level of PAC is beneficial for keeping psychological and physical health in family caregivers, none of the reviewed studies investigated whether BA could improve PAC or not. Additionally, none of the reviewed studies examine the efficacy of BA on physical health in family caregivers. This study further adds a body of knowledge of BA on self-rated health in family caregivers of PWD.

This BA protocol was refined and standardized by the qualitative study to be culturally sensitive to suit Chinese dementia caregiving circumstances. After this pilot study, the BA protocol could be applied in large clinical settings and communities in China to support family caregivers of PWD. Furthermore, after the pilot study, this revised BA protocol can also be applied in other regions, since family caregivers around the world would share the similar experience and burden on dementia caregiving (S. W.-C. Chan, 2010).

Additionally, the telephone-based approach in this study further increases the flexibility of delivering BA in family caregivers. Even though several studies have proved it is efficient to deliver BA by telephone in the general population, few studies have investigated the efficacy of a telephone-based BA in family caregivers of PWD. As discussed before, many family caregivers were not able to get enough support from other family members and communities, so they did not have enough time to go out to participate in group courses. This telephone-based approach could make more family caregivers to get access to BA treatment easily.

7.6 Strengths and limitations

7.6.1 Strengths

This doctoral research project has several strengths in research design and implementation. Firstly, different from other BA interventions published in the current literature, this study was designed based on the MRC Framework for Developing and Evaluating Complex Interventions (Craig et al., 2008). The MRC framework provided us with a guide to ensure that the development of a complex intervention is evidence-based, and it allowed us to thoroughly examine the feasibility and acceptability of the methodological procedures before moving to the stage of the main study. The first two stages (Development, Feasibility and Piloting) were applied in this doctoral research project. The BA protocol was developed based on widely used BA theories, BA manuals, and systematic reviews to ensure the whole research plan was evidence-based. Several BA intervention protocols and books compiled by experienced clinical practitioners and psychologists were also employed to guide the development of BA intervention. One of the strengths of this study was that the development of BA protocol was evidence-based, and all of the approaches assured that the revised BA protocol could be applied in clinical practice practically and conveniently.

Secondly, to make this BA intervention culturally sensitive for Chinese family caregivers, qualitative interviews prior to the pilot study was adopted to validate the protocol further. It is worthy to note that BA focused on the psychological aspects of the Chinese family caregivers of PWD in this study. The various BA techniques were associated with participants' behaviors and thoughts, personal beliefs of caregiving roles, and the approaches to coping with caregiving. The cultural values and social notions would affect the psychological aspects and the delivery approach in psychosocial interventions (Chu, Leino, Pflum, & Sue, 2016). Therefore, It is essential to consider the cultural issues when delivering psychosocial interventions (Moodley, Gielen, & Wu, 2013), and the intervention contents should be adapted to Chinese culture. This BA intervention was provided by a Chinese Ph.D. candidate in the nursing discipline and has been trained to address the Chinese cultural issues when delivering interventions. Highlighting the Chinses cultural issues might also contribute to the effectiveness of BA in improving people's psychosocial adaptation to the impact of sleep.

Thirdly, in the second stage of the MRC framework, we combined quantitative and qualitative research to enhance the understanding and interpretation of the feasibility and acceptability outcomes. The semi-structured interviews nested within the pilot RCT further highlighted the potential factors that facilitate the participation and adherence of the pilot RCT. Furthermore, it also profoundly explored the mechanism of the treatment effects of this pilot study. The findings of this current study provided valuable implications for the implementation of the future main study on the use of BA intervention to improve sleep for Chinese family caregivers.

Fourthly, even though this pilot RCT mainly focused on testing the feasibility and acceptability of the revised BA protocol as well as the whole methodological procedures of the RCT. The effects of BA on sleep, depression, as well as other physical and psychological parts in family caregivers of PWD, were also preliminarily tested in this pilot study. These preliminary efficacy of BA provided some basic research evidence in this area and the advanced understanding of the psychotherapeutic role of BA. The interpretation of the study findings from both the perspectives of statistical importance and clinical importance enabled a comprehensive understanding of the role of BA in sleep improvement in both research and clinical settings. It provided valuable information to family caregivers and clinicians in terms of their clinical decision making on the use of BA in routine practice. However, the data analysis of this pilot study was somewhat underpowered due to the small sample size.

Fifthly, the BA intervention adopted individual telephone-based format intervention, and it saved time and energy of family caregivers to participate in a series of intervention sessions. The individual telephone-based format in our study is a feasible approach/format to be used for psychosocial interventions for family caregivers of PWD. As family caregivers were facing a tight schedule in taking care of PWD, this format has been an appropriate and useful modality for family caregivers to participate flexibly.

Lastly, the BA intervention was delivered by a nurse researcher throughout the whole study period, which could minimize the variation in the intervention delivering proves by the different interventionist, and thus improve the internal validity of the study. However, this may also reduce the intervention quality since there was much workload for one nurse researcher in the whole study period. Therefore, future studies could train more community nurses to be the interventionist for BA intervention under a uniform training process. Community nurses could expand their role in delivering psychosocial interventions for family caregivers of PWD, and they are suggested to be an appropriate health professional in delivering the BA intervention as the majority of PWD live in community settings (Prince, Comas-Herrera, Knapp, Guerchet, & Karagiannidou, 2016).

7.6.2 Limitations

1. Convenience sampling

One of the limitations of this pilot RCT was the application of convenience sampling. The convenience sampling weakened the representativeness and generalizability of research findings. Jager, Putnick, and Bornstein (2017) indicated that convenience sampling was a nonprobability sampling method that might reduce the statistical power when interpreting the outcomes to the targeted population. Additionally, even though study participants were recruited from different communities and one hospital, most participants were recruited from the hospital, which may also present a limitation in the selection of study sites.

2. Single-blinding was followed

Another limitation of this study was that participants were likely to know their treatment allocation at the post-intervention assessment, which means we only followed the single-blind in this phase of the study. The understanding of the treatment assignment could affect participants' behaviors in treatments and their response to the outcome measures (Karanicolas et al., 2010). For example, participants in the control group may not follow the study protocol if they know that they are not receiving active treatment. They will seek additional help from other resources and finally will be more likely to leave the study without providing any outcome data. For those who know they are receiving active treatment are more likely to perform better to get effective outcome data than blinded participants (K. F. Schulz & Grimes, 2002). Studies that do not follow the full blinding procedure will be more likely to provide biased measurements of the intervention effects (K. F. Schulz & Grimes, 2002).

The interventionist was not blinded, either. The blinded interventionists will be less likely to transfer their attitudes and additional knowledge to the participants than unblinded interventionists (Karanicolas et al., 2010). The unblinded participants and interventionists will increase the risk of having ascertainment and performance bias (Day & Altman, 2000). However, the nature of this pilot RCT made a complete blinding design impossible among all participants to the treatment conditions at the post-intervention measurements. Therefore, researchers should make sure that the post-intervention data could be collected as objective as possible. Furthermore, researchers could consider applying repeated measurements of study outcomes and reporting the level of agreement achieved by the assessors (Karanicolas et al., 2010).

3. Self-report outcomes

The application of the self-reported outcome measures was also one of the limitations in this pilot RCT. The sleep quality, leisure activities, and other psychological outcomes were all completed by the participants. Recall bias will be emerged from the self-reported outcome measures, and lower the reporting accuracy of patient-administered instruments, which further decrease the internal validity of the study outcomes (Rosenman, Tennekoon, & Hill, 2011). The recall bias can be affected by the study participants' characteristics and time interval for recalling. For example, participants with lower educational level or older age are more likely to commit recall inaccuracies (Geisen, Strohm, Stringer, Kopp, & Richards, 2012). Literature suggested that memory loss of older age could contribute to the inaccurate measurement and the underestimation of the subjective outcomes (Luo & Craik, 2008). Hassan (2006) suggested researchers to use data from other sources to verify the subjective data to minimize recall bias, such as using biological variables or direct observation related to the measured outcomes. Therefore, objective sleep should also be assessed in the future main study by a wrist accelerometer with a light monitor (GENEactiv original). Actigraphy can provide a non-invasive and objective method of measuring habitual sleep and activity levels in naturalistic settings by using specific scoring algorithms (Sadeh, 2011), and is comparable to PSG as a valid and reliable measure of sleep-wake parameters, particularly for sleep onset and wake times. The algorithm for analysis has been published and used to assess sleep-wake disturbance in those with and without mental health problems (van Hees et al., 2015). Total sleep time, daytime naps, and sleep fragmentation will be all measured.

The *subjective* sleep quality in family caregivers of PWD is consistently reported as poorer than it is in age and gender-matched non-caregiving controls. However, the report that the *objective* sleep in caregivers is poorer compared to non-caregiving controls is still inconsistent. Some studies have reported that low sleep quality in family caregivers of PWD has been confirmed subjectively as well as objectively (Fonareva et al., 2011; Von Känel et al., 2010). However, despite this, some studies found that there is no significant difference in objectively measured sleep between caregivers and non-caregivers even though subjective sleep is worse in caregivers. Based on these findings, caregivers' interpretations of their sleep situations might lead to misperceptions about the quality of their sleep. Therefore, both objective and subjective measures are necessary to provide a comprehensive report on sleep in family caregivers of PWD.

4. Clinical depression and/or sleep disturbance was not been listed as one of the inclusion criteria for participants in this pilot RCT.

As this study was a pilot study that aimed to test the feasibility and acceptability of conducting BA in Chinese family caregivers of PWD, and preliminarily examine the efficacy of BA on improving sleep quality and other psychological aspects, the level of clinical depression and/or sleep disturbance was not been listed as one of the inclusion criteria for participants. However, the study results may be influenced by the relatively loose inclusion criteria. To investigate a more accurate efficacy for BA on improving sleep quality, future main study should apply a more rigorous inclusion criteria by only including family caregivers with clinical depression or sleep disturbance.

5. Usual care as the control group

The application of usual care in the control group is another limitation in this study. Usual care was ‘the wide range of care that is provided in a community whether it is adequate or not, without a normative judgment’ (Dawson et al., 2009). Researchers should pay specific attention to a study that applies usual care as a control group. The major obstacle of adopting usual care is to ensure that participants in the control group could receive usual care as provided in daily practice (Barkauskas, Lusk, & Eakin, 2005). However, researchers’ various actions may affect behaviors of family caregivers and PWD. For example, the behaviors of caregivers in the control group could be induced when they were informed with the trail and asked to return informed consent, or when they were asked to complete questionnaires, and these actions will draw their attention to the possible interventions and their situations. They will finally make them change their help-seeking behaviors. It may influence the study outcome and the interpretation of the study (Smelt, van der Weele, Blom, Gussekloo, & Assendelft, 2010). Therefore, researchers should carefully consider how to minimize the influence of the study information on participants in the control group.

According to some literature, a predefined treatment protocol should be given to the participants in the control group (Godwin et al., 2003). In this way, the variations in the treatments between intervention and control groups could be easier to interpret. However, some researchers argue that the external validity could be improved by putting participants in the control group in daily practice to confront with the heterogeneity in real settings, rather than making them receive a treatment chosen by the researchers (Degenholtz, Parker, & Reynolds III, 2002; Smelt et al., 2010). It is difficult to assess the internal and external validity of the study design without complete information of the control group. Therefore, as suggested by CONSORT statement extension for pragmatic trials (Zwarenstein et al., 2008), researchers should provide a detailed description of the study design and the care provided to participants in the control group. This will allow the researcher to evaluate whether the care provided to the control group is sufficiently representative for the usual care in daily practice.

In addition, the application of usual care as control group may increase the in-person interaction effect on the efficacy of BA intervention. Since usual care did not incorporate the ingredients that are subsumed under the placebo effect (Fava, Tomba, & Bech, 2017). In the course of treating incontinence, the interventionist provided education and advice on sleep and leisure activities. The amount of contact with the interventionist, the status of the interventionist, and the quality of the relationship can influence the study outcomes. These nonspecific aspects of treatment may be helpful even if they are not regarded as part of the treatment regimen being evaluated (Whitehead, 2004). Therefore, in the future main study, we could give the similar contacts to the participants in the control group, and minimize the impact of in-person interaction on the study results.

6. Follow-up will be added in the future main study

We did not include follow-up in this study, and follow-up will be added in the future main study. Post-intervention follow up is the extended follow up, which starts from the end of the scheduled intervention period. It is important to have long term follow-up since the persistent effects can be detected after years (Heart Protection Study Collaborative Group, 2011). National Research Council (1994) explained that why it is important to evaluate the long term effects: (1) to ensure that the intervention has met the study objectives which were set out at the beginning of the study, and (2) to evaluate whether the intervention has worked or not under the frustrated social issues. As suggested by some research, sleep disturbance could be a long-lasting condition in some individuals (Lande & Gragnani, 2010). However, there is a lack of description of the longer-term prognosis of sleep disturbance, and more repeat measurements are needed. The future main study should include follow-up to test if the effects of the BA intervention on sleep quality can be maintained over time.

7.7 Implications for future study and clinical practice

7.7.1 Implications for future study

This current study demonstrated that BA was effective in improving sleep and psychological outcomes for family caregivers of PWD. The findings of this current study provided valuable implications for the implementation of the future main study on the use of BA intervention to improve sleep for Chinese family caregivers.

Firstly, different family caregivers hold various views on “Daily pleasant events tracking and mood rating form.” Some family caregivers considered to keep this recording method, and some suggested to change it to small diaries. Most of the family caregivers who suggested to change recording form to small diaries could take turns to take care of PWD, and they would have more personal time to carry out more complex tasks. Therefore, health professionals and clinical workers are recommended to work with families and friends to develop strategies to support caregivers, and design interventions based on individual demands and personal condition.

Secondly, the focus of BA intervention is to facilitate family caregivers to enact these coping skills in real-life settings (Borrelli, 2011). With the progression of dementia, family caregivers might meet various stressful situations in different stages, and we hope that these coping skills and behavior changes could last for the long term. In the future main study, a long-term observation of the participants' behavior changes is recommended to be included.

Thirdly, apart from the sleep and psychological health of family caregivers, the frequency and severity of neuropsychiatric symptoms of PWD should also be measured in the future main study by using valid instruments. As PWD's behavioral problems are also the main risk factor for sleep disturbance of their family caregivers (Cerejeira et al., 2012), examining the effects of BA on PWD could further explain the mechanism of the sleep improvement among family caregivers. Besides, for future study participants with older age and lower education level, objective measure of sleep to ensure the accuracy of the self-report data and eliminate possible recall bias induced by memory loss.

Fourthly, the control group could be designed as "waitlist control" in the future main study. "Waitlist control" means participants will receive the usual care and will later receive the intervention in addition to the usual care. There is typically a known effective therapy or a minimum level of "usual care" expected to depend upon the severity of the clinical condition

(Kinser & Robins, 2013). Therefore, it will be more ethical to offer the same treatment for participating in family caregivers.

7.7.2 Implication for clinical practice and policy

1. Generalizing BA for family caregivers of PWD in Chinese communities

It is promising to generalize BA for family caregivers of PWD in Chinese communities. This study has reported BA was feasible and acceptable to be implemented in family caregivers of PWD in China. BA also has the potential to improve sleep quality and psychological health in family caregivers.

BA has been expanded to different ethnic, racial, and gender diversity (Dimidjian et al., 2011). There has been a continuous increase in the clinical and scientific interest in BA for family caregivers in recent years. BA has also been included in the National Institute for Health and Clinical Excellence guidelines for treating depression (National Collaborating Centre for Mental, 2010). Chinese family caregivers suffered from high psychological and physical morbidity. Since in China, cultural tradition, level of economic development, and national medical care system are fostering home care for dementia, resulting in family members provide a large amount of care and support to PWD (J. Wang et al., 2014). The ‘one-child policy’ and the aging population in China multiplied the burden of adults in caring for relatives PWD. However, family caregivers are lack of support from communities. Therefore, it is necessary to implement BA in communities to improve the psychological and physical health of family caregivers of PWD in China.

BA can be delivered by more junior staff with less training, making it a cost-effective option (Ekers, Richards, McMillan, Bland, & Gilbody, 2011). More clinical staff and health professionals can be trained as BA treatment providers, which means the generalizability of BA can be broader. More family caregivers could get access and receive benefits from this cost-effective treatment.

2. Training more community nurses to be intervention providers

It is highly recommended to train community nurses as the intervention providers generate BA intervention to a larger site. As most of the family caregivers with their PWD living in the communities (Prince et al., 2016), community nurses are more accessible to family caregivers. In countries with a good system of dementia care, nurses are actively involved in the management of the disease, as well as in overseeing paid caregivers and providing family caregivers with the information they need. (Chien & Lee, 2011). By coordinating dementia interventions (e.g., residential visits and evaluations, psychoeducation schemes, telephone assistance, support groups for caregivers), nurses could help caregivers to perform their duties better and could decrease both caregiver workload and the rate of dementia patients hospitalization. (Chien & Lee, 2011; L.-Q. Wang, Chien, & Lee, 2012). In China, most health professionals working in community care centers are nurses who also interact more closely with the local community. Therefore, nurses are well-suited to manage residential care for dementia patients and to provide assistance to caregivers. (Ministry of Health, 2012). Despite this, nurses' roles are presently restricted to assisting doctors in the provision of medical treatment, and they do not enjoy much independence in fronting primary care management (Ministry of Health, 2012; Wei, Zakus, Liang, & Sun, 2005). Additionally, psychiatric, psychological, or social care services are unavailable, while the Alzheimer's Association of China does not offer dementia care services either (Alzheimer's Disease Chinese, 2012). Besides, Chinese community hospitals only keep records for diabetes, high blood pressure, stroke, coronary heart disease, and asthma, and there is no record for dementia (国家基本公共卫生服务项目管理平台, 2020). Therefore, to better serve and assist family caregivers and PWD, community hospitals are suggested to keep records for dementia.

3. Novel methods facilitated interventions are necessary

Novel methods facilitated interventions (telephone, video, internet, and bibliography) are promising and effective for family caregivers, especially those who live in rural areas and areas with limited transportation. Family caregivers of PWD usually have limited time and energy to participate in psychological treatments. However, they extremely need those treatments as they are suffering from a high psychological and physical burden, especially for Chinese family caregivers. The development of telehealth interventions easily accessible to family caregivers continue to be important and worth the sustained effort. Many studies have attempted to deliver BA in internet-based format since BA has been proved to be an evidence-based intervention with low-intensity that could be easily expanded (Huguet et al., 2018). However, no BA intervention for family caregivers has been delivered through the internet. Huguet et al. (2018) did a meta-analysis to investigate the efficacy of Internet-delivered BA, and the Internet-based BA in non-clinical settings showed promising effects in reducing depression and anxiety outcomes at post-treatment and short follow-up. BA has the potential to be a cost-effective treatment option, especially when delivered via novel formats (e.g., Internet). Early evidence suggests that the use of the Internet can reduce the therapist time in a full face-to-face BA intervention while maintaining the same treatment quality (Ly et al., 2015).

Even though individual telephone or internet-based intervention is more convenient and time-saving for family caregivers, it blocks the communication between family caregivers. Communication between caregiver and care recipients, family, other caregivers, and health care providers have a strong influence on the caregiving experience (Fletcher, Miaskowski, Given, & Schumacher, 2012). Health improvement interventions delivered in a group setting are complex adaptive social processes with interactions between the group leader, participants, and the wider community and environment (Hoddinott, Allan, Avenell, & Britten, 2010). Therefore, in the future, we could make good use of online platforms (e.g., zoom, group video through Wechat) to combine group intervention and the internet. Family caregivers could better communicate and share caregiving experience with others, and also save more time and energy through this method.

Chapter Eight: Conclusions

Sleep disturbance is a common problem in family caregivers of PWD, and it has many negative impacts on physical and psychological health not only in family caregivers but also in PWD. The individual telephone-based BA intervention in this study reported being feasible and acceptable in Chinses family caregivers of PWD. It also has a promising effect on improving sleep quality and psychosocial outcomes for family caregivers of PWD. This study pioneers a structured psychotherapeutic care program for Chinese family caregivers of PWD and filled several methodological and practical research gaps existing in the previous literature. Primarily, this study has added research evidence on the effectiveness of the BA in improving family caregivers' sleep quality and psychological health, particularly in a Chinese context. Future studies could follow this revised BA protocol to improve sleep quality and psychological health in Chinese family caregivers of PWD.

The revised individual telephone-based BA intervention protocol of this study was informed by both quantitative and qualitative evidence. The quantitative evidence was based on a systematic review and meta-analysis of BA in family caregivers of PWD. This systematic review presented the promising effects of BA on depression, as well as other psychological and physical health in family caregivers. However, no studies examined the effects of BA on sleep, and very few BA interventions were conducted within a Chinese context. The qualitative evidence was based on semi-structured interviews in 20 Chinses family caregivers of PWD, highlighting the significance of Chinese cultural values in participating in pleasant leisure activity in their caregiving lives. These cultural values, such as “filial piety” and 'fatalistic voluntarism' were applied to guide the revision of the BA protocol. Several BA therapeutic techniques were interchangeably adopted through eight BA sessions. For example, caregiving skills, daily monitoring, activity selection, activity planning, activity scheduling, and mood tracking.

A pilot study was conducted to assess the feasibility and acceptability of individual telephone-based BA intervention on 72 Chinese family caregivers of PWD. Additionally, a nested post-intervention semi-structured interview was conducted in 19 participants from the BA intervention group to explore participants' experiences of participating in the pilot RCT and receiving the BA intervention. The significant changes in participants' sleep quality, depression, leisure activities, PAC, and caregiving burden highlight the practical relevance and clinical importance of the BA intervention. The methodological procedures of applying BA to improve sleep was proved to be feasible and acceptable. The satisfactory recruitment rate and retention rate were identified during subject recruitment and the follow-up process, and good acceptability of the study questionnaires and adequate treatment adherence were also identified during the study implementation period.

This pilot RCT addressed several knowledge gaps in the literature: (1) the lack of BA interventions aiming at improving sleep quality in family caregivers of PWD; (2) the lack of interventional studies in improving physical and psychological health in family caregivers within a Chinese context, especially for the family caregivers in the mainland of China; (3) the lack of studies applying a rigorous methodology to revise BA intervention protocol to be culturally sensitive; (4) the flexibility of delivering BA by applying a relatively brief and convenient intervention (eight weekly individual telephone-based sessions). The findings of this study highlighted the importance of cultural values and pleasant leisure activity in dementia caregiving.

In conclusion, refinement of the intervention format and the various components of the BA intervention need to be considered before conducting a full RCT to confirm the effectiveness of BA intervention further. This study indicated the potential value of the integration of the BA program into routine caregiving support. Future studies should train community nurses to deliver BA during their day-to-day clinical practice.

References

Abreu, W., Tolson, D., Jackson, G. A., & Costa, N. (2020). A cross-sectional study of family caregiver burden and psychological distress linked to frailty and functional dependency of a relative with advanced dementia. *Dementia, 19*(2), 301-318.

Adams, M., Caffrey, L., & McKevitt, C. (2015). Barriers and opportunities for enhancing patient recruitment and retention in clinical research: findings from an interview study in an NHS academic health science centre. *Health Research Policy and Systems, 13*(1), 8.

Affrunti, N. W., & Creed, T. A. (2019). The factor structure of the Cognitive Therapy Rating Scale (CTRS) in a sample of community mental health clinicians. *Cognitive Therapy and Research, 43*(3), 642-655.

Alzheimer's Disease Chinese. (2012). Dementia:living together. Retrieved April 6, 2020, from http://www.adc.org.cn/html/news/mtbd_1454.shtml

Alzheimer's Disease International. (2019). Dementia statistics. Retrieved August 28, 2020, from https://www.alz.co.uk/research/statistics

Alzheimer Association. (2019). 2019 Alzheimer's disease facts and figures. Retrieved April 30, 2020, from https://www.alz.org/media/documents/alzheimers-facts-and-figures-2019-r.pdf

Alzheimer Association. (2020). Fact sheet: Alzheimer’s disease caregivers. Retrieved April 29, 2020, from https://act.alz.org/site/DocServer/caregivers_fact_sheet.pdf?docID=3022

American Psychological Association. (2011). Zarit Burden Interview. Retrieved May 20, 2020, from https://www.apa.org/pi/about/publications/caregivers/practice-settings/assessment/tools/zarit

American Psychology Association. (2016). Treatment target: Depression. Retrieved Mar 17, 2020, from https://www.div12.org/diagnosis/depression/

Aminoff, M., Boller, F., & Swaab, D. (2011). We spend about one-third of our life either sleeping or attempting to do so. *Handbook of clinical neurology, 98*, vii-vii.

