**FULL STUDY 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

**SHORT STUDY TITLE / ACRONYM** The Frail-LESS study

**RESEARCH REFERENCE NUMBERS**

IRAS Number:290128

Brunel REC Number: 27051-NHS-Jan/2021- 31003-2

Contents

[SIGNATURE PAGE 3](#_Toc70503501)

[KEY STUDY CONTACTS 4](#_Toc70503502)

[STUDY SUMMARY 4](#_Toc70503503)

[ROLE OF STUDY SPONSOR AND FUNDER 5](#_Toc70503504)

[ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES 5](#_Toc70503505)

[PROTOCOL CONTRIBUTORS 6](#_Toc70503506)

[PARTICIPANT FLOW DIAGRAM 7](#_Toc70503507)

[STUDY PROTOCOL 8](#_Toc70503508)

[BACKGROUND 8](#_Toc70503509)

[STUDY AIMS AND OBJECTIVES 10](#_Toc70503510)

[STUDY DESIGN/METHODS 10](#_Toc70503511)

[Study design 10](#_Toc70503512)

[Participants 11](#_Toc70503513)

[Sample size 11](#_Toc70503514)

[Recruitment 12](#_Toc70503515)

[Screening and eligibility confirmation 12](#_Toc70503516)

[Randomisation 12](#_Toc70503517)

[The Frail-LESS (LEss Sitting and Sarcopenia in Frail older adults) intervention 13](#_Toc70503518)

[Intervention development 13](#_Toc70503519)

[Intervention protocol 13](#_Toc70503520)

[Control group 15](#_Toc70503521)

[Data collection 15](#_Toc70503522)

[Data analysis 18](#_Toc70503523)

[Trial feasibility and safety 19](#_Toc70503524)

[Process evaluation, intervention acceptability and fidelity 19](#_Toc70503525)

[Preliminary effects of the intervention 19](#_Toc70503526)

[Data storage 20](#_Toc70503527)

[REFERENCES 21](#_Toc70503528)

# SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor’s SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

|  |
| --- |
| **Chief Investigator:** |
| Signature: ........................................................ |  | Date:  |
| Name: (please print): Dr Daniel Bailey......................................................................................................  |  |  |

# KEY STUDY CONTACTS

|  |  |
| --- | --- |
| hief Investigator | Dr Daniel BaileyDepartment of Life SciencesBrunel University LondonKingston LaneUxbridgeUB8 3PHTel: 01895 265363Email: Daniel.bailey@brunel.ac.uk |
| Sponsor | Brunel University LondonKingston LaneUxbridgeUB8 3PH |
| Funder | Abbeyfield Research Foundation (grant number: BAILEY2020) |

# STUDY SUMMARY

|  |  |
| --- | --- |
| Study 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 |
| Short title | The Frail-LESS study |
| Study Design | Randomised controlled feasibility trial |
| Study Participants | Older adults with mild frailty |
| Planned Size of Sample | 60 participants |
| Planned Study Period | 18 months |

# ROLE OF STUDY SPONSOR AND FUNDER

The Sponsor of this study is the Brunel University London. The sponsor is responsible for the overall conduct and management of the study. The funder, Abbeyfield Research Foundation, has reviewed the study protocol as part of the grant award process. The funder will not have any involvement with the conduct of the study, data analysis or presentation of the findings.

# ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES

PROJECT TEAM

The project team will comprise of the Principal Investigator, the co-investigators and the Research Assistant. The team will meet every 3 months to discuss day-to-day running of the project, direction of the research, participant recruitment and conduct/amendments to the protocols as relevant. Updates from these meetings will be provided to the PSC.

TRIAL STEERING COMMITTEE (TSC)

The TSC comprises of an independent Chair, an independent expert in the study area, a lay person, the principal investigator and one co-investigator and will meet every 6 months. The TSC will advise, via the Chair, on relevant aspects of the project to the funder, sponsor and host institution. It will monitor progress of the project, protocol adherence, substantial protocol amendments and participant safety. The TSC will also advise the investigators on all aspects of the project.

