

Study design of a pilot randomized digital health intervention to support lifestyle management in adults with metabolic syndrome

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Abstract

Background

Digital health interventions are increasingly used to support lifestyle modification in adults at cardiometabolic risk; however, evidence regarding feasibility and implementation of such approaches in metabolic syndrome remains limited.

Objectives

This paper describes the design and rationale of a pilot randomized study evaluating the feasibility, acceptability, and implementation characteristics of a digital health–supported lifestyle intervention for adults with metabolic syndrome.

Methods

The study adopts a parallel-group pilot randomized design. Adults meeting criteria for metabolic syndrome will be allocated to an intervention group receiving a technology-enabled lifestyle support program or to a comparator condition. Primary outcomes focus on feasibility-related metrics, including recruitment, retention, adherence, and user engagement. Secondary exploratory outcomes include changes in anthropometric and cardiometabolic parameters. Data collection procedures, intervention components, and analytical strategies are detailed to inform future definitive trials.

Discussion

This study design aims to generate methodological and practical insights regarding the implementation of digital health interventions in cardiometabolic care. Findings will inform the refinement and scaling of future fully powered randomized trials.

Trial registration

Not applicable. This pilot study is designed to assess feasibility, acceptability, and implementation-related outcomes and is not intended to evaluate clinical effectiveness or to inform clinical decisionmaking or regulatory approval. Therefore, trial registration was not pursued.

Highlights

- Pilot randomized trial integrating mHealth with fish promotion in Chile.
- Feasibility and adherence outcomes for an 8-week digital nutrition program.

- Evaluates cardiometabolic indicators linked to metabolic syndrome risk.
- Jack mackerel selected for local relevance and n-3 fatty acid content.

INTRODUCTION

Noncommunicable diseases (NCDs) are among the leading causes of global morbidity and mortality, accounting for approximately two-thirds of all deaths, while cardiovascular diseases (CVD) alone represent nearly half of these fatalities [1]. This scenario poses not only a public health challenge but also a substantial socioeconomic burden due to high healthcare costs, productivity loss, and diminished quality of life—particularly among working-age adults. Despite public health efforts, the incidence of NCDs continues to rise, suggesting that current preventive approaches are insufficient to address their complex determinants. Among major risk conditions, metabolic syndrome (MetS) comprises a cluster of physiological, biochemical, and clinical abnormalities—including abdominal obesity, dyslipidemia, hypertension, and impaired glycemia—that significantly increase the risk of CVD, type 2 diabetes, and related complications [2]. In Chile, an estimated 40.1% of adults present MetS, reaching up to 58% among individuals aged 45–64 years, with no significant sex differences [3]. Diagnosis follows International Diabetes Federation criteria, requiring abdominal obesity (waist circumference ≥ 90 cm in men or ≥ 80 cm in women and/or BMI ≥ 30 kg/m²) plus at least two of the following: hypertriglyceridemia (≥ 150 mg/dL) or specific treatment; reduced HDL cholesterol (< 40 mg/dL in men and < 50 mg/dL in women) or treatment; hypertension ($\geq 130/85$ mmHg) or treatment; and fasting plasma glucose ≥ 100 mg/dL or a prior diagnosis of diabetes mellitus [4,5]. Early identification of these factors is critical to implement interventions targeting metabolic and cardiovascular risk, thereby reducing complications and the associated strain on health systems.

Regular fish consumption has emerged as a promising nutritional strategy for preventing cardiometabolic risk factors, supported by epidemiological and intervention evidence [2,6]. Fish provides concentrated amounts of essential nutrients—high-biological-value proteins, omega-3 fatty acids (EPA and DHA), vitamin D, selenium, iodine, and taurine—that influence inflammation, lipid homeostasis, and insulin sensitivity [7,8]. Proposed molecular mechanisms include modulation of pro-inflammatory cytokines (e.g., TNF- α , IL-6) by n-3 fatty acids; inhibition of intestinal bile acid absorption by bioactive peptides derived from fish proteins; and improvements in endothelial function and lipid profiles [9,10]. Although jack mackerel is an oily fish with a substantial n-3 fatty acid profile, it also contributes bioactive peptides and other essential nutrients with cardioprotective and lipid-modulating effects, supporting its selection for nutritional interventions [10]. Nevertheless, heterogeneity in study designs and differences across fish species limit generalizability, underscoring the need for more controlled and species-specific interventions.

