



BMJ Open Effects of combining positive psychological intervention and lifestyle intervention on improving cardiovascular health for at-risk older adults: study protocol of a Chinese multicentric community-based randomised controlled trial (ACCOMPLI-CH)

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ABSTRACT

Introduction Cardiovascular health is influenced by various factors, including not only physiological and behavioural ones but also psychological well-being. However, when developing comprehensive preventive approaches, psychological interventions often receive less attention, despite their possible multiple mechanisms on cardiovascular health. Incorporating both healthy behaviour and psychological well-being promotion would be a more efficacious preventive approach. This study aims to investigate the effects of a community-based multicomponent intervention combining positive psychological intervention and lifestyle intervention on improving cardiovascular health among older adults with risk factors of cardiovascular diseases.

Methods and analysis This study is a multicentre, community-based, randomised controlled trial with 18 months of intervention and follow-up for community-dwelling older adults aged 60 years and above with risk factors for cardiovascular health. Intervention activities last 6 months and are composed of in-person group training sessions of 60–80 min led by trained group instructors and weekly self-monitoring homework. Participants are randomly assigned to a multicomponent intervention ‘Harmony’ group (24 sessions of positive psychology and lifestyle intervention delivered weekly), an active control ‘Lifestyle’ group (eight sessions of lifestyle intervention delivered every 3–4 weeks) or a waitlist control group (no intervention activities). Positive psychological training sessions are designed using well-known techniques derived from positive psychology theories with adaptations to Chinese culture, and lifestyle training sessions are developed according to national guidelines. The primary outcome includes the change of a composite score of systolic blood pressure, total cholesterol, high-

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is the first large-scale randomised controlled trial conducted in China that investigates the causal effects of enhancing psychological well-being when combined with lifestyle intervention on cardiovascular health among community-dwelling older adults.
- ⇒ The outcome measurements cover various aspects of cardiovascular health-related factors, particularly the inclusion of psychosocial factors, allowing the formation of a comprehensive profile and examination of the impact of the intervention through different potential pathways.
- ⇒ This trial is conducted at the community level in multiple cities across different geographical regions of China, and the training content is tailored to Chinese culture, so future dissemination would benefit a wide range of population.
- ⇒ Clinically relevant outcomes, such as incident cardiovascular disease, are recorded and treated as additional or exploratory outcomes because those would require a longer follow-up period or a substantially larger sample size to observe significant changes.

density lipoprotein and low-density lipoprotein levels, as well as psychological well-being measured from three perspectives, including hedonic, eudaimonic and evaluative well-being. Secondary assessments include other measures for physical and biological indicators, psychological well-being, health behaviours, social connection factors and overall cognitive functions. Primary data analyses will follow the intention-to-treat principle. To examine the effects of intervention, multilevel

mixed models will be performed. In case of any differences in baseline participant characteristics, they will be adjusted for as covariates.

Ethics and dissemination A centralised ethics review process was conducted, and the study protocol was approved by the ethics committee of the Institutional Review Board of the Institute of Psychology, Chinese Academy of Sciences in April 2022. A signed written informed consent form will be obtained from all participants. On completion, the trial results will be disseminated through published manuscripts and presentations at scientific conferences.

Trial registration number ChiCTR2200062929.

INTRODUCTION

Cardiovascular disease (CVD) has been reported as a major cause of global mortality and rising healthcare costs,¹ and this problem is more prominent in China with an increasing prevalence of CVD observed over the past few decades, particularly for older adults.² To promote healthy longevity, public health advocates have emphasised the importance of early screening, prevention and disease management.³ Numerous studies have pointed out that the adoption and maintenance of healthy lifestyles are keys to good cardiovascular health (CVH), particularly those targeting modifiable health-behaviour-related risk factors, such as physical activity, dietary habits, tobacco exposure and obesity.¹⁴ Despite the effort allocated in designing and implementing preventive measures consisting of only health behaviour promotion, more and more research has pointed out that psychological well-being (PWB) has a critical role in contributing to CVH.^{5 6} Thus, multicomponent interventions that incorporate both lifestyle and PWB training could be a desirable non-pharmaceutical preventive approach.

