DIETARY BEHAVIOUR CHANGE INTERVENTION FOR MANAGING SARCOPENIC OBESITY AMONG COMMUNITY-DWELLING OLDER PEOPLE: A PILOT RANDOMISED CONTROLLED TRIAL

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PhD

The Hong Kong Polytechnic University

2021

The Hong Kong Polytechnic University

School of Nursing

Dietary behaviour change intervention for managing sarcopenic obesity among community-dwelling older people: a pilot randomised controlled trial

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

August 2021

Certificate of Originality

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Abstract

Background

Sarcopenic obesity, a combined condition of muscle loss and fat accumulation, could cause morbidity, falls, metabolic problems, or even mortality. Plenty of interventional studies have been conducted assessing sarcopenic obesity management primarily through exercise and supplements. While exercise is not suitable for all older people, especially for those with physical limitations, and supplements may cause side effects. Comparatively, changing dietary behaviour could help older people develop a healthy dietary habits and have long-term effects on managing sarcopenic obesity. The present study aimed to develop a dietary behaviour change intervention and to evaluate the feasibility and preliminary effects of the intervention on managing sarcopenic obesity among older people in the community.

Methods

This study followed the Medical Research Council 2008 guideline to develop and evaluate the intervention protocol. The intervention was developed based on an evidence-based literature review and the Delphi method, by which the intervention components, including the intervention duration, the dose of calorie and protein intake, and intervention guidebook, were identified. A pilot randomised controlled trial nested with a qualitative interview was conducted to evaluate the feasibility and preliminary effects of the intervention.

This pilot study was a two-armed single-blind trial, which was conducted in three community health centres in Nanjing, China. Sixty participants aged 60 years old or above were allocated to two groups in a 1:1 ratio by block randomisation. The experimental group received a 15-week dietary behaviour change (DBC) intervention (12% caloric reduction/day + 1.2-1.5 g/kg body weight/day intake of protein), which included 6 face-to-face sessions and weekly telephone calls. Behaviour change techniques were utilised during the intervention, which included establishing risk perception, outcome expectancies, coping planning, and actions to enhance self-efficacy. The purposive sampling method was used to identify twenty-one participants from the experimental group with various levels of compliance to food diary taken, who were invited to individual semi-structured interviews after the intervention to explore their perceptions about the intervention process. The control group received regular social interaction at a similar frequency and timing to the experimental group. The feasibility assessment covered the following elements: recruitment, safety, and acceptability of the intervention components. The preliminary effects of the intervention were assessed at baseline (T0) and post-intervention (T1) by evaluating the following outcomes: body composition, handgrip strength, physical performance, nutrition self-efficacy, dietary quality, nutritional status and health status. The data analysis followed the intention-to-treat principle. Descriptive statistics, Chi-square test, Mann Whitney U test, independent t-test, generalised estimating equation, missing completely at random analysis, and content analysis were used to

analyse the data.

Results

The feasibility of the DBC intervention was confirmed by the recruitment rate (57.14%), the response rate of the measurement tool (100%), and the retention rate (83.33%). No adverse events were reported. The percent of people who attended face-to-face sessions at least five times was 73.33%, the adherence rate of people taking food diary rated as moderate or above was 26.66%. The compliance rate to adequate protein intake was 66.67%, and calorie intake for male participants decreased from 1715±284 kcal/day to 1571±267 kcal/day, for female participants decreased from 1696±231 kcal/day to 1451±195 kcal/day. Four themes were synthesised from the qualitative interviews after the intervention: overall perceptions of intervention, barriers in participating in the intervention, facilitators for implementing the intervention, and suggestions for the future program. The participants felt the design of the DBC intervention was acceptable and helpful for them, and they presented desires for learning nutritional knowledge. Compared with the control group, participants in the experimental group significantly reduced the body weight (Wald χ^2=4.90, p=0.027, d=1.22) and improved the dietary quality (Wald χ^2=12.66, p<0.001, d=1.31). However, the skeletal muscle mass (Wald χ^2=5.62, p=0.018, d=0.84) and the fat free mass (Wald χ^2=7.49, p=0.006, d=1.11) of participants in the experimental group were also reduced significantly. The handgrip strength (increased from 15.37 ± 1.08 kg to 18.21 ± 1.68 kg) and 6-m gait

speed (increased from 0.91 ± 0.02 m/s to 0.99 ± 0.03 m/s) in the experimental group showed a trend of increase from baseline to post-intervention.

Conclusions

The dietary behavioural change to increase protein intake and reduce calorie intake can be achieved by older people under the dietary intervention, which has incorporated the behaviour change techniques. The 15-week DBC intervention could significantly decrease the body weight, and presented a trend to increase the handgrip strength and gait speed, but the skeletal muscle mass was decreased simultaneously. Cautions are needed for the generalisation of this study's findings because the insufficient statistic power caused by the small sample size.

Significance

This study combined behaviour change techniques with dietary interventions, which is novel in the research area related to sarcopenic obesity, which addressed the limitations of previous studies in managing sarcopenic obesity. The qualitative results of this study provided us with a better understanding of current older people's needs and concerns in dietary behaviour change. This study indicated the pressing needs to provide professional nutrition knowledge addressing muscle function to community-dwelling older people. This study also demonstrated the potential for employing dietary behaviour change intervention in community healthcare.

Research Output Arising from the Study

Journal Publications:

Yin, Y. H., Liu, J. Y. W., Välimäki, M., Fan, T. M., Leung, K. M., Ng, M. W., Tsang, T. Y., Wong, K. P. (2021) Effectiveness of nutritional advice for community-dwelling obese older adults with frailty: a systematic review and meta-analysis. *Frontiers in Nutrition*. (IF: 6.576)

Yin, Y. H., Liu, J. Y. W., & Välimäki, M. (2020) Effectiveness of non-pharmacological interventions on the management of sarcopenic obesity: A systematic review and meta-analysis. *Experimental Gerontology*, 110937. doi.org/10.1016/j.exger.2020.110937. (IF: 4.032)

Conference Presentations:

Yin, Y.H., Liu, J.Y.W., & Välimäki, M. (2021) The effect of dietary behaviour change intervention on managing sarcopenic obesity in community-dwelling older people: a pilot randomised study. International Conference on Frailty and Sarcopenia Research (ICFSR).

Yin, Y.H., Liu, J.Y.W., Välimäki, M., et al. (2020) Effectiveness of nutritional education in body composition and function for obese older adults with frailty. 2020 NHCGNE Virtual Leadership Conference. United States.

Yin, Y.H., Liu, J.Y.W., & Välimäki, M. (2020) Effectiveness of non-pharmacological interventions on the management of sarcopenic obesity: a systematic review and meta-analysis. The 23rd East Asian Forum of Nursing Scholars (EAFONS). Chiang Mai, Thailand: Chiang Mai University Faculty of Nursing.

Yin, Y.H., Liu, J.Y.W., & Välimäki, M. (2020) Effectiveness of nutritional education for community-dwelling obese older adults with frailty: a systematic review and meta-analysis. 2020 Gerontological Society of American Annual Scientific Meeting. Online, United States: GSA.

Yin, Y.H., Zhang, W.W., Yang, D.D. (2019) Effectiveness of protein intake interventions on muscle building and physical function in older people with sarcopenia: a systematic review and meta-analysis. The 11th Asia Pacific Conference on Clinical Nutrition (APCCN). Nanjing, China: Chinese Nutrition Society.

Awards:

01/2020 Best Post Presentation Award at the 23rd East Asian Forum of Nursing Scholars (EAFONS) Conference

Acknowledgements

My Ph.D. journey is about to arrive its destination. In this journey, I have grown from a novice who is extremely new in scientific research to be a doctor of philosophy. This experience brought me lots of gains and further built my character. Here, I would like to thank many people who have given me support, guidance, and encouragement in the past three years.

I would like to express my deep gratitude to my supervisors. My chief supervisor, Dr. Justina Liu, led me into the door of scientific research, guided me to think critically, listened to my thoughts, and cultivated me to work rigorously. My grateful thanks are also extended to my co-supervisor, Prof. Maritta Välimäki, for her valuable guidance, insightful feedback, and continuously encouragement to me. They patiently taught me what research is and nourished me with knowledge bit by bit. I am so grateful, and I will follow in their footsteps on research in the future.

I would like to thank the experts involved in the consultation; they provided valuable time and comments to help me develop the intervention guidebook. I would like to thank the colleagues from the Nanjing Medical University and the nurses from the community health centres; they gave lots of support in the data collection. Special thanks should also go to the participants who participated in the study.

Particularly, I would like to thank my family, who gave me strong support and be my solid backing. Whenever I encountered difficulties or felt depressed, they always gave me strength. Their unconditional love always accompanied me. I especially

would like to thank my lovely son, Ruirui, for bringing me so much happiness.

Finally, I would like to thank my classmates. Thank you for your precious peer support and selfless sharing. Together, we encountered the strike of COVID-19. We encouraged each other, the experience of which made our friendship go further.

May we all the best in the future!

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LIST OF ABBREVIATIONS

BCT	Behaviour change technique
BIA	Bioelectrical impedance analysis
BMI	Body mass index
BMR	Basal metabolic rate
DBC	Dietary behaviour change
DQI-I	Dietary quality index-International
HAPA	Health action process approach
IPAQ-SF	International physical activity questionnaire short-form
MNA	Mini nutritional assessment
MRC	Medical research council
PBF	Percent of body fat
RA	Research assistant
RCT	Randomised controlled trial
SF-36	36-item short form health survey
SMI	Skeletal muscle mass index
SPPB	Short physical performance battery
TIDieR	Template for intervention description and replication

STATISTICAL ACRONYMS

95% CI	Ninety-five percent confidence interval
GEE	generalised estimating equation
MCAR	Missing completely at random
ICC	intraclass correlation coefficient
CVI	content validity index
d	Cohen's *d*
p	*p*-value
df	degree of freedom
SD	standard deviation
SE	standard error
Wald χ^2	Wald Chi-square
χ^2	Chi-square
α	Cronbach's alpha

CHAPTER 1 INTRODUCTION

Sarcopenic obesity is a critical concept during the ageing process. According to different diagnostic methods used, its prevalence in the USA ranged from 4% to 94% in women and 4% to 84% in men (Batsis et al., 2013). The prevalence of sarcopenic obesity in China ranged from 3.2% to 20.4% in women and 13.8% to 27.0% in men (Chen et al., 2014). Sarcopenic obesity can lead to adverse health outcomes, significantly increasing the risk of developing fatigue, physical disability, poor quality of life, institutionalisation, morbidity, and mortality (Polyzos & Margioris, 2018; Stenholm et al., 2008).

Sarcopenic obesity is a physical condition in the ageing process where fat accumulation is simultaneously accompanied by muscle loss (Newman et al., 2005; Roubenoff, 2004). The concept of sarcopenic obesity includes two components (Newman et al., 2005; Roubenoff, 2004). First, 'sarcopenia' is a progressive and generalised muscle impairment. In European experts' newest consensus (Cruz-Jentoft et al., 2019), low muscle strength is the primary parameter of the diagnostic criterion of sarcopenia, low muscle quantity/quality is to confirm the diagnosis, and low physical performance defines the severity level. Asian consensus is similar to European's. The main difference is that the cut-off values of muscle mass, muscle strength and physical performance are based on Asian population values instead of Caucasians (Chen et al., 2020). Second, 'obesity' is the term for abundant fat mass

accumulation that negatively affects health (WHO, 2000). According to WHO (2000), obesity is diagnosed as body mass index (BMI) ≥ 30 kg/m^2 and central obesity as waist circumference ≥ 102 cm in men and ≥ 88 cm in women. Due to different body build, obesity is diagnosed as BMI ≥ 28 kg/m^2 and central obesity as waist circumference ≥ 85 cm in men and ≥ 80 cm in women in China (Chen, 2004).

There are different factors leading to sarcopenic obesity. Natural ageing is one of the main contributing factors, although the ageing-related pathway of sarcopenic obesity is multifactorial. A loss of motor neurons and muscle fibres, insulin resistance, chronic low-grade inflammatory, increased oxidative stress, circulation of more free fatty acids, and declined growth hormone and testosterone hormone can result in the increase of body fat and the loss of muscle mass and function (Goisser et al., 2015; Kob et al., 2015; Nakano et al., 2017). Behavioural factors such as reduced physical activity or insufficient nutrients intake also contribute to body composition change (Goisser et al., 2015). Research has shown that adequate protein intake is essential for muscle building, but the protein intake tends to decrease among the older population (Polyzos & Margioris, 2018), which accelerates muscle loss. Besides, weight gain and fat accumulation are often the results of a negative balance between physical activity and dietary intake (Goisser et al., 2015).

Currently, there is no approved pharmacy in managing sarcopenic obesity, and the interventions were mainly non-pharmacological (Goisser et al., 2015). A systematic review of the current interventional studies in managing sarcopenic obesity

has been conducted, the detailed presentation of which will be presented in Chapter 2. A research gap of implementing dietary behaviour change (DBC) intervention in community older people with sarcopenic obesity was identified. The nutritional intervention means modifying nutrition-related activities or actions that lead to specific nutrition or health outcomes (WHO, 2021), which includes oral supplements intake and dietary intervention. Dietary intervention mentioned in this study differed from other nutritional interventions like oral/enteral, parenteral, or pharmacological methods (WHO, 2021). The dietary intervention in this study focused on daily food intake, which aimed to adjust individual practices and dietary habits via education, i.e., intaking the appropriate amount of energy and protein.

Chapter 3 shows the development of DBC intervention by following the Medical Research Council framework, which contained two stages: development and feasibility piloting (Craig et al., 2008). Stage I of the study was shown in this chapter to develop a DBC intervention for managing sarcopenic obesity among community-dwelling older people. The intervention protocol development process was based on an evidence-based literature review and the Delphi method.

Chapter 4 presents Stage II of the study, which was to investigate the feasibility and preliminary effects of the DBC intervention compared with usual care via a pilot trial. The detailed methods of this pilot trial guided by the CONSORT statement to randomised pilot and feasibility trials (Eldridge et al., 2016) will also be presented. In Chapter 5, the results of this pilot study, including the feasibility, acceptability, and

preliminary effects outcomes, will be presented. A discussion of the results will be reported in Chapter 6 together with the strengths and limitations of this study. The implications of this study in clinical practice and research will be discussed as well, followed by the conclusions in Chapter 7.

CHAPTER 2 LITERATURE REVIEW

Different interventional studies have already been conducted to manage sarcopenic obesity, but only a few reviews have systematically evaluated the effectiveness of these interventions. One review (Theodorakopoulos et al., 2017) only included two studies. Another three systematic reviews (Hita-Contreras et al., 2018; Hsu et al., 2019; Martínez-Amat et al., 2018) mainly focused on exercise interventions, and the results were contradictory. Still, systematic reviews are lacking to comprehensively evaluate the effectiveness of different non-pharmacological interventions (e.g., exercise, nutritional intervention) on managing sarcopenic obesity. No systematic reviews have described the diagnostic criteria of sarcopenic obesity, either. The various diagnostic criteria in previous interventional studies lead to lacking representativeness of participants, which might affect the true effects of the interventions. This chapter will report the systematic review we conducted, which has been published (Yin, Liu, & Välimäki, 2020).

2.1 Systematic review objectives

The systematic review had three objectives: 1) to describe the criteria used to diagnose people with sarcopenic obesity; 2) to describe the components of the non-pharmacological interventions managing sarcopenic obesity; 3) to evaluate the effectiveness of the non-pharmacological interventions for managing sarcopenic obesity.

2.2 Methods

The systematic review was performed by referring to the PRISMA statement (Moher

et al., 2010) and registered at PROSPERO (CRD42019122452).

2.2.1 Eligible criteria

The inclusion criteria were based on the 'PICOS' (population, intervention, comparator, outcome and study) approach (Schardt et al., 2007). Randomised controlled trials were included if using non-pharmacological interventions to manage body composition, muscle strength and physical performance. Detailed inclusion criteria are presented in Table 2.1.

Table 2. 1 Inclusion criteria of studies based on 'PICOS'

PICOS term	Criteria
Population	adult people with sarcopenic obesity [diagnosis of sarcopenia include the diagnosis of low muscle mass according to the European's consensus (Cruz-Jentoft et al., 2019)]
Intervention	different non-pharmacological interventions, but not be limited to, exercise, nutritional supplements, psychosocial intervention, multifactorial intervention
Comparison	non-pharmacological interventions or a placebo or blank control
Outcomes	including parameters of body composition (e.g., appendicular skeletal muscle mass, percentage of body fat, weight, BMI), muscle strength (e.g., grip strength, etc.) and physical performance (e.g., gait speed, etc.)
Studies	randomised controlled trials (RCTs) or cluster RCTs written in Chinese or English, conference paper and thesis were also considered during literature searching except conference abstracts.

Studies were excluded if the screening criteria were not strictly targeted on sarcopenic obesity, e.g., overweight rather than obese. Studies were excluded if pharmacological methods such as pills, injections or other pharmaceuticals were used.

2.2.2 Search strategy

Eligible RCTs or cluster RCTs published in Chinese or English from six databases

(EMBASE, PubMed, Cochrane Library, PsycINFO, CINAHL and Scopus) without limits to the published year were considered. The search terms were 'sarcopenic obesity', 'sarcopenia or sarcopenic', 'obesity or overweight or obese', 'adiposity or adipos*', which combined with the Boolean operators (OR/AND) (an example of PubMed search strategy was provided in Appendix 1). Reference lists of previous systematic reviews and included studies were manually searched.

2.2.3 Study selection and quality assessment

Two reviewers selected studies independently with EndNote X8 software according to the title and abstract, then screened the full text. Any disagreements were discussed and solved with a third reviewer until a consensus was achieved. The quality of included studies was assessed by two reviewers independently using the Cochrane Risk of Bias Tool (Higgins et al., 2011). The risk of bias graph was conducted by using Review Manager (RevMan) 5.3. Studies were rated as high/low/unclear risk in terms of performance bias, selection bias, attrition bias, and detection bias. The funnel plot was not conducted because of insufficient numbers of studies.

2.2.4 Data extraction and data analysis

The extracted data included: author, title, age, gender, settings, sample size, blinding, group design, intervention duration, assessment tools and time points, and outcome data (including body composition, muscle strength and gait speed). The diagnostic criteria of each study were extracted in a separate table. The intervention components were summarised according to the template for intervention description and replication

(TIDieR) checklist and guideline (Hoffmann et al., 2014).

Meta-analysis of random effects model in RevMan 5.3 was conducted to estimate the effects of non-pharmacological interventions on the outcomes, including percent of body weight, BMI, skeletal muscle mass index, appendicular skeletal muscle mass, fat-free mass, grip strength, and gait speed. Subgroup analyses were conducted according to the operationalisation of sarcopenia in terms of different estimation methods of skeletal muscle mass index (e.g., adjusted by height/weight/BMI). A p-value of ≤ 0.1 for the chi-square test indicates the presence of heterogeneity (Higgins et al., 2003). Qualitative synthesis was used in the outcomes that were not included in the meta-analysis. The quality of the evidence was assessed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) (GRADE Working Group, 2004), which was rated according to five categories: risk of bias, imprecision, inconsistency, indirectioness, and other factors such as publication bias (Balshem et al., 2011).

2.3 Results

2.3.1 Characteristics of included studies

Among 5092 identified articles, 16 articles that contained 12 studies were included (see Figure 2.1: PRISMA Flowchart showing the study selection).

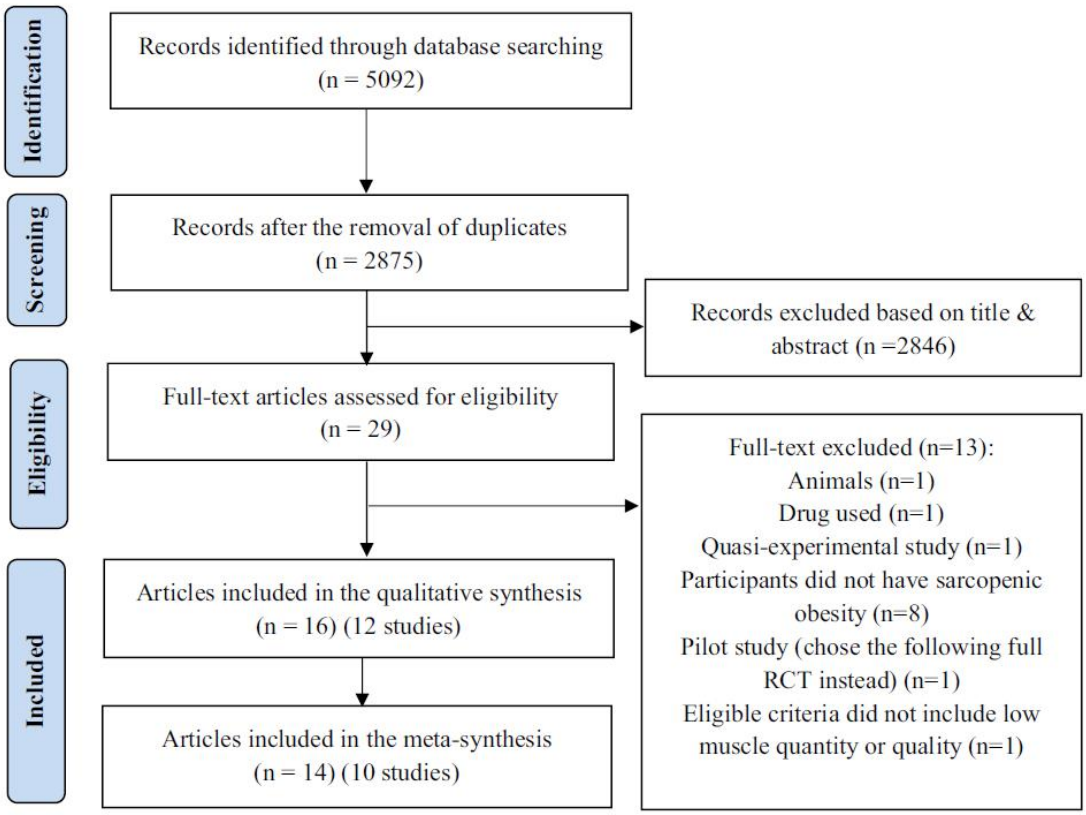


Figure 2. 1 PRISMA Flowchart showing the study selection

The included 12 studies were conducted from 2014 to 2017. The sample size of participants in the studies ranged from 18 to 139, and 863 participants from the 12 studies were recruited. The average age of participants was 72.01 ± 7.76 years old (Characteristics of the studies included in the review are shown in Table 2.2).

Table 2. 2 Characteristics of the studies included in the review

Author, year	Country/Region	Setting & Intervention duration	Population (sample size) Mean age	Group design (number, age)	Compliance number & Attrition	Assessment time point	Outcomes
Kemmler et al., 2017	Germany	Community 16 weeks	≥70 years old men (N=100) 77.4±4.8	①Protein (n=33, 78.1±5.1) ②WBEMS&Protein (n=33, 77.1±4.3) ③CG (n=34, 76.9±5.1)	92 8%	Baseline, Week 16	Sarcopenia Z-Score, total body fat, ASM, SMI, grip strength, PBF
Kemmler et al., 2016	Germany	Community 26 weeks	≥70 years old women (N=75) 77.0±4.3	①WBEMS (n=25, 77.3 ± 4.9) ②WBEMS&Protein (n=25, 76.4±2.9) ③CG (n=25, 77.4 ± 4.9)	67 10.67%	Baseline, Week 26	Sarcopenia Z-Score total body fat, PBF, SMI, grip strength, gait speed
Kim et al., 2016	Japan	Community 3 months	≥70 years old women (N=139) 81.1±4.6	①Combined Exercise + Nutrition (n=36, 80.9±4.2) ②Combined Exercise (n=35, 81.4±4.3) ③Nutrition (n=34, 81.2±4.9) ④Health education (n=34, 81.1±5.1)	137 1.44%	Baseline 3-month	Muscle mass, body fat mass, PBF, ASM, SMI, grip strength, walking speed
Balachandran et al., 2014	USA	Community 15 weeks	60-90 years old people (N=21) 71.3±7.8	①Power circuit (HSC group, n=11, 71.6±7.8) ②Hypertrophy (SH group, n=10, 71±8.2)	17 19.05%	Baseline, Week 15	SPPB, SMI, PBF, IADL, grip strength
Chen et al., 2017	Taiwan	Community 8 weeks	65-75 years old people (N=93) 68.8±3.3	①Resistance (RT, n=22, 68.9±4.4) ②Aerobic (AT, n=24, 69.3±3.0) ③Combined exercise (CT, n=25, 68.5±2.7) ④CG (n=22, 68.6±3.1)	60 35.48%	Baseline, week 8, week 12	SMM, SMI, body fat mass, BMI, PBF, visceral fat area, grip strength, maximum back/knee extensor strength, maximum knee
Liao et al., 2018	Taiwan	Rehabilitation centre 12 weeks	60-80 years older women (N=56) 67.3±5.2	①Elastic resistance group (n=33, 66.67±4.54) ②CG (n=23, 68.32±6.05)	50 12%	Baseline, 3-month, 9-month	FFM, LMI, TFM, PBF, SMI, grip strength, leg strength, upper extremity, lower extremity, gait speed, TUG
Gadelha et al., 2016	Brazil	Community 24 weeks	60-80 years old women (N=133) 67.0±5.2	①Resistance training group (n=69, 66.79±5.40) ②CG (n=64, 67.27±5.04)	133 0%	Baseline, Week 24	TFFM, PBF, AFFM, isokinetic peak torque

Park et al., 2017	Korea	Community 24 weeks	≥65 years old women (N=50) 74.1±6.1	①Aerobic & resistance exercise group (n=25, 73.5±7.1) ②CG (n=25, 74.7±5.1)	50 0%	Baseline, Week 24	PBF, ASM, WC, gait speed, left and right grip strength, physical activity
Sammarco et al., 2017	Italy	Community 4 months	41-74 years old women (N=18) 55.0±9.6	①Hypocaloric diet plus placebo (n=9, 58±10) ②Hypocaloric high-protein diet (n=9, 53±8.9)	18 0%	Baseline, 4-month	Weight, fat mass, FFM, grip strength, SPPB
Zhou et al., 2018	Mainland China	Community pension centre 28 weeks	60-80 years old men (N=48) 69.5±5.2	①Electrical acupuncture +Nutrition (n=23, 70.35±5.36) ②Nutrition (n=25, 68.8±5.08)	48 0%	Baseline, Week 4, Week 12, Week 20, Week 28	PBF, ASMM/Height^2
Muscariello et al., 2016	Italy	Community 3 months	>65 years old women (N=104) 66.7±4.9	①Normal protein intake hypocaloric diet (n=50, 66.4±4.5) ②High protein intake hypocaloric diet (n=54, 66.9±5.2)	104 N/A	Baseline, 3-month	MMI, FMI, FFM, FFMI, BMI, WC, grip strength
Nabuco et al., 2019	Brazil	Community 16 weeks	>60 years old women (N=26) 69.1±4.1	①Whey protein (n=13, 68.0±4.2) ②Placebo (n=13,70.1±3.9)	26 0%	Week 1, Week 2, Week 15, Week 16	WC, PBF, trunk/total fat mass, ALST, 1 RM tests, 10-m walk test, RSP

Notes: SMI=skeletal muscle mass index; ASM=appendicular skeletal muscle mass; PBF=Percentage of body fat; WBEMS=whole-body electromyostimulation; VFA=visceral fat area; FFM=fat-free mass; TSM= total skeletal muscle mass; MMI=muscle mass index; LLM=leg lean mass; TFM=total fat mass; TUG=time up and go test; IADL=instrumental activities of daily living; TFFM=total fat-free mass; AFFM=appendicular fat-free mass; WC=waist circumstance; SPPB=short physical performance battery; FMI=fat mass index; FFMI=Fat-free mass index; ALST=appendicular lean soft tissue; RSP=rising from the sitting position test.

Three studies did not clearly explain the random sequence generation, and eight studies did not display the details of allocation concealment. Five studies did not reveal the blinding of assessors. One study did not report the management of incomplete data. Three studies met all assessment criteria and were rated as low risk of bias. The results of the risk of bias evaluation are shown in Figure 2.2.

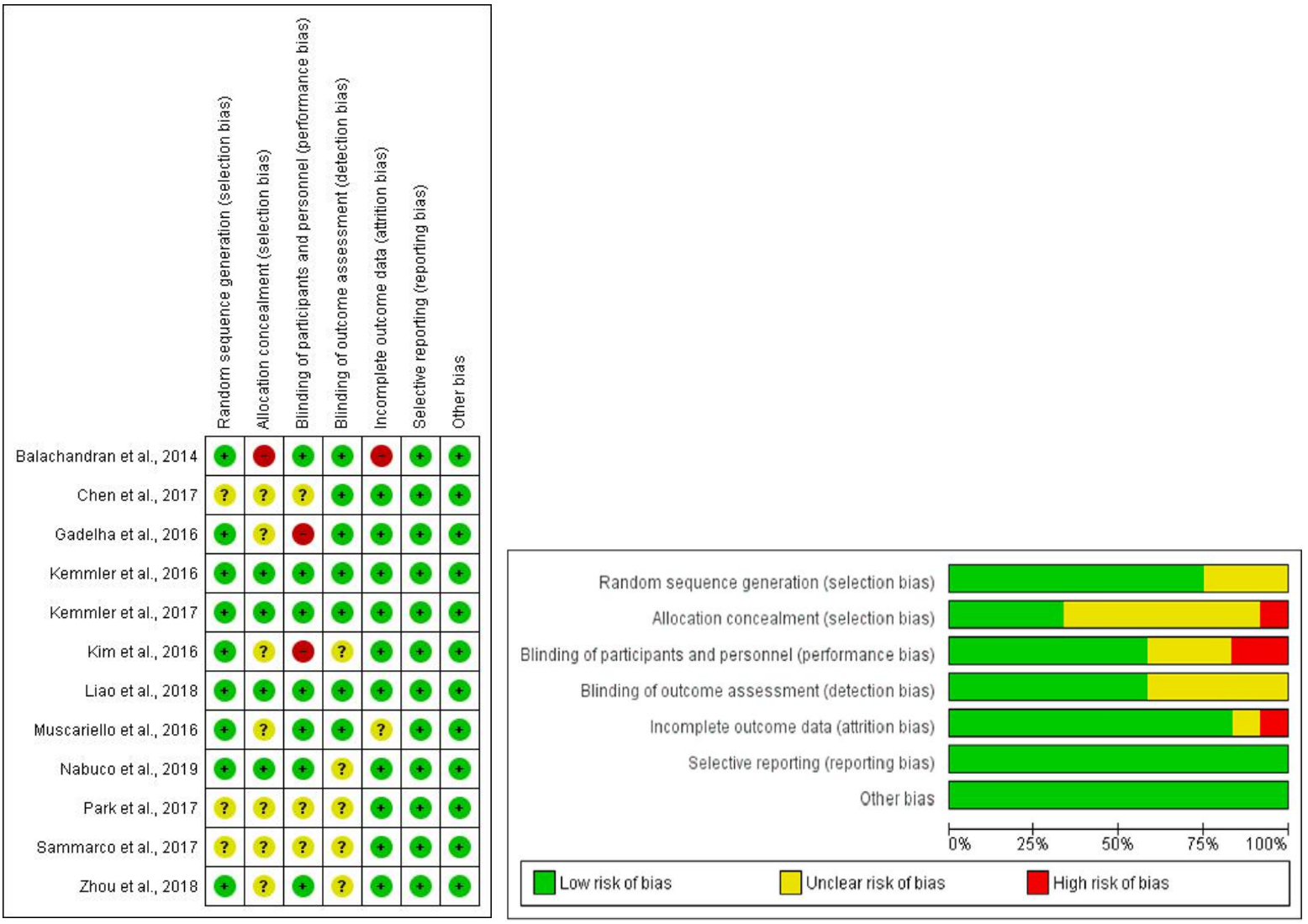


Figure 2. 2 Risk of bias graph

2.3.2 Diagnostic criteria of sarcopenic obesity used in studies (Objective 1)

All studies measured the muscle quantity as diagnostic criteria for sarcopenia. Only two studies (Balachandran et al., 2014; Kim et al., 2016) also included gait speed and grip strength in the screening criteria. For the diagnostic parameter of obesity, six studies used percent of body fat (PBF), five studies chose BMI, one study (Chen et al., 2017) used both percent of body fat and visceral fat area (VFA $\geq$ 100cm^2). The cut-off points of each parameter varied between studies by referring to different standards based on different populations. Detailed information about the diagnostic criteria of sarcopenic obesity in included studies is presented in Table 2.3.