Prospective and intervention studies have reported that regular fish intake is associated with significant reductions in waist circumference, triglycerides, and fasting glucose, as well as increases in HDL-C, particularly among adults with overweight or obesity [11,12]. Oily fish has long been recommended for

its n-3 content, and jack mackerel specifically provides meaningful bioactives that may contribute to lowering metabolic and cardiovascular risk [10,13,14]. The choice of jack mackerel in this intervention is grounded in its local availability and preliminary evidence suggesting clinically relevant benefits after a weekly intake of 400 grams distributed over three portions, observed in 8-week intervention studies [12–15]. However, its impact still needs to be evaluated in the Chilean population, considering cultural factors, dietary habits, and long-term adherence.

In parallel, mobile health (mHealth) technologies have emerged as innovative tools for the prevention and management of chronic diseases by enabling personalized education, remote monitoring, and direct patient communication [16,17]. These interventions have demonstrated efficacy in improving cardiometabolic indicators, body composition, and adherence to lifestyle recommendations, offering scalable and sustainable alternatives to traditional strategies that are often costly and time-demanding for both professionals and patients [18]. More recently, interventions leveraging reinforcement learning and intelligent mobile platforms have yielded promising results for adherence to healthy habits, glycemic optimization, and blood-pressure control, highlighting the scalable, sustainable potential of mHealth tools for primary MetS prevention and for promoting specific nutritional behaviors [19,20]. Despite this promise, there remains a notable gap in studies that integrate evidence-based nutritional strategies with mHealth interventions among Chilean adults, limiting understanding of feasibility, adherence, and effectiveness in local contexts.

In response, we propose a pilot mHealth educational system aimed at promoting jack mackerel consumption alongside personalized nutrition education among Chilean adults aged 45–64 years receiving care at the Centro de Atención Integral Médico-Odontológico Dr. Manuel Barros Monje. This integrative approach seeks not only to improve adherence to fish consumption but also to assess its impact on cardiovascular indicators associated with MetS, generating preliminary evidence to inform larger-scale interventions and the development of recommendations tailored to the Chilean context.

Working hypothesis

Implementing an 8-week mHealth educational system that promotes fish (jack mackerel) consumption and provides personalized nutrition education is feasible and improves cardiovascular indicators of metabolic syndrome (MetS) in adults aged 45–64 years.

Aim

To evaluate the feasibility and preliminary impact of an mHealth educational system that promotes jack mackerel consumption and delivers personalized nutrition education for MetS prevention in adults aged 45–64 years.

METHODS

This is a pilot, investigator-initiated, randomized, controlled, parallel-group intervention trial designed to assess the feasibility and preliminary effectiveness of an mHealth educational system that promotes jack mackerel consumption and improves cardiovascular indicators associated with metabolic syndrome (MetS) in adults aged 45–64 years.

Study arms

- **Intervention group:** Receives the 8-week intervention consisting of provision of 400 g/week of jack mackerel ($\approx$ 3 recommended portions/week) plus personalized nutrition education delivered via the mHealth system.
- **Control group:** Receives jack mackerel and outcome assessments only (no digital educational component).

Inclusion criteria

Chilean adults or Spanish-speaking immigrants aged 45–64 years; registered users of participating centers (Centro de Atención Integral Médico-Odontológico Dr. Manuel Barros Monje); availability for the 8-week study; signed informed consent; and ownership of a smartphone compatible with the mHealth platform.

Exclusion criteria

Fish allergy; diets incompatible with jack mackerel; psychiatric conditions that preclude participation; pregnancy or lactation; use of medications that could interfere with study indicators; and concurrent enrollment in other clinical studies.