PUBLIC ADVISORY GROUP (PAG)

The PAG will implement their terms of reference from the onset which will focus on three core areas: supporting the development and direction of the research, development of information resources and dissemination of research findings. The PAG will be comprised of an independent chair, the Principal Investigator, and three older adults from the Brunel Older People’s Reference Group. The PAG will meet every 3 months.

# PROTOCOL CONTRIBUTORS

Dr Daniel Bailey, Brunel University London, Daniel.bailey@brunel.ac.uk

Professor Christina Victor, Brunel University London, christina.victor@brunel.ac.uk

Dr Cherry Kilbride, Brunel University London, cherry.kilbride@brunel.ac.uk

Professor Angel Chater, University of Bedfordshire, angel.chater@beds.ac.uk

Professor David Hewson, University of Bedfordshire, David.hewson@beds.ac.uk

# PARTICIPANT FLOW DIAGRAM

#

# STUDY PROTOCOL

## BACKGROUND

Sarcopenia is a progressive and generalised loss of muscle mass and muscle function with advancing age1. This condition is associated with a range of health problems such as functional disability, falls, unplanned hospital admissions, poor quality of life, osteoporosis, cardiovascular disease and early death2. Sarcopenia causes a rapid rate of decline in activities of daily living (ADL) in community-dwelling older adults with 19-39% of adults with sarcopenia becoming dependent in ADL over a 2 year period3. The prevalence of sarcopenia is difficult to establish due to lack of a consensus definition. However, the prevalence in older community-dwelling populations could be as high as 29%4. In community-dwelling older men and women in the UK, the prevalence of sarcopenia was 4.6% and 7.9%, respectively5. Analysis of half a million people from the UK Biobank found that the prevalence of probable sarcopenia (low hand grip strength) was 5.3% in 40-70 year-olds and this increased with age: 2.5%, 4.5%, and 7.6% in the 40–49, 50–59, and 60–70 age groups, respectively6. Sarcopenia thus represents a major clinical problem for older adult public health due to its prevalence and health consequences.

Sarcopenia is considered one of the main contributors to the development of frailty and is a key mediator of the pathway through which the negative health outcomes of frailty arise7. Frailty is characterised by diminished strength, endurance, and physiologic function that increases vulnerability to dependency and death8. The presence of mild frailty increases the risk of all-cause mortality, unplanned hospitalisation and nursing home admission by 92%, 93% and 89%, respectively9. The risk of these adverse health outcomes is markedly higher when adults progress to moderate and severe frailty9. It is thus vital to develop interventions that reduce the progression of sarcopenia and frailty in older adults who are mildly frail to maintain their independent living and reduce the risk of health problems.

Sedentary behaviour is defined as any waking behaviour with a low energy expenditure while sitting, lying or reclined. The general older adult population spend 9.4 hours a day being sedentary (equivalent to 65-80% of their waking day) according to a systematic review of 350,000 participants across 22 studies10. Sedentary time is significantly higher in frail adults than non-frail (9.6 vs. 8.2 hours/day) when measured using accelerometers11. This is problematic as daily sitting time is negatively associated with muscle mass and physical function12,13 and each additional hour of daily sitting increases sarcopenia risk by 33% in community-dwelling older adults14. More frequent breaks in sitting (i.e. moving from sitting to standing or walking) is related to better physical function, reduced difficulty in ADL, lower frailty level and 45% reduced risk of sarcopenia in older adults13,15-17. Reducing and breaking up sitting is recommended in UK physical activity guidelines for older adults and is particularly encouraged for frail older adults for whom more strenuous activities are less feasible18. Interventions are thus needed that reduce and break up sitting to improve sarcopenia, slow progression of frailty and maintain independent living.