Andrén, S., & Elmståhl, S. (2005). Family caregivers' subjective experiences of satisfaction in dementia care: aspects of burden, subjective health and sense of coherence. *Scandinavian Journal of Caring Sciences, 19*(2), 157-168.

Au, A. (2015). Developing volunteer-assisted behavioral activation teleprograms to meet the needs of Chinese dementia caregivers. *Clinical Gerontologist, 38*(3), 190-202.

Au, A., Gallagher-Thompson, D., Wong, M., Leung, J., Chan, W., Chan, C., . . . Chan, K. (2015). Behavioral activation for dementia caregivers: scheduling pleasant events and enhancing communications. *Clinical Interventions in Aging, 10*, 611-619.

Au, A., Yip, H.-M., Lai, S., Ngai, S., Cheng, S.-T., Losada, A., . . . Gallagher-Thompson, D. (2019). Telephone-based behavioral activation intervention for dementia family caregivers: Outcomes and mediation effect of a randomized controlled trial. *Patient Education and Counseling*.

Barkauskas, V. H., Lusk, S. L., & Eakin, B. L. (2005). Selecting control interventions for clinical outcome studies. *Western Journal of Nursing Research, 27*(3), 346-363.

Barnes, S. A., Mallinckrodt, C. H., Lindborg, S. R., & Carter, M. K. (2008). The impact of missing data and how it is handled on the rate of false‐positive results in drug development. *Pharmaceutical Statistics: The Journal of Applied Statistics in the Pharmaceutical Industry, 7*(3), 215-225.

Beaudreau, S. A., Spira, A. P., Gray, H. L., Depp, C. A., Long, J., Rothkopf, M., & Gallagher-Thompson, D. (2008). The relationship between objectively measured sleep disturbance and dementia family caregiver distress and burden. *Journal of Geriatric Psychiatry and Neurology, 21*(3), 159-165.

Bedini, L. A., & Gladwell, N. J. (2014). Caregiving as a life transition: Implications for leisure service providers. *Journal of Park and Recreation Administration, 32*(1).

Bedini, L. A., Labban, J. D., Gladwell, N. J., & Dudley, W. N. (2018). The effects of leisure on stress and health of family caregivers. *International Journal of Stress Management, 25*(S1), 43.

Beekman, A. T., de Beurs, E., van Balkom, A. J., Deeg, D. J., van Dyck, R., & van Tilburg, W. (2000). Anxiety and depression in later life: co-occurrence and communality of risk factors. *American Journal of Psychiatry, 157*(1), 89-95.

Bell, M. L., Kenward, M. G., Fairclough, D. L., & Horton, N. J. (2013). Differential dropout and bias in randomised controlled trials: when it matters and when it may not. *BMJ, 346,* e8668.

Billingham, S. A., Whitehead, A. L., & Julious, S. A. (2013). An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database. *BMC Medical Research Methodology, 13*(1), 104.

Borrelli, B. (2011). The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. *Journal of Public Health Dentistry, 71,* S52-S63.

Borrelli, B., Sepinwall, D., Ernst, D., Bellg, A. J., Czajkowski, S., Breger, R., . . . Ogedegbe, G. (2005). A new tool to assess treatment fidelity and evaluation of treatment fidelity across

10 years of health behavior research. *Journal of Consulting and Clinical Psychology, 73*(5), 852.

Bourgeois, M. S., Schulz, R., Burgio, L. D., & Beach, S. (2002). Skills training for spouses of patients with Alzheimer's disease: Outcomes of an intervention study. *Journal of Clinical Geropsychology, 8*(1), 53-73.

Bowen, D. J., Kreuter, M., Spring, B., Cofta-Woerpel, L., Linnan, L., Weiner, D., . . . Fernandez, M. (2009). How we design feasibility studies. *American Journal of Preventive Medicine, 36*(5), 452-457.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology, 3*(2), 77-101.

Brodaty, H., & Cumming, A. (2010). Dementia services in Australia. *International Journal of Geriatric Psychiatry, 25*(9), 887-995.

Brodaty, H., & Donkin, M. (2009). Family caregivers of people with dementia. *Dialogues in Clinical Neuroscience, 11*(2), 217.

Brodaty, H., Green, A., & Koschera, A. (2003). Meta‐analysis of psychosocial interventions for caregivers of people with dementia. *Journal of the American Geriatrics Society, 51*(5), 657-664.

Brookmeyer, R., Corrada, M. M., Curriero, F. C., & Kawas, C. (2002). Survival following a diagnosis of Alzheimer disease. *Archives of Neurology, 59*(11), 1764-1767.

Browne, R. H. (1995). On the use of a pilot sample for sample size determination. *Statistics in Medicine, 14*(17), 1933-1940.

Brummett, B. H., Babyak, M. A., Siegler, I. C., Vitaliano, P. P., Ballard, E. L., Gwyther, L. P., & Williams, R. B. (2006). Associations among perceptions of social support, negative affect, and quality of sleep in caregivers and noncaregivers. *Health Psychology, 25*(2), 220.

Buysse, D. J., Hall, M. L., Strollo, P. J., Kamarck, T. W., Owens, J., Lee, L., . . . Matthews, K. A. (2008). Relationships between the Pittsburgh Sleep Quality Index (PSQI), Epworth Sleepiness Scale (ESS), and clinical/polysomnographic measures in a community sample. *Journal of Clinical Sleep Medicine, 4*(06), 563-571.

Buysse, D. J., Reynolds III, C. F., Monk, T. H., Berman, S. R., & Kupfer, D. J. (1989). The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Research, 28*(2), 193-213.

Byar, D. P., Simon, R. M., Friedewald, W. T., Schlesselman, J. J., DeMets, D. L., Ellenberg, J. H., . . . Ware, J. H. (1976). Randomized clinical trials: perspectives on some recent ideas. *New England Journal of Medicine*, *295*(2), 74-80.

Carskadon, M. A., & Dement, W. C. (2005). Normal human sleep: an overview. *Principles and Practice of Sleep Medicine, 4,* 13-23.

Cartwright, J. C., Archbold, P. G., Stewart, B. J., & Limandri, B. (1994). Enrichment processes in family caregiving to frail elders. *Advances in Nursing Science*.

Castro, C. M., Lee, K. A., Bliwise, D. L., Urizar, G. G., Woodward, S. H., & King, A. C. (2009). Sleep patterns and sleep-related factors between caregiving and non-caregiving women. *Behavioral Sleep Medicine*, *7*(3), 164-179.

Cerejeira, J., Lagarto, L., & Mukaetova-Ladinska, E. (2012). Behavioral and psychological symptoms of dementia. *Frontiers in Neurology, 3*, 73.

Chambless, D. L., & Hollon, S. D. (1998). Defining empirically supported therapies. *Journal of Consulting and Clinical Psychology, 66*(1), 7.

Chan, H. Y. (2008). *The Experiences of Hong Kong Family Caregivers of Elders with Dementia: An Exploratory Study.* (Doctor of Philosiphy), Chinese University of Hong Kong, Hong Kong.

Chan, S. W.-C. (2010). Family caregiving in dementia: the Asian perspective of a global problem. *Dementia and Geriatric Cognitive Disorders, 30*(6), 469-478.

Chattillion, E. A., Ceglowski, J., Roepke, S. K., von Kanel, R., Losada, A., Mills, P. J., . . . Mausbach, B. T. (2013). Pleasant events, activity restriction, and blood pressure in dementia caregivers. *Health Psychology, 32*(7), 793-801.

Chattillion, E. A., Mausbach, B. T., Roepke, S. K., von Känel, R., Mills, P. J., Dimsdale, J. E., . . . Grant, I. (2012). Leisure activities, caregiving demands and catecholamine levels in dementia caregivers. *Psychology & Health, 27*(10), 1134-1149.

Cheng, S.-T., Fung, H. H., Chan, W. C., & Lam, L. C. (2016). Short-term effects of a gain-focused reappraisal intervention for dementia caregivers: a double-blind cluster-randomized controlled trial. *The American Journal of Geriatric Psychiatry, 24*(9), 740-750.

Chien, W. T., & Lee, I. Y. (2011). Randomized controlled trial of a dementia care programme for families of home-resided older people with dementia. *Journal of Advanced Nursing, 67*(4), 774-787.

Chin, W. Y., Choi, E. P. H., Chan, K. T. Y., & Wong, C. K. H. (2015). The psychometric properties of the center for epidemiologic studies depression scale in Chinese primary care patients: factor structure, construct validity, reliability, sensitivity and responsiveness. *PLOS ONE, 10*(8), e0135131.

Chiu, Y.-C., Lee, Y.-N., Wang, P.-C., Chang, T.-H., Li, C.-L., Hsu, W.-C., & Lee, S.-H. (2014). Family caregivers' sleep disturbance and its associations with multilevel stressors when caring for patients with dementia. *Aging & Mental Health, 18*(1), 92-101.

Chu, J., Leino, A., Pflum, S., & Sue, S. (2016). A model for the theoretical basis of cultural competency to guide psychotherapy. *Professional Psychology: Research and Practice, 47*(1), 18.

Concato, J., Shah, N., & Horwitz, R. I. (2000). Randomized, controlled trials, observational studies, and the hierarchy of research designs. *New England Journal of Medicine, 342*(25), 1887-1892.

Conde-Sala, J. L., Garre-Olmo, J., Turró-Garriga, O., Vilalta-Franch, J., & López-Pousa, S. (2010). Differential features of burden between spouse and adult-child caregivers of patients with Alzheimer's disease: An exploratory comparative design. *International Journal of Nursing Studies, 47*(10), 1262-1273.

Cook, T. D., & Campbell, D. T. (1976). The design and conduct of true experiments and quasi-experiments in field settings. In M. D. Dunnette (Ed.), Handbook of Industrial and Organizational Psychology (pp. 223-326).

Coon, D. W., Thompson, L., Steffen, A., Sorocco, K., & Gallagher-Thompson, D. (2003). Anger and depression management: psychoeducational skill training interventions for women caregivers of a relative with dementia. *The Gerontologist, 43*(5), 678-689.

Cormier, R. (1990). Sleep Disturbances. In H. Walker, W. Hall & J. Hurst (Eds.), *Clinical Methods: The History, Physical, and Laboratory Examinations.* Boston: Butterworths.

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*, *337*, a1655.

Creese, J., Bédard, M., Brazil, K., & Chambers, L. (2008). Sleep disturbances in spousal caregivers of individuals with Alzheimer's disease. *International Psychogeriatrics*, *20*(1), 149-161.

Cuijpers, P., Van Straten, A., & Warmerdam, L. (2007). Behavioral activation treatments of depression: A meta-analysis. *Clinical Psychology Review*, *27*(3), 318-326.

Cuijpers, P., van Straten, A., & Warmerdam, L. (2008). Are individual and group treatments equally effective in the treatment of depression in adults?: a meta-analysis. *The European Journal of Psychiatry*, *22*(1), 38-51.

Cupidi, C., Realmuto, S., Coco, G. L., Cinturino, A., Talamanca, S., Arnao, V., . . . Coco, D. L. (2012). Sleep quality in caregivers of patients with Alzheimer's disease and Parkinson's disease and its relationship to quality of life. *International Psychogeriatrics*, *24*(11), 1827-1835.

DaCruz, D. (2002). You have a choice, dear patient. *BMJ, 324*, 674.

Dassel, K. B., & Carr, D. C. (2016). Does Dementia Caregiving Accelerate Frailty? Findings From the Health and Retirement Study. *Gerontologist*, *56*(3), 444-450.

Dassel, K. B., Carr, D. C., & Vitaliano, P. (2017). Does Caring for a Spouse With Dementia Accelerate Cognitive Decline? Findings From the Health and Retirement Study. *Gerontologist, 57*(2), 319-328.

Daughters, S. B., Braun, A. R., Sargeant, M. N., Reynolds, E. K., Hopko, D. R., Blanco, C., & Lejuez, C. (2008). Effectiveness of a brief behavioral treatment for inner-city illicit drug users with elevated depressive symptoms: the life enhancement treatment for substance use (LETS Act!). *Journal of Clinical Psychiatry, 69*(1), 122.

Dawson, L., Zarin, D. A., Emanuel, E. J., Friedman, L. M., Chaudhari, B., & Goodman, S. N. (2009). Considering usual medical care in clinical trial design. *PLoS Medicine, 6*(9).

Day, S. J., & Altman, D. G. (2000). Blinding in clinical trials and other studies. *BMJ, 321*(7259), 504.

de Medeiros, M. M. D., Carletti, T. M., Magno, M. B., Maia, L. C., Cavalcanti, Y. W., & Rodrigues-Garcia, R. C. M. (2020). Does the institutionalization influence elderly's quality of life? A systematic review and meta–analysis. *BMC Geriatrics, 20*(1), 44.

Degenholtz, H. B., Parker, L. S., & Reynolds III, C. F. (2002). Trial design and informed consent for a clinic-based study with a treatment as usual control arm. *Ethics & Behavior, 12*(1), 43-62.

Del-Pino-Casado, R., & Ordóñez-Urbano, C. (2016). Effects of satisfaction with leisure time in family carers of elderly dependents. *Atencion Primaria, 48*(5), 295-300.

Dimidjian, S., Barrera Jr, M., Martell, C., Muñoz, R. F., & Lewinsohn, P. M. (2011). The origins and current status of behavioral activation treatments for depression. *Annual Review of Clinical Psychology, 7*, 1-38.

Ding, Y., Liu, J., Tang, F. P., & Zeng, H. (2014). Analysis of current status and influencing factors associated with the family burden of senile dementia. *Chinese General Practice, 17*(3), 256-260.

Donnellan, W. J., Bennett, K. M., & Soulsby, L. K. (2017). Family close but friends closer: exploring social support and resilience in older spousal dementia carers. *Aging & Mental Health, 21*(11), 1222-1228.

Duggleby, W., Williams, A., Wright, K., & Bollinger, S. (2009). Renewing everyday hope: the hope experience of family caregivers of persons with dementia. *Issues in Mental Health Nursing, 30*(8), 514-521.

Ekers, D., Richards, D., McMillan, D., Bland, J. M., & Gilbody, S. (2011). Behavioural activation delivered by the non-specialist: phase II randomised controlled trial. *British Journal of Psychiatry, 198*(1), 66-72.

Ekers, D., Webster, L., Van Straten, A., Cuijpers, P., Richards, D., & Gilbody, S. (2014). Behavioural activation for depression; an update of meta-analysis of effectiveness and sub group analysis. *PLOS ONE, 9*(6).

Eldridge, S. M., Lancaster, G. A., Campbell, M. J., Thabane, L., Hopewell, S., Coleman, C. L., & Bond, C. M. (2016). Defining feasibility and pilot studies in preparation for randomised controlled trials: development of a conceptual framework. *PLOS ONE, 11*(3), e0150205.

Etters, L., Goodall, D., & Harrison, B. E. (2008). Caregiver burden among dementia patient caregivers: a review of the literature. *Journal of the American Academy of Nurse Practitioners, 20*(8), 423-428.

Everitt, B. (2006). Medical Statistics from A to Z: A Guide for Clinicians and Medical Students (2nd ed.). Cambridge: Cambridge University Press.

Family Caregiver Alliance. (2019a). Caregiver statistics: Demographics. Retrieved April 29, 2020, from https://www.caregiver.org/caregiver-statistics-demographics

Family Caregiver Alliance. (2019b). Caregiver statistics: Demographics. Retrieved August 28, 2020, from https://www.caregiver.org/caregiver-statistics-demographics

Family Caregiver Alliance. (2019c). A Caregivers Bill of Rights. Retrieved November, 2019, from https://www.caregiver.org/caregiver%E2%80%99s-bill-rights

Family Caregiver Alliance. (2020). Caregiver depression: A silent health crisis. Retrieved April 30s, 2020, from https://www.caregiver.org/caregiver-depression-silent-health-crisis

Fava, G. A., Tomba, E., & Bech, P. (2017). Clinical pharmacopsychology: conceptual foundations and emerging tasks. *Psychotherapy and psychosomatics*, *86*(3), 134-140.

Ferguson, C. J. (2009). An effect size primer: A guide for clinicians and researchers. *Professional Psychology: Research and Practice, 40*(5), 532.

Flaskerud, J. H., Carter, P. A., & Lee, P. (2000). Distressing emotions in female caregivers of people with AIDS, age-related dementias, and advanced-stage cancers. *Perspectives in Psychiatric Care, 36*(4), 121-130.

Fletcher, B. S., Miaskowski, C., Given, B., & Schumacher, K. (2012). The cancer family caregiving experience: an updated and expanded conceptual model. *European Journal of Oncology Nursing*, *16*(4), 387-398.

Fonareva, I., Amen, A. M., Zajdel, D. P., Ellingson, R. M., & Oken, B. S. (2011). Assessing sleep architecture in dementia caregivers at home using an ambulatory polysomnographic system. *Journal of Geriatric Psychiatry and Neurology*, *24*(1), 50-59.

Fowler, C. N., Kott, K., Wicks, M. N., & Rutledge, C. (2016). Self-efficacy and sleep among caregivers of older adults with dementia: Effect of an interprofessional virtual healthcare neighborhood. *Journal of Gerontological Nursing*, *42*(11), 39-47.

Gallagher-Thompson, D., Solano, N., McGee, J. S., Krisztal, E., Kaye, J., Coon, D., & Thompson, L. W. (2002). Coping with caregiving: Reducing stress and improving quality of life. Retrieved May 30, 2020, from http://med.stanford.edu/oac/manuals/CWC_english/

Gao, C., Chapagain, N. Y., & Scullin, M. K. (2019). Sleep duration and sleep quality in caregivers of patients with dementia: A systematic review and meta-analysis. *JAMA Network Open, 2*(8), e199891-e199891.

García-Alberca, J. M., Lara, J. P., & Berthier, M. L. (2011). Anxiety and depression in caregivers are associated with patient and caregiver characteristics in Alzheimer's disease. *The International Journal of Psychiatry in Medicine, 41*(1), 57-69.

Gawrysiak, M., Nicholas, C., & Hopko, D. R. (2009). Behavioral activation for moderately depressed university students: Randomized controlled trial. *Journal of Counseling Psychology, 56*(3), 468.

Geisen, E., Strohm, C., Stringer, M. C., Kopp, B., & Richards, A. (2012). *Examining the relationship between the accuracy of self-reported data and the availability of respondent financial records.* Paper presented at the Annual Meeting of the American Association for Public Opinion Research, Orlando, May.

Gelfand, D. E. (2001). *Age through ethnic lenses: Caring for the elderly in a multicultural society*: Rowman & Littlefield Publishers.

Gibson, R. H., Gander, P. H., Dowell, A. C., & Jones, L. M. (2017). Non-pharmacological interventions for managing dementia-related sleep problems within community dwelling pairs: A mixed-method approach. *Dementia, 16*(8), 967-984.

Gill, P., Stewart, K., Treasure, E., & Chadwick, B. (2008). Methods of data collection in qualitative research: interviews and focus groups. *British Dental Journal, 204*(6), 291.

Glasziou, P. P., & Irwig, L. M. (1995). An evidence based approach to individualising treatment. *BMJ, 311*(7016), 1356.

Global Council on Brain Health. (2016). The brain–sleep connection: GCBH recommendations on sleep and brain health. Retrieved Mar 18, 2020, from https://www.aarp.org/content/dam/aarp/health/healthy-living/2017/01/gcbh-recommendations-sleep-and-brain-health-aarp.pdf

Godwin, M., Ruhland, L., Casson, I., MacDonald, S., Delva, D., Birtwhistle, R., . . . Seguin, R. (2003). Pragmatic controlled clinical trials in primary care: the struggle between external and internal validity. *BMC Medical Research Methodology, 3*(1), 28.

Gold, D. P., Cohen, C., Shulman, K., Zucchero, C., Andres, D., & Etezadi, J. (1995). Caregiving and dementia: Predicting negative and positive outcomes for caregivers. *The International Journal of Aging and Human Development, 41*(3), 183-201.

Gonyea, J. G., O'Connor, M. K., & Boyle, P. A. (2006). Project CARE: a randomized controlled trial of a behavioral intervention group for Alzheimer's disease caregivers. *The Gerontologist, 46*(6), 827-832.

Gupta, S. K. (2011). Intention-to-treat concept: a review. *Perspectives in Clinical Research, 2*(3), 109.

Harkins, S. W., Chapman, C. R., & Eisdorfer, C. (1979). Memory loss and response bias in senescence. *Journal of Gerontology, 34*(1), 66-72.

Harvey, A. G., & Tang, N. K. (2012). (Mis) perception of sleep in insomnia: A puzzle and a resolution. *Psychological Bulletin, 138*(1), 77.

Hassan, E. (2006). Recall bias can be a threat to retrospective and prospective research designs. *The Internet Journal of Epidemiology, 3*(2), 339-412.

Hawkley, L. C., Preacher, K. J., & Cacioppo, J. T. (2010). Loneliness impairs daytime functioning but not sleep duration. *Health Psychology, 29*(2), 124.

Haynes, R. B., Devereaux, P. J., & Guyatt, G. H. (2002). Physicians' and patients' choices in evidence based practice: Evidence does not make decisions, people do. *BMJ: British Medical Journal, 324*(7350), 1350.

Heart Protection Study Collaborative Group. (2011). Effects on 11-year mortality and morbidity of lowering LDL cholesterol with simvastatin for about 5 years in 20 536 high-risk individuals: a randomised controlled trial. *The Lancet, 378*(9808), 2013-2020.

Hellström, I., Nolan, M., & Lundh, U. (2005). 'We do things together' A case study of 'couplehood'in dementia. *Dementia, 4*(1), 7-22.

Hertzog, M. A. (2008). Considerations in determining sample size for pilot studies. *Research in Nursing & Health, 31*(2), 180-191.

Hewison, J., & Haines, A. (2006). Overcoming barriers to recruitment in health research. *BMJ, 333*(7562), 300-302.

Hilgeman, M. M., Allen, R. S., DeCoster, J., & Burgio, L. D. (2007). Positive aspects of caregiving as a moderator of treatment outcome over 12 months. *Psychology and Aging, 22*(2), 361.

Hirano, A., Suzuki, Y., Kuzuya, M., Onishi, J., Ban, N., & Umegaki, H. (2011). Influence of regular exercise on subjective sense of burden and physical symptoms in community-dwelling caregivers of dementia patients: a randomized controlled trial. *Archives of Gerontology and Geriatrics, 53*(2), e158-e163.

Hirano, A., Umegaki, H., Suzuki, Y., Hayashi, T., & Kuzuya, M. (2016). Effects of leisure activities at home on perceived care burden and the endocrine system of caregivers of dementia patients: a randomized controlled study. *International Psychogeriatrics, 28*(2), 261-268.

Hirano, A., Umegaki, H., Suzuki, Y., Hayashi, T., & Kuzuya, M. (2016). Effects of leisure activities at home on perceived care burden and the endocrine system of caregivers of dementia patients: a randomized controlled study. *International Psychogeriatrics, 28*(2), 261-268.

Ho, J. S. (2017). *Mediators and moderators of dementia caregiver depression and CVD risk outcomes in the pleasant events program.* (AAI10141809 Ph.D.), University of California, San Diego. Retrieved from https://search.proquest.com/docview/1910783698?accountid=14548

Hoddinott, P., Allan, K., Avenell, A., & Britten, J. (2010). Group interventions to improve health outcomes: a framework for their design and delivery. *BMC Public Health, 10*(1), 800.

Holland, J. M., Thompson, L. W., Tzuang, M., & Gallagher-Thompson, D. (2010). Psychosocial factors among Chinese American women dementia caregivers and their association with salivary cortisol: Results of an exploratory study. *Ageing International, 35*(2), 109-127.

