

BMJ Open Cardioprotective and mentally protective effects of the Mediterranean-dietary approaches to stop hypertension intervention for neurodegenerative delay diet combined with forest bathing among adults with elevated blood cholesterol: a parallel group randomised controlled study protocol

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ABSTRACT

Introduction The prevalence of cardiovascular diseases (CVDs) is rapidly increasing across Asia, with the burden particularly high among individuals aged ≥ 50 years. Elevated low-density lipoprotein cholesterol (LDL-C) level is a well-established causal risk factor for CVDs. Mediterranean-Dietary Approaches to Stop Hypertension Intervention for Neurodegenerative Delay (MIND) diet is a cardioprotective diet, which is rich in plant-based foods. Combining it with stress-reducing practices, including forest bathing (FB), which involves immersive exposure to forest environments, has been shown to reduce LDL-C levels and other cardiovascular risk factors by modulating pro-inflammatory responses. However, existing evidence is limited due to small sample sizes and poor study design. Therefore, this study aims to investigate whether the MIND diet combined with FB can reduce CVD risks among Chinese adults in Hong Kong. It also compares the effects of the MIND diet combined with FB on cardiovascular and mental health.

Methods and analysis A single-blind, randomised controlled trial involving three groups will be used to assess the impact of the MIND diet combined with FB on LDL-C levels in adults aged 50–75 years with elevated LDL-C levels. Participants ($n=273$) from local community centres will be randomly assigned to the MIND-plus-FB (who will receive nutrition education, follow the MIND diet for 12 weeks and participate in regular FB sessions), MIND-alone (who will receive nutrition education and follow the MIND diet for 12 weeks) or routine care (who will continue their usual activities and receive a general health talk along with pamphlets on cardiovascular risks) group. The change in LDL-C levels will be measured at weeks 4 and 12 (primary outcome). Additionally, changes in high-density lipoprotein cholesterol level, triglyceride level, glucose level, systolic blood pressure,

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The study employs a randomised controlled trial design with three parallel arms, which minimises selection bias and enhances the reliability of causal inferences.
- ⇒ The three-arm structure enables direct comparisons between two interventions (MIND-plus-FB vs MIND alone) and a control group (routine care), facilitating evaluation of the most effective approach.
- ⇒ While researchers are blinded to group assignments, participants are not, which may influence participant behaviour or responses.
- ⇒ As a multicentre study, conducting the study across multiple sites increases the generalisability and applicability of the findings.

waist circumference, body mass index, anxiety levels and emotional state will also be assessed at weeks 4 and 12. Statistical analyses will include intent-to-treat, χ^2 test, analysis of variance and generalised estimating equations.

Ethics and dissemination This study has been approved by the Research Ethics Committee of Tung Wah College, Hong Kong (reference number: REC2023164). Research findings will be disseminated through publication in peer-reviewed journals and presentations at academic and primary healthcare conferences.

Trial registration number ClinicalTrials.gov ID: [NCT06222632](https://clinicaltrials.gov/study/NCT06222632), registered on 25 January 2024. The ClinicalTrials.gov data are available at: <https://clinicaltrials.gov/study/NCT06222632?term=NCT06222632&rank=1&a=2&tab=history>



INTRODUCTION

Background

Cardiovascular diseases (CVDs), particularly ischaemic heart disease and stroke, are the leading causes of global mortality and morbidity. The global prevalence of CVDs was estimated at 523 million cases in 2019, culminating in approximately 18.6 million mortalities. Ischaemic heart disease and stroke were also implicated in 182 and 143 million cases of disability, respectively.¹ Current clinical guidelines consistently recommend lowering low-density lipoprotein cholesterol (LDL-C) levels to <2.6 mmol/L as a primary strategy for preventing CVDs and advocate initiating statin therapy in adults aged 40–77 years whose LDL-C levels exceed 3.4 mmol/L.² However, previous research has identified a reluctance among some individuals to initiate statin therapy due to concerns about potential adverse effects,³ thereby increasing their risk of developing CVD.