Table 2. 3 Diagnostic criteria for sarcopenic obesity used in the included studies

Studies	Diagnostic criteria for sarcopenia						Diagnostic criteria for obesity		
	Low muscle strength	Low muscle mass				Low physical performance	BMI	PBF	Other criteria
		Adjusted by weight	Adjusted by height^2	Adjusted by BMI	Other criteria				
Kemmler et al., 2017				<0.789				>27%	
Kemmler et al., 2016			<5.75 kg/m^2					>35%	
Kim et al., 2016	Grip strength Women<17.0 kg		≤5.67 kg/m^2			Gait speed <1 m/s		≥32%	
Balachandran et al., 2014	Grip strength Men <30kg; Women<20 kg		Men: ≤10.76 kg/m^2 Women: ≤6.76 kg/m^2			Gait speed ≤1 m/s	>30 kg/m^2		
Chen et al., 2017		Men: ≤32.5% Women: ≤25.7%					≥25 kg/m^2		VFA ≥100cm^2
Liao et al., 2018		<27.6%						≥30%	
Gadelha et al., 2016					AFFM= -13,012 + 16,737× [Height (m)] + 0.07231× [FM (kg)]		≥30 kg/m^2		
Park et al., 2017		< 25.1%					≥25 kg/m^2		
Sammarco et al., 2017					<90% of subject's ideal FFM, (ideal FFM = 0,75 × ideal body weight + 0.25 × excess body weight)			>34.8 %	
Zhou et al., 2018			≤ 7.0kg/m^2					≥25%	
Muscariello et al., 2016			≤7.3 kg/m^2				≥30 kg/m^2	≥35%	WC >88.0 cm FMI≥9.5kg/m^2
Nabuco et al., 2019					Appendicular lean soft tissue < 15.02 kg			≥35%	

Notes: BMI=body mass index; PBF=percentage of body fat; AFFM=appendicular fat-free mass; FFM=fat-free mass; VFA=visceral fat area; MMI=muscle mass index; WC=waist circumference; FMI=fat mass index.

2.3.3 The components of different non-pharmacological interventions (Objective 2

The components of the non-pharmacological interventions varied. Exercise interventions were solely performed in five studies, nutritional interventions were solely performed in only one study, and five studies combined exercise and nutritional interventions. Electrical acupuncture was used in one study, which lasted 20 mins with a frequency of 5 Hz, 20 mins per time, once every three days for 12 weeks. Types of exercises included resistance exercise, aerobic exercise, and exercise machine (i.e., whole-body electromyostimulation and hydraulic exercise machine). The duration of the exercise interventions ranged from 8 to 26 weeks, and the dose varied from 20 mins to 400 mins per week. Nutritional interventions included hypocaloric methods and oral supplements like protein, amino acid, tea catechin, and vitamin D. Only two studies used hypocaloric methods to manage obese conditions. One study (Sammarco et al., 2017) chose to control the calorie as 60%-65% reduction of the whole kcal, another one (Muscariello et al., 2016) chose to ingest 20-25 kcal/kg desirable body weight/day. The durations of nutritional interventions ranged from 12 weeks to 28 weeks. The comparative treatments used in these studies included providing health education or keeping previous usual habits (Table 2.4).

The attrition rate of included studies ranged from 0% to 35.48%. Participants' adherence to different forms of interventions was generally monitored by either face-to-face interviews, telephone calls, or self-reported diaries. In exercise studies,

attendances to face-to-face sessions were often checked to reflect the participants' adherence to interventions. In nutritional studies, the use of a self-administrated food diary was the main method to monitor participants adherence to nutritional instructions, utilised together with frequent telephone calls (4 studies). However, five studies (Balachandran et al., 2014; Chen et al., 2017; Gadelha et al., 2016; Liao et al., 2018; Park, Kwon, & Park, 2017) did not report the methods for checking participants' adherence. Seldom studies reported the participants' adherence to interventions, especially for nutritional studies; how well the participants followed the nutritional instructions was unknown.

Table 2. 4 Description of the interventions of the included studies (modified based on TIDieR checklist) (Hoffmann et al., 2014)

Author	Brief name	Category [a]	Materials and Procedures	Who provided and how	Where, when and how much	How well (adherence)	Comparison group
Kemmler et al., 2017	WB-EMS & Isolated protein supplementation	Exercise, Nutrition, Combined	① WB-EMS equipment (miha bodytec®). A session consisted of 10–14 dynamic exercises structured in one to two sets of eight repetitions performed without any additional weights in a standing position. ② Daily take of whey protein powder and vitamin-D individually based on a 4-day dietary protocol (3 weekdays, 1 weekend day) recorded immediately before and after the trial.	One instructor coached two applicants face to face while taking WB-EMS in a group.	Location N/A. *WB-EMS*: 1.5 times/ week for 20 min/time. *Protein*: daily intake of 1.7–1.8 g/kg/day body mass. The whey protein powder contains 80% of (whey) protein with a caloric value of 1526 kJ/100g (360 kcal/100g). *Vitamin-D*: daily dose of 800 IU. 16 weeks	Adherence was monitored biweekly either by personal interviews or by phone calls. Lost to follow: WBEMS&P: n=3, Protein: n=2, CG: n=3	Take vitamin-D 800 IU/day independently.
Kemmler et al., 2016	WB-EMS, Protein & vitamin-D supplementation	Exercise, Nutrition, Combined	① WB-EMS equipment (miha bodytec®): up to four participants performed a video guided WB-EMS program in a supine sitting/lying position with slight movements of the lower and upper limbs. ② Whey protein powder (FortiFit; Nutricia) & Cholecalciferol (vitamin-D): Supplements were provided on a monthly basis. Participants of the WB-EMS&P group were not supplemented with isolated vitamin D.	Instructors closely cooperate with participants face to face in groups to maintain the intensity of WBEMS training.	Location N/A. *WBEMS*: once a week for 20 min after 8 weeks. *Protein*: 40g/day including 635 kJ caloric, 21g whey protein. *Vitamin-D*: 800 IU/day. 26 weeks	The compliance with dietary supplements was monitored via monthly phone call. Lost to follow-up: WBEMS: n=1, WBEMS&P: n=4, CG: n=3	Health Consultation and Vitamin-D Graduate nutritionist gave one-hour group lecture and individual counselling, with a focus on energy balance and the importance of protein intake.
Kim et al., 2016	Exercise Supplements	Exercise, Nutrition	① Exercise (Resistance: chair, resistance band, hydraulic machine; Aerobic: stationary bicycle):	One instructor coached all four face-to-face	Location: Tokyo Metropolitan Institute of Gerontology.	Participants recorded supplements intake via	Only health education, no exercise or nutrition is

			each exercise session was divided into the warm-up, weight/machine training, stationary bicycle aerobic exercise, and chair/standing exercise. ② Nutrition: take amino acid supplementation and tea catechin daily.	exercise classes, three trainers present at every class to assist.	*Exercise*: twice per week. 60 mins per time. *Nutrition*: 3.0g essential amino acid and 20 μg vitamin D, 350 mL of tea fortified with 540g of catechin daily. *Health education*: once every 2 weeks, a total of six times. 3 months	diary logs every 2 weeks to monitor adherence along with empty packets and bottle caps. Lost to follow-up: Exercise: n=1, Nutrition: n=1	included.
Balachandran et al., 2014	Power circuit training (HSC group) & Strength/Hypertrophy training (SH group)	Exercise	Pneumatic exercise machines (Keiser A420). The HSC group performed 3 sets of 10–12 repetitions on each machine. Participants moved to the next machine after each set with no recovery between sets. One circuit was completed when the participant completed one set on all 11 machines.	A minimum of two trainers (exercise physiology major) supervised the training face to face.	Location N/A Twice per week. HSC: 40-45 mins per time SH: 55-60mins per time 15 weeks	Adherence checking N/A. Lost to follow-up: HSC: n=3, SH: n=1	The SH group performed 3 sets of 10–12 repetitions using 70% of their 1RM on each machine before moving to the next exercise. A 1–2 min recovery was provided between sets. When participants could do 3 sets of 12 repetitions, the load was increased by 5% for the next workout session.

Chen et al., 2017	Resistance training (RT) Aerobic training (AT) Combined training (CT)	Exercise	Weight-training equipment ① RT: 3 sets of 8–12 repetitions with a 2–3 minutes rest between sets. The difficulty of the exercise was adjusted every 2 weeks in ascending order from simple to difficult. ② AT: 5–10 minutes of dynamic stretching and warm-up, 40–45 minutes of the actual training, 10 minutes of closing and relaxation exercises. ③ CT: performed each training mode once a week with the AT following 48 hours after the RT.	Qualified professional trainer supervised the training face to face.	Location N/A RT, AT: two 60-minute sessions per week. CT: each training once a week. 8 weeks	Adherence checking N/A. Lost to follow-up: AT: n=9, RT: n=7, CT: n=10, CG: n=7	Maintain day-to-day lifestyles and dietary habits, be prohibited from engaging in any exercises.
Liao et al., 2018	Elastic band resistance training	Exercise	Theraband products (Hygenic Co.,) Participants individually perform with elastic bands in small groups (less than 6 people). Each exercise session involved a 10-minute warm-up, followed by resistance training exercises (35–40mins), and finally a cool-down routine (5 mins). Types of exercise: shoulders, arms, lower limbs, chest and abdomen.	Licenced senior physical therapist supervised and trained the training sessions face to face.	Location: A group physical therapy classroom in hospital. 3 training sessions weekly, nearly 1 hour every session. 12 weeks	Adherence checking N/A. Lost to follow-up: EG: n=4 CG: n=5	A 40-minute lesson about sarcopenic obesity and the home exercise concept.
Gadelha et al.,2016	Resistance training program	Exercise	Materials N/A After a general warm up, resistance was then adjusted to an estimated 1-RM (repeated in four-week intervals). Three sets of each exercise, and one minute rest between sets. Progressive	Capable professionals supervised all training sessions and 1-RM measurements face to face.	Location N/A 3 times per week 24 weeks	Adherence checking N/A. Lost to follow-up: n=0	Maintain usual activities.

			intensity increase (First 4 weeks: 60% of 1-RM; Second 4 weeks: 70%; Remaining 16 weeks: 80%); Decreased repetitions respectively: 12, 10, 8.				
Park et al., 2017	Combined aerobic and resistance exercises	Exercise	Elastic band (Thera-Band) ① Resistance exercises were performed with elastic band exercises for 8–15 repetitions per set (in weeks 1–12, 8–11 repetitions per set; in weeks 13–24, 12–15 repetitions per set), 2–3 sets (1 min rest between sets), 20–30 min per session for 3 days per week. ② Aerobic exercise involved various walking activities (sideways, backward, and forward walking and slow and fast indoor walking) for 30–50 min per session, 5 days per week, with a rating of perceived exertion (RPE) in the 13–17 range.	An exercise specialist supervised the exercise face to face.	Location: N/A 50-80 mins per time, 5 days per week 24 weeks	Adherence checking N/A. Lost to follow-up: n=0 (but mean attendance rate was 92%)	Maintain individual lifestyles
Sammarco et al., 2017	Hypocaloric diet with protein supplementation	Nutrition	Low-caloric high-protein diet: – energy = basal metabolic rate-10% according to calorimetry; – protein intake: 1.2–1.4 g / kg body weight reference / day with 15 g of protein of high biological value for each main meal (breakfast, lunch and dinner);	Participants practiced at home individually. Details were N/A.	Location: participant's home Dose referred to the previous column. 4 months	Adherence to diets was evaluated by a 7-day dietary record at baseline and at week 4, 8, 12, 16, and was reinforced by the dietitians through counselling and phone	Low-calorie diet plus placebo: -- daily energy intake = metabolic rate-10% according to calorimetry; -- protein intake: 0.8–1 g / kg body weight reference /

			– essential amino acids < branched-chain amino acids < leucine equal to 15 g/day by administration of supplement; – carbohydrate: 60–65% of kcal complex; – fat: to satisfy the required amount of energy; 30% saturated; – report non-protein kcal/g nitrogen = 100/1; – sodium: less than 5 g/day in hypertensive subjects.			calls every 2 weeks. Lost to follow-up: n=0	day; – carbohydrates: 60–65% of whole kcal; – fat: to supply the required amount of energy, with 30% saturated; – sodium: 5- 6 g/day, or less than 5 g / day in hypertensive subjects.
Zhou et al., 2018	Electrical acupuncture & Essential amino acid supplements	Electrical acupuncture	Sterile disposable acupuncture needles (CE-0197) ① Electrical Acupuncture: The acupuncture points (LI14 and LI11 pair, ST31 and ST34 pair) were punctured for 20 mins with a frequency of 5 Hz, wave duration of 1 ms, and strength of 1.5 mA. ②Essential amino acids were taken orally (20g in total, 10:00 AM and 5:00 PM). The breakfast, lunch, and dinner were scheduled at 7: 00 AM, 12: 00 noon, and 7: 00 PM. The total calories of the food were 1.58 × (13.5 × weight (kg) + 487). Those who take less than 80% of total calories 5 times would be excluded from the study.	Two qualified acupuncture physicians conducted the acupuncture. Two cooks were responsible for the meal supply.	Location: community pension centre Acupuncture: 20 mins per time, once every 3 days for 12 weeks; Amino acids: twice per day for 28 weeks. 28 weeks	Record the food intake. A reminder call for drug intake was made once every 7 days. Lost to follow-up: n=0	Only took the amino acid supplements.

Muscariello et al.,2016	Self-administered higher protein intake	Nutrition	① Every participant's calorie intake was approximately 20–25 kcal/kg DBW/day. ② Participants were treated with 1.2 g/kg DBW/day of proteins (breakfast 25%–30% g, lunch 35%–40% g, dinner 35%–40% g).	Participants practiced at home individually. Details were N/A.	Location: participant's home Dose referred to the previous column. 3 months	Taking daily food diary, self-administered, and three reports of 24-hour recall every month during the follow-up. Lost to follow-up: N/A.	Participants were administered with 0.8 g/kg DBW/day of proteins (breakfast 25%–30% g, lunch 35%–40% g, dinner 35%–40% g).
Nabuco et al., 2019	Whey protein following resistance exercise	Exercise, Combined	① After each training session, participants took 35g whey protein (Lacprodan, Arla Foods). ② Resistance training sessions were conducted 3 times per week, including chest press, horizontal leg press, seated row, knee extension, etc.	Physical education professionals	Location: University training facility & participant's home 35 g whey protein per training session 16 weeks	24-h dietary recall was applied via Virtual Nutri Plus software. Lost to follow-up: n=0	Maltodextrin (New Millen, Brazil) was used as placebo, and mixed with non-caloric sugar-free drinks.

Notes: [a] We classified the interventions into four categories: exercise, nutrition, combined exercise and nutrition, electrical acupuncture.
WB-EMS=whole-Body electromyostimulation

2.3.4 Effectiveness of non-pharmacological interventions (Objective 3)

The effectiveness of non-pharmacological interventions was reported in the sequence of different outcomes, including body composition (percent of body fat, BMI, skeletal muscle mass index, appendicular skeletal muscle mass), handgrip strength, and gait speed (an explanation of these outcomes is shown in Section 3.3, Chapter 3), which were the core components for diagnosing sarcopenic obesity. The quality of the evidence level from low to high shown in Table 2.5 was based on the results of GRADE (GRADE Working Group, 2004).

Eight studies (n=639) that measured the percent of body fat to denote body composition were included in the meta-analysis. There was a significant decrease in the percent of body fat with the exercise interventions compared to the usual care (MD: -1.08%, 95% CI: -1.99, -0.17, P=0.02, I^2=50%; Fig 2.3A) were identified based on all eight studies. According to the GRADE, this evidence was rated as low-quality (Table 2.5). However, the effects of the nutritional interventions either solely or combined with exercise on the percent of body fat were not statistically significant compared with the usual care (Figure 2.3B, C).

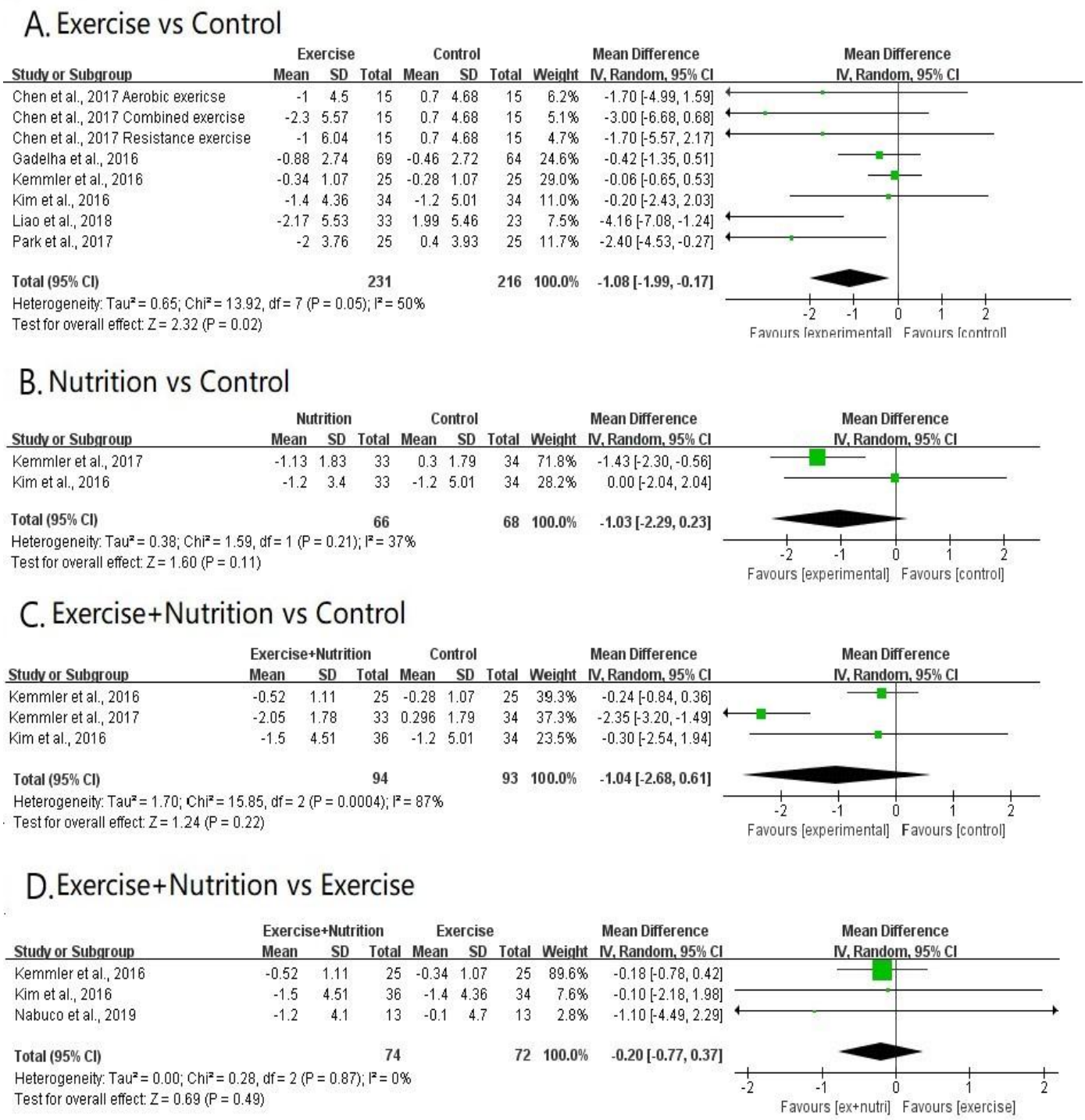


Figure 2. 3 Forest plots of the effectiveness of exercise and nutrition on the percent of body fat

Two studies (n=193) were involved in the meta-analysis that measured BMI to reflect participants' body composition. The overall effect of exercise on reducing BMI was not significant compared to the usual care (MD: -0.17 kg/m^2, 95% CI: -0.67, 0.33, p=0.50, I^2=0%; Fig 2.4). In one individual study (Muscariello et al., 2016), a significant decrease in BMI values was found in the calorie control groups, both with or without protein intake (30.7±1.3 vs 32.0±2.3 kg/m^2, p<0.01; 30.3±0.9 vs 31.1±2.9 kg/m^2, p<0.01).

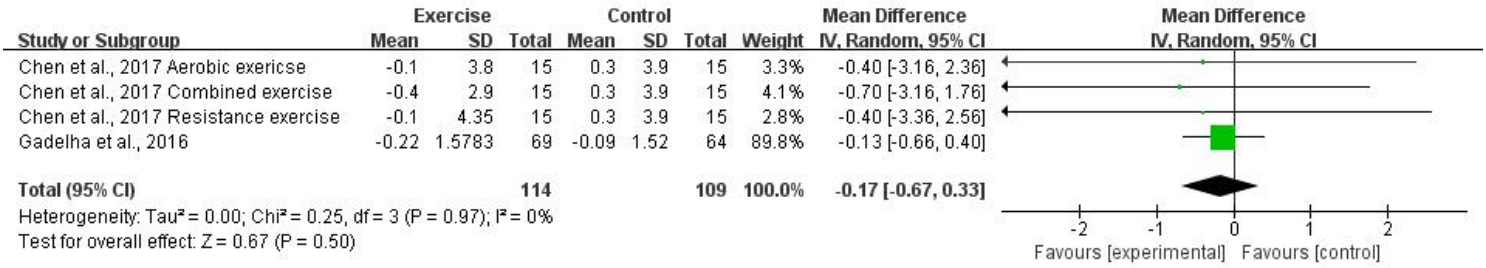


Figure 2. 4 Forest plot of the effectiveness of exercise on BMI

Five studies (n=585) were involved in the meta-analysis that measured the skeletal muscle mass index to reflect participants' body composition. Either solely performed or combined, exercise and nutritional interventions had no significant effects on the skeletal muscle mass index compared with usual care (Fig 2.5A, B, C).

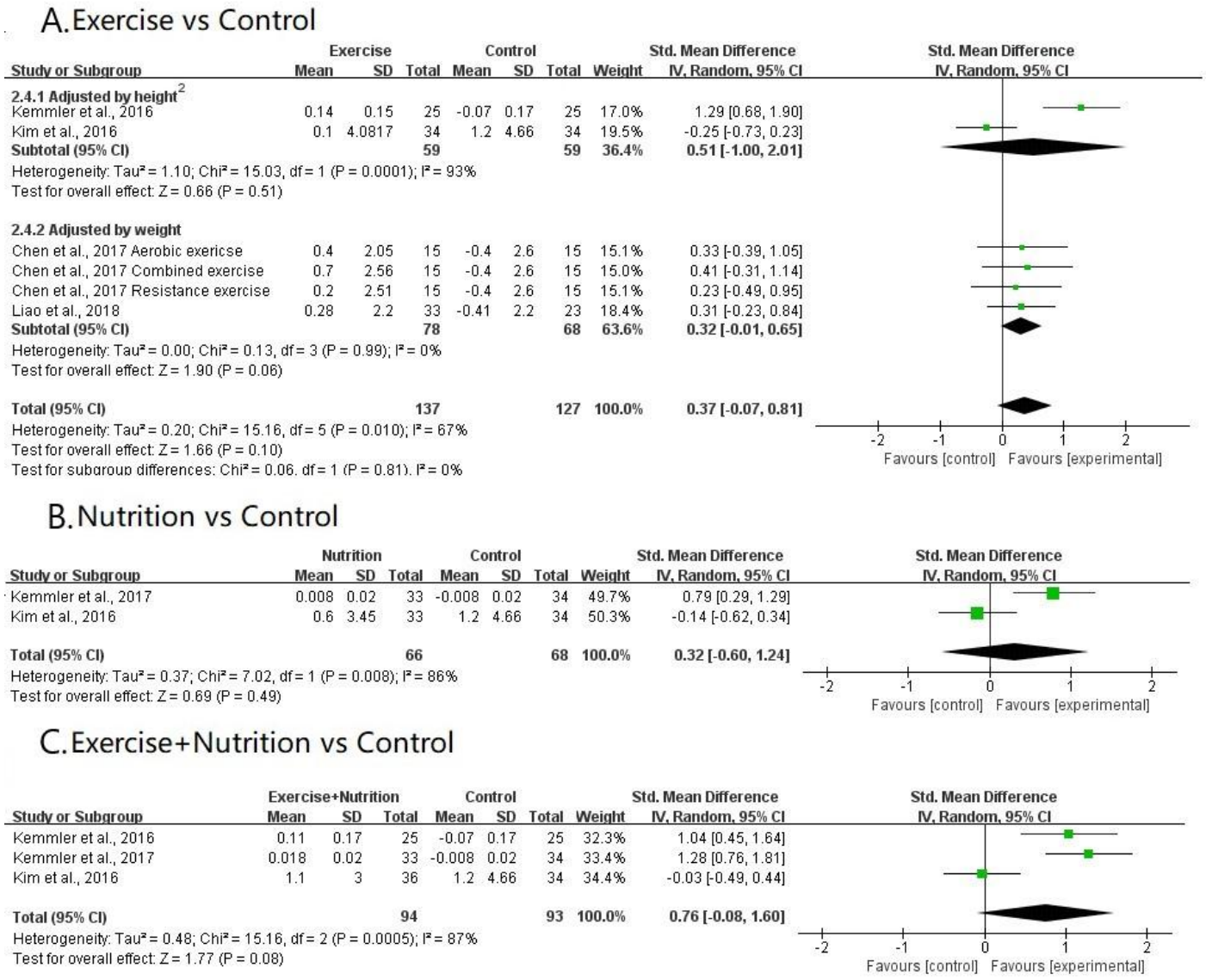


Figure 2. 5 Forest plots of the effectiveness of exercise and nutrition on skeletal muscle mass index

Three studies (n=255) were involved in the meta-analyses that measured the appendicular skeletal muscle mass (ASM) to reflect participants' body composition. Exercise combined with nutritional interventions had significant effects on increasing ASM (MD: 0.41 kg, 95% CI: 0.10, 0.72, p=0.01, I^2=8%; Fig 2.6B), with the evidence was moderate level based on the GRADE (Table 2.5). However, no significant effects on ASM were shown for exercise (Fig 2.6A).

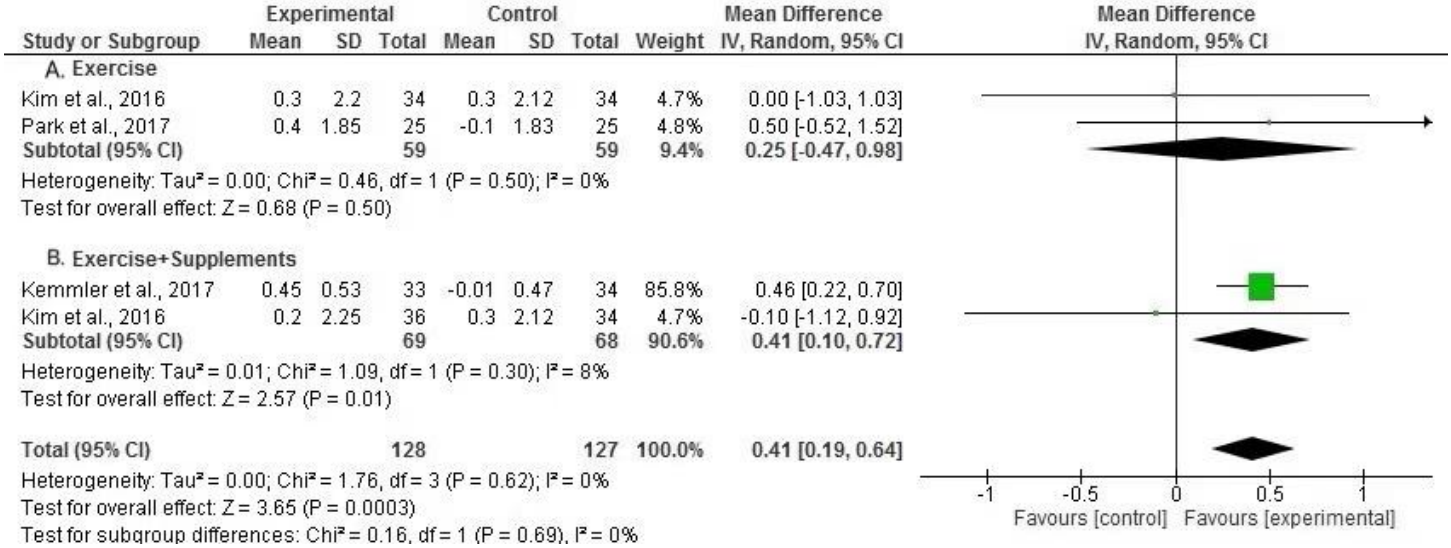


Figure 2. 6 Forest plots of the effectiveness of exercise and nutrition on appendicular skeletal muscle mass

Six studies (n=635) that measured the handgrip strength were involved in the meta-analysis to compare the effects of various interventions with the usual care. Exercise alone or combined with nutritional interventions showed significant effects on handgrip strength, with the evidence being of high and low-quality based on GRADE (Table 2.5), respectively (Exercise: MD: 1.70 kg, 95% CI: 0.36, 3.04, p=0.01, I^2=59%, Fig. 2.7A; Exercise + Nutritional interventions: MD: 1.24 kg, 95% CI: 0.48, 1.99, p =0.001, I^2=0%, Fig 2.7C), while no significant influence was found in nutritional interventions (Fig 2.7B). Additionally, the meta-analysis comparing the effects of low-caloric high-protein diets and low-caloric low-protein diets on handgrip strength showed no significant differences (MD: 5.54 kg, 95% CI: -5.04, 16.13, p=0.30, I^2=97%; Fig 2.7D).