Hori, H., Koga, N., Hidese, S., Nagashima, A., Kim, Y., Higuchi, T., & Kunugi, H. (2016). 24-h activity rhythm and sleep in depressed outpatients. *Journal of Psychiatric Research, 77*, 27-34.

Huang, G. D., Bull, J., McKee, K. J., Mahon, E., Harper, B., & Roberts, J. N. (2018). Clinical trials recruitment planning: a proposed framework from the clinical trials transformation initiative. *Contemporary Clinical Trials, 66*, 74-79.

Huguet, A., Miller, A., Kisely, S., Rao, S., Saadat, N., & McGrath, P. J. (2018). A systematic review and meta-analysis on the efficacy of Internet-delivered behavioral activation. *Journal of Affective Disorders, 235*, 27-38.

Irwin, M. R., Cole, J. C., & Nicassio, P. M. (2006). Comparative meta-analysis of behavioral interventions for insomnia and their efficacy in middle-aged adults and in older adults 55+ years of age. *Health Psychology, 25*(1), 3.

Jacobson, N. S., Dobson, K. S., Truax, P. A., Addis, M. E., Koerner, K., Gollan, J. K., . . . Prince, S. E. (1996). A component analysis of cognitive-behavioral treatment for depression. *Journal of Consulting and Clinical Psychology, 64*(2), 295.

Jacobson, N. S., Martell, C. R., & Dimidjian, S. (2001). Behavioral activation treatment for depression: Returning to contextual roots. *Clinical Psychology: Science and Practice, 8*(3), 255-270.

Jager, J., Putnick, D. L., & Bornstein, M. H. (2017). II. More than just convenient: The scientific merits of homogeneous convenience samples. *Monographs of the Society for Research in Child Development, 82*(2), 13-30.

Jensen, C. J., Ferrari, M., & Cavanaugh, J. C. (2004). Building on the benefits: Assessing satisfaction and well-being in elder care. *Ageing International, 29*(1), 88-110.

Jia, L., Quan, M., Fu, Y., Zhao, T., Li, Y., Wei, C., . . . Jia, J. (2020). Dementia in China: epidemiology, clinical management, and research advances. *The Lancet Neurology, 19*(1), 81-92.

Kabisch, M., Ruckes, C., Seibert-Grafe, M., & Blettner, M. (2011). Randomized controlled trials: part 17 of a series on evaluation of scientific publications. *Deutsches Ärzteblatt International, 108*(39), 663.

Kadam, R. A., Borde, S. U., Madas, S. A., Salvi, S. S., & Limaye, S. S. (2016). Challenges in recruitment and retention of clinical trial subjects. *Perspectives in Clinical Research, 7*(3), 137.

Kanter, J. W., Busch, A. M., & Rusch, L. C. (2009). The CBT distinctive features series.Behavioral activation: Distinctive features. Routledge/Taylor & Francis Group.

Kanter, J. W., Manos, R. C., Bowe, W. M., Baruch, D. E., Busch, A. M., & Rusch, L. C. (2010). What is behavioral activation?: A review of the empirical literature. *Clinical Psychology Review, 30*(6), 608-620.

Kanter, J. W., & Puspitasari, A. J. (2012). Cognitive behavior therapy: Core principles for practice (pp. 215-216). Hoboken, N.J: Wiley.

Karanicolas, P. J., Farrokhyar, F., & Bhandari, M. (2010). Blinding: Who, what, when, why, how? *Canadian Journal of Surgery, 53*(5), 345.

Khorsan, R., & Crawford, C. (2014). External validity and model validity: a conceptual approach for systematic review methodology. *Evidence-Based Complementary and Alternative Medicine, 2014*.

Kim, E.-J., & Dimsdale, J. E. (2007). The effect of psychosocial stress on sleep: a review of polysomnographic evidence. *Behavioral Sleep Medicine, 5*(4), 256-278.

Kim, H., & Rose, K. (2011). Sleep disturbances in family caregivers: an overview of the state of the science. *Archives of Psychiatric Nursing, 25*(6), 456-468.

Kim, M.-D., Hong, S.-C., Lee, C.-I., Kim, S.-Y., Kang, I.-O., & Lee, S.-Y. (2009). Caregiver burden among caregivers of Koreans with dementia. *Gerontology, 55*(1), 106-113.

King, A. C., Baumann, K., O'Sullivan, P., Wilcox, S., & Castro, C. (2002). Effects of moderate-intensity exercise on physiological, behavioral, and emotional responses to family caregiving: a randomized controlled trial. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences, 57*(1), M26-M36.

Kinser, P. A., & Robins, J. L. (2013). Control group design: enhancing rigor in research of mind-body therapies for depression. *Evidence-Based Complementary and Alternative Medicine, 2013*.

Kline, C. (2013). Sleep Quality. In M. D. Gellman & J. R. Turner (Eds.), *Encyclopedia of behavioral medicine* (pp. 1811-1813). New York, NY: Springer New York.

Ko, K.-T., Yip, P.-K., Liu, S.-I., & Huang, C.-R. (2008). Chinese version of the Zarit Caregiver Burden Interview: a validation study. *The American Journal of Geriatric Psychiatry, 16*(6), 513-518.

Kochar, J., Fredman, L., Stone, K. L., Cauley, J. A., & Fractures, S. o. O. (2007). Sleep problems in elderly women caregivers depend on the level of depressive symptoms: Results of the Caregiver–Study of Osteoporotic Fractures. *Journal of the American Geriatrics Society, 55*(12), 2003-2009.

Korn, L., Logsdon, R. G., Polissar, N. L., Gomez-Beloz, A., Waters, T., & Rÿser, R. (2009). A randomized trial of a CAM therapy for stress reduction in American Indian and Alaskan Native family caregivers. *The Gerontologist, 49*(3), 368-377.

Krueger, C., & Tian, L. (2004). A comparison of the general linear mixed model and repeated measures ANOVA using a dataset with multiple missing data points. *Biological Research for Nursing, 6*(2), 151-157.

Krueger, R. A., & Casey, M. A. (2002). Designing and conducting focus group interviews. Retrieved May 28, 2020, from http://www.eiu/~ihec/Krueger-FocusGroupInterviews.pdf

Kryger, M., Roth, G., Eloni, D., & Dement, W. (2005). *Principles and practice of sleep medicine*. New York: WB Saunders Co Google Scholar.

Kuo, L. M., Huang, H. L., Huang, H. L., Liang, J., Chiu, Y. C., Chen, S. T., . . . Shyu, Y. I. L. (2013). A home-based training program improves Taiwanese family caregivers' quality of life and decreases their risk for depression: a randomized controlled trial. *International Journal of Geriatric Psychiatry, 28*(5), 504-513.

Lachin, J. M. (2016). Fallacies of last observation carried forward analyses. *Clinical Trials, 13*(2), 161-168.

Lai, D. W. (2010). Filial piety, caregiving appraisal, and caregiving burden. *Research on Aging, 32*(2), 200-223.

Lande, R. G., & Gragnani, C. (2010). Nonpharmacologic approaches to the management of insomnia. *The Journal of the American Osteopathic Association, 110*(12), 695-701.

Larkin, J. P., & Hopcroft, B. M. (1993). In-hospital respite as a moderator of caregiver stress. *Health & Social Work, 18*(2), 132-138.

LaRue, A., Bank, L., Jarvik, U., & Hetland, M. (1979). Health in old age: how do physicians' ratings and self-ratings compare? *Journal of Gerontology, 34*(5), 687-691.

Lee, D. (2008). Health-related quality of life in dementia caregiving: relationships with sleep quality and daytime sleepiness. *Primary Care & Community Psychiatry, 13*(3), 119-125.

Lee, D., Heo, S. H., Yoon, S.-S., Chang, D.-I., Lee, S., Rhee, H.-Y., . . . Park, K.-C. (2014). Sleep disturbances and predictive factors in caregivers of patients with mild cognitive impairment and dementia. *Journal of Clinical Neurology, 10*(4), 304-313.

Lee, D., Morgan, K., & Lindesay, J. (2007). Effect of institutional respite care on the sleep of people with dementia and their primary caregivers. *Journal of the American Geriatrics Society, 55*(2), 252-258.

Lee, L., Hillier, L. M., Stolee, P., Heckman, G., Gagnon, M., McAiney, C. A., & Harvey, D. (2010). Enhancing dementia care: a primary care–based memory clinic. *Journal of the American Geriatrics Society, 58*(11), 2197-2204.

Lee, M., Ryoo, J. H., Chung, M., Anderson, J. G., Rose, K., & Williams, I. C. (2019). Effective interventions for depressive symptoms among caregivers of people with dementia: A systematic review and meta-analysis. *Dementia*, 1471301218822640.

Lejuez, C., Hopko, D. R., Acierno, R., Daughters, S. B., & Pagoto, S. L. (2011). Ten year revision of the brief behavioral activation treatment for depression: revised treatment manual. *Behavior Modification, 35*(2), 111-161.

Lejuez, C. W., Hopko, D. R., & Hopko, S. D. (2001). A brief behavioral activation treatment for depression: Treatment manual. *Behavior Modification, 25*(2), 255-286.

Leon, A. C., Davis, L. L., & Kraemer, H. C. (2011). The role and interpretation of pilot studies in clinical research. *Journal of Psychiatric Research, 45*(5), 626-629.

Leung, F. W., & Rao, S. S. (2009). Fecal incontinence in the elderly. *Gastroenterol Clin North Am, 38*(3), 503-511.

Levin, K. A. (2007). Study design VII. Randomised controlled trials. *Evidence-Based Dentistry, 8*(1), 22.

Lewinsohn, P. M. (1974). A behavioral approach to depression. *Essential Papers on Depression*, 150-172.

Lewinsohn, P. M., & Graf, M. (1973). Pleasant activities and depression. *Journal of Consulting and Clinical Psychology, 41*(2), 261.

Lewinsohn, P. M., Sullivan, J. M., & Grosscup, S. J. (1980). Changing reinforcing events: an approach to the treatment of depression. *Psychotherapy: Theory, Research & Practice, 17*(3), 322.

Li, Z., & Zhang, R. (2007). Reliability and validity of Chinese version of Positive Aspects of Caregiving. *Chinese Journal of Nursing, 42*(12), 1068.

Lilly, M. L., Richards, B. S., & Buckwalter, K. C. (2003). Friends and social support in dementia caregiving: Assessment and intervention. *Journal of Gerontological Nursing, 29*(1), 29-36.

Lim, J., Griva, K., Goh, J., Chionh, H. L., & Yap, P. (2011). Coping strategies influence caregiver outcomes among Asian family caregivers of persons with dementia in Singapore. *Alzheimer Disease & Associated Disorders, 25*(1), 34-41.

Lim, M. M., Gerstner, J. R., & Holtzman, D. M. (2014). The sleep–wake cycle and Alzheimer's disease: what do we know? *Neurodegenerative disease management, 4*(5), 351-362.

Lip, G. Y., & Blann, A. (1997). von Willebrand factor: a marker of endothelial dysfunction in vascular disorders? *Cardiovascular Research, 34*(2), 255-265.

Liu, S., Li, C., Shi, Z., Wang, X., Zhou, Y., Liu, S., . . . Ji, Y. (2017). Caregiver burden and prevalence of depression, anxiety and sleep disturbances in Alzheimer's disease caregivers in China. *Journal of Clinical Nursing, 26*(9-10), 1291-1300.

Losada, A., Márquez‐González, M., & Romero‐Moreno, R. (2011). Mechanisms of action of a psychological intervention for dementia caregivers: effects of behavioral activation and modification of dysfunctional thoughts. *International Journal of Geriatric Psychiatry, 26*(11), 1119-1127.

Lou, V. W., Lau, B. H.-P., & Cheung, K. S.-L. (2015). Positive aspects of caregiving (PAC): Scale validation among Chinese dementia caregivers (CG). *Archives of Gerontology and Geriatrics, 60*(2), 299-306.

Luik, A. I., Zuurbier, L. A., Direk, N., Hofman, A., Van Someren, E. J., & Tiemeier, H. (2015). 24-hour activity rhythm and sleep disturbances in depression and anxiety: A population-based study of middle-aged and older persons. *Depression and Anxiety, 32*(9), 684-692.

Luo, L., & Craik, F. I. (2008). Aging and memory: A cognitive approach. *The Canadian Journal of Psychiatry, 53*(6), 346-353.

Ly, K. H., Topooco, N., Cederlund, H., Wallin, A., Bergström, J., Molander, O., . . . Andersson, G. (2015). Smartphone-supported versus full behavioural activation for depression: a randomised controlled trial. *PLOS ONE, 10*(5).

Márquez-González, M., Losada, A., Izal, M., Pérez-Rojo, G., & Montorio, I. (2007). Modification of dysfunctional thoughts about caregiving in dementia family caregivers: Description and outcomes of an intervention programme. *Aging & Mental Health, 11*(6), 616-625.

Ma, Y., Mazumdar, M., & Memtsoudis, S. G. (2012). Beyond repeated-measures analysis of variance: advanced statistical methods for the analysis of longitudinal data in anesthesia research. *Regional Anesthesia & Pain Medicine, 37*(1), 99-105.

MacPherson, L., Tull, M. T., Matusiewicz, A. K., Rodman, S., Strong, D. R., Kahler, C. W., . . . Lejuez, C. (2010). Randomized controlled trial of behavioral activation smoking cessation treatment for smokers with elevated depressive symptoms. *Journal of Consulting and Clinical Psychology, 78*(1), 55.

MacPhillamy, D. J., & Lewinsohn, P. M. (1974). Depression as a function of levels of desired and obtained pleasure. *Journal of Abnormal Psychology, 83*(6), 651.

MacPhillamy, D. J., & Lewinsohn, P. M. (1982). The pleasant events schedule: Studies on reliability, validity, and scale intercorrelation. *Journal of Consulting and Clinical Psychology, 50*(3), 363.

Maggio, M., Guralnik, J. M., Longo, D. L., & Ferrucci, L. (2006). Interleukin-6 in aging and chronic disease: a magnificent pathway. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences, 61*(6), 575-584.

Maglione, J. E., Ancoli-Israel, S., Peters, K. W., Paudel, M. L., Yaffe, K., Ensrud, K. E., . . . Group, S. o. O. F. R. (2014). Depressive symptoms and circadian activity rhythm disturbances in community-dwelling older women. *The American Journal of Geriatric Psychiatry, 22*(4), 349-361.

Mahoney, D. F. (2003). Vigilance: evolution and definition for caregivers of family members with Alzheimer's disease. *Journal of Gerontological Nursing, 29*(8), 24-30.

Mallinckrodt, C. H., Sanger, T. M., Dubé, S., DeBrota, D. J., Molenberghs, G., Carroll, R. J., . . . Tollefson, G. D. (2003). Assessing and interpreting treatment effects in longitudinal clinical trials with missing data. *Biological Psychiatry, 53*(8), 754-760.

Mandani, B., Hosseini, S. A., Hosseini, M. A., Noori, A. K., & Ardakani, M. R. K. (2018). Perception of family caregivers about barriers of leisure in care of individuals with chronic psychiatric disorders: a qualitative study. *Electronic Physician, 10*(3), 6516.

Markarian, S. A., Pickett, S. M., Deveson, D. F., & Kanona, B. B. (2013). A model of BIS/BAS sensitivity, emotion regulation difficulties, and depression, anxiety, and stress symptoms in relation to sleep quality. *Psychiatry Research, 210*(1), 281-286.

Markowitz, J. C. (2003). Depression in context: Strategies for guided action. *American Journal of Psychiatry, 160*(7), 1366-1366.

Martell, C. R., Dimidjian, S., & Herman-Dunn, R. (2013). *Behavioral activation for depression: A clinician's guide*. New York: Guilford Press.

Mausbach, B. T., Ancoli-Israel, S., von Känel, R., Patterson, T. L., Aschbacher, K., Mills, P. J., . . . Grant, I. (2006). Sleep disturbance, norepinephrine, and D-Dimer are all related in elderly care-givers of people with alzheimer disease. *Sleep, 29*(10), 1347-1352.

Mausbach, B. T., Chattillion, E., Roepke, S. K., Ziegler, M. G., Milic, M., von Känel, R., . . . Grant, I. (2012). A longitudinal analysis of the relations among stress, depressive symptoms, leisure satisfaction, and endothelial function in caregivers. *Health Psychology, 31*(4), 433-440.

Mausbach, B. T., Coon, D. W., Depp, C., Rabinowitz, Y. G., Wilson-Arias, E., Kraemer, H. C., . . . Gallagher-Thompson, D. (2004). Ethnicity and time to institutionalization of dementia patients: a comparison of Latina and Caucasian female family caregivers. *Journal of the American Geriatrics Society, 52*(7), 1077-1084.

Mausbach, B. T., Patterson, T. L., Grant, I., Mausbach, B. T., Patterson, T. L., & Grant, I. (2008). Is depression in Alzheimer's caregivers really due to activity restriction? A preliminary mediational test of the Activity Restriction Model. *Journal of Behavior Therapy & Experimental Psychiatry, 39*(4), 459-466.

Mausbach, B. T., Roepke, S. K., Depp, C. A., Moore, R., Patterson, T. L., & Grant, I. (2011). Integration of the pleasant events and activity restriction models: Development and validation of a “PEAR” model of negative outcomes in Alzheimer's caregivers. *Behavior Therapy, 42*(1), 78-88.

Mausbach, B. T., Romero-Moreno, R., Bos, T., von Känel, R., Ziegler, M. G., Allison, M. A., . . . Grant, I. (2017). Engagement in pleasant leisure activities and blood pressure: A 5-year longitudinal study in Alzheimer caregivers. *Psychosomatic Medicine, 79*(7), 735-741.

Mazzucchelli, T. G., Kane, R. T., & Rees, C. S. (2009). Behavioral activation treatments for depression in adults: a meta‐analysis and review. *Clinical Psychology: Science and Practice*, *16*(4), 383-411.

Mazzucchelli, T. G., Kane, R. T., & Rees, C. S. (2010). Behavioral activation interventions for well-being: A meta-analysis. *The Journal of Positive Psychology, 5*(2), 105-121.

McCabe, M., You, E., & Tatangelo, G. (2016). Hearing their voice: a systematic review of dementia family caregivers' needs. *The Gerontologist, 56*(5), e70-e88.

McCall, W. V. (2005). Diagnosis and management of insomnia in older people. *Journal of the American Geriatrics Society, 53*(S7), S272-S277.

McConaghy, R., & Caltabiano, M. L. (2005). Caring for a person with dementia: Exploring relationships between perceived burden, depression, coping and well‐being. *Nursing & Health Sciences, 7*(2), 81-91.

McCurry, S., Gibbons, L., Logsdon, R., & Teri, L. (2004). *Longitudinal changes in sleep and psychosocial function in Alzheimer's patients and family caregivers.* Paper presented at the Sleep (Vol. 27, pp. 121-121).

McCurry, S. M., Logsdon, R. G., Teri, L., & Vitiello, M. V. (2007). Sleep disturbances in caregivers of persons with dementia: contributing factors and treatment implications. *Sleep Medicine Reviews, 11*(2), 143-153.

McCurry, S. M., Pike, K. C., Vitiello, M. V., Logsdon, R. G., & Teri, L. (2008). Factors associated with concordance and variability of sleep quality in persons with Alzheimer's disease and their caregivers. *Sleep, 31*(5), 741-748.

McCurry, S. M., & Teri, L. (1996). Sleep disturbance in elderly caregivers of dementia patients. *Clinical Gerontologist, 16*(2), 51-66.

McKibbin, C. L., Ancoli-Israel, S., Dimsdale, J., Archuleta, C., von Kanel, R., Mills, P., . . . Grant, I. (2005). Sleep in spousal caregivers of people with Alzheimer's disease. *Sleep, 28*(10), 1245-1250.

Medic, G., Wille, M., & Hemels, M. E. (2017). Short- and long-term health consequences of sleep disruption. *Nature and science of sleep, 9*, 151-161.

Melvin, G. A., & Molloy, G. N. (2000). Some psychometric properties of the Positive and Negative Affect Schedule among Australian youth. *Psychological Reports, 86*(3_suppl), 1209-1212.

Mills, E. J., Seely, D., Rachlis, B., Griffith, L., Wu, P., Wilson, K., . . . Wright, J. R. (2006). Barriers to participation in clinical trials of cancer: a meta-analysis and systematic review of patient-reported factors. *The Lancet Oncology, 7*(2), 141-148.

Mills, P. J., Ancoli-Israel, S., von Känel, R., Mausbach, B. T., Aschbacher, K., Patterson, T. L., . . . Grant, I. (2009). Effects of gender and dementia severity on Alzheimer’s disease caregivers’ sleep and biomarkers of coagulation and inflammation. *Brain, Behavior, and Immunity, 23*(5), 605-610.

Ministry of Health. (2012). Current situation on seniors health issue in China. . Retrieved April 6, 2020, from http://www.cncaprc.gov.cn/tongji/19409.jhtml

Ministry of Human Resources and Social Security. (2009). Medicine catalogue for the national basic medical insurance, work - related injury insurance and maternity insurance.

Retrieved April 6, 2020, from http://news.pharmnet.com.cn/news/2009/12/01/284566.html

Moher, D., Shamseer, L., Clarke, M., Ghersi, D., Liberati, A., Petticrew, M., . . . Stewart, L. A. (2015). Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews, 4*(1), 1.

Moncher, F. J., & Prinz, R. J. (1991). Treatment fidelity in outcome studies. *Clinical Psychology Review, 11*(3), 247-266.

Montgomery, P., & Dennis, J. (2004). A systematic review of non-pharmacological therapies for sleep problems in later life. *Sleep Medicine Reviews, 8*(1), 47-62.

Moodley, R., Gielen, U. P., & Wu, R. (2013). *Handbook of counseling and psychotherapy in an international context*: Routledge.

Moore, R. C., Chattillion, E. A., Ceglowski, J., Ho, J., von Känel, R., Mills, P. J., . . . Mausbach, B. T. (2013). A randomized clinical trial of Behavioral Activation (BA) therapy for improving psychological and physical health in dementia caregivers: Results of the Pleasant Events Program (PEP). *Behaviour Research and Therapy, 51*(10), 623-632.

Moore, R. C., Harmell, A. L., Chattillion, E., Ancoli-Israel, S., Grant, I., & Mausbach, B. T. (2011). PEAR model and sleep outcomes in dementia caregivers: influence of activity restriction and pleasant events on sleep disturbances. *International Psychogeriatrics, 23*(9), 1462-1469.

Morano, C. L. (2000). Comparative analysis of a moderating and mediating model of stress, appraisal, and coping in Hispanic and non-Hispanic Alzheimer's disease caregivers. *ProQuest ETD Collection for FIU*, AAI9949326.

National Collaborating Centre for Mental, H. (2010). National Institute for Health and Clinical Excellence: Guidance *Depression: The Treatment and Management of Depression in Adults (Updated Edition)*. Leicester (UK): British Psychological Society

National Institute of Health. (2020). Sleep deprivation and deficiency. Retrieved June 16, 2020, from https://www.nhlbi.nih.gov/health-topics/sleep-deprivation-and-deficiency

National Research Council. (1994). *Information systems and measurement for assessing program effects: Implications for family planning programs in developing countries*. Washington, DC: The National Academies Press.

Newington, L., & Metcalfe, A. (2014). Factors influencing recruitment to research: qualitative study of the experiences and perceptions of research teams. *BMC Medical Research Methodology*, *14*(1), 10.

Noonan, A. E., Tennstedt, S. L., & Rebelsky, F. G. (1996). Making the best of it: Themes of meaning among informal caregivers to the elderly. *Journal of Aging Studies, 10*(4), 313-327.

Norlander, T., Johansson, Å., & Bood, S. Å. (2005). The affective personality: Its relation to quality of sleep, well-being and stress. *Social Behavior and Personality: An International Journal, 33*(7), 709-722.

North, R. J., Holahan, C. J., Moos, R. H., & Cronkite, R. C. (2008). Family support, family income, and happiness: a 10-year perspective. *Journal of Family Psychology*, *22*(3), 475.

O'Donohue, W. T., & Fisher, J. E. (2012). *Cognitive behavior therapy: Core principles for practice*: John Wiley & Sons.