Psychosocial stress refers to the behavioural and physiological responses to adverse life circumstances encountered in daily living.⁴ Persistent psychosocial stress elevates LDL-C levels and activates the sympathetic nervous system and hypothalamic-pituitary-adrenal axis, increasing cortisol levels in the bloodstream and contributing to hypertension, visceral obesity and elevated CVD risk.⁴ CVDs are primarily driven by sustained inflammatory processes within the vascular system, which lead to the development of atherosclerosis.

Elevated LDL-C levels (>3.4 mmol/L) and prolonged psychosocial stress exposure increase the secretion of pro-inflammatory cytokines, such as interleukin (IL)-1 beta, IL-1, IL-6, tumour necrosis factor-alpha and C reactive protein. This leads to insulin resistance, lipid accumulation, visceral obesity, salt retention, high blood pressure and elevated heart rate, all of which contribute to a higher risk of CVD-associated morbidity and mortality.^{2,5} Chronic production of inflammatory cytokines increases the risk of CVD in individuals aged >50 years.⁴

Notably, most cardiovascular events are largely preventable by modifying behavioural risk factors. Studies suggest that the Mediterranean-Dietary Approaches to Stop Hypertension (DASH) Intervention for Neurodegenerative Delay (MIND) diet, which emphasises 10 brain-healthy, plant-based foods, offers advantages such as weight loss and reduced risks of metabolic syndrome, cognitive decline and depression.⁶ Stress-reducing practices, such as forest bathing (FB), which involve immersive bodily and sensory engagement with forest environments, promote relaxation and cognitive restoration.⁷ This practice can lead to reduced blood pressure, lower anxiety levels and improved moods.^{7,8} Due to the high prevalence of stress and demanding lifestyles in Hong Kong, many residents frequently consume fast foods, such as preserved vegetables, processed and canned meats, potato chips and prawn crackers.⁹ This dietary pattern, compounded by persistent stress, elevates the risks of hypercholesterolaemia and hypertension, making these interventions particularly relevant for the Hong Kong population.^{10,11}

This study hypothesises that adopting the MIND diet in combination with FB will additively reduce CVD risk factors. A pilot randomised controlled trial (RCT) conducted by our research team reported that the MIND diet combined with FB and the MIND diet alone have the potential to reduce cardiovascular risk factors, including lowering LDL-C levels, reducing anxiety and promoting a positive mood in adults with hypertension after a 4-week intervention, likely owing to their anti-inflammatory properties.¹² Although the MIND diet and FB independently have been shown to reduce LDL-C levels, blood pressure and stress, findings from the pilot RCT suggest that FB enhances the MIND diet's effect in reducing CVD risk factors in the short term. Further evaluation is warranted to assess the combined therapeutic benefits of the MIND diet and FB on cardiovascular and mental health outcomes among Chinese adults with higher CVD risk factors, using a larger sample size and extended intervention period.

Study objectives

This randomised controlled trial aims to establish a protocol for evaluating the efficacy of the MIND diet combined with FB in lowering CVD risk factors among Chinese adults aged 50–75 years with elevated risk of CVDs in the Hong Kong Special Administrative Region (SAR), China.

This study's primary outcome is to compare the effects of the MIND diet combined with FB versus the MIND diet alone and routine care in lowering LDL-C levels over a 12-week intervention. Secondary outcomes include evaluating the impact of the three interventions on LDL-C at week 4, cardiovascular risk factors (total cholesterol, high-density lipoprotein cholesterol (HDL-C), triglyceride, and glycaemic levels and systolic blood pressure (SBP)), adiposity (waist circumference and body mass index) and mental health outcomes (anxiety and mood) at weeks 4 and 12. The study will also examine whether demographic characteristics, lifestyle behaviours and medication regimens moderate the intervention effects across the study groups.