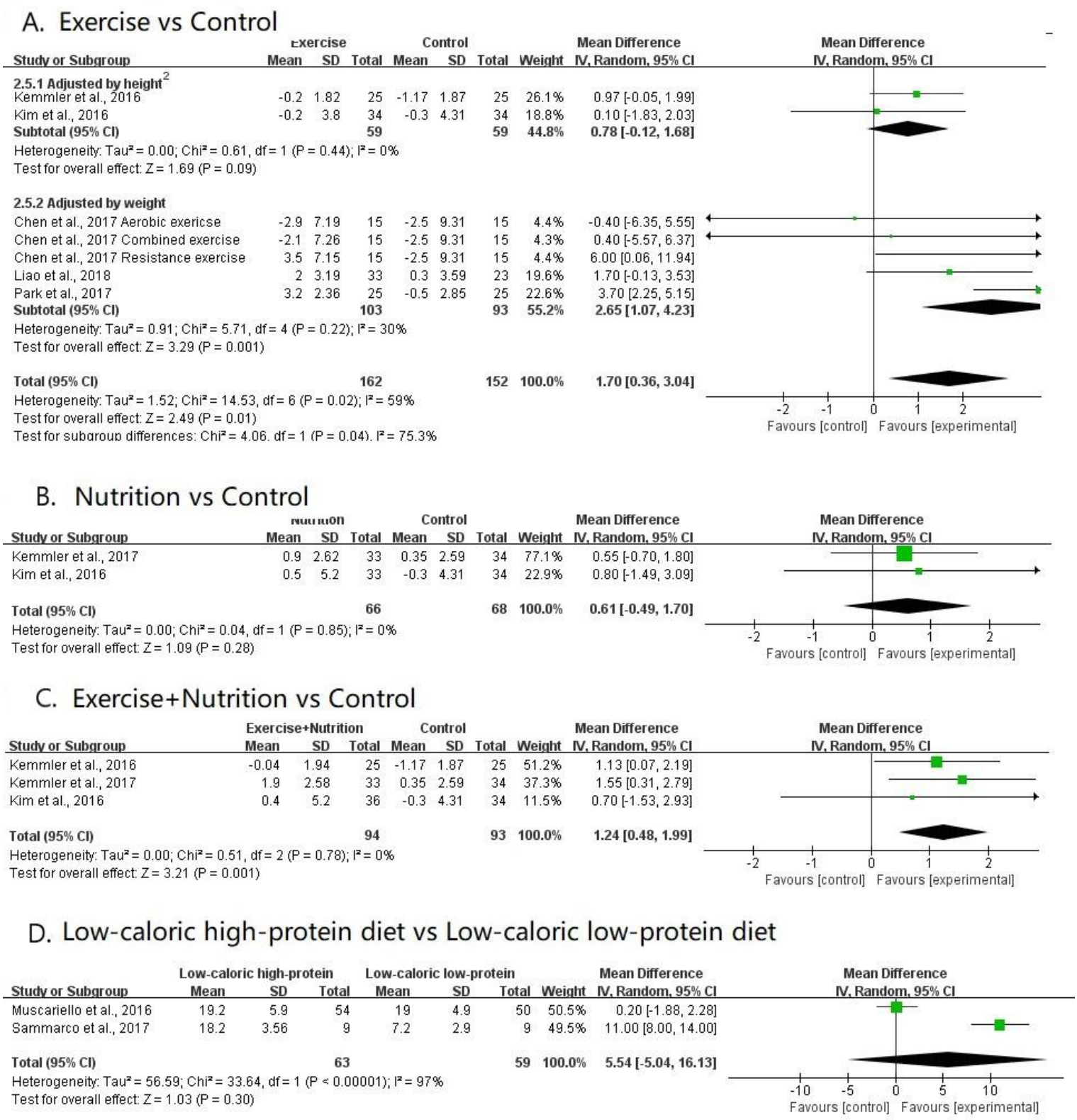
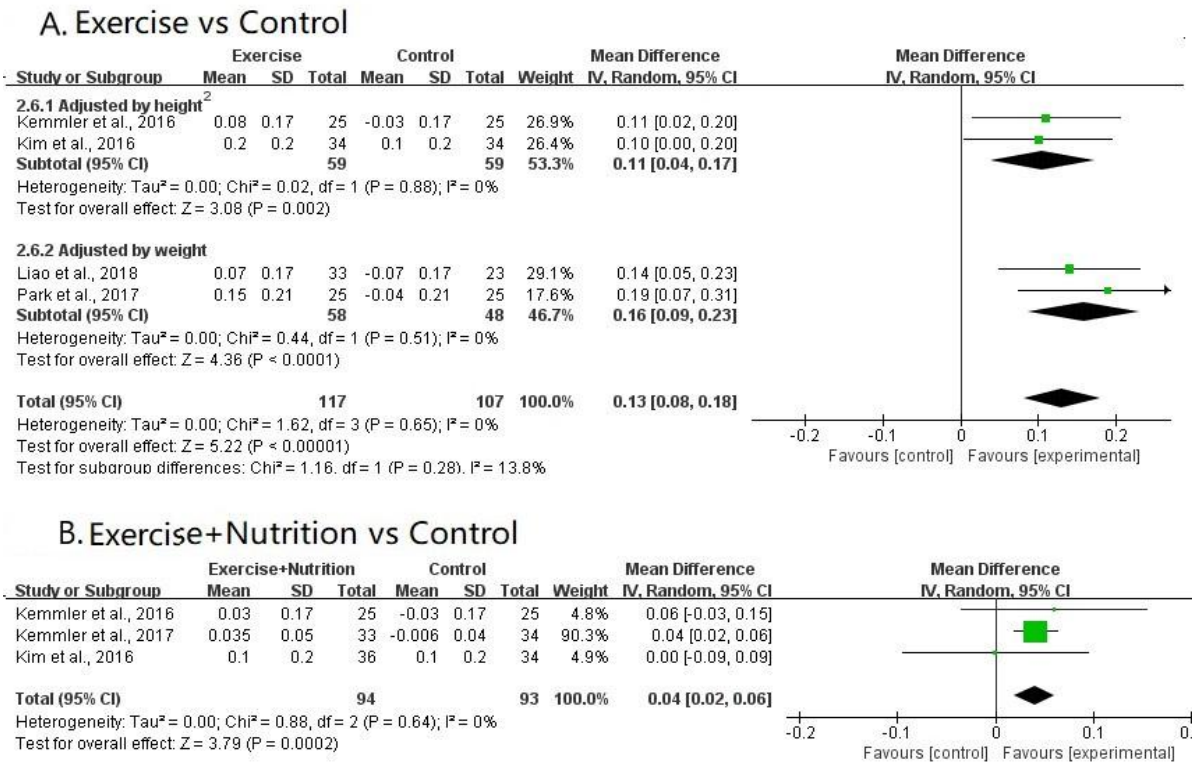


Figure 2. 7 Forest plots of the effectiveness of exercise and supplements on handgrip strength

For the parameters related to physical performance, data were available for the meta-analyses of various interventions compared with the usual care from 5 studies (n= 411) that measured gait speed. Exercise solely or combined with nutritional interventions were shown to have significant effects on gait speed, with the evidence being of moderate and high-quality based on GRADE, respectively (Exercise: MD: 0.13 m/s, 95% CI: 0.08, 0.18, p<0.00001, I^2=0%, Fig. 2.8A; Exercise + Nutritional interventions: MD: 0.04 m/s, 95% CI: 0.02, 0.06, p=0.0002, I^2=0%, Fig 2.8B). In addition, based on the narrative synthesis, the type of high-speed circuit exercise intervention was reported to have had a significant effect on the short physical performance battery (SPPB) but had no significant effect on the instrumental



activities of daily living (Balachandran et al., 2014).

Figure 2. 8 Forest plot of the effectiveness of exercise and supplements on gait speed

For the subgroup analyses depending on different diagnostic criteria for sarcopenia (i.e., skeletal muscle mass adjusted by height^2 versus adjusted by weight), the effects of exercise interventions were shown to be significantly different in terms of handgrip strength (Chi^2=4.06; p=0.04, Fig 2.7A), but not in skeletal muscle mass index (Chi^2=0.19; p=0.66, Fig 2.5) or gait speed (Chi^2=1.16; p=0.28, Fig 2.8A).

Table 2. 5 GRADE Summary of Findings

GRADE Summary of Findings for all comparisons among trials included in systematic review				
Outcomes	№ of RCTs	№ of participants	Anticipated absolute effects* (95% CI) Risk with Intervention	Certainty of the evidence (GRADE)
Exercise versus Usual care				
ASM follow up: range 3 months to 24 weeks	2	118	MD **0.25 higher** (0.47 lower to 0.98 higher)	⊕⊕⊕◯ MODERATE [a,b,c]
SMI follow up: range 8 weeks to 26 weeks	4	234	SMD **0.37 higher** (0.08 lower to 0.82 higher)	⊕◯◯◯ VERY LOW [a,d,e]
Grip strength follow up: range 8 weeks to 26 weeks	5	284	MD **1.63 higher** (0.94 higher to 2.32 higher)	⊕⊕◯◯ LOW [a,e]
Gait speed follow up: range 8 weeks to 26 weeks	4	224	MD **0.13 higher** (0.08 higher to 0.18 higher)	⊕⊕⊕◯ MODERATE
PBF follow up: range 8 weeks to 26 weeks	6	417	MD **1.08 lower** (1.99 lower to 0.17 lower)	⊕⊕◯◯ LOW [a,e]
Nutrition versus usual care				
SMI - follow up: range 3 months to 16 weeks	2	134	SMD **0.32 SD higher** (0.6 lower to 1.24 higher)	⊕⊕◯◯ LOW [a,f]
Grip strength follow up: range 3 months to 16 weeks	2	134	MD **0.61 higher** (0.49 lower to 1.7 higher)	⊕⊕⊕◯ MODERATE [a]
PBF follow up: range 3 months to 16 weeks	2	134	MD **1.03 lower** (2.28 lower to 0.23 higher)	⊕⊕⊕◯ MODERATE [a]
Exercise + Nutrition versus usual care				
ASM follow up: range 3 months to 16 weeks	2	137	MD **0.41 higher** (0.1 higher to 0.72 higher)	⊕⊕⊕◯ MODERATE [a]
SMI follow up: range 3 months to 26 weeks	3	187	SMD **0.76 higher** (0.08 lower to 1.6 higher)	⊕⊕◯◯ LOW [a,g]
Grip strength follow up: range 3 months to 26 weeks	3	187	MD **1.24 higher** (0.48 higher to 1.99 higher)	⊕⊕⊕◯ MODERATE [a]

Gait speed follow up: range 3 months to 26 weeks	3	187	MD **0.04 higher** (0.02 higher to 0.06 higher)	⊕⊕⊕◯ MODERATE [a]
PBF follow up: range 3 months to 26 weeks	3	187	MD **1.04 lower** (2.68 lower to 0.61 higher)	⊕⊕◯◯ LOW [a,h]
Exercise + Nutrition versus Exercise				
PBF follow up: range 3 months to 26 weeks	3	146	MD **0.2 lower** (0.77 lower to 0.37 higher)	⊕⊕⊕◯ MODERATE [a]
Low-caloric high-protein diet versus Low-caloric low-protein diet				
Grip strength follow up: range 3 months to 4 months	2	122	MD **5.54 higher** (5.04 lower to 16.13 higher)	⊕◯◯◯ VERY LOW [a,i,j]

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **MD:** Mean difference

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. Selection bias, performance bias and detection bias were unclear in one study.

b. Heterogeneity test showed that P =0.62, I^2=0%.

c. Negative outcomes were also reported and the sample size were relatively big.

d. Heterogeneity test showed that P =0.04, I^2=56%.

e. Potential publication bias was existed.

f. Heterogeneity test showed that P=0.008, I^2=86%.

g. Heterogeneity test showed that P=0.0005, I^2=87%.

h. Heterogeneity test showed that P=0.0004, I^2=87%.

i. Heterogeneity test showed P<0.00001, I^2 =97%.

j. One study had small sample size (n=18).

ASM: appendicular skeletal muscle mass; SMI: skeletal muscle mass; PBF: percent of body fat.

2.4 Discussion

Different diagnostic criteria used in previous studies towards sarcopenic obesity were described in this systematic review. We found that the studies lacked including muscle strength as the diagnostic criteria. This systematic review also described the components of the non-pharmacological interventions. We found that exercise in different styles (aerobic, resistance and exercise machine) and nutritional interventions (supplements intake and dietary intervention) were mainly used in current studies. Finally, this systematic review indicated that exercise solely or combined with nutritional interventions effectively improved handgrip strength and gait speed. The effects of exercise and nutritional interventions (either solely or combined) in improving body composition were inconsistent.

2.4.1 Discussion about the diagnostic criteria for sarcopenic obesity

Most previous studies (10/12) only included muscle quantity (i.e., muscle mass) as the diagnostic criterion for sarcopenic obese people. However, they ignored the importance of including muscle strength and physical performance to confirm sarcopenic obesity. According to the newest consensus on sarcopenia (Bhasin et al., 2020; Chen et al., 2020; Cruz-Jentoft et al., 2019), muscle strength and physical performance are the primary criteria for screening sarcopenic people. Significantly, low muscle strength is a sensitive criterion to detect an early stage of the sarcopenic condition (Chen et al., 2020). If studies only screened muscle mass to identify

participants, they may have missed many potential participants in their early stages of sarcopenic obesity.

2.4.2 Discussion about the effectiveness of interventions

The meta-analyses and narrative synthesis results supported that exercise effectively reduced body fat, increased muscle strength and gait speed, but did not significantly increase skeletal muscle mass index or BMI. Resistance exercise may be the most effective type of exercise for increasing muscle strength. Even though exercise combined with nutrition did not show a better effect than exercise solely on muscle strength or gait speed, the meta-analysis showed that combined intervention of exercise and nutrition (i.e., protein supplements) was significantly better in increasing appendicular skeletal muscle mass, which may indicate that protein is essential for protein building muscle. This is supported by another article that enough protein supply is needed for the normal function of myofibres (Kob et al., 2015).

The role of nutritional interventions could not be ignored in muscle building and fat loss. An individual study (Muscariello et al., 2016) showed that taking protein by 1.2 g/kg desirable body weight/day for 3 months could significantly change muscle mass index. Sammarco's (2017) study concluded that taking protein with 1.2-1.4 g/kg body weight reference/day for 4 months could significantly reduce weight while preserving lean body mass. In addition, our review indicated that hypocaloric intake is effective for decreasing body fat, which was consistent with the previous systematic review (Liao et al., 2017). The body fat mass of the participants in these two studies

both decreased significantly after the intervention. Due to limited studies, meta-analysis for comparing the effectiveness of nutritional interventions based on different durations could not be conducted. While according to Zhou (2018) and Muscariello (2016), three months of nutritional interventions by controlling calorie intake may be sufficient for losing body fat.

In addition, inconsistent results in the effectiveness of nutritional studies might be because of the limitations in study design. First, part of the evidence for nutritional interventions was based on short-term studies (e.g. less than eight weeks) rather than long-term clinical studies, which are of utmost importance (e.g. three months or more) (Yin, Liu, & Välimäki, 2020). Because long-term interventions can give more precise assessments of an intervention's relative benefits and costs by considering the muscle building is not short (Hill et al., 2016). Second, methods like behavioural change techniques should be incorporated into the study design to improve participants' adherence to the nutritional intervention. Because the longer the study, the more the challenges of maintaining participants' compliance increase. Even though methods for checking adherence were mentioned, the included studies seldom reported the results of participants' adherence to the nutritional instructions. Only numbers of people lost to follow-up were reported. The inconsistent result in the effectiveness of nutritional interventions may be related to participants' compliance (Crichton et al., 2012). In addition, previous nutritional interventions mainly used oral supplements, and seldom studies focused on dietary intervention to modify participants' food intake to adopt a

healthier diet in daily life. Oral supplements may have potential side effects such as dehydration, liver and kidney damage, bloating, and calcium loss (Schaafsma, 2009; Wolfe, 2000). While nutritional interventions focus on daily food (we define as the dietary intervention in this study) are safer than supplements (Banu, 2020), which can be considered to explore the effect on managing sarcopenic obesity.

2.4.3 Limitations of the systematic review

This systematic review had some limitations. First, some meta-analyses only contained two studies, which might affect the generalisability of the results. The conclusion of this systematic review needs to be treated with caution. Second, some articles that were published beyond English or Chinese may have been missed because of the language limits in the literature search.

2.5 Research gap

Based on the literature review, a research gap could be found: no studies combined dietary interventions (i.e., caloric restriction and adequate protein intake) with behaviour change techniques to manage sarcopenic obesity in older people. Detailed elaboration of the research gap is presented as follows.

First, nutritional intervention plays an indispensable role in muscle building and fat reduction (Goisser et al., 2015). Protein is an essential ingredient for building muscle, whereas a hypocaloric diet is effective in fat reduction. In addition, obese older people may not be suitable for extensive exercise because of potential sports

injuries (Nicholl, Coleman, & Williams, 1995). However, the results of nutritional intervention effects were inconsistent among studies. The systematic review (Yin, Liu, & Välimäki, 2020) also indicated some limitations in the nutritional studies, e.g., little information on the participants' compliance with the dietary regimen, unclear intervention components. There is ample space in the research towards nutritional interventions, especially for examining the pure effects of nutritional interventions.

Second, considering the forms of nutritional interventions (i.e., oral supplements or diet), oral supplements were reported to have kinds of side effects (Schaafsma, 2009; Wolfe, 2000). We believe that modifying the dietary habits of people with sarcopenic obesity is more appropriate and may produce longer-term benefits than solely giving dietary supplements, which is also emphasised by the Dietary Guidelines for Americans (U.S. Department of Agriculture & U.S. Department of Health and Human Services, 2020).

Third, in terms of dietary interventions, hypocaloric intake can effectively decrease body fat (Goisser et al., 2015), and adequate protein intake can preserve muscle loss during weight reduction. The literature indicated that higher protein intake prevents lean mass loss caused by weight reduction, and generous intakes of high-quality protein can overcome anabolic resistance in ageing muscle in older people with sarcopenic obesity (Goisser et al., 2015; Katsanos et al., 2005; McDonald et al., 2015; Paddon-Jones et al., 2006).

Forth, incorporating behaviour change techniques into the dietary intervention

could help improve the participants' compliance with interventions. Behaviour change techniques (BCTs) used in an intervention usually mean the elements to modify or divert causal processes that direct behaviour, which can be observed and replicated (Michie, Abraham, et al., 2011; Michie & Johnston, 2013). The BCTs may contain the characteristics like self-monitoring, problem-solving, coping plan, persuasive argument, review behaviour goals, behavioural rehearsal, etc. (Michie et al., 2013). Effective BCTs have been commonly used to change dietary habits (Van Achterberg et al., 2011), promote physical activity (Michie et al., 2009), and smoking cessation (Michie, Hyder, et al., 2011).

CHAPTER 3 DEVELOPMENT OF THE DBC INTERVENTION

This chapter describes the development of an evidence-based DBC intervention for sarcopenic obese older people living in the community. The Medical Research Council framework (Craig et al., 2008) has recommended four stages for developing a complex intervention. The four stages are Stage 1: development (of the intervention); Stage 2: feasibility and piloting; Stage 3: evaluation; Stage 4: implementation. Due to the pilot nature of this doctoral study, only the first two stages were adopted, i.e., development of the intervention and testing its feasibility (Figure 3.1). This chapter describes the first stage of the MRC guidelines, which included three specific steps: identifying evidence base, identifying theory, and identifying outcomes and processes.

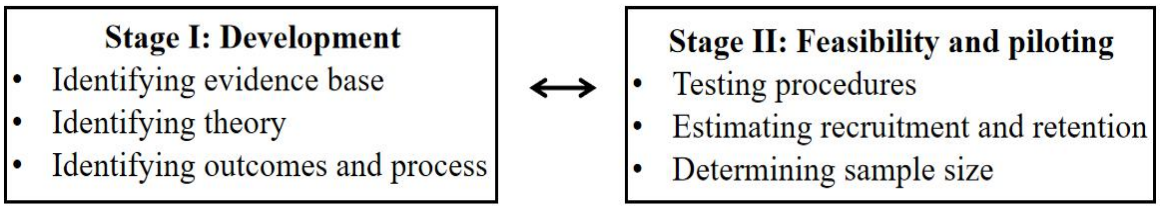


Figure 3. 1 Two stages contained in this study by referring to the MRC Guideline 2008 (Craig et al., 2008)

3.1 Identifying the evidence base

In order to develop a high-quality intervention, the evidence based on an in-depth literature review is required (Craig et al., 2008). In this study, we first confirmed the physiological mechanism of caloric restriction and protein intake in

changing the body composition by in-depth literature review. Then we hypothesised the dosage of caloric restriction and protein intake employed in the evidence-based DBC intervention:

First, the physiological mechanism of protein in muscle building lies in that muscle tissue consists mainly of protein and is the largest reservoir of amino acids (AAs) in the body (Goisser et al., 2015). Skeletal muscle cell mass is influenced by protein turnover/degradation in all phases of life (Anthony, 2016). Protein turnover is integral to muscle, and the balance between anabolism and catabolism is essential for muscle fibres building (Welch, 2014). On the other hand, the proteolytic processes would influence skeletal muscle mass via the autophagy lysosomal system, ubiquitin-proteasome pathway, and calcium-dependent calpains (Anthony, 2016; Pasiakos & Carbone, 2014). The AAs absorbed from dietary intake (especially essential AAs) have a stimulatory effect on muscle protein synthesis after feeding (Goisser et al., 2015). Besides, older people need a higher per-meal protein threshold to stimulate protein synthesis than younger ones to promote anabolism (Bauer et al., 2013; Pasiakos & Carbone, 2014). However, the mechanism of the caloric restriction is still unclear even though the calorie restriction has been proposed and proved to be effective in reducing boy fat by decades (Anderson, Shanmuganayagam, & Weindruch, 2009). Reduced core body temperature and cellular divisions, and lower metabolic rate are believed to be potential explanations for how the calorie restriction

works (Bergamini et al., 2003; Conti et al., 2006; Nikolai et al., 2015).

Second, we hypothesised that a 12% reduction of daily calorie intake based on estimated energy expenditure and protein intake of 1.2 - 1.5 g/kg body weight/day would lead to fat loss while preserving muscle mass. Two studies (Muscariello et al., 2016; Sammarco et al., 2017) included in our systematic review showed that 1.2 g/kg body weight /day of protein intake could achieve significant changes on increasing muscle mass. WHO recommended that 0.8 g/kg body weight/day protein intake from the dietary allowance is the basic dose for adults aged 18 or above (WHO, 2007), but the dose is always argued to be inadequate for the older adults aged 60 or above to maintain or regain muscle mass by many researchers (Beasley, Shikany, & Thomson, 2013; Deutz et al., 2014; Dideriksen, Reitelseder, & Holm, 2013; Goisser et al., 2015; Paddon-Jones & Leidy, 2014). Because older people are less responsive to anabolic stimuli, the sensitivity of muscle protein synthesis to anabolic stimuli was impaired by advancing ageing and the physical inactivity process (Tomé, 2017). More protein intake is recommended to compensate for the impaired response to muscle protein synthesis (Tomé, 2017). A study (Bauer et al., 2013) conducted by the European Union Geriatric Medicine Society recommended that at least 1.0 – 1.2 g/kg body weight/day of protein should be taken for the healthy older adults, and other older adults who have special needs should take even more (i.e. ≥1.2 g/kg body weight/day). Additional guidelines and recommendations (Deutz et al., 2014; Morley et al., 2010;

Paddon-Jones & Leidy, 2014) indicated that 0.8-1.5 g/kg body weight/day of protein is recommended for the older people who would like to keep optimal muscle function with ageing. Therefore, we decided the amount of protein intake in this pilot study was 1.2 – 1.5 g/kg body weight/day.

For the caloric restriction for older people, it is noteworthy that the amount of caloric restriction varied significantly between studies, and no golden standard of calorie range could be found for individuals with sarcopenic obesity (Goisser et al., 2015). For older people, a stringent caloric restriction is harmful and could exacerbate muscle loss conditions. One review (Fontana & Klein, 2007) published in JAMA with 11 clinical studies (longitudinal, cross-sectional and RCTs) concluded that caloric restriction with over 45% reduction might lead to severe problems like anaemia, depression, neuro deficits, and muscle loss. This review also mentioned that a 20%-25% reduction of caloric intake effectively reduces body fat, but the lean body mass may also be reduced. The author further confirmed that too strict calorie restriction is harmful in specific populations, including older people. Other researchers support this view that a very low-energy diet (< 1000 kcal/day) is strongly discouraged among older people (Parr, Coffey, & Hawley, 2013; Villareal et al., 2005). However, a moderate 11.9% reduction of calorie intake could promote a sustained average weight reduction, simultaneously safeguarding muscle mass (Kraus et al., 2019).

3.2 Identifying the theory

In this study, we have chosen the Health Action Process Approach (HAPA) (Schwarzer, 2008; Schwarzer & Luszczynska, 2008) model to guide the design of the behaviour change strategies. HAPA model is a psychological, behavioural change model to describe and predict improvements in health-related behaviours. The reasons to select the HAPA model were two-fold:

First, the HAPA model builds a bridge between motivation and action with planning (i.e., action planning and coping planning), which can help the participants successfully transfer the motivation into action. In behaviour change theories, forming an intention is not enough for an individual to take real action. (Schwarzer et al., 2018). The motivation may not be necessarily translated into actual behaviour. An intention-behaviour gap always prevents people from behaving in line with their intentions (Sheeran, 2002). Post-intentional mediators (i.e., action planning and coping planning) are needed to overcome the gap.

Second, the HAPA has already been found effective in previous health behavioural change studies; therefore, we believed this model could also guide our study. For example, the HAPA model has been used in promoting physical activity (Chiu et al., 2011) or healthy eating habits (Schwarzer & Renner, 2000). A six-month two-armed randomised controlled trial, inspired by the HAPA model, was conducted to examine the changes in fruit and vegetable intake levels among men and women by

online lifestyle intervention in Italy, Spain, and Greece (Schwarzer, Warner, Fleig, Gholami, Serra-Majem, et al., 2018). The diet scores of participants with lower motivational prerequisites increased significantly after the online intervention. Besides, a meta-analysis of studies applying the HAPA model revealed that the correlations among the constructs were positive, and the effects of volitional self-efficacy on dietary behaviours were significant (Zhang et al., 2019).

The HAPA model contains two phases: the motivational and volitional phases (Schwarzer & Luszczynska, 2008). In the motivational phase, risk awareness, self-efficacy and outcome expectancies are three key attributes for motivating individuals to form an intention to change their unhealthy lifestyle. An individual develops an intention to act after risk perception is formed, and individuals with high "action self-efficacy" are more like to initiate a new behaviour. But it is still insufficient for an individual to develop an intention substantially; maintenance self-efficacy and planning are also essential. The "good intention" has to be changed into detailed instructions like "how to practice the intention". Therefore, more proximal factors such as planning and recovery self-efficacy should be addressed in the volitional phase. In summary, the HAPA model is suitable for guiding the design of the delivery of the DBC intervention to participants (Figure 3.2).

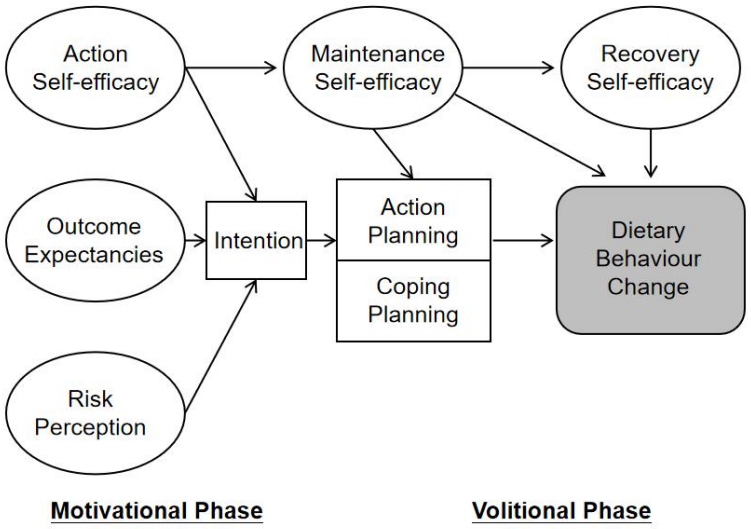


Figure 3. 2 Health Action Process Approach (HAPA) for guiding the intervention design (Modified Schwarzer & Luszczynska, 2008)

In this study, the motivation stage with an aim to cultivate participants' intention to change their dietary behaviours was incorporated. The education about the definition, health consequences, risk factors of sarcopenic obesity, and the relationship between sarcopenic obesity and diet was given to cultivate risk awareness. Meanwhile, expected benefits and plans of good dietary behaviour were discussed in order to increase participants' outcome expectations. Therefore, we hypothesise that the combination of behavioural change techniques in a dietary intervention can sustain a health-related behaviour change of people, which may benefit the loss of body fat mass and muscle mass growth. We propose the conceptual framework of the study as follows (Figure 3.3).

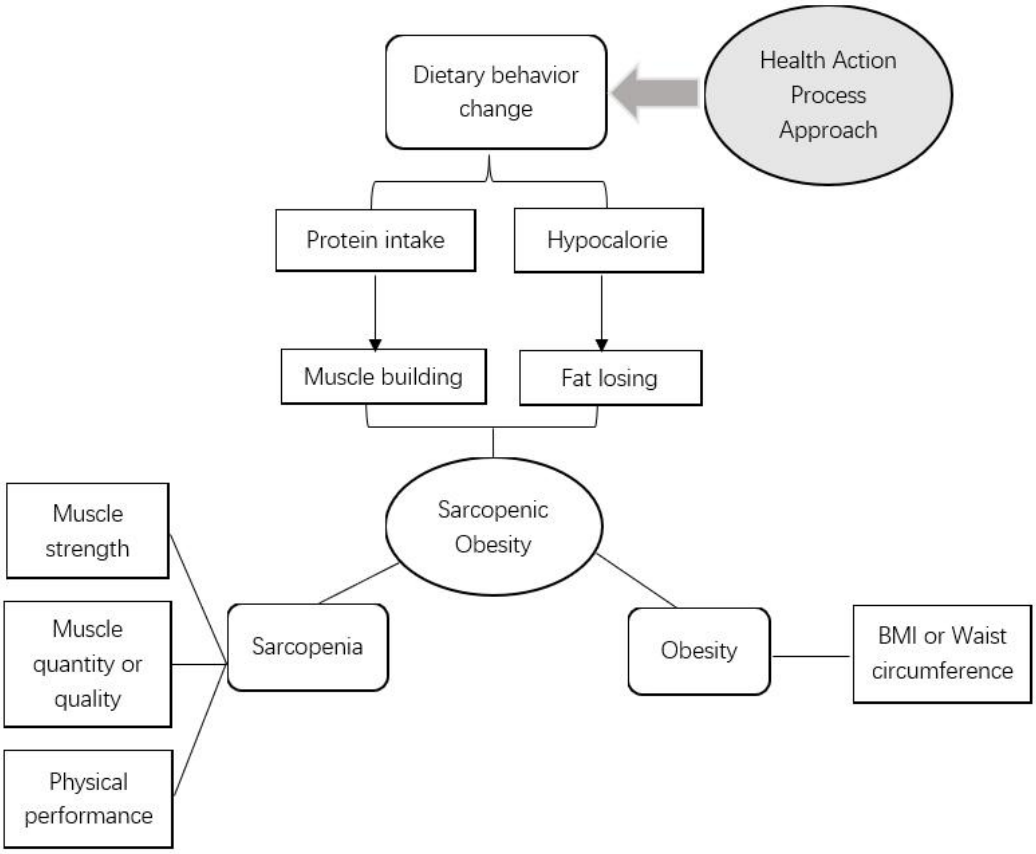


Figure 3. 3 Conceptual framework of the study

3.3 Identifying outcomes

The following primary outcomes were identified based on the conceptual framework, including body composition, muscle strength, physical performance, and anthropometric parameters. Specifically, primary outcomes involved in the above parameters are shown detailedly in following Table 3.1. These parameters are the key components for the diagnosis of sarcopenic obesity according to the Asian and European consensus on sarcopenia (Cruz-Jentoft et al., 2019; Chen et al., 2020).

Table 3. 1 Identified primary outcomes (Cruz-Jentoft et al., 2019)

Sarcopenia-related outcomes	Body composition	1. *Skeletal muscle mass*: represents the majority of muscle tissue. It is the type of muscle that powers the movement of the skeleton, as in walking and lifting. 2. *Skeletal muscle mass index*: was calculated by dividing the limb skeletal muscle mass (kg) by the square of the height (m^2). 3. *Fat-free mass*: refers to all of the body components except fat, including body's water, bone, organs, and muscle content. 4. *Body fat mass*: the actual weight of fat in the body. 5. *Percent of body fat*: the total mass of fat divided by total body mass, multiplied by 100. 6. *Visceral fat level*: the level of fat surrounding the organs.
	Muscle strength	*Handgrip strength*: the force applied by the hand to pull on or suspend from objects and is a specific part of hand strength.
	Physical performance	*Gait speed*: the time one takes to walk a specified distance on level surfaces over a short distance. *Short Physical Performance Battery*: a group of measures that combines the results of the gait speed, chair stand and balance tests.
Obesity-related outcomes	Anthropometric parameters	BMI, body weight, waist circumference, waist-hip ratio

In addition to primary outcomes, we also hypothesised secondary outcomes, including nutrition self-efficacy, nutritional status, diet quality and health status, could be improved after the DBC intervention. According to the HAPA model, self-efficacy is a vital mediator for behaviour change (Schwarzer & Luszczynska, 2008). In this pilot study, participants' nutrition self-efficacy may be improved during the dietary behaviour change process. The change of dietary behaviour may improve the participants' diet quality (Miller, Weinhold, & Nagaraja, 2016) and then improve their

nutritional status (Vellas et al., 2000). The improvement of physical condition could help improve the health status of older people based on previous studies, which indicated a strong relationship between health status and physical performance (Syddall et al., 2009).

3.4 The DBC intervention

A brief introduction of the DBC intervention and the rationale behind it is shown in the following paragraphs. The key intervention components were presented briefly in Table 3.2 refers to the TIDieR (Template for Intervention Description and Replication) Checklist (Hoffmann et al., 2014). For detailed information about intervention delivery, please refer to Chapter 4 Methods (Section 4.4).