Several studies have established the associations between psychological factors and CVD. More importantly, a growing amount of evidence suggests that positive PWB, which refers to positive thoughts and feelings when people evaluate their lives, has independent contributions.⁵ According to a recent scientific statement that reviewed a wide variety of research, higher levels of positive PWB, such as positive affect, sense of purpose and optimism, are associated with better CVH outcomes and lower incident CVD and risks.⁷

As a result, although still limited, some intervention studies have been conducted to examine the effects of increasing positive PWB for patients with CVD. In this field, the widely used approach for PWB enhancement is positive psychological intervention (PPI). A recent meta-analysis of 15 randomised controlled trials (RCTs) showed that PPI can significantly improve CVD patients' positive well-being, including positive affect, life satisfaction and happiness, and at the same time reduce negative psychological factors, such as distress and anxiety levels.⁸ Another systematic review found that when combining PPI with health-behaviour-focused intervention, participants were more likely to improve their participation in health behaviours (most evidence was found for physical activities).⁹ A few PPI trials even reported beneficial effects for CVD-related biological markers, for example,

inflammation indicators,^{10 11} although these effects are constrained by the small sample sizes of trials and have been less consistently observed.^{12 13} Hardly any studies have investigated the effects of PPI on at-risk populations, such as those with diabetes or hypertension.^{14 15} However, the findings were mixed and should be interpreted with caution due to the small sample sizes and study designs. It is also important to note that those studies focused on samples with a single risk factor of CVD, whereas the at-risk individuals of CVD usually have multiple risk factors across various aspects, such as physical, lifestyle and, of course, psychological factors.⁴⁻⁷ Therefore, it is crucial to conduct studies that include multiple risk factor individuals, which would enhance the generalisability and validity of findings.

Different pathways are proposed by which PWB can impact CVH: direct biological pathways related to chronic stress (such as inflammatory response, lipid homeostasis and hormone regulation), indirect effects on health behaviours and influence on psychosocial factors when encountering stressful experiences.⁵⁻⁷ Lifestyle intervention is usually used as a regular strategy for CVH promotion, but adopting and maintaining a healthy lifestyle remain challenging for many people. As pointed out in the most recent Chinese national report on physical activity, only 26.1% of older adults have regular engagement in physical activities every week.¹⁶ A study examining the temporal change of lifestyle risk factors for CVD in China showed that the level of physical activity participation decreased over the last few decades, and this declining trend together with unhealthy dietary habits like high salt intake has been continuously leading to CVD burden.⁴ Enhancing PWB would not only have an independent contribution to CVH but also reinforce individuals to put behavioural intention into actual engagement in healthy behaviours by increasing motivation and helping with goal setting, which are vital factors emphasised in theories of behavioural change.¹⁷ Thus, relative to single-domain interventions, multidomain interventions that promote healthy behaviours and PWB comprehensively would be more efficacious, as these training components would facilitate each other for improving CVH and reducing the risk of CVD.

However, insofar as the evidence emerged, most have been from cross-sectional and longitudinal observational studies, which usually yield correlational relationships rather than causal relationships. As reviewed previously, among the few RCTs of either PPI only or combining PPI with lifestyle interventions, the participants were limited to clinical patients in primary care settings or at-risk individuals with only one or two risk factors, small sample sizes were used, and physical and biological outcome measures were inadequate. These issues are more obvious for relevant research in China,^{18 19} despite the enormous demand and urgent need.^{4 20} More concerns have been raised, particularly among older adults, with the effects of rapid population ageing²⁰ and ageing in place (ie, staying in one's own home with ageing) for most Chinese older

adults.²¹ The China-PAR project (Prediction for CVD Risk in China) also showed that age contributed the most when predicting the risk of CVD for Chinese adults.²² As such, from the preventive perspective, it is necessary to design community-based intervention programmes that would be more suitable and beneficial for Chinese older adults.

