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The SHEEP Trial (Smart Health Education and Exercise Program): Protocol for a Pilot Randomized Controlled Trial in Community-Dwelling Older Adults with Possible Sarcopenia

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Title page

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DECLARATIONS

Ethics approval and consent to participate

This study was conducted in accordance with the principles of the Declaration of Helsinki. This study was initially approved by the Research Ethics Committee of Xiangya School of Nursing, Central South University, China (Approval No. E2025197). Following the relocation of the principal investigator to Shandong Xiehe University, additional ethical approval was obtained from the Research Ethics Committee of Shandong Xiehe University (Approval No. LLSC-KY03-2026068). All participants will provide informed consent prior to participation in the study. For participants with literacy or communication difficulties, oral informed consent will be obtained and documented in accordance with ethical approval requirements.

Consent for publication

Not applicable. This manuscript does not contain any individual participant data, images, or videos that require consent for publication.

Data availability statement

Not applicable. This is a study protocol; no data were generated or analysed. Future de-identified data may be available from the corresponding author upon reasonable request and with institutional approval.

Conflicts of interest

The authors declare that they have no competing interests.

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Author statement

Ya Shi: conceptualization, methodology, visualization, project administration, writing – original draft, writing – reviewing & editing.

Emma Stanmore: conceptualization, methodology, supervision, writing – original draft, writing – reviewing & editing.

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Xia Xu: conceptualization, methodology, writing – original draft.
Can Gu: conceptualization, resources, supervision, funding acquisition, writing – reviewing & editing.
Chris Todd: conceptualization, methodology, project administration, supervision, writing – reviewing & editing.
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Trial registration

ISRCTN registry, ISRCTN13070522, Registered 19 October 2026

The SHEEP Trial

(Smart Health Education and Exercise Program):

Protocol for a Pilot Randomized Controlled Trial in Community-Dwelling Older Adults with Possible Sarcopenia

Abstract

Background

Possible sarcopenia is highly prevalent among community-dwelling older adults, yet scalable and theory-informed digital interventions targeting sarcopenia prevention remain limited. To address this gap, we co-designed a multicomponent social media-based intervention (SHEEP: Smart Health Education and Exercise Program) integrating digital health education, structured home-based exercise, wearable activity monitoring, and behavioural support using a mobile social media platform.

Objectives

This pilot randomised controlled trial aims to evaluate the feasibility and acceptability of the SHEEP intervention and trial procedures among community-dwelling older adults with possible sarcopenia. Secondary objectives are to obtain preliminary estimates of intervention effects and outcome variability to inform the design of a future definitive randomised controlled trial.

Methods

This is a two-arm, parallel-group pilot randomised controlled trial conducted in community settings in Changsha, China. Sixty participants aged ≥60 years with possible sarcopenia will be individually randomised in a 1:1 ratio to either the SHEEP intervention group or a time-matched active digital health education control group. The intervention will be delivered over 12 weeks, followed by a 12-week follow-up period.

The SHEEP intervention includes seven short health education videos delivered via a social media platform, an 11-week progressive multicomponent home-based exercise programme following a one-week health education phase, wearable activity monitoring using a Huawei Band 10 smart wristband, and behavioural support based on objective activity data during the intervention period. The control group will receive digital health education materials only and will also wear a wearable device for outcome assessment purposes. Assessments will be conducted at baseline and at regular intervals throughout the intervention and follow-up periods. Primary outcomes include feasibility metrics such as recruitment, retention, adherence, data completeness, and acceptability. Secondary exploratory outcomes include muscle strength, physical performance, body composition, dietary diversity, sarcopenia-related quality of life, sarcopenia-specific knowledge, beliefs and behaviours, and wearable-derived physical activity, resting heart rate, and sleep measures. Semi-structured qualitative interviews will be conducted to explore participant experiences and optimise future implementation.

Discussion

This pilot trial will provide critical evidence on the feasibility, acceptability, and implementation processes of a digital social media-based multicomponent intervention for sarcopenia prevention. Findings will inform the refinement of intervention components and trial procedures and support the design of a future fully powered randomised controlled trial.

Trial registration

ISRCTN registry, ISRCTN13070522, Registered 19 October 2026

Keywords

Sarcopenia; Pilot randomized controlled trial; Digital health intervention; Social media; Home-based exercise; Community-dwelling older adults

Introduction

In the 2025 consensus update, the Asian Working Group for Sarcopenia (AWGS) reframed possible sarcopenia as a screening category defined primarily by age-specific low handgrip strength, serving as a critical indicator for early lifestyle intervention in community settings[1]. This conceptual shift aligns with the Global Leadership Initiative in Sarcopenia (GLIS) consensus, which positions muscle strength as a core component of sarcopenia definition and reclassifies physical performance as an outcome measure rather than a diagnostic criterion[2]. Unlike confirmed sarcopenia, which requires concurrent low muscle mass, possible sarcopenia enables earlier identification before substantial muscle atrophy occurs[3], as longitudinal evidence indicates that age-related decline in muscle strength substantially outpaces the loss of muscle mass[4]. Community-dwelling older adults with possible sarcopenia are at increased risk of falls, functional decline, hospitalisation, reduced quality of life, disability, and mortality[5–8]. Consequently, current international guidelines consistently recommend early screening and timely initiation of non-pharmacological interventions, particularly exercise-based programmes, before irreversible deterioration occurs[1,9–11].

Exercise is widely recognised as the cornerstone intervention for preventing and managing sarcopenia[1,12]. However, translating the proven efficacy of exercise into sustained participation in real world community settings remains challenging. Although numerous exercise interventions have demonstrated favourable physiological outcomes, long term adherence among older adults is frequently suboptimal because of declining motivation, inadequate behavioural support and limited access to continuous supervision[13–15]. Therefore, an important challenge in sarcopenia prevention is no longer determining whether exercise is effective but rather identifying practical strategies that enable older adults to initiate, maintain and integrate exercise into their daily lives[14,15].

Our research programme has systematically addressed this challenge through

successive stages of evidence generation. First, our scoping review identified substantial gaps in community-based interventions for possible sarcopenia[16]. Specifically, relatively few interventions targeted individuals at the stage of possible sarcopenia, health education was rarely integrated with exercise, and most educational approaches relied on traditional face to face sessions or printed materials rather than behaviour change strategies delivered through digital platforms. These findings highlighted the need for innovative interventions capable of improving both knowledge and sustained exercise participation.

Subsequently, we conducted a systematic review and meta-analysis evaluating digitally delivered interventions for sarcopenia prevention and management[17]. The review demonstrated that digital interventions have considerable potential to improve muscle strength and physical performance; however, their effectiveness appeared to depend largely on intervention design rather than the use of technology alone. This finding is corroborated by two recent independent meta-analyses, which confirmed that while digital health interventions can improve muscle mass and grip strength, their effects on broader physical function and quality of life are selective or uncertain, with clinical benefits highly contingent upon specific design features such as real-time interaction and personalized feedback[18,19]. Consequently, multicomponent interventions combining exercise with behavioural support consistently demonstrate greater benefits than single-component programmes. Nevertheless, considerable heterogeneity in intervention content, limited use of objective adherence monitoring, inadequate reporting of intervention fidelity, and an overall low certainty of evidence remain important limitations within the current evidence base[17–19]. Collectively, these findings suggest that future interventions should move beyond simple digital delivery towards theory-informed, behaviour-focused, and objectively monitored programmes.