**The need for a new intervention:** A number of interventions have shown promise for reducing sedentary behaviour in community-dwelling older adults19. For example, an 8-week intervention consisting of five phone calls using motivational interviewing, goal setting, self-monitoring diaries and mailed feedback significantly reduced sitting by 27 minutes and increased breaks in sitting by 2 per day20. However, interventions focusing on reductions in sitting in older adults have been short-term (<3 months), poor quality, have lacked evaluation of health outcomes relevant to older adults, and have predominantly been conducted with generally healthy participants19. In what appears to be the only randomised controlled trial (RCT) in older adults, a 12-week intervention using face-to-face and phone consultations, goal setting, and self-monitoring using a wearable device and smartphone app interface significantly improved physical function (standing up from a chair)21. There appears to be just one study in *frailer* older adults, which trialled an intervention using face-to-face motivational interviewing, functional test feedback, visual and real-time feedback on sitting using a wearable device. After 14 weeks, there were significant improvements in physical function (timed up and go and sit-to-stand tests) and quality of life despite no significant change in total sitting time22. However, this pilot study was underpowered to detect changes in sitting and did not include a control group to allow comparison with usual care. The limited evidence available suggests that interventions may be effective for reducing sitting and could improve physical function and wellbeing in older adults. However, there is very limited evidence of effectiveness in *frail* older adults, which is essential to understand if reducing sitting can help maintain functional independence and improve their wellbeing. Furthermore, the feasibility, safety and acceptability of an intervention to reduce and break up sitting that is delivered remotely and suitable during times of social isolation or social distancing has not been evaluated. This is important for older adults who are socially isolated (i.e. lack a sense of belonging socially and lack engagement with others, which may represent 7-17% of the older population23), unable to leave the home, unable to travel to intervention venues, or do not engage due to inconvenience. This is particularly relevant for older adults during COVID-19 who need to be stringent with social distancing due to a higher risk of severe illness and death, regardless of their medical condition24. The median age of COVID-19-related hospital admissions in the UK is 73 years and adults aged 60-69 and 70-79 years have a 163% and 400% increased risk of dying while in hospital than younger adults25. Their usual opportunities to be active during travel, leisure (e.g. attending exercise or rehabilitation sessions) and socially supported activity (e.g. walking with friends) could be reduced. Sitting time may be higher for domestic entertainment purposes, such as watching TV, using a computer and reading. Indeed, screen time increased and physical activity levels decreased significantly in the general population during the early stages of the pandemic in China26. The COVID-19 pandemic could thus be exacerbating the progression of sarcopenia and frailty, which could lead to an accelerated loss of independence. It is thus critical that an intervention is available that can be delivered remotely to support frail older adults in reducing and breaking up their sitting during times of social distancing and isolation, economic constraints, access difficulties and remote healthcare support.

## STUDY AIMS AND OBJECTIVES

The primary aim of this study is to examine the feasibility of conducting an RCT of a remotely delivered intervention to support frail older adults in reducing and breaking up sitting.

The main objectives are to:

1. Establish and refine a recruitment strategy, determine participant attrition in the trial, and evaluate completion rates for the outcome measures.

2. Assess the acceptability of randomisation to the intervention and usual care, acceptability and safety of the intervention and data collection procedures, and intervention fidelity and adherence.

The secondary objectives are to derive preliminary estimates of intervention effects on (a) sarcopenia, (b) physical functioning, (c) sarcopenia-specific quality of life, (d) device measured daily sitting, prolonged sitting, breaks from sitting, standing and stepping, and (e) psychological wellbeing, mood and quality of life.

## STUDY DESIGN/METHODS

### Study design

This will be a mixed-methods randomised controlled feasibility trial with an embedded process evaluation conducted in line with MRC guidelines for the development and evaluation of complex interventions27. After baseline measures, each participant will be randomised to either an intervention or control group. The 24-week intervention period will then commence and follow-up measurements will be repeated at 12 and 24 weeks after baseline measures. A 6-month duration was deemed appropriate for (a) addressing the main aims of the study in relation to intervention acceptability, safety, adherence and study attrition, and (b) enabling chronic adaptations to occur in relation to measures of sarcopenia.

### Participants

The inclusion criteria are:

* Community-dwelling older adults aged ≥65 years.
* Mild frailty classified according to the Clinical Frailty Scale28. 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.
* 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.
* 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 person29 (see Screening questionnaires in supporting documents).

Exclusion criteria are:

* Unable to ambulate independently.
* Unable to communicate in English in order to meet the requirements of the study procedures.
* Any unstable medical conditions.
* Cognitive impairment (score ≥7 in the 6 Item Cognitive Impairment Test30; see Screening questionnaires). This test will be administered over the phone by a researcher.
* Fitted with a pacemaker as this would preclude participants from completing the muscle mass measurements.