In the Ameliorate Cardiovascular Condition through Positive Psychology and Lifestyle Intervention in China (ACCOMPLI-CH) trial, we aim to develop a multicentre community-based intervention trial on combining PPI and health behaviour promotion and examine its effects for improving CVH for older adults. The multicentre nature of this trial would bring heterogeneity of the sample, which could increase the generalisation of the study results. To ensure room for improvement, we target individuals with risk factors from a wide spectrum, including well-known biological and behavioural factors, as well as psychological and social factors.⁴⁻⁷ In terms of the design for intervention treatment, a multi-component intervention of PWB and lifestyle promotion would be compared with a lifestyle intervention group, which is treated as an active control, and then compared with a waitlist control without any intervention activities. Therefore, we expect the multicomponent intervention would be more effective in increasing CVH relative to the lifestyle intervention only, as PWB could facilitate health behaviours that contribute to better CVH and have some direct biological impacts at the same time. Comparing the lifestyle intervention group, which is a widely used approach, to the waitlist control group, we would be able to examine whether lifestyle management solo could be effective in community settings for a wider and more mixed population.

METHODS

Design and setting

ACCOMPLI-CH is a multicentre, community-based, prospective, RCT with 18 months of intervention and follow-up. This trial is registered at the Chinese Clinical Trial Registry (www.chictr.org.cn), number ChiCTR2200062929. The current study follows the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement.

The study flow is shown in [figure 1](#). Assessments and intervention activities will be conducted in person at local community resident/healthcare centres. Written consent will be obtained from participants before assessments. After potential participants are checked for eligibility, they will complete baseline assessments by trained personnel. Participants will be randomly assigned to one of the study groups (multidomain intervention 'Harmony' group vs active control 'Lifestyle' group vs waitlist control group), such that there will be group training visits weekly for the harmony group and training visits every 3–4 weeks for the lifestyle group. The waitlist group will not receive any training activities. During the intervention, participants

from all groups will be asked to complete monthly brief questionnaires either in person or via telephone (details described in the Assessment subsection). After completing the 6-month intervention, participants will be asked to undergo the post-intervention assessment. They will then be invited back for the follow-up assessment 18 months after the baseline.

Intervention sites will be located in five metropolitan cities (Beijing, Shanghai, Changsha, Chongqing and Nanchang), which are in different geographical regions of China (North, East, Middle China, Southwest and Southeast). At each site (ie, city), participants will be recruited from multiple local community resident centres and community healthcare hospitals.

Participants

The targeted population will consist of community-dwelling older adults aged 60 years and above who have risk factors threatening CVH. The risk will be evaluated using the cardiovascular risk score²² and possession of at least two of the well-recognised risk factors.⁴⁻⁷ Detailed inclusion and exclusion criteria are presented in [table 1](#).

Potential participants will be recruited via various sources, including inviting individuals from participant pools that are established through previous studies, recommendations from general practitioners and nurses, recruitment flyers posted at local community centres and healthcare centres and word-of-mouth advertisements among participants. Recruitment was planned to be started in August 2022, but due to the influence of the COVID-19 pandemic, the recruitment was delayed and not restarted until April 2023. The study will be conducted over the course of 2 to three years (April 2023 to April 2026).

An adjustment of the minimum education level was made, that is, from junior high school listed in the trial registry (9 years of education) to elementary school (6 years of education), in order to better align with the educational profile of the target population; protocol amendment has been approved by the relevant ethical authorities.

Randomisation and blinding

Eligible participants will be randomly assigned (1:1:1) to the harmony (PPI and lifestyle intervention), lifestyle (lifestyle intervention) or waitlist group. Group allocation will be carried out by an independent researcher using a computer-generated randomisation procedure. In case of spouse or partner participation, the pair will be assigned to the same allocation group to avoid contamination.

Participants and group instructors for leading intervention activities are blinded to the study design and hypotheses. Outcome assessments at any time point during this trial will be administered by trained assessors who are blinded to group allocation and study hypotheses and not involved in any intervention activities.