We hypothesise that participants receiving the MIND diet combined with FB will exhibit a significantly greater reduction in LDL-C levels after 12 weeks than those receiving the MIND diet alone or routine care. Moreover, the MIND diet combined with FB will lead to superior improvements in cardiovascular risk factors, adiposity measures and mental health status compared with the MIND diet alone and routine care.

Trial design

This study is a single-blind, three-arm RCT with a block design (1:1:1). Eligible participants will be randomly assigned to the MIND-plus-FB, MIND-alone or routine care group. The MIND-plus-FB and MIND-alone groups will receive interventions, while the routine care group will serve as the control. Group allocation will be assigned to groups using a random number generator and block

randomisation procedures with a block size of six or 12. As a single-blind trial, only the assessors will be blinded to the participants' group assignment.

METHODS AND ANALYSIS

Study setting and participants

The study is planned to begin on 1 March 2024 and conclude on 28 February 2027. Chinese adults aged 50–75 years with elevated LDL-C levels will be recruited from local community centres located in four of the 18 districts in Hong Kong SAR, China. Community centres in Hong Kong, such as district health and neighbourhood centres, are commonly operated by non-governmental or non-profit organisations. These centres provide a range of social services and community support, including skill development programmes, recreational activities and health screening and promotion initiatives for specific groups, making them suitable venues for engaging the target population.

Posters will be shared on the centres' websites or WhatsApp groups 2 months before the intervention begins. Potential participants will be invited to complete an online self-administered questionnaire collecting demographic details. The research team members will promote the study through phone calls, email and online registration links. After completing the questionnaire, participants will undergo a health screening administered by a trained research assistant (RA) or healthcare provider to determine eligibility.

Eligibility

Inclusion criteria

These include the following:

- ▶ Aged 50–75 years.
- ▶ Chinese ethnicity.
- ▶ Ability to speak and read Chinese (Cantonese).
- ▶ Point-of-care test (POCT) showing LDL-C level >2.6 mmol/L.
- ▶ State and Trait Anxiety Inventory (STAI) score ≥ 38 .
- ▶ Physically fit to participate in mild-intensity exercises.

Exclusion criteria

These comprise the following:

- ▶ Conditions that may be difficult to manage, such as chronic obstructive pulmonary disease and chronic kidney disease.
- ▶ Allergy to more than one type of food, such as nuts, berries, olive oil or fish.
- ▶ Prescription of medication for a clinically diagnosed mental disorder or a condition.
- ▶ Current or prior participation (within the last 3 months) in any dietary or relaxation programme.
- ▶ Pregnant.
- ▶ Those SBP ≥ 159 mm Hg.
- ▶ Inability to walk independently.

Consent

Written informed consent will be obtained during the eligibility screening by an RA who has been trained by

the research team. Participation in the study is entirely voluntary, and participants may withdraw at any time without negative consequences. All collected data will be anonymised and treated with strict confidentiality and not shared with third parties. Data files will be encrypted, and hard copies will be stored securely in a locked cabinet within a locked room.

Interventions

Choice of comparators

Selecting comparators in this study enables the assessment of the potential additive influence of the MIND diet and FB. The MIND-plus-FB group received both dietary and environmental interventions to establish their combined effect. Only the diet is included in the MIND-alone group. The routine care group continues their standard practices, receives general health talks related to cardiovascular risks and is given pamphlets from the Department of Health of Hong Kong SAR, China, serving as the reference group. Such an arrangement allows for a detailed evaluation of the interventions' impact on modifying established cardiovascular risk factors and mental health, to understand their applicability in preventing CVDs.

Intervention description

This study will investigate the effects of the MIND diet combined with FB in a three-arm intervention. Eligible participants will be assigned to one of the following three groups: (1) the MIND-plus-FB group will undergo a 12-week MIND diet intervention, including four consecutive weeks of nutrition education sessions. They will also participate in four consecutive FB sessions designed to enhance compliance with the MIND diet and support other necessary lifestyle changes; (2) the MIND-alone group will receive the same nutrition education sessions and dietary intervention as the MIND-plus-FB group for the same duration, but without the FB sessions; (3) the routine care group will continue their usual activities and receive a general health talk and pamphlets on cardiovascular risks.