### Sample size

Sample sizes between 24 and 50 have been recommended for feasibility studies31,32. To enable us to evaluate acceptability of the intervention, acceptability to randomisation, and attrition in each study group (n=20 in each), we will target a sample size of 40. To allow for 30% attrition, we aim to recruit 60 participants for the study.

### Recruitment

This will be via GPs where study information will be sent out via the GP practice SMS text messaging services to potentially eligible patients. Patients with mild frailty (electronic frailty index [eFI] score of 0.13-0.249) will be identified using a database search based on the eFI, which all GP practices are required to use for adults aged ≥65 years. This will be supported by Local Clinical Research Networks. We will also recruit via our Brunel Older People’s Reference Group via an email to the group, library and church groups (via email; see email to gatekeepers in supporting documents), community groups, social media and a project webpage (<https://tinyurl.com/Frail-less-study>). Participants recruited via these latter routes will be mapped back to their GP practice. Potentially eligible participants will be asked to express their interest in a variety of ways by email, phone, returning a reply slip to the research team, or by scanning a QR code provided on recruitment materials that will take them to the project website in which a webform (hosted on Qualtrics) allows individuals to confidentially provide their name and email address. A researcher will then contact interested volunteers by email and telephone to screen them.

### Screening and eligibility confirmation

Individuals who express interest in taking part will be screened via email and telephone by a member of the research team according to the inclusion criteria above (see Screening questionnaires in supporting documents). Individuals who remain potentially eligible will be invited to complete baseline data collection after providing informed consent. Eligibility will be confirmed in relation to frailty status by a Chartered Physiotherapist on arrival to the baseline data collection session. Eligibility in relation to sitting >60% of the day will also be confirmed during baseline activity monitoring assessment (see below). This will involve each participant enrolled into the study wearing an activity monitor for a period of 7 continuous days. If a participant does not sit for this proportion of the day, they will be excluded from the study after being provided with feedback on their sitting time and being thanks for their involvement thus far.

### Randomisation

Participants will be individually randomised in a 1:1 (intervention:control) ratio using a fixed block size of four. This approach is being used to increase the likelihood of balanced numbers in the trial arms. The randomisation will be conducted by a researcher independent from the study team. The research team and participant will be blinded to each participant’s group allocation until baseline data collection measurements have been completed and their eligibility confirmed.

## The Frail-LESS (LEss Sitting and Sarcopenia in Frail older adults) intervention

### Intervention development

The Frail-LESS intervention; which comprises of tailored feedback, education, a wearable device, health coaching and peer support to help reduce and break up sitting; was developed following the Medical Research Council guidance for developing and evaluating complex interventions27. We developed the intervention using the Behaviour Change Wheel (BCW), which has the COM-B (Capability, Opportunity, Motivation-Behaviour) system at its hub. This provides a framework enabling translation of a COM-B behavioural diagnosis to the design of an evidence-informed intervention33. We used the BCW framework to conduct a mapping exercise of barriers and facilitators for reducing and breaking up sitting time to the BCW intervention functions and policy categories through which those functions would be supported. Next, the optimal behaviour change techniques (BCTs)34 to reduce and break up sitting and their mode of delivery were identified. The barriers, facilitators and BCTs were drawn from a systematic review and thematic synthesis of older adults’ perceptions of sedentary behaviour, which included 351 participants across 15 studies35. This approach has been used to develop cost-effective interventions that significantly reduced sitting and improved cardiovascular health and psychological wellbeing in office workers in the short and long-term36-39 and within a community setting40. The proposed intervention was then refined following consultation with the Brunel Older people’s Reference Group taking into consideration the APEASE criteria (Acceptability, Practicability, Effectiveness/cost-effectiveness, Affordability, Safety/side-effects, Equity)41 and the ability for the intervention to be delivered remotely.