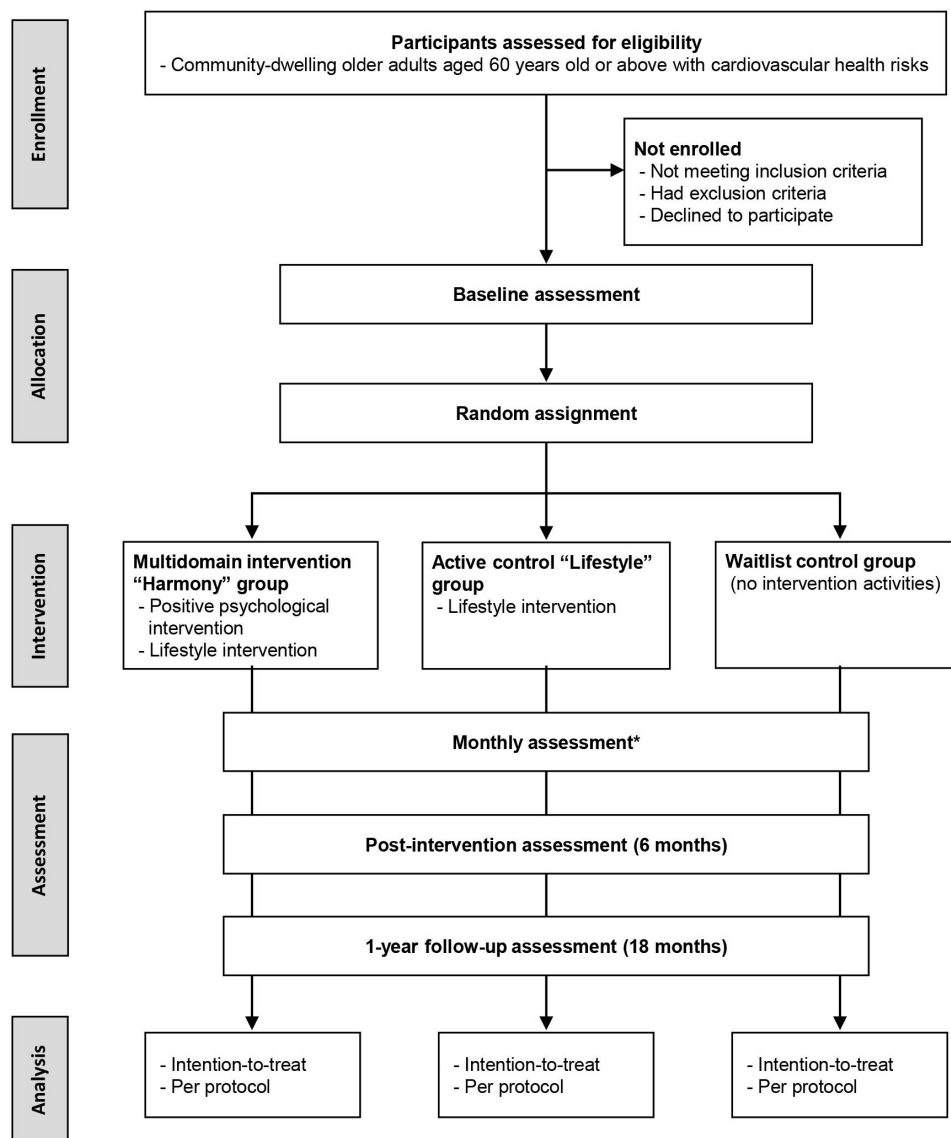


Figure 1 Study flow chart. *Brief questionnaires delivered in person or via telephone during the intervention.

Intervention

The intervention training (both harmony and lifestyle groups) will be composed of two parts: in-person group training sessions led by trained professional personnel and at-home self-monitoring completed as homework. This approach may help maintain adherence while keeping the training intensity at acceptable levels for older adults in community settings.²³ The group training is designed to incorporate group activities that aim to encourage peer support for learning new information, sharing experiences and feelings and practising new skills. The use of self-monitoring homework aims to help improve self-management behaviours and skills learnt during training and apply them to daily life. The group instructors for the harmony group are trained psychologists/counsellors plus research assistants, and for the lifestyle group, trained research assistants.

