ISRCTN17158017 https://doi.org/10.1186/ISRCTN17158017

Improving health and maintaining independent living in frail older adults by reducing sitting time

Submission date
02/08/2021

Recruitment status
No longer recruiting

Registration date
06/08/2021

Overall study status
Completed

Last Edited
15/10/2024

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
We all lose muscle and strength as we get older (this is called sarcopenia) and this can affect how well we can do everyday activities. Reducing the amount of time spent sitting down could help improve older people's strength, balance, ability to carry out everyday activities (e.g. standing up from a chair, walking and climbing stairs) and help them to maintain their independence for longer. The aim of this study is to test a new remotely delivered programme to reduce sitting behaviour in older adults to help them with doing these types of everyday activities.

Who can participate?
Community-dwelling adults aged 65 years or older who may be losing strength which could make it harder for them to do everyday activities. The researchers are looking for people who may need help with some daily tasks like 'heavy' housework (e.g. hoovering, ironing, cleaning the floor) and getting about on public transport or getting in and out of a car.

What does the study involve?
Participants will be involved in the study for about 6 months. The researchers will first take a set of health and behaviour measurements from each participant and will then randomly enter them into either the control group or the intervention group. Regardless of which group they are in, the researchers will repeat the health and behaviour measurements again 3 and 6 months later. Participants in the intervention group will receive the Frail-LESS programme straight away, which will last for 6 months and will include the following:
1. An education programme about the health benefits of sitting less and ways that participants can try to reduce their sitting time.
2. A device that is worn on the wrist to support with sitting less. This device tracks sitting time and sends alerts to encourage the user to get up and move more often.
3. Sessions with a health coach over the phone or by video call who will help in meeting targets for reducing sitting behaviour.
4. Participants will be able to join a Frail-LESS peer support group, which will have other members in it from the study. They will be able to support each other in reducing their sitting

time during regular meetings and by keeping in touch by phone and email.
Participants in the control group will be asked to continue with their normal daily behaviours for 6 months. They will take part in the same measurements as the intervention group during this time. After 6 months, their involvement in the study will end but they will have the opportunity to receive the Frail-LESS programme. It is important to have a control group to see how the Frail-LESS programme works compared to people who aren't receiving it.
During the study the researchers will take measures to see how well participants' bodies function physically by testing balance, normal walking speed, how easily they can rise and stand up from a chair, and how hard they can grip with their hand. The amount of muscle in the body will be measured by sticking four small electrode pads to the hand and foot. The researchers can work out muscle levels by sending a very small safe electrical current through the body. They will also measure height and weight and ask participants to complete some questionnaires around health and lifestyle. They will take measures of sitting and physical activity using a device that is attached to the thigh for 8 days.

What are the possible benefits and risks of participating?
Participants may experience improvements in their health from receiving the intervention; this includes the control group who can have the intervention at the end of the study. The researchers are hoping this study leads to a larger study that may help to change healthcare for older adults to help them stay independent with everyday activities like standing up, walking and climbing stairs. Participants will receive £30 of shopping gift vouchers if they take part in all of the measurements and return the activity monitor each time they have worn it. Participants will be reimbursed travel expenses for any visits they make to the university as part of this study. There is a small chance of skin irritation from the dressing used to attach the activity monitor to the skin. If this happens, participants should remove the activity monitor immediately and discuss the problem with the research team. When the researchers measure how well the participant's body functions there may be a risk of injury. During these measures, participants will need to wear suitable footwear (flat heels) to minimise the risk of falling and do the tests without any obvious trip hazards. There is a small risk of experiencing some distress during the optional interview. Participants can end the interview at any point without giving a reason why and can seek support from their GP if they feel this is appropriate.

Where is the study run from?
Brunel University London (UK)

When is the study starting and how long is it expected to run for?
May 2021 to February 2023

Who is funding the study?
Abbeyfield Research Foundation (UK)

Who is the main contact?
Dr Daniel Bailey
daniel.bailey@brunel.ac.uk

Study website
https://tinyurl.com/Frail-less-study

Contact information

Type(s)

Scientific

Contact name
Dr Daniel Bailey

ORCID ID
http://orcid.org/0000-0003-3772-630X

Contact details
Brunel University London
Kingston Lane
Uxbridge
United Kingdom
UB8 3PH
+44 (0)1895 265363
daniel.bailey@brunel.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
290128

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
3.0, IRAS 290128, CPMS 49016

Study information

Scientific Title
Reducing sarcopenia and maintaining independent living in frail older adults via reductions in sitting time: the Frail-LESS (LEss Sitting and Sarcopenia in Frail older adults) intervention

Acronym
Frail-LESS

Study objectives
The Frail-LESS intervention will be acceptable and it will be feasible to deliver and evaluate the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 26/05/2021, South Central - Berkshire B Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8253, +44 (0)207 104 8068, +44 (0)207 104 8276; berkshireb.rec@hra.nhs.uk), REC ref: 21/SC/0107

Study design
Mixed-methods randomized controlled feasibility trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Frailty and sarcopenia

Interventions
Participants will be randomly allocated to a control or intervention group for 6 months (an independent researcher will use computer generated lists for randomisation of participants in a 1:1 (intervention:control) ratio with a fixed block size of four).