Ong, A. D., Kim, S., Young, S., & Steptoe, A. (2017). Positive affect and sleep: A systematic review. *Sleep Medicine Reviews, 35,* 21-32.

Oregon Department of Human Services (DHS). (2013). Family Caregiver Handbook. Retrieved from https://adrcoforegon.org/forms/Family%20Caregiver%20Handbook%20Final.pdf?t=Family%20Caregiver%20Handbook

Orgeta, V., Brede, J., & Livingston, G. (2017). Behavioural activation for depression in older people: systematic review and meta-analysis. *The British Journal of Psychiatry, 211*(5), 274-279.

Ory, M. G., Hoffman III, R. R., Yee, J. L., Tennstedt, S., & Schulz, R. (1999). Prevalence and impact of caregiving: a detailed comparison between dementia and nondementia caregivers. *The Gerontologist, 39*(2), 177-186.

Pearson, N. (1988). An assessment of relief hospital admissions for elderly patients with dementia. *Health Trends, 20*(4), 120-121.

Peng, H.-L., Lorenz, R. A., & Chang, Y.-P. (2019). Factors associated with sleep in family caregivers of individuals with dementia. *Perspectives in Psychiatric Care, 55*(1), 95-102.

Peng, H. L., & Chang, Y. P. (2013). Sleep disturbance in family caregivers of individuals with dementia: a review of the literature. *Perspectives in Psychiatric Care, 49*(2), 135-146.

Perry, J., & Bontinen, K. (2001). Evaluation of a weekend respite program for persons with Alzheimer disease. *The Canadian Journal of Nursing Research, 33*(1), 81-95.

Pinquart, M., & Sörensen, S. (2003). Associations of stressors and uplifts of caregiving with caregiver burden and depressive mood: a meta-analysis. *The Journals of Gerontology Series B: Psychological Sciences and Social Sciences, 58*(2), P112-P128.

Pinquart, M., Sörensen, S., Pinquart, M., & Sörensen, S. (2006). Helping caregivers of persons with dementia: which interventions work and how large are their effects? *International Psychogeriatrics, 18*(4), 577-595.

Pollak, C. P., & Stokes, P. E. (1997). Circadian rest‐activity rhythms in demented and nondemented older community residents and their caregivers. *Journal of the American Geriatrics Society, 45*(4), 446-452.

Pope, C., & Mays, N. (1999). *Qualitative research in health care*. London, UK: BMJ books

Portney, L. G., & Watkins, M. P. (2000). *Foundations of clinical research: applications to practice* (3rd ed.): F. A. Davis Company.

Pribulick, M., Willams, I. C., & Fahs, P. S. (2010). Strategies to reduce barriers to recruitment and participation. *Online Journal of Rural Nursing and Health Care, 10*(1), 22-33.

Prick, A.-E., de Lange, J., Twisk, J., & Pot, A. M. (2015). The effects of a multi-component dyadic intervention on the psychological distress of family caregivers providing care to people with dementia: a randomized controlled trial. *International Psychogeriatrics, 27*(12), 2031-2044.

Prince, M., Brodaty, H., Uwakwe, R., Acosta, D., Ferri, C. P., Guerra, M., . . . Salas, A. (2012). Strain and its correlates among carers of people with dementia in low‐income and middle‐income countries. A 10/66 Dementia Research Group population‐based survey. *International Journal of Geriatric Psychiatry, 27*(7), 670-682.

Prince, M., Comas-Herrera, A., Knapp, M., Guerchet, M., & Karagiannidou, M. (2016). World Alzheimer report 2016: improving healthcare for people living with dementia: coverage, quality and costs now and in the future. London, UK: Alzheimer’s Disease International.

Prince, M., Guerchet, M., & Prina, M. (2013). Policy brief for heads of government: the global impact of dementia 2013-2050. London: Alzheimer's Disease International.

Radloff, L. S. (1977). The CES-D scale: A self-report depression scale for research in the general population. *AppliedC Psychological Measurement, 1*(3), 385-401.

Rakowski, W., Fleishman, J. A., Mor, V., & Bryant, S. A. (1993). Self-assessments of health and mortality among older persons: Do questions other than global self-rated health predict mortality? *Research on Aging, 15*(1), 92-116.

Reed, D. L., & Sacco, W. P. (2016). Measuring Sleep Efficiency: What Should the Denominator Be? *Journal of Clinical Sleep Medicine, 12*(2), 263-266.

Riedel, B. W., & Lichstein, K. L. (2000). Insomnia and daytime functioning. *Sleep Medicine Reviews, 4*(3), 277-298.

Roberts, J., & Dicenso, A. (1999). Identifying the best research design to fit the question. Part 1: quantitative designs. *Evidence-Based Nursing, 2*(1), 4-6.

Roland, M., & Torgerson, D. J. (1998). Understanding controlled trials: What are pragmatic trials? *British Medical Journal, 316*(7127), 285.

Romero-Moreno, R., Ḿrquez-Gonźlez, M., Mausbach, B. T., & Losada, A. (2012). Variables modulating depression in dementia caregivers: A longitudinal study. *International Psychogeriatrics*, *24*(8), 1316-1324.

Rosenman, R., Tennekoon, V., & Hill, L. G. (2011). Measuring bias in self-reported data. *International Journal of Behavioural & Healthcare Research, 2*(4), 320.

Rowe, M. A., Kairalla, J. A., & McCrae, C. S. (2010). Sleep in dementia caregivers and the effect of a nighttime monitoring system. *Journal of Nursing Scholarship, 42*(3), 338-347.

Rowe, M. A., McCrae, C. S., Campbell, J. M., Benito, A. P., & Cheng, J. (2008). Sleep pattern differences between older adult dementia caregivers and older adult noncaregivers using objective and subjective measures. *Journal of Clinical Sleep Medicine, 4*(04), 362-369.

Rowe, M. A., Vandeveer, S. S., Greenblum, C. A., List, C. N., Fernandez, R. M., Mixson, N. E., & Ahn, H. C. (2011). Persons with dementia missing in the community: Is it wandering or something unique? *BMC Geriatrics, 11*(1), 28.

Ruckmani, A., & Vishaly, S. (2012). Assessment of barriers in subject recruitment for clinical trials. *Journal of Clinical Research & Bioethics, 3*, 1.

Sadeh, A. (2011). The role and validity of actigraphy in sleep medicine: an update. *Sleep Medicine Reviews, 15*(4), 259-267.

Schneeweiss, S. (2006). Sensitivity analysis and external adjustment for unmeasured confounders in epidemiologic database studies of therapeutics. *Pharmacoepidemiology and Drug Safety, 15*(5), 291-303.

Schneider, J., Murray, J., Banerjee, S., & Mann, A. (1999). EUROCARE: a cross‐national study of co‐resident spouse carers for people with Alzheimer's disease: I—factors associated with carer burden. *International Journal of Geriatric Psychiatry, 14*(8), 651-661.

Schulz, K. F., & Grimes, D. A. (2002). Blinding in randomised trials: hiding who got what. *The Lancet, 359*(9307), 696-700.

Schulz, R., Belle, S. H., Czaja, S. J., McGinnis, K. A., Stevens, A., & Zhang, S. (2004). Long-term care placement of dementia patients and caregiver health and well-being. *JAMA, 292*(8), 961-967.

Semler, C. N., & Harvey, A. G. (2005). Misperception of sleep can adversely affect daytime functioning in insomnia. *Behaviour Research and Therapy, 43*(7), 843-856.

Shafer, A. B. (2006). Meta-analysis of the factor structures of four depression questionnaires: Beck, CES-D, Hamilton, and Zung. *Journal of Clinical Psychology, 62*(1), 123-146.

Shao, J., & Zhong, B. (2003). Last observation carry-forward and last observation analysis. *Statistics in Medicine, 22*(15), 2429-2441.

Shaw, B. F., Elkin, I., Yamaguchi, J., Olmsted, M., Vallis, T. M., Dobson, K. S., . . . Imber, S. D. (1999). Therapist competence ratings in relation to clinical outcome in cognitive therapy of depression. *Journal of consulting and clinical psychology, 67*(6), 837.

Shrivastava, D., Jung, S., Saadat, M., Sirohi, R., & Crewson, K. (2014). How to interpret the results of a sleep study. *Journal of Community Hospital Internal Medicine Perspectives, 4*(5), 24983.

Siemens, I., & Hazelton, L. (2011). Communicating with families of dementia patients: Practical guide to relieving caregiver stress. *Canadian Family Physician, 57*(7), 801-802.

Signe, A., & Elmståhl, S. (2008). Psychosocial intervention for family caregivers of people with dementia reduces caregiver's burden: development and effect after 6 and 12 months. *Scandinavian Journal of Caring Sciences, 22*(1), 98-109.

Simón, M. A., Bueno, A. M., Otero, P., Blanco, V., & Vázquez, F. L. (2019). Insomnia in female family caregivers of totally dependent patients with dementia: An exploratory study. *Psicología Conductual, 27*(1), 107-119.

Simpson, C., & Carter, P. (2013). Dementia behavioural and psychiatric symptoms: effect on caregiver's sleep. *Journal of Clinical Nursing, 22*(21-22), 3042-3052.

Simpson, C., & Carter, P. A. (2010). Pilot study of a brief behavioral sleep intervention for caregivers of individuals with dementia. *Research in Gerontological Nursing, 3*(1), 19-29.

Skinner, B. F. (1953). *Science and human behavior*. New York Simon and Schuster.

Smelt, A. F., van der Weele, G. M., Blom, J. W., Gussekloo, J., & Assendelft, W. J. (2010). How usual is usual care in pragmatic intervention studies in primary care? An overview of recent trials. *British Journal of General Practice, 60*(576), e305-e318.

Spielman, A. J. (1986). Assessment of insomnia. *Clinical Psychology Review, 6*(1), 11-25.

Spira, A. P., Friedman, L., Beaudreau, S. A., Ancoli-Israel, S., Hernandez, B., Sheikh, J., & Yesavage, J. (2010). Sleep and physical functioning in family caregivers of older adults with memory impairment. *International Psychogeriatrics, 22*(2), 306-311.

Springate, B. A., & Tremont, G. (2014). Dimensions of caregiver burden in dementia: impact of demographic, mood, and care recipient variables. *The American Journal of Geriatric Psychiatry, 22*(3), 294-300.

Stanford Geriatric Education Center. (2020). Request training materials for using Behavioral Activation to reduce depression in older adults,. Retrieved May 27th, 2020, from https://sgec.stanford.edu/resources/training/behavior-activation.html

Stanford Medicine. (2017). Coping with caregiving. Retrieved August 10, 2018, from http://med.stanford.edu/oac/manuals/CWC_english.html

Steffen, A. M. (2000). Anger management for dementia caregivers: A preliminary study using video and telephone interventions. *Behavior Therapy, 31*(2), 281-299.

Steffen, A. M., & Gant, J. R. (2016). A telehealth behavioral coaching intervention for neurocognitive disorder family carers. *International Journal of Geriatric Psychiatry, 31*(2), 195-203.

Stepanski, E. J., & Wyatt, J. K. (2003). Use of sleep hygiene in the treatment of insomnia. *Sleep Medicine Reviews, 7*(3), 215-225.

Stevens, J. P. (2012). Analysis of covariance *Applied Multivariate Statistics for the Social Sciences, Fifth Edition* (pp. 299-326): Routledge.

Suresh, K. (2011). An overview of randomization techniques: an unbiased assessment of outcome in clinical research. *Journal of Human Reproductive Sciences, 4*(1), 8.

Tarlow, B. J., Wisniewski, S. R., Belle, S. H., Rubert, M., Ory, M. G., & Gallagher-Thompson, D. (2004). Positive aspects of caregiving: Contributions of the REACH project to the development of new measures for Alzheimer's caregiving. *Research on Aging, 26*(4), 429-453.

Taylor, R. J., Chatters, L. M., Woodward, A. T., & Brown, E. (2013). Racial and ethnic differences in extended family, friendship, fictive kin, and congregational informal support networks. *Family Relations, 62*(4), 609-624.

Teri, L., Gibbons, L. E., McCurry, S. M., Logsdon, R. G., Buchner, D. M., Barlow, W. E., . . . Larson, E. B. (2003). Exercise plus behavioral management in patients with Alzheimer disease: a randomized controlled trial. *JAMA, 290*(15), 2015-2022.

Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L. P., . . . Goldsmith, C. H. (2010). A tutorial on pilot studies: the what, why and how. *BMC Medical Research Methodology, 10*(1), 1.

Thabane, L., Mbuagbaw, L., Zhang, S., Samaan, Z., Marcucci, M., Ye, C., . . . Kosa, D. (2013). A tutorial on sensitivity analyses in clinical trials: the what, why, when and how. *BMC Medical Research Methodology, 13*(1), 92.

Thompson, B. T., & Schoenfeld, D. (2007). Usual care as the control group in clinical trials of nonpharmacologic interventions. *Proceedings of the American Thoracic Society, 4*(7), 577-582.

Thompson, L. W., Solano, N., Kinoshita, L., Coon, D. W., Mausbach, B., & Gallagher-Thompson, D. (2002). Pleasurable activities and mood: differences between Latina and Caucasian dementia family caregivers. *Journal of Mental Health & Aging*, 211-224.

Tighe, C. A., Shoji, K. D., Dautovich, N. D., Lichstein, K. L., & Scogin, F. (2016). Affective mediators of the association between pleasant events and global sleep quality in community-dwelling adults. *Journal of Behavioral Medicine*, *39*(1), 170-177.

Tong, A., Sainsbury, P., & Craig, J. (2007). Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care, 19*(6), 349-357.

Tremont, G. (2011). Family caregiving in dementia. *Medicine and Health, Rhode Island, 94*(2), 36.

Tremont, G., Duncan Davis, J., Bishop, D. S., & Fortinsky, R. H. (2008). Telephone-delivered psychosocial intervention reduces burden in dementia caregivers. *Dementia*, *7*(4), 503-520.

Tsai, P.-S., Wang, S.-Y., Wang, M.-Y., Su, C.-T., Yang, T.-T., Huang, C.-J., & Fang, S.-C. (2005). Psychometric evaluation of the Chinese version of the Pittsburgh Sleep Quality Index (CPSQI) in primary insomnia and control subjects. *Quality of Life Research, 14*(8), 1943-1952.

van Hees, V. T., Sabia, S., Anderson, K. N., Denton, S. J., Oliver, J., Catt, M., . . . Singh-Manoux, A. (2015). A novel, open access method to assess sleep duration using a wrist-worn accelerometer. *PLOS ONE, 10*(11), e0142533.

Van Wijngaarden, E., Van der Wedden, H., Henning, Z., Komen, R., & The, A.-M. (2018). Entangled in uncertainty: The experience of living with dementia from the perspective of family caregivers. *PLOS ONE, 13*(6).

Vanderwerker, L. C., Laff, R. E., Kadan-Lottick, N. S., McColl, S., & Prigerson, H. G. (2005). Psychiatric disorders and mental health service use among caregivers of advanced cancer patients. *Journal of Clinical Oncology, 23*(28), 6899.

Von Känel, R., Ancoli-Israel, S., Dimsdale, J. E., Mills, P. J., Mausbach, B. T., Ziegler, M. G., . . . Grant, I. (2010). Sleep and biomarkers of atherosclerosis in elderly Alzheimer caregivers and controls. *Gerontology, 56*(1), 41-50.

von Känel, R., Dimsdale, J. E., Ancoli-Israel, S., Mills, P. J., Patterson, T. L., McKibbin, C. L., . . . Grant, I. (2006). Poor sleep is associated with higher plasma proinflammatory cytokine interleukin-6 and procoagulant marker fibrin D-dimer in older caregivers of people with Alzheimer's disease. *Journal of the American Geriatrics Society, 54*(3), 431-437.

von Känel, R., Mausbach, B. T., Ancoli-Israel, S., Dimsdale, J. E., Mills, P. J., Patterson, T. L., . . . Allison, M. (2012). Sleep in spousal Alzheimer caregivers: a longitudinal study with a focus on the effects of major patient transitions on sleep. *Sleep, 35*(2), 247-255.

von Kanel, R., Mausbach, B. T., Mills, P. J., Dimsdale, J. E., Patterson, T. L., Ancoli-Israel, S., . . . Grant, I. (2014). Longitudinal relationship of low leisure satisfaction but not depressive symptoms with systemic low-grade inflammation in dementia caregivers. *The Journals of Gerontology. Series B, Psychological Sciences and Social Sciences, 69*(3), 397-407.

Waller, A., Dilworth, S., Mansfield, E., & Sanson-Fisher, R. (2017). Computer and telephone delivered interventions to support caregivers of people with dementia: a systematic review of research output and quality. *BMC Geriatrics, 17*(1), 265.

Wang, D. S. (2012). Caregiving for dementia in Asian communities: Implications for practice. *Journal of Ethnic And Cultural Diversity in Social Work, 21*(3), 249-273.

Wang, J., Xiao, L. D., He, G. P., & De Bellis, A. (2014). Family caregiver challenges in dementia care in a country with undeveloped dementia services. *Journal of Advanced Nursing, 70*(6), 1369-1380.

Wang, L.-Q., Chien, W.-T., & Lee, I. Y. (2012). An experimental study on the effectiveness of a mutual support group for family caregivers of a relative with dementia in mainland China. *Contemporary Nurse*, *40*(2), 210-224.

Watkins, M., & Redfern, S. J. (1997). Evaluation of a new night nursing service for elderly people suffering from dementia. *Journal of Clinical Nursing, 6*(6), 485-494.

Wei, X., Zakus, D., Liang, H., & Sun, X. (2005). The Shanghai case: A qualitative evaluation of community health reform in response to the challenge of population ageing. *The International Journal of Health Planning and Management, 20*(3), 269-286.

White, T. M., Townsend, A. L., & Stephens, M. A. P. (2000). Comparisons of African American and White women in the parent care role. *The Gerontologist*, *40*(6), 718-728.

Whitehead, W. E. (2004). Control groups appropriate for behavioral interventions. *Gastroenterology, 126,* S159-S163.

Whitlatch, C. J., Judge, K., Zarit, S. H., & Femia, E. (2006). Dyadic intervention for family caregivers and care receivers in early-stage dementia. *The Gerontologist, 46*(5), 688-694.

Wilcox, S., & King, A. C. (1999). Sleep complaints in older women who are family caregivers. *The Journals of Gerontology Series B: Psychological Sciences and Social Sciences, 54*(3), P189-P198.

Wilks, S. E., & Croom, B. (2008). Perceived stress and resilience in Alzheimer's disease caregivers: Testing moderation and mediation models of social support. *Aging and Mental Health, 12*(3), 357-365.

Williams, I. C. (2005). Emotional health of black and white dementia caregivers: a contextual examination. *The Journals of Gerontology Series B: Psychological Sciences and Social Sciences, 60*(6), P287-P295.

Wimo, A., von Strauss, E., Nordberg, G., Sassi, F., & Johansson, L. (2002). Time spent on informal and formal care giving for persons with dementia in Sweden. *Health Policy, 61*(3), 255-268.

Win, K. K., Chong, M. S., Ali, N., Chan, M., & Lim, W. S. (2017). Burden among Family caregivers of Dementia in the Oldest-Old: an exploratory study. *Frontiers in medicine, 4*, 205.

Winter, L., & Gitlin, L. N. (2007). Evaluation of a telephone-based support group intervention for female caregivers of community-dwelling individuals with dementia. *American Journal of Alzheimer's Disease & Other Dementias®, 21*(6), 391-397.

World Health Organization. (2014). China: Improving home care for dementia patients. Retrieved April 30, 2020, from http://www.who.int/features/2014/china-dementia-patients/en/

World Health Organization. (2019). Dementia. Retrieved August 28, 2020, from https://www.who.int/news-room/fact-sheets/detail/dementia

World Health Organization. (2017). Dementia. Retrieved April 15, 2020, from http://www.who.int/mediacentre/factsheets/fs362/en/

Wu, B., Petrovsky, D. V., Wang, J., Xu, H., Zhu, Z., McConnell, E. S., & Corrazzini, K. N. (2019). Dementia caregiver interventions in Chinese people: A systematic review. *Journal of Advanced Nursing, 75*(3), 528-542.

Xu, J., Wang, J., Wimo, A., Fratiglioni, L., & Qiu, C. (2017). The economic burden of dementia in China, 1990–2030: implications for health policy. *Bulletin of the World Health Organization, 95*(1), 18.

XU, X. Y., KWAN, R. Y. C., & LEUNG, A. Y. M. (2020a). Behavioural activation for family dementia caregivers: A systematic review and meta-analysis. *Geriatric Nursing*.

Xu, X. Y., Kwan, R. Y. C., & Leung, A. Y. M. (2020b). Factors associated with the risk of cardiovascular disease in family caregivers of people with dementia: a systematic review. *Journal of International Medical Research, 48*(1), 0300060519845472.

Yeaton, W. H., & Sechrest, L. (1981). Critical dimensions in the choice and maintenance of successful treatments: strength, integrity, and effectiveness. *Journal of Consulting and Clinical Psychology, 49*(2), 156.

Yelland, L. N., Makrides, M., McPhee, A. J., Quinlivan, J., & Gibson, R. A. (2016). Importance of adequate sample sizes in fatty acid intervention trials. *Prostaglandins, Leukotrienes and Essential Fatty Acids, 107*, 8-11.

Yen, W. J., Huang, X. Y., Ma, W. F., Lee, S., & Lee, C. H. (2009). A Chinese version of the Meaning in Caregiving Scale: An assessment of its reliability and validity. *Perspectives in Psychiatric Care, 45*(2), 140-150.

Yeung, E. H., Szeto, A., Richardson, D., Lai, S. h., Lim, E., & Cameron, J. I. (2015). The experiences and needs of C hinese‐C anadian stroke survivors and family caregivers as they re‐integrate into the community. *Health & Social Care in the Community, 23*(5), 523-531.

Young, J., & Beck, A. T. (1980). Cognitive therapy scale: Rating manual. "© J.E. Young & A.T. Beck, 1980. Used with permission

Zanetti, O., Solerte, S., & Cantoni, F. (2009). Life expectancy in Alzheimer's disease (AD). *Archives of Gerontology and Geriatrics, 49*, 237-243.

Zarit, S. H., Reever, K. E., & Bach-Peterson, J. (1980). Relatives of the impaired elderly: correlates of feelings of burden. *The Gerontologist, 20*(6), 649-655.

Zawadzki, L., Mondon, K., Peru, N., Hommet, C., Constans, T., Gaillard, P., & Camus, V. (2011). Attitudes towards Alzheimer's disease as a risk factor for caregiver burden. *International Psychogeriatrics, 23*(9), 1451-1461.

Zeng, L., Zhu, X., Meng, X., Mao, Y., Wu, Q., Shi, Y., & Zhou, L. (2014). Responsibility and burden from the perspective of seniors' family caregivers: a qualitative study in Shanghai, China. *International Journal of Clinical and Experimental Medicine, 7*(7), 1818.

Zhong, Y., Wang, J., & Nicholas, S. (2020). Social support and depressive symptoms among family caregivers of older people with disabilities in four provinces of urban China: the mediating role of caregiver burden. *BMC Geriatrics, 20*(1), 3.

Zwaanswijk, M., Peeters, J. M., Van Beek, A. P., Meerveld, J. H., & Francke, A. L. (2013). Informal caregivers of people with dementia: problems, needs and support in the initial stage and in subsequent stages of dementia: a questionnaire survey. *The Open Nursing Journal, 7*, 6.

Zwarenstein, M., Treweek, S., Gagnier, J. J., Altman, D. G., Tunis, S., Haynes, B., . . . Moher, D. (2008). Improving the reporting of pragmatic trials: an extension of the CONSORT statement. *BMJ, 337*, a2390.