Criteria for discontinuing or modifying allocated interventions

Participants may be withdrawn from their assigned group if they experience severe side effects, including allergic reactions or deterioration of their health condition. Modifications in the interventions will be made if the participant's health changes or if the participant wishes to withdraw. Any changes made shall be recorded to assess their potential impact on the study objectives.

Strategies to improve adherence to interventions

Participants will continue their usual daily activities during the intervention. A logbook will be provided to record and keep track of their adherence to both the MIND and FB programmes. Weekly group WhatsApp calls will provide support and address any questions or challenges they may encounter. If participants fail to



adhere to the intervention, an RA will provide feedback and help address the issues.

Relevant concomitant care permitted or prohibited during the trial

Participants may continue using prescribed medications for chronic diseases, including antihypertensive medications and statins, as advised by their medical doctors, provided these drugs do not interfere with the study protocols' implementation. However, they are not allowed to enrol in other dietary or relaxation programmes during the study to ensure that the recorded effects are solely attributable to the implementation of the interventions.

Provisions for post-trial care

Healthcare professionals will evaluate the participants' cardiovascular and mental health status at the end of the trial. They will provide recommendations based on the test results to enhance overall health outcomes. The risk of harm is low in this study; however, potential harms include dietary alterations that might adversely affect participants or psychological distress likely caused by the assessment. Participants are advised to inform the research team or private investigator (PI) immediately. Potential hazards of FB sessions include physical injury, insect bites and attacks by monkeys or wild boar. Participants will be advised on how to react to these encounters. FB guides, who are trained in wilderness first aid, ensure safety during walks.

Outcomes

The first measure of efficacy in this study will be the percentage change in LDL-C at week 12. Secondary outcomes will include the impact of changes in LDL-C levels at week four on HDL-C, triglyceride, glucose and total cholesterol levels; SBP; waist circumference; body mass index; anxiety levels and mood state at weeks 4 and 12. SBP will be evaluated using a standardised digital automatic home blood pressure monitor (Omron M6 Comfort, HEM-7221-E) that conforms to the 2010 European Society of Hypertension International Protocol Revision guidelines.¹³ The RAs will take participants' blood pressure in a sitting position after they have rested for approximately 10–15 min. Two blood pressure readings will be taken 5 mins apart, and the average will be recorded for comparison. POCT will be used to collect blood samples for the lipid panel, including total cholesterol, HDL-C, triglyceride, LDL-C and glucose levels. The testing will be conducted using the CardioChek PA, which is a Food and Drug Administration-cleared device endorsed by the CDC's Cholesterol Reference Method Laboratory Network (CRMLN).¹⁴ Participants are required to fast for 6–8 hours before POCT. Abdominal obesity will be determined by measuring the participants' waist circumference with a non-stretchable elastic band placed between the lower border of the ribs and the crest of the ilium. Anxiety levels and mood states will be evaluated using two well-validated self-reported Chinese questionnaires: the STAI and Profile of Mood States Short

Form (POMS-SF). These instruments have demonstrated significantly high reliability: alpha values ranged from 0.81 to 0.90 and 0.98 to 0.99 for the STAI and POMS-SF, respectively.^{15–17} Adherence to the MIND dietary pattern will be assessed by calculating the MIND diet score using a validated semiquantitative Food Frequency Questionnaire.¹¹ The MIND diet score evaluates adherence by assigning 0.0, 0.5 or 1.0 to 10 healthy and five unhealthy food groups, with a maximum score of 15 indicating the highest level of adherence. All physiological measurements and self-reporting questionnaires will take approximately 20 min per participant and will be recorded at the following three time points: before the intervention (baseline assessment, T0) and after the fourth (T1) and 12th (T2) week of the intervention. Trained RAs will collect all screening and assessment data and measurements at the community centre or in the classroom of the college that has been identified to reduce variations in the results. **Figure 1** shows the schedule of intervention and follow-up.