Guided by these evidence syntheses, we subsequently developed the Smart Health Education and Exercise Program (SHEEP) as a digitally supported behaviour change intervention for community-dwelling older adults with possible sarcopenia. Intervention development followed the Medical Research Council framework for

complex interventions[20] and was informed by the Behaviour Change Wheel[21] together with the eLiFE conceptual framework[22]. Through a co design process involving older adults, healthcare professionals and researchers, SHEEP integrated three complementary components: social media-based health education, progressive home-based exercise and continuous digital support to facilitate long term behaviour change[23]. The intervention was subsequently evaluated in a prospective single arm feasibility study, which demonstrated favourable acceptability, high participant satisfaction and encouraging preliminary improvements in muscle function and health related behaviours[24,25]. Importantly, participants reported positive experiences with the digital delivery format and expressed willingness to continue exercising beyond the intervention period[24,25].

Despite these encouraging findings, several important uncertainties remain before undertaking a definitive randomised controlled trial. First, recruitment procedures require optimisation to improve efficiency and participant representativeness[26]. Findings from our ongoing community muscle health screening suggest that expanding recruitment beyond younger old adults may improve inclusion of older men, who appear to experience clinically meaningful declines in muscle strength at older ages. Second, the previous feasibility study lacked a comparator group, precluding preliminary estimation of between group intervention effects[27]. Third, the previous feasibility study relied primarily on self-reported exercise records[28,29]. The present trial adds wearable-derived measures of overall daily physical activity to complement self-reported exercise participation; completion of prescribed exercise sessions will continue to be assessed using exercise diaries. Finally, additional evidence is required regarding trial procedures, intervention fidelity, participant retention and outcome variability before progression to a fully powered effectiveness trial[30].

Accordingly, the present study represents the next phase of the SHEEP research programme. Building upon previous evidence synthesis, intervention development, co design and feasibility evaluation, this pilot randomised controlled trial incorporates several important refinements, including an optimised community screening-based

recruitment strategy, a randomised controlled design, a time-matched active digital comparator and wearable-derived monitoring of overall daily physical activity. Together, these refinements will establish the feasibility of conducting a definitive randomised controlled trial while providing preliminary estimates of intervention effects and implementation outcomes in community dwelling older adults with possible sarcopenia.

Study aims and objectives

Overall aim

The overall aim of this pilot randomised controlled trial is to determine whether the Smart Health Education and Exercise Program (SHEEP) and its associated trial procedures are sufficiently feasible and acceptable to support progression to a future definitive randomised controlled trial for community-dwelling older adults with possible sarcopenia.

Specific objectives

This pilot trial has the following specific objectives:

1. To evaluate the feasibility of an optimised community screening-based recruitment strategy for identifying and enrolling community-dwelling older adults with possible sarcopenia.
2. To assess participant retention, intervention adherence, intervention fidelity, and the acceptability of the SHEEP intervention, the time-matched active comparator, and overall trial procedures.
3. To evaluate the feasibility of integrating wearable activity monitoring into a digitally supported home-based exercise programme, including the completeness, usability, and acceptability of objectively collected physical activity data.
4. To assess the feasibility and completeness of outcome measurement procedures and estimate key trial parameters, including recruitment and retention rates, adherence,

outcome variability, and missing data, to inform the design and sample size calculation of a future definitive randomised controlled trial.

5. To obtain preliminary estimates of the effects of the SHEEP intervention on muscle strength, physical performance, body composition, sarcopenia-related quality of life, objectively measured physical activity, and health behaviours, in order to inform the selection of primary outcomes and estimate intervention effect sizes for a future definitive trial.

Methods

Study design

This study is a two-arm, parallel-group, mixed-methods pilot randomised controlled trial designed to evaluate the feasibility and acceptability of the SHEEP intervention and trial procedures and to obtain preliminary estimates of intervention effects and outcome variability. The study will also generate preliminary estimates of outcome variability to inform the design of a future fully powered definitive randomised controlled trial. Eligible participants will be randomly allocated in a 1:1 ratio to either the SHEEP intervention group or a time-matched active digital health education control group using a computer-generated random allocation sequence. The intervention period will last 12 weeks, followed by a 12-week follow-up assessment.

Quantitative assessments will be conducted at baseline before randomisation (T0), monthly during the 12-week intervention period (T1–T3), and monthly during the subsequent 12-week post-intervention follow-up period (T4–T6). Objective physical and body composition outcomes will be assessed at all seven time points, whereas questionnaire-based outcomes will be administered at selected time points according to their intended purpose and to minimise participant burden. Semi-structured qualitative interviews will be conducted with a purposive sample of participants following completion of the intervention to explore intervention acceptability, trial procedures, wearable activity monitoring, barriers and facilitators to participation, and

recommendations for optimisation of the future definitive trial.

By integrating quantitative and qualitative findings, this mixed-methods pilot trial will provide a comprehensive evaluation of trial feasibility, intervention implementation, implementation outcomes and participant experiences. This pilot trial represents the next phase of the SHEEP research programme and is intended to optimise intervention delivery and trial procedures before progression to a future definitive randomised controlled trial. This study protocol has been developed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2025 statement[31] and the Template for Intervention Description and Replication (TIDieR) checklist[32].

Study setting

This pilot randomised controlled trial will be conducted in Changsha, Hunan Province, China, in collaboration with local community healthcare providers. Participant recruitment, intervention delivery and outcome assessments will be undertaken across four urban residential communities: Yannong Community Phase V, Yannong Community Phase VI, Zhongtie Xijiangyue Residential Community, and Haojiayuan Residential Community. These communities represent typical urban settings for community-dwelling older adults and have established partnerships with the research team through an ongoing community muscle health screening programme.

Potential participants will be identified through community-based muscle health screening and invited to undergo eligibility assessment. Eligible participants who provide written informed consent will be individually randomised in a 1:1 ratio to either the SHEEP intervention group or the time-matched active digital health education control group, irrespective of their community of residence. Individual randomisation was selected to minimise selection bias while allowing participants from all participating communities to receive either study condition. Community healthcare staff will assist the research team with participant recruitment, scheduling of outcome assessments and coordination of study procedures throughout the trial.

Eligibility criteria

Potential participants identified through the community muscle health screening programme will undergo eligibility assessment by trained health professionals and the principal investigator (PI). Participants must meet all inclusion criteria and none of the exclusion criteria.

· Inclusion criteria

Participants will be eligible if they:

1) are aged 60 years or older.

2) are community-dwelling older adults residing in Changsha, China.

3) have low handgrip strength consistent with the AWGS 2025 age-specific criteria for possible sarcopenia[1]: for participants aged 60–64 years, <34 kg for men and <20 kg for women; for participants aged ≥65 years, <28 kg for men and <18 kg for women.

4) own a smartphone with internet access and are able and willing to use Douyin (Chinese TikTok) and WeChat following appropriate instruction.

5) are able to perform home-based exercise safely and independently.

6) are willing to wear a Huawei Band 10 smart wristband throughout the study period.

7) are able to attend scheduled community assessments throughout the study.

8) provide written informed consent.

· Exclusion criteria

Participants will be excluded if they:

1) have severe cognitive impairment, dementia, major psychiatric illness, or communication difficulties that would prevent informed consent or participation.

2) have unstable or severe cardiovascular, respiratory, neurological, musculoskeletal or other medical conditions that would make exercise unsafe, as determined by the research team.