Sample size: Forty participants randomized 1:1 ($n = 20$ per arm). This pilot size aligns with typical pilot proportions ($\approx$ 10–20% of the intended main trial) and a precision-oriented approach (95% confidence, $p = 0.5$, margin of error $E = 0.05$), and is feasible across both centers.

Randomization and blinding: The random allocation sequence will be generated by a member of the research team not involved in participant recruitment, intervention delivery, or outcome assessment, using a computer-generated randomization procedure. A restricted randomization strategy will be applied, consisting of stratified randomization by sex and baseline health status (presence or absence of hypertension, diabetes, or prior cardiovascular conditions), followed by simple random allocation within each stratum in a 1:1 ratio. To minimize predictability, the detailed randomization list and any blocking structure will be stored in a separate document inaccessible to personnel responsible for participant enrollment or assignment. The allocation sequence will be implemented using a centralized, password-protected digital file, accessed only by the designated researcher responsible for allocation. Personnel involved in participant enrollment and baseline assessment will not have access to the random allocation sequence. Due to the nature of the intervention, participants and intervention providers cannot be blinded to group assignment. However, outcome assessors and data analysts will be blinded to

allocation, with study groups coded using anonymized labels until completion of the primary analyses. Unblinding will occur only after database lock or if deemed necessary for participant safety, following consultation with the principal investigator.

Strategies for achieving adequate participant enrollment

To achieve the target sample size, recruitment was integrated into routine healthcare visits at the participating centers and supported by active dissemination of the project through on-site posters and virtual communication channels. Individuals who expressed interest were contacted by the research team, received standardized study information, and provided written informed consent prior to enrollment. Following enrollment, participants were systematically followed to coordinate biological sample collection and dietary assessment interviews, facilitating continued participation and minimizing losses to follow-up during the recruitment phase.

Procedures and outcomes

Baseline (week 0): Assessment of MetS indicators—abdominal obesity (waist circumference), blood pressure, triglycerides, HDL-C, and fasting glucose. Additional variables: weight, height, history of chronic conditions (hypertension, diabetes, dyslipidemia, stroke or other), age, sex, education, insurance coverage (FONASA/ISAPRE), number of children, sleep hours, working hours, current medications, dietary supplements, timing of last laboratory tests, physical activity frequency, current smoking status, self-perceived recent health changes, and motivation stage (Transtheoretical Model).

Intervention delivery: The intervention group receives an 8-week supply plan (400 g/week) and automated adherence support (reminders and brief surveys). The mHealth curriculum provides weekly instant-messaging content for 8 weeks: Mondays—cognitive-behavioral motivation; Tuesdays and Thursdays—nutrition education ($\approx$ 60% fish-focused). The control group receives fish and assessments without mHealth messages.

Concomitant care

During the trial, participants are permitted to continue receiving usual medical care and routine healthcare services, including stable pharmacological treatment for chronic conditions such as hypertension, diabetes, or dyslipidaemia. Initiation of new dietary interventions, omega-3 fatty acid supplements, fish oil capsules, or structured lifestyle programs specifically targeting metabolic syndrome is discouraged during the study period, as these may interfere with the interpretation of intervention effects. Any relevant changes in medications, dietary supplements, or healthcare interventions occurring during the trial will be recorded and considered in the analysis.

Strategies to improve and monitor adherence

Several strategies are implemented to promote adherence to the allocated intervention and comparator protocols. Participants in both study arms receive pre-portioned jack mackerel supplies corresponding to the prescribed intake of 400 g/week, accompanied by clear verbal and written instructions on preparation and consumption. In the intervention group, adherence is further supported through the mHealth system, which delivers scheduled educational and motivational messages, automated reminders, and brief follow-up prompts designed to reinforce dietary recommendations and sustained engagement. Adherence monitoring is conducted using repeated dietary assessments, including 24-hour dietary recalls administered at baseline, week 4, and week 8, and a focused food frequency questionnaire targeting animal-source protein intake. Self-reported fish consumption is quantified and compared against the prescribed weekly intake. Platform engagement metrics (e.g., message delivery and interaction indicators) are used to monitor adherence to the digital component in the intervention group. Trial conduct is monitored on an ongoing basis by the research team, with scheduled checks aligned with study visits and follow-up contacts to verify protocol adherence, data completeness, and timely completion of assessments. Given the pilot nature, short duration, and minimal-risk profile of the study, no independent trial monitoring body has been established. For both groups, deviations from the prescribed intake, missed assessments, and reasons for non-adherence are documented and considered in the interpretation of feasibility and preliminary effectiveness outcomes.