There were three phases in the DBC intervention, including the intention phase, the planning phase and the action phase, which were in line with the three phases of the HAPA model. The three phases contained six sessions which were in line with the design of the intervention guidebook. The first three face-to-face sessions were arranged during the intention and planning phases. The remaining three sessions were conducted as booster sessions once per month to help participants execute the diet plan during the action phase, and weekly telephone follow-up was arranged for help monitoring. The interventionist was the doctoral researcher, who was a qualified weight management coach and a registered nurse. The DBC intervention was tailored because the participants differed in personal physical conditions and dietary habits,

and tailored dietary intervention was niche targeting as a promising strategy to promote participants' diets (Eyles & Mhurchu, 2009). The total intervention duration would be 15 weeks. According to our systematic review, 12-week diet modification may be sufficient for reducing fat mass, while the appropriate duration for increasing muscle mass is main inconclusive. According to Muscariello's (2016) RCT, muscle mass index was increased significantly after a three-month nutritional intervention with increased protein intake in older people. Considering the combination of behaviour change techniques, we decided to spend extra three weeks on delivering the motivation phase to strengthen the behaviour change techniques provided to the participants.

Table 3. 2 Description of intervention components

Brief name	Dietary behaviour change (DBC) intervention
Why (goal)	To evaluate the feasibility and preliminary effects of DBC intervention on the management of sarcopenic obesity in terms of the following outcomes: body composition, handgrip strength, and physical performance, nutritional status, nutrition self-efficacy, and health status.
Materials	Guidebook, food weighing scale, food model, food diary
Procedure	Three phases were contained in the intervention protocol: 1. Intention phase (1st and 2nd week, 2 face-to-face sessions) 2. Planning phase (3rd week, 1 face-to-face session) 3. Action phase (4th – 15th week, 3 face-to-face sessions + weekly telephone follow up)
Who provided	Doctoral researcher qualified as a weight management coach and registered nurse
How	Individual face-to-face sessions + telephone follow up
Where	Community health centre

When and How much	Six face-to-face sessions (week 1, 2, 3, 4, 8 & 12), totally 15 weeks; Weekly telephone call since week 4; 12% caloric reduction/day + protein intake of 1.2-1.5 g/kg desired body weight/day
Tailoring	Individual dietary plan based on personal lifestyle and habit.
How well	Participants were asked to take a food diary to monitor their diet, and the diary was checked by the researcher in each face-to-face session.

3.5 Development of DBC intervention guidebook

3.5.1 Introduction of the guidebook

A guidebook was developed based on the intervention components (examples shown in Appendix 2) to help deliver the DBC intervention. The guidebook contained the content of dietary recommendations and behaviour change techniques. The Dietary Guidelines for Chinese Residents 2016 (Chinese Nutrition Society, 2016) was referred to when developing the dietary content of the guidebook in order to make the dietary instructions culturally sensitive. At the preface of the guidebook, a brief introduction of the program and the benefits of joining the program were given. Following the preface were six chapters, the content of each chapter was delivered during every face-to-face session. Table 3.3 presents the contents and objectives of each chapter of the guidebook.

Table 3. 3 Introduction of the DBC intervention guidebook

Chapters	Contents	Objectives
Chapter 1: What is sarcopenic obesity	1. Introduction of sarcopenic obesity: the definition of sarcopenic obesity, the function of muscle, the adverse health outcomes of sarcopenic obesity, risk factors of sarcopenic obesity, and factors for preventing sarcopenic obesity	To establish the participants' awareness of sarcopenic obesity and to arouse their interests and attention to muscle mass.
	2. Relationship between diet and sarcopenic obesity: the relation between nutrition and ageing, the association between muscle and protein, and the association between obesity and calorie	To establish participants' awareness of a healthy diet and establish their motivation and self-efficacy to change dietary behaviour.
Chapter 2: Dietary guidelines	1. What is a balanced diet 2. Protein sources 3. Caloric restriction	To present the potential benefits of changing dietary behaviour and to make them aware of the disadvantages of their existing diets.
Chapter 3: Diet plan	1. Make your diet plan 2. How to record your food intake	To translate participants' motivation into an actual plan.
Chapter 4, 5, 6: 1st, 2nd, and 3rd sharing & communication meeting	1. Evaluating daily diet 2. Problems solving 3. Experience sharing 4. Target reviewing	To guide the delivery of the behaviour change techniques.

3.5.2 Delphi method for validating the content of DBC intervention guidebook

The Delphi method was used to validate the content of the guidebook because it is well suited as an iterative process to collect anonymous comments from experts, especially when we want to validate our understanding of an issue, i.e., the content of the guidebook (Skulmoski, Hartman, & Krahn, 2007).

3.5.2.1 Expert panel

Purposive sampling was used to invite the experts as the sampling method could help us to identify the information-rich cases through the most proper and available resources (Etikan, Musa, & Alkassim, 2016). There are no standard requirements for determining sample size in a Delphi study, and the participants' expertise is more important than the sample size (Wilkes, 2015). The size of the participants in previous studies also varied. No specific recommendations can be identified (Wilkes, 2015). The response rate will be superior if the sample size is smaller and homogeneous because the answer rate will be higher, and data analysis will be more accessible (Wilkes, 2015). In this study, the roles of the experts were to evaluate the content of the guidebook by rating the content validity index, which usually requires 3 to 10 experts (Lynn, 1986). Eventually, seven experts were invited to the Delphi method according to the following criteria. Firstly, they must hold a bachelor or higher degree in health-related areas. Secondly, they should have more than five years of working experience related to nutrition and diet.

The characteristics of the seven experts are shown in following Table 3.4. The experts were from Hong Kong (2/7, 28.6%) and mainland China (5/7, 71.4%), who were familiar with Chinese people’s dietary behaviour. Among the seven experts, 4 of them are dietitians, 1 of them is a nutritionist, and 2 of them are chief physicians. All experts work in the nutritional area, who have working experience of 5-10 years (2/7,

28.6%), 10-20 years (4/7, 57.1%), and more than 20 years (1/7, 4.3%). All have a bachelor's degree in nutrition, and 6 of them have attained master's degree level (85.7%).

Table 3. 4 Characteristics of experts panel for the content validity of the guidebook

Characteristics of the Experts (N=7)	Number (%)
Qualifications	
Dietitian	4 (57.1)
Nutritionist	1 (14.3)
Chief physician	2 (28.6)
Registration location	
Hong Kong	2 (28.6)
Mainland China	5 (71.4)
Years of working	
5-10 years	2 (28.6)
10-20 years	4 (57.1)
>20 years	1 (14.3)
Highest academic qualification	
Bachelor's degree	1 (14.3)
Master's degree	6 (85.7)
Working places	
Hospital	5 (71.4)
College	1 (14.3)
Company	1 (14.3)

3.5.2.2 Procedures

Invitation letters were sent to the experts by email, together with the background information about the study. Informed consent forms were obtained before implementation. All the experts did not know who else was invited to ensure anonymity. The procedure of the Delphi method is shown in Figure 3.4.

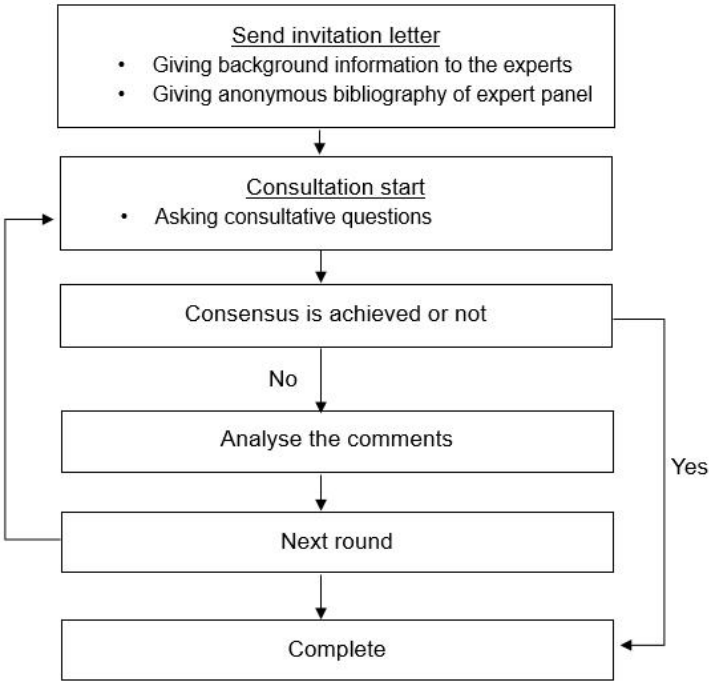


Figure 3.4 The procedure of the Delphi method (totally two rounds)

Experts' comments were collected via email by using a 4-point Likert content validity scale. The content validity of the whole dietary behaviour change protocol was evaluated by using the content validity index (CVI) (Lynn, 1986; Rubio et al., 2003). The CVI of each item was calculated by dividing the total number of experts (N=7) by the number of experts who rated "totally agree" (score of 4) or "agree" (score of 3). A value of 0.83 as a satisfactory cut-off value of content validity for

item-level CVI was used (Lynn, 1986). The doctoral researcher designed the content validity evaluation form (Appendix 3) based on the intervention components, which had 18 items. The items included the dose of the protein intake, the quantity of the calorie restriction, the total duration of the intervention, the content of dietary recommendation, the food recording method, the frequency and sessions of the intervention, and the techniques of the dietary behaviour change. The experts assessed each item on a 4-point Likert scale, ranging from 1 to 4 (1 = totally disagree, 2 = disagree, 3 = agree, and 4 = totally agree). The experts were asked to give suggestions with supporting evidence for the "total disagree" and "disagree" items. The experts could also give suggestions on the intervention protocol beyond the given items.

Since no consensus was achieved after the first round of the Delphi method, we revised the content of the guidebook according to the experts' comments (see next Section 3.5.2.3). Then a second round of the Delphi method was launched. Eventually, the CVI reached the satisfactory value of > 0.8 in all the items

3.5.2.3 Results of Delphi methods

Two rounds of content validity assessment were conducted, the results of the content validity assessment are presented in Table 3.5.

Table 3. 5 Results of the content validity assessment of the DBC intervention guidebook

Items	Number of experts rating "totally agree" (4)	Number of experts rating "agree" (3)	Number of experts rating content valid (3 or 4)	CVI [a]
1st Round				
1. The introduction of sarcopenic obesity in Chapter 1 (page 1) is relevant to establish participants' awareness of sarcopenic obesity.	2	5	7	1.00
2. The contents related to the potential risks of unmanaged sarcopenic obesity in Chapter 1 (page 2) is relevant to establish participants' awareness of sarcopenic obesity.	2	5	7	1.00
3. The content about the relationship between diet modification and sarcopenic obesity in Chapter 1 (pages 4-5) is relevant to establish participants' awareness of sarcopenic obesity.	2	5	7	1.00
4. Overall, Chapter 1 (pages 1-5) is easy to understand.	2	5	7	1.00
5. The introduction to balanced diet in Chapter 2 (pages 6-8) is relevant to help participants establish a basic understanding of food types.	4	2	6	0.86
6. The introduction to high-quality protein sources in Chapter 2 (page 9) is relevant to help participants choose the food which contains high-quality proteins.	4	1	5	**0.71**
7. Overall, Chapter 2 (pages 6-9) is easy to understand.	4	2	6	0.86
8. The protein intake of 1.2-1.5 g/kg DBW/day is appropriate for older people with sarcopenic obesity to increase their muscle mass (Chapter 3, page 10).	0	7	7	1.00
9. A 12% reduction in daily total caloric intake is appropriate for older people with sarcopenic obesity to lose their body fat (Chapter 3, page 10).	2	3	5	**0.71**
10. The recommended food types in the table in Chapter 3 (page 10) are appropriate for older people with sarcopenic obesity.	1	4	5	**0.71**

11. The diet plan table in Chapter 3 (page 10) is appropriate to be used for participants to design their diet.	0	5	5	**0.71**
12. The picture of "my plate" in Chapter 3 (page 11) is appropriate in helping participants to design their diet.	2	3	5	**0.71**
13. The picture of "my plate" in Chapter 3 (page 11) is clear to participants.	3	2	5	**0.71**
14. The first food recording method in Chapter 3 (pages 12-14) is easy to understand.	1	5	6	0.86
15. The second food recording method in Chapter 3 (pages 15-16) is easy to understand.	1	4	5	**0.71**
16. The total duration of the intervention (15 weeks) is appropriate for reducing body fat.	2	4	6	0.86
17. The total duration of the intervention (15 weeks) is appropriate for increasing muscle mass.	1	5	6	0.86
18. The food record table in the attachment (page 21) is easy for participants to record their daily food intake.	1	4	5	**0.71**
2nd Round				
1. The introduction of sarcopenic obesity in Chapter 1 (page 1) is relevant to establish participants' awareness of sarcopenic obesity.	5	2	7	1.00
2. The contents related to the potential risks of unmanaged sarcopenic obesity in Chapter 1 (page 2) is relevant to establish participants' awareness of sarcopenic obesity.	4	3	7	1.00
3. The content about the relationship between diet modification and sarcopenic obesity in Chapter 1 (pages 4-5) is relevant to establish participants' awareness of sarcopenic obesity.	4	3	7	1.00

4. Overall, Chapter 1 (pages 1-5) is easy to understand.	4	3	7	1.00
5. The introduction to balanced diet in Chapter 2 (pages 6-8) is relevant to help participants establish a basic understanding of food types.	5	2	7	1.00
6. The introduction to high-quality protein sources in Chapter 2 (page 9) is relevant to help participants choose the food which contains high-quality proteins.	4	3	7	1.00
7. Overall, Chapter 2 (pages 6-9) is easy to understand.	4	3	7	1.00
8. The protein intake of 1.2-1.5 g/kg DBW/day is appropriate for older people with sarcopenic obesity to increase their muscle mass (Chapter 3, page 10).	4	3	7	1.00
9. A 12% reduction in daily total caloric intake is appropriate for older people with sarcopenic obesity to lose their body fat (Chapter 3, page 10).	4	3	7	1.00
10. The recommended food types in the table in Chapter 3 (page 10) are appropriate for older people with sarcopenic obesity.	2	5	7	1.00
11. The diet plan table in Chapter 3 (page 10) is appropriate to be used for participants to design their diet.	0	7	7	1.00
12. The picture of “my plate” in Chapter 3 (page 11) is appropriate in helping participants to design their diet.	3	4	7	1.00
13. The picture of “my plate” in Chapter 3 (page 11) is clear to participants.	4	3	7	1.00
14. The first food recording method in Chapter 3 (pages 12-14) is easy to understand.	1	6	7	1.00
~~15. The second food recording method in Chapter 3 (pages 15-16) is easy to understand.~~ (This item was deleted because the second food recording method was deleted in the revised version of the guidebook)				
16. The total duration of the intervention (15 weeks) is appropriate for reducing body fat.	1	6	7	1.00

17. The total duration of the intervention (15 weeks) is appropriate for increasing muscle mass.	0	7	7	1.00
18. The food record table in the attachment (page 21) is easy for participants to record their daily food intake.	2	5	7	1.00

Notes: a=the item-level CVI; CVI=content validity index; DBC=dietary behaviour change.

In the first round, the score of eight items was 0.71 (less than 0.83). The experts commented mainly about the methods used for teaching participants how to measure food amount, the underpinning rationale of the range of caloric restriction, the recommended high-quality protein sources, the recommended concept of “food plate” in the guidebook, and the diet plan table. The major comments of the experts are described in Table 3.6. Modifications were made after the first round of consultation, which was also summarised in the table. In the second round, the score of all items was 1.00.

Table 3. 6 Comments of the experts on the content of the guidebook

Items	Detailed comments	Actions taken
1. Methods used for teaching participants measuring food amount	The hand palms measurement method is not accurate because various people have various sizes of palms, and it is hard to visualise the food size with hands.	We chose to delete the hand palms measurement method by only keeping the food exchange method. During the face-to-face sessions, food models were also used to help demonstrate the food measurement method.
2. Underpinning rationale of the range of caloric restriction	a. The actual metabolism of older people needs to be considered, and the measurement of resting metabolism is suggested. b. The impact of exercise on reducing fat should be considered as well.	The participant's basal metabolic rate was measured before and after the intervention, and the daily exercise was assessed by IPAQ as well. In data analysis, the confounding effect of exercise was analysed.
3. Recommended high-quality protein sources	a. Standardise language terms for describing the food; b. Add "nuts & seeds" for protein sources even though they are in high fat. c. Delete the recommendation of "consume 15 g soy bean/day".	The terms for describing the food were revised by referring to standardised terms recommended by the Chinese Nutrition Society. The protein sources were enriched and adjusted accordingly.
4. Recommended concept of "food plate"	"My plate" may be not suitable for the Chinese dining style.	The participants were not required to eat on a plate. The function of the plate was to give the participants an awareness of the proportion of each type of food.
5. Diet plan table needs to be revised to be concise	a. Examples should be given to help participants make diet plans; b. List the weight of common foods to help the participants plan their diet reasonably.	Examples of a diet plan were added, and food models were used in face-to-face sessions, including the pictures of food models were printed in the guidebook.

Note: IPAQ=International physical activity questionnaire.

3.5.3 Readability test of the guidebook

The individual interview was conducted to evaluate the readability of the content, whether or not the contents in the guidebook were easy to understand by the older people. The interview was conducted in Nanjing, China. Five older people aged 60 or above (mean age were 65.6 ± 10.33 years old) from the community, without cognitive or mental problems and being able to read and speak in Chinese, were invited by convenient sample method to read and comment on the guidebook. Two people received a college education, and the other three had a high school education.

The participants were given one week to read the guidebook. After they finished reading, the doctoral researcher interviewed the participants individually via online face-to-face meetings (the covid-19 situation prevented offline gathering activity during that period). The doctoral researcher further explained the content where the participants did not understand before the interview. During the interview, ten questions were asked (Table 3.7). The words, sentences, or other particular content which the participants felt difficult to understand were recorded.

Table 3. 7 Questions asked in the interview about understandability test of guidebook content

Questions
1. Is Chapter 1 (pages 1-5) easy to understand? 第 1 章節容易理解(第 1-5 頁)嗎？
2. Can Chapter 1 (pages 1-3) help you establish an awareness of sarcopenic obesity? 第 1 章節可以幫你對肌少性肥胖建立一個基礎的認識(第 1-3 頁)嗎？
3. Can Chapter 1 (pages 4-5) help you understand the relation between diet and sarcopenic obesity? 第 1 章節可以幫你瞭解飲食和肌少性肥胖之間的聯繫（第 4-5 頁）嗎？
4. Is Chapter 2 (pages 6-9) easy to understand? 第 2 章節容易理解(第 6-9 頁)嗎？
5. Can Chapter 2 (pages 6-9) help you establish a basic understanding of food types? 第 2 章節可以幫你對食物的種類有一個基本的瞭解（第 6-9 頁）嗎？
6. Is the diet plan table in Chapter 3 (page 10) easy to understand? 第 3 章節中膳食計畫的表格容易理解(第 10 頁)嗎？
7. Is the first food recording method in Chapter 3 (pages 12-14) easy to understand? 第 3 章節中的第一種記錄食物量的方法容易理解（第 12-14 頁）嗎？
8. Is the second food recording method in Chapter 3 (pages 15-16) easy to understand? 第 2 章節中的第二種記錄食物量的方法容易理解（第 15-16 頁）嗎？
9. Are Chapter 4-6 (pages 17-20) easy to understand? [1] 第 4、5、6 章節容易理解(第 17-20 頁) [1] 嗎？
10. Is the food recording table in the appendix (page 21) easy to follow? 附表中膳食記錄表容易執行（第 21 頁）嗎？
Do you have any other suggestions? 您還有其他建議嗎？

After reading the guidebook, the participants all reported that the content was not

difficult to understand. The content could let them have a basic awareness of sarcopenic obesity, including the importance of diet. However, they felt it was a little difficult to understand some professional terms (e.g., “卡路里” calorie, “預後” prognosis). Table 3.8 presents the comments from the participants. The doctoral researcher modified slightly to popularise the professional terms into plain expression based on the participants’ feedback.

Table 3. 8 Comments from the older participants on the guidebook

NO.	Age	Gender	Education level	Overall Comments
1	60	Male	College	He understood most of the content except some professional terms like “預後”. The first chapter could make him understand the concept of sarcopenic obesity and the relationship between diet and sarcopenic obesity.
2	84	Male	College	He can understand the content without difficulties and provided some quite good suggestions, such as some older adults who live alone may have difficulties controlling the size and quality of each meal. They may also lack the mood to spend time on the diet.
3	62	Female	High school	The content was not difficult to understand for her, but she often forgot the main points of the guidebook. She had to read very often to remember the knowledge. She needed help in understanding Chapter 3 about the diet plan (page 10).
4	62	Male	High school	The content was easy to understand for him except for measuring food amount, which needed the researcher to explain more.
5	60	Female	High school	She can understand the content and know how to control the diet as suggested. But she could not figure out how much energy each food contained without further explanation.

3.6 Summary

This pilot study contained two stages for developing and testing the DBC intervention using the MRC framework. This chapter introduced Stage I: development of the DBC intervention based on an evidence-based literature review and HAPA model. A guidebook containing the major components of the intervention was developed and validated through the Delphi method. Two rounds of the Delphi method were conducted among seven experts until all item-CVIs reached 1.00. The readability of the guidebook content was acceptable among five people (mean age= 65.6±10.33 years old) with different education levels.

CHAPTER 4 METHODS OF THE PILOT STUDY

According to Stage II of the MRC framework (Craig et al., 2008), testing the feasibility of intervention delivery and acceptability to participants is essential for developing a novel intervention. This chapter reports the method of a pilot randomised trial to test the feasibility and preliminary effects of the DBC intervention. A pilot study can address sample size, recruitment, and challenges of complex interventions (Craig et al., 2008). We chose a randomised controlled trial (RCT) because it is a high level of evidence for the cause-and-effect examination in the healthcare research area (Evans, 2003).

4.1 Research objectives

The specific objectives of the pilot study were:

(1) To test the feasibility and acceptability of the DBC intervention among community-dwelling older people with sarcopenic obesity, in terms of:

a) Feasibility of subject recruitment which included the length of recruitment, the eligible rate, and recruitment rate;

b) Feasibility of measurement tool including participant's time spent on completing the measurement and proportion of missing values;

c) Safety of the intervention which was reported of adverse events;

d) Acceptability of the DBC intervention, including prospective acceptability,

concurrent acceptability, and retrospective acceptability.

(2) To evaluate the preliminary effects of DBC intervention on managing sarcopenic obesity in terms of the following outcomes: body composition, handgrip strength, physical performance, nutritional status, nutrition self-efficacy, dietary quality, and health status.

We hypothesised that: the experimental group who received the DBC intervention would show significant improvements in body composition, handgrip strength, physical performance, nutritional status, nutrition self-efficacy, dietary quality, and health status immediately after the completion of intervention when compared with the control group who received usual care.

4.2 Trial Design

This pilot study was designed as a pilot RCT with a 1:1 ratio. The trial was two-armed because we would like to compare the effects of DBC intervention with usual care. The design of this pilot RCT was referred to the Consolidated Standards of Reporting Trials (CONSORT) for pilot and feasibility studies (Eldridge et al., 2016). A semi-structured individual interview of the experimental group was nested with the pilot RCT after the intervention. This pilot study has been registered in ClinicalTrials (NCT04690985).

4.3 Participants

4.3.1 Eligible criteria

The inclusion criteria were community-dwelling older people who:

(a) were aged 60 years or above according to China's definition for the age of the older people (China's General Office, 2013);

(b) met the condition of sarcopenic obesity according to the Asian Working Group for Sarcopenia (AWGS) 2019 (Chen et al., 2020) and China's guidelines for obesity (Chinese Department of Disease Control., 2006), which included: ① handgrip strength lower than 28 kg for men and lower than 18 kg for women, or physical performance reflected by 5-time chair stand test ≥ 12 s; ② BMI ≥ 28%, or waist circumference ≥ 85 cm in men and ≥ 80 cm in women;

(c) were able to communicate, read, and write in Chinese without significant hearing and vision problems to ensure they understand our instructions;

(d) were not suffering from severe heart diseases or metabolic disorders (e.g. renal diseases, diabetes) or autoimmune disease, cancer, or any other diseases/conditions which may affect food intake and digestion;

(e) did not take medications that may influence eating behaviour, digestion, or metabolism (such as weight loss medication);

(f) having any medical implant devices such as pacemakers because low-level currents will flow through the body when doing the bioelectric impedance analysis

(BIA by InBody 270, Korea) which may cause malfunction of the device.

The exclusion criteria were older people who:

(a) were already adhering to special diet restrictions, including diabetes-specific diet, vegetarian, ketogenic diet, etc.;

(b) had been diagnosed with alcohol addiction, which was an important factor for obesity;

(c) had already been taken part in other clinical trials.

Participants in the experimental group who had completed the intervention were invited to participate in a semi-structured individual interview after the intervention to collect their perceptions of the intervention. In order to collect information from participants with various levels of compliance to the intervention, participants were selected based on their compliance with taking the food diary. Participants with good, moderate, and bad compliance to food diary taken (frequency of food diary taken as '6-7 days/week', '3-5 days/week, and '0-2 days/week', respectively) were recruited as evenly as possible. The final sample size of interviewees was also determined according to the data saturation in the actual interview.

4.3.2 Settings

Participants were recruited from three community health centres in Nanjing, China. Nanjing is the capital city of Jiangsu Province with an excellent economic

level in China (GDP ranked top 10 in the country) (Nanjing Government, 2020). As of February 2020, the older population over 60 years old in Nanjing had reached 1.568 million, accounting for 22% of the whole population (Xu, 2020). All three community health centres were funded by the China government and under the supervision of the Health Department of China, which provided basic medical services to the residents living nearby. Each community healthcare centre provides services to 30,000-50,000 people. According to the government's policy, individuals aged 60 years or above may have a free annual physical examination by the community health centres.

4.4 Interventions

4.4.1 Dietary Behaviour Change group

The participants in the DBC group received individual dietary behaviour change interventions in the community healthcare centre. The intervention was delivered by the doctoral researcher, who is a registered nurse and a qualified weight management coach from the Chinese Nutrition Society. The intervention delivery included three phases and six individual face-to-face sessions nested with weekly telephone calls to enhance the participant's compliance to dietary behaviour change. The description of the intervention implementation is shown in Table 4.1.

Table 4. 1 HAPA-based DBC intervention protocol

Phase	Aims	Time	How	Material	Content
Intention phase (2 sessions)	To establish participants' awareness of SO, to introduce the knowledge about diet and to motivate their intention to change behaviour.	Week 1	One-hour face-to-face talk in Week 1, 2	The Dietary Guidebook	A guidebook was distributed to the participants. They were educated about the concept of SO, including 'What is SO', 'What are the health consequences of SO', 'What are the risk factors of SO', 'What are the preventive treatment of SO', 'What is the relationship between SO and diet'. (SO=sarcopenic obesity)
		Week 2			The participants were introduced to the knowledge of a balanced diet for older people (high quality of protein and low calorie).
Planning phase (1 session)	To help participants transform their intention into a detailed plan and to teach them to record their daily food intake.	Week 3	One-hour face-to-face talk in Week 3	a) The Dietary Guidebook b) Electronic weighing scale c) Food model	Helping the participants to develop a plan to eliminate the worries and establish the confidence to take action. Dietary plans focused on two aspects, which were enhancing protein intake (1.2 – 1.5 g/kg DBW/day) and restricting calorie intake (12% reduction). Training the participants to record their daily food intake by teaching basic food weighing and recording methods.
Action phase (3 sessions)	To help the participants execute the dietary plan continuously.	Week 4-15	a) One-hour face-to-face talk in Week 4, 8, 12; b) Weekly telephone call	a) The Dietary Guidebook b) Food diary c) Electronic weighing scale	Four strategies were used to improve the participants' self-efficacy in all 3 sessions: (1) Acquiring encouragement through the achievement of the goal and engaging in the dietary change; (2) Recovery from setbacks through failure sharing and troubleshooting; (3) Gaining successful experiences from the researcher by sharing other participant's experiences; (4) Further clarifying the goal via continuous guidance of the plan execution. <u>Details of strategy were as follows:</u> - To self-evaluate the achievement of the goals and compliance of the action plans; - To acknowledge the accomplishments to promote positive perceived response; - To share the difficulties or obstacles during the execution of the plans; - To give suggestions and help based on the specific problems; - To share the positive examples and feelings from other participants via the researcher; - To continue to refine the goals and action plans and review the outcome expectations; - To guide the participants to develop their plans for the sustainability of the action.

The first phase identified the “intention phase”. This phase included two weekly 1-hour face-to-face sessions. Each participant was given a guidebook (Appendix 1). The participants were educated about the concept of sarcopenic obesity and its association with healthy dieting.

The second phase was the “planning phase”. The researcher helped participants to develop a plan, eliminate potential worries and establish the confidence to take action. The participants were asked to follow a hypo-caloric high-protein diet (12% calorie reduction of the estimated energy expenditure and protein intake of 1.2 – 1.5 g/kg body weight/day). For example, the estimated energy expenditure was around 30 kcal/desired body weight/day for people with a light physical activity level. A food diary notebook (Appendix 4) was given to each participant. Food recording methods and food exchange lists were taught, and the participants were trained to acquire a basic awareness of how to identify food portions sizes corresponding to 90 kcal (1 portion food = 90 kcal), which is commonly used for measuring food size (Frobisher & Maxwell, 2003). For this purpose, single portion pictures of different food types were shown in the guidebook. Food models (Figure 4.1) were also used in the face-to-face teaching to let the participants directly sense how much a portion of different food (90 kcal) is.

Figure 4. 1 Sample of food models used in teaching

Furthermore, each participant was provided with a scale for weighing the food (Figure 4.2). The guidebook highlighted the major food types rich in high-quality protein, such as fish, meat, egg, shrimp, dairy, and beans.

Figure 4. 2 Scale distributed to participants for helping weigh the food

The third phase was the “action phase”, including three individual face-to-face monthly sessions in Week 4, 8, and 12. The participants received weekly telephone calls to remind them of keeping the food diary, questions encountered during the intervention process were answered. The compliance to the dosage of calories and

protein was assessed monthly during the face-to-face sessions by the doctoral researcher according to the food diary. But if the participant did not keep a good record in the food diary, a 3-days food recall method was used to assess the food intake, which is a commonly used method in dietary studies (Yang et al., 2010). Further guidance was given to the participants if the participant relapsed from compliance with the diet plan. Behaviour change strategies were used to improve the participants' self-efficacy and motivations during all three sessions (see Table 4.1).

4.4.2 Control group

The control group were asked to continue with their usual diet habits. One RA, not involved in other procedures from this pilot study, contacted the participants to offer health talks unrelated to sarcopenic obesity or diet modification. A standard manual for telephone follow-up was referred to (Appendix 5: Manual for telephone follow-up of the control group). The contacts number and timing were similar to the experimental group to control the social effect.

4.5 Outcomes

4.5.1 Feasibility, acceptability, and effects outcomes

The outcomes included feasibility, acceptability, and effects outcomes. Detailed introductions of the outcomes were shown in Table 4.2: Summary of outcome measurements. The measurement was conducted at two intervals, at baseline (T0)

before the intervention and post-intervention (T1, one week after the intervention). Socio-demographic data were collected at T0, including age, gender, marital status, education level, religious belief, diet and exercise habits, morbidities, medications, and the number of hospital and out-patient clinic visits during the previous three months. Participants' physical activity status was measured at T0 and T1 by using the International Physical Activity Questionnaire Short-form (IPAQ-SF) (Lee et al., 2011), to assess the effects of potential confounding factors since physical activity may bring changes to body composition (Beaudart et al., 2017; Ribeiro et al., 2020). Effects data were collected at T0 and T1. Feasibility and acceptability data were collected throughout the study. The measurement forms were provided in Appendix 6: Demographic and Clinical Data Collection Form.