3) have medical contraindications to moderate-intensity exercise.

4) have contraindications to bioelectrical impedance analysis (e.g., implanted cardiac pacemaker or other electronic medical devices).

5) are currently participating in another structured exercise or rehabilitation programme that is likely to influence study outcomes.

6) are unable or unwilling to comply with study procedures.

Recruitment, consent and withdrawal

Participant recruitment will be undertaken through an ongoing community muscle health screening programme conducted in collaboration with four participating communities in Changsha, China. Community healthcare staff will invite all community-dwelling adults aged 60 years and older to attend a free muscle health screening session. During the screening, demographic information, medical history, physical performance, handgrip strength, body composition and questionnaire data will be collected. Individuals identified as having low handgrip strength consistent with the AWGS 2025 age-specific criteria will be considered potential participants for the present pilot trial.

Potentially eligible individuals will be contacted by the research team and invited to attend an eligibility assessment. During this visit, trained research staff will confirm the inclusion and exclusion criteria, explain the purpose and procedures of the study, answer participants' questions and provide a Participant Information Sheet. Individuals who remain interested in participation will be given adequate time (at least 24 hours) to consider participation before providing written informed consent.

Following informed consent and completion of all baseline assessments, participants will be individually randomised in a 1:1 ratio to either the SHEEP intervention group or the time-matched active digital health education control group. Participants allocated to each group will subsequently receive the corresponding intervention according to the study protocol.

Participation in this study is entirely voluntary. Participants may withdraw from the study at any time without providing a reason and without affecting their access to

routine healthcare or community services. Where possible, participants who withdraw from the intervention will be invited to complete follow-up assessments unless they request that no further data be collected. Data collected prior to withdrawal will be retained and analysed unless the participant specifically requests that their data be removed, where permitted by applicable ethical and regulatory requirements.

Research ethics

Ethical approval was obtained from the relevant institutional research ethics committees before trial initiation. Institutional names and approval numbers have been withheld for blinded peer review and are provided in the separate title page. The trial will be conducted in accordance with the Declaration of Helsinki and applicable national regulations governing research involving human participants. Written informed consent will be obtained from all participants before enrolment.

Written informed consent will be obtained from all participants before enrolment. Participants will receive both verbal and written information about the study, including its purpose, procedures, potential benefits and risks, confidentiality arrangements, and their right to withdraw at any time without providing a reason and without affecting their access to routine healthcare or community services.

Any substantive protocol amendments will be submitted to the responsible research ethics committee(s) for approval before implementation. All protocol amendments will be documented using version-controlled study documents.

Participant confidentiality will be strictly maintained throughout the study. Personal identifying information will be stored separately from research data and replaced with unique study identification numbers. Electronic data will be password protected and accessible only to authorised members of the research team. Data collected from wearable devices will be used solely for research purposes and handled in accordance with institutional data management policies and applicable data protection regulations.

Sample size

As this is a pilot randomised controlled trial, the primary objective is to evaluate the feasibility and acceptability of the SHEEP intervention and trial procedures rather than to formally test intervention effectiveness. Consequently, the sample size was not determined using a conventional hypothesis-testing power calculation[33,34]. Instead, the sample size was selected to provide sufficiently precise estimates of key feasibility parameters, including participant recruitment, retention, intervention adherence, outcome completion and the variability of clinical outcome measures, which are required to optimise the design of a future fully powered definitive randomised controlled trial. This approach is consistent with current methodological guidance for pilot randomised trials, which recommends that pilot studies focus on estimating parameters required for planning subsequent definitive trials rather than testing treatment effectiveness[33,35].

Methodological studies suggest that approximately 25 to 30 participants per group provide adequate precision for estimating feasibility outcomes and the variability of clinical outcomes in pilot randomised controlled trials[36,37]. Therefore, a total of 60 participants (30 per group) will be recruited. Allowing for an anticipated attrition rate of approximately 15%, it is expected that at least 25 participants per group will complete the study. This sample size is expected to provide sufficient information to evaluate recruitment, intervention delivery, participant adherence, retention, repeated outcome assessments and wearable activity monitoring, while generating robust estimates of clinical outcome variability and preliminary between-group differences to inform the design and sample size calculation of a future fully powered definitive randomised controlled trial.

Randomisation, allocation concealment and blinding

Eligible participants who have completed baseline assessments and provided written informed consent will be individually randomised in a 1:1 ratio to either the SHEEP intervention group or the time-matched active digital health education control

group. The randomisation sequence will be generated by an independent researcher using a computer-generated random number sequence[38]. Randomisation will be performed using variable block sizes to ensure balanced group allocation while maintaining allocation unpredictability.

Allocation concealment will be achieved using sequentially numbered, opaque, sealed envelopes[39] prepared by an independent researcher who is not involved in participant recruitment, eligibility assessment or outcome measurement. Following completion of baseline assessments, the principal investigator will open the next envelope in sequence to determine the participant's group allocation.

Due to the nature of the intervention, blinding of participants and intervention providers is not feasible because the intervention involves different methods of delivering health education and exercise support. However, outcome assessors responsible for physical performance measurements and data analysts will remain blinded to group allocation wherever possible to minimise assessment and analysis bias[38,39]. Participants will be reminded not to disclose their allocation during outcome assessments.

Intervention

· Intervention group (SHEEP)

Participants allocated to the intervention group will receive the Smart Health Education and Exercise Program (SHEEP), a multicomponent digital health intervention designed to promote muscle health and prevent the progression of possible sarcopenia among community-dwelling older adults. The intervention integrates four complementary components: (1) digital health education, (2) structured home-based multicomponent exercise, (3) wearable activity monitoring, and (4) ongoing behavioural support.

Digital health education

Participants will receive seven short educational videos (approximately 4–6

minutes each) through Douyin (TikTok China) during the first week of the intervention. The videos cover the following topics: Understanding sarcopenia, Risk factors for sarcopenia, Consequences of sarcopenia, Early signs and symptoms, Community screening for sarcopenia, Exercise strategies for muscle health, Nutrition for sarcopenia prevention. Participants may watch the videos at their own pace and revisit them throughout the intervention period[23].

Home-based exercise programme

Following the one-week health education phase, participants will commence the exercise phase from Week 2. The overall intervention period spans 12 weeks, encompassing the health education and 11 weeks of structured exercise training. The exercise programme retains the core structural components and exercise modalities of our preceding feasibility study[24,25], with the total duration extended to 11 weeks and the prescription standardised to a minimum of three sessions per week to align with current sarcopenia prevention guidelines. Each session lasts approximately 30 minutes and comprises four components: warm-up (3 minutes), aerobic training (8 minutes), resistance training (16 minutes), and flexibility training (3 minutes).

Participants will be prescribed a minimum of three sessions per week at moderate intensity (corresponding to a rating of 3–4 on the Borg Category-Ratio 10 [CR-10] Scale). Resistance training will be performed using adjustable plastic water bottles (initial options: 500 ml or 1000 ml). A standardised progression protocol will be applied: participants will increase the load by adding 100–500 ml of water to each bottle every three weeks, based on their individual tolerance and perceived exertion. The programme was developed based on current evidence, including the FaME programme and the Otago Exercise Programme[40,41], and further refined through stakeholder co-design involving geriatricians, nurses, physiotherapists and older adults[23].