Explanation for choice of comparator

The control group was designed to receive jack mackerel and outcome assessments without access to the mHealth educational component. This comparator was selected to isolate the incremental effect of the mHealth-based educational intervention on adherence, engagement, and cardiometabolic outcomes, while controlling for the nutritional effects of fish consumption itself. By providing jack mackerel to both groups, the study minimizes confounding related to dietary exposure and ensures that any between-group differences can be primarily attributed to the digital educational strategy rather than to differences in food provision.

Dietary assessments

At baseline, conduct one 24-hour dietary recall using the five-step method, followed by a brief food frequency questionnaire (animal-source proteins only) and a Healthy Eating Index (HEI) form. At week 4, repeat a 24-hour recall and the abbreviated animal-protein FFQ (no HEI). At week 8 (post-intervention), reassess blood pressure, weight, waist circumference, triglycerides, HDL-C, and fasting glucose; repeat the 24-hour recall, the protein-focused FFQ, and the HEI. The intervention group also completes an anonymous user-satisfaction survey on the mHealth system.

Feasibility and adherence metrics: Recruitment, retention, data completeness, intervention fidelity (message delivery and receipt), platform engagement analytics, and self-reported fish intake. **Clinical outcomes (preliminary):** Within-participant change from baseline to week 8 in MetS indicators (waist circumference, blood pressure, triglycerides, HDL-C, fasting glucose). Protocol deviations, withdrawals, and reasons will be recorded and explored for impact (Fig. 1).

Expected outcomes

The expected outcomes of this pilot trial include evidence on the feasibility and acceptability of an mHealth educational system designed to promote adherence to jack mackerel consumption as a complementary strategy for cardiometabolic health. Feasibility will be primarily assessed through adherence to the prescribed intake of jack mackerel and engagement with the digital platform, providing insight into the usability and acceptability of the intervention in adults aged 45–64 years. In addition, the study is expected to generate preliminary estimates of changes in dietary intake, particularly jack mackerel consumption, assessed before and after the intervention using multiple complementary dietary assessment tools, including 24-hour dietary recalls (R24h), a quantified food frequency questionnaire focused on animal-source proteins, and the Healthy Eating Index (HEI). These measures will allow characterization of changes in overall diet quality and protein-source patterns associated with the intervention. The study is also expected to yield exploratory estimates of the magnitude and direction of change in cardiovascular indicators associated with metabolic syndrome following the 8-week intervention. Changes in waist circumference, blood pressure, triglycerides, HDL-cholesterol, and fasting glucose will be evaluated relative to baseline to explore potential cardiometabolic benefits attributable to the intervention. Given the pilot nature of the study, findings will be interpreted as exploratory, with the expectation that at least one metabolic syndrome–related indicator may show a clinically meaningful improvement, thereby informing the design, outcome selection, and sample size calculation of a future definitive trial.

Ethics approval and consent to participate: The study adheres to the Declaration of Helsinki and was approved by the Scientific Ethics Committee of the Aconcagua Health Service (Carta-C.E.C 56/2024). Written informed consent was obtained from all participants prior to study enrollment. Data confidentiality and the right to withdraw without penalty were ensured.

Consent for publication: Not applicable.

Availability of data and materials: The datasets generated and/or analyzed during the current study are not publicly available due to ethical and data protection considerations, but are available from the corresponding author upon reasonable request.