Sample size

A pilot study conducted by our team demonstrated that participants who received the MIND-plus-FB or MIND-alone interventions experienced greater reductions in LDL-C levels than those receiving routine care, with an effect size (Cohen's *f* statistic) of 0.2.⁸ A total of 273 participants will be required to test the effects of the three interventions (MIND plus FB, MIND alone and routine care) on LDL-C reduction at a 5% significance level (two-sided test) with 80% power, accounting for a 10% attrition rate. This translates to 91 participants per group, in a 1:1:1 ratio. The sample size was estimated using the F-test in G*Power V.3.1.9.4.

Recruitment

The target population for this study will be 273 participants. Several techniques will be employed to ensure the target population is reached. Invitation posters will be distributed 2 months before the intervention by placing them at various community centres, announcing the intervention online and posting on social media sites. As part of the intervention, information meetings will be held at community centres to explain the study protocol and highlight the advantages of participation. Participants randomised into the routine care group will be offered the opportunity to join the MIND or FB group after finishing the study. Interested participants will be asked to complete a demographic survey either onsite or online and undergo POCT. Follow-up reminders via calls, WhatsApp or emails will be sent to all potentially eligible participants to remind them about the research and encourage them to participate.

Assignment of interventions: allocation

Participants will be assigned to groups using a random number generator and block randomisation procedures with a block size of six or 12. An independent statistician