Wearable activity monitoring

Participants will wear a Huawei Band 10 continuously throughout the 24-week

study period. The wearable device will automatically generate estimates of daily physical activity, resting heart rate, and sleep-related parameters[42]. During the 12-week intervention period, selected wearable-derived data will also be used to support self-monitoring and behavioural feedback. During the subsequent 12-week post-intervention follow-up period, wearable monitoring will continue for outcome assessment only, with no further personalised behavioural feedback based on wearable data.

Throughout the 24-week monitoring period, participants in both groups will receive weekly support from the research team to synchronise their Huawei Band 10 data with the paired smartphone application. Support will be provided through brief in-person assistance or scheduled telephone guidance, according to participants' needs. Researchers will check whether synchronisation has been completed and document technical difficulties and any apparent gaps in the available records. This procedure is intended to support regular data transfer and reduce the risk of data loss.

Wearable monitoring procedures were refined through preliminary usability testing. During June–August 2026, ten community-dwelling older adults participated in preliminary training and an approximately one-month trial of the Huawei Band 10. Difficulties with screen readability, remembering operating procedures, and initiating and terminating active exercise recordings persisted despite repeated instruction. These findings informed the decision to use passive monitoring in the present trial rather than participant-initiated workout recordings. Participation in prescribed exercise will therefore be assessed using exercise diaries reviewed during weekly follow-up. Wearable-derived daily activity measures will be used to characterise overall physical activity rather than to verify completion of prescribed exercise sessions.

Behavioural support

Behavioural support will be delivered during the 12-week intervention period using WeChat and telephone communication. At each monthly follow-up visit during this period, researchers will review participants' wearable activity data together with

them, discuss progress towards exercise goals, identify barriers to participation, and provide personalised encouragement and problem-solving strategies[43,44]. The wearable data will therefore be used as a behavioural coaching tool during the intervention period to facilitate self-monitoring, motivation and adherence to the exercise programme.

Intervention fidelity

All intervention materials, exercise videos and behavioural support procedures will be standardised using a predefined intervention manual[45,46]. Intervention fidelity will be monitored through records of educational video completion, exercise participation, wearable device data and monthly follow-up contacts.

· ***Control group***

Participants allocated to the control group will receive an active digital health education control programme designed to match the intervention group's exposure to health information and researcher contact time over the 12-week period, while strictly excluding any structured exercise prescriptions, progressive training, or behavioural coaching[47].

To accommodate varying levels of digital literacy and visual acuity common among older adults, the educational materials will be delivered in dual formats: electronic PDF documents via WeChat and printed booklets with enlarged fonts. The content will cover 12 weekly themes related to healthy ageing, muscle health, physical activity, and nutrition.

To ensure time-matched attention, all 12 educational materials will be distributed simultaneously in Week 1. However, to maintain engagement and align with the 12-week trial duration, researchers will deliver a brief, structured reinforcement of one specific theme each week during the subsequent 11 weeks (via WeChat or brief telephone calls). During these weekly contacts, researchers will also assist control participants with synchronising their Huawei Band 10 data to support regular data transfer and reduce the risk of data loss, while verbally confirming whether they have

read the educational materials. Importantly, both groups will receive weekly researcher contact. For both groups, this contact will include assistance with wearable data synchronisation to prevent data loss. Additionally, the intervention group will receive behavioural support, while the control group will receive educational reinforcement. This dual-purpose contact ensures a high degree of matching in researcher attention and contact time across the trial.

Participants in the control group will also wear a Huawei Band 10 throughout the 24-week study period using the same monitoring procedures as the intervention group. Wearable-derived data will be collected solely for passive outcome assessment and will not be used to provide exercise guidance, personalized feedback, goal setting, or behavioural support. To maintain retention and comparable assessment schedules, control participants will attend the same scheduled assessment visits as the intervention group but will not receive any exercise counselling or motivational interviewing. Researcher contact time for both groups will be systematically recorded in a trial contact log to evaluate the fidelity of time-matching between the two arms.

Outcome measures and assessment procedures

Outcome framework

Given the pilot nature of the present randomised controlled trial, the primary focus will be on the feasibility and acceptability of the intervention and trial procedures rather than formal evaluation of intervention effectiveness. Outcomes are therefore organised into four categories: primary feasibility outcomes, a key clinical outcome, secondary exploratory outcomes, and process and qualitative evaluation outcomes. Baseline demographic, health and digital characteristics will additionally be collected to characterise the study population and to support exploratory analyses of factors potentially associated with intervention engagement and retention.

Baseline characteristics

Baseline demographic and health characteristics will be collected before

randomisation. These will include age, sex, educational attainment, chronic health conditions, long-term medication use, recent hospitalisation and surgery, history of falls, use of walking aids, and health conditions that may affect participation in physical activity.

Baseline digital characteristics will also be assessed because the SHEEP intervention relies on social media and wearable technologies. A brief digital technology questionnaire will assess smartphone ownership and proficiency, frequency of WeChat use, frequency of short-video use, previous use of health-related mobile applications, and previous experience with smartwatches or activity trackers. eHealth literacy will be assessed at baseline using the eight-item Chinese version of the eHealth Literacy Scale (eHEALS)[48]. These measures will primarily be used to characterise the digital profile of participants and, exploratorily, to examine whether baseline digital experience and eHealth literacy are associated with intervention engagement, adherence, wearable data completeness, or retention[49].

Baseline physiological measurements, including resting blood pressure, heart rate, peripheral oxygen saturation and body temperature, will also be recorded to characterise participants and support safe participation in physical assessments and exercise.

Primary feasibility outcomes

The primary outcomes of this pilot trial will assess the feasibility of progression to a future definitive randomised controlled trial[50,51]. These will include recruitment, retention, intervention adherence, acceptability, completeness of outcome data collection, intervention fidelity, and safety.

Recruitment feasibility will be described using the numbers of individuals identified through the preceding community screening programme, approached for trial participation, assessed for eligibility, eligible, consenting, completing baseline assessment, and randomised. Recruitment rates and reasons for non-participation or exclusion will be reported descriptively.

Retention will be assessed as the proportion of randomised participants remaining in the study at the end of the 12-week intervention and at the final 24-week follow-up. Reasons for withdrawal and loss to follow-up will be documented.

Intervention adherence will be assessed separately for the major components of the SHEEP programme. Digital health education engagement will be evaluated using completion or viewing records for the educational materials. Exercise adherence will be assessed using intervention records and self-reported exercise participation, including frequency of prescribed exercise sessions. Wearable use will be evaluated using participant-reported non-wear and technical difficulties, together with outcome-specific data availability. Data availability will not be interpreted as a direct measure of wear duration. We will also assess the feasibility of the weekly data synchronisation protocol, including the proportion of participants requiring in-person assistance versus remote guidance.

Acceptability of the intervention and trial procedures will be assessed using participant feedback collected during follow-up and post-intervention qualitative interviews. Particular attention will be given to the acceptability of short-video health education, home-based exercise, wearable monitoring, behavioural support, repeated outcome assessment, and overall study burden.

Outcome data completeness will be calculated for each major measure and assessment timepoint, including questionnaire, physical performance, body composition and wearable-derived outcomes. Reasons for missing or incomplete measurements will be recorded where available.

Intervention fidelity will be evaluated using records of intervention delivery, educational content exposure, exercise participation, wearable use, and scheduled behavioural support contacts.

Safety will be assessed throughout the trial[52]. Adverse events potentially related to exercise or study procedures, including falls, musculoskeletal symptoms, dizziness, cardiovascular symptoms and other unexpected events, will be recorded together with their severity, relatedness and subsequent management.