Table 4. 2 Summary of outcome measurements

Outcomes		Measurement methods	Descriptions
Feasibility	Feasibility of subject recruitment	① Length of recruitment ② Eligible rate (percent of people fulfil the inclusion criteria among the number of people screened) ③ Recruitment rate (percent of people enrolled among the number of eligible participants)	The recruitment rate of 50% indicates an acceptable level (Yin, Liu, & Välimäki, 2020).
	Feasibility of measurement tools	① Proportion of missing values in all items ② Time spent for completing the measurements ③ Understandability about the instruments	The proportion of missing data for each variable was suggested to be less than 5% (Schafer, 1999).
	Safety of the intervention	CONSORT Extension for Harms checklist (Ioannidis et al., 2004).	Reporting adverse events.
Acceptability (Sekhon, Cartwright, & Francis, 2017)	Prospective acceptability	① Affective attitude (reflected by recruitment rate); ② Burden (reasons for rejecting participation).	How the participants feel about the intervention prior to participating in the intervention.
	Concurrent acceptability	① Attendance rate (numbers of face-to-face sessions attendance); ② Retention rate (percent of complete follow-up); ③ Attrition rate (percent of lost follow-up); ④ Adherence to food diary taken (good as '6-7 days/week', moderate as '3-5 days/week', bad as '0-2 days/week'); ⑤ Compliance to diet instruction (protein and calorie intake); ⑥ Reasons of drop out	Participant's acceptability whilst during the intervention delivery period. Compliance of adequate protein intake: the percent of people whose score of protein adequate in the DQI-I was 5. Compliance of calorie control: calculating the calorie amount based on the food diary and 3-day food recall monthly.
	Retrospective acceptability	A semi-structured individual interview	To interview participants' feelings about the intervention after completing the study.

Primary effects			
Obesity-related outcomes			
Anthropometry	Body weight (kg), BMI (kg/m^2), Waist circumference (cm), Waist-hip ratio		Nearest to 0.1 cm and 0.1 kg.
Sarcopenia-related outcomes			
Body composition	Skeletal muscle mass (kg), Fat-free mass (kg), Body fat mass (kg), Percent of body fat, Visceral fat score, SMI (kg/m^2) [1]	Bioelectrical impedance analysis (InBody 270, Korea)	To assess a person's body composition nearest to 0.1 kg. The reliability and accuracy of InBody machine were tested as good (Garcia et al., 2020).
Muscle strength	Handgrip strength (kg)	Handheld Jamar Hydraulic Hand Dynamometer	To assess a person's upper-limb strength (Guerra & Amaral, 2009).
Physical performance	6-m gait speed (m/s)		
	SPPB	To assess a person's physical function from three aspects (Pavasini et al., 2016) ① standing for 10 seconds with feet in three different positions; ② 3-m or 4-m walking speed test; ③ time to rise from a chair for five consecutive times.	Scores range from 0 (worst) to 100 (best).
Secondary effects			
Nutrition self-efficacy		HAPA Nutrition Self-efficacy Scale [2]	The scale has 5 items, and each item ranges from 1 to 4, with a higher score means higher self-efficacy.
Dietary quality		DQI-I Food diary	To measure participant's usual food consumption and nutrient intake from four aspects: variety, adequacy, moderation, and overall balance. The

		scores range from 0 (lowest quality) to 100 (highest quality).
Nutritional status	MNA [3]	The score range from 0 to14; a higher score means better nutritional status.
Health status	SF-36 [4]	To assess participant's health status from vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health. A lower score suggests greater disability, while a higher score depicts less disability (total score ranges from 0 to100).

Notes: BMI=body mass index; SMI=skeletal muscle mass index; CONSORT= Consolidated Standards of Reporting Trials; SPPB=Short Physical Performance Battery; HAPA=Health Action Process Approach; DQI-I=Dietary Quality Index-International; MNA=Mini Nutritional Assessment; SF-36=36-item short form health survey.

1 Definition of the body composition related parameters was explained in Table 3.1;

2 The internal consistency (Cronbach's alpha) of the HAPA Nutrition Self-efficacy Scale was 0.87 (Zhou et al., 2015), Cronbach's alpha= 0.92;

3 The Cronbach's α of internal consistency reliability of MNA was 0.711 when tested in the Chinese population. The correlation coefficient r was 0.661 (p=0.000) compared to another widely used scale (Nutrition Risk Screening Scale) (He & Liu, 2010);

4 The Cronbach's coefficients of SF-36 ranged from 0.72 to 0.88 by tested in the Chinese population. Convergent validity and discriminant validity of items compared with its hypothesised scale were satisfactory for all except the social functioning scale. (Li, Wang, & Shen, 2003).

4.5.2 Translation and validation of Nutrition Self-efficacy Scale, the Chinese version

The Nutrition Self-efficacy Scale contained five items to measure one domain (i.e., adults' confidence in changing their nutritional behaviours). According to our knowledge, no published Nutrition Self-efficacy Scale on Chinese version or psychometric properties in the Chinese population could be found. Therefore, we translated the scale and tested its psychometric properties among the Chinese people. The translation of the Nutrition Self-efficacy Scale was approved by the original author, Prof. Ralf Schwarzer. All participants involved in the study were informed about the purpose and procedures.

4.5.2.1 Methods

The study was conducted in November 2019, including three phases: instrument translation, content validation, and reliability assessment. A panel of experts were invited to content validation. A prospective observational design was employed for the reliability test. Since the scale only contains one domain, construct validation was not needed (Schwarzer & Renner, 2009).

Instrument translation The translation of the scale contained three stages: forward-translation, backward-translation, and consensus making (Sousa & Rojjanasrirat, 2011). First, the original English version was forward-translated into

Chinese by two translators independently, who were bilingual speakers in native Chinese (Mandarin) and English. Both of the translators had master degrees in nursing. Another two researchers discussed the two versions of translation and drafted a Chinese version. Then, another two bilingual speakers in native Chinese (Mandarin) and English backward-translated the draft into English. Finally, the backward-translated English version was compared with the original English scale. The panel discussed and reached a consensus on the final Chinese version of the Nutrition Self-efficacy Scale.

Content validity A panel of five experts examined the content validity of the scale, who worked in the Department of Clinical Nutrition from three tertiary hospitals, with a master degree either in nutrition or medicine. They all had extensive working experience with older adults, with a working length of 6 to 30 years (average working length were 14.4±9.81 years). They were invited to rate whether the content of each item adequately reflected the intended construct of the scale. The rating used the content validity index (CVI) with a 4-point Likert scale: 1=irrelevant item; 2= a little relevant, major revision needed; 3=relevant, minor modification needed; 4=very relevant (Souza, Alexandre, & Guirardello, 2017). The experts' committee were required to give detailed comments on an item rated 1 or 2. If a satisfactory level of CVI value were not achieved, a second-round would be conducted after the revision until consensus was reached. Panel members were also invited to comment on the

scale's readability to ensure the general population understood the content.

Reliability The reliability, including the internal consistency and stability of the scale, was estimated. Stability assessment was performed using the test-retest method with a duration of 10-14 days, which is an appropriate time interval to avoid recall bias (Souza, Alexandre, & Guirardello, 2017).

Sample Participants were recruited if they were 18 years or older, literate, and without cognitive problems. According to the literature, approximately ten subjects for each item are needed for the reliability test (Raykov & Marcoulides, 2011). When the minimum required sample size reaches 80, the validity estimation would be robust (Hobart et al., 2012). Considering this scale had never been tested in the Chinese population, a convenience sample of 458 participants was recruited via an online survey platform.

The sample size for test-retest reliability assessment was usually based on a rule of thumb, and a sample size of 30 is considered as fair and less than 30 as poor (Stevens, 2012). Bujang and Baharum (2017) proposed if we want to detect an intraclass correlation coefficient (ICC) of 0.70 with 80% power, a minimum sample size of 10 is needed. For the interpretation of the results in our study, minimum values of 0.70 are considered satisfactory. Therefore, we decided the sample size for test-retest reliability assessment were 30 after synthesizing all the references. The participants who joined the test-retest were recruited independently without joining

the main psychometric study.

Data analysis The SPSS 26.0 was used for analysing data. Descriptive statistics were performed to present the participants' characteristics. Content validity was measured using CVI. For each item, item-level CVI (I-CVI) was calculated by the proportion of experts who rated "relevant (minor revision)" or "very relevant" (Lynn, 1986). Scale-level CVI (S-CVI) was calculated by averaging the I-CVIs for all items. For the experts' panel of five or fewer, the acceptable concordance index should be 0.80 as a satisfactory level, preferably higher than 0.09 (Polit & Beck, 2006; Souza, Alexandre, & Guirardello, 2017).

Internal consistency was estimated via Cronbach's alpha coefficient and corrected item-to-total correction of the items. The minimal acceptable Cronbach's alpha was specified as .70 (Gliem & Gliem, 2003; Nunnally & Bernstein, 1994), and adequate item-to-total correlation was set as 0.30 (Souza, Alexandre, & Guirardello, 2017). Test-retest reliability was estimated via the intraclass correlation coefficient (ICC), and the minimum values of 0.70 were considered satisfactory (Nunnally & Bernstein, 1994).

4.5.2.2 Results

Sample characteristics. Table 4.3 presents the demographics of participants involved in the test-retest and overall evaluation of the translated scale. Totally 458 participants (mean age = 37.76 ± 11.88 years old) completed the main investigation,

the majority of whom were female (66.6%) and married (72.7%). The majority of participants received undergraduate education (78.8%). The monthly income of participants mainly was lower than 10,000 (65.7%). For the test-retest sample, the mean age was 37.40 ± 10.17 years old, and 80% were female; over 80% of them received undergraduate education.

Table 4. 3 Demographics of participants involved in the psychometric property evaluation of Nutrition Self-efficacy Scale, the Chinese version

	Test-retest sample (n=30) *n* (%)	Overall sample (n=458) *n* (%)
Age (mean, SD)	37.40±10.17	37.76±11.88
Gender		
Male	6 (20.0)	153 (33.4)
Female	24 (80.0)	305 (66.6)
Marital status		
Single/Divorced/Widowed	2 (6.7)	125 (27.3)
Married/Partner relationship	28 (93.3)	333 (72.7)
Education level		
Postgraduate	10 (33.3)	100 (21.8)
Undergraduate	14 (46.7)	261 (57.0)
High school	4 (13.3)	67 (14.6)
Junior school or less	2 (6.7)	30 (6.6)
Religious belief		
None	29 (96.7)	396 (86.5)
Muslim	1 (3.3)	1 (0.2)
Buddhist	/	41 (9.0)
Taoist	/	1 (0.2)
Christ	/	11 (2.4)
Others	/	8 (1.7)
Monthly income (RMB)		
> 15,000	3 (10.0)	69 (15.1)
10,000-15,000	8 (26.7)	88 (19.2)
5,000-9,999	8 (26.7)	139 (30.3)
<5,000	11 (36.7)	162 (35.4)

Notes: SD=standard deviation

Content validity The results of content validity are presented in Table 4.4. The I-CVI of five items ranged from 0.80 to 1.00, and the S-CVI was 0.96, which indicated adequate content validity of this scale. Comments from the expert who rated item 3 as “a little relevant” were about whether the general population could understand “营養方式”. According to the readability test among panel people from

the test-retest participants, they all understood item 3. Therefore, we kept the original translation.

Five participants with secondary school education level from the test-retest sample were invited by convenient method to comment on the scale's readability. All participants reported that the content of the scale was readable and understandable; they could follow the instructions.

Table 4. 4 Content validity assessment results of translated Nutrition Self-efficacy Scale

Items	1 Number of experts rating "Irrelevant"	2 Number of experts rating "A little relevant"	3 Number of experts rating "Relevant"	4 Number of experts rating "Very relevant"	I-CVI
1. …即使我需要很長時間來養成必要的習慣 …even if I need a long time to develop the necessary routines				5	1.00
2. …即使我不得不嘗試很多次它才能有效果 …even if I have to try several times until it works				5	1.00
3. …即使我不得不重新考慮我的整個營養方式 …even if I have to rethink my entire way of nutrition		1	1	3	.80
4. …即使在我剛開始嘗試時沒有得到其他人的大力支持 …even if I do not receive a great deal of support from others when making my first attempts				5	1.00
5. …即使我不得不制定一個詳細的計畫 …even if I have to make a detailed plan			1	4	1.00
S-CVI					.96

Notes: I-CVI=item-level content validity index; S-CVI=scale-level content validity index.

Reliability Cronbach's alpha was .92, which indicated a good internal consistency of the scale. Item-to-total correlation ranged from .763 to .807, which indicated adequate item-to-total correlations. Test-retest reliability assessment results are shown in Table 4.5. ICC of five items was above .80, which indicated adequate stability of the scale.

Table 4. 5 Test-retest reliability of the Nutrition Self-efficacy Scale, Chinese version (n=30)

Items	ICC	95%CI
1...even if I need a long time to develop the necessary routines.	.93	.86-.97
2...even if I have to try several times until it works.	.86	.71-.93
3...even if I have to rethink my entire way of nutrition.	.93	.86-.97
4...even if I do not receive a great deal of support from others when making my first attempts.	.89	.77-.95
5...even if I have to make a detailed plan.	.88	.75-.94
Total score	.97	.93-.99

Notes: ICC=intra-class correlation coefficient; CI=confidence interval.

4.6 Sample size

There were 60 participants included in this trial. A pilot study sample size always refers to the rules of thumb, and a formal sample size calculation may not require (Thabane et al., 2010). The primary focus of a pilot study was to test the feasibility of

the intervention protocol, measurement instrument, and other methodological procedures (Craig et al., 2008; Lancaster, Dodd, & Williamson, 2004; Thabane et al., 2010). However, given that the secondary focus of this pilot study was to estimate the preliminary effects of the DBC intervention, the sample size of this pilot study should be reasonable enough to provide a valuable estimation of parameters for future main study sample size calculation (Teare et al., 2014). Hertzog (2008) suggested that a minimum of 30 participants per group would be necessary for a pilot study to estimate a between-group effect size since it could yield confidence intervals, the lower limits of which could define the range of the power analysis. Hence, we decided the sample size for this pilot study were 30 for each group (60 in total).

4.7 Recruitment and sampling

Convenience sampling was used to recruit participants from the three community health centres because it is difficult to retrieve the detailed health background of all potential participants in the community. A truly random sample cannot be guaranteed. The study was promoted by displaying the posters in the centres. Initially, potential participants were identified by the community nurses among the overweight or obese older people attending the centres. Then, potential participants were screened for eligibility by the doctoral researcher according to the sample selection criteria. The community physician ascertained whether the participant's physical health condition was suitable for the study. If an older person were eligible for the study, we would

provide the information sheet and ask for consent. If the older people agreed to join, baseline assessments and randomised allocation would be arranged subsequently.

4.8 Randomisation

Eligible participants were interviewed for obtaining their written informed consent (Appendix 7: Information sheet; Appendix 8: Consent form). Afterwards, socio-demographic data and a baseline assessment were collected before randomisation. The block randomisation method was utilised (block size=4) to ensure that an equally balanced number of participants could be allocated to each study group (i.e. the DBC or the control groups) (Suresh, 2011). The randomisation table was obtained from the Research Randomizer software (https://www.randomizer.org/). A research assistant (RA) generated a random sequence code, who was not involved in the intervention implementation or outcome assessments. Each participant was coded with a subject ID number according to the sequence of consent. Allocation concealment was ensured by using sealed envelopes and upheld until the group assignment was completed.

4.9 Blinding

To avoid performance bias and detection bias, the blinding during the implementation of the intervention and outcome assessment should be considered (Karanicolas, Farrokhyar, & Bhandari, 2010). Due to the nature of our proposed

nutritional intervention, it is impossible to conduct blinding on participants and the researcher who delivered the intervention. Therefore, the pilot study was single-blinded, which means only the outcome assessors were blinded to the group allocation.

Strategies were used to reduce the chance of leakage about the group allocation to the assessor. First, the assessor was unaware of the research objectives or hypothesis. The assessor was also well-trained to prevent the participants from revealing the group information in an appropriate way. Second, the participants were instructed to avoid disclosing their group information, and the doctoral researcher accompanied the measurement process. Third, the group allocation was conducted after the baseline assessment, which could avoid the group label leakage to some extent.

4.10 Qualitative data collection

In addition to the quantitative data collection, participants from the experimental group were selected for an individual semi-structured interview based on their levels of adherence to food diary taking. The interview was conducted within one week after completing the intervention by the doctoral researcher in a private meeting room in the community centre to avoid disturbance from other people. The meeting room is where the participants received the DBC intervention, meaning that they are already familiar with the environment.

The interviewees were informed about the purpose and procedures of the interview, then the following questions in Table 4.6 were asked. At the end of the interview, an open-ended question was asked to obtain further information which might be relevant: “Is there anything else you would like to tell me?”. The whole interview process was audio-taped, and field notes were taken to record the non-verbal reactions of the interviewees.

Table 4. 6 Open-ended questions asked in the semi-structured interview

Items	Questions
Q1	How do you feel about the whole dietary behaviour change process?
Q2	To what extent do you think the intervention is helpful for you?
Q3	What factors do you think facilitated your change in dietary behaviour?
Q4	Then what factors do you think hindered your change in dietary behaviour?
Q5	Was your motivation increased after the first two face-to-face meetings?
Q6	Was the dietary plan helpful for you to turn the motivation into action?
Q7	Did your family support your dietary behaviour change? If not, why?
Q8	Now the study has finished, will you consider keeping this dietary behaviour? If not, could you please tell me the reasons?
Q9	In your opinion, what are the strengths and weaknesses of the intervention? Do you have any suggestions?

4.11 Statistical methods

4.11.1 Quantitative data analysis

IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA) was used to conduct the data management and analysis. The level of significance was set as $p < 0.05$ for a two-tailed test. Details of data analysis are presented in the following sections.

4.11.1.1 Data entry and clean

The data was coded and entered into SPSS 26.0 to create a dataset initially by a research assistant who was not involved in group allocation and intervention. The doctoral student then checked the accuracy by comparing it to the paper recordings of the raw data. The doctoral student conducted further data cleaning. For the continuous variables, descriptive statistics (i.e., minimum value, maximum value, and mean score) was performed to check whether the score range fell within the normal range. For the categorical variables, frequency counts were run to identify the mistakes in codes. Wrong entries or missing values were checked and corrected before data analysis.

4.11.1.2 Missing data management

Little's Missing Completely at Random (MCAR) test was performed to check whether the missingness in a given variable is independent of any other observed or unobserved variables (Little, 1988). There was no missing data at baseline in this study, and the missing data at post-test in all items was < 1%. The result of Little's MCAR test (χ^2 = 26.49, *df* = 28, *p* = .546) indicated that the missingness was completely at random. The intention-to-treat (ITT) principle was followed for analysing the data.

The imputation was not performed in this study because the standard generalised estimating equation (GEE) model was employed in the statistical analysis, and normally in GEE analysis, the multiple imputation is not necessary because it may

cause an overestimation of the standard errors of the estimated regression coefficients (Twisk & de Vente, 2002). Besides, GEE could use all available data for modelling incomplete data (Fitzmaurice, Laird, & Ware, 2012).

4.11.1.3 Statistical analysis

4.11.1.3.1 The homogeneity test of demographic data and baseline outcomes of interest

The between-group comparison was performed to check the homogeneity of the two groups at baseline. For the continuous variables of demographic data and baseline outcomes of interest (i.e., body weight, handgrip strength, gait speed, waist circumference, waist-hip ratio, skeletal muscle mass, fat mass, BMI, percent of body fat, visceral fat grade, fat-free mass, basic metabolic rate, skeletal muscle mass index, short physical performance battery, mini nutritional assessment, nutrition self-efficacy, SF-36), Shapiro-Wilk test was performed to check the assumption of normality. If the assumption was not violated, the independent sample t-test was performed; otherwise, the Mann Whitney U test was performed. The chi-square test or Fisher's exact test were performed for the categorical variables (i.e., gender, nationality, education level, marital status, religion, income level, medical history, eating/cooking habits, and physical activity level). If any differences were identified in the demographic data and outcomes of interest at baseline, the factors would be considered as co-variants during the statistical analysis.

4.11.1.3.2 The statistical analysis of feasibility outcomes

Descriptive statistics (absolute number and percentage of participants) were used to present the feasibility outcomes, which included the length of recruitment, eligible rate, recruitment rate, attendance rate (attendance to the face-to-face sessions), retention rate, attrition rate, and adherence rate (adherence to food record taking).

4.11.1.3.3 The statistical analysis of intervention efficacy outcomes

GEE was performed to examine the changes in the mean values of the outcomes by group assignment across time, which included the primary outcomes (handgrip strength, anthropometry related variables, body composition related variables, physical performance-related variables) and secondary outcomes (nutritional status, nutrition self-efficacy, SF-36 health survey).

GEE generalises the quasi-likelihood approach to a generalised linear model that does not require a likelihood and estimates with an unknown correlation between outcomes (Hardin, 2005). The GEE model was developed by Liang and Zeger (1986), and it was flexible for analysing response variables that were not normally distributed. GEE's main advantage is that it only needs the mean structure without requiring the correct specification of the multivariate distribution (Ziegler & Vens, 2010). It is commonly used in longitudinal or repeated measures studies to manage unmeasured dependence between outcomes (Ballinger, 2004). If the data are missing completely at random (MCAR), the GEE is still applicable to provide consistent estimations (Hardin,

2005).

In this study, the missing variables were caused by drop-out, and the missingness was MCAR. The main effects and interactions of group and time can be tested by applying GEE to estimate regression coefficients and standard errors with sampling distributions that are asymptotically normal (Liang & Zeger, 1986). To avoid covariate effects, all the GEE analyses were adjusted for two covariates (the variable related to height, education level, and physical activity level). The first-order autoregressive (AR(1)) working correlation structure was chosen for all the GEE analyses, which is generally used for analysing data in different time point, as the correlation between variables decreases when measurement separation increase over time (Ballinger, 2004).

The effect size was calculated by using Cohen's *d* (Cohen, 2013), which is defined as the difference between two means divided by a standard deviation for the data, i.e.

$$d = \frac{\bar{x}_1 - \bar{x}_2}{s} = \frac{\mu_1 - \mu_2}{s}$$

$$s = \sqrt{\frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2}{n_1 + n_2 - 2}}$$

The magnitudes of d = 0.20 was regarded as small effect size, d = 0.50 was regarded as medium effect size, d = 0.80 was regarded as large effect size, and d = 1.20 was regarded as very large effect size, which was initially suggested by Cohen

(2013) and expanded by Sawilowsky (2009).

4.11.2 Qualitative data analysis

Content analysis was employed inductively to analyse the qualitative data, which is a flexible method for analysing text data and has been widely used in qualitative studies (Hsieh & Shannon, 2005). The field notes were also analysed. After each interview, the interviewer transcribed the voice record into text immediately. An RA was hired to help with the transcription. Two researchers checked the accuracy of the transcripts together. NVivo 12 software was used to manage the data to help identify common codes from the transcripts. Two researchers worked independently on the coding and identifying of the codes. The research team then discussed the identified codes and came to an agreement on them, grouping them into categories with the support of verbatim data. Then, the categories were condensed and/or reorganised when deemed necessary. The research team examined the categories for consistency, reached a consensus about the meaning and structure, and devised a list of finalised categories. A set of themes with supporting verbatim data were finally generated to identify the perceptions of participants.

4.12 Intervention fidelity

As suggested by the National Institutes of Health (NIH) Behaviour Change Consortium, intervention fidelity was guaranteed in this study in five components:

intervention design, training of providers, intervention delivery, receipt of intervention, and enactment of skills gained from the intervention (Bellg et al., 2004). Intervention fidelity refers to the extent to which the core components of interventions are implemented according to the initial protocol (Gearing et al., 2011), and the methodologies used to enhance the validity and reliability of the interventions (Bellg et al., 2004). Enhancing intervention fidelity is vital in interventional studies to avoid Type I (a "false positive" finding) or Type II errors (a "false negative" finding). A fidelity checklist (Appendix 10) was used to check the delivery of the intervention. Details of the intervention fidelity enhancement methods are described in Chapter 5 (section 5.4).

4.13 Ethical considerations

The ethical approval has already been obtained from the Human Subjects Ethics Review Committee of the Hong Kong Polytechnic University (HSEARS20191007001) (Appendix 9). Information sheet (Appendix 7), which included study purpose, procedures, potential harms, and data safety, were given to participants. Written informed consent (Appendix 8) was obtained from all participants after being given the study's introduction. We reassured each participant that they could withdraw from the study at any time without penalties. The principle of protecting research subjects was observed in accordance with the Helsinki Declaration. Data confidentiality was maintained at all times in accordance with the privacy ordinance. The questionnaires

hardcopies were locked in the principal investigator's office, while the soft copy is encrypted and accessed only by the investigators and the research assistants.

Additionally, the researchers worked together to monitor the potential occurrence of adverse effects on the participants. Standard guidelines (Appendix 11) were distributed to the participants for managing symptoms of intolerance. Individual advice was offered from the dietitian, and a physician referral was made to safeguard the participants' safety and well-being throughout the study.

4.14 Summary

This study aimed to evaluate the feasibility, acceptability, and preliminary effects of dietary behaviour change intervention on managing sarcopenic obesity among older people in the community. An assessor-blind, two parallel-group, pilot RCT was conducted. Sixty community-dwelling older adults (≥ 60 years old) were assigned randomly to either the experimental or the control groups at a 1:1 ratio. The experimental group received a 15-week dietary intervention, including six face-to-face sessions and weekly telephone calls. The control group received regular health talk to control the social interaction effect. Twenty-one participants from the experimental group were invited to join an individual semi-structured interview. Data were collected at baseline (T0) and post-intervention (T1). The ITT principle was followed in statistic analysis. Descriptive statistics, independent t-test, Mann Whitney U-test, Chi-square test, and standard GEE were performed in analysing the

quantitative data. Content analysis was used to analyse the qualitative data. The fidelity of the intervention was enhanced during the process.

CHAPTER 5 RESULTS

This chapter reported the results of the pilot study, including the feasibility, acceptability and preliminary effects of DBC intervention, which was in accordance with the research objectives. The DBC intervention was feasible and well-accepted in community older people, but the preliminary effects of DBC interventions in improving body composition were not significant. Detailed reports for the results are presented in the following sections.

5.1 Recruitment and participants flow

Subject recruitment was conducted between June 2020 and November 2020 in three community health centres in Nanjing, China. Around 2000 older people aged 60 or above were screened, and 105 people fulfilled the criteria. Among the 105 people, 45 people declined participation. The reasons included having no time occupied by housework or taking care of grandchildren or other family members (34 people), no interest (4 people), lack of support from family (2 people), and not permanently resident in Nanjing (5 people). Eventually, 60 people were enrolled after receiving written informed consent and then were allocated randomly into two groups after baseline assessment. The eligible rate was around 5.25% (105/2000), and the recruitment rate was 57.14% (60/105), which has met an acceptable level of 50% recruitment rate. After the intervention, 10 participants (16.67%, 10/60) dropped out,

including 4 from the experimental group and 6 from the control group. The following Figure 5.1 shows the flow of participants recruitment as recommended by the CONSORT statement (Eldridge et al., 2016).

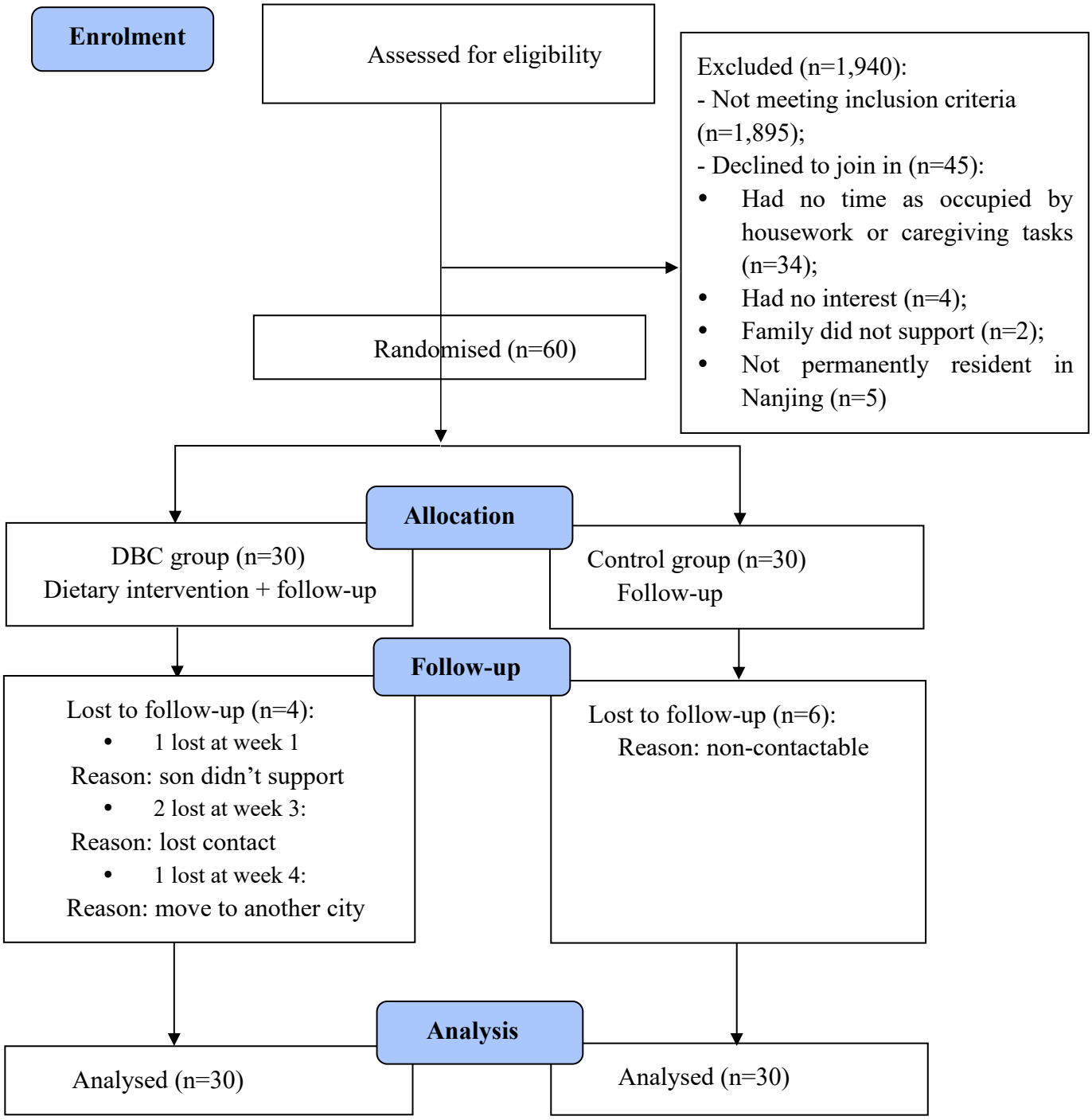


Figure 5. 1The CONSORT diagram of this pilot study procedure

Note: DBC=dietary behaviour change

5.2 Baseline data

5.2.1 Demographics of participants

The demographics of the participants involved in this pilot study are shown in Table 5.1. Forty-two females (70%) and 18 males (30%) were included in the study. The mean age of participants was 68.13 ± 6.12 years old. There were 53.33% of participants lived with their children. Twenty-four participants (40%) only received primary school education, and only 5 participants (8.33%) had a diploma/ bachelor or higher degree. The majority of the participants did not have any religious belief, and the rest were either Buddhist (1/60, 1.67%) or Christian (5/60, 8.33%). Four participants (6.67%) were vegetarians. Many participants have several kinds of diseases, e.g., hypertension (30/60, 50%), hyperlipidemia (14/60, 23.3%), and fatty liver (23/60, 38.3%).