Participants in the control group will not receive any intervention but will complete the same measurements as the intervention group.

Each participant randomised to the intervention group will receive the Frail-LESS intervention for approximately 24 weeks. This will include:

1. Tailored feedback based on baseline sitting measurements
2. Education programme that will cover information on the health risks of sitting too much, benefits of reducing sitting, awareness of own sitting time, goal setting, action planning, potential barriers, and examples of adaptable activities to reduce sitting based on preference and capabilities
3. Wearable device that tracks sitting time, steps and calories burnt. A coloured move bar fills up to alert the user if they have been sitting for too long and prompts the user to get up and walk for a couple of minutes so the bar can be reset. The user can connect the device to a smartphone app or website if they wish to so they can set and monitor goals and access real-time feedback
4. Health coaching sessions harnessed on the G.R.O.W (Goals, Reality, Options, Will) model that will take each participant through the four stages to enhance/enable intrinsic self-determined motivation, capability and opportunity. Calls will involve reviewing goals and problem-solving
5. Peer support in the Frail-LESS support group

Intervention Type
Behavioural

Primary outcome measure
Feasibility outcome measures calculated at the end of the study:
1. Participant eligibility will be calculated as: participants eligible/participants assessed for eligibility x 100
2. Recruitment rate will be calculated as: participants randomised / number of eligible participants screened x 100
3. Retention rate will be calculated as: participants completing the intervention/participants enrolled x 100)
4. Completion rates for the data collection measures will be calculated as: participants providing full outcome data/participants completing the study x 100
5. Acceptability of the intervention will be evaluated using self-report questionnaires that include closed and open-ended questions around engagement with the different intervention components. Self-report questionnaires will be completed by all participants to explore if the data collection measurements affected their behaviour. Semi-structured interviews will be completed with a subset of intervention participants to examine acceptability of the intervention. Semi-structured interviews will also assess the suitability of data collection procedures with a subset of control and intervention participants

Secondary outcome measures
Measured at baseline, 3 months and 6 months:
1. Sarcopenia: This will be measured in line with the European consensus definition:
1.1. Handgrip strength will be measured using a handgrip dynamometer (Takei Scientific Instruments Co., Ltd, Niigata, Japan). Information on the presence of any co-morbidities that may interfere with hand grip measures (e.g. arthritis) will be collected by self-report prior to the measure being taken. This will be performed on the dominant hand whilst standing with the elbow fully extended. Participants will complete three maximum attempts with a 1-min rest between each and the average recorded45.
1.2. Muscle mass will be estimated using the Bodystat 1500 (Bodystat Ltd, Isle of Man) bioelectrical impedance device. Participants will be required to fast for 4 hours prior to this measurement and to avoid vigorous physical activity (i.e. physical activity that makes you breathe hard and fast and would make it not possible to say more than a few words without pausing for breath), caffeine and alcohol to standardise hydration status, which can affect estimates of body composition when measured via bioelectrical impedance analysis.
1.3. Physical performance will be measured using the Short Physical Performance Battery (SPPB) which includes standing balance, walking speed and rising from a chair. Standing balance will be tested using tandem, semi-tandem and side-by-side stands. A researcher will demonstrate the task and will then support one arm while the participant positions their feet. The support will then be released and timing started. Timing will be stopped when the feet move, the participant grasps the researcher for support or once 10 seconds has passed. For the semi-tandem stand, the heel of one foot (participant's preference) is placed to the side of the first toe of the other foot. If this position cannot be held for 10 seconds, participants will be assessed with the feet in the side-by-side position. If the semi-tandem position is held for 10 seconds, participants will also be evaluated in the full tandem position (up to 10 seconds) with the heel of one foot directly in front of the toes of the other foot. An 8-foot walking course will be used to evaluate walking speed with participants instructed to "walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the shop". The walk will be timed and will be performed twice with the fastest time used for analysis. The rising from a chair task will be completed using a straight-backed chair placed next to a wall. Participants will fold their arms