Key clinical outcome

Handgrip strength will be designated as the key clinical outcome. This selection is based on its central role in identifying possible sarcopenia and on findings from the preceding feasibility study suggesting that handgrip strength is responsive to the SHEEP intervention. In this pilot trial, between-group estimates and variability in handgrip strength will be used primarily to inform the selection of outcomes and sample size assumptions for the future definitive randomised controlled trial rather than to provide confirmatory evidence of intervention effectiveness.

Handgrip strength will be measured using a calibrated digital hand-held dynamometer (EH101, Xiangshan Inc., Guangdong, China)[53]. Participants will be seated with the shoulder adducted, elbow flexed to approximately 90°, and wrist in a neutral position[54]. Three maximal trials will be performed for each hand with approximately 30 seconds of rest between trials. The highest valid value obtained across the six measurements will be used as the primary handgrip strength measure[54,55].

Secondary exploratory outcomes

Secondary outcomes will include physical performance, anthropometry, body composition, dietary diversity, sarcopenia-related quality of life, sarcopenia-specific knowledge, beliefs and behaviours, and wearable-derived physical activity, resting heart rate, and sleep measures. Because this is a pilot trial, analyses of these outcomes will be exploratory and will focus on estimation of change, variability and preliminary between-group differences rather than formal efficacy testing.

Physical performance

Consistent with the AWGS 2025 framework[1], which designates physical performance as an outcome measure rather than a diagnostic criterion, this trial will evaluate changes in 3-Metre Walk Test (3MWT) and the Five Times Sit-to-Stand Test (FTSST) as exploratory secondary outcomes.

For the 3MWT, participants will be instructed to walk at their usual walking speed

along a standardised 5-metre walkway comprising a 1-metre acceleration zone, a 3-metre timed section, and a 1-metre deceleration zone. Walking time will be recorded over the central 3-metre section using a stopwatch, and gait speed will be calculated in metres per second. Three trials will be conducted, with an appropriate rest interval between trials, and the mean gait speed across the three valid trials will be used for analysis[56]. The 3-metre timed course was selected based on practical experience from the preceding feasibility study, in which space constraints affected implementation of the 4-metre walking assessment in some community settings[24]. The standardised 1-metre acceleration and deceleration zones are intended to minimise the influence of starting and stopping on timed walking performance while maintaining feasibility across community-based assessment sites.

For the FTSST, participants will be seated in an armless chair of standardised height and instructed to stand up and sit down five times as quickly as safely possible, with their arms crossed over the chest where feasible. Timing will begin on the command to start and end when the participant returns to the seated position following the fifth stand. Following a familiarisation trial, two timed trials will be performed with an appropriate rest interval, and the shorter valid completion time will be used for analysis[57].

Anthropometry and body composition

Height and body weight will be measured using calibrated equipment, and body mass index will be calculated as weight in kilograms divided by height in metres squared. Waist circumference and bilateral calf circumference will be measured using a non-stretchable measuring tape according to standardised procedures[10].

Body composition will be assessed using a multi-frequency bioelectrical impedance analysis device (InBody S10; Biospace, Seoul, Korea) according to the manufacturer's standardised protocol[58,59]. Measures will include skeletal muscle mass, appendicular skeletal muscle mass (ASM), skeletal muscle index, regional muscle mass, body fat mass, body fat percentage and other relevant body composition indices. Bioelectrical impedance assessment will not be undertaken in participants for whom

721 the procedure is contraindicated. Sarcopenia will be defined according to the AWGS
722 2025 criteria, which incorporate both height-adjusted (ASM/height^2) and BMI-adjusted
723 (ASM/BMI) cutoffs for low muscle mass, using age-specific thresholds as
724 recommended for participants aged 60–64 years and those aged ≥65 years. This
725 approach ensures diagnostic sensitivity across varying body compositions[1].

726 ***Dietary diversity***

727 Dietary diversity will be assessed using an eight-food-group dietary diversity
728 measure based on food consumption during the previous day. Participants will indicate
729 whether they consumed foods from each of the following categories: whole or coarse
730 grains, vegetables, fruits, meat and poultry, aquatic foods, soy products and nuts, eggs,
731 and milk and dairy products[60]. One point will be assigned for each food group
732 consumed, yielding a total score ranging from 0 to 8, with higher scores indicating
733 greater dietary diversity. This measure is intended to capture potentially modifiable
734 dietary behaviours relevant to sarcopenia prevention rather than nutritional risk or
735 malnutrition status[61].

736 ***Sarcopenia-related knowledge, beliefs and behaviours***

737 Sarcopenia-related knowledge, beliefs and preventive behaviours will be assessed
738 using the pre-final version of the Knowledge, Belief, and Behaviour Questionnaire on
739 Sarcopenia for Older Adults (KBBQ-SOA). The KBBQ-SOA is a sarcopenia-specific
740 instrument developed within the Knowledge-Belief-Behaviour framework and
741 informed by constructs from the Health Belief Model and Theory of Planned Behaviour.
742 Its development follows the Consensus-based Standards for the selection of health
743 Measurement Instruments (COSMIN) framework and has been described in a
744 previously published protocol[62].

745 The version used in the present pilot trial has undergone item development and
746 expert consultation for content validation but has not yet completed full psychometric
747 validation. It will therefore be used as a preliminary outcome measure to explore
748 changes in sarcopenia-specific knowledge, beliefs and preventive behaviours and to
749 evaluate the practical feasibility of incorporating the instrument into a future definitive

trial. Findings based on KBBQ-SOA scores will be interpreted as exploratory.

Sarcopenia-related quality of life

Sarcopenia-related quality of life will be assessed using the Sarcopenia Quality of Life questionnaire (SarQoL)[63]. Scores will be calculated according to the established scoring procedure, with higher scores indicating better sarcopenia-related quality of life.

Wearable-derived physical activity, resting heart rate, and sleep outcomes

Participants in both groups will wear a Huawei Band 10 throughout the 24-week study period. Physical activity outcomes will include daily step count, activity energy expenditure, active hours, and distance. The heart rate outcome will be device-reported daily resting heart rate. Sleep-related outcomes will include total sleep duration, nocturnal sleep duration, nap duration, overall sleep score, number of nocturnal awakenings, percentages of light sleep, deep sleep and rapid eye movement sleep, deep sleep continuity score, breathing quality score, and mean heart rate, heart rate variability, oxygen saturation and respiratory rate during sleep. All wearable-derived outcomes will be treated as exploratory device-derived estimates generated by the device's proprietary algorithms.

Process evaluation

Process evaluation will examine how the SHEEP intervention is implemented and experienced in practice[64]. Measures will include exposure to digital education materials, exercise participation, wearable engagement, behavioural support contacts, implementation fidelity, technical difficulties, and deviations from the planned intervention. During the 12-week post-intervention follow-up period, maintenance of exercise behaviour will be assessed monthly using brief self-reported information on whether participants continue to engage in the exercise programme and their frequency of exercise participation. Baseline digital characteristics and eHealth literacy will not be treated as intervention outcomes but may be explored as contextual factors associated with intervention engagement, wearable adherence, data completeness or attrition. Digital acceptability will be evaluated primarily after participants have

experienced the intervention rather than through the prospective technology-acceptance and future-participation questions used in the preceding screening study. Post-intervention evaluation will therefore focus on actual experiences of ease of use, perceived usefulness, burden, satisfaction, willingness to continue using the digital components, and perceived barriers and facilitators.

Qualitative evaluation

Following completion of the 12-week intervention, semi-structured interviews will be conducted with a purposive sample of participants from both groups[65], including participants with differing levels of intervention engagement and, where feasible, individuals who discontinue the intervention[66,67].

Interviews will explore experiences of trial participation, acceptability of the intervention and comparator, digital health education, home-based exercise, wearable monitoring, behavioural support, perceived physical and behavioural changes, barriers and facilitators to engagement, burden of outcome assessments, and recommendations for refining the intervention and trial procedures before a future definitive randomised controlled trial[68].

Assessment schedule

Assessments will be conducted at baseline before randomisation (T0), monthly during the 12-week intervention period (T1–T3), and monthly during the subsequent 12-week post-intervention follow-up period (T4–T6). Objective physical and body composition measures will therefore be assessed at seven time points from baseline to Month 6. The monthly assessment schedule was informed by the preceding single-arm feasibility study, in which repeated assessments were successfully implemented and provided longitudinal information on changes in muscle-related outcomes[24]. Questionnaire-based outcomes will be administered at selected time points according to their intended purpose and to minimise participant burden, while wearable-derived data and intervention adherence will be collected continuously throughout the relevant

study periods. Table 1 presents the schedule of enrolment, interventions, and assessments.

Table 1. SPIRIT Schedule of Enrolment, Interventions and Assessments

Study period	**Enrolment**	**Intervention period (12 weeks)**			**Post-intervention follow-up (12 weeks)**		
Time point	**T0 (Baseline)**	**T1 (Week 4)**	**T2 (Week 8)**	**T3 (Week 12)**	**T4 (Week 16)**	**T5 (Week 20)**	**T6 (Week 24)**
Enrolment							
Eligibility screen	*						
Informed consent	*						
Randomisation	*						
Interventions							
SHEEP intervention (education + exercise + wearable + behavioural support)		←	—	→			
Active digital health education (control + wearable)		←	—	→			
Assessments							
Demographic/health characteristics	✓						
Digital technology history	✓						
eHEALS	✓						
Handgrip strength	✓	✓	✓	✓	✓	✓	✓
3MWT	✓	✓	✓	✓	✓	✓	✓
FTSST	✓	✓	✓	✓	✓	✓	✓
Anthropometry	✓	✓	✓	✓	✓	✓	✓
BIA/body composition	✓	✓	✓	✓	✓	✓	✓
Dietary diversity	✓	✓	✓	✓	✓	✓	✓
KBBQ-SOA	✓			✓			✓
SarQoL	✓			✓			✓
Continuous and other assessments							
Wearable data	start	←	—	—	—	—	→
Exercise adherence (SHEEP group only)		←	—	→			
Post-intervention exercise maintenance (SHEEP group only)					←	—	→
Adverse events		←	—	—	—	—	→
Acceptability/process measures		Brief	Brief	✓	Brief	Brief	✓
Qualitative interview				✓			

Note: T0, baseline; T1, week 4; T2, week 8; T3, week 12 (end of intervention); T4, week 16; T5, week 20; T6, week 24 (end of follow-up). Abbreviations: 3MWT, 3-Metre Walk Test; FTSST, Five Times Sit-to-Stand Test; BIA, bioelectrical impedance analysis; KBBQ-SOA, Knowledge, Belief,

and Behaviour Questionnaire on Sarcopenia for Older Adults; SarQoL, Sarcopenia Quality of Life questionnaire; eHEALS, eHealth Literacy Scale.

Timeline

Participant recruitment is planned to commence on 1 January 2027 and will be completed by 14 January 2027, with a target sample of 60 participants to be enrolled. Potential participants will be identified from a preceding community-based muscle health screening programme. Between December 2026 and January 2027, pre-screening contact will be undertaken to introduce the study and gauge interest; this stage will not involve any trial-specific assessments or informed consent. Formal enrolment and baseline assessment will commence on 1 January 2027, with the first participant expected to be enrolled on that date, consistent with the registered Date of First Enrolment. Following baseline assessment, eligible participants will be individually randomised in a 1:1 ratio to the SHEEP intervention group or the time-matched active digital health education control group. Each participant will complete a 12-week intervention period followed by a 12-week follow-up period. Outcome assessments will be conducted according to the predefined assessment schedule, and semi-structured interviews will be undertaken following completion of the intervention to explore participants' experiences and acceptability of the intervention and trial procedures. Allowing for staggered recruitment and completion of the 24-week study period, final participant follow-up is expected to be completed by July 2027, with subsequent data analysis and reporting. Figure 1 shows the study design and participant flow of the Pilot SHEEP.

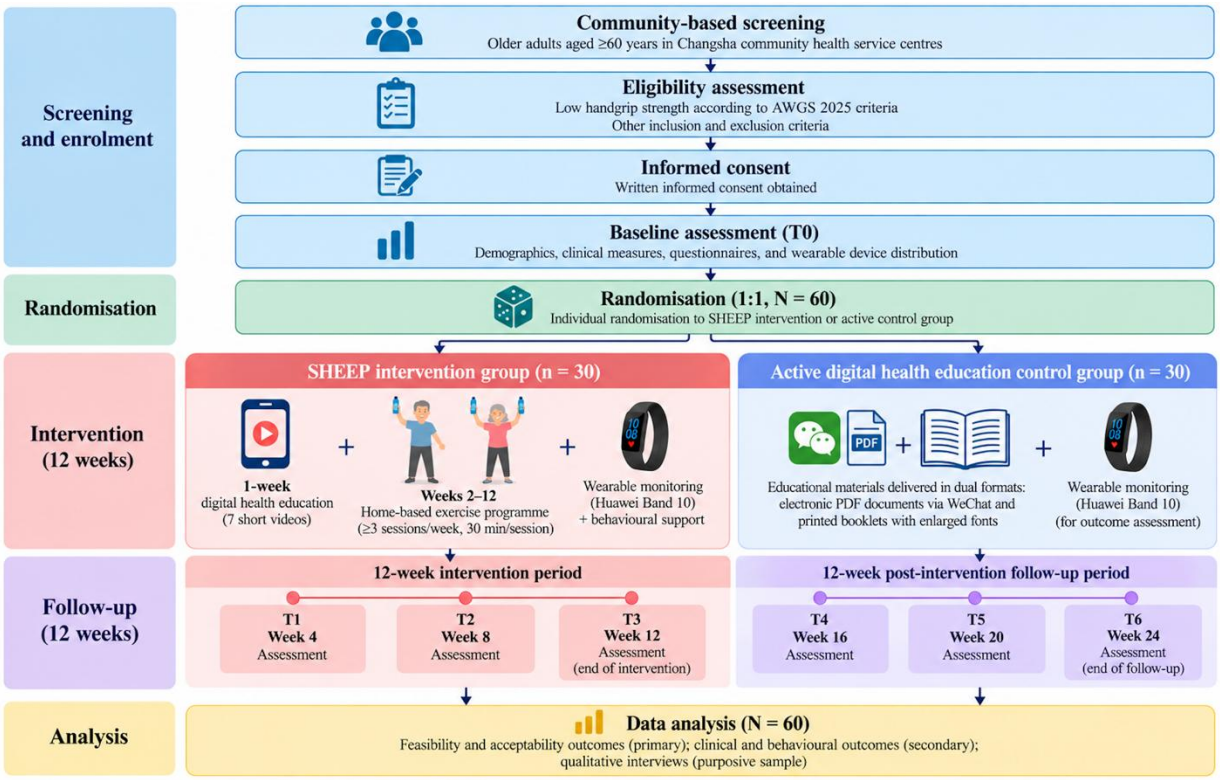


Figure 1. Study Design and Participant Flow of the SHEEP Pilot Randomized Controlled Trial

Note: The figure illustrates participant screening, enrolment, randomisation, intervention allocation, and assessments over the 24-week study period. Sixty participants will be randomised (1:1) to the SHEEP intervention or active control group. Abbreviations: SHEEP, Smart Health Education and Exercise Program; AWGS, Asian Working Group for Sarcopenia.

Progression criteria

To determine whether the pilot trial provides sufficient evidence to proceed to a definitive randomised controlled trial, a set of pre-specified progression criteria will be applied. These criteria are informed by methodological recommendations for pilot trials and by the findings of our preceding single-arm feasibility study. A traffic-light approach will be used to guide decisions regarding progression (go), modification (amend), or discontinuation (stop). Table 2 shows the detailed progression criteria for this pilot trial.

Table 2. Progression criteria for the pilot trial

Domain	Indicator	Green (Proceed)	Amber (Amend and proceed)	Red (Stop/ redesign)
Recruitment	Proportion of target sample recruited within the 2-week recruitment window	≥ 80%	≥60% to <80%	< 60%
Retention	Proportion of randomised participants retained at 24-week follow-up	≥ 80%	≥70% to <80%	< 70%
Exercise adherence	Proportion of participants completing ≥ 70% of prescribed exercise sessions	≥ 60%	≥40% to <60%	< 40%
Outcome completeness	Proportion of completed key clinical outcome assessments (e.g., handgrip strength) across all time points	≥ 85%	≥70% to <85%	< 70%
Wearable data availability	Proportion of scheduled participant-days with usable daily step-count data over the 24-week study period	≥ 70%	≥50% to <70%	< 50%
Safety	Occurrence of adverse events (AEs) and serious adverse events (SAEs)	No intervention-related SAEs	Intervention-related non-serious AEs (e.g., mild musculoskeletal pain) that are manageable without protocol modification	Any intervention-related SAE, or unexpected AEs requiring major protocol modification or trial suspension

Note: Wearable progression criteria use daily step-count availability across all scheduled participant-days over 24 weeks for all randomised participants. Other wearable outcomes will be assessed separately. Low or zero step counts alone do not invalidate a record. Decision rules will be applied in the following order:

· Stop/review (Red): Any safety-domain Red rating or ≥2 Red domains will pause progression pending review. Any intervention-related SAE, whether expected or unexpected, triggers safety review. Progression requires resolution of safety concerns and any necessary ethics approvals; otherwise, redesign or discontinuation will be considered.

· Amend and proceed (Amber): If no overall Red rule applies, ≥2 Amber domains or one non-safety Red domain will prompt review of whether progression with modifications is warranted.

· Proceed (Green): All domains Green, or one Amber with all others Green, supports progression without major modifications.

Within the safety domain, Red takes precedence over Amber, and Green applies only if neither criterion is met. Decisions will be made by the research team and Trial Steering Committee, informed by qualitative findings. These rules govern progression to a definitive RCT, not immediate safety management during the pilot.

Statistical analysis

Quantitative data analysis

All quantitative analyses will be conducted using IBM SPSS Statistics (version 27.0) and/or R statistical software. Baseline characteristics will be summarised using descriptive statistics, including means and standard deviations for continuous variables and frequencies and percentages for categorical variables. Between-group baseline comparability will be assessed descriptively rather than inferentially, in line with recommendations for pilot randomised controlled trials[69]. The primary analysis will focus on feasibility outcomes, including recruitment, retention, adherence, and data completeness. These outcomes will be reported as proportions with corresponding 95% confidence intervals.

As this is a pilot trial, it is not formally powered to detect statistically significant differences in clinical outcomes. However, to provide preliminary parameter estimates for the design of a future definitive trial, exploratory analyses of secondary clinical outcomes will be conducted. For continuous outcomes, between-group differences will be estimated using mixed-effects models, and p-values will be reported (using a two-sided α level of 0.05) solely to describe exploratory trends and effect sizes, rather than to infer definitive efficacy. All p-values will be unadjusted for multiple comparisons and will be interpreted with caution, in conjunction with the estimated 95% confidence intervals and the primary feasibility findings.

Analysis of clinical outcomes

Given the repeated-measures design, longitudinal changes in clinical and behavioural outcomes, including handgrip strength, physical performance, anthropometric and body composition measures, dietary diversity, sarcopenia-related

quality of life, sarcopenia-specific knowledge, beliefs and behaviours, and wearable-derived outcomes, will be analysed using mixed-effects models as appropriate to the distribution and measurement schedule of each outcome[70]. Models will include fixed effects for group, time, and the group-by-time interaction, with participant-level random effects to account for repeated observations.

Handling of missing data

All analyses will follow an intention-to-treat principle[71]. Missing data patterns will be examined, and if necessary, multiple imputation methods will be considered under the assumption that data are missing at random[72]. Sensitivity analyses using available-case data will also be conducted.

Wearable device data analysis

Wearable-derived outcomes will be aggregated into daily and weekly averages for analysis. Given the characteristics of the consumer-grade device and the behavioral patterns of older adults, data validity will be verified using a combined objective and subjective approach.

Review of data availability and reported non-wear. Daily step-count records will be reviewed during weekly follow-up. Low or zero step counts will not, by themselves, be classified as invalid. Participants will be asked about forgotten wear, prolonged device removal, charging, and technical problems during the preceding week. Days with confirmed full-day non-wear will be treated as missing. Reported partial-day non-wear and uncertain wear status will be documented separately. Low-activity records will be retained unless there is independent evidence of incomplete recording.

Sleep data. Sleep parameters, including total sleep duration, sleep stages, overall sleep score, and mean heart rate during sleep, are automatically processed by the device's proprietary algorithms. Incomplete wear time at night (e.g., removing the device before bed or due to a loose strap) frequently results in missing sleep records or absent nocturnal heart rate readings. Nights with no device-generated sleep records will be treated as missing data. During weekly follow-ups, participants will be prompted to explain the reasons for missing sleep records (e.g., forgot to wear it overnight, loose

strap) to assist in data cleaning.

Heart rate data. Device-reported daily resting heart rate (RHR) will be collected as an exploratory outcome. This measure is distinct from nocturnal heart rate and is generated by the device's proprietary algorithms based on daytime, awake, and non-active status. No additional reading-level artifact filtering will be undertaken for RHR. Unavailable RHR values (e.g., due to loose wear during the day) will be recorded as missing. Unusual values will prompt verification of the source record and follow-up regarding relevant symptoms or device problems, rather than automatic exclusion.

Days or weeks identified as missing will be handled according to the predefined missing data strategy (multiple imputation under a missing-at-random assumption, with sensitivity analyses using available cases). Longitudinal changes will be analysed using mixed-effects models. Compliance with wearable use and the proportion of valid data retained after cleaning will be summarised descriptively and reported as part of the primary feasibility outcomes.

Weekly aggregation and data availability. Weekly summaries will be calculated separately for each outcome when at least three usable daily or nightly observations are available within the corresponding seven-day study week. Weekly means will be calculated using only the available observations, with the denominator equal to the number of observations contributing to that mean. Missing observations will not be assigned zero values. If fewer than three usable observations are available, the weekly summary for that outcome will be recorded as missing, while the available daily or nightly observations will be retained. Data availability will be reported separately as the number of usable observations divided by the number of scheduled daily or nightly observations, expressed as a percentage.

Qualitative data analysis

All semi-structured interviews will be audio-recorded and transcribed verbatim in Chinese. Analysis will be conducted in Chinese, with selected quotations translated into English for reporting. Data will be analysed using reflexive thematic analysis following Braun and Clarke's six-phase approach[73,74]. NVivo software will support data

management and coding. Coding will combine inductive engagement with participants' accounts and deductive attention to concepts informing the SHEEP intervention, including the Behaviour Change Wheel and eLiFE framework. These concepts will sensitise the analysis rather than constitute a fixed coding framework. Researchers will maintain reflexive notes to examine how their assumptions and involvement in intervention development shape interpretation. Collaborative discussions will explore alternative interpretations and refine developing codes and themes, thereby enriching the depth of the analysis. Themes will be developed and reviewed iteratively against the coded extracts and the full dataset. Qualitative findings will be integrated with quantitative feasibility outcomes to identify barriers, explain patterns of engagement, and inform refinement of the intervention and future definitive trial procedures.

Data management

All study data will be collected, stored and managed in accordance with applicable Chinese data protection requirements and relevant institutional data governance policies. Each participant will be assigned a unique study identification number upon enrolment. Personal identifiable information will be stored separately from research data in a password-protected, encrypted file accessible only to the principal investigator and authorised members of the research team. All analytical datasets will be de-identified prior to analysis. Quantitative data, including questionnaire responses, anthropometric measures, physical performance outcomes and body composition data, will be entered into a secure electronic database with restricted access. Data quality will be ensured through double data checking and routine consistency verification. Wearable data will be synchronised weekly with the paired smartphone application with support from the research team. Synchronisation difficulties and apparent data gaps will be documented. The synchronised data will be securely extracted from the platform and stored in encrypted files on a secure institutional server. These data will be linked to participant study IDs only and will not contain identifiable personal information.

Audio recordings from qualitative interviews will be stored on encrypted, password-protected devices before being transferred to a secure institutional server. All recordings will be transcribed verbatim, anonymised, and the original audio files will be deleted following transcription verification. All study data will be stored securely for a minimum of 10 years after study completion in accordance with institutional and regulatory requirements. Access to the final dataset will be restricted to the research team. Any data sharing for secondary analysis will be conducted only after full anonymisation and in accordance with ethical approval.

Study monitoring

The principal investigator (PI) will have overall responsibility for the conduct of the trial, including coordination of recruitment, intervention delivery and follow-up procedures across participating community sites. At each participating community site, a designated community coordinator will assist with participant identification and administrative support for recruitment. Community coordinators will not be involved in randomisation procedures, outcome assessment or data analysis to minimise the risk of selection or information bias. The randomisation process, outcome assessment and data analysis will be conducted by members of the research team who are independent from recruitment procedures and blinded to group allocation where feasible. A joint research team comprising investigators from China and the United Kingdom will oversee trial quality assurance, including monitoring of protocol adherence, intervention fidelity and data integrity. Monthly online meetings will be held to review study progress, address operational challenges and ensure consistency in trial implementation across sites.

Data quality will be monitored regularly through range checks, completeness checks and verification of wearable device data completeness and consistency. Any protocol deviations will be documented, reviewed and reported during monthly meetings. A risk management framework has been established prior to study initiation.

Potential risks to participants (e.g. exercise-related adverse events), organisational risks (e.g. recruitment delays) and methodological risks (e.g. attrition or missing data) have been identified. Procedures for monitoring, reporting and responding to adverse events will be implemented throughout the trial period in accordance with institutional ethical requirements. Serious adverse events will be reported to the ethics committee in accordance with regulatory requirements, and appropriate action will be taken to ensure participant safety.

Discussion

This pilot randomised controlled trial aims to evaluate the feasibility and acceptability of a social media-based multicomponent intervention (SHEEP), combining digital health education, structured home-based exercise, wearable activity monitoring, and behavioural support, for community-dwelling older adults with possible sarcopenia. By adopting a mixed-methods design, this study will generate comprehensive evidence on both the quantitative feasibility of trial procedures and the qualitative experiences of participants, thereby informing the optimisation of a future definitive randomised controlled trial.

Unlike previous studies that have predominantly focused on face-to-face or printed health education approaches[16], this study integrates a fully digital delivery model using social media platforms and wearable technologies. This design allows for continuous monitoring of physical activity and health-related behaviours, while also enabling real-time behavioural support. The findings will therefore provide novel insights into how digital health interventions can be operationalised in community-based sarcopenia prevention among older adults.

The study is expected to contribute to the growing literature on digital health interventions by providing empirical evidence on recruitment feasibility, participant adherence, intervention acceptability, and data collection procedures in a real-world community setting. In addition, preliminary estimates of outcome variability and

between-group differences will be used to inform the design and sample size calculation of a future fully powered randomised controlled trial.

This trial is among the first to operationalise the AWGS 2025 diagnostic framework in a community-based intervention context. While AWGS 2025 extends screening to middle-aged adults (50–64 years)[1], we retained the inclusion threshold of ≥60 years to align with China's established definition of older adults and maintain comparability with our preceding feasibility study. Participants aged 60–64 years will be evaluated using the newly established middle-aged cutoffs—a distinction that will be carefully examined in subgroup analyses.

Several limitations should be acknowledged. First, as a pilot randomised controlled trial, the sample size is not powered to detect statistically significant differences in clinical outcomes; therefore, all effectiveness-related findings should be interpreted as exploratory. Second, although individual randomisation will be used, the study will be conducted in a limited number of urban communities in Changsha, China, which may restrict generalisability to other regions or healthcare settings. Third, the intervention requires participants to have access to a smartphone and internet connection, which may introduce selection bias and limit applicability to digitally excluded populations. Future studies should consider hybrid delivery models combining digital and offline approaches to improve inclusivity[75]. Fourth, although wearable devices provide objective measures of physical activity and sleep, device accuracy and participant adherence to wearing the device may introduce measurement variability. Finally, the newly developed KBBQ-SOA instrument used to assess knowledge, belief and behaviour is currently in an early validation stage[62]. Although it has undergone expert consultation and content refinement, further psychometric testing will be required in larger studies. Besides, the reliance on self-reported clarification during weekly follow-ups to distinguish non-wear days from true low-activity days may introduce recall bias; however, this pragmatic approach was necessary to balance data completeness with the practical realities of older adults' daily routines.

Study findings will be disseminated through peer-reviewed publications, academic

conferences and community engagement activities. Summarised results will also be shared with participating communities through lay summaries and public engagement events. De-identified participant-level data will not be publicly available due to ethical and privacy considerations but may be available from the corresponding author upon reasonable request and subject to institutional approval. Future research should evaluate the effectiveness of the SHEEP intervention in a fully powered multicentre randomised controlled trial and explore the scalability of integrating wearable technology and social media-based interventions into routine community-based sarcopenia prevention programmes.

Supporting information

S1 File. SPIRIT 2025 Statement checklist completed for the SHEEP pilot randomised controlled trial (PDF).

S2 File. Template for Intervention Description and Replication (TIDieR) checklist completed for the SHEEP intervention (PDF).

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