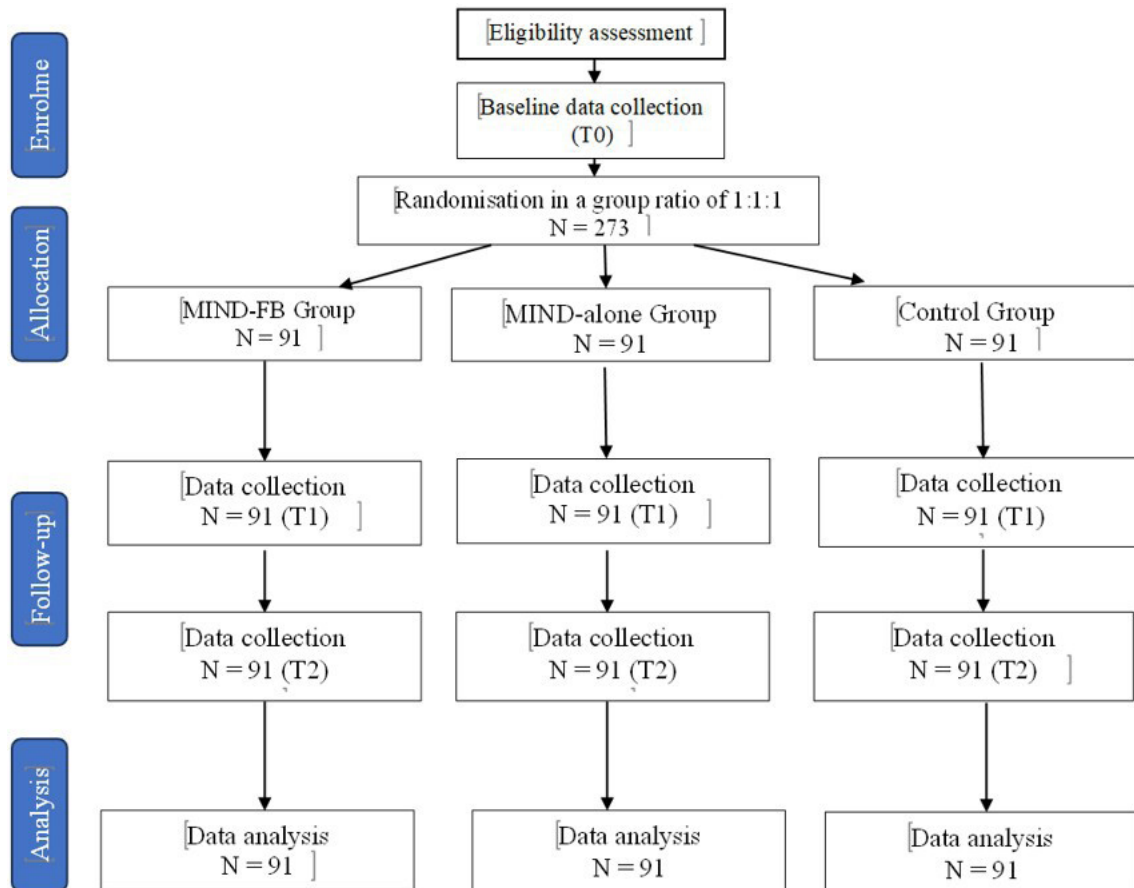


Figure 1 Intervention schedule and follow-up. DASH, Dietary Approaches to Stop Hypertension; FB, forest bathing; MIND, Mediterranean-DASH Intervention for Neurodegenerative Delay.

will prepare the allocation sequence using computer-generated random numbers. Only RAs will be involved in recruiting participants. All assignments to interventions will be done independently by another research team member to ensure that the recruiters are blinded. Each participant will receive a unique serial number, and a research team member will keep a record containing their names and assigned group numbers.

The allocation sequence will be masked in sequentially numbered, opaque, sealed envelopes to reduce any influence from participant grouping. Trained RAs will conduct enrolments but will have no interaction with the study participants regarding their assignment to any of the intervention arms. A different RA will be responsible for enrolling participants.

Assignment of interventions: blinding

This study will be conducted as a single-blind RCT; therefore, the assessors will be blinded to the participants' group allocations. However, the participants, individuals assisting with the randomisation procedure and the intervention provider will be aware of the group assignment. The procedure for unblinding will not be applicable.

Data collection and management

Plans for assessment and collection of outcomes

Measures for this trial will include a combination of self-administered questionnaires, POCT and assessments at baseline and outcome measures. POCT will be conducted at baseline, week 4 and week 12 to measure participants' lipid panel (LDL-C, HDL-C, triglyceride and glucose levels). Genetic testing will not be performed in this trial. Procedures for data collection will also be highly controlled to facilitate comparisons across different centres. RAs responsible for conducting the evaluation will undergo rigorous training to ensure that the data are comparable. Double measurements will be made to minimise error wherever possible. All assessors will be trained in the specific assessment procedure to reduce variability and increase reliability. The study instruments will include standardised questionnaires of cardiovascular and mental health status and POCT for biomarkers of CVDs. According to the literature reviewed in this study, these tools are reliable and valid in similar populations. Data collection forms will be described in a future publication of the study protocol. All data will be deidentified, encrypted and securely archived. Paper copies will be stored in a locked drawer inside a locked room.



Plans to promote participant retention and complete follow-up

Participants will receive reminders via WhatsApp or phone calls 2 days before the sessions. Incentives will be provided, including transportation fares for FB sessions and supermarket vouchers for purchasing the recommended foods, to capture the likelihood of complete follow-up. The reasons for discontinuation or deviation will be documented.

Data management

Research team members will handle data entry and verification in a secure database. All files will be encrypted and stored on researchers' desktop computers, which will be equipped with desktop locks for added security. Participant names will be masked with serial numbers to ensure that their identities remain unknown to the researchers. Only the individual who manages the random allocation assignment will retain the list containing the participants' names and the corresponding serial numbers. Data will be entered twice by trained RAs to assess consistency. Range checks will also be performed to clean the dataset. Data management is described in detail in the study protocol.

Confidentiality

All data collected will be anonymised and maintained with strict confidentiality and will not be shared with third parties. Data files will be encrypted, and hard copies will be securely stored in a locked cabinet within a locked room.