国家基本公共卫生服务项目管理平台. (2020). 居民健康档案管理服务规范. Retrieved April 28, 2020, from http://www.nbphsp.org.cn/jbgw/jkda/

Appendix A Behavioral activation for family dementia caregivers: A systematic review and meta-analysis

(31469)

Geriatric Nursing 000 (2020) 1–9

Contents lists available at ScienceDirect

Geriatric Nursing

journal homepage: www.gnjournal.com

Behavioural activation for family dementia caregivers: A systematic review and meta-analysis

Xin Yi XU, PhD student, Rick Yiu Cho KWAN, PhD, Angela Yee Man LEUNG, PhD*

Centre for Gerontological Nursing, School of Nursing, The Hong Kong Polytechnic University, Hung Hom, Kowloon, Hong Kong

ARTICLE INFO

Article history:
Received 16 October 2019
Received in revised form 12 February 2020
Accepted 14 February 2020
Available online xxx

Keywords:
Behavioral activation
Depression
Family caregiver
Dementia

ABSTRACT

The current study aims to investigate the effectiveness of behavioral activation (BA) for family dementia caregivers. A systematic literature search was conducted through PubMed, Medline, CINAHL, Cochrane, Embase and PsycINFO for studies published from March 1988 to September 2019. Standardized mean differences (SMDs) were combined to synthesize pooled effect measures using random effects. The review was based on ten randomized controlled trials. Depression was significantly reduced after participants received BA ($n = 9$; 786 participants; SMD = −0.69; 95% CI: −1.12 to −0.25; $p = 0.002$). BA also has a positive impact on other areas of psychological health (e.g., self-efficacy, anxiety, and distress) and physical health (e.g., interleukin-6) in family dementia caregivers. In conclusion, BA not only has a moderate effect on reducing depression but also has the potential to improve other areas of psychological and cardiovascular health in family caregivers. However, more interventional studies of BA for family dementia caregivers are needed.

Background

Dementia is one of the major causes of disability and dependency in older people, and it is now the seventh-most common cause of death in the world.[1] Most people with dementia (PWD) are cared for at home by family caregivers.[2] A family caregiver is a nonprofessional who provides unpaid care for one or more family members in the home. Because of the high dependency of PWD, family caregivers are responsible for most of their daily routines, including assisting with eating, dressing, bathing and toileting.[3] Family caregivers must also manage changing demands and unexpected behavior because of the relentless cognitive deterioration of PWD.[4] They spend approximately 286 h per month (nearly 10 h per day) on their caregiving duties.[5]

Depression is a common mental disorder among family dementia caregivers.[6,7] A body of evidence exists to suggest that people caring for PWD in the home are more prone to depression than others are and that they are at greater risk than are people caring for people with conditions other than dementia.[8–10] A substantial and significant relationship exists between depression and the level of engagement in pleasant activities; a depressed person engages in fewer activities of this nature.[11,12] Family dementia caregivers have scarce time available for leisure, given their duty to spend long and laborious hours providing care. In addition, family caregivers may be ashamed of and embarrassed by the patient's condition, which cuts them off from their friends and other family members.[13] Therefore, family dementia caregivers reported performing fewer pleasant leisure activities, experiencing less leisure satisfaction and being less willing to take part in pleasant leisure activities compared to a control sample of noncaregivers.[8,14]

Behavioral activation (BA) is a way to increase pleasant leisure activities among family dementia caregivers. BA assumes that clients should be assisted with the ability to engage in behaviors that they find pleasurable or fulfilled. BA is rooted in the biological basis of behavior. Beginning with the pioneering work of Peter Lewinsohn and colleagues[12,15,16] revitalizing the components of CBT[17,18] and culminating in its current status,[19–21] BA gained prominent status as an effective treatment across a range of clinical settings. BA is an 'outside in' treatment that focuses on changing the way a person acts. In contrast, CBT is an 'inside out' treatment in which therapists focus on helping clients change the way they think.[22] A prominent feature of BA is the technique of indulging in enjoyable activities at set times, with the aim of increasing positive response-contingent environmental reinforcement. The rationale is that involvement in pleasurable and positive things can assist caregivers in rediscovering the pleasant features of their lives.[23,24] Scheduling activities to facilitate positive reinforcement emerged as the core element across all forms of BA. Therefore, the goal of BA should be to help clients become involved in a diversity of pleasurable, personally meaningful, and rewarding activities, thus encouraging stable positive reinforcement.[25]

BA is attractive because it is relatively uncomplicated, time-efficient and does not require complex skills from participants or therapists.[21] Some systematic reviews and meta-analyses have supported and strengthened the evidence base that suggests that BA is

---

* Corresponding author.
E-mail address: angela.ym.leung@ (A.Y.M. LEUNG).

https://doi.org/10.1016/j.gerinurse.2020.02.003
0197-4572/$ – see front matter © 2020 Published by Elsevier Inc.

effective in reducing depression in the general public.[19–21] There are several meta-analyses of caregiver interventions available, but few have officially examined BA therapy as a specific intervention (they have most likely included BA therapies in the category of cognitive behavioral therapy (CBT)). Knowledge of how BA is effective in reducing those symptoms in family dementia caregivers remains limited. The current study applied a systematic review and meta-analysis to determine how BA affects depression and other areas of the psychological and physical health of family dementia caregivers.

Methods

This review was conducted in line with the PRISMA guidelines for reporting systematic reviews.[26]

Eligibility criteria

This review exclusively included randomized controlled trials (RCTs) that applied BA theories to family dementia caregivers. No restrictions were applied to the intervention delivery format or the duration or frequency of intervention sessions. There was also no restriction on sample size, since the exclusion of studies with a small sample size would have contributed to publication bias. Studies that were not primary studies, including systematic reviews, editorials and 'letters to the editor', were excluded from this review. Practice guidelines and study protocols were also excluded.

Participants were family dementia caregivers. Studies were excluded if the participants were employees caring for PWD. There was no limitation on gender or age or on the length of time over which caregivers provided care. However, participants had to be the primary caregiver of a patient. Participants did not need to have a clinical diagnosis of a depression disorder.

Search strategy

An electronic database search of PubMed, Medline, CINAHL, Cochrane, Embase and PsycINFO was carried out using the following keyword search terms: dementia OR Alzheimer OR "cognitive impairment" AND caregiv* AND "behavioral therapy" OR "behavioral activation" OR "activity scheduling" OR "activity restriction" OR "leisure activities" OR "pleasurable activities". This search was conducted from February 2018 to September 2019. Studies published from March 1988 to September 2019 and written in English were reviewed.

Study selection and data extraction

First, duplicate references were eliminated. This was followed by a separate review of abstracts to remove any documents that did not focus on the subject matter of interest. A different member of the survey team was then tasked with reading through the full version of references as a more rigorous means of screening for relevance. A third team member arbitrated on any disagreement that arose between the reviewers regarding the relevance of a given reference.

Data were extracted from all the studies that were included in the sample, according to the guidelines of the Cochrane Handbook for Systematic Reviews of Interventions, by two reviewers independently.[27] Any inconsistency within the retrieved information was resolved by the third team member. The data extraction form included "author and year", "country", "type of dementia", "relationship with PWD", "participant details", "intervention details", "comparison details", "depression measures", "immediate postintervention findings" and "follow-up findings".

Risk of bias within individual studies

A project team member independently reviewed each reference to ascertain whether there was a risk of bias contained within it using the Cochrane Collaboration's tool.[28] The second member of the team rated all of the included studies to check for agreement, and the third was again available to arbitrate in case of any differences of opinion.

Data synthesis

The references were summarized using descriptive statistics. Outcome measures were combined, and a meta-analysis was conducted, where appropriate. When sufficient data were not available for conducting a meta-analysis for a specific outcome, the results of individual studies were listed instead of a pooled effect size.

Data analysis

Data synthesis was conducted by Review Manager Version 5.3.[29] This review estimated poststudy outcomes between experimental and control groups. Standardized mean differences (SMDs) were calculated if the research studies used different depression scales. The heterogeneity between studies was measured by the p-value from Cochran's Q statistic and the value of I^2. Heterogeneity was significant when the *p*-value < 0.10 for Cochran's *Q* test.[30] The results of the studies were estimated by random-effects models if the I^2 value was greater than 50%. The overall effect sizes and 95% confidence intervals were calculated to estimate the pooled treatment effects. Effect size was interpreted in accordance with Cohen,[31] where 0.2 represents a small effect, 0.5 a medium effect and 0.8 a large effect.

Results

Study selection

Study selection began with the 797 references that were initially obtained. Two studies were identified from other systematic reviews. Of these, 405 were duplicates, so these were removed from the sample. Then, 394 studies remained for further analysis, of which 381 were found to be not relevant to the study objectives. This left 13 references, of which three were eliminated after their full text was read; this was because one was a study protocol, one did not investigate the effect of BA on family dementia caregivers, and one did not apply the BA principle. Ten studies therefore remained for systematic review. The data selection process is shown in Fig. 1 as a PRISMA flow diagram.

Participants

A total of 895 participants, originating from China, Spain, Japan, the Netherlands and the United States, were included in this review, with sample sizes ranging from 41 to 118. The mean age of participants receiving an intervention ranged from 55.2 to 81.1 years, and the majority were female (57.1–100.0%). Most of the family caregivers were adult children and spouses. Family caregivers devoted 8.22–11.53 h per day to taking care of a relative with dementia. Table 1 shows the participants' characteristics in the included studies.

Intervention and control group characteristics

Interventions

The intervention duration ranged from 5 to 20 weeks, and each session ranged from 15 min to 90 min. Four interventions ware administered by telephone,[32–35] while the other six were administered through direct contact. One study[36] followed participants for one year after treatment, and three studies followed participants for six months after baseline.[33,37,38]

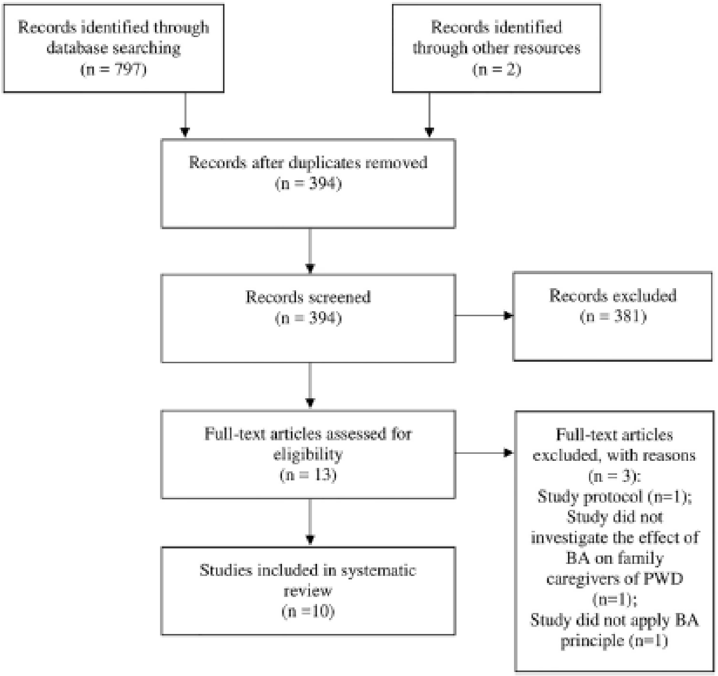


Fig. 1. PRISMA flow-chart of study selection.

The intervention program reported by Losada et al. (2011)[39] was adapted from the intervention study described in the study of Márquez-González and Losada[40]; specifically, the program trained caregivers in the techniques and skills necessary to acknowledge and analyze cognitive barriers to self-help and participation in pleasant activities. Au and her team[32–35] developed an intervention based on Lewinson's BA model, which focuses on increasing the frequency and duration of engagement in pleasant activities. Bourgeois et al. (2002)[38] also developed a workshop according to Lewinsohn's theories. The intervention of Moore et al. (2013)[36] was adapted from the published treatment manual of Lejuez,[41] which aimed to encourage participants to both select and engage in leisure activities. Gonyea et al. (2006)[42] based their intervention on the principle of behavior therapy and behavioral activation. The interventions of Prick et al. (2015)'s study[37] and Steffen et al. (2016)[33] were for dementia dyads. Prick et al. translated and adjusted the dyadic intervention of Teri et al. (2003),[43] and they expanded a version of pleasant activity training to more than three sessions for both caregivers and care recipients. Coon et al. (2003)[44] developed the Depression Management Class based on cognitive-behavioral components but also emphasized behavioral components. In addition, most of the studies included homework in their BA interventions.[33–37,39,42] However, only Losada et al. (2011)[39] mentioned to assess and discuss homework in their training sessions.

The attrition rate of each study ranged from 3.1% to 23.3%. For the intervention assessment, Losada et al. (2011)[39] measured treatment completion rates and treatment fidelity by assessing participants' knowledge and competence with regard to the contents and skills in the intervention. The mean number of sessions attended by participants was 9.2 out of 12, and there was a significant increase in caregivers' knowledge about the contents of BA after intervention. Bourgeois et al. (2002)[38] also measured treatment fidelity by assessing treatment delivery, treatment receipt, treatment enactment, and treatment satisfaction, all caregivers (100%) attended the required workshop, and 89% questionnaires were returned and reported a high degree of satisfaction with all intervention components. Au et al. (2019)[32] measured treatment fidelity by a rating system, and all interventionist were asked to rate whether they were able to follow the intervention protocol. Over 60% of the interventionists in the intervention group considered the intervention to be fully covered, and most caregivers were willing to share their experiences and frustrations. Moore et al. (2013)[36] found that participants in an intervention were slightly, but not significantly, less happy with the number of sessions than a control sample of caregivers who were not administered the intervention. Prick et al. (2015)[37] found that caregiver dropouts had a significantly lower education level than caregiver completers did, and 75.4% participants were moderate compliant with the protocol. In addition, nearly 88% of the participants attended at least four out of five weekly sessions and the postintervention assessments in Gonyea et al. (2006)'s study.[42]

Controls

The duration and dosage of controls were comparable to those of interventions in each study, and no members of a control sample were administered BA treatment. The nature of the treatment of control group members differed from one study to another. In the studies of Losada et al. (2011)[39] and Hirano et al. (2016),[45] caregivers in the control group received standard care from care centers, which was not described in the study. Moore et al. (2013)[36] provided some of this information, including details of the topics commonly included

Table 1
Characteristics of the participants of reviewed studies.

Study (authors and year)	Country (city/state)	Type of dementia	Relationship with PWD	Total		BA caregivers			Controls			Duration of caregiving (years)	Hours spent per day (BA/control) (hours)
				Age (mean ± sd)	Sex (female, No.%)	No.	Age (mean ± sd)	Sex (female, No.%)	No.	Age (mean ± sd)	Sex (female, No.%)		
Au et al. 2019	Hong Kong	Alzheimer's disease	Spouse, children, siblings, daughter/ son-in-law	NI	NI	56	57.4 ± 9.7	83.9	55	56.8 ± 10.8	78.2	4.2 ± 2.2 3.8 ± 1.4	10.9 ± 8.3 10.9 ± 7.0
Steffen et al. 2016	The U.S.	Dementia/ neurocognitive	Spouse, adult children	60.3 ± 10.8	100.0	28	NI	100.0	38	NI	100.0		
Au et al. 2015	Hong Kong	Alzheimer's disease	Spouse, kin, sibling	NI	NI	29	55.2 ± 8.8	93.1	30	57.9 ± 12.5	73.3	3.2 ± 2.3 3.1 ± 1.7	8.8 ± 8.1 10.7 ± 9.2
Au. 2015	Hong Kong	Alzheimer's disease	Spouse, kin, sibling	NI	NI	49	81.1 ± 6.2	63.1	44	80.7 ± 7.0	63.6		11.4 ± 9.2 9.4 ± 8.6
Prick et al. 2015	Netherland	Dementia	Spouse, adult relatives, friends	72.0 ± 10.1	72.1	57	73.0 ± 9.9	66.7	54	71.0 ± 10.3	77.8		≥ 4 h/ day
Moore et al. 2013	The U.S.	Dementia	Family caregivers	NI	NI	49	70.9 ± 7.6	81.6	51	71.3 ± 9.1	66.7	5.4 ± 4.9 4.0 ± 2.4	8.2 ± 5.0 8.0 ± 5.4
Losada et al. 2011	Spain	Dementia	Spouse, parents, other relatives	NI	NI	68	60.6 ± 11.5	81.7	50	59.4 ± 12.6	84.0	50.8 ± 40.8 (months) 60.8 ± 54.2 (months)	11.5 ± 8.1 10.0 ± 6.7
Gonyea et al. 2006	Japan	Alzheimer's disease	Spouse, adult children	64.4 ± 13.8	67	40	NI	NI	40	NI	NI		≥ 4 h/ week
Coon et al. 2003	The U.S.	Dementia	Spouse, adult children	73.4 ± 8.4	100	64	NI	100.0	52	NI	100.0	40.7 ± 30.5 (months)	
Bourgeois et al. 2002	The U.S.	Alzheimer's disease	Adult relative, neighbors, friends	NI	NI	21	74.0 ± 6.3	57.1	20	70.4 ± 5.9	55.0		≥ 8 h/ day

NI: no information.
PWD: people with dementia.

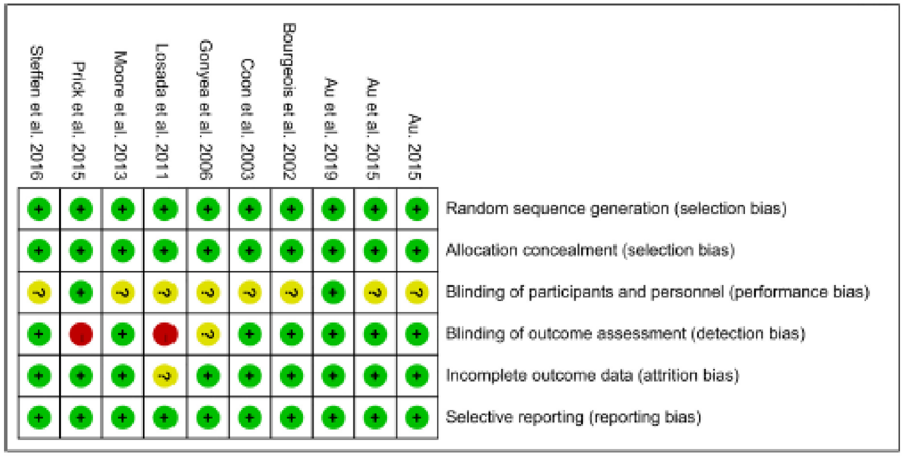
in information packages provided by community agencies to the control group. Similarly, Prick et al. (2015)[37] and Gonyea et al. (2006)[42] also provided information support for comparison groups. Au and her team[32-35] provided caregivers in the control group with materials, information packages, and psychoeducation. Bourgeois et al. (2002)[38] provided home visits to caregivers in the control condition, but they did not provide any of the information or skills training content presented in the treatment group.

Outcome measures

The studies used a variety of measures to evaluate depression, in seven studies the Center for Epidemiologic Studies Depression Scale (CES-D)[32,34–39] was used, in one study the Beck Depression Inventory-II (BDI-II)[33] was used, and in one study the BDI[44] was used.

Risk of bias across the included studies

The assessment of the bias in individual studies is given in Fig. 2. All of the studies were considered to be at low risk of selection bias in



	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)
Au. 2015	+	+	?	+	+	+
Au et al. 2015	+	+	?	+	+	+
Au et al. 2019	+	+	+	+	+	+
Bourgeois et al. 2002	+	+	?	+	+	+
Coon et al. 2003	+	+	?	+	+	+
Gonyea et al. 2006	+	+	?	?	+	+
Losada et al. 2011	+	+	?	●	?	+
Moore et al. 2013	+	+	?	+	+	+
Prick et al. 2015	+	+	+	●	+	+
Steffen et al. 2016	+	+	?	+	+	+

Fig. 2. Risk of bias of each study.

terms of "random sequence generation" and "allocation concealment". This is because in all reviewed studies, the randomization procedure and allocation concealment method were well reported. Only Prick et al. (2015)[37] and Au et al. (2019)[32] specified whether study participants were "blind" to the intervention; therefore, a high risk of performance bias was associated with almost all of the studies. However, BA is an interventional study, so it is difficult for participants to be "blind" to receiving BA. The studies of Losada et al. (2011)[39] and Prick et al. (2015)[37] were considered to be at high risk of detection bias because they did not use "blind" assessors. No study received a high-risk rating for attrition bias, reporting bias or any other bias.

Results of individual studies

The main findings from the included studies are summarized in Table 2. Depression or depressive symptomatology decreased significantly after BA in the eight studies.[32–36,38,39,44] Caregiving self-efficacy also improved after the BA intervention in three studies.[32,33,44] Burden was not significantly reduced in the Coon et al. (2003) study[42] but it was significantly reduced in the Au et al. (2019) study.[32] BA also significantly reduced negative aspects of caregiving,[36] anxiety,[33] anger and hostility,[44] and caregiver strain,[38] among family dementia caregivers. Only Losada et al. (2011)[39] reported both an increase in engagement in leisure activities and a reduction in dysfunctional thinking in relation to caring for PWD. Regarding physical health issues, IL-6[36] significantly decreased after BA intervention in family dementia caregivers compared with control group members. Although both studies[42,45] reported that the frequency and severity of neuropsychiatric symptoms in PWD did not decrease after the BA intervention, family caregivers' distress related to neuropsychiatric symptoms still significantly improved after the intervention.[42]

For follow-up, Moore et al. (2013)[36] followed participants for one year, Prick et al. (2015)[37] followed participants for three months, and Steffen et al. (2016)[33] followed participants for six months, but no significant difference was shown in study outcomes between the BA and control groups. Only family dementia caregivers in the study of Bourgeois et al. (2002)[38] showed significant improvement in caregiver strain after three and six months of follow-up.

Overall effect of BA on the reduction of depressive symptoms

The meta-analysis was performed to compare the effects of BA on depression in the intervention groups versus the control groups. Only the study of Gonyea et al. (2016)[42] was excluded due to insufficient data on depression. The pooled effects of BA on depression are summarized in Fig. 3, which compares the BA groups with the control groups in the immediate posttest period. Family dementia caregivers receiving BA demonstrated a statistically significant reduction in depressive symptoms ($n = 9$; 786 participants; SMD = -0.69; 95% CI: -1.12 to -0.25; $p = 0.002$).[32–39,44] There was significant heterogeneity in the studies ($I^2 = 88\%$, $p < 0.001$).

Discussion

This systematic review, with a meta-analysis, has shown that BA has both psychological and physical benefits for family dementia caregivers. BA had a moderate effect on reducing depression among family dementia caregivers compared with control groups provided with psychoeducation or informational support. The results of the current review study have indicated that BA seemed to have a favorable impact on reducing depression. A previous meta-analysis has suggested that the effect sizes of interventions targeted toward psychological morbidity in family dementia caregivers range from 0.24[46] to 0.31.[47] In the review of Pinquart et al. (2006),[46] the effect sizes of interventions, including psychoeducation, counselling/case management, support, training of care recipients, respite care and multicomponent interventions targeting depression in family dementia caregivers, range from 0.01 to 0.36. Only family caregivers in the study of Prick et al. (2015) did not have significantly reduced depression levels after the BA intervention. This may be because family caregivers lost more private time when completing the intervention together with other care recipients. In addition, they may feel more controlled by care recipients when talking about their feelings and thoughts. Therefore, their depression level did not significantly decrease or even improve after the intervention. Thus, BA only for caregivers may be more efficient in reducing depression among family dementia caregivers. Meanwhile, given that there is only one dyadic BA intervention, more studies are needed to investigate the effects of dyadic BA on both family caregivers and care recipients.

As proposed by O'Donohue and Fisher (2012),[48] by providing BA techniques, especially activity scheduling, new activation behaviors can be motivated directly, which creates a path from T (Treatment) to B (Behavior) (shown in Fig. 4). Meanwhile, positive reinforcement also strengthens activation behaviors and is represented by an arrow back from R (Reinforcement) to B. As positive reinforcement can improve M (Mood) in participants, there is an arrow from R to M. The cycle can decrease depressive symptoms over time, which is the common theme of all of the research analyzed in this paper. However, it is not easy for caregivers to do this, given their care responsibilities and long-standing feelings of stress. BA, which started from being a self-monitoring exercise, can be easily tailored to meet the needs of family dementia caregivers,[41] but its positive impacts can only be sustained if participants implement what they learn from training sessions into their daily lives. This is why there is 'homework' (e.g., daily activity logs of BA activities) for participants to complete after each session[41] in most of the included studies. Meanwhile, most studies which included homework usually had a lower attrition rate and higher compliance as well as satisfaction with the intervention.[37–39,42] In addition, Losada et al. (2011)[39] mentioned to assess and discuss homework in each session, and there was a significant increase in caregivers' knowledge about the contents of BA after intervention. Therefore, in order to improve the efficiency of the BA intervention, homework should be added as one of the components and time should be given to discuss and analyze the homework.