Participants assigned to the harmony group will receive a 24-session multidomain training curriculum (13

sessions on PPI, 8 on lifestyle intervention, 1 for kickoff introduction, 1 for midterm review and 1 for close-out review), of which the group sessions and homework will be delivered weekly. Group training sessions for the lifestyle group are eight lifestyle intervention sessions that are identical to those in the harmony group, which will be delivered every 3–4 weeks with the homework required to be completed on a weekly basis so that the overall training timeline length would be the same for the lifestyle and harmony groups (about 6 months). Sessions range from 60 to 80 min. The session details of themes, training content and homework are illustrated in online supplemental table 1.

Positive psychological intervention

Although there are some variations, there is substantial agreement that PWB is defined as positive feelings and thoughts that people have when evaluating their lives and experiences,^{5 24} and the appraisals are not

Table 1 Participant inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> ▶ Aged 60–80 years old. ▶ Cardiovascular risk score ≥ 5, indicating a medium to high risk. ▶ Possessing ≥ 2 cardiovascular risk factors defined as: <ul style="list-style-type: none"> – Obesity by Chinese guideline: BMI ≥ 28 kg/m². – Physical inactivity defined as below the WHO norm of 150 min of intermediate exercise per week. – Excessive alcohol consumption defined as >100 g alcohol intake per week. – Current smoker. – Depressive symptoms indicated by PHQ-9 score ≥ 5. – Symptoms of anxiety indicated by GAD-7 score ≥ 5. – Psychological stress indicated by PSS-14 score ≥ 25. – Loneliness indicated by DJGLS-6 score ≥ 2 and/or social isolation defined as living alone – History of diagnosed chronic cardiovascular conditions including hypertension, myocardial infarction, angina pectoris and/or atrial fibrillation. – History of diagnosed diabetes mellitus and/or hyperlipidaemia. 	<ul style="list-style-type: none"> ▶ Substantially poor cognitive performance indicated by MMSE score <24. ▶ Illiterate or incomplete education at elementary level (<6 years) that would limit the ability to understand the contents of assessment and intervention. ▶ Moderately severe or severe symptoms of depression indicated by PHQ-9 score ≥ 15. ▶ Severe symptoms of anxiety indicated by GAD-7 score ≥ 15. ▶ Expression of suicidal thoughts indicated by PHQ-9 item 9 score >0. ▶ Undergoing acute cardiovascular disease conditions. ▶ Any conditions that prohibit the participation of intervention activities, such as severe loss of vision, hearing, mobility or communicative abilities.

BMI, body mass index; DJGLS-6, 6-Item De Jong Loneliness Scale; GAD-7, Generalized Anxiety Disorder 7-Item Scale; MMSE, Mini-Mental State Examination; PHQ-9, Patient Health Questionnaire; PSS-14, Perceived Stress 14-Item Scale.

only overall ones but also specific ones when people react to events, other people and environment. PPI is a favourable method designed to enhance PWB with specific strategies targeting cognitions, feelings and behaviours.²⁵ Thus, the PPI component of the ACCOMPLI-CH trial focuses on coaching participants to reinforce positive cognitions about themselves (positive cognition), positively regulate their feelings and experiences (positive experience) and construct and maintain positive social relationships with others (positive relationships). Based on the diverse themes commonly used in the PPI literature^{26 27} and comments from a focus group of local older adults, 13 thematic sessions are developed. Five sessions are developed for the positive cognition module: accomplishment, character strengths, meaning in life, values and principles, and goals. Four sessions for the positive experience module: mindfulness, coping with negative emotions, optimism and savouring. Lastly, four sessions for the positive relationship module: gratitude, family relations, broad social interactions and prosocial behaviour. The techniques are commonly used worldwide, but the specific materials are adapted to Chinese culture. For example, in the session for values and principles, instead of Schwartz's values circumplex,^{26 27} the eight virtues from Confucianism are used as they are more familiar to older Chinese adults. Each session also has designated homework so that participants can review and practise what they learn in daily life. Since the goal is to increase CVH eventually, the training materials also coordinate with lifestyle management; for instance,

in the session-themed goals, one of the group activities will be goal setting and implementation using health behaviour change as an example to achieve CVH.