The mode of delivery of the BCTs in this intervention will be *the use of tailoring and technology* (as described below), which older adults most frequently identified for reducing sitting time in a systematic review35. A meta-analysis also reported significant reductions in sedentary time and improvements in physical functioning in response to technology behaviour change interventions in older adults42. The intervention takes into account that some older adults may find the use of technology problematic35 by allowing participants to tailor the mode of delivery of the tailored feedback, education programme and peer support as described below.

### Intervention protocol

Each participant randomised to the intervention group will receive the Frail-LESS intervention for approximately 24 weeks. The tailored feedback sheet, education programme and wearable device will be provided to each participant by the research team at the start of the intervention, which commences after randomisation to this study group. After randomisation to this group, participants will be asked to indicate their preferences for receiving each of the intervention components as per below.

*Tailored feedback:* Each intervention participant will receive a personalised feedback sheet based on their baseline sitting measurement. This will include a graphical representation and written explanation of their total sitting time, prolonged sitting and number of breaks from sitting. The sheet will be emailed or sent by post depending on participant preference.

*Education programme*: Participants will be provided with a link to an online education programme (viewable via a computer or smart device) or will be sent the programme in a paper-based workbook form dependent on personal preference. The programme 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 (e.g. sit to standing gradually with less support from arms, standing, mini squats, calf raises, walking).

*Wearable device:* A Garmin Vivofit wrist-worn device (<https://buy.garmin.com/en-GB/GB/p/582444>) will be provided to each participant and will be accompanied by a guidance document for its use. The device 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.

*Health coaching:* Participants will have an individual health coaching session with a health coach within 3-5 days after being provided with the above intervention components. Further support will take place at approximately 2, 6, 12 and 18 weeks after the start of the intervention. All health coaching sessions will take place via video call or telephone based on participant preference. The consultations will be semi-structured tailored sessions harnessed on the G.R.O.W (Goals, Reality, Options, Will) model43 that will take each participant through the four stages to enhance/enable intrinsic self-determined motivation, capability and opportunity. The initial session will focus on a discussion around Goals, Reality (barriers to reducing sitting), Options (self-selected behaviour change tools), and Will (confidence to change, how to action plan and monitor progress). Subsequent calls will involve reviewing goals and problem-solving.

 *Peer support:* Participants will be provided with the opportunity to join a Frail-LESS support group to provide one another peer support. The group will interact using a WhatsApp and/or Facebook group, exchanging phone numbers and/or email addresses. A support group meeting will be organised every other month by the research team for members to attend in person or virtually.

## Control group

Participants randomised to this group will not receive any intervention but will complete the same measurements as the intervention group. After the trial has concluded, they will be offered use of the intervention package for 24 weeks except from the health coach support.

## Data collection

Participants enrolled into the study will be invited to complete baseline measures, which will include demographic data (date of birth, sex, ethnicity, employment status, comorbidities, living alone/with others, access to a green space, type of home, stairs to home, COVID-19 circumstances e.g. vaccinated, social distancing, shielding, self-isolating, current or previous COVID-19 diagnosis), height using a portable stadiometer and weight using electronic weighing scales. The below measures will be collected at baseline and then 12 and 24 weeks after baseline measures have been completed. All questionnaires will be completed online using Qualtrics (Qualtrics, London, UK) or paper-based dependent on participant preference. Each participant will receive a £10 shopping gift voucher at each data collection time point if they take part in the data collection procedures and return the activity monitor to the research team. Travel expenses will also be reimbursed for visits made to the university for data collection.

**COVID-19 contingency:** If there are restrictions in place at government or university level that mean study participants are unable to attend in-person laboratory testing, then the measures will take place at participants’ homes and/or be adapted as described where relevant below.

*Trial feasibility:* This will be assessed based on recruitment, retention rates and missing data rates for each of the study measurements.

 *Sarcopenia:* This will be measured in line with the European consensus definition44. Hand grip strength using a hand grip dynamometer (Takei Scientific Instruments Co., Ltd, Niigata, Japan) will measure muscle strength. 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. The Bodystat 1500 (Bodystat Ltd, Isle of Man) bioelectrical impedance device will be used to estimate muscle mass. 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 analysis46. Physical performance will be measured using the Short Physical Performance Battery (SPPB) which includes standing balance, walking speed and rising from a chair47. 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 guidelines47. In addition to these measures, the SARC-F questionnaire (see Data collection questionnaires in supporting documents) will be used for participants to self-report their ability to carry a heavy load, walking, rising from a chair, climbing stairs, and falls frequency48. The SARC-F has been validated for sarcopenia classification that has comparable predictive ability to international diagnostic criteria44.