Only three studies[32,38,39] assessed treatment fidelity by using different measurements in this systematic review. However, only Bourgeois et al. (2002)[38] carefully measured treatment fidelity by assessing treatment delivery, treatment receipt, treatment enactment, and treatment satisfaction. Other two studies[32,39] just simply measured treatment fidelity by assessing participants' knowledge and competence, as well as rating interventionists whether they were able to follow the intervention protocol or not. Treatment fidelity is usually defined as the extent to what the intervention is implemented as intended.[49] Several studies have reported that there was a strong relationship between treatment fidelity and treatment effectiveness.[50,51] Therefore, the result of this meta-analysis could be influenced by the treatment fidelity of each study. To further explain the effectiveness of BA on depression among family dementia caregivers, future studies should assess treatment fidelity. Meanwhile, there is lack of a consistent treatment fidelity model for BA programs, which may perpetuate the difference between studies.[49] Developing a standard treatment fidelity tool would allow investigation of treatment fidelity in BA programs in future.

BA, despite being initially designed to reduce depression, can also be used to alleviate other forms of mental health issues and physical health among caregivers. For instance, Moore et al. (2013)[36] reported that BA had a positive impact on reducing negative feelings, as well as IL-6, which is a biomarker of cardiovascular disease (CVD) risk in family dementia caregivers. In addition, the included study revealed a trend in reducing the burden among family dementia caregivers after BA.[32,42] A number of observational studies have also shown a

Table 2
Characteristics of the reviewed studies.

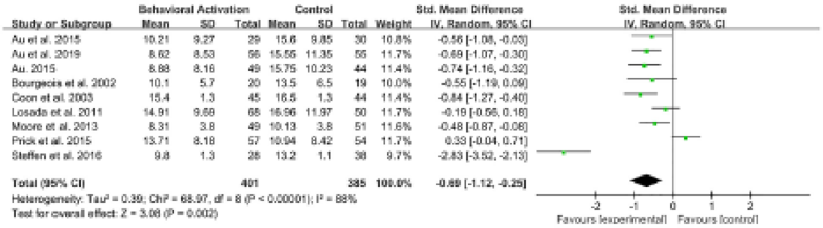
Author, year	Number of participants (intervention/ control)	Intervention		Comparison		Measures for depression	Post-intervention outcomes		Follow-up findings
		Dosage	Component	Dosage	Component		Outcomes with significant results	Outcomes with non-significant results	
Au et al. 2019	56/55	• 20 weeks • 12 sessions (4 weekly sessions + 8 biweekly sessions) • 20 min/ session	• Psychoeducation • Behavioral activation • Telephone based	• 20 weeks • 12 sessions (4 weekly sessions + 8 biweekly sessions) • 20 min/ session	• Caregiver's health • Care recipient's needs • Caregiver's routines • Social support • Telephone based	CES-D	Depression; Burden; Self-efficacy; Relationship satisfaction	NI	NI
Steffen et al. 2016	33/41	• 16 weeks • 12 sessions (10 weekly sessions+ 2 biweekly maintenance calls) • 30–50 min/ session	• Behavioral activation for both carer and care recipient • Relaxation • Caregiving self-efficacy • Telephone based • Video + workbook	• 14 weeks • 1 session/ two weeks • 20 min/ session	• Basic care guide • Telephone based	BDI-II	Depressive symptomatology; Negative mood; Anxiety; Caregiving self-efficacy	Hostility	6 months: NS
Au et al. 2015	29/30	• 16 weeks • 1–2 sessions /two weeks • 15–20 min /session	• Pleasant event scheduling • Effect communication training • Telephone based	• 16 weeks • 1–2 sessions /two weeks • 15–20 min /session	• Psychoeducation • Information support • Telephone based	CES-D	Depression; Relationship Satisfaction	NI	NI
Au. 2015	49/44	• 16 weeks • 1–2 sessions /two weeks • 15–20 min /session	• Pleasant event scheduling • Effect communication training • Telephone based	• 16 weeks • 1–2 sessions /two weeks • 15–20 min /session	• Psychoeducation • Information support • Telephone based	CES-D	Depression	NI	NI
Prick et al. 2015	57/54	• 16 weeks • 1–2 session /two weeks • 60 min / session	• Psychoeducation • Communication skills training • Pleasant activity training • Dyadic intervention • Home visits	• 16 weeks • 1 session /month • 10 min /session	• Usual care • Information support • Car driving • General health in dementia • Phone calls	CES-D	NI	Depression; Feelings of role-overload; General health; Observable behavioral problems in PWD	6 months: NS
Moore et al. 2013	49/51	• 6 weeks • 6 sessions (4 in-home sessions + 2 weekly telephone based sessions) • 15–60 min /session	• Monitoring time • Identifying leisure activities • Developing activity hierarchy • Scheduling/participating leisure activities and tracking moods	• 6 weeks • 6 sessions (4 in-home sessions + 2 weekly telephone based sessions) • 15–60 min /session	Information support	CES-D	Depression; Negative affect; IL-6	Positive affect; D-dimer	1 year: NS
Losada et al. 2011	68/50	• 12 weeks • 1 session /week • 1.5–2 h /session	• Acknowledge, analyze, and flexibilize dysfunctional thoughts • Analysis of cognitive barriers to do pleasant activities • Analyze and discuss of homework • Group education	• NI	• Usual care	CES-D;	Depression; Dysfunctional thoughts; Frequency of leisure activities	NI	NI
Gonyea et al. 2006	40/40		• Pleasant events and improving		• General information on ageing and	None		Burden; Frequency and	NI

(continued on next page)

Table 2 (*Continued*)

Author, year	Number of participants (intervention/ control)	Intervention		Comparison		Measures for depression	Post-intervention outcomes		Follow-up findings
		Dosage	Component	Dosage	Component		Outcomes with significant results	Outcomes with non-significant results	
		• 5 weeks • 1 session /week • 90 min /session	communication • Pleasant events and understanding behavior • Understanding and changing difficult behaviors • Group meeting	• 5 weeks • 1 session /week • 90 min /session	Alzheimer's disease • Home safety tips • Techniques for improved communication • Support • Group meeting		Caregiver distress related to neuropsychiatric symptoms	severity of neuropsychiatric symptoms of PWD	
Coon et al. 2003	64/52	• 16 weeks • 10 sessions (8 weekly teaching sessions + 2 monthly skill reinforcement sessions) • 2 h /week	• Problem solving • Pleasant event scheduling • Mood controlling • Group meeting	• NI	• Wait-list	BDI	Anger and hostility; Depressed mood; Self-efficacy	Coping	NI
Bourgeois et al. 2002	21/20	• 12 weeks • 1 session / week • 1 h / week	• Increasing pleasant events • Problem solving • Relaxation techniques • Group workshop	• 12 weeks • 1 session / week • 1 h / week	• Medication change • Mood rating • Caregiving issue	CES-D	Mood; Patient problem behaviors; Depression; Caregiver strain	Anger; Anxiety; Self-efficacy; Perceived stress; Perceived health	3 months: mood, patient problem behaviors, caregiver strain; 6 months: mood, patient problem behaviors, caregiver strain

BDI: Beck Depression Inventory.
CES-D: Center for Epidemiologic Studies-Depression Scale.
IL-6: interlukin-6.
NI: no information.
NS: not significant.



	Behavioral Activation			Control				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Au et al. 2015	10.21	9.27	29	15.6	9.85	30	10.8%	-0.56 [-1.08, -0.03]
Au et al. 2019	8.62	8.53	56	15.56	11.35	55	11.7%	-0.69 [-1.07, -0.30]
Au. 2015	8.88	8.16	49	15.75	10.23	44	11.4%	-0.74 [-1.16, -0.32]
Bourgeois et al. 2002	10.1	5.7	20	13.5	6.5	19	10.0%	-0.55 [-1.19, 0.09]
Coon et al. 2003	15.4	1.3	45	16.5	1.3	44	11.4%	-0.84 [-1.27, -0.40]
Losada et al. 2011	14.91	9.69	68	16.96	11.97	50	11.7%	-0.19 [-0.56, 0.18]
Moore et al. 2013	8.31	3.8	49	10.13	3.8	51	11.6%	-0.48 [-0.87, -0.08]
Prick et al. 2015	13.71	8.18	57	10.94	8.42	54	11.7%	0.33 [-0.04, 0.71]
Steffen et al. 2016	9.8	1.3	28	13.2	1.1	38	9.7%	-2.83 [-3.52, -2.13]
Total (95% CI)			**401**			**385**	**100.0%**	**-0.69 [-1.12, -0.25]**

Heterogeneity: Tau² = 0.39; Chi² = 68.97, df = 8 (P < 0.00001); I² = 88%

Test for overall effect: Z = 3.08 (P = 0.002)

Fig. 3. Forest plot of meta-analysis. The effect sizes and meta-analyzed overall effect for decreasing depression in family dementia caregivers are shown.

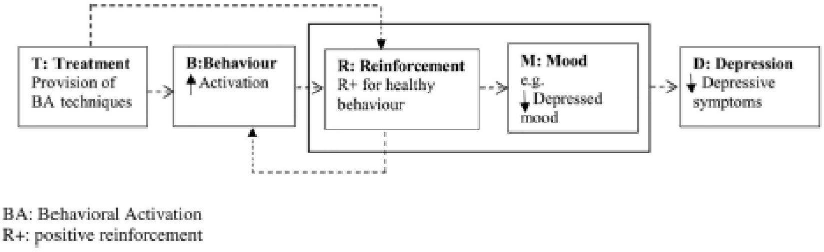


Fig. 4. BA's theory of treatment mechanism (Extracted from O'Donohue and Fisher (2012) Figure 9.2 BA's model of treatment).

positive relationship between engagement in pleasant leisure activities and reduced psychological distress and CVD risk.[52–54] However, more interventional studies are still needed to examine the effect of BA on other psychological and physical aspects in family dementia caregivers.

It is important to investigate the obstacles that caregivers may face in implementing BA in their daily lives. Therefore, focus groups or interviews are needed to understand such obstacles so that nurses can make adjustments to treatments accordingly. Future levels of compliance among participants might increase if BA interventions were administered using telephone and online resources, provided that it is still possible to provide the required training using this new means of delivery. In fact, telephone- and internet-based interventions have already been demonstrated to enhance the physical and mental health of family dementia caregivers.[55–57] Family caregivers can become 'overstretched' when participating in prolonged periods of intervention due to their caregiving demands, and this can make it difficult for them to leave their home to seek support through traditional face-to-face intervention. Making contact online or by telephone is one possible solution to this issue that healthcare personnel might consider.

There are also several limitations of this review that need to be acknowledged. First, the studies examined were conducted across a wide range of geographic locations, so the findings may not be generalizable to different populations. There were also methodological limitations associated with the studies included in this review, since the risk of bias in the studies did not take study selection into account.

Recommendations for future research

Only a few clinical trials were identified in this review, so more research can be conducted to investigate the effects of BA on family dementia caregivers. There are several recommendations for future research. First, changes in psychological symptoms, such as stress, anxiety and psychological burden after the BA intervention, could be examined more thoroughly in future studies. Measures of changes in physical health, such as heart rate, might also be investigated. Second, the daily implementation of BA measures should be carefully monitored and recorded. The compilation of a reflective diary could help researchers understand participants' adherence to the BA protocol and examine the relationship between levels of compliance and study outcomes. Further research might also include a more precise definition and measurement of engagement in leisure pursuits; for instance, actigraphs might be used to record the amount of physical exercise undertaken. To improve the implementation of BA measures, follow-up telephone calls can be made. Third, the heterogeneity of the intervention protocols used in these studies was a concern in terms of their duration, the content and format of the BA intervention, the emphasis of the intervention and the outcome measures used. Therefore, it is necessary to identify a standardized intervention protocol for BA in future research involving family dementia caregivers. Finally, the BA interventions in the included studies were based on different approaches; telephone-based BA was shown to be effective in reducing depression in the studies by Au and colleagues[32,34,35] and Steffen et al. (2016).[33] This finding suggests that the option of the quicker and easier delivery of BA by telephone to caregivers might be worthy of consideration in the future.

Conclusion

This meta-analysis and systematic review has suggested that BA is a promising intervention for reducing depression among family dementia caregivers. The available evidence shows that BA has the potential to improve other forms of psychological distress (e.g., caregiving burden, self-efficacy stress) and reduce CVD risk. Future studies are needed to focus on even better ways of administering BA to family dementia caregivers to improve their physical and psychological health.

Acknowledgments

None.

References

1. World Health Organization. *Mental Health*. 2017. http://www.who.int/mental_health/neurology/dementia/en/. Accessed 14 June 2018.
2. World Health Organization. *China: Improving Home Care for Dementia Patients*. 2014. http://www.who.int/features/2014/china-dementia-patients/en/. Accessed 20 June 2018.
3. Brodaty H, Donkin M. Family caregivers of people with dementia. *Dialogues Clin Neurosci*. 2009;11(2):217.
4. Tremont G. Family caregiving in dementia. *Med Health R I*. 2011;94(2):36.
5. Wimo A, von Strauss E, Nordberg G, Sassi F, Johansson L. Time spent on informal and formal care giving for persons with dementia in Sweden. *Health Policy*. 2002;61(3):255–268. https://doi.org/10.1016/s0168-8510(02)00010-6.
6. Clare L, Wilson BA, Carter G, Breen K, Berrios GE, Hodges JR. Depression and anxiety in memory clinic attenders and their carers: implications for evaluating the effectiveness of cognitive rehabilitation interventions. *Int J Geriatr Psychiatry*. 2002;17(10):962–967. https://doi.org/10.1002/gps.735.
7. Adkins VK. Treatment of depressive disorders of spousal caregivers of persons with Alzheimer's disease: a review. *Am J Alzheimer's Dis*. 1999;14(5):289–293. https://doi.org/10.1177/153331759901400501.
8. Ory MG, Hoffman III RR, Yee JL, Tennstedt S, Schulz R. Prevalence and impact of caregiving: a detailed comparison between dementia and nondementia caregivers. *Gerontologist*. 1999;39(2):177–186. https://doi.org/10.1093/geront/39.2.177.
9. Fisher GG, Franks MM, Plassman BL, et al. Caring for individuals with dementia and cognitive impairment, not dementia: findings from the aging, demographics, and memory study. *J Am Geriatr Soc*. 2011;59(3):488–494. https://doi.org/10.1111/j.1532-5415.2010.03304.x.
10. Brodaty H, Donkin M. Family caregivers of people with dementia. *Dialogues Clin Neurosci*. 2009;11(Jun (2)):217–228. https://doi.org/10.1034/j.1600-0579.2003.00210.x.
11. Lewinsohn PM, Libet J. Pleasant events, activity schedules, and depressions. *JAP*. 1972;79(3):291. http://dx.doi.org/10.1037/h0033207.
12. Lewinsohn PM, Graf M. Pleasant activities and depression. *J Consult Clin Psychol*. 1973;41(2):261. http://dx.doi.org/10.1037/h0035142.
13. Zarit SH, Edwards AB. Family Caregiving: Research and Clinical Intervention Handbook of the Clinical Psychology of Ageing. 2nd ed. 2008:255–288.
14. Mausbach BT, Patterson TL, Grant I, Mausbach BT, Patterson TL, Grant I. Is depression in Alzheimer's caregivers really due to activity restriction? a preliminary mediational test of the Activity Restriction Model. *J Behav Ther Exp Psychiatry*. 2008;39(4):459–466. https://doi.org/10.1016/j.jbtep.2007.12.001.
15. Lewinsohn PM. A behavioral approach to depression. *The Psychology of Depression: Contemporary Theory and Research*. John Wiley & Sons; 1974:150–172.
16. Lewinsohn PM, Sullivan JM, Grosscup SJ. Changing reinforcing events: an approach to the treatment of depression. *Psychotherapy*. 1980;17(3):322.
17. Jacobson NS, Dobson KS, Truax PA, et al. A component analysis of cognitive-behavioral treatment for depression. *J Consult Clin Psychol*. 1996;64(2):295.
18. Kanter JW, Busch AM, Rusch LC. *Behavioral Activation. The CBT Distinctive Features Series*. Routledge Taylor & Francis; 2009.
19. Cuijpers P, Van Straten A, Warmerdam L. Behavioral activation treatments of depression: a meta-analysis. *Clin Psychol Rev*. 2007;27(3):318–326. https://doi.org/10.1016/j.cpr.2006.11.001.
20. Mazzucchelli TG, Kane RT, Rees CS. Behavioral activation treatments for depression in adults: a meta–analysis and review. *Clin Psychol Sci*. 2009;16(4):383–411. https://doi.org/10.1111/j.1468-2850.2009.01178.x.
21. Mazzucchelli TG, Kane RT, Rees CS. Behavioral activation interventions for well-being: a meta-analysis. *J Posit Psychol*. 2010;5(2):105–121. https://doi.org/10.1080/17439760903569154.
22. Richards DA, Ekers D, McMillan D, et al. Cost and outcome of behavioural activation versus cognitive behavioural therapy for depression (COBRA): a randomised, controlled, non-inferiority trial. *Lancet*. 2016;388(10047):871–880. https://doi.org/10.1016/S0140-6736(16)31140-0.
23. Martell CR, Dimidjian S, Herman-Dunn R. *Behavioral Activation for Depression: a Clinician's Guide*. New York: Guilford Press; 2013.
24. Lewinsohn PM, Weinstein MS, Alper T. A behavioral approach to the group treatment of depressed persons: a methodological contribution. *J Clin Psychol*. 1970;26(4):525–532. https://doi.org/10.1002/1097-4679.
25. Kanter JW, Puspitasari AJ. Behavioral activation. *Cognitive Behavior Therapy: Core Principles for Practice*. Wiley; 2012:215–216.
26. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev*. 2015;4(1):1.
27. Higgins J, Deeks JJ. Selecting studies and collecting data. *Cochrane Handbook for Systematic Reviews of Interventions: Cochrane Book Series* 2008:2008:151–185. https://doi.org/10.1002/9780470712184.ch7.
28. Higgins JP, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ*. 2011;343:d5928. https://doi.org/10.1136/bmj.d5928.
29. *Review Manager. Version 5.3*. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014; 2013.
30. Huedo-Medina TB, Sánchez-Meca J, Marín-Martínez F, Botella J. Assessing heterogeneity in meta-analysis: q statistic or I^2 index? *Psychol Methods*. 2006;11(2):193. http://dx.doi.org/10.1037/1082-989X.11.2.193.
31. Cohen J. Statistical power analysis. *Curr Dir Psychol Sci*. 1992;1(3):98–101. http://dx.doi.org/10.1111/1467-8721.ep10768783.
32. Au A, Yip H-M, Lai S, et al. Telephone-based behavioral activation intervention for dementia family caregivers: outcomes and mediation effect of a randomized controlled trial. *Patient Educ Couns*. 2019. https://doi.org/10.1016/j.pec.2019.06.009.
33. Steffen AM, Gant JR. A telehealth behavioral coaching intervention for neurocognitive disorder family carers. *Int J Geriatr Psychiatry*. 2016;31(2):195–203. https://doi.org/10.1002/gps.4312.
34. Au A, Gallagher-Thompson D, Wong M, et al. Behavioral activation for dementia caregivers: scheduling pleasant events and enhancing communications. *Clin Interv Aging*. 2015;10:611–619. https://doi.org/10.2147/CIA.S72348.
35. Au A. Developing volunteer-assisted behavioral activation teleprograms to meet the needs of Chinese dementia caregivers. *Clin Gerontol*. 2015;38(3):190–202. https://doi.org/10.1080/07317115.2015.1008118.
36. Moore RC, Chattillion EA, Ceglowski J, et al. A randomized clinical trial of Behavioral Activation (BA) therapy for improving psychological and physical health in dementia caregivers: results of the Pleasant Events Program (PEP). *Behav Res Ther*. 2013;51(10):623–632. https://doi.org/10.1016/j.brat.2013.07.005.
37. Prick A-E, de Lange J, Twisk J, Pot AM. The effects of a multi-component dyadic intervention on the psychological distress of family caregivers providing care to people with dementia: a randomized controlled trial. *Int Psychogeriatr*. 2015;27(12):2031–2044. https://doi.org/10.1017/S104161021500071X.
38. Bourgeois MS, Schulz R, Burgio LD, Beach S. Skills training for spouses of patients with Alzheimer's disease: outcomes of an intervention study. *J Clin Geropsychol*. 2002;8(1):53–73.
39. Losada A, Márquez–González M, Romero–Moreno R. Mechanisms of action of a psychological intervention for dementia caregivers: effects of behavioral activation and modification of dysfunctional thoughts. *Int J Geriatr Psychiatry*. 2011;26(11):1119–1127. https://doi.org/10.1002/gps.2648.
40. Márquez-González M, Losada A, Izal M, Pérez-Rojo G, Montorio I. Modification of dysfunctional thoughts about caregiving in dementia family caregivers: description and outcomes of an intervention programme. *Aging Ment Health*. 2007;11(6):616–625. https://doi.org/10.1080/13607860701368455.
41. Lejuez CW, Hopko DR, Hopko SD. A brief behavioral activation treatment for depression: treatment manual. *Behav Modif*. 2001;25(2):255–286. https://doi.org/10.1177/0145445501252005.
42. Gonyea JG, O'Connor MK, Boyle PA. Project CARE: a randomized controlled trial of a behavioral intervention group for Alzheimer's disease caregivers. *Gerontologist*. 2006;46(6):827–832. https://doi.org/10.1093/geront/46.6.827.
43. Teri L, Gibbons LE, McCurry SM, et al. Exercise plus behavioral management in patients with Alzheimer disease: a randomized controlled trial. *JAMA*. 2003;290(15):2015–2022. https://doi.org/10.1001/jama.290.15.2015.
44. Coon DW, Thompson L, Steffen A, Sorocco K, Gallagher-Thompson D. Anger and depression management: psychoeducational skill training interventions for women caregivers of a relative with dementia. *Gerontologist*. 2003;43(5):678–689. https://doi.org/10.1093/geront/43.5.678.
45. Hirano A, Umegaki H, Suzuki Y, Hayashi T, Kuzuya M. Effects of leisure activities at home on perceived care burden and the endocrine system of caregivers of dementia patients: a randomized controlled study. *Int Psychogeriatr*. 2016;28(2):261–268. https://doi.org/10.1017/S1041610215001295.
46. Pinquart M, Sörensen S, Pinquart M, Sörensen S. Helping caregivers of persons with dementia: which interventions work and how large are their effects? *Int Psychogeriatr*. 2006;18(4):577–595. https://doi.org/10.1017/S1041610206003462.
47. Brodaty H, Green A, Koschera A. Meta–analysis of psychosocial interventions for caregivers of people with dementia. *J Am Geriatr Soc*. 2003;51(5):657–664. https://doi.org/10.1034/j.1600-0579.2003.00210.x.
48. O'Donohue WT, Fisher JE. *Cognitive Behavior Therapy: Core Principles for Practice*. John Wiley & Sons; 2012.
49. Prowse P-T, Nagel TM. A meta-evaluation: the role of treatment fidelity within psychosocial interventions during the last decade. *Afr J Psychiatry*. 2015;18(2). https://doi.org/10.4172/2378-5756.1000251.
50. Dorsey S, Pullmann MD, Deblinger E, et al. Improving practice in community-based settings: a randomized trial of supervision-study protocol. *Implement Sci*. 2013;8(1):89. https://doi.org/10.1111/j.1752-7325.2011.00233.x.
51. Borrelli B. The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. *J Public Health Dent*. 2011;71(s1):S52–S63. https://doi.org/10.1111/j.1752-7325.2011.00233.x.
52. Chattillion EA, Ceglowski J, Roepke SK, et al. Pleasant events, activity restriction, and blood pressure in dementia caregivers. *Health Psychol*. 2013;32(Jul (7)):793–801. http://dx.doi.org/10.1037/a0029412.
53. Ho JS. *Mediators and Moderators of Dementia Caregiver Depression and CVD Risk Outcomes in the Pleasant Events Program*. San Diego: University of California; 2017.
54. Mausbach BT, Romero-Moreno R, Bos T, et al. Engagement in pleasant leisure activities and blood pressure: a 5-year longitudinal study in Alzheimer caregivers. *Psychosom Med*. 2017;79(7):735–741. https://doi.org/10.1016/j.jbtep.2007.12.001.
55. Winter L, Gitlin LN. Evaluation of a telephone-based support group intervention for female caregivers of community-dwelling individuals with dementia. *Am J Alzheimers Dis Other Demen*. 2007;21(6):391–397. https://doi.org/10.1177/1533317506291371.
56. Tremont G, Duncan Davis J, Bishop DS, Fortinsky RH. Telephone-delivered psychosocial intervention reduces burden in dementia caregivers. *Dementia*. 2008;7(4):503–520. https://doi.org/10.1177/1471301208096632.
57. Steffen AM. Anger management for dementia caregivers: a preliminary study using video and telephone interventions. *Behav Ther*. 2000;31(2):281–299. https://doi.org/10.1016/S0005-7894(00)80016-7.