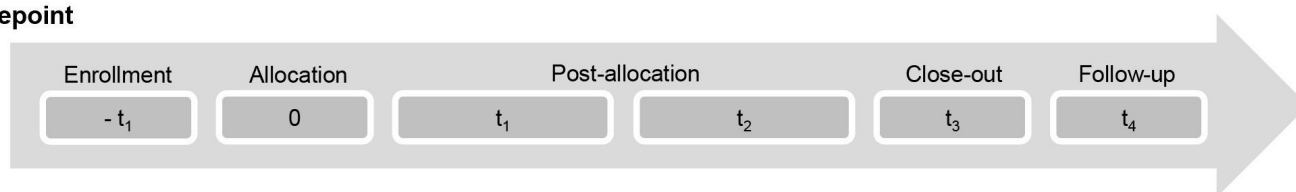
Lifestyle intervention

In accordance with the national guidelines for lifestyle management for CVH among older adults,^{28 29} eight group sessions are developed, in which three are for physical exercises, three are for nutrition, one is for sleep and one is for other health behaviours (tobacco use, alcohol consumption and medication adherence). The training contents are tailored to older adults in Chinese community settings, for example, one exercise session is about teaching Baduanjin (eight segments of brocade), which is a traditional Chinese mind-body exercise that presents low risk and several physical benefits for older adults with CVD risks.³⁰ Although there are eight group sessions, homework assignments are designed on a weekly basis so that participants are reminded to reinforce health behaviours such as physical exercise and healthy eating every day throughout the whole intervention programme.

Assessments

As depicted in figure 2, there are four comprehensive assessment visits overall, including one for screening in which basic demographic information and eligibility measures will be collected, one baseline visit assessing all outcome measures, one post-intervention visit assessing all outcomes again and one follow-up visit assessing most of the measures except for exploratory outcomes.

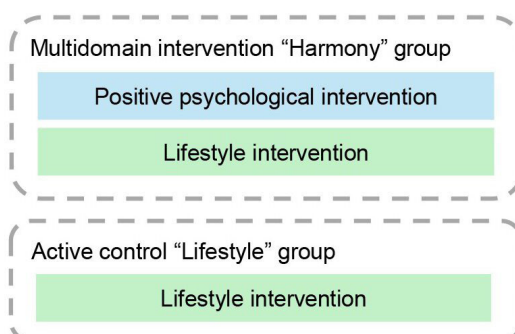
Timepoint



Enrollment



Interventions



Assessments

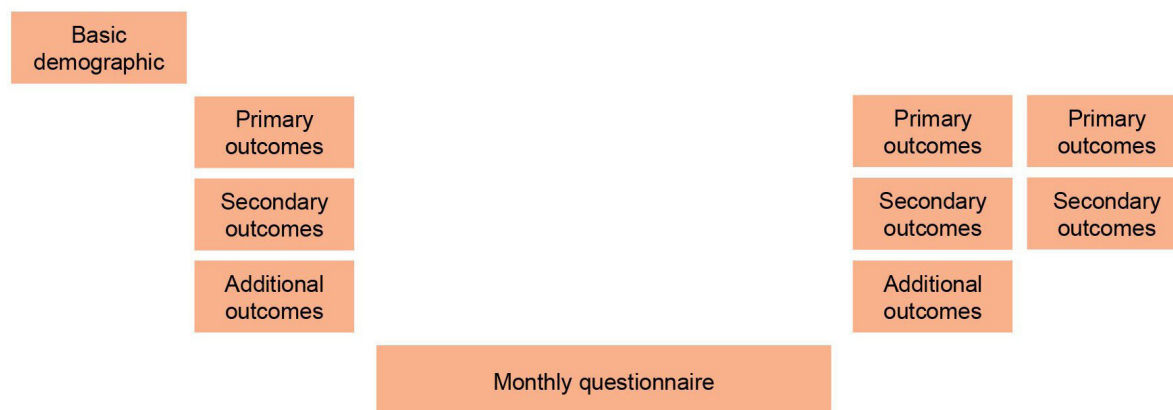


Figure 2 Study timeline and assessment schedule. t₁ = start of intervention activities; t₂ = end of 6-month intervention activities; t₃ = immediate post-intervention assessment; t₄ = follow-up assessment at 18 months.