Confidentiality and data protection: Personal information from potential and enrolled participants will be collected using standardized case report forms and electronic records by authorized members of the research team. All participants will be assigned a unique study identification code, and identifiable information will be stored separately from research data. During the trial, access to identifiable data will be restricted to the principal investigator and designated research staff, and electronic data will be stored on password-protected, encrypted institutional servers. Any physical documents will be kept in locked cabinets at the coordinating site. For analysis and reporting, data will be fully de-identified, and only anonymized datasets will be used. No personal identifiers will be shared outside the research team. After study completion, data will be securely archived in accordance with institutional policies and ethical approval, ensuring confidentiality before, during, and after the trial.

Ancillary and post-trial care and compensation: Given the non-pharmacological and minimal-risk nature of this pilot nutritional intervention, no specific provisions for financial compensation are provided for participants in the event of harm related to trial participation. If a participant experiences any adverse event potentially related to the study, appropriate clinical care will be provided through the usual healthcare services of the participating centers, and the event will be documented and managed in accordance with institutional and ethical guidelines. No additional post-trial care beyond standard clinical follow-up is planned.

Communication of protocol amendments: Any important modifications to the study protocol, including changes to eligibility criteria, interventions, outcome assessments, or study procedures, will be formally documented and communicated in a timely manner. In the event of such modifications, a protocol amendment request will be submitted to the relevant Scientific Ethics Committee for review and approval prior to implementation. Once approved, protocol amendments will be communicated to all study investigators, participating centers, and relevant institutional authorities, and, when applicable, to study participants if the changes affect their participation, safety, or informed consent. All approved protocol modifications will be recorded and transparently reported in any publications arising from the trial.

Protocol and statistical analysis plan access: The full study protocol and statistical analysis plan are not publicly available. Both documents were developed specifically for this pilot study and are maintained by the research team at the coordinating institution. They are available from the corresponding author upon reasonable request.

Data access and sharing: Individual participant data will be de-identified prior to any sharing, and a complete data dictionary will be generated to document all study variables. The statistical code used for data cleaning and analysis, along with relevant study materials, will not be publicly available. De-identified individual participant data, the data dictionary, and statistical code may be made available by the corresponding author upon reasonable request, subject to approval by the research team and compliance with ethical and data protection requirements. Requests will be evaluated to ensure that data use is consistent with the original study objectives and participant consent.

Dissemination of trial results: The results of this pilot trial will be communicated to study participants, healthcare professionals, and the scientific community. Participants will receive a brief summary of the main study findings written in plain, non-technical language, delivered electronically or in person upon study completion. Results will be disseminated to healthcare professionals and researchers through publication in peer-reviewed scientific journals and presentation at national and international scientific meetings. Given the pilot and feasibility nature of the study, results are intended to inform the design of a future definitive trial rather than to support immediate changes in clinical practice.

Trial registration: Not applicable. This pilot study is designed to assess feasibility, acceptability, and implementation-related outcomes and is not intended to evaluate clinical effectiveness or to inform clinical decision-making or regulatory approval. Therefore, trial registration was not pursued.

Planned statistical analysis: We will conduct a comprehensive analysis to evaluate intervention effectiveness and feasibility. Descriptive statistics will summarize demographic, clinical, and anthropometric characteristics by study arm. Prior to analysis, data completeness will be systematically evaluated. Variables (columns) and observations (rows) presenting more than 80% missing data will be excluded due to their limited informational value and potential to introduce bias. The extent and patterns of the remaining missing data will be explored descriptively to ensure that such exclusions do not result in meaningful imbalances between study arms. All analyses will be conducted using available data, with the effective sample size reported for each outcome. Between-group differences in change from baseline to 8 weeks for metabolic-syndrome indicators—waist circumference, blood pressure, triglycerides, HDL-C, and fasting glucose—will be assessed primarily with analysis of covariance (ANCOVA) models adjusting for baseline values; complementary analyses will use mixed-effects models with random intercepts for participants to account for within-subject correlation over time. When parametric assumptions are not met (assessed via visual inspection and Shapiro–Wilk tests), non-parametric alternatives (e.g., rank-based ANCOVA or Mann–Whitney tests on change scores) will be used. For simple comparisons we will also report paired and independent-samples t-tests, as appropriate, alongside non-parametric counterparts.