Statistical methods

Statistical methods for primary and secondary outcomes

All statistical analyses will be conducted using IBM SPSS Statistics for Windows, V.29 (IBM, Armonk, New York, USA). A significant level of 0.05 will be used for all two-tailed tests. Intention-to-treat analysis will be used to handle any missing follow-up data. Baseline demographics, socioeconomic data, lifestyle characteristics, medical history and medication regimens across the three groups will be compared using χ^2 tests and one-way analysis of variance with post-hoc comparisons. Changes in LDL-C levels and other outcomes at weeks 4 and 12 will be evaluated using generalised estimating equation (GEE) models, which will adjust for random errors from cluster sampling. Secondary analyses will be used to refine these GEE models by adjusting for potential confounders such as demographic characteristics and socioeconomic status. Separate GEE models will be used to assess dietary changes across the three groups at weeks 4 and 12.

Interim analyses

This trial will conduct only a final analysis of the results; no interim analyses are planned. A mid-term progress report is required 15 months after the project holder initiates the project. The following report will be submitted to the relevant Research Grants Council of Hong Kong Committee/panel members to review the project's progress and to investigate any issues identified with the project. An independent data monitoring committee

(DMC) will terminate the trial early if health concerns related to safety or other crucial matters are raised. Interim results will be blinded, and only this committee will decide whether to continue or terminate the trial.

Methods for additional analyses

Post-hoc analyses will be conducted adjusting for covariates including age, sex, baseline LDL-C level and compliance with the MIND diet/FB intervention. Subgroup analyses will be used to examine the impact of the MIND diet/FB intervention across participants according to age group, sex, the presence of medication use, physical activity level and the presence of comorbidities. Intention-to-treat analysis will be used to account for missing data at follow-up. We will double-check and ensure that no data are missing at baseline.

Plans for access to the full protocol, participant-level data and statistical code

These data include the full trial protocol, participant-level data and, where applicable, statistical code. All of these will be provided following data anonymisation and masking per Good Clinical Practice guidelines set forth by the RCG, on reasonable request. The request will be made to the principal investigator, and access will be granted in a manner that safeguards participant anonymity and upholds data privacy rights.

Oversight and monitoring

Coordinating centre and trial steering committee composition

The administering centre, including the PI and trained RAs, will serve as the main body responsible for organising the trial activities, such as recruitment, data collection and assessment. Specifically, the PI will manage the overall conduct of the trial. The RAs, who will be selected and trained, will perform various important activities during the trial, including project management and day-to-day running. An independent trial steering committee specialising in cardiovascular health, dietetics and mental health will oversee the trial, ensure proper implementation of the trial protocol and address any ethical issues and safety concerns.

Data monitoring committee composition and role

The DMC, including the Tung Wah College (TWC) research committee, will comprise three independent members with experience in clinical trials, biostatistics and CVDs. Additionally, the DMC will oversee the trial's safety, efficacy and data quality. They will meet at fixed intervals to review the data and advise whether the trial should proceed, be altered or be terminated. The DMC will also have a direct line of accountability to the trial's steering committee.

Adverse event reporting and harms

All adverse events (AEs) that occur during the trial will be noted and documented by trained RAs and reported to the PI within 24 hours throughout the trial. Severities of AEs (SAEs) will be reported to the ethics committee

in the shortest time possible, and within 1 day of their occurrence in this case. Any AE or SAE that occurs will be recorded, along with the link to the intervention. The trial steering committee will examine these AE reports and take corrective action if necessary.

Trial auditing frequency and plans

This trial will undergo periodic audits by an independent auditor who will be hired solely to scrutinise expenditures. The auditors will not be involved in the trial, and their role will be limited to financial accountability. Finally, the outcome of the audit will be reported to the trial steering and ethics committees to ensure the study remains within the set budget.

Protocol amendment communication plan

Any substantial changes to the trial protocol will be promptly reported to the ethics committee, trial participants and other stakeholders. All changes will be entered into the trial registry and communicated to the trial participants. Patients will also be educated on any changes anticipated to influence their continued enrolment in the trial.