**COVID-19 contingency:** If laboratory testing is not possible due to COVID-19, a member of the research team will attend each participant’s home to take the physical sarcopenia measures (i.e. hand grip, muscle mass, standing balance, walking speed and rising from a chair) following the protocols described above. For participants considered at high risk of a fall, a researcher will be within an outstretched arms distance so that they can provide support if needed during the balance, walking speed and rising from a chair tasks (if the chair has no arms). For muscle mass measures, participants will be asked to place the electrode pads on themselves under guidance from a researcher. For the walking speed test, if there is not an 8-foot space available, a shorter course using the maximum available distance will be used and standardised within participant. The height of the chair used will be measured and a photo taken to ensure that the same chair is used in the subsequent time points.

*Physical function:* In addition to the SBBP measures, difficulty with ADL will be assessed using the validated Groningen Activity Restriction Scale49, 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 (see Data collection questionnaires in supporting documents).

*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 transitions50,51. 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. A guidance document and video will also be provided advising participants on how to attach the device in case they need to re-attach it during the monitoring period.

**COVID-19 contingency:** The activPAL device and diary will be provided to participants during a data collection session taking place in each participant’s home. Participants will be required to attached the activity monitor to themselves under guidance from a researcher.

*Mood, wellbeing and quality of life:* Sarcopenia-specific quality of life will be measured using the validated SarQoL questionnaire52 (see SarQol questionnaire in supporting documents), 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. The SarQol is scored using an automated code available from [www.sarqol.org](http://www.sarqol.org). Health service use, prescription use and pain relief medication use will be self-reported using a modified version of the Client Service Receipt Inventory (see Data collection questionnaires). The feasibility of collecting these measures is important to inform cost-effectiveness evaluation in a full trial. The Positive and Negative Affect Schedule will measure positive and negative mood53 (see Data collection questionnaires). Subjective wellbeing will be measured using the Office for National Statistics 4-item scale54 (see Data collection questionnaires).

*Safety*: Pain (using a 100-mm visual analogue scale)55 and fatigue (using the Fatigue Severity Scale56) over the last week will be measured in addition to self-reported number of episodes of falls, unplanned hospital admissions, unplanned GP visits and adverse at each data collection point (see Data collection questionnaires). Adverse events will also be recorded ad-hoc if reported by a participant.

*Process evaluation, intervention acceptability and fidelity:* A process evaluation will help to understand the contextual factors that might affect implementation and outcomes of the intervention, implementation of the trial itself, mechanisms helping to explain the impact of the trial, reasons for non-participation and intervention fidelity (i.e. BCTs received vs. those intended and level of engagement across the intervention components)57. Process evaluation questionnaires with scaled, closed and open questions will be completed by all participants (see Process Evaluation questionnaires in supporting documents). Semi-structured individual in-person, video call or phone call interviews will be conducted by a researcher with a subset of control and intervention participants to evaluate suitability of data collection procedures and if completing these measures or being part of the control group motivated them to change their lifestyle behaviours (see Interview schedules in supporting documents). Interviews with intervention participants will also evaluate intervention acceptability (including compliance with intervention components, facilitators and barriers to participation/compliance) and other aspects of APEASE41. Health coaches will also be interviewed to assess the feasibility and fidelity of delivering the coaching sessions. They will also be asked to record 30% of their coaching sessions, which will be used in training booster ‘supervision’ sessions to monitor health coaching G.R.O.W and BCT delivery and so that additional support can be provided to increase intervention fidelity. Individuals who were eligible but did not volunteer to take part and those who dropped out during the study will be invited to complete a questionnaire to explore the reasons for this (see Non-participation and Withdrawal questionnaires in supporting documents). The number of health coaching sessions that the participants attend will also be recorded. Interviews with participants will be conducted until no new information (themes) is being provided (likely n=15 participants58). Interviews will be conducted with all health coaches to assess the feasibility and fidelity of delivering the sessions using the G.R.O.W model and delivery of the intended BCTs.