and be instructed to stand up once from the chair. If this is performed successfully, participants will be asked to stand up and sit down as quickly as possibly five times, which will be timed. Each of the SPPB tests are scored on a 0-4 scale following published guidelines.
1.4. Self-reported ability to carry a heavy load, walking, rising from a chair, climbing stairs, and falls frequency will be measured using the SARC-F questionnaire. The SARC-F has been validated for sarcopenia classification that has a comparable predictive ability to international diagnostic criteria.
2. Physical function: difficulty with ADL will be assessed using the validated Groningen Activity Restriction Scale, which asks participants to rate their level of independence for 18 frequent daily activities e.g. dressing yourself, going up and down stairs, making the bed.
3. Sitting, standing and stepping: This will be measured using the activPAL device, which will be worn on the thigh for 24 hours per day for 7 consecutive full days. This device provides valid and reliable measures of sitting, standing, stepping and postural transitions. Participants will record the time they woke up and got out of bed, any times they undertook employed work, time they went to bed, and if the device was removed in a diary. A researcher will help each participant with attaching the monitor to their thigh and provide them with a copy of the diary during their data collection session.
4. Mood, wellbeing and quality of life:
4.1. Sarcopenia-specific quality of life will be measured using the validated SarQoL questionnaire, which measures quality of life across seven domains: (1) physical and mental health, (2) locomotion, (3) body composition, (4) functionality, (5) ADL, (6) leisure activities, and (7) fears.
4.2. Health service use, prescription use and pain relief medication use will be self-reported using a modified version of the Client Service Receipt Inventory
4.3. Positive and negative mood will be measured using the Positive and Negative Affect Schedule
4.4. Subjective wellbeing will be measured using the Office for National Statistics 4-item scale
5. Safety:
5.1. Pain measured using a 100-mm visual analogue scale
5.2. Fatigue measured using the Fatigue Severity Scale over the last week
5.3. Number of episodes of falls, unplanned hospital admissions, unplanned GP visits and adverse events will be self-reported at each data collection point. Adverse events will also be recorded ad-hoc if reported by a participant.

Overall study start date
26/05/2021

Completion date
08/02/2023

Eligibility

Key inclusion criteria
1. Community-dwelling older adults aged ≥65 years
2. Mild frailty classified according to the Clinical Frailty Scale. This describes people who have more evident slowing, and need help in high order instrumental activities of daily living (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework
3. Spend the majority of the day (>60%) sitting. This will be initially measured by self-report using the International Physical Activity Questionnaire item on daily sitting ("During the last 7 days, how much time did you spend sitting on a week day?"). This will be confirmed with a device-

based measure during baseline data collection
4. Functional Ambulation Category rating of ≥4 i.e. able to ambulate independently with or without a walking aid on level surfaces without supervision or assistance from another person

Participant type(s)
Mixed

Age group
Senior

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Unable to ambulate independently
2. Unable to communicate in English in order to meet the requirements of the study procedures
3. Any unstable medical conditions
4. Cognitive impairment (score ≥7 in the 6 Item Cognitive Impairment Test). This test will be administered over the phone by a researcher
5. Fitted with a pacemaker as this would preclude participants from completing the muscle mass measurements

Date of first enrolment
20/09/2021

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Brunel University London
Kingston Lane
Uxbridge
United Kingdom
UB8 3PH

Sponsor information

Organisation
Brunel University London

Sponsor details
Kingston Lane
Uxbridge
England
United Kingdom
UB8 3PH
+44 (0)1895 266416
derek.healy@brunel.ac.uk

Sponsor type
University/education

Website
https://www.brunel.ac.uk/

ROR
https://ror.org/00dn4t376

Funder(s)

Funder type
Charity

Funder Name
Abbeyfield Research Foundation

Alternative Name(s)
The Abbeyfield Research Foundation, ARF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Findings will be disseminated to lay, academic, practice, and policy-based audiences including:
1. Summary of findings to participants via a newsletter
2. Dedicated University webpage, newsletters and social media
3. Summary report to key stakeholders
4. Publication in a scientific journal
5. Presentation at conferences

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan
Current participant level data sharing statement as of 28/03/2024:

The datasets generated and analysed during the current study will be stored in a publicly available repository (https://brunel.figshare.com/)

Previous participant level data sharing statement:

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Daniel Bailey (daniel.bailey@brunel.ac.uk). Anonymised participant-level data will be available for a period of 10 years after the study end. Data will be available upon reasonable requests for purposes such as secondary analysis. consent from participants will be obtained for these purposes.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0		03/08/2021	No	Yes
Protocol file	version 3.0		03/08/2021	No	No
Protocol article		07/01/2023	09/01/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article		09/09/2024	10/09/2024	Yes	No
Results article	Acceptability	11/10/2024	15/10/2024	Yes	No