Table 5. 1 Demographics of the participants by group assignment (N=60)

Variable	Total (n=60) *n* (%)	DBC group (n=30) *n* (%)	Control group (n=30) *n* (%)	χ^2/z	*p*
Age (mean, SD)	68.13 (6.12)	68.87 (6.51)	67.40 (5.72)	-.70 (z)	.481
Gender				2.86[a]	.091
Female	42 (70)	18 (60)	24 (80)		
Male	18 (30)	12 (40)	6 (20)		
Marital status				.87[b]	.353
Married	55 (91.67)	26 (86.67)	29 (96.67)		
Single/Divorced/Widow	5 (8.33)	4 (13.33)	1 (3.33)		
Living with children				1.071[a]	.301
Yes	32 (53.33%)	18 (60%)	14 (46.67%)		
No	28 (46.67%)	12 (40%)	16 (53.33%)		
Nationality				.00[b]	1.000
Han	59 (98.33)	29 (96.67)	30 (100)		
Minority	1 (1.67)	1 (3.33)	0 (0)		
Education level				8.20[b]	**.041**
Primary school	24 (40)	7 (23.33)	17 (56.67)		
Secondary school	16 (26.67)	11 (36.67)	5 (16.67)		
High school	15 (25)	10 (33.33)	5 (16.67)		
Diploma/Bachelor degree or above	5 (8.33)	2 (6.67)	3 (10)		
Religious belief				1.20[b]	1.000
Christianity	5 (8.33)	2 (6.67)	3 (10)		
Buddhism	1 (1.67)	1 (3.33)	0 (0)		
None	54 (90)	27 (90)	27 (90)		
Household monthly income (CNY)				3.50[b]	.324
< 3,000	17 (28.33)	6 (20)	11 (36.67)		
3,000 - 5,999	25 (41.67)	12 (40)	13 (43.33)		
6,000 – 10,000	11 (18.33)	7 (23.33)	4 (13.33)		
> 10, 000	7 (11.67)	5 (16.67)	2 (6.67)		
Alcohol				4.55[b]	.327

Never	48 (80)	22 (73.33)	26 (86.67)		
Once/month	3 (5)	3 (10)	0 (0)		
2 - 4 times/month	3 (5)	2 (6.67)	1 (3.33)		
2 – 3 times/week	1 (1.67)	0 (0)	1 (3.33)		
≥ 4 times/week	5 (8.33)	3 (10)	2 (6.67)		
Smoking				3.69[b]	.270
Never	53 (88.33)	25 (83.33)	28 (93.33)		
Smoking cessation	1 (1.67)	1 (3.33)	0 (0)		
< 1 pack/day	5 (8.33)	4 (13.33)	1 (3.33)		
1-2 packs/day	1 (1.67)	0 (0)	1 (3.33)		
Vegetarian				.00[b]	1.000
Yes	4 (6.67)	2 (6.67)	2 (6.67)		
No	56 (93.33)	28 (93.33)	28 (93.33)		
Cooking				.42[a]	.812
Self	52 (86.67)	26 (86.7)	26 (86.7)		
Others	12 (20)	7 (23.3)	5 (16.7)		
IPAQ				.49[b]	.909
Low	4 (6.67)	2 (6.67)	2 (6.67)		
Moderate	40 (66.67)	19 (63.33)	21 (70)		
High	16 (26.67)	9 (30)	7 (23.33)		
Morbidity				10.47[a]	.063
Hypertension	30 (50)	12 (40)	18 (60)		
Hyperlipidemia	14 (23.3)	9 (30)	5 (16.7)		
Fatty liver	23 (38.3)	14 (46.7)	9 (30)		
Others	13 (21.7)	10 (33.3)	3 (10)		
None	8 (13.3)	4 (13.3)	4 (13.3)		

Notes: DBC = dietary behaviour change; SD = standard deviation; CNY = Chinese yuan; IPAQ = International physical activity questionnaire.

[a] Chi - square test

[b] Fisher's exact test

5.2.2 The comparison between the intervention group and control group at baseline

Most of the participants' demographic information did not differ between the experimental and the control group (the *p*-value ranged from 0.063 to 1.000). However, the experimental group participants were more educated than the participants in the control group (χ^2 =8.20, *p*=0.041). The body height of participants in the experimental group was also significantly higher than participants in the control group (*t*=-2.10, *p*=0.035). Therefore, the statistical analysis of intervention effects was adjusted by height and education level.

There were no statistically significant differences between the experimental and control groups in the outcome of interest at baseline, with the *p*-value ranging from 0.066 to 0.955. Details of the homogeneity test results of demographics and outcomes of interest are shown in Table 5.2.

Table 5. 2 Comparison of the outcomes of interest at baseline (N=60)

Variable	Total (n=60) Mean (SD)	DBC group (n=30) Mean (SD)	Control group (n=30) Mean (SD)	*t/z*	*p*
Handgrip strength (kg)	14.92 (5.46)	15.37 (6.03)	14.47 (4.88)	-.536[a]	.592
Anthropometry					
Height (cm)	157.43 (6.17)	159.08 (6.35)	155.78 (5.62)	-2.10[a]	.035
Body weight (kg)	73.79 (8.44)	75.28 (8.89)	72.29 (7.81)	1.38[b]	.173
Waist circumference (cm)	98.01 (7.01)	99.28 (7.36)	96.73 (6.51)	-1.09[b]	.160
Waist-Hip ratio	0.96 (0.14)	0.99 (0.18)	0.94 (0.05)	-1.61[a]	.107
BMI (kg/m^2)	29.88 (3.05)	29.98 (3.44)	29.77 (2.66)	-.11[a]	.912
Body composition					
Skeletal muscle mass (kg)	24.23 (3.69)	25.06 (3.88)	23.40 (3.35)	1.77[b]	.082
Fat free mass (kg)	44.30 (6.22)	45.77 (6.61)	42.82 (5.51)	1.88[b]	.066
Body fat mass (kg)	29.35 (6.12)	29.22 (6.85)	29.47 (5.41)	-.44[a]	.663
Percent of body fat (%)	40.02 (5.56)	39.35 (6.08)	40.70 (5.01)	-.94[b]	.351
SMI (kg/m^2)	7.18 (0.82)	7.31 (0.92)	7.05 (0.70)	1.22[b]	.28
Visceral fat level	14.43 (3.07)	14.20 (3.19)	14.67 (2.98)	-.59[b]	.560
Physical performance					
6-m Gait speed (m/s)	.88 (0.15)	.91 (0.12)	.85 (0.17)	-1.69[a]	.097
SPPB (0-12, higher score indicate better mobility)	10.77 (1.45)	10.87 (1.22)	10.67 (1.67)	-.18[a]	.859
MNA	13.22 (1.39)	13.00 (1.66)	13.43 (1.04)	-.94[a]	.347
Nutrition self-efficacy	14.63 (3.67)	15.20 (3.56)	14.07 (3.76)	-1.33[a]	.183
SF-36					
PF	77.33 (23.42)	81.00 (27.93)	73.67 (17.56)	-.52[a]	.607
RP	80.00 (39.00)	80.83 (39.22)	79.17 (39.44)	-.25[a]	.805
BP	15.67 (15.98)	14.33 (16.75)	17.00 (15.35)	-.85[a]	.393
GH	54.75 (7.33)	54.50 (7.35)	55.00 (7.43)	-.39[a]	.693
VT	53.50 (11.25)	54.83 (12.76)	52.17 (9.53)	-.57[a]	.572
SF	60.63 (11.47)	60.42 (8.74)	60.83 (13.82)	-.06[a]	.955
RE	80.00 (38.91)	82.22 (37.89)	77.78 (40.43)	-.56[a]	.574
MH	55.20 (10.87)	55.73 (12.29)	54.67 (9.42)	.38[b]	.707

HT	56.25 (17.60)	55.00 (16.61)	57.50 (18.74)	-.51[a]	.613
DQI-I (total)	58.43 (11.53)	60.03 (11.27)	56.83 (11.76)	1.076[b]	.286

Notes: SD= standard deviation; BMI= body mass index; SMI= skeletal muscle mass index; SPPB= short physical performance battery; MNA= mini nutritional assessment; SF-36= the short form (36) health survey; PF= physical functioning; RP= role limitation due to physical problems; BP= bodily pain; GH= general health; VT= vitality; SF= social functioning; RE= role limitation due to emotional problems; MH= mental health; HT= reported health transition; DQI-I= Dietary Quality Index-International.

[a] Mann-Whitney U test.

[b] Independent Samples t-test.

5.3 Outcomes and estimation

5.3.1 Feasibility of the intervention

The recruitment lasted for six months. There were around 2000 older people screened, and 105 people fulfilled the criteria. Sixty of them agreed to join in the pilot study. The eligible rate was about 5.25% (105/2000), and the recruitment rate was 57.14% (60/105). The average time needed to complete all outcome measurements was 30 minutes. The participants all understood and completed measures as required. There were no missing values at baseline, and the proportion of missing values in all items was <1% in the post-test. No adverse events were reported from the participants, either in the experimental or control groups.

5.3.2 Acceptability of the intervention

Prospective acceptability was reflected by affective attitude (recruitment rate) and burden (reasons for refusing to join in the study) in this study. The recruitment rate was 57.14% (60 people were enrolled among 105 people who fulfilled the inclusion criteria), which was acceptable (over 50%). Reasons for rejecting joining were as follows: had no time as occupied by housework or caregiving 32.38% (34/105), had no interest 3.81% (4/105), the family did not support 1.90% (2/105), and not permanently resident in Nanjing 4.76% (5/105).

Concurrent acceptability was presented by attendance rate (numbers of sessions attended), retention rate, attrition rate, and adherence rate (adherence to food diary

taking and compliance to diet instruction).

In this study, 20 out of 30 participants (66.67%) in the experimental group attended all the sessions (six sessions in total), two participants attended five sessions (2/30, 6.67%), two participants attended four sessions (2/30, 6.67%), one participant attended two sessions (1/30, 3.33%), one participant attended once (1/30, 3.33%). Four participants dropped out during the intervention (4/30, 13.33%). The percent of participants who attended more than five times were 73.33%.

The overall retention rate of this study was 83.3% (50/60), and the attrition rate was 16.7% (10/60). Specifically, the retention rate in the experimental group was 86.67% (26/30). The reasons for participants dropping out included lost follow-up (5/60, 8.33%), having no time (3/60, 5%), moving to another city (1/60, 1.67%), and lack of family support (1/60, 1.67%).

The adherence of remaining participants in the experimental group for food diary taking was: rated as good was 23.33% (7/30), rated as moderate was 3.33% (1/30), rated as bad was 60% (18/30), and drop out 13.33% (4/30). The compliance to adequate protein intake in the experimental group was 66.67% (20/30). The male participants (n=10) intake calories from 1715±284 kcal/day at baseline to 1571±267 kcal/day at post-test, and the female participants (n=16) intake calories from 1696±231 kcal/day at baseline to 1451±195 kcal/day at post-test.

Retrospective acceptability was investigated after the intervention by interviewing the participants in the experimental group individually. The facilitators

and barriers of implementing the interventions and participants' perceptions of the study were explored. Details of the qualitative interview results were presented in the following Section 5.3.2.1:

5.3.2.1 Characteristics of the interviewees

Semi-structured individual interviews were conducted within two weeks after the completion of the intervention. Twenty-one participants from the experimental group attended the interview when data saturation was achieved. The mean age of the interviewees was 68.19 ±6.30 years old. The adherence of the interviewees for food diary taking were diverse as good (7/21), moderate (1/21), and bad (13/21). Details of the characteristics of the participants are shown in Table 5.3.

Table 5. 3 Demographics of interviewees (n=21)

Demographics	Count (%)
Gender	
Female	14 (66.7%)
Male	7 (33.3)
Marital status	
Married	19 (90.5%)
Single/Divorced/Widow	2 (9.5%)
Education level	
Primary school	4 (19.0%)
Secondary school	8 (38.1%)
High school	8 (38.1)
Diploma/Bachelor degree or above	1 (4.8%)
Religious belief	
Christ	2 (9.5%)
Buddhist	1 (4.8%)
None	18 (85.7%)
Household monthly income (CNY)	
<3,000	4 (19.0%)
3,000 – 5,999	7 (33.3%)
6,000 – 10,000	6 (28.6%)
>10,000	4 (19.0%)
Vegetarian	
No	19 (90.5%)
Yes	2 (9.5%)

5.3.2.2 Themes and sub-themes

The themes and sub-themes are listed in the following Table 5.4.

Table 5. 4 Themes and sub-themes generated from the content analysis

Themes	Sub-themes
1. Overall perceptions of the DBC intervention	1a. Be helpful for the health.
	1b. Be motivated to change dietary behaviour.
	1c. Arrangements of intervention sessions were acceptable.
2. Barriers in participating in the DBC intervention	2a. Barriers in food diary taken.
	2b. Difficult to estimate the food amount.
	2c. Yield to offspring's taste.
	2d. Not willing to waste leftovers.
3. Facilitators for implementing the DBC intervention	3a. Care about self's health.
	3b. Support from the families.
	3c. Care about self's body image.
	3d. Support from the diet instructor
4. Suggestions for future program	4. The content could be broader and flexible.

Theme 1: Overall perceptions of the DBC intervention

Sub-theme 1a: Be helpful for the health

All interviewees felt the DBC intervention was helpful to promote their health. They felt the DBC program was meaningful in helping them gain professional knowledge in a healthy diet, especially when there was too much wrong information online. They did not know how to distinguish the correctness. The DBC program helped the interviewees to know better about the food type and daily recommended food amount.

I think this course is helpful to me. I usually pay a lot of attention to nutrition knowledge, but there is too much wrong information online. This course provided me with professional knowledge. (P1)

I feel (this course is) pretty good. By attending the course, I have a concept about what calorie is and try to control them a little bit. What you said inspires me. I can feel my weight this year is much lighter than last year. (P2)

The class is helpful for me. Before taking the course, I didn't know too much about nutritional knowledge. After taking the course, I learnt more. (P7)

Sub-theme 1b: Be motivated to change dietary behaviour

All interviewees felt a desire to change their dietary behaviour after joining the intervention program. Before joining the DBC intervention, they lacked the motivation to change unhealthy behaviour even though they knew some behaviours were not good. The courses taught in the sessions accelerated them to reflect whether their previous dietary behaviours were wrong and to change unhealthy dietary habits, such as controlling the fatty food intake, enriching the dietary pattern, controlling the food amount before cooking, etc.

I didn't know nutrition knowledge before, and I thought sweet potatoes were vegetables. Now I know that sweet potatoes are also a kind of staple food. Now, if I eat sweet potatoes, I won't overeat rice anymore. (P3)

I eat according to your recipe. Instead of fried eggs, now I choose to eat boiled eggs. Now I insist on eating one egg every morning to gain sufficient daily protein

intake. (P8)

Actually, I knew a little bit of nutrition knowledge before, but diet habits are hard to change. After taking your courses, I realised that my unhealthy diet habits must be changed. Otherwise, it is not good for my health. (P11)

Sub-theme 1c: Arrangements of intervention sessions were acceptable.

The arrangements of intervention sessions in terms of the frequency of face-to-face meetings, the content of the courses, and the telephone follow-up were acceptable by all interviewees. Interestingly, some interviewees liked the food diary taken because it could help them to better plan daily meals.

(Taking food diary and attending sessions) It doesn't bother me. After all, I don't have anything to do since I retired, now I don't need to work, and I don't have too many activities every day. So the frequency of the sessions is acceptable for me. (P5)

It is completely OK for me. As long as you call me, I will come to participate. Because I have nothing to do at home, it (attending the sessions) is considered an activity for me. (P8)

Recording the food makes my dietary pattern much clearer. For example, if I feel I have not eaten the meat for a long time, but I couldn't recall how long it is, I just check the food diary, and I'll know when I have eaten it, then I will plan when to buy meat in the following days. (P1)

Theme 2: Barriers in participating in the DBC intervention

Sub-theme 2a: Barriers in food diary taken

The majority of the interviewees presented that they have barriers in keeping the food diary, the reasons of which were: being busy looking after grandchildren, easy to forget, forgetting how to write the food's name in characters, and feeling no need to take food diary due to a regular daily eating pattern.

To be honest, we are not very well educated, and sometimes the characters of the foods name cannot be recalled and written. Besides, it's (taking food diary) just like taking medicine, although the doctor told me to take medication every day, I would forget it occasionally. (P5)

Taking care of grandchildren has delayed a lot of things. I am too busy to sit down, so I miss recording the food very often. (P6)

In fact, it is not too troublesome. I eat similar foods regularly every day, and there are no big differences. Even if I take notes of what I eat, it is almost the same every day. I can remember what I eat, so I feel it is not necessary to write it down. (P7)

Sub-theme 2b: Difficult to estimate the food amount

Quite a few interviewees reported it was difficult for them to estimate the food amount even though each of them had been given a food scale and taught how to use it. The Chinese dining style made it is challenging to estimate each one's eating amount of food, and they were unlikely to adopt a split meal system.

It's not easy to control the amount of food. I feel that I can eat as much as I want. I eat when I'm hungry, and I stop eating when I am full. There are no specific

standards for me. (P8)

A packaged food, for example, a cake, I can put it on the scale and weigh it. But for a bowl of cooked rice, I can't weigh it before eating and then weigh it after eating. It seems that I have no such habit. It is troublesome, and the food amount can only be estimated. (P5)

Sub-theme 2c: Yield to offspring's taste

Most of the interviewees lived together with their children to help look after the grandchildren. They tended to put their children's and grandchildren's taste in the priority instead of themselves. Only one interviewee chose to cook and eat alone because he could not accommodate himself to the children's appetite.

The obstacle is that our family eats together, which means I eat with my daughter, son-in-law, and grandchildren. So I seldom consider planning my own diet well. (P3)

My husband and I like to eat fish, but our children do not like it. Considering the children, we don't buy fish very often. (P7)

We always consider the children's appetite when we prepare the food instead of ourselves. (P20)

Category 2d: Not willing to waste leftovers

Not willing to waste leftovers is another barrier to dietary behaviour change. Most interviewees chose to eat overnight leftovers, especially for the meat, because they all experienced hard times when they were young. The poor quality of life in the past still affects their current life habits, making them think wasting food is terrible.

However, this phenomenon of leftovers was improved because they learnt to control the food amount when cooking.

We were poor when we were young, so I feel it is too wasteful to pour the leftovers. I always eat it all. Now I gradually start to change my bad behaviour after joining your program, and I cook less food. (P3)

We never waste leftovers. My grandma died at the age of 96, and she ate the leftovers. My mother died at the age of 92, and she also ate the leftovers. I believe that everyone's physique is different. (P7)

Theme 3: Facilitators for participating in the DBC intervention

Sub-theme 3a: Care about self's health

The most mentioned facilitators for participating in the DBC intervention were that interviewees cared about themselves' health and did not want to add burden to their children. Parts of the interviewees live with their spouses, and their children are busy without having time to look after them, so they are worried that nobody could take care of them if they fell ill. In addition, after attending the first two sessions, they all have the sense that sarcopenic obesity may lead to bad health outcomes, and diet has strong relations to sarcopenic obesity. Therefore, they were very willing to learn the nutritional knowledge and adherence to what they were taught in the sessions.

Our children are not around. If my husband and I get sick, no one can take care of us. We have to take care of ourselves, so we care about daily diet quality. (P1)

This year my husband passed away. I learnt a lesson from his bad living habits.

Especially after taking your courses, I am more aware of the importance of a healthy diet. (P9)

My legs are painful when I walk, and I feel a little burdensome. It was inconvenient on many occasions when I was fat. For example, it was difficult and uncomfortable to tie shoes and bend over. So I want to change. (P16)

Early this year, I had cerebral infarction. Before that, I thought my body was perfect, but then I doubted it. I started to control my weight and pay attention to my food intake. (P20)

Sub-theme 3b: Support from the families

The support from the family members was another crucial facilitator for the interviewees participating in the DBC intervention. The interviewees presented that they received encouragement from their partners or children, and some family members even are motivated to pay attention to their dietary behaviours.

My family support me to do so. My daughter even said, mom, you seem to be thinner this year than last year. I also need to pay attention to my weight. (P3)

My family support me to control my diet. My husband was even afraid that I would not insist on it. He continued to remind me. (P21)

Sub-theme 3c: Care about self's body image

Interviewees' attention to their image also motivates them to change their dietary behaviours, which both male and female interviewees mentioned. They were more concerned about the fat accumulation in the abdomen and legs. Some female

interviewees were concerned about the effects of fat body shape on the beauty of wearing clothes.

When I was young, I had been at 60 kg for at least 20 or 30 years. With the advantage of age, my belly has become looser than before. There are so many beautiful clothes that I can't wear in summer. (P1, female)

Because my body is fat without too much muscle, it is puffiness. From the deep of my heart, I want to get rid of the annoying fat. (P5, male)

Sub-theme 3d: Support from the diet instructor

The behaviour change techniques used by the diet instructor was helpful for participants to change their dietary behaviour. The participants mentioned that the support from the diet instructor was essential for them to insist on the dietary behaviour change. First, the diet instructor changed their mind about eating. Before joining the program, they were unaware of sarcopenic obesity and did not pay attention to muscle function. Instead, they paid more attention to controlling the salt or sugar in daily meals to avoid hypertension and diabetes. After joining the program, they realised the risk of sarcopenic obesity and the critical influence of muscle mass on physical function, motivating them to change their dietary behaviour. Second, the diet instructor helped them solve problems encountered during the intervention process. The encouragement from the diet instructor gave them strong support to overcome the barriers (mentioned above in *Theme 2*). For example, they learnt to distinguish food types such as carbohydrates (e.g., sweet potato) under the guidance

of the diet instructor, which gave them the confidence to continue the dietary plan. They also gained confidence and achievements from the decrease in body weight.

What you said is inspiring for me, and your courses are pretty good (P3).

I couldn't distinguish between staple food and vegetables before. Now that I know what food is the staple food, I start to control the intake amount. My weight has also lost five or six catties. I am lucky to meet you, and it gives me a lot of strength (P9).

Theme 4: Suggestions for future program

Sub-theme 4: The content could be broader and flexible

Some interviewees suggested that the content of the sessions could be related to diet and other health-related information, and the content of the courses should fit people with different literacy levels.

The cultural level of the older population in our generation is very different, and it is good to deliver something that some people can easily understand. But for us who had higher education, the content could be more profound. (P15)

5.3.2.3 Trustworthiness of the content analysis

The trustworthiness of the content analysis results was achieved by referring to the assessment criteria: credibility, confirmability, transferability, and dependability (Graneheim & Lundman, 2004; Lincoln & Guba, 1985).

Credibility refers to confidence in the truth of the data and interpretations (Polit

& Beck, 2004). The credibility in this study was achieved by choosing appropriate interviewees and approaches to gather data, peer debriefing, and showing representative quotations from the transcribed text (Graneheim & Lundman, 2004). Interviewees were selected with various genders, education levels, and performance in adherence to keeping a food diary, which could help achieve a richer variation of the perceptions from the participants. The peer debriefing was completed by double-checking the transcripts, themes, and categories by the doctoral researcher and another independent researcher separately and then comparing the similarities and differences. Any differences were confirmed with interviewees to ensure the extractions manifest their real perceptions. In this case, confirmability was also achieved by including two or more independent people to check the data's accuracy, relevance, or meaning.

Dependability refers to the degree to which data change over time and modifications are made during the analysis process (Lincoln and Guba, 1985). This study's dependability was established by questioning the same areas for all the interviewees and documenting each step of the interviewing and analysis process to ensure the consistency of the content over time.

Transferability refers to 'the extent to which the findings can be transferred to other settings or groups' (Polit and Hungler, 1999, p.717). Considering this study is novel, no similar published study was found for comparison. However, a clear and distinct description of the settings, characteristics of participants, data collection,

analysis process, and appropriate quotations were given in this thesis, enhancing transferability.

5.3.3 Effects outcomes

We accepted the hypothesis that the experimental group significantly reduced body weight and improved dietary quality immediately after the intervention compared with the control group. However, we rejected the hypothesis that the experimental group significantly improved muscle mass, handgrip strength, physical performance, nutritional status, nutrition self-efficacy, and health status compared with the control group.

5.3.3.1 Effects of DBC intervention on primary outcomes

Table 5.5 showed the effects of DBC intervention on primary outcomes over 15 weeks from baseline. There was significant group-by-time interaction on the body weight (Wald χ^2 =4.90, p=0.027), skeletal muscle mass (Wald χ^2 =5.62, p=0.018), and fat-free mass (Wald χ^2 =7.49, p=0.006). However, other variables did not show significant differences in group-by-time interaction, with the Wald χ^2 varied between 0.13-7.49 and the p-value varied between 0.051-0.718. The time effects from baseline to post-test in the two groups were significant on the handgrip strength (Wald χ^2 =9.95, p=0.002), body weight (Wald χ^2 =1.13, p=0.027), visceral fat level (Wald χ^2 =8.16, p=0.004), gait speed (Wald χ^2 =26.13, p<0.001), and short physical performance battery (Wald χ^2 =14.50, p<0.001). The group effects were not significant in all variables. The effects were very large on body weight (d=1.22), and

large on skeletal muscle mass (d=0.99), fat free mass (d=1.11), and skeletal muscle mass index (d=0.84). The effects on other outcomes were small to medium (d=0.12~0.68). A trend of decrease in waist circumference (from 99.28 ± 1.32 cm to 98.42 ± 1.39 cm), a trend of increase in handgrip strength (from 15.37 ± 1.08 kg to 18.21 ± 1.68 kg) and gait speed (from 0.91 ± 0.02 m/s to 0.99 ± 0.03 m/s) within the experimental group from baseline to post-intervention could be observed.

Table 5. 5 Intervention effects on primary outcomes by group assignment across time using GEE (N=60)

Outcomes	Mean (SE)		Test of adjusted GEE model effects [a]						Effect size
	Baseline	Post	Time effect		Group effect		Group-by-time effect		*d*
			Wald χ^2	*p*	Wald χ^2	*p*	Wald χ^2	*p*	
Handgrip strength (kg)			9.95	.002	1.16	.282	1.96	.162	.45
DBC group	15.37 (1.08)	18.21 (1.68)							
Control group	14.47 (0.88)	15.56 (1.20)							
Anthropometry									
Body weight (kg)			1.13	.027	.788	.375	4.90	**.027**	1.22
DBC group	75.28 (1.60)	74.78 (1.90)							
Control group	72.29 (1.40)	73.71 (1.62)							
Waist circumference (cm)			0.00	.968	0.81	.367	2.57	.109	.56
DBC group	99.28 (1.32)	98.42 (1.39)							
Control group	96.73 (1.17)	97.65 (1.53)							
Waist-Hip ratio			1.54	.215	2.50	.114	1.96	.161	.20
DBC group	0.99 (0.03)	0.95 (0.01)							
Control group	0.94 (0.01)	0.94 (0.01)							
BMI (kg/m^2)			0.17	.681	0.00	.970	1.54	.214	.40
DBC group	29.98 (0.62)	29.66 (0.67)							
Control group	29.77 (0.48)	29.93 (0.56)							
Body composition									
Skeletal muscle mass (kg)			1.34	.247	1.06	.303	5.62	**.018**	.99
DBC group	25.06 (0.70)	24.74 (0.90)							
Control group	23.40 (0.60)	24.35 (0.67)							
Fat free mass (kg)			1.38	.240	1.101	.294	7.49	**.006**	1.11
DBC group	45.77 (1.19)	45.08 (1.51)							
Control group	42.82 (0.99)	44.55 (1.10)							

Body fat mass (kg)			0.73	.391	0.00	.976	0.28	.599	.18
DBC group	29.22 (1.23)	29.77 (1.28)							
Control group	29.47 (0.97)	29.60 (1.00)							
Percent of body fat (%)			0.01	.932	0.38	.537	0.75	.388	.25
DBC group	39.35 (1.09)	39.83 (1.25)							
Control group	40.70 (0.90)	40.11 (0.85)							
SMI (kg/m^2)			0.05	.829	0.54	.462	3.45	.063	.84
DBC group	7.31 (0.16)	7.23 (0.19)							
Control group	7.05 (0.13)	7.16 (0.15)							
Visceral fat level			8.16	.004	0.00	.999	3.09	.079	.56
DBC group	14.20 (0.57)	15.42 (0.65)							
Control group	14.67 (0.53)	14.96 (0.52)							
Physical performance									
6-m Gait speed (m/s)			26.13	<.001	0.30	.587	3.82	.051	.47
DBC group	.91 (0.02)	.99 (0.03)							
Control group	.85 (0.03)	1.01 (0.03)							
SPPB			14.50	<.001	1.35	.246	1.18	.278	.31
DBC group	10.87 (0.22)	11.62 (0.13)							
Control group	10.67 (0.30)	11.08 (0.30)							

Notes: DBC= dietary behaviour change; SE= standard error, GEE= generalised estimating equation, BMI= body mass index; SMI= skeletal muscle mass index; SPPB=short physical performance battery.

[a] Adjusted by height, education level and IPAQ.

5.3.3.2 Effects of DBC intervention on secondary outcomes

Table 5.6 showed the effects of DBC intervention on secondary outcomes over 15 weeks from baseline. There was significant group-by-time interaction on the dietary quality index total score (Wald χ^2 =12.66, p<0.001), but other outcomes did not show significant differences after the intervention with the Wald χ^2 varied between 0.08-2.15 and the p-value varied between 0.142-0.780. The time effects were significant on three domains of the SF-36 health survey, i.e., body pain (Wald χ^2 =4.28, p=0.039), general health (Wald χ^2 =6.44, p=0.011), and mental health (Wald χ^2 =4.05, p=0.044). The group effects were significant on nutrition self-efficacy (Wald χ^2 =4.35, p=0.037) and physical functioning of SF-36 (Wald χ^2 =5.71, p=0.017). The effect on improving the dietary quality index was very large (d=1.31), and the effects on other secondary outcomes were small (d=0.13~0.39).

Table 5. 6 Intervention effects on secondary outcomes by group assignment across time using GEE (N=60)

Outcomes	Mean (SE)		Test of adjusted GEE model effects [a]						Effect size
	Baseline	Post	Time effect		Group effect		Group-by-time effect		*d*
			Wald χ^2	*p*	Wald χ^2	*p*	Wald χ^2	*p*	
MNA			.47	.495	2.24	.134	.08	.780	.33
DBC group	13.00 (0.30)	12.92 (0.19)							
Control group	13.43 (0.19)	13.25 (0.21)							
Nutrition self-efficacy			2.92	.087	4.35	.037	.69	.406	.23
DBC group	15.20 (0.64)	16.69 (0.64)							
Control group	14.07 (0.68)	14.58 (0.80)							
SF-36									
PF			4.07	.044	5.71	.017	.25	.614	.13
DBC group	81.00 (5.01)	88.08 (1.22)							
Control group	73.67 (3.15)	77.92 (2.45)							
RP			.65	.419	2.25	.134	2.15	.142	.39
DBC group	80.83 (7.04)	95.19 (3.85)							
Control group	79.17 (7.08)	75.00 (8.46)							
BP			4.28	.039	1.86	.172	.74	.389	.23
DBC group	14.33 (3.01)	8.46 (1.86)							
Control group	17.00 (2.75)	14.58 (2.95)							
GH			6.44	.011	.52	.472	.29	.588	.15
DBC group	54.50 (1.32)	50.00 (2.21)							
Control group	55.00 (1.33)	52.08 (1.52)							
VT			.89	.346	1.08	.300	.25	.618	.14

DBC group	54.83 (2.29)	55.58 (1.20)							
Control group	52.17 (1.71)	54.58 (1.50)							
SF			.79	.374	.75	.386	2.05	.152	.39
DBC group	60.42 (1.57)	64.42 (1.62)							
Control group	60.83 (2.48)	59.90 (2.44)							
RE			1.82	.177	.85	.355	.32	.575	.15
DBC group	82.22 (6.80)	92.31 (5.23)							
Control group	77.78 (7.26)	81.94 (7.60)							
MH			4.05	.044	1.70	.192	1.56	.212	.33
DBC group	55.73 (2.21)	60.00 (1.63)							
Control group	54.67 (1.69)	55.67 (1.27)							
HT			2.58	.108	2.05	.152	1.36	.243	.32
DBC group	55.00 (2.98)	47.12 (3.92)							
Control group	57.50 (3.36)	56.25 (3.68)							
DQI-I (total)			25.14	<.001	3.35	.067	12.66	**<.001**	1.31
DBC group	60.03 (2.02)	65.92 (2.35)							
Control group	56.83 (2.11)	57.83 (2.43)							
IPAQ			26.87	<.001	.00	1.000	.49	.483	

Notes: DBC= dietary behaviour change; SE= standard error; GEE= generalised estimating equation; SPPB= short physical performance battery; MNA= mini nutritional assessment; SF-36= the short form (36) health survey; PF= physical functioning; RP= role limitation due to physical problems; BP= bodily pain; GH= general health; VT= vitality; SF= social functioning; RE= role limitation due to emotional problems; MH= mental health; HT= reported health transition; DQI-I= Dietary Quality Index-International; IPAQ= International physical activity questionnaire.