## Data analysis

Data will be analysed using both quantitative and qualitative approaches centred around trial feasibility, safety, and intervention acceptability and fidelity.

### Trial feasibility and safety

Participant eligibility (number of participants eligible / number of participants assessed for eligibility x 100), participant recruitment (number of participants randomised / number of eligible participants screened x 100), participant retention (number of participants who complete follow up measures / number enrolled into the study x 100) and missing data (number of complete datasets for each outcome measure / number of participants enrolled into the study x 100) rates will be calculated to assess trial feasibility. To assess trial safety, the frequency of falls, hospital admissions and serious adverse events will be calculated in addition to exploring trends in pain and fatigue (using mean±SD).

### Process evaluation, intervention acceptability and fidelity

All interviews will be transcribed verbatim and analysed using the Framework Method59. This will enable identification of how acceptable the participants found the intervention and any improvements needed, the intervention’s active ingredients (e.g. the process through which participants engaged in different parts of the intervention), appropriateness of data collection procedures, and feasibility of the health coaching and peer support. The intervention will also be evaluated in the context of the APEASE criteria of the BCW41. This will explore the intervention’s Affordability (Can it be delivered financially?), Practicability (Can it be delivered as designed?), Effectiveness and cost-effectiveness (Does it work, is it cost-effective?), Acceptability (Is it judged appropriate by relevant stakeholders?), Side-effects/safety (Does it have any unwanted side-effects or unintended consequences?), and Equity (Will it reduce or increase the disparities in health/wellbeing and can it be accessed without causing disparity?). Each intervention strategy and BCT will then be scored on a rating scale for each of the APEASE criteria41. Intervention fidelity will be explored in terms of participant and health coach’s experiences during the intervention in relation to the proposed protocol. Rating scales within the process evaluation questionnaires will be analysed using descriptive statistics. Open-ended responses will be used to deductively identify content related to the APEASE criteria.

### Preliminary effects of the intervention

Descriptive statistics will be used to summarise and explore trends in the primary (sarcopenia) and secondary outcomes (physical function; sarcopenia-specific quality of life; daily and prolonged sitting, breaks in sitting, standing and stepping; mood, wellbeing and quality of life). Continuous data will be summarised as mean±SD and categorical data as frequency, counts and percentages. Cohen’s *d* effect sizes will be used to explore magnitudes of change.

### Data storage

Personal participant data will be retained for a period of 12 months following the study end date. Research data will be retained for a period of 10 years following the study end date.

# REFERENCES

1. Fielding RA, Vellas B, Evans WJ, et al. Sarcopenia: an undiagnosed condition in older adults. Current consensus definition: prevalence, etiology, and consequences. International working group on sarcopenia. *J Am Med Dir Assoc.* 2011;12(4):249-256.

2. Beaudart C, Zaaria M, Pasleau F, et al. Health Outcomes of Sarcopenia: A Systematic Review and Meta-Analysis. *PLoS One.* 2017;12(1):e0169548.

3. Tanimoto Y, Watanabe M, Sun W, et al. Association of sarcopenia with functional decline in community-dwelling elderly subjects in Japan. *Geriatr Gerontol Int.* 2013;13(4):958-963.

4. Cruz-Jentoft AJ, Landi F, Schneider SM, et al. Prevalence of and interventions for sarcopenia in ageing adults: a systematic review. Report of the International Sarcopenia Initiative (EWGSOP and IWGS). *Age Ageing.* 2014;43(6):748-759.

5. Patel HP, Syddall HE, Jameson K, et al. Prevalence of sarcopenia in community-dwelling older people in the UK using the European Working Group on Sarcopenia in Older People (EWGSOP) definition: findings from the Hertfordshire Cohort Study (HCS). *Age Ageing.* 2013;42(3):378-384.

6. Dodds RM, Granic A, Robinson SM, et al. Sarcopenia, long-term conditions, and multimorbidity: findings from UK Biobank participants. *J Cachexia Sarcopenia Muscle.* 2020;11(1):62-68.