Patient and public involvement statement

Participants and the public were not involved in the design, conduct, reporting or dissemination plans of this research.

ETHICS AND DISSEMINATION

Ethics approval for this project was granted by the Research Ethics Committee of TWC, Hong Kong (reference number: REC2023164). Written informed consent will be obtained from all participants by an RA trained by the research team (ie, the authors).

The trial outcomes will be published in scientific journals, presented at national and international conferences and reported to trial participants at the study site in a summarised form. Furthermore, the implications will be disseminated to healthcare practitioners, policymakers and community groups to provide useful knowledge that can enhance practices and policies related to cardiovascular and mental health.

DISCUSSION

This RCT aims to investigate the potential benefits of combining the MIND diet with FB in reducing CVD risk factors and improving mental health in Chinese adults aged 50–75 years who are at high risk for CVDs. This study specifically examines the effects of the following three interventions: MIND plus FB, MIND alone and routine care. The study implications will provide insights into the efficacy of the MIND diet combined with FB as an intervention for minimising CVD risk factors and enhancing mental health among the adult population. Participants may directly gain from the interventions, such as the MIND diet, MIND plus FB and health talks, which will

address participants' CVD risk factors and mental health. The delivery of these interventions may enable multiple outcomes that comprehensively assist participants in making dietary modifications, engaging in low-intensity physical activity and practising relaxation. Furthermore, this trial is expected to generate additional evidence on the efficacy of this potent intervention in lowering CVD risk factors and enhancing mental health in the intended population. If confirmed in this study, positive results will demonstrate that the timely adoption of the MIND diet combined with FB can lead to a notable improvement in the quality of life of adults with high LDL-C levels.

This trial's results will be significant to regional healthcare facilities, as the study could demonstrate that the MIND diet combined with FB is a viable therapy for adults with elevated LDL-C levels. The findings obtained from these interventions will be communicated at conferences, through publications, websites and workshops to foster understanding and eventual acceptance among various categories of health professionals and the general public. This RCT will have the potential to make a notable contribution towards preventing and lowering the risk of CVDs. Therefore, proving the effectiveness of the MIND diet combined with FB in this study could bring tangible benefits to clinical nutrition practices, dietary interventions and outdoor activities such as forest walks. It would also enhance patient education, self-management and stress management. Furthermore, implementing these evidence-based interventions can reduce the burden of CVDs on the population and improve overall health outcomes.

TRIAL STATUS

Protocol version/date: V.1.0/amendment 0 (24 January 2024).

Replaces: V.2.0/amendment 1 (25 March 2024).

Revision: the overall status was updated from 'not yet recruiting' to 'enrolling by invitation'. Additionally, the study start date was changed from '1 March 2024 (estimated)' to '1 March 2024 (actual)', along with updates to the contact person and location. This change was made to reflect the current status of the study.

Recruitment start date: 1 March 2024.

Recruitment completion date: the recruitment phase is expected to end by 30 April 2026, subject to potential changes or delays.

Trial primary sponsor: research ethics committee of TWC, Hong Kong. Email: ro@twc.edu.hk. Reference number: REC2023164.

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Contributors PSQL and KYY conceived the study and developed the protocol, with input from DCNW, KSY, CPY and AYL. PSQL, KYY and DCNW developed the statistical analysis plan. PSQL wrote the first draft of the manuscript. PSQL and KYY made subsequent revisions, with critical feedback from DCNW, KSY, CPY and AYL. PSQL and KYY contributed to the refinement and finalisation of the study protocol and trial implementation. All authors contributed to the preparation of this manuscript and have reviewed and approved the final version. KYY is the guarantor of this work and accepts full responsibility for the integrity of the data and the accuracy of the analysis.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the Research Ethics Committee of Tung Wah College, Hong Kong (reference number: REC2023164). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

Data availability statement Data are available upon reasonable request.

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