Primary outcomes

Based on the goals and rationale of this trial, the effectiveness of the intervention will be examined from two aspects: CVH index and PWB.

CVH will be examined by a composite z-score of systolic blood pressure, total cholesterol, high-density lipoprotein and low-density lipoprotein levels. For each parameter, a z-score will be calculated. The composite z-score will be the average of those z-scores of individual parameters. Blood pressure will be the average of measuring twice the right arm with an Omron upper arm cuff monitor in a resting sitting position. Fasting blood tests will be performed for the lipid profile at community

hospitals. These measures are chosen after taking several considerations into account. First, they are included in the calculation of the cardiovascular risk score,²² which could be expected to change due to the intervention, and a composite score would help illustrate the overall potential effect of the intervention on CVH. Second, we would like not to include self-reporting measures for health behaviours such as physical activity and nutrition questionnaires for our primary outcomes, since the self-reports may be prone to reporting bias, though self-reports are widely and commonly used. Lastly, clinically relevant outcomes, such as incident CVD, are not used

because a longer follow-up period or considerably larger sample size would have been required for those.

PWB will be evaluated from three perspectives³¹: hedonic well-being, which will be measured by the Positive Affect and Negative Affect Scale (PANAS)³²; eudaimonic well-being, which will be measured by the Meaning in Life Questionnaire³³; evaluative well-being, which will be measured by Satisfaction with Life Scale.³⁴ These measures are widely used in relevant literature.

Secondary outcomes

The main secondary outcomes include the individual components of the primary outcomes, other physical and biological indicators such as diastolic blood pressure, triglyceride levels, waist circumference and body mass index and other psychological health measures such as the Life Orientation Test for optimism,³⁵ Mindful Attention Awareness Scale for mindfulness,³⁶ Patient Health Questionnaire for depressive symptoms,³⁷ Generalized Anxiety Disorder 7-Item Scale for anxiety symptoms³⁸ and Perceived Stress 14-Item Scale for stress level,³⁹ health behaviours such as the Physical Activity Scale for the Elderly scale for physical activity level,⁴⁰ Pittsburgh sleep quality index for sleep quality,⁴¹ self-reported dietary habits,^{23 29} social connection indicators such as 6-Item De Jong Loneliness Scale for loneliness,⁴² Lubben Social Network Scale 6 items for social network size,⁴³ frequencies for participations in social activities, and Multidimensional Scale of Perceived Social Support⁴⁴ and subjective self-reports of health status, such as rating on overall health condition, number of sick days during a week and subjective age. Other secondary outcomes include the Mini-Mental State Examination for global cognitive function,⁴⁵ Prospective and Retrospective Memory Questionnaire for self-report memory ability⁴⁶ and major life events.

Additional/exploratory outcomes

For exploratory purposes for the effects of intervention, clinical outcomes including incident CVD and mortality will be recorded, as well as subjective memory complaints.⁴⁷ The Simplified Type A Personality questionnaire for CVH-related personality⁴⁸ and the Mental Health Inventory for the Elderly for overall mental health⁴⁹ are administered at baseline only since the time frames for these two measures are longer than the intervention period. In addition, based on the variation of resource availabilities at different testing sites, a subsample of participants will be asked to complete some additional measures. High-sensitivity C reactive protein level (taken together with lipid blood test) will be used as an inflammatory indicator. To examine the effects on hormone regulation in reaction to stress, particularly the function of the hypothalamic-pituitary-adrenal axis, long-term cortisol and cortisone levels will be tested with a hair sample.⁵⁰ A computerised emotional Flanker task using schematic faces of positive and negative emotions will be used,⁵¹ which would be a relatively objective assessment of emotional processing. Wearable devices (sports

watches) will be used for assessing daily physical activity (eg, number of steps) and sleep activity (eg, total sleep duration, nap duration) by asking consenting participants to wear the devices for 7 consecutive days.

Monthly assessment

To investigate the effects of the intervention programme with a relatively momentary perspective, all participants will also be asked to complete the PANAS for positive and negative affect, subjective rating on overall health and a number of sick days during a week at the end of each month during the 6 months of intervention. Since the comprehensive post-intervention assessment will be given, there will be 5 monthly assessments in total.