7. Bernabei R, Martone AM, Vetrano DL, et al. Frailty, Physical Frailty, Sarcopenia: A New Conceptual Model. *Stud Health Technol Inform.* 2014;203:78-84.

8. Morley JE, Vellas B, van Kan GA, et al. Frailty consensus: a call to action. *J Am Med Dir Assoc.* 2013;14(6):392-397.

9. Clegg A, Bates C, Young J, et al. Development and validation of an electronic frailty index using routine primary care electronic health record data. *Age Ageing.* 2016;45(3):353-360.

10. Harvey JA, Chastin SF, Skelton DA. How Sedentary are Older People? A Systematic Review of the Amount of Sedentary Behavior. *J Aging Phys Act.* 2015;23(3):471-487.

11. Blodgett J, Theou O, Kirkland S, et al. The association between sedentary behaviour, moderate-vigorous physical activity and frailty in NHANES cohorts. *Maturitas.* 2015;80(2):187-191.

12. Manas A, Del Pozo-Cruz B, Garcia-Garcia FJ, et al. Role of objectively measured sedentary behaviour in physical performance, frailty and mortality among older adults: A short systematic review. *Eur J Sport Sci.* 2017;17(7):940-953.

13. Reid N, Healy GN, Gianoudis J, et al. Association of sitting time and breaks in sitting with muscle mass, strength, function, and inflammation in community-dwelling older adults. *Osteoporos Int.* 2018;29(6):1341-1350.

14. Gianoudis J, Bailey CA, Daly RM. Associations between sedentary behaviour and body composition, muscle function and sarcopenia in community-dwelling older adults. *Osteoporos Int.* 2015;26(2):571-579.

15. Sardinha LB, Ekelund U, dos Santos L, et al. Breaking-up sedentary time is associated with impairment in activities of daily living. *Exp Gerontol.* 2015;72:57-62.

16. Sardinha LB, Santos DA, Silva AM, et al. Breaking-up sedentary time is associated with physical function in older adults. *J Gerontol A Biol Sci Med Sci.* 2015;70(1):119-124.

17. Del Pozo-Cruz B, Manas A, Martin-Garcia M, et al. Frailty is associated with objectively assessed sedentary behaviour patterns in older adults: Evidence from the Toledo Study for Healthy Aging (TSHA). *PLoS One.* 2017;12(9):e0183911.

18. Department of Health and Social Care. UK Chief Medical Officers' Physical Activity Guidelines. Available at: <https://www.gov.uk/government/publications/physical-activity-guidelines-uk-chief-medical-officers-report>. 2019.

19. Copeland JL, Ashe MC, Biddle SJ, et al. Sedentary time in older adults: a critical review of measurement, associations with health, and interventions. *Br J Sports Med.* 2017;51(21):1539.

20. Rosenberg DE, Gell NM, Jones SM, et al. The Feasibility of Reducing Sitting Time in Overweight and Obese Older Adults. *Health Educ Behav.* 2015;42(5):669-676.

21. Barone Gibbs B, Brach JS, Byard T, et al. Reducing Sedentary Behavior Versus Increasing Moderate-to-Vigorous Intensity Physical Activity in Older Adults. *J Aging Health.* 2017;29(2):247-267.

22. Harvey J, Chastin S, Skelton D. Breaking sedentary behaviour has the potential to increase/maintain function in frail older adults. *J Frailyy, Sarcopenia and Falls.* 2018;3(1):26-34.

23. Dickens AP, Richards SH, Greaves CJ, et al. Interventions targeting social isolation in older people: a systematic review. *BMC Public Health.* 2011;11(1):647.

24. Public Health England. Staying at home and away from others (social distancing). Available at: <https://www.gov.uk/government/publications/full-guidance-on-staying-at-home-and-away-from-others/full-guidance-on-staying-at-home-and-away-from-others> (accessed 6 May 2020).

25. Docherty AB, Harrison EM, Green CA, et al. Features of 20 133 UK patients in hospital with covid-19 using the ISARIC WHO Clinical Characterisation Protocol: prospective observational cohort study. *BMJ.* 2020;369:m1985.

26. Qin F, Song