Appendix B Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

YOU MUST PROVIDE A RESPONSE FOR ALL ITEMS. ENTER N/A IF NOT APPLICABLE

No. Item	**Guide questions/description**	**Reported on Page #**
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	
3. Occupation	What was their occupation at the time of the study?	
4. Gender	Was the researcher male or female?	
5. Experience and training	What experience or training did the researcher have?	
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	
12. Sample size	How many participants were in the study?	

13. Non-participation	How many people refused to participate or dropped out? Reasons?	
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	
20. Field notes	Were field notes made during and/or after the inter view or focus group?	
21. Duration	What was the duration of the inter views or focus group?	
22. Data saturation	Was data saturation discussed?	
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	
25. Description of the coding tree	Did authors provide a description of the coding tree?	
26. Derivation of themes	Were themes identified in advance or derived from the data?	
27. Software	What software, if applicable, was used to manage the data?	
28. Participant checking	Did participants provide feedback on the findings?	
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
30. Data and findings consistent	Was there consistency between the data presented and the findings?	
31. Clarity of major themes	Were major themes clearly presented in the findings?	
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	

Appendix C Treatment fidelity checklist

Rate: Present, Absent but should be present, and Not Applicable. If present, describe the strategy used for that component.

Treatment Design

1. Provide information about treatment dose in the intervention condition
    a. Length of contact (minutes)
    b. Number of contacts
    c. Content of treatment
    d. Duration of contact over time
2. Provide information about treatment dose in the comparison condition
    a. Length of contact (minutes)
    b. Number of contacts
    c. Content of treatment
    d. Duration of contact over time
    e. Method to ensure that dose is equivalent between conditions.
    f. Method to ensure that dose is equivalent for participants within conditions.
3. Specification of provider credentials that are needed.
4. Theoretical model upon which the intervention is based is clearly articulated.
    a. The active ingredients are specified and incorporated into the intervention
    b. Use of experts or protocol review group to determine whether the intervention protocol reflects the underlying theoretical model or clinical guidelines
    c. Plan to ensure that the measures reflect the hypothesized theoretical constructs/mechanisms of action
5. Potential confounders that limit the ability to make conclusions at the end of the trial are identified? [1]

6. Plan to address possible setbacks in implementation (i.e., back-up systems or providers)

   If more than one intervention is described, all described equally well.

Training Providers

1. Description of how providers will be trained (manual of training procedures))
2. Standardization of provider training (especially if multiple waves of training are needed for multiple groups of providers).
3. Assessment of provider skill acquisition.
4. Assessment and monitoring of provider skill maintenance over time
5. Characteristics being sought in a treatment provider are articulated a priori. Characteristics that should be avoided in a treatment provider are articulated a priori.
6. At the hiring stage, assessment of whether or not there is a good fit between the provider and the intervention (e.g., ensure that providers find the intervention acceptable, credible and potentially efficacious
7. There is a training plan that takes into account trainees' different education and experience and learning styles.

Delivery of Treatment

10. Method to ensure that the content of the intervention is delivered as specified.
11. Method to ensure that the dose of the intervention is delivered as specified.
12. Mechanism to assess if the provider actually adhered to the intervention plan or in the case of computer delivered interventions, method to assess participants' contact with the information.
13. Assessment of non-specific treatment effects.
14. Use of treatment manual.
15. There is a plan for the assessment of whether or not the active ingredients were delivered.

16. There is a plan for the assessment of whether or not proscribed components were delivered. (e.g., components that are unnecessary or unhelpful)
17. There is a plan for how will contamination between conditions be prevented.
18. There is an a priori specification of treatment fidelity (e.g, providers adhere to delivering >80% of components).

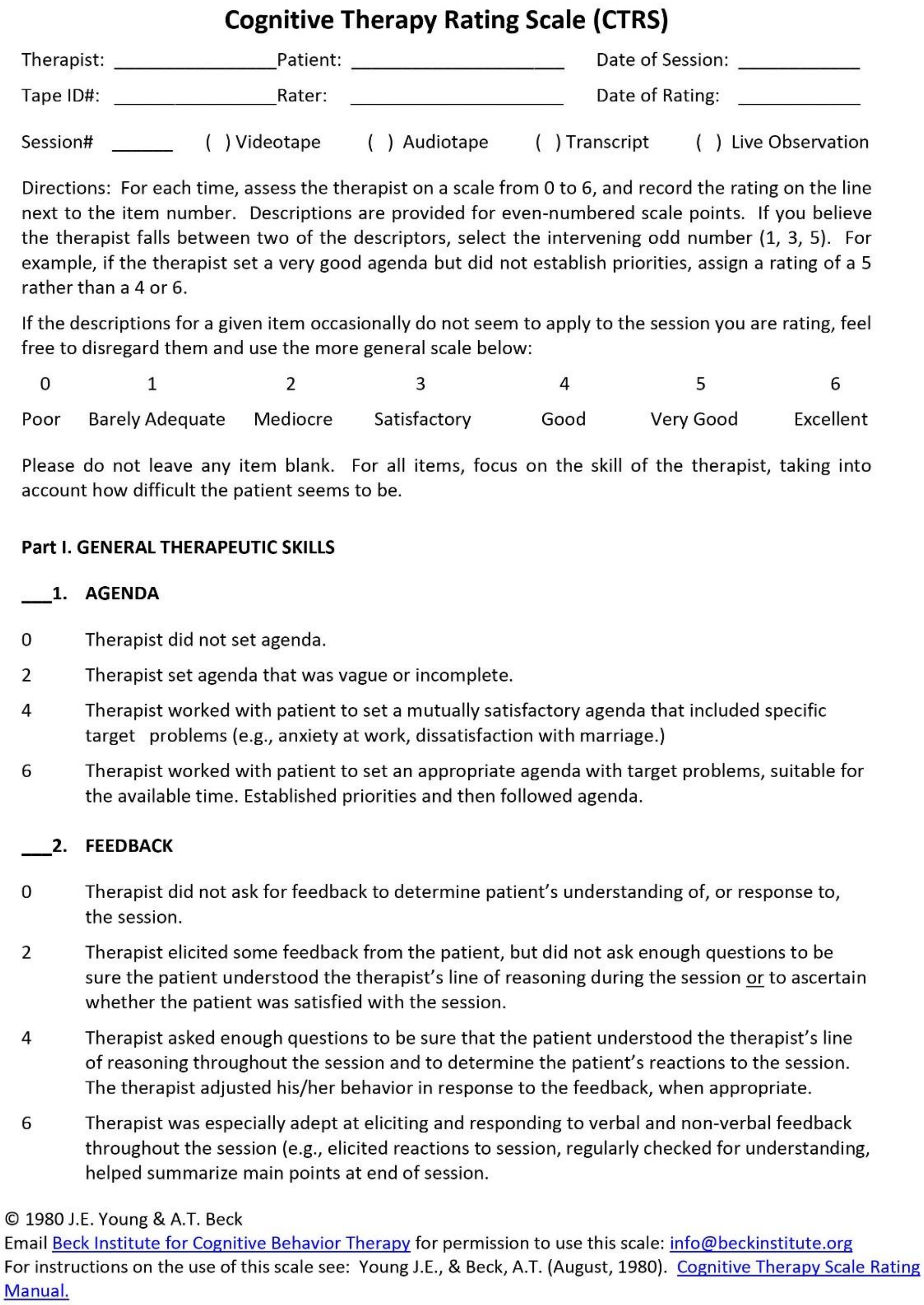
Receipt of Treatment

6. There is an assessment of the degree to which participants understood the intervention.
7. There are specification of strategies that will be used to improve participant comprehension of the intervention.
8. The participants' ability to perform the intervention skills will be assessed during the intervention period.
9. A strategy will be used to improve subject performance of intervention skills during the intervention period.
10. Multicultural factors considered in the development and delivery of the intervention (e.g., provided in native language; protocol is consistent with the values of the target group).

Enactment of Treatment Skills

3. Participant performance of the intervention skills will be assessed in settings in which the intervention might be applied.
4. A strategy will be used to assess performance of the intervention skills in settings in which the intervention might be applied.

Appendix D Cognitive Therapy Rating Scale (CTRS)



Cognitive Therapy Rating Scale (CTRS)

Therapist: ________________Patient: _____________________ Date of Session: ____________

Tape ID#: ________________Rater: _____________________ Date of Rating: ____________

Session# ______ ( ) Videotape ( ) Audiotape ( ) Transcript ( ) Live Observation

Directions: For each time, assess the therapist on a scale from 0 to 6, and record the rating on the line next to the item number. Descriptions are provided for even-numbered scale points. If you believe the therapist falls between two of the descriptors, select the intervening odd number (1, 3, 5). For example, if the therapist set a very good agenda but did not establish priorities, assign a rating of a 5 rather than a 4 or 6.

If the descriptions for a given item occasionally do not seem to apply to the session you are rating, feel free to disregard them and use the more general scale below:

0	1	2	3	4	5	6
Poor	Barely Adequate	Mediocre	Satisfactory	Good	Very Good	Excellent

Please do not leave any item blank. For all items, focus on the skill of the therapist, taking into account how difficult the patient seems to be.

Part I. GENERAL THERAPEUTIC SKILLS

___1. AGENDA

0 Therapist did not set agenda.

2 Therapist set agenda that was vague or incomplete.

4 Therapist worked with patient to set a mutually satisfactory agenda that included specific target problems (e.g., anxiety at work, dissatisfaction with marriage.)

6 Therapist worked with patient to set an appropriate agenda with target problems, suitable for the available time. Established priorities and then followed agenda.

___2. FEEDBACK

0 Therapist did not ask for feedback to determine patient's understanding of, or response to, the session.

2 Therapist elicited some feedback from the patient, but did not ask enough questions to be sure the patient understood the therapist's line of reasoning during the session or to ascertain whether the patient was satisfied with the session.

4 Therapist asked enough questions to be sure that the patient understood the therapist's line of reasoning throughout the session and to determine the patient's reactions to the session. The therapist adjusted his/her behavior in response to the feedback, when appropriate.

6 Therapist was especially adept at eliciting and responding to verbal and non-verbal feedback throughout the session (e.g., elicited reactions to session, regularly checked for understanding, helped summarize main points at end of session.

For instructions on the use of this scale see: Young J.E., & Beck, A.T. (August, 1980). Cognitive Therapy Scale Rating Manual.

___3. UNDERSTANDING

0 Therapist repeatedly failed to understand what the patient explicitly said and thus consistently missed the point. Poor empathic skills.

2 Therapist was usually able to reflect or rephrase what the patient explicitly said, but repeatedly failed to respond to more subtle communication. Limited ability to listen and empathize.

4 Therapist generally seemed to grasp the patient's "internal reality" as reflected by both what the patient explicitly said and what the patient communicated in more subtle ways. Good ability to listen and empathize.

6 Therapist seemed to understand the patient's "internal reality" thoroughly and was adept at communicating this understanding through appropriate verbal and non-verbal responses to the patient (e.g., the tone of the therapist's response conveyed a sympathetic understanding of the patient's "message"). Excellent listening and empathic skills.

___4. INTERPERSONAL EFFECTIVENESS

0 Therapist had poor interpersonal skills. Seemed hostile, demeaning, or in some other way destructive to the patient.

2 Therapist did not seem destructive, but had significant interpersonal problems. At times, therapist appeared unnecessarily impatient, aloof, insincere or had difficulty conveying confidence and competence.

4 Therapist displayed a satisfactory degree of warmth, concern, confidence, genuineness, and professionalism. No significant interpersonal problems.

6 Therapist displayed optimal levels of warmth, concern, confidence, genuineness, and professionalism, appropriate for this particular patient in this session.

___5. COLLABORATION

0 Therapist did not attempt to set up a collaboration with patient.

2 Therapist attempted to collaborate with patient, but had difficulty either defining a problem that the patient considered important or establishing rapport.

4 Therapist was able to collaborate with patient, focus on a problem that both patient and therapist considered important, and establish rapport.

6 Collaboration seemed excellent; therapist encouraged patient as much as possible to take an active role during the session (e.g., by offering choices) so they could function as a "team".

For instructions on the use of this scale see: Young J.E., & Beck, A.T. (August, 1980). Cognitive Therapy Scale Rating Manual.

___6. PACING AND EFFICIENT USE OF TIME

0 Therapist made no attempt to structure therapy time. Session seemed aimless.

2 Session had some direction, but the therapist had significant problems with structuring or pacing (e.g., too little structure, inflexible about structure, too slowly paced, too rapidly paced).

4 Therapist was reasonably successful at using time efficiently. Therapist maintained appropriate control over flow of discussion and pacing.

6 Therapist used time efficiently by tactfully limiting peripheral and unproductive discussion and by pacing the session as rapidly as was appropriate for the patient.

Part II. CONCEPTUALIZATION, STRATEGY, AND TECHNIQUE

___7. GUIDED DISCOVERY

0 Therapist relied primarily on debate, persuasion, or "lecturing." Therapist seemed to be "cross-examining" patient, putting the patient on the defensive, or forcing his/her point of view on the patient.

2 Therapist relied too heavily on persuasion and debate, rather than guided discovery. However, therapist's style was supportive enough that patient did not seem to feel attacked or defensive.

4 Therapist, for the most part, helped patient see new perspectives through guided discovery (e.g., examining evidence, considering alternatives, weighing advantages and disadvantages) rather than through debate. Used questioning appropriately.

6 Therapist was especially adept at using guided discovery during the session to explore problems and help patient draw his/her own conclusions. Achieved an excellent balance between skillful questioning and other modes of intervention.

___8. FOCUSING ON KEY COGNITIONS OR BEHAVIORS

0 Therapist did not attempt to elicit specific thoughts, assumptions, images, meanings, or behaviors.

2 Therapist used appropriate techniques to elicit cognitions or behaviors; however, therapist had difficulty finding a focus or focused on cognitions/behaviors that were irrelevant to the patient's key problems.

4 Therapist focused on specific cognitions or behaviors relevant to the target problem. However, therapist could have focused on more central cognitions or behaviors that offered greater promise for progress.

6 Therapist very skillfully focused on key thoughts, assumptions, behaviors, etc. that were most relevant to the problem area and offered considerable promise for progress.

For instructions on the use of this scale see: Young J.E., & Beck, A.T. (August, 1980). Cognitive Therapy Scale Rating Manual.

___**9. STRATEGY FOR CHANGE** *(Note: For this item, focus on the quality of the therapist's strategy for change, not on how effectively the strategy was implemented or whether change actually occurred.)*

0 Therapist did not select cognitive-behavioral techniques.

2 Therapist selected cognitive-behavioral techniques; however, either the overall strategy for bringing about change seemed vague or did not seem promising in helping the patient

4 Therapist seemed to have a generally coherent strategy for change that showed reasonable promise and incorporated cognitive-behavioral techniques.

6 Therapist followed a consistent strategy for change that seemed very promising and incorporated the most appropriate cognitive-behavioral techniques.

___**10. APPLICATION OF COGNITIVE-BEHAVIORAL TECHNIQUES** (*Note: For this item, focus on how skillfully the techniques were applied, not on how appropriate they were for the target problem or whether change actually occurred.)*

0 Therapist did not apply any cognitive-behavioral techniques.

2 Therapist used cognitive-behavioral techniques, but there were significant flaws in the way they were applied.

4 Therapist applied cognitive-behavioral techniques with moderate skill.

6 Therapist very skillfully and resourcefully employed cognitive-behavioral techniques.

___**11. HOMEWORK**

0 Therapist did not attempt to incorporate homework relevant to cognitive therapy.

2 Therapist had significant difficulties incorporating homework (e.g., did not review previous homework, did not explain homework in sufficient detail, assigned inappropriate homework).

4 Therapist reviewed previous homework and assigned "standard" cognitive therapy homework generally relevant to issues dealt with in session. Homework was explained in sufficient detail.

6 Therapist reviewed previous homework and carefully assigned homework drawn from cognitive therapy for the coming week. Assignment seemed "custom tailored" to help patient incorporate new perspectives, test hypotheses, experiment with new behaviors discussed during session, etc.

For instructions on the use of this scale see: Young J.E., & Beck, A.T. (August, 1980). Cognitive Therapy Scale Rating Manual.

被访者编号：

Appendix E Instrument sheet for study outcome measurements

您好！本问卷旨在了解照顾认知障碍症患者对您身体及心里状况的影响，以便我们更好地为您提供服务。本调查所有的问题都不涉及能辨认您身份的信息，答案无对错之分，请您根据自己的实际情况在您认为最合适的答案上打勾（√）。我们会完全对您所填内容保密。您的参与不仅有利于您的心理调适，而且将会对其他照顾者产生积极的影响和巨大的贡献。衷心感谢您的合作！

祝您心想事成，平安幸福！

第一部分：一般情况调查

1. 您的年龄：________

2. 您的性别：

□男　□女

3. 您的受教育程度：

□没有受过教育　□小学　□中学　□大学　□硕士　□博士

4. 您的宗教信仰：

□无宗教信仰　□佛教　□基督教　□道教　□其他 ___________

5. 您的工作：

□在职　□在家做兼职　□辞职　□病休　□全职太太　□务农　□退休

□其他 _____

6. 您的家庭月收入：

□<5000　□5000-10000　□10000-15000　□>15000

7. 您与患者的关系：

□夫妻　□子女　□兄弟姐妹　□父母　□其他 ____

8. 您为患者提供了多久的照顾：__________月

9. 您每天为患者提供多长时间的照顾：__________小时

10. 您一星期照顾患者几天：__________天

11. 您对与患者之间的关系评价是：

□非常好　□好　□较好　□一般　□差　□非常差

12. 您是否曾经吸烟?

□没有　□曾经有，已戒烟　□有，每日吸一包烟或以下

□每日吸 1 包烟以上，但不足两包烟　□每日吸 2 包烟和以上

13. 您是否曾经饮酒?

□不饮酒　□每月饮酒一次　□每月 2-4 次　□每週 2-3 次　□每週 4 次和以上

14. 请您对您的身体状况整体打分（10 分为非常健康，1 分为非常不健康，5 分为马马虎虎）：__________分

15. 血压：舒张压__________mmHg　收缩压__________mmHg

16. 心率：__________次/分钟

被访者编号：

第二部分 休闲娱乐活动状况评估

我们希望了解您一个月大概花多少时间来做下列的休闲娱乐活动

在过去一个月……	没有	很少	一般	常常
1. 看电视				
2. 上网				
3. 听音乐、玩乐器、唱歌				
4. 读书、看报纸				
5. 锻炼身体（散步、跳舞、打球、游泳等）				
6. 聊天				
7. 和朋友吃饭				
8. 和家人聚会				
9. 逛市场				
10. 打麻将、打牌、下棋				
11. 养花、种菜				
12. 和宠物互动				
13. 写字、画画				
14. 其它：				

被访者编号:

第三部分：抑郁状况评估

以下句子描述一些自我感觉或行为。请选出最接近您过去一周的状况。

	没有或基本没有 (不足一天)	少有 (1～2 天)	常有 (3～4 天)	几乎一直有 (5～7)
1) 我最近烦一些原来不烦心的事				
2) 我不想吃东西，胃口不好				
3) 我觉得沮丧，就算有家人和朋友帮助也不管用				
4) 我觉得自己和别人一样好				
5) 我不能集中精力做事				
6) 我感到情绪低沉				
7) 我觉得做每件事都费力				
8) 我感到未来有希望				
9) 我觉得一直以来都很失败				
10) 我感到害怕				
11) 我睡不安稳				
12) 我感到快乐				
13) 我比平时说话要少				
14) 我觉得孤独				
15) 我觉得人们对我不太友好				
16) 我觉得生活得很有意思				
17) 我哭过或想哭				
18) 我感到悲伤难过				
19) 我觉得别人不喜欢我				
20) 我提不起劲儿来做事				

被访者编号：

第四部分：照顾者积极感受评估

虽然在照顾患病家人的过程中，您会遇到很多困难，但是在照顾过程中也会有不同程度的积极感受，请您根据自己的状况做出合适的选择。

照顾家人使您有这种感觉

	非常不同意	有些不同意	中立态度	有些同意	非常同意
1）使我感到自己更加有用					
2）使我对自己感觉良好					
3）使我觉得自己被人需要					
4）使我觉得自己被人感激					
5）使我觉得自己很重要					
6）使我觉得自己很坚强自信					
7）使我更加感激生活					
8）使我对生活的态度更加积极					
9）使我与他人的关系更加牢固					

被访者编号：

第五部分 照顾负担评估

	没有	偶尔	有时	经常	总是
1）您是否认为，您所照料的病人会对您提出过多的照顾要求？					
2）您是否认为，由于护理病人会使自己的时间不够？					
3）您是否认为，在照料病人和努力做好家务及工作之间，您会感到有压力？					
4）您是否认为，因病人的行为而感到为难？					
5）您是否认为，有病人在您的身边而感到烦恼？					
6）您是否认为，您的病人已经影响到了您和您的家人与朋友之间的关系？					
7）您是否认为，对未来感到担心？					
8）您是否认为，病人依赖于您？					
9）当病人在您身边时，您感到紧张吗？					
10）您是否认为，由于护理病人，您的健康受到影响？					
11）您是否认为，由于护理病人，您没有时间办自己的私事？					
12）您是否认为，由于护理病人，您的社交受到影响？					
13）您有没有由于病人在家，放弃朋友来家的想法？					
14）您是否认为，病人只期盼您的照顾，您好像是他/她唯一可依赖的人？					

	没有	偶尔	有时	经常	总是
15）您是否认为，除外您的花费，您没有余钱护理病人?					
16）您是否认为，您有可能花更多的时间照顾病人?					
17）您是否认为，开始护理以来，按照自己的意愿生活已经不可能了?					
18）您是否希望，能把病人留给别人来照顾?					
19）您对病人有不知如何是好的情形吗?					
20）您认为应该为病人做更多的事情吗?					
21）您认为在护理患者上您能做得更好吗?					
22）综合看来您怎样评价自己在护理上的负担?					

第六部分 睡眠状况评估

下面一些问题是关于您最近 1 个月的睡眠情况，请选择或填写最符合您近 1 个月实际情况的答案。请回答下列问题

1. 近 1 个月，晚上上床睡觉通常 ____点钟。

2. 近 1 个月，从上床到入睡通常需要____分钟。

3. 近 1 个月，通常早上____点起床

4. 近 1 个月，每夜通常实际睡眠_____小时（不等于卧床时间）。

对下列问题请选择 1 个最适合您的答案。

5. 近 1 个月 ， 因下列情况影响睡眠而烦恼:

	无	<1 次/周	1-2 次/周	≥ 3 次/周
a. 入睡困难				
b. 夜间易醒或早醒				
c. 夜间去厕所				
d. 呼吸不畅				
e. 咳嗽或鼾声高				
f. 感觉冷				
g. 感觉热				
h. 做恶梦				
i. 疼痛不适				
j. 其它影响睡眠的事情, 如有，请说明:				

6. 近 1 个月，总的来说，您认为自己的睡眠质量

□很好 □较好 □较差 □很差

7. 近 1 个月，您用药物催眠的情况

□无 □<1 次/周 □1-2 次/周 □≥ 3 次/周

8. 近 1 个月，您常感到困倦吗?