Primary implementation outcomes include feasibility (recruitment, retention, completeness of data, and intervention fidelity) and acceptability/engagement (mHealth message reach, open/response rates, and platform usage analytics). Adherence to consuming 400 g/week of jack mackerel and to nutrition recommendations will be quantified from consumption logs and follow-up surveys. Qualitative feedback on usability, perceptions, and satisfaction with the mHealth system will be analyzed using rapid content analysis with dual coding and consensus, generating themes to inform refinement prior to a main trial.

All hypothesis tests will use a two-sided α predetermined a priori. Given the pilot nature, emphasis will be placed on estimation (mean changes, adjusted mean differences, standardized effect sizes such as Hedges g) with 95% confidence intervals rather than formal multiplicity-controlled hypothesis testing. Missing outcome data will be handled using multiple imputation under a missing-at-random assumption; sensitivity analyses will compare complete-case and per-protocol sets to the primary intention-to-treat analysis. Results will be reported in line with CONSORT 2010 and its extension for pilot and feasibility trials. In addition, the SPIRIT 2025 guidelines were used, which provide a standard way of reporting protocols and findings from randomized trials [21] (**Table 1**).

Data monitoring and trial oversight: This is a pilot, single-centre, investigator-initiated trial coordinated by the Universidad de Valparaíso, which is responsible for overall study management, implementation, and data management. Given the feasibility focus, short duration, small sample size, and minimal-risk, non-pharmacological nutritional intervention, no independent Data Monitoring Committee (DMC) has been established. Participant safety and data integrity will be overseen by the principal investigator and the research team through routine monitoring of data completeness, adherence to the study protocol, and systematic documentation of any reported adverse events. No interim analyses for efficacy or safety are planned, and access to trial data will remain restricted to the research team. Any decision to

terminate the trial prematurely, if required due to unforeseen safety concerns or operational issues, will rest with the principal investigator, in consultation with the research team.

Assessment of harms: Potential harms are defined as any adverse events or unintended effects occurring during the study period that may be related to jack mackerel consumption or study procedures. These include, but are not limited to, gastrointestinal discomfort, allergic reactions, or any other symptoms reported by participants. Harms will be assessed systematically throughout the 8-week intervention using structured participant self-report during scheduled follow-up contacts and study visits, as well as through spontaneous reporting by participants at any time. All adverse events will be documented, reviewed by the research team, and classified according to severity and relatedness to the intervention. Given the non-pharmacological and low-risk nature of the study, serious adverse events are not anticipated.

Criteria for discontinuing or modifying the allocated intervention: Participation in the trial and delivery of the allocated intervention may be discontinued or modified for an individual participant under the following circumstances: (i) participant request or withdrawal of informed consent at any time without penalty; (ii) occurrence of adverse events potentially related to fish consumption or study procedures, such as allergic reactions, persistent gastrointestinal symptoms, or other clinically relevant conditions; (iii) identification of a new medical condition or initiation of treatment that is incompatible with continued participation; or (iv) inability to comply with study procedures or follow-up assessments. In such cases, the intervention will be discontinued, and the participant will be referred for appropriate clinical care if needed.

DISCUSSION

We anticipate that an mHealth-based intervention will improve adherence to fish intake and produce favorable changes in cardiometabolic indicators associated with metabolic syndrome, consistent with prior work showing that mobile technologies in nutrition support self-management, enhance motivation, and can augment the impact of dietary interventions [22,23]. As a pilot, this study will allow us to validate procedures, evaluate acceptability, and iteratively refine content and delivery before a fully powered trial.