Adverse events

This trial is considered low risk because it focuses on promoting PWB and health behaviours through psychological counselling, education and lifestyle advice, and no medications are prescribed. Although serious adverse events would not be expected, we will record and monitor any possible events during the monthly assessments and also during the routine intervention activities for the harmony and lifestyle groups. Since there is physical exercise training, musculoskeletal or connective problems such as muscle soreness and joint pain might occur. Additionally, negative emotions may be expressed during the PPI activities. However, because group instructors are trained professional psychologists/counsellors and research assistants (mostly graduate students in psychology or geriatrics) and the instructor manual also provides steps and tips for handling possible intervention-related adverse events, safety would be largely ensured.

Quality control and data management

The study quality is continuously monitored at all stages of data acquisition and for the intervention activities. Data will be collected and validated at each centre (city-level) and also monitored by the research team throughout the trial. Assessments will be administered by trained personnel, and data input will be done by different trained assistants using Epidata. Medical data for biological indicators will be collected from hospitals. Data will be checked at least three times, including one after data entry, one at each centre by centre supervisors and one at the research team level, before merging to the central database. The dataset will be de-identified and stored on a secured server, and only primary researchers will have access to the dataset. For group instructors leading the intervention activities, a structured instructor protocol manual is established by the research team for them to follow. The protocol manual includes general guidelines and tips for leading the activities, specific lesson plans for all group sessions, PowerPoint slides to be presented to participants, multimedia aids (videos and music) and homework sheets. Within-centre and cross-centre meetings are regularly organised so that the quality and progress of the intervention can be monitored.

Patient and public involvement

Community-dwelling older adults were involved in the development of this protocol, particularly during the design of the intervention training content. A focus group was established to provide perspectives on possible themes for the training sessions. During the trial, community centre personnel will help with participant recruitment, such as distributing recruitment information and contacting potential participants for eligibility screening. Enrolled participants will evaluate their experiences of intervention participation at the end of the study.

Statistical considerations

Sample size

Originally, we planned to calculate our sample size based on both the primary outcome for CVH and PWB. Nonetheless, since the results on biological indicators such as blood pressure and lipid profiles are relatively mixed, we base the sample size calculation on expected changes in PWB. According to meta-analyses,^{8 52 53} the estimated effect size ranges from small to medium, about 0.23–0.48. Therefore, to be conservative, with an α of 0.05 and a small effect size of 0.23, to achieve a power of 0.8, the minimum sample size per group is 298. Assuming a dropout rate of about 15% according to similar studies in local community settings,^{23 54} a size of 350 participants per group will be needed, and thus, the estimated total number of participants is 1050. This protocol amendment was approved by the local ethics committee (Institutional Review Board of the Institute of Psychology) before the completion of participant recruitment.

Data analyses

Primary data analyses will follow the intention-to-treat principle, such that participants who drop out during the programme will be invited back at the end of the intervention and follow-up for post-baseline assessments. To examine the effects of intervention, multilevel mixed models will be used to compare the between-group differences in changes in outcomes, meanwhile accounting for participant variability by assessing the random effects of intercepts and slopes for participants. Linear models will be used for continuous variables, and generalised linear models will be used for categorical variables. If there are any differences in baseline participant characteristics, they will be adjusted as covariates. Statistical adjustments will be applied to multiple tests. Sensitivity analyses will be conducted per protocol and also based on characteristics of individual differences. Missing data will be imputed using multiple imputation methods. Data analyses will be performed using SPSS V.28 and R V.4.3.3.

ETHICS AND DISSEMINATION

A centralised ethics review process was conducted for this multicentre study. As the Institute of Psychology at the Chinese Academy of Sciences is the main funding recipient and primary coordinating institute, the study

protocol was approved by the ethics committee of the Institutional Review Board of the Institute of Psychology, Chinese Academy of Sciences in April 2022, approval number H22070. A signed written informed consent form will be obtained from all participants at their screening and baseline assessments (see online supplemental file 2 for sample participant consent forms). After trial completion, the results will be disseminated through published manuscripts and presentations at scientific conferences.

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