[a] Adjusted by height, education level and IPAQ.

5.4 Intervention Fidelity

Intervention fidelity should be considered in five aspects: intervention design, training of providers, intervention delivery, receipt of intervention, and enactment of skills gained from the intervention (Bellg et al., 2004). The five aspects were utilised in this pilot study to ensure the rigour of the study.

Intervention design: The components of the DBC intervention was based on the Health Action Process Approach (HAPA) theory (Schwarzer & Luszczynska, 2008) and evidence synthesised from the systematic review and in-depth literature review. The content validity of the intervention protocol was also estimated through the Delphi method by collecting comments from experts in the nutrition and diet field, during which process the intervention protocol was modified twice. Afterwards, a standardised intervention protocol was developed and formatted to guide the delivery (see Chapter 3).

Training of providers: In this study, the intervention provider was the doctoral research student, a registered nurse with extensive working experience with older people and qualified as a weight management coach by the Chinese Nutrition Society. Both face-to-face sessions and telephone follow-up of the experimental group were completed by the doctoral researcher, which guaranteed the consistency of the intervention. For the follow-up of the control group, a postgraduate nursing student was trained to conduct the face-to-face and telephone follow-up. The student was trained on how to choose the talk topic, avoid disclosing information related to intervention, deal with an emergency, and guarantee the consistency of communication by following the standardised manual (Appendix 5). Several times of rehearsals were conducted before the start-up to ensure

the student's competency.

Additionally, the training of RA, who was responsible for quantitative data collection, was strictly performed. To assess the RA's competency, the inter- and intra-rater reliabilities were evaluated by the intra-class correlations (ICC). An acceptable level of reliability (ICC > 0.9) was established by comparing the scores obtained by the RA and doctoral researcher before the start of the study and checking them monthly throughout the data collection period. These procedures are necessary to ensure that quality assessments were performed as intended.

Intervention delivery: The intervention was delivered according to a written intervention manual, which could help maximise the consistency of the implementation of DBC intervention among different participants. A checklist (Appendix 10) was used to check the performance of intervention delivery by a trained research assistant monthly. The fidelity rate (> 90%) was considered acceptable (Bellg et al., 2004). Each participant in the experimental group was given a standardised booklet to help guide the behaviour change. Weekly telephone calls inserted in the fact-to-face sessions help remind the implementation of DBC intervention, facilitating *Receipt of the intervention*. The content of the intervention booklet was also assessed by older people in the Delphi process, which aimed to ensure the guidebook is easy to understand by the older people. If the participants had questions or barriers during the study period, they were welcomed to the inquiry during the face-to-face sessions and telephone follow-up.

Enactment of skills: The participants utilised the knowledge and techniques about healthy diet from the study in their daily lives.

5.5 Summary

The DBC intervention was feasible in the community-dwelling older people with sarcopenic obesity, with the recruitment rate (57.14%), retention rate (83.3%), and attrition rate (16.7%). The adherence to food diary taking rated as good was 23.33%, moderate was 3.33%, and bad was 60%. According to the interview results, all participants showed satisfactory acceptability in the intervention process, even though barriers existed in changing their dietary behaviours. The DBC intervention significantly reduced body weight and improved dietary quality, but skeletal muscle mass and fat-free mass were decreased concurrently. But there was a positive trend in handgrip strength and gait speed within the experimental group. A further discussion of the results will be presented in the next chapter.

CHAPTER 6 DISCUSSION

The novel contribution of this study to current knowledge is that behaviour change techniques were utilised with dietary intervention among sarcopenic obese older people in the community setting, which was not seen in previous studies. The utilisation of behaviour change techniques facilitated the older people to change their dietary behaviour to arouse their motivation, identify coping plans, and overcome barriers to adopting the dietary behaviour change. This study demonstrated the feasibility, acceptability, and preliminary effects of implementing DBC intervention in community-dwelling older people with sarcopenic obesity. A comprehensive discussion of the results is presented as follows.

6.1 Discussion of the results

6.1.1 Discussion about the feasibility of this study

The DBC intervention was feasible among Chinese community-dwelling older people with sarcopenic obesity because the recruitment rate (percent of people agreed to participate among all eligible people) met the acceptable level as we expected, and the total length for recruitment was within half a year. The massive flow of older people in the community health centres ensured the smooth progress of recruitment. The recruitment rate reflects the ease of sample recruitment. This information is essential to estimate the duration and manpower that may be needed to recruit a sufficient sample size in the main study (Cooper et al., 2008). However, extensive screening may be needed considering the relatively low eligible rate (percent of people fulfil the eligible

criteria among all older people). It is difficult to compare the eligible rate with previous interventional studies because the eligible rate varied greatly among different studies. For example, the eligible rate in some studies could reach 62.36% (Chen et al., 2017), while in some studies, the eligible rate was only 3.21% or 7.62% (Kemmler et al., 2016; Kemmler et al., 2017). These various prevalent rates were because of lacking standardisation in the diagnosis criteria of sarcopenic obesity, various diagnostic criteria for screening the participants were used in previous studies. Not up to recent years, the European and Asian Working Group on sarcopenia have come to the consensus of diagnostic methods for sarcopenic obesity, which emphasised muscle strength screening.

Our study included participants with poor muscle strength and physical performance. The muscle mass was not included in the inclusion criteria because the consensus of Asia and America in sarcopenia recommended that lifestyle modifications in diet should be implemented in the early stage of sarcopenia (Chen et al., 2020). Poor muscle strength and physical performance were emphasised in the early stage of screening sarcopenia (Bhasin et al., 2020; Chen et al., 2020). As sarcopenia is a vital part of sarcopenic obesity, therefore, we refer to the Asian and American consensus on sarcopenia screening to identify participants in the early stages of sarcopenic obesity.

However, the eligible rate of older people with sarcopenic obesity was still not high under the current criterion, which may indicate a low prevalence of sarcopenic obesity in China. But one previous investigation (Meng et al., 2014) showed that the prevalence of sarcopenic obesity among 101 males (aged 80 or above) in Beijing, China was 40.0% when using relative appendicular skeletal muscle for screening, and 95% when using skeletal muscle mass index. In contrast, Du et al. (2019) reported the prevalence of

sarcopenic obesity was 7.0% in males and 2.4% in females after screening 213 males and 418 females in Shanghai, China, which referred to the old Asian criteria for sarcopenic obesity. One thing that needs to notice is that neither study used the updated diagnostic criteria of sarcopenic obesity. Therefore, the eligible rate of older people with sarcopenic obesity may still need to be further explored.

In addition, we analysed other potential reasons that may lead to the relatively low eligible rate in this study compared to previous prevalence studies. First, the older people were reluctant to visit the community health centres due to the fear of being infected by the COVID-19 virus. The data collection was suspended for six months due to the pandemic. We might not get a comprehensive sample. Second, the average age of the participants was 68.13 ± 6.12 years old, which were relatively young. However, the sarcopenic condition is more and more prevalent among the older population (i.e., 70 years or above) because the muscle loss and fat accumulation are positively related to the age increase (Cruz-Jentoft et al., 2019), which may contribute to a higher prevalence in previous cross-sectional studies (average age=88.8±3.7 years old) (Meng et al., 2014).

6.1.2 Discussion about the acceptability of DBC intervention

Basically, the participants accepted the DBC intervention based on the relatively high attendance rate, and they presented positive feedback to the intervention. However, the compliance rate of keeping a food diary and food advice still have room for improvement. According to the qualitative interview, the behaviour change techniques (BCTs) may play an important role in facilitating participants' acceptability of the DBC intervention. The continuous support by the interventionist during the intervention

process was reported as a crucial factor for behaviour change. Previous studies aimed for lifestyle modification usually focused on providing knowledge, materials and professional education, which may be insufficient to make any behavioural changes (Van Achterberg et al., 2011). Instead, providing alternative strategies to deal with obstacles in actual practice may be more effective to change the behaviour, such as promoting participants' awareness of risk behaviour or facilitating participants' self-monitoring (Schwarzer & Luszczynska, 2008).

Specific Chinese contextual culture may bring some barriers to the participant's acceptability of the DBC intervention. For example, Chinese older people are usually expected to take care of their grandchildren. Due to time constraints, they may be reluctant to participate in health promotion programmes (Xu, 2019). According to our qualitative interview, the acceptability of the DBC intervention was mainly affected by internal (e.g., previous eating habits, forgetfulness, laziness) and external factors (e.g., economic level, the complexity of food recording, specific Chinese culture). Among these factors, Chinese culture, family mode, and dining style played important roles in participants' acceptance of the DBC intervention. We will discuss more the cultural influences on dietary behaviour change in the following paragraphs.

First, the participants' previous personal experiences brought great barriers to changing their dietary behaviour. The participants, who experienced poor lives, were reluctant to waste food, including leftovers. They usually eat up all the food, which would lead to excessive food intake. This exposure in participants' early lives greatly impacts eating habits in subsequent adulthood (Mikkilä et al., 2004; Zeng et al., 2021).

Second, the traditional Chinese family mode is another critical barrier in changing

participants' dietary behaviour. According to our qualitative review after the intervention, the common barrier for preventing dietary behaviour change was that the participants needed to take care of grandchildren. They had no enough time to plan their own diet, and they put the children's taste prior to themselves (Ma, 2015). Other researchers also reported this kind of phenomenon, young children have the priority to receive food, and their food quality is always the best (Ma, 2015), which was consistent with our interview results. We also found grandparents always sacrifice their own needs in the choice of food types.

Third, Chinese families usually eat together. This dining culture makes older people seldom split meals with families. Most Chinese families eat in a grouped dining system because sharing food is regarded as a close relationship and atmosphere within a Chinese family (Ma, 2015), which is different from Western's separate dining style. Therefore, it would be difficult to let the participants eat separately with their families, and it caused difficulties for participants to control the amount of food intake.

6.1.3 Discussion about the preliminary effects of DBC intervention

This study supported the hypotheses that a 15-week dietary behaviour change intervention could significantly reduce body weight. On the other hand, the results also reject the hypotheses that the 15-week dietary behaviour intervention failed to significantly increase muscle mass/strength, reduce body fat, or improve physical performance. However, we found a trend of increased muscle strength and physical performance from baseline to post-intervention in the experimental group.

6.1.3.1 Preliminary effects of DBC intervention on body composition

The findings demonstrated that the body weight could be decreased significantly while muscle mass may decrease simultaneously. This preliminary finding is consistent with previous interventional studies (Muscariello et al., 2016; Sammarco et al., 2017), which showed that fat-free mass/lean body mass of older people decreased associated with weight reduction after taking a hypocaloric diet for 3 or 4 months, respectively. Plenty of research also reported the phenomenon of muscle loss along with weight reduction (Cava, Yeat, & Mittendorfer, 2017; Fukushima et al., 2016; Goisser et al., 2015). Obese adults could lose 2-10% of muscle mass when they reduce 8-10% of diet-induced weight (Bosy-Westphal et al., 2009; Ross et al., 2000; Santanasto et al., 2011; Villareal et al., 2011).

The results of our pilot study turned out the effects of enriched protein intake on preventing muscle loss were weak. However, previous empirical evidence showed that sufficient protein intake in the dietary intervention helps muscle building during weight reduction (Anthony, 2016; Beasley, Shikany, & Thomson, 2013; McDonald et al., 2015), which was the reason that we adopted this as one of the core components in the DBC intervention. Several reasons may contribute to these results. Firstly, with a relatively small sample size in this pilot study, the statistical power may not be sufficient to detect the difference between the experimental and control groups (Cohen, 1992). Secondly, muscular tissue contains more water than fatty tissue, and the amount of water in the body is the most important factor in the short-term fluctuation of body weight (Panorchan et al., 2015; Reljic et al., 2013; Sergi et al., 2003). Therefore, the change of water affects the density of muscular tissue and then affects the total weight of muscle (Panorchan et

al., 2015), which may explain why most weight loss was muscle loss rather than fat loss in our study. Thirdly, the intervention duration may be insufficient for estimating the effects of dietary interventions on body composition, even though the intervention duration of our study (15 weeks) was not short when compared to previous dietary interventional studies for sarcopenic obesity (3 months and 4 months, respectively) (Muscariello et al., 2016; Sammarco et al., 2017). The preliminary results of this pilot study may indicate a longer time is needed to see the effect in terms of muscle building.

Additionally, the nonsignificant changes in body fat mass and percent of body fat were beyond our expectation, because according to previous research (Muscariello et al., 2016; Sammarco et al., 2017) and our systematic review (Yin, Liu, & Välimäki, 2020), caloric restriction is an effective method for reducing body fat. Several reasons may contribute to this result. Firstly, it may be related to the compliance of participants to the dietary advice. The complexity of food amount recording may make older people underestimate their food intake compared to their actual intake, which is a common limitation in diet control intervention (Chandon & Wansink, 2007) that people tend to underestimate their calorie intake. Secondly, the dieting culture may affect participants' diet control. The dietary pattern of the Chinese population has changed from a traditional diet based on plant-based foods to a Western-style diet, the intake of animal foods such as meat is increasing, and the consumption of refined grains and some deep-processed foods is on the rise (Pan, Wang, & Pan, 2021; Zeng et al., 2021), which may contribute to fat accumulation (Bazzano et al., 2005; Ji et al., 2020). Besides, as mentioned in the previous section, Chinese families are used to eating together rather than individual serving, which may affect the participants by other family members. Even though the participants were

encouraged to eat individually, this traditional eating style causes difficulties for them to control the amount of food intake.

Moreover, the nonsignificant changes in waist circumference may be caused by the nonsignificant changes in body fat mass, even though the body weight reduced significantly. Usually, waist circumference is a sensitive indicator of obesity, and it can reflect the variation of body weight (Dobbelsteyn et al., 2001; Gill et al., 2003). However, we could still observe a trend of decrease in waist circumference for the experimental group (from 99.28 ± 1.32 cm to 98.42 ± 1.39 cm). In contrast, the control group showed a trend of increase (from 96.73 ± 1.17 cm to 97.65 ± 1.53 cm). The DBC intervention may decrease waist circumference significantly if bigger sample size is performed in the future full trial.

6.1.3.2 Preliminary effects of DBC intervention on muscle strength and physical performance

Muscle strength was not improved significantly between the group across time in our pilot study, but a trend of increase within the experimental group from baseline to post-test could be found (increased from 15.37 ± 1.08 kg to 18.21 ± 1.68 kg). Previous studies have reported the close correlation between muscle strength and muscle mass, and the decline of muscle strength was preliminarily caused by the decrease in muscle mass (Goodpaster et al., 2006; Hayashida et al., 2014; Reed et al., 1991). A 5-year longitudinal study of 1678 older people (70-79 years old) from America reported that a decline in muscle strength did not parallel with muscle mass decline (Delmonico et al., 2009). Hayashida et al. (2014) also found strong correlations between knee extension strength

and appendicular muscle mass in both older females (corr=0.31, $p<0.01$) and males (corr=0.41, $p<0.01$) after investigating 318 older adults aged ⩾ 65 years. Therefore, the nonsignificant changes in muscle strength maybe because of the skeletal muscle loss in our study.

In addition to the aforementioned muscle strength outcome, gait speed and the grade of the short physical performance battery (SPPB) scale were improved but not significantly between groups across time. This result is consistent with previous studies (Sammarco et al., 2017) in sarcopenic obesity using dietary interventions for three months among middle-aged and older people. Based on our literature review, physical function (gait speed and SPPB) is associated with muscle mass and strength. It is well known that declined muscle strength due to loss of muscle fibres or motor neurons is closely related to decreased walking speed and consequent adaptions (Mendes et al., 2018). Previous research also reported that the loss of muscle mass would lead to functional decline, especially in older populations (Janssen, 2010; Rolland et al., 2008; Tanimoto et al., 2012). Another potential reason for nonsignificant results in gait speed is the obese condition of participants (mean BMI of pre- and post- are both > 29 kg/cm^2). A cross-sectional study from Portugal in 1500 older adults ⩾65 years old showed that women with slower gait speed usually had higher BMI compared to those with high gait speed ($p < 0.001$), and those under nutritional risk walked more slowly (Mendes et al., 2018). In our study, even though the body weight reduced significantly in the DBC group, while the fat mass did not show significant changes, and the value of BMI in the post-test was still high in the DBC group (29.66 ± 0.67 kg/m^2), which may contribute to the nonsignificant changes in gait speed.

Despite the muscle strength and physical performance did not show significant improvement across the group and time, we still can observe a trend of increase in these two outcomes in the experimental group. Considering this is only a pilot study, the sample size is relatively small, the statistical power may be affected accordingly.

6.1.3.3 Preliminary effects of DBC intervention on dietary quality, nutrition self-efficacy and health status

For the secondary outcomes, the study showed a 15-week dietary behaviour change intervention could significantly improve the dietary quality, but the effects on improving nutrition self-efficacy, nutritional status, or health status were not significant.

The nutritional status measured by Mini-Nutrition Assessment (MNA) did not change significantly, while from another point of view, the dietary intervention did not bring damages to participants' nutritional status. The nutritional status of both groups was normal at baseline and in the post-test. Therefore, the nonsignificant change in nutritional status from baseline to post-test was understandable.

The interesting point is that the dietary quality was improved while the nutrition self-efficacy had no significant change, which means the participants lacked self-confidence in controlling their diet even though they had followed the diet instruction leading to improve the quality of their diet. One potential reason for the non-significant improvement in nutrition self-efficacy is the high baseline value leading to a ceiling effect. That means participants' self-efficacy on diet control was already very high before the intervention. With a low statistical power in a pilot study, it may be more difficult to see the significant changes.

Participants' health status is multifactorial rather than just based on their nutritional

status (Mutharayappa & Bhat, 2008), which may be a potential reason for nonsignificant changes in health status identified in this study. For example, some participants had chronic pain/disease (e.g., arthrophlogosis, gastritis), which bothered them for a long time and could not be solved within a short period. Dietary behaviour change may help preserve physical function, but it is hard to solve other morbidities.

6.2 Strength of this study

To our knowledge, this is the first study that combined behaviour change techniques with dietary interventions to manage sarcopenic obesity. This study has strengths in several aspects. First, the design of this study is rigorous. We developed the study by following the MRC Framework for Developing and Evaluating Complex Interventions (Craig et al., 2008) and designed the pilot RCT by referring to the CONSORT statement (Eldridge et al., 2016). The intervention protocol of this study was developed based on an evidence-based literature review and sound theoretical framework. Besides, the content of the intervention guidebook, which included the key components of the intervention protocol, was validated by experts through the Delphi method. Several rounds of revision of the guidebook were conducted to make the content to be optimal. In the revision process, we also listened to the opinions of the older population to ensure the guidebook was understandable.

Second, the intervention in this study was individualised rather than using a uniform standard, which is crucial for dietary interventions considering the heterogeneity among participants. The lifestyle, meal timing, confidence, and family context varied among different participants. In this study, an individualised diet plan was conducted, and staged

goals were set by considering each participant's specific case.

Third, the fidelity of the intervention was monitored strictly. The NIH Behaviour Change Consortium treatment fidelity recommendations were referred during the study (Bellg et al., 2004). Five aspects were considered to enhance the fidelity: intervention design, training of intervention providers, intervention delivery, receipt of intervention, and enactment of skills gained from the intervention (details see Section 5.4). These strategies adopted in fidelity monitoring helped to minimise the possibilities of Type I and Type II errors.

6.3 Limitations of this study

There are still some limitations existing in this study. First, the double-blinding (blinding of interventionist and participants) was challenging to perform due to the nature of the study. Even though we kept continuous social contact with the control group to avoid the confounding effects of psychosocial contact, the Hawthorne effect still cannot be compensated entirely, and performance bias may occur in the interventional group. Additionally, the subjects were recruited from three community healthcare centres. We tried our best to avoid contamination by asking the participants to avoid talking about the intervention content to others. The chances of communication between the two groups were minimal. However, we could not claim that there was no possibility of contamination.

Second, the assessment method of food intake in this study may cause bias in estimating food intake amount. Because the amount of food intake was self-reported by the participants, even though they had been educated about measuring methods,

variations between the actual food intake and the estimated amount may still be great. However, the food diary is the most widely used method in current dietary intervention studies. Considering the study was conducted in a community-dwelling setting, it is impossible to use laboratory methods to measure the energy intake of each participant. We also considered using digital methods (e.g., technological equipment or application program) to help record the food intake; however, the accuracy of digital methods is yet to be improved, and the problems of self-report remain unsolved (Subar et al., 2010).

Third, the interventionist conducted the semi-structured interview by herself because the interventionist was the one who was most familiar with the core sections of the whole intervention process. However, the participants may hide their honest reflection of the intervention and cause participants bias (i.e., acquiescence bias or friendliness bias) (Turner, 2010; Shivanee, 2019). We adopted the following strategies to reduce this effect: open-ended questions were asked to avoid participants simply agreeing/disagreeing, and to provide the participants a range of options instead of simple 'Yes' or 'No'. The interviewer guided them to talk freely without concerns and to provide a truthful and honest answer. The interviewer asked questions in different ways if the answers sounded not true

Fourth, the education levels of participants included in the readability test of the intervention guidebook (high school or college) were different from the participants enrolled in the pilot RCT (vary from primary school to college), the contents in the guidebook may not be suitable for those without high school education level. This phenomenon was caused due to the convenience sampling method that we used in recruitment. However, the main function of this guidebook was to assist the face-to-face

sessions instead of stand-alone learning material. The participants reflected in the interview that they could understand the content of the guidebook with the explanation given during the face-to-face consultation.

6.4 Implications of this study

6.4.1 Implications in clinical practice

The study had some implications in clinical practice. First, there is a pressing need to provide professional nutrition knowledge about sarcopenic obesity to community-dwelling older people. The older people presented a strong desire of learning professional nutrition knowledge during the intervention process. On the other hand, the older people had no awareness of the importance of adequate protein intake in their daily diet. Considering the adverse health outcomes aroused by sarcopenic obesity, the need of providing professional nutrition knowledge to older people in community-dwelling settings is pressing.

Second, community nurses could play a role in implementing the DBC intervention, which has been proved to be a feasible method to improve older people's dietary quality. In our study, the participants produced a desire to change their dietary behaviour, overcome obstacles, and finally improve dietary quality. However, it was challenging for older people to change their behaviour by relying solely on self-control. Suppose community nurses can play a supervisory role and use behaviour change techniques (e.g., workshops or telephone follow-up or online guidance), which may have a positive effect on helping older people change into healthier dietary behaviour.

6.4.2 Implications in research

This pilot study could provide several suggestions for future research. First, a longer intervention duration may be needed for DBC intervention to increase muscle mass, while supporting evidence still needs to be further explored. Even though this pilot study's preliminary results in muscle mass were negative, the function of protein on muscle building still deserves to be addressed (Goisser et al., 2015; Schoenfeld & Aragon, 2018). Evidence showed that building muscle may need at least 6 months (Zhou, 2018). Therefore we suggest extending the current intervention duration from 15 weeks to 24 weeks to allow sufficient time for the muscle to grow. Additionally, we would like to see if any daily behaviour changes could be sustained, leading to longer-term effects. Therefore, we suggest including follow up assessment at 3, 6 months after the completion of the intervention. Second, methods for promoting participants' compliance with diet instructions need to be explored. Besides food diary, other high-tech approaches with high accuracy for recording food intake could be explored. Third, we also need to design the intervention to be better tailored to older Chinese people who could not balance their roles in taking care of grandchildren and planning their daily meals. Having family members' support is essential (Aggarwal et al., 2010). In future studies, contextual factors need to be explored and considered, such as involving family members in the intervention process. Finally, the current results showed that the current DBC intervention is relatively weak in increasing muscle mass. In the future study, we may need to add components related to physical activity in the intervention considering the effects of physical activity in muscle building.

6.5 Summary

Even though extensive screening work may be needed, the DBC intervention was feasible among older people with sarcopenic obesity in community settings. Behaviour change techniques should be contextualised by considering external and internal hindering factors in the dietary intervention process, especially the Chinese dining culture and older people's personal experience. Multi factors may lead to the preliminary negative results of the DBC intervention in managing sarcopenic obesity, but a positive trend could be observed within the experimental group. The hypothesis still could be expected in a future study with a bigger sample size and longer intervention duration. In clinical practice, the need to provide professional nutrition knowledge about sarcopenic obesity to community-dwelling older people should be addressed, and the potential for employing DBC intervention in community healthcare could be explored.

CHAPTER 7 CONCLUSION

This study aimed to develop an evidence-based dietary behaviour change (DBC) intervention to manage sarcopenic obesity among the community-dwelling older people and investigate the feasibility and preliminary effects of the intervention. This study filled the research gap that combined dietary intervention and behaviour change techniques to manage sarcopenic obesity in the early stage, and the most updated diagnostic criteria of sarcopenic obesity were used. The design of both quantitative and qualitative methods provided a comprehensive result to test the feasibility of the DBC intervention. Rigorous study design and strict fidelity monitoring ensured the high quality of this study, which provided sufficient information for the creation of the future main trial.

This study showed that DBC intervention is feasible and acceptable in older people with sarcopenic obesity in community settings. However, the generalisability of the study results was defective considering the relatively small sample size. The results of this study reflect that the need of providing professional nutrition knowledge in community-dwelling settings is pressing. The intervention design also needs to be better tailored to the current living condition of older Chinese people who may not balance between taking care of grandchildren and planning their own's daily meals.

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APPENDICES

Appendix 1 Search strategy used in PubMed

Example of search strategy in PubMed
Date searched: 16/09/2019
Years covered: all
Limits: humans, English/Chinese

#	Search term	Numbers
#1	sarcopenic obesity [tiab]	459
#2	sarcopenia [mh] OR sarcopenic [tiab]	3466
#3	obesity [mh] OR overweight [tiab] OR obese [tiab]	208277
#4	adiposity [mh] OR adipos* [tiab]	57440
#5	#3 OR #4	244652
#6	#2 AND #5	716
#7	#1 OR # 6	774

Appendix 2 Examples of the guidebook

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

Dietary Guidebook for Older People with Sarcoepnic Obesity

The Hong Kong Polytechnic University

Centre for Gerontological Nursing

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肌少性肥胖老年人膳食指導手冊

香港理工大學護理學院

老年護理研究中心

第一節 認識肌少性肥胖

課程大綱

1. 什麼是肌少性肥胖？肌肉有什麼作用？
2. 肌少性肥胖有什麼危害？
3. 有哪些危險因素會導致肌少性肥胖？
4. 有哪些因素可以預防或緩解肌少性肥胖？
5. 膳食與肌少性肥胖的關係

小講座 1：肌少性肥胖

什麼是肌少性肥胖？

肌少性肥胖是指肌肉逐漸減少，同時伴隨脂肪增加的一種機體狀態，它同時包含了肌少症和肥胖兩種狀態。

隨著年齡的增長，骨骼肌品質和肌肉功能逐漸減退，脂肪在體內漸漸堆積。生理情況下，50 歲以後肌肉量平均每年減少 1–2%，60 歲以後肌肉量減少約達 30%，80 歲以後肌肉量減少可高達 50%。

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第二節 老年人膳食指南

小講座：老年人膳食指南[1]

一、 平衡膳食

1、 少量多次用餐，食物種類豐富

老年人積極主動參與烹飪，每天進餐次數可採用三餐兩點制或三餐三點制，且每天用餐應定時定量。*每天的膳食應包括穀薯類、蔬菜水果類、畜禽魚蛋奶類、大豆類等食物*。

- 穀類為主，粗細搭配，適量攝入全穀物食品

谷類食物含有豐富的碳水化合物，也是提供 B 族維生素、礦物質、膳食纖維和蛋白質的重要食物來源。每餐主食可選用不同種類的穀薯類食材，如米飯、麵條、饅頭、紅薯、土豆等。 全穀物食物一般包括小麥、玉米、大麥、燕麥、糙米、高粱、薏米、蕎麥等。

- 常吃魚、禽、蛋和瘦肉類，保證優質蛋白質供應

魚、禽、蛋和瘦肉均屬於動物性食物，富含優質蛋白質、脂溶性微生物、B 族維生素和礦物質等，但脂肪含量較多，能量高，應適量攝入，尤其內臟和皮不建議食用，脂肪含量較高。禽類（雞鴨鵝）脂肪含量也相對較低，其脂肪酸組成優於畜類脂肪，選擇應先於畜肉（豬牛羊）。肉類也應當選擇瘦肉。蛋類各種營養成分比較齊全，但膽固醇含量也高，適量攝入。

- 適量攝入奶類、大豆及其製品

[1] 參考中國營養學會編制的《中國老年人膳食指南 2016》，關注重特殊人群膳食需遵循普新建議。

第三節 健康膳食計畫

課程大綱

1、 學習如何記錄膳食
2、 制定自己的膳食計畫

今日活動一：學習如何記錄膳食

記錄每天的膳食，可以幫助我們更好地管理自己的膳食結構。膳食記錄的方法有很多，最簡便易行的就是通過日記法，記錄每一餐的食物種類和數量。

一份食物是多少？

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附表

我的膳食記錄（示例）

日期	早餐（食物名稱+份量）	午餐（食物名稱+份量）	晚餐（食物名稱+份量）	飲水	加餐	
					時間	食物
星期一	小米粥 1 份+雞蛋 1 個+牛奶 1 杯（250ml）	糙米飯 1 份+青椒肉絲 1 份+清炒菠菜 1 份+炒青菜 1 份+紫菜蛋湯（幹紫菜半隻手大小+1 個雞蛋）	麵條 1 份+家常豆腐一份+香菇油菜（香菇 3 個，油菜 2 個拳頭大小）+清蒸鱸魚 1 份	6 杯水（1500ml）	09:30	蘋果 1 份（約 200g）
					15:30	無糖優酪乳一份 100g
星期二						
星期三						
星期四						
星期五						
星期六						
星期日						

您也可以選擇拍下每一餐的照片哦。

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Appendix 3 Content Validity Index (CVI) Form for the DBC Intervention Guidebook

Aim: To evaluate the clarity, appropriateness, relevance, and understandability of the content in the dietary intervention guidebook.

Instructions:

Please read the booklet (pages 1-16) which will be used to explain the concept of sarcopenic obesity and the diet modification to older people with sarcopenic obesity. Please rate each item below using the Likert scale ranging 1 to 4 (1 = totally inappropriate, 2 = inappropriate, 3 = appropriate, and 4 = very appropriate). For any items, please give suggestions for improvement. You could also give other suggestions on the booklet beyond the items.

Items	Totally disagree (1)	Disagree (2)	Agree (3)	Totally agree (4)	Comments
1. The introduction of sarcopenic obesity in Chapter 1 (page 1) is relevant to establish participants' awareness of sarcopenic obesity.					
2. The contents related to the potential risks of unmanaged sarcopenic obesity in Chapter 1 (page 2) is relevant to establish participants' awareness of sarcopenic obesity.					
3. The content about the relationship between diet modification and sarcopenic obesity in Chapter 1 (pages 4-5) is relevant to establish participants' awareness of sarcopenic obesity.					
4. Overall, Chapter 1 (pages 1-5) is easy to understand.					