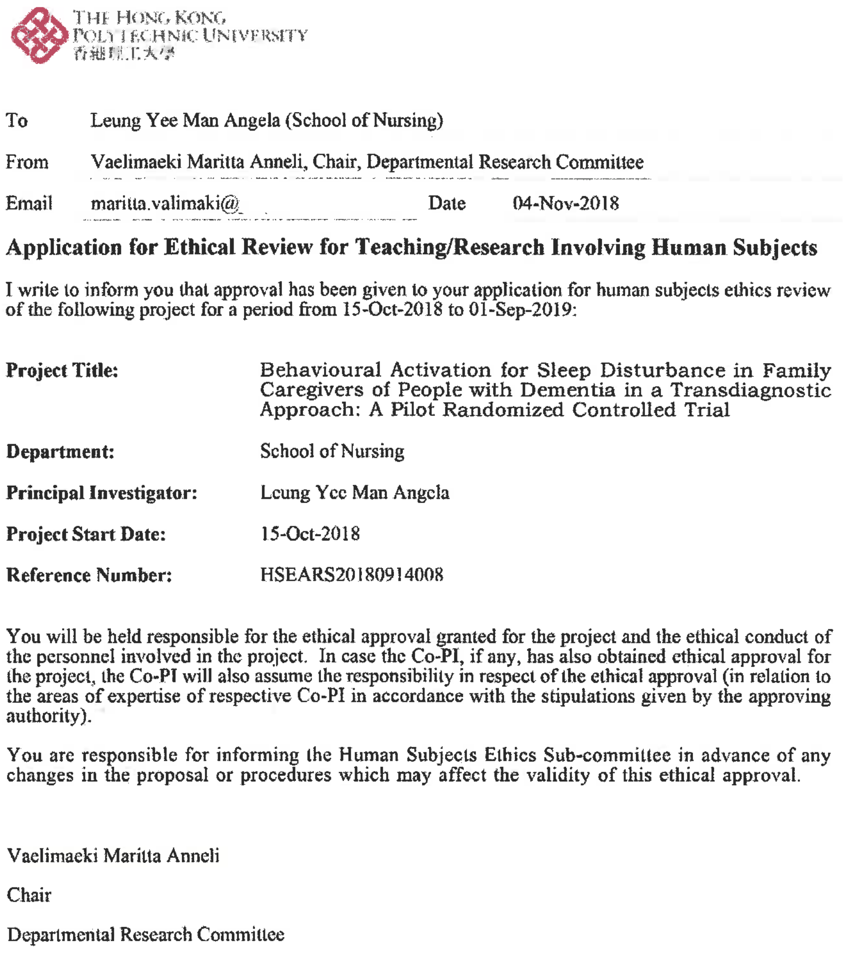
□无 □<1 次/周 □1-2 次/周 □≥ 3 次/周

9. 近 1 个月，您做事情的精力不足吗?

□没有 □偶尔有 □有时有 □经常有

全卷完，谢谢参与!

Appendix F Ethical approval



THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

To Leung Yee Man Angela (School of Nursing)

From Vaelimaeki Maritta Anneli, Chair, Departmental Research Committee

Email maritta.valimaki@ Date 04-Nov-2018

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 15-Oct-2018 to 01-Sep-2019:

Project Title:	Behavioural Activation for Sleep Disturbance in Family Caregivers of People with Dementia in a Transdiagnostic Approach: A Pilot Randomized Controlled Trial
Department:	School of Nursing
Principal Investigator:	Lcung Ycc Man Angcla
Project Start Date:	15-Oct-2018
Reference Number:	HSEARS20180914008

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 Human Subjects Ethics Sub-committee in advance of any changes in the proposal or procedures which may affect the validity of this ethical approval.

Vaelimaeki Maritta Anneli

Chair

Departmental Research Committee

Appendix G Information sheet

THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學

有关资料

行为激活疗法改善认知障碍症患者家庭照顾者心理状况的随机对照预实验

诚邀您参加梁绮雯博士和关耀祖博士负责监督，徐欣怡女士负责执行的研究计划。徐欣怡女士是香港理工大学护理学院的在读博士研究生。

这项研究的目的是评估行为激活疗法对改善认知障碍症患者家庭照顾者心理状况的效果。您将被邀请在干预之前和干预完成后各填写一份问卷，每次约需15分钟。该项目是一个通过电话沟通的干预活动，属于随机对照研究。

如果您被分配在干预组，您将接受为期八周的干预。前四周您将每周定期参加一次通过电话沟通的活动，持续约10-15分钟。干预活动包括心理教育、行为激活疗法技巧练习、照顾技巧分享等。该干预措施不会引起明显的不适。在电话沟通过程中，可能需要您分享照顾认知障碍患者的体验，我们会制定措施保护您的隐私。后四周您将每周定期接到电话访问，持续约5分钟。干预活动包括行为激活疗法的追踪和答疑。

如果您被分配在对照组，将不会参加上述干预活动。如果你需要，我们会在您填写完两次问卷后，将干预活动的资料寄给您，期望对应对照顾压力和改善心情有所帮助。无论您是否参与干预活动，在研究过程中如出现任何不适，可以随时与徐欣怡女士联系，以寻求帮助。

除此之外，在您完成这个试验之后，我们还会邀请您参加一个半结构式的访谈。该访谈是一对一的形式，访谈期间仅有您和徐女士参加。该访谈的目的在于探索研究参与者参加整个试验的体验。在访谈的过程中，徐女士将会问你一些问题，整个访谈过程将全程录音。在您完成试验以后，徐女士将会和您确认最方便的时间进行访谈。

您享有充分的权利在研究开始之前或之后决定退出这项研究，而不会受到任何对您不正常的待遇或被追究责任。所有与您相关的信息都会保密及加上编码，一切资料的编码只有研究人员得悉。在研究结束后会对所有资料进行销毁处理。

如果您对这些研究有任何的不满，可随时与香港理工大学人类实验对象操守小组委员会秘书莫小姐联络（地址：香港理工大学研究事务处转交）。

如果您想获得更多有关这项研究的资料, 请与徐欣怡女士联络，电话186330　　，或联络她的导师梁绮雯博士，电话+852-2766　　。

谢谢您有兴趣参与这项研究。

主要研究员(PI)

梁绮雯博士

Appendix H Consent form

THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學

参与研究同意书

行为激活疗法改善认知障碍症患者家庭照顾者心理状况的随机对照预实验

本人________________同意参加由梁绮雯博士和关耀祖博士负责监督，徐欣怡女士开展的上述研究。

本人理解此研究所得的资料可能被用作未来的研究及学术交流，但本人的隐私权利将得以保留，即本人的个人资料不会被公开。

研究人员已向本人清楚解释列在所附资料卡上的研究程序，本人理解当中涉及的利益及风险；本人自愿参与研究项目。

本人理解本人有权就程序的任何部分提出疑问，并有权随时退出而不受任何不正常的待遇或被追究责任。

参加者姓名：______________________________________

参加者签名：______________________________________

研究人员姓名：______________________________________

研究人员签名：______________________________________

日期：______________________________________

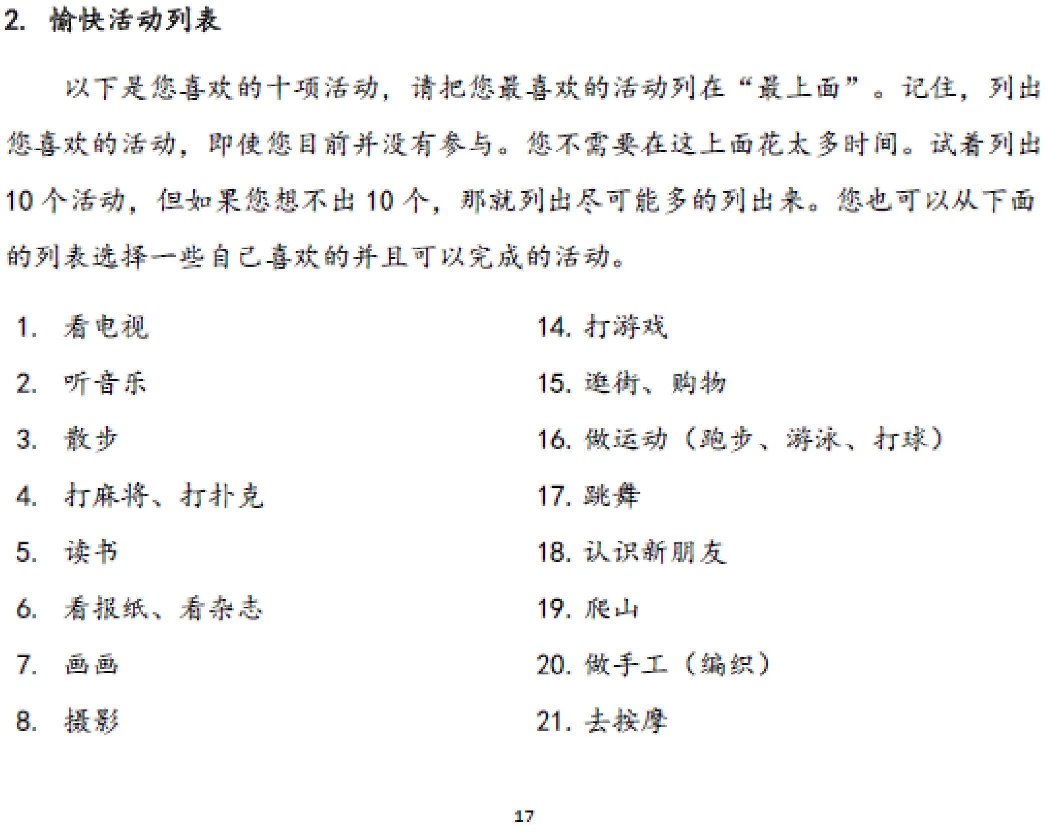
Appendix I Consolidated criteria for reporting qualitative studies (COREQ) for pre-intervention semi-structured interviews

No. Item	**Guide questions/description**	**Reported on Page #**
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	Not applicable
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	Interviewer: MPhil Facilitator: Bsc
3. Occupation	What was their occupation at the time of the study?	Interviewer: student Facilitator: clinical staff
4. Gender	Was the researcher male or female?	Interviewer: female Facilitator: female
5. Experience and training	What experience or training did the researcher have?	Interviewer: have been focus groups' facilitators. Facilitator: has been trained for interviews
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	No
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Reasons for doing the research
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Reasons
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Content analysis
Participant selection		

10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Convenience sampling
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Face to face
12. Sample size	How many participants were in the study?	20
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Three people refused to participate: two people were not available, one person felt embarrassed to talk.
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Homes and clinic
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Demographic data
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Yes
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Audio
20. Field notes	Were field notes made during and/or after the inter view or focus group?	Yes
21. Duration	What was the duration of the inter views or focus group?	Around 30-45 minutes
22. Data saturation	Was data saturation discussed?	Yes
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	Two
25. Description of the coding tree	Did authors provide a description of the coding tree?	Yes
26. Derivation of themes	Were themes identified in advance or derived from the data?	No
27. Software	What software, if applicable, was used to manage the data?	NVivo
28. Participant checking	Did participants provide feedback on the	No

	findings?	
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Yes
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes

Appendix J Examples of pleasant leisure activities for family caregivers of PWD

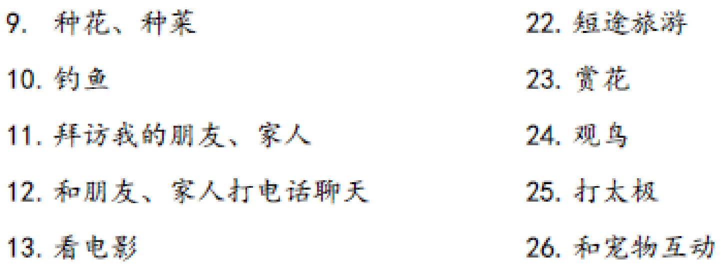


2. 愉快活动列表

以下是您喜欢的十项活动，请把您最喜欢的活动列在“最上面”。记住，列出您喜欢的活动，即使您目前并没有参与。您不需要在这上面花太多时间。试着列出10个活动，但如果您想不出10个，那就列出尽可能多的列出来。您也可以从下面的列表选择一些自己喜欢的并且可以完成的活动。

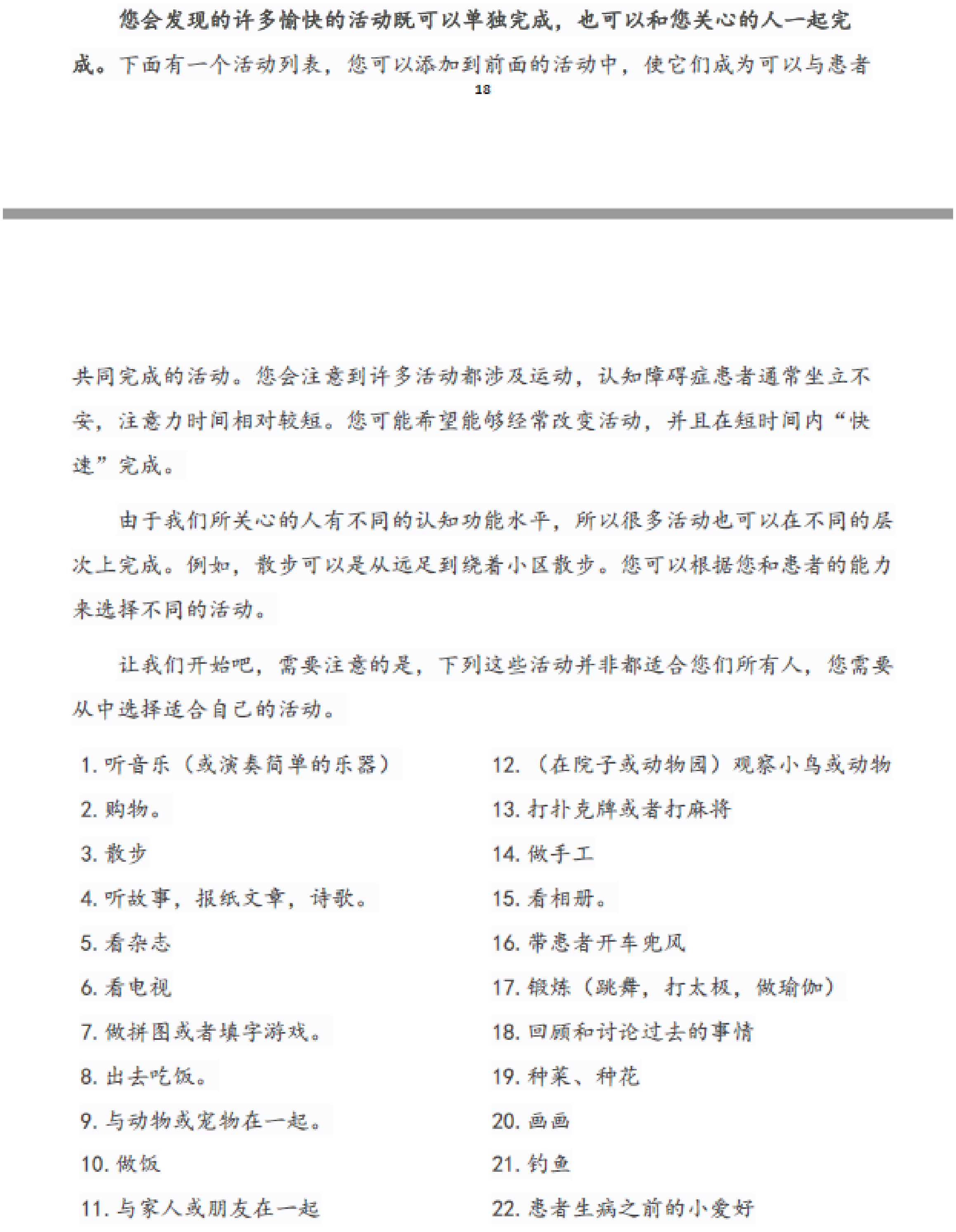
1. 看电视
2. 听音乐
3. 散步
4. 打麻将、打扑克
5. 读书
6. 看报纸、看杂志
7. 画画
8. 摄影

14. 打游戏
15. 逛街、购物
16. 做运动（跑步、游泳、打球）
17. 跳舞
18. 认识新朋友
19. 爬山
20. 做手工（编织）
21. 去按摩



9. 种花、种菜
10. 钓鱼
11. 拜访我的朋友、家人
12. 和朋友、家人打电话聊天
13. 看电影

22. 短途旅游
23. 赏花
24. 观鸟
25. 打太极
26. 和宠物互动



您会发现的许多愉快的活动既可以单独完成，也可以和您关心的人一起完成。下面有一个活动列表，您可以添加到前面的活动中，使它们成为可以与患者

共同完成的活动。您会注意到许多活动都涉及运动，认知障碍症患者通常坐立不安，注意力时间相对较短。您可能希望能够经常改变活动，并且在短时间内“快速”完成。

由于我们所关心的人有不同的认知功能水平，所以很多活动也可以在不同的层次上完成。例如，散步可以是从远足到绕着小区散步。您可以根据您和患者的能力来选择不同的活动。

让我们开始吧，需要注意的是，下列这些活动并非都适合您们所有人，您需要从中选择适合自己的活动。

1. 听音乐（或演奏简单的乐器）
2. 购物。
3. 散步
4. 听故事，报纸文章，诗歌。
5. 看杂志
6. 看电视
7. 做拼图或者填字游戏。
8. 出去吃饭。
9. 与动物或宠物在一起。
10. 做饭
11. 与家人或朋友在一起
12. （在院子或动物园）观察小鸟或动物
13. 打扑克牌或者打麻将
14. 做手工
15. 看相册。
16. 带患者开车兜风
17. 锻炼（跳舞，打太极，做瑜伽）
18. 回顾和讨论过去的事情
19. 种菜、种花
20. 画画
21. 钓鱼
22. 患者生病之前的小爱好

Appendix K Top ten favorable activities

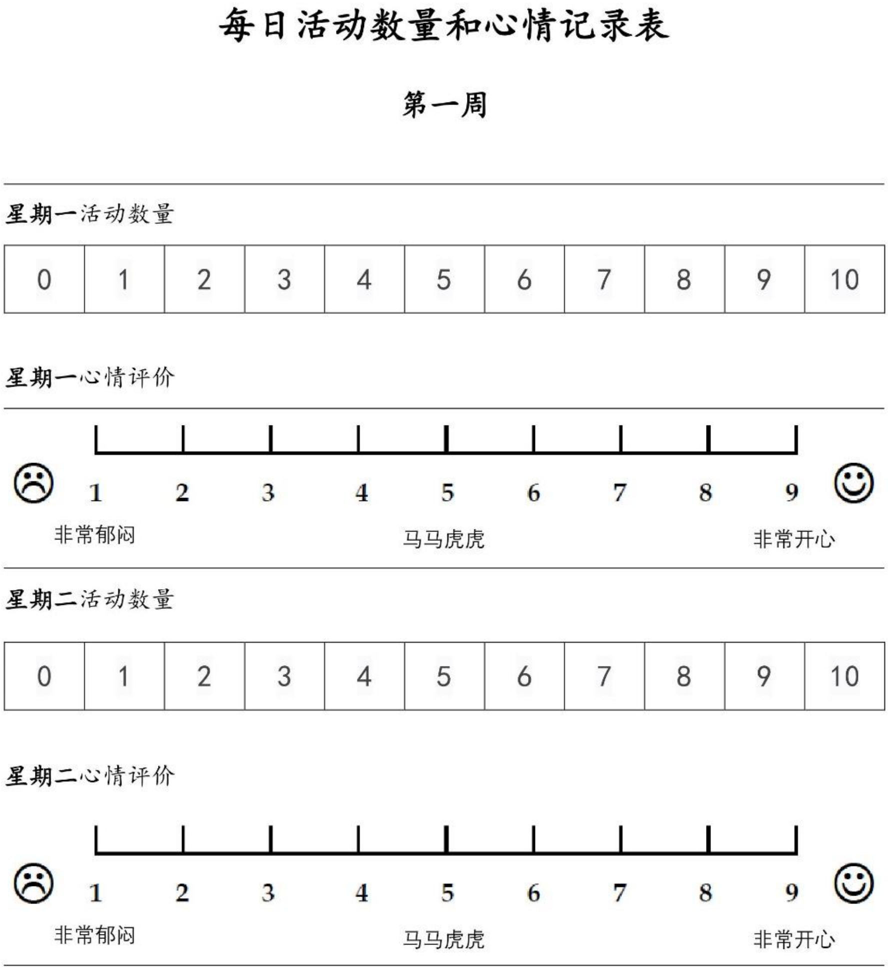
我最喜欢做的十大活动

1.
2.
3.
4.
5.
6.
7.
8.
9.
10.

我最喜欢和家人做的五大活动

1.
2.
3.
4.
5.

Appendix L Daily pleasant events tracking and mood rating form



每日活动数量和心情记录表

第一周

星期一活动数量

0	1	2	3	4	5	6	7	8	9	10

星期一心情评价

☹ 1 2 3 4 5 6 7 8 9 ☺

非常郁闷 马马虎虎 非常开心

星期二活动数量

0	1	2	3	4	5	6	7	8	9	10

星期二心情评价

☹ 1 2 3 4 5 6 7 8 9 ☺

非常郁闷 马马虎虎 非常开心

星期三活动数量

0	1	2	3	4	5	6	7	8	9	10

星期三心情评价

☹ 1 2 3 4 5 6 7 8 9 ☺

非常郁闷 马马虎虎 非常开心

星期四活动数量

0	1	2	3	4	5	6	7	8	9	10

星期四心情评价

☹ 1 2 3 4 5 6 7 8 9 ☺

非常郁闷 马马虎虎 非常开心

星期五活动数量

0	1	2	3	4	5	6	7	8	9	10

星期五心情评价

☹ 1 2 3 4 5 6 7 8 9 ☺

非常郁闷 马马虎虎 非常开心

星期六活动数量

0	1	2	3	4	5	6	7	8	9	10

星期六心情评价

☹ 1 2 3 4 5 6 7 8 9 ☺

非常郁闷 马马虎虎 非常开心

星期日活动数量

0	1	2	3	4	5	6	7	8	9	10

星期日心情评价

☹ 1 2 3 4 5 6 7 8 9 ☺

非常郁闷 马马虎虎 非常开心

Appendix M Consolidated criteria for reporting qualitative studies (COREQ) for post-intervention semi-structured interviews

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	Not applicable
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	Interviewer: MPhil Facilitator: Bsc
3. Occupation	What was their occupation at the time of the study?	Interviewer: student Facilitator: clinical staff
4. Gender	Was the researcher male or female?	Interviewer: female Facilitator: female
5. Experience and training	What experience or training did the researcher have?	Interviewer: have conducted semi-structured interviews Facilitator: has been semi-structured interviews
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	Yes: intervention provider and participants
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Reasons for doing the research
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Reasons
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography,	Content analysis

	phenomenology, content analysis	
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Purposive sampling
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Face to face
12. Sample size	How many participants were in the study?	19
13. Non-participation	How many people refused to participate or dropped out? Reasons?	One person refused to participate: time inconvenience
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Homes and clinic
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Demographic data
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Yes
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Audio
20. Field notes	Were field notes made during and/or after the inter view or focus group?	Yes
21. Duration	What was the duration of the inter views or focus group?	Around 30-45 minutes
22. Data saturation	Was data saturation discussed?	Yes
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	Two
25. Description of the coding tree	Did authors provide a description of the coding tree?	Yes
26. Derivation of themes	Were themes identified in advance or derived from the data?	No
27. Software	What software, if applicable, was used to manage the data?	NVivo
28. Participant checking	Did participants provide feedback on the findings?	No
Reporting		

29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Yes
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes