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Feasibility and acceptability of a SHEEP among community-dwelling young-older adults with possible sarcopenia

Submission date
01/09/2023

Recruitment status
No longer recruiting

Registration date
14/09/2023

Overall study status
Completed

Last Edited
07/01/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Despite the comparatively high prevalence of possible sarcopenia among young-older adults in the community, there is currently no available and effective social media-based intervention to increase the awareness and behaviour of the target population to prevent sarcopenia. Using the co-design methodology, we developed a multicomponent intervention strategy of health education and exercise for sarcopenia prevention utilizing the TikTok platform. The primary purpose of this study is to examine the feasibility and acceptability of the social-media-based health education plus exercise programme (SHEEP) intervention to enhance muscle function in community-dwelling young-older adults with possible sarcopenia. This study will be the first social-media-based multicomponent intervention program for community young to old adults with possible sarcopenia to improve their muscle function, awareness and behaviour in preventing sarcopenia. Findings will generate new evidence regarding the use of social media in health education for improving awareness of sarcopenia prevention, as well as the feasibility of using social media to influence participants' behavioural changes through exercise. This may help researchers identify ways to optimise the acceptability and efficacy of the SHEEP intervention for the targeted population.

Who can participate?
Chinese residents living in the community in Changsha, China, who are 60 - 69 years old with possible sarcopenia

What does the study involve?
This protocol outlines the entire research procedure for a prospective single-arm pre-post feasibility study employing a mixed-method design, which will be conducted between April 2024 and July 2024. Based on the TikTok platform, participants will be required to view a total of seven health education videos in the first week, and each video lasts four to six minutes. Then, participants will receive a six-week multi-component exercise through TikTok, with at least three sessions/week, 30 minutes/session, and moderate intensity. Finally, a nine-week follow-up will be conducted. Data collection will be conducted at baseline, post-intervention and follow-up periods. The primary outcome will include evaluating recruitment capability, data collection

procedure, outcome measurement, intervention procedures' acceptability, researchers’ ability to manage and implement the study, etc. The secondary outcome is to compare standard measures for muscle function (e.g. handgrip strength, skeletal muscle mass, physical performance), body composition (e.g. body fat, body mass index, bone mineral), and other measures (e.g. perceived knowledge, personal motivation, behavioural skills). Finally, all participants will be offered a semi-structured interview to assess their in-depth experiences with the intervention and research process.

What are the possible benefits and risks of participating?
Participants in the research receive the following advantages:
1. They can learn about sarcopenia and how to prevent it in advance
2. It may increase participants' awareness and behaviour to prevent sarcopenia
3. Access to a professional medical team to monitor and maintain their muscle health
4. Their contribution to this study will be disseminated to the broader community to assist more seniors in preventing sarcopenia

Participation in this research carries the following risks:
1. Participants in an exercise intervention may sustain an injury, such as a sprain or a stumble, due to improper form
2. Due to the ineffectiveness of the intervention in this study, they may be unable to prevent sarcopenia

Potential for Distress: Some participants may feel uncomfortable in semi-structured interviews due to poor communication skills, lonely or socially isolated. It is possible that some may find interview questions or the interview process relating to this upsetting. At the end of each interview, the researcher will talk briefly with the participants about how they are feeling following the interview and inform them. Mild distress: Encourage the participant to speak to a family member for support, or offer to contact a family member or friend on the participant's behalf. Moderate distress: Immediately inform the participant's nominated family member or friend and ask them to contact the participant quickly. High distress: Contact emergency services and the participant's nominated family member or friend. In all instances, the researcher will seek support from their supervisor/line manager.

Where is the study run from?
The University of Manchester (UK)

When is the study starting and how long is it expected to run for?
March 2021 to September 2024

Who is funding the study?
1. The University of Manchester-China Scholarship Council Joint Scholarship
2. National Institute for Health and Care Research (NIHR) Senior Investigator Award to Prof Todd (NIHR200299)

Who is the main contact?
Ya Shi, ya.shi@postgrad.manchester.ac.uk (UK)

Contact information

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Feasibility and acceptability of a social-media-based health education plus exercise programme (SHEEP) to improve muscle function among community-dwelling young-older adults with possible sarcopenia

Acronym
SHEEP

Study objectives
1. The social-media-based health education plus exercise programme (SHEEP) is feasible and acceptable among young-older adults with possible sarcopenia in the community.
2. The SHEEP has a potentially beneficial impact on muscle function among young-older adults with possible sarcopenia in the community.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/04/2024, University Research Ethics Committee (UREC) (The University of Manchester, Research Governance, Ethics and Integrity, Oxford Rd, Manchester, M13 9PL, United Kingdom; +44 (0) 161 306 6000; research.ethics@manchester.ac.uk), ref: 2023-18502-32033

Study design
Single-arm prospective pre-post mixed methods study

Primary study design
Interventional

Study type(s)
Other, Prevention, Efficacy

Health condition(s) or problem(s) studied
Prevention of sarcopenia among young-old adults with possible sarcopenia in the community

Interventions
Current interventions:
A single-arm prospective pre-post study will be conducted to evaluate the feasibility, acceptability, and preliminary impact of the social-media-based health education plus exercise programme (SHEEP) on the prevention of possible sarcopenia in community-dwelling young-older adults. In this six-week exercise intervention with a nine-week follow-up study, both quantitative and qualitative methods will be employed to evaluate the outcomes.

Participants will receive the SHEEP intervention strategy, which consists of one-week health education and a six-week exercise. Participants will be required to view a total of seven health education videos posted on TikTok in the first week, including the following:
1. What is sarcopenia?
2. What are the common influence factors of sarcopenia?
3. What are the adverse effects of sarcopenia?
4. What are the manifestations of sarcopenia in life?
5. What are the common screening methods for sarcopenia?
6. What are the exercise methods to prevent sarcopenia?
7. What are the nutritional methods to improve sarcopenia?

Each video lasts four to six minutes. There is no restriction on the number of views, so participants are allowed to determine the number of videos per day. Participants must attend the exercise session on TikTok following completion of the health education learning. The duration of the exercise is fixed at 30 minutes and comprises four types of exercise: 3-minute warm-up training, 10-minute aerobic training, 14-minute resistance training, and 3-minute flexibility training. The frequency of exercise must be at least 3 times/week, and participants can increase the frequency of training per week based on their own situation. The overall exercise intensity is moderate. The resistance exercise is performed using a water-filled mineral water container. The progressive intensity of resistance exercise is divided into two modes: 500ml, 1000ml, 1500ml rise mode and 1000ml, 1500ml, 2000ml rise mode. Participants can select the mode that best suits their needs, and it is suggested that they increase one heavyweight every three weeks.

Previous interventions:
A single-arm prospective pre-post study will be conducted to evaluate the feasibility, acceptability, and preliminary impact of the social-media-based health education plus exercise programme (SHEEP) on the prevention of possible sarcopenia in community-dwelling young-older adults. In this ten-week intervention with a nine-week follow-up study, both quantitative and qualitative methods will be employed to evaluate the outcomes.

Participants will receive the SHEEP intervention strategy, which consists of one-week health education and a nine-week exercise. Participants will be required to view a total of seven health education videos posted on TikTok in the first week, including the following:
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Intervention Type
Mixed

Primary outcome(s)
Feasibility and acceptability measured using a Research record sheet (Self-developed) throughout the study

Key secondary outcome(s))
Current secondary outcome measures as of 01/02/2024:
1. Handgrip strength measured using a Digital hand-held dynamometer at T0, 4, 7, 10, and 13
2. Anthropometric measurements (e.g. weight, height) measured using a Stadiometer + Scale + Plastic tape at T0, 10 and 13
3. Body composition (e.g. muscle mass, body fat) measured using a Bioelectrical impedance analyzer device at T0, 4, 7, 10, and 13
4. Physical performance measured using the 4-Meter Walk Test and the Five Times Sit to Stand Test both at T0, 10 and 13
5. Nutrition state measured using the Mini-Nutritional Assessment Short Form at T0, 10 and 13
6. Perceived knowledge measured using 21 true or false quizzes related to sarcopenia (Self-developed) at T0, 1, 4, 10 and 13
7. Personal motivation measured using the Self-efficacy for Managing Chronic Disease 6-item

Scale at T0, 10 and 13
8. Behavioural skills measured using the Self-management Behaviour for Chronic Disease Scale at T0, 10 and 13
9. Behaviour change monitoring measured using an Exercise adherence sheet (Self-developed) throughout the study, Records of viewing and sharing sarcopenia-related information (Self-developed) throughout the study, Willingness to formulate habits of regular exercise (Self-developed) at T0, 10 and 13 and Records of exposure percentage of exercise and sarcopenia related videos (Self-developed) at T0, 4, 7, 10, and 13

T0 = baseline; T1= 1-week post-intervention; T4= 3-week post-intervention; T7 = 6-week post-intervention; T10 = 3-week follow-up; T13 = 6-week follow-up.

Previous secondary outcome measures:
1. Handgrip strength measured using a Digital hand-held dynamometer at T0, 4, 7, 10, 13, 16 and 19
2. Anthropometric measurements (e.g. weight, height) measured using a Stadiometer + Scale + Plastic tape at T0, 10 and 19
3. Body composition (e.g. muscle mass, body fat) measured using a Bioelectrical impedance analyzer device at T0, 4, 7, 10, 13, 16 and 19
4. Physical performance measured using the 4-Meter Walk Test and the Five Times Sit to Stand Test both at T0, 10 and 19
5. Nutrition state measured using the Mini-Nutritional Assessment Short Form at T0, 10 and 19
6. Perceived knowledge measured using 21 true or false quizzes related to sarcopenia (Self-developed) at T0, 1, 4, 10 and 19
7. Personal motivation measured using the Self-efficacy for Managing Chronic Disease 6-item Scale at T0, 10 and 19
8. Behavioural skills measured using the Self-management Behaviour for Chronic Disease Scale at T0, 10 and 19
9. Behaviour change monitoring measured using an Exercise adherence sheet (Self-developed) throughout the study, Records of viewing and sharing sarcopenia-related information (Self-developed) throughout the study, Willingness to formulate habits of regular exercise (Self-developed) at T0, 10 and 19 and Records of exposure percentage of exercise and sarcopenia related videos (Self-developed) at T0, 4, 7, 10, 13, 16 and 19.

T0 = baseline; T1= 1-week post-intervention; T4= 4-week post-intervention; T7 = 7-week post-intervention; T10 = 10-week post-intervention; T13 = 3-week follow-up; T16 = 6-week follow-up; T19 = 9-week follow-up.

Completion date
01/09/2024

Eligibility

Key inclusion criteria
1. 60 - 69 years old
2. Chinese residents living in the community
3. Willingness to use TikTok
4. Individuals with possible sarcopenia, as defined by low Grip Strength [M:<28 kg, F:<18kg] in accordance with the 2019 Asian working group consensus on diagnosis criteria for sarcopenia
5. Informed consent for screening and research

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 years

Upper age limit
69 years

Sex
All

Total final enrolment
35

Key exclusion criteria
1. Unable to communicate or independently complete learning and exercise using TikTok
2. Serious or unstable medical illness, such as severe cardiovascular or respiratory conditions, mental disorders, dementia, etc.
3. Currently undertaking moderate-intensity exercise (≥ 150mins/week)
4. Contraindications for the use of Bioelectrical Impedance Analysis (BIA), such as people with implanted cardiac pacemakers, or other electronic devices or metal grafts, or with significant pitting oedema, or with limb dysfunction or body paralysis, or while taking medications that affect body composition, such as diuretics or glucocorticoids

Date of first enrolment
06/05/2024

Date of final enrolment
19/05/2024

Locations

Countries of recruitment
China

Study participating centre
Sanchaji Community Health Service Centre
Yuelu District
Yinpan North Road
Yuehua New Garden

Changsha
China
410023

Study participating centre
Guanshaling Community Health Service Centre
Yuelu District, Guanshaling Street,
Yuehua Road, and Gushan Paradise
Changsha
China
410023

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Organisation
China Scholarship Council

Funder(s)

Funder type
Government

Funder Name
University of Manchester

Alternative Name(s)
University of Manchester in United Kingdom, University of Manchester UK, The University of Manchester, UoM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Ya Shi, ya.shi@postgrad.manchester.ac.uk. Anonymised data will be shared using a discipline-specific UK-based data repository, the Health Data Research Innovation Gateway (https://www.re3data.org/repository/r3d100013505). Data will be shared after all data collection and analysis is completed in this study around May 2024. The study team will ensure that participants consent to the anonymised sharing of data (primary outcome, secondary outcome and interview data) by including this as a statement in the consent forms: "I agree that any anonymised data collected, including body measurements, questionnaires, compliance and interview data, may be made available to other researchers".

Ensuring Confidentiality: In the participant information sheets, participants will be fully briefed on how their confidentiality will be ensured. Personal data will be pseudonymised as soon as possible. Any identifying information will be removed and replaced with a random ID number. For the interview recording, verbal consent will be recorded and stored separately from the semi-structured interview. Only the research team will have access to the key that links this ID number to personal information. The pseudonymised key will be stored in a separate secure location to the data files (and consent recording for interviews) and all data collected will be securely stored (password encrypted) on University of Manchester systems.

The research will be conducted in line with the following policies and guidelines:
- The University of Manchester Research Data Management Policy
- The University of Manchester Data Protection Policy
- The University of Manchester Records Management Policy
- The University of Manchester Publications Policy

- The University of Manchester IT Policies and guidelines
- The University of Manchester Intellectual Property Policy
- The University of Manchester Social Media and guidelines for use in research
- The University of Manchester Standard Operating Procedure for taking recordings of participants for research projects.

Ensuring informed consent: The participant information sheets and the consent forms clearly outline the procedures involved in the study (for both the intervention and follow-up stages of the study). These forms were produced as per the University of Manchester Research Ethics guidelines and templates. During the recruitment process, researchers will first ask for older adults' permission by telephone call before meeting them. Then, researchers will provide older adults with a comprehensive description of the research's contents and objectives. If they are still interested in the study, researchers will carefully follow a consent script where they will read the consent form to the participants and acquire paper consent or verbal consent before proceeding to the next stage. Moreover, consent is requested to allow data to be shared and re-used during this stage. Participants will be provided with the contact details of the PI and encouraged to get in touch with any questions prior to consenting to take part in the study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/01/2025	07/01/2025	Yes	No
Protocol file		17/04/2024	18/04/2024	No	No