5. The introduction to balanced diet in Chapter 2 (pages 6-8) is relevant to help participants establish a basic understanding of food types.					
6. The introduction to high quality protein sources in Chapter 2 (page 9) is relevant to help participants choose the food which contains high quality proteins.					
7. Overall, Chapter 2 (pages 6-9) is easy to understand.					
8. The protein intake of 1.2-1.5 g/kg DBW/day is appropriate for older people with sarcopenic obesity to increase their muscle mass (Chapter 3, page 10).					
9. A 12% reduction in daily total caloric intake is appropriate for older people with sarcopenic obesity to lose their body fat (Chapter 3, page 10).					
10. The recommended food types in the table in Chapter 3 (page 10) are appropriate for older people with sarcopenic obesity.					
11. The diet plan table in Chapter 3 (page 10) is appropriate to be used for participants to design their diet.					
12. The picture of “my plate” in Chapter 3 (page 11) is appropriate in helping participants to design					

their diet.					
13. The picture of “my plate” in Chapter 3 (page 11) is clear to participants.					
14. The first food recording method in Chapter 3 (pages 12-14) is easy to understand.					
15. The second food recording method in Chapter 3 (pages 15-16) is easy to understand.					
16. The total duration of the intervention (15 weeks) is appropriate for reducing body fat.					
17. The total duration of the intervention (15 weeks) is appropriate for increasing muscle mass.					
18. The food record table in the attachment (page 21) is easy for participants to record their daily food intake.					
Other comments on the booklet					

DBW: desired body weight

Appendix 4 Food diary distributed to the experimental group

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我的膳食日記

吃好每一餐，保持好身材，健康永相伴

第一周

日期	早餐（食物名稱+重量/份量）	午餐（食物名稱+重量/份量）	晚餐（食物名稱+重量/份量）	飲水	加餐	
					加餐時間	加餐食物

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Appendix 5 Manual for telephone follow-up of the control group

Notes:

- The purpose of follow-up with control group is to control the confounding factors of social effect that may affect the examination of intervention efficacy on experimental group.
- The telephone call for each time is around 10 minutes, you can shorten or extend depending on the actual situation.
- At the first time, you can greet and introduce yourself, then introduce the purpose of follow-up and arrangements (including frequency of follow-up and length for each time follow-up).
- Avoid to mention any topic related to diet, exercise, or sarcopenic obesity.
- Use simple words/phrases that older people can understand.
- Please take notes of all special issues occur in the telephone follow-up including participant's self-reported problems, and inform the doctoral researcher in time.
- If the participant asks questions about health care problems, you can give answers based on your knowledge, but do not make specific drug recommendations in order to avoid disputes. You can suggest the participant to consult with doctors.
- In the end of telephone call, make appointment for next time follow-up.
- If the participant wants to drop out, ask for her/his concerns, and try to solve the concerns and persuade her/him to stay. If failed to retain, then record the reasons for dropping out.

Followings are suggested topics:

Topic one: Health education about hypertension

- Do you have high blood pressure?

➢ *If yes*

- Do you usually measure blood pressure? Blood pressure needs to be measured regularly, you can measure at home if you have the measurement instrument or you can measure in the community health centre. Normally, if the "high pressure" is greater than 140 and the "low pressure" is greater than 90, we will say the blood pressure is a bit high. You should follow the medicine prescribed by your doctor, and be compliant to take medicine. You can't stop the medicine or change the dosage by yourself. Be sure to listen to the doctor's advice, it is very important. When you get up, do not make violent movements, it is better to get up slowly. In addition, smoking and drinking will have certain effects on blood pressure, especially smoking can harden blood vessels and cause cardiovascular diseases such as coronary heart diseases.

➢ *If no*

- Oh, that's great. You can measure the blood pressure regularly in the community health centre. Hypertension is a relatively common disease among older people, and now many young people also have high blood pressure. Normally, if "high pressure" is greater than 140 and "low pressure" is greater than 90, it is considered as high blood pressure. As for the symptoms of high blood pressure, there are usually headaches and dizziness, etc. If there is a family history of high blood pressure, such as if one of your parents have high blood pressure, you should pay a little attention and monitor your blood pressure regularly.

Topic two: Health education for cold seasons

- Recently, the weather has been cold and the climate has become dry. Older people should pay attention to health care in winter. The first is to keep warm and avoid to get cold. You can wear scarf, hat, and gloves when you go out. Because if the older people's immune system is weak when the cold air strikes, they are prone to catch colds. If the older people have chronic diseases such as asthma, it is also easy to be triggered. We also suggest to use warm water to brush your teeth in winter. After washing your face, you can apply a little skin care cream because the weather here is too dry. Too dry skin is easy to be itchy or to get eczema, it is better to pay attention to moisturizing.
- When it's cold outside, we all like to close the doors and windows tightly. Over time, the indoor air is not fresh, which can easily cause respiratory diseases. You can open the windows for a while every day to let the indoor air circulate.
- Always keep a good mood and avoid emotional excitement. If there is anything unhappy, don't hold it in your heart, you can talk to your family and friends. A happy mood is beneficial for a healthy body.

Topic three: Preventing falls in the older people

- Older people need to pay special attention to avoid falling, because falls can easily lead to fractures and bleeding. If older people are fractured, it may take a long time to recover due to the slow metabolism.
- Every morning when you wake up, do not rush to get up. You can lie down on the bed for several minutes, then lean on the head of the bed for several minutes, then sit on the side of the bed for several minutes, and then get up, which can effectively prevent postural hypotension and prevent falls.
- If you exercise regularly, it is better to have a partner to exercise together, or to do exercises in a public area like gyms or parks, in case someone can help you if necessary. Yourself also need to take precautions when exercising.
- The furniture in your home should be arranged neatly, especially those on the aisles. Avoid piling up debris in the aisle, which may affect walking.

Example:

- Good morning, I am XXX, the research assistant of this program. How are you recently?
  - *If fine, then going on to introduce the arrangements.*
  - *If not fine, then ask for reasons and try to ease the emotion.*
- We are so happy to have you join in this program. In the following 15 weeks, we will contact with you via telephone monthly and may talk with you for 10 minutes each time. Is it OK for you?
  - *If fine, then continue.*
  - *If not fine, ask for reasons, try to negotiate with her/him to set out appropriate arrangements.*
- Today I would like to talk about health knowledge about hypertension. Do you have hypertension? (Following communication refer to Topic 1)

Appendix 6 Demographic and Clinical Data Collection Form (Chinese version)

"飲食行為干預對社區老年人肌少性肥胖管理的可行性隨機對照研究" 評估檢查表

姓　名：_____　　隨機編號：_____

評估者：_____　　評估日期：_____

評估次序：T0（基線測試）/T1（干預結束後 1 星期）

評估類目	已進行評估
1、InBody 身體成分測試	☐
2、手握力	☐
3、SPPB 簡易體能狀況量表	☐
4、MNA 微型營養評價量表	☐
5、SF-36 健康調查量表	☐
6、IPAQ-SF 國際體力活動量表	☐
7、HAPA 營養自我效能量表	☐
8、3 日膳食回顧	☐

一般資料

姓名____ 性別____ 出生日期：___年__月 民族____ 婚否____ 職業____ 宗教信仰_____ 手機_____ (連絡人手機)_____ 聯繫地址_____						
教育程度	□未接受正式教育	□小學	□初中	家庭月收入	□3000元以下	□3000-5999元
	□高中	□大專或本科	□研究生以上		□6000-10000元	□10000元以上

既往史、生活史、過敏史

過敏史	食物：_____ 藥物：_____		
既往病史 □高血壓 □高血脂 □糖尿病 □甲狀腺疾病 □腎臟疾病 □痛風 □脂肪肝 □其他_____			
飲酒情況	□不飲酒 □每月飲酒1次 □每月飲酒2-4次 □每週飲酒2-3次 □每週飲酒4次及以上	吸煙情況	□不吸煙 □曾經吸煙，已戒煙 □每日吸1包煙及以下 □每日吸1-2包煙 □每日吸2包煙及以上
是否素食者	□是 □否	三餐飲食	□一日三餐，飲食規律 □三餐之外，加餐（下午茶或夜宵之類） □飲食不規律，常有一兩餐不吃 □其他_____
在外就餐	□一周有≥5天 □一周有3-4天 □一周有1-2天 □基本上每天在家裡吃飯	負責做飯的人	□您本人 □您的家人 □保姆 □其他_____
目前患有的其它疾病及用藥 疾病名稱 用藥名稱 治療起止時間		□有	□無

1、InBody身體成分測試

檢測項目		檢測結果
查體	身高	
	體重	
	腰圍	
	臀圍	
	小腿圍	
	體重指數	
	體脂率	
	內臟脂肪面積	
	去脂體重	
	總骨骼肌肉量	
	四肢肌肉量	
	骨骼肌量/身高^2	
	骨骼肌量/體重×100%	

2、手握力

手握力：_____kg

(測試慣用手，測 2 次，取數值大的那次)

3、SPPB 簡易體能狀況量表 (p4-8)

(1)平衡測驗得分：

A. 雙腳併攏站立

堅持 10 秒	☐ 1 分
未堅持 10 秒	☐ 0 分
未進行該動作	☐ 0 分

如果得分為 0，結束測試。

如果堅持時間＜10 秒，記錄堅持時間：____秒。

如果受試者未進行該動作，請選擇：
1. 嘗試但未成功
2. 受試者無法在無輔助工具幫助下完成該動作
3. 測試者認為該動作對受試者不安全
4. 受試者覺得該動作不安全
5. 受試者無法正確理解如何完成該動作
6. 其他（請說明）：
7. 受試者放棄

B - 半串聯站立

堅持 10 秒	☐ 1 分
未堅持 10 秒	☐ 0 分
未進行該動作	☐ 0 分 (原因____)

如果得分為 0，結束測試。

如果堅持時間＜10 秒，記錄堅持時間：____秒。

C - 串聯站立

堅持 10 秒	☐ 2 分
堅持 3—9.99 秒	☐ 1 分
堅持＜3 秒	☐ 0 分
未進行該動作	☐ 0 分 (原因____)

如果堅持時間＜10 秒，記錄堅持時間：____秒。

D - 平衡測驗總得分：____分

說明：_____
_____
_____
_____
_____

(2)步行速度測驗評分

步行測試的長度：4 米☐ 3 米☐

A. 第一次步行速度測試的時間（秒）

1. 3或4米的時間___ ____.____ ____秒

2. 如果受試者沒有盡力測試或失敗，說明為什麼：

盡力了但是不能	1
受試者沒有幫助不能行走	2
沒有盡力，你覺得不安全	3
沒有盡力，受試者覺得不安全	4
受試者不能理解指示	5
其他（請說明）	6
受試者拒絕	7

完成打分和去坐-站測試

3.第一次步行速度測試的說明　　沒有☐　手杖☐　其他☐

說明：_____

_____

_____

B. 第二次步行速度測試的時間(秒)

1. 3或4米的時間___ ____.___ ___秒

2.如果受試者沒有盡力測試或失敗，圈繞為什麼：

盡力了但是不能	1
受試者沒有幫助不能行走	2
沒有盡力，你覺得不安全	3
沒有盡力，受試者覺得不安全	4
受試者不能理解指示	5
其他（請說明）	6
受試者拒絕	7

3.第一次步行速度測試的說明　　沒有☐　手杖☐　其他☐

二次步行測試中較快一次所需的時間？

記錄二次中短的時間___ ____.___ ___秒

（如果僅僅只有一次，記錄那次時間）__ __.__ _秒

如果受試者不能步行：☐0分

4米步行		**3米步行**	
如果時間超過8.70秒	☐1分	如果時間超過6.52秒	☐1分
如果時間在6.21到8.70之間	☐2分	如果時間在4.66到6.52之間	☐2分
如果時間在4.82到6.20之間	☐3分	如果時間在3.62到4.65之間	☐3分
如果時間少於4.82秒	☐4分	如果時間少於3.62秒	☐4分

3. 坐站試驗評分

單獨坐站測試

A.不用幫助，安全站立　　YES☐　NO☐

B.結果

受試者不用雙手站立　　☐→去進行重複坐站測試

受試者用雙手站立　　☐→結束實驗，計為0分

測試不能完成　　☐→結束實驗，計為0分

C・如果受試者沒有盡力測試或不能，詢問為什麼

盡力了但是不能　　1

受試者沒有幫助不能站立　　2

沒有盡力，你覺得不安全　　3

沒有盡力，受試者覺得不安全　　4

受試者不能理解指示　5

其他（請說明）　6

受試者拒絕　7

重複坐站測試

A. 安全站立 5 次　YES☐　NO☐

B. 如果成功站立 5 次，記錄時間（秒）

完成 5 次站立的時間——.——

C・如果受試者沒有盡力測試或不能，詢問為什麼

盡力了但是不能　1

受試者沒有幫助不能站立　2

沒有盡力，你覺得不安全　3

沒有盡力，受試者覺得不安全　4

受試者不能理解指示　5

其他（請說明）　6

受試者拒絕　7

重複站立計分

如果受試者不能完成 5 次站立或完成站立時間大於 60 秒　☐0 分

如果坐站時間大於等於 16.70 秒　☐1 分

如果坐站時間在 13.70 到 16.69 秒之間　☐2 分

如果坐站時間在 11.20 到 13.69 秒之間　☐3 分

如果坐站時間小於等於 11.19 秒　☐4 分

完成簡易體能狀況量表計分

測試計分

平衡測試計分　——分

步行速度測試計分　　——分

坐站測試計分　　——分

總計分　　——分（上述分數總和）

4、MNA 微型營養評價量表

A 過去三個月有沒有因為食欲不振、消化問題、咀嚼或吞咽困難而減少食量？
- 0=食量嚴重減少
- 1=食量中度減少
- 2=食量沒有改變

B 過去三個月內體重下降的情況
- 0=體重下降大於 3 公斤
- 1=不知道
- 2=體重下降 1-3 公斤
- 3=體重沒有下降

C 活動能力
- 0=需長期臥床或坐輪椅
- 1=可以下床或離開輪椅，但不能外出
- 2=可以外出

D 過去三個月內有沒有受到心理創傷或患上急性疾病？
- 0=有
- 2=沒有

E 精神心理問題
- 0=嚴重癡呆或抑鬱
- 1=輕度癡呆
- 2=沒有精神心理問題

F1 身體品質指數（BMI）（kg/m^2）
- 0= BMI<19
- 1= 19≤ BMI <21
- 2= 21≤ BMI <23
- 3= BMI ≥23

若不知道 F1，則跳至 F2

F2 小腿圍 （CC）（釐米，cm）
- 0= CC<31
- 3= CC≥31

篩選分數　　（最高 14 分）

12-14 分☐　正常營業狀況
8-11 分 ☐　有營養不良的風險
0-7 分 ☐　營養不良

5、SF-36 健康調查量表

SF-36 量表的內容：

1、　　總體來講，您的健康狀況是：

①非常好　　②很好　　③好　　④一般　　⑤差

2、跟 1 年以前比您覺得自己的健康狀況是：

①比 1 年前好多了　　②比 1 年前好一些　　③跟 1 年前差不多　　④比 1 年前差一些　　⑤比 1 年前差多了

（權重或得分依次為 1，2，3，4 和 5）

健康和日常活動

3、以下這些問題都和日常活動有關。請您想一想，您的健康狀況是否限制了這些活動？如果有限制，程度如何？

（1）重體力活動。如跑步舉重、參加劇烈運動等：

①限制很大　　②有些限制　　③毫無限制

（權重或得分依次為 1，2，3；下同）注意：如果採用漢化版本，則得分為 1，2，3，4，則得分轉換時做相應的改變。

（2）適度的活動。如移動一張桌子、掃地、打太極拳、做簡單體操等：

①限制很大　　②有些限制　　③毫無限制

（3）手提日用品。如買菜、購物等：

①限制很大　　②有些限制　　③毫無限制

（4）上幾層樓梯：

①限制很大　　②有些限制　　③毫無限制

（5）上一層樓梯：

①限制很大　　②有些限制　　③毫無限制

（6）彎腰、屈膝、下蹲：

①限制很大　　②有些限制　　③毫無限制

（7）步行 1500 米以上的路程：

①限制很大　　②有些限制　　③毫無限制

（8）步行 1000 米的路程：

①限制很大　　②有些限制　　③毫無限制

（9）步行 100 米的路程：

①限制很大　　②有些限制　　③毫無限制

（10）自己洗澡、穿衣：

①限制很大　　②有些限制　　③毫無限制

4、在過去 4 個星期裡，您的工作和日常活動有無因為身體健康的原因而出現以下這些問題？

（1）減少了工作或其他活動時間：

①是　　②不是

（權重或得分依次為 1，2；下同）

（2）本來想要做的事情只能完成一部分：

①是　　②不是

（3）想要幹的工作或活動種類受到限制：

①是　　②不是

（4）完成工作或其他活動困難增多（比如需要額外的努力）：

①是　②不是

5、在過去 4 個星期裡，您的工作和日常活動有無因為情緒的原因（如困惱或憂慮）而出現以下這些問題？

(1) 減少了工作或活動時間：

①是　②不是

（權重或得分依次為 1，2；下同）

(2) 本來想要做的事情只能完成一部分：

①是　②不是

(3) 幹事情不如平時仔細：

①是　②不是

6、在過去 4 個星期裡，您的健康或情緒不好在多大程度上影響了您與家人、朋友、鄰居或集體的正常社會交往？

①完全沒有影響　②有一點影響　③中等影響　④影響很大　⑤影響非常大

（權重或得分依次為 5，4，3，2，1）

7、在過去 4 個星期裡，您有身體疼痛嗎？

①完全沒有疼痛　②有一點疼痛　③中等疼痛　④嚴重疼痛　⑤很嚴重疼痛

（權重或得分依次為 6，5.4，4.2，3.1，2.2，1）

8、在過去 4 個星期裡，您的身體疼痛影響了您的工作和家務嗎？

①完全沒有影響　②有一點影響　③中等影響　④影響很大　⑤影響非常大

（如果 7 無 8 無，權重或得分依次為 6，4.75，3.5，2.25，1.0；如果為 7 有 8 無，則為 5，4，3，2，1）

您的感覺

9、以下這些問題是關於過去 1 個月裡您自己的感覺，對每一個問題所說的事情，您的情況是什麼樣的？

(1) 您覺得生活充實：

①所有的時間　②大部分時間　③比較多時間　④一部分時間　⑤小部分時間　⑥沒有這種感覺

（權重或得分依次為 6，5，4，3，2，1）

(2) 您是一個敏感的人：

①所有的時間　②大部分時間　③比較多時間　④一部分時間　⑤小部分時間　⑥沒有這種感覺

（權重或得分依次為 1，2，3，4，5，6）

(3) 您的情緒非常不好，什麼事都不能使您高興起來：

①所有的時間　②大部分時間　③比較多時間　④一部分時間　⑤小部分時間　⑥沒有這種感覺

（權重或得分依次為 1，2，3，4，5，6）

(4) 您的心理很平靜：

①所有的時間　②大部分時間　③比較多時間　④一部分時間　⑤小部分時間　⑥沒有這種感覺

（權重或得分依次為 6，5，4，3，2，1）

(5) 您做事精力充沛：

①所有的時間　②大部分時間　③比較多時間　④一部分時間　⑤小部分時間　⑥沒有這種感覺

（權重或得分依次為 6，5，4，3，2，1）

(6) 您的情緒低落：

①所有的時間　②大部分時間　③比較多時間　④一部分時間　⑤小部分時間　⑥沒有這種感覺

（權重或得分依次為 1，2，3，4，5，6）

(7) 您覺得筋疲力盡：

①所有的時間　②大部分時間　③比較多時間　④一部分時間　⑤小部分時間　⑥沒有這種感覺

（權重或得分依次為 1，2，3，4，5，6）

(8) 您是個快樂的人：

①所有的時間　②大部分時間　③比較多時間　④一部分時間　⑤小部分時間　⑥沒有這種感覺

（權重或得分依次為 6，5，4，3，2，1）

(9) 您感覺厭煩：

①所有的時間　②大部分時間　③比較多時間　④一部分時間　⑤小部分時間　⑥沒有這種感覺

（權重或得分依次為 1，2，3，4，5，6）

10、不健康影響了您的社會活動（如走親訪友）：

①所有的時間　②大部分時間　③比較多時間　④一部分時間　⑤小部分時間　⑥沒有這種感覺

（權重或得分依次為 1，2，3，4，5）

總體健康情況

11、請看下列每一個問題，哪一種答案最符合您的情況？

(1) 我好象比別人容易生病：

①絕對正確　②大部分正確　③不能肯定　④大部分錯誤　⑤絕對錯誤

（權重或得分依次為 1，2，3，4，5）

(2) 我跟周圍人一樣健康：

①絕對正確　②大部分正確　③不能肯定　④大部分錯誤　⑤絕對錯誤

（權重或得分依次為 5，4，3，2，1）

(3) 我認為我的健康狀況在變壞：

①絕對正確　②大部分正確　③不能肯定　④大部分錯誤　⑤絕對錯誤

（權重或得分依次為 1，2，3，4，5）

(4) 我的健康狀況非常好：

①絕對正確　②大部分正確　③不能肯定　④大部分錯誤　⑤絕對錯誤

（權重或得分依次為 5，4，3，2，1）

6、IPAQ-SF 國際體力活動量表

1、最近 7 天內，您有幾天做了劇烈的體育活動，像是提重物、挖掘、有氧運動或是快速騎車？

每週____天

☐ 無相關體育活動 →跳到問題 3

2、在這其中一天您通常會花多少時間在劇烈的體育活動上？

每天____小時____分鐘

☐ 不知道或不確定

3、最近 7 天內，您有幾天做了適度的體育活動，像是提輕的物品、以平常的速度騎車或打雙人網球？請不要包括走路。

每週____天

☐ 無適度體育活動 →跳到問題 5

4、在這其中一天您通常會花多少時間在適度的體育活動上？

每天____小時____分鐘

☐ 不知道或不確定

5、最近 7 天內，您有幾天是步行，且一次步行至少 10 分鐘？

每週____天

☐ 沒有步行 →跳到問題 7

6、在這其中一天您通常花多少時間在步行上？

每天____小時____分鐘

☐ 不知道或不確定

7、最近七天內，工作日您有多久時間是坐著的？

每天____小時____分鐘

☐ 不知道或不確定

7、營養自我效能量表

“你有多大把握可以克服以下困難？”

我可以設法堅持健康飲食，…

題號	條目	（1） 非常不確定	（2） 部分不確定	（3） 部分確定	（4） 非常確定
1	…即使我需要很長時間來養成必要的習慣				
2	…即使我不得不嘗試很多次它才能有效果				
3	…即使我不得不重新考慮我的整個營養方式				
4	…即使在我剛開始嘗試時沒有得到其他人的大力支持				
5	…即使我不得不制定一個詳細的計畫				

8、膳食回顧

日期	早餐（食物名稱+重量/份量）	午餐（食物名稱+重量/份量）	晚餐（食物名稱+重量/份量）	飲水	加餐	
					加餐時間	加餐食物

InBody 270 used to measure the body composition

Jamar Hydraulic Hand Dynamometer used to measure the handgrip strength

Appendix 7 Information Sheet

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

Form A for scale translation and validation

INFORMATION SHEET

TRANSLATION AND VALIDATION OF THE CHINESE VERSION OF THE NUTRITION SELF-EFFICACY SCALE

You are invited to participate in the above project conducted by Yueheng Yin, who is a postgraduate student of the School of Nursing in The Hong Kong Polytechnic University. The project has been approved by the Human Subjects Ethics Sub-committee (HSESC) (or its Delegate) of The Hong Kong Polytechnic University (HSESC Reference Number: 20191007001).

The aims/objectives of this project are to translate and validate the Chinese version of the Nutrition Self-Efficacy Scale which will help to develop better treatment on nutrition in China.

You are invited to complete a questionnaire, which will take you about 5 minutes.

The testing should not result in any undue discomfort.

The information you provide as part of the project is the research data. Any research data from which you can be identified is known as personal data. Personal data does not include data where the identity has been removed (anonymous data). We will minimize our use of personal data in the study as much as possible. The researcher and his team, supervisor, collaborator (including Dr. Justina Liu, Prof. Maritta Valimaki and Yueheng Yin within Hong Kong) will have access to personal data and research data for the purposes of the study. Responsible members of The Hong Kong Polytechnic University may be given access for monitoring and/or audit of the research.

All information related to you will remain confidential and (will be identifiable by codes only known to the researchers). The information collected will be kept until 3 years after project publication or public release of research results). The Hong Kong Polytechnic University takes reasonable precautions to prevent the loss, misappropriation, unauthorized access or destruction of the information you provide.

You have every right to withdraw from the study before or during the measurement without penalty of any kind.

If you have any questions, you may ask our helpers now or later, even after the study has started.

You may contact Yueheng Yin (tel. no.: (852) _ / email: _ k)
or Dr Justina Liu (tel. no.: _ / email: _ :) of PolyU under the following situations:

a. if you have any other questions in relation to the study;

b. if, under very rare conditions, you become injured as a result of your participation in the study; or
c. if you want to get access to/or change your personal data before (the expiry date).

In the event you have any complaints about the conduct of this research study, you may contact the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University in writing (c/o Research Office of the University) stating clearly the responsible person and department of this study as well as the HSESC Reference Number.

Thank you for your interest in participating in this study.

Yueheng Yin
Principal Investigator/Chief Investigator

Hung Hom Kowloon Hong Kong 香港 九龍 紅磡
Tel 電話 (852) 2766 5111 Fax 傳真 (852) 2784 3374
Email 電郵 polyu@polyu.edu.hk
Website 網址 www.polyu.edu.hk

Form C for pilot RCT

INFORMATION SHEET

THE EFFECT OF DIETARY BEHAVIOUR CHANGE INTERVENTION ON MANAGING SARCOPENIC OBESITY IN COMMUNITY-DWELLING OLDER PEOPLE: A PILOT RANDOMIZED STUDY

You are invited to participate in the above project conducted by Yueheng Yin, who is a postgraduate student of the School of Nursing in The Hong Kong Polytechnic University. The project has been approved by the Human Subjects Ethics Sub-committee (HSESC) (or its Delegate) of The Hong Kong Polytechnic University (HSESC Reference Number: 20191007001).

The aims/objectives of this project are to examine the feasibility and the preliminary effects of the dietary behaviour change intervention on body composition for older people with sarcopenic obesity.

You are invited to join a pilot randomized study, which will take you about 15 weeks.

The testing should not result in any undue discomfort.

The information you provide as part of the project is the research data. Any research data from which you can be identified is known as personal data. Personal data does not include data where the identity has been removed (anonymous data). We will minimize our use of personal data in the study as much as possible. The researcher and his team, supervisor, collaborator (including Dr. Justina Liu and Prof. Maritta Valimaki within Hong Kong) will have access to personal data and research data for the purposes of the study. Responsible members of The Hong Kong Polytechnic University may be given access for monitoring and/or audit of the research.

All information related to you will remain confidential and (will be identifiable by codes only known to the researchers). The information collected will be kept until 3 years after project publication or public release of research results). The Hong Kong Polytechnic University takes reasonable precautions to prevent the loss, misappropriation, unauthorized access or destruction of the information you provide.

You have every right to withdraw from the study before or during the measurement without penalty of any kind.

If you have any questions, you may ask our helpers now or later, even after the study has started.

You may contact Yueheng Yin (tel. no.: // email: 'c) or Dr Justina Liu (tel. no.: / email: 'c) of PolyU under the following situations:

a.if you have any other questions in relation to the study;

b.if, under very rare conditions, you become injured as a result of your participation in the study; or

c.if you want to get access to/or change your personal data before (the expiry date).

In the event you have any complaints about the conduct of this research study, you may contact the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University in writing (c/o Research Office of the University) stating clearly the responsible person and department of this study as well as the HSESC Reference Number.

Thank you for your interest in participating in this study.

Yueheng Yin
Principal Investigator/Chief Investigator

Hung Hom Kowloon Hong Kong 香港九龍 紅磡
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Website 網址 www.polyu.edu.hk

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

CONSENT TO PARTICIPATE IN RESEARCH

The Effect of Dietary Behaviour Change Intervention on Managing Sarcoepnic Obesity in Community-dwelling Older People: a Pilot Randomized Study

I _____ hereby consent to participate in the captioned research conducted by Yueheng Yin.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. I understand the benefit and risks involved. My participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

Name of participant

Signature of participant _____

Name of Parent or Guardian (if applicable) _____

Signature of Parent or Guardian (if applicable) _____

Name of researcher

Signature of researcher

Date

Hung Hom Kowloon Hong Kong 香港 九龍 紅磡
Tel 電話 (852) 2766 5111 Fax 傳真 (852) 2784 3374
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THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

CONSENT TO PARTICIPATE IN RESEARCH

Translation and Validation of the Chinese Version of the Nutrition Self-Efficacy Scale

I _____ hereby consent to participate in the captioned research conducted by Yueheng Yin.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. I understand the benefit and risks involved. My participation in the project is voluntary.

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Name of participant _____

Signature of participant _____

Name of Parent or Guardian (if applicable) _____

Signature of Parent or Guardian (if applicable) _____

Name of researcher _____

Signature of researcher _____

Date _____

Hung Hom Kowloon Hong Kong 香港 九龍 紅磡
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Appendix 9 Ethical approval

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

To	Liu Yat Wa Justina (School of Nursing)		
From	Mak Kit Yi, Delegate, Faculty Research Committee		
Email	@polyu.edu.hk	Date	15-Oct-2019

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 31-Oct-2019 to 30-Sep-2020:

Project Title:	The effect of dietary behaviour change intervention on managing sarcopenic obesity in community-dwelling older people: a pilot randomized study
Department:	School of Nursing
Principal Investigator:	Liu Yat Wa Justina
Project Start Date:	31-Oct-2019
Reference Number:	HSEARS20191007001

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.

Mak Kit Yi

Delegate

Faculty Research Committee (on behalf of Human Subjects Ethics Sub-Committee)

Appendix 10 Fidelity Checklist

Date of intervention:_____

Session 1		**Consistent (✓)**	**Inconsistent (✓)**	**Remarks**
1	Greetings and self-introduction			
2	Introduction of the project (including the research purpose, duration, and arrangements of face-to-face sessions & telephone follow-up)			
3	Introduction of sarcopenic obesity (including definition, dangers, risk factors, and preventing factors of sarcopenic obesity; and function of muscle)			
4	Introduction of relationship between diet and sarcopenic obesity (including relation between nutrition and ageing, muscle and protein, obesity and calorie)			
5	Summarise (emphasising the significance of sarcopenic obesity especially focusing on the associated adverse health outcomes, and the strong relationship between diet and sarcopenic obesity)			
Session 2				
1	Greetings, and review of last session			
2	Introduction of balanced diet			
3	Introduction of sources of high quality of protein			
4	Introduction of caloric restriction			
5	Summarise (emphasising the importance of protein intake and caloric restriction for older people with sarcopenic obesity, emphasizing potential benefits for maintaining high-protein hypocaloric diet, and trying to establish the motivation and self-efficacy of participants to change diet)			
Session 3				
1	Greetings, and review of previous sessions			
2	Teaching methods of measuring food amount (introducing the concept of food portion, 1 portion food=90 kcal)			
3	Teaching how to take food diary			
4	Making dietary plan (emphasizing daily dietary goal)			
5	Summarise (reiterating the diet plan and goals, eliminating participants' worries, and establishing participants' confidence)			
Session 4				
1	Greetings and checking food diary (check the compliance)			
2	Acknowledge the accomplishments			
3	Asking participants whether had any difficulties, helping solve problems			
4	Sharing positive examples of others to encourage the participants			
5	Refining the dietary goals and action plans, and review the outcome expectations			

Assessor:_____

Session 5				
1	Greetings and checking food diary (check the compliance)			
2	Acknowledge the accomplishments			
3	Asking participants whether had any difficulties, helping solve problems			
4	Sharing positive examples of others to encourage the participants			
5	Refining the dietary goals and action plans, and review the outcome expectations			
Session 6				
1	Greetings and checking food diary (check the compliance)			
2	Acknowledge the accomplishments			
3	Asking participants whether had any difficulties, helping solve problems			
4	Sharing positive examples of others to encourage the participants			
5	Refining the dietary goals and action plans, and review the outcome expectations			

Appendix 11 Guideline for the management of untoward effects in the dietary behaviour change program

a) Please contact the doctoral researcher if the participants have the following symptoms:

- Gastrointestinal symptoms, e.g., stomach ache, nausea, vomiting.

- Hypoglycemia, i.e., dizziness, sweating, hunger, palpitations, shakiness, and pale skin.

- Suspected symptoms of anorexia, e.g., eating extremely little, unstable emotion, gastrointestinal symptoms, decreased sleep quality.

- Malnutrition, i.e., very quick weight loss, reduced appetite, feeling tired all the time, weaker, getting ill often and taking a long time to recover, wounds taking a long time to heal, poor concentration, feeling cold most of the time, low mood or depression.

b) If hypoglycemia happens, ask the participant to eat carbohydrates such as sugars.

c) Prevent the happen of falls caused by the above symptoms.

d) Refer to the physician as needed.

e) In all cases, a follow-up call will be conducted by the research personnel.