Integrating digital nutrition education offers a scalable, efficient, and potentially sustainable approach to MetS prevention in middle-aged adults, complementing traditional lifestyle counseling and pharmacotherapy [24,25]. The choice of jack mackerel—as a locally available source of n-3 fatty acids, bioactive peptides, and essential micronutrients—is supported by evidence indicating cardiovascular risk reduction and enhances cultural and economic feasibility in the Chilean context.

CONCLUSION

This study has limitations. First, the small sample and pilot design limit generalizability and statistical power. Second, the 8-week duration may be insufficient to assess the durability of effects. Third, self-reported adherence to fish consumption and app use may introduce reporting bias. Future research

should include adequately powered randomized trials, incorporate objective biomarkers of fish intake, and extend follow-up to confirm and expand these findings.

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Competing interests: The authors declare no financial or personal relationships that could inappropriately influence (bias) the work reported in this paper.

Authors' contributions: A.B. conceived the study, served as principal investigator, led the execution of the project, and drafted the main manuscript. M.B. contributed to project execution and data collection. P.P. and S.R. were responsible for project coordination and oversight. J.Q. contributed to manuscript writing and editorial refinement. All authors reviewed and approved the final manuscript.

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TABLE

Table 1 is available in the Supplementary Files section.

Figures

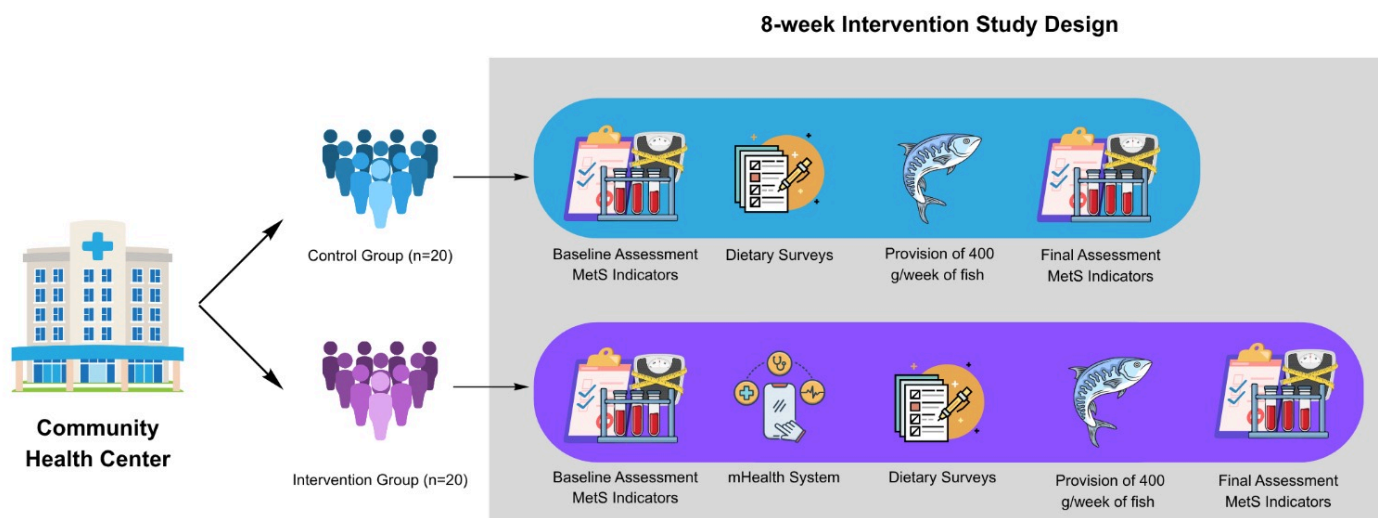


Figure 1

Study design of the 8-week pilot intervention. Overview of the 8-week pilot randomized study design conducted in a community health center. Participants are allocated to a control group or an intervention group ($n = 20$ per group). Both groups undergo baseline and final assessments of metabolic syndrome indicators and complete dietary surveys. The intervention group additionally receives a digital mHealth-supported lifestyle intervention, while both groups receive the provision of 400 g/week of fish during the intervention period.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [SPIRIT2025TABLE1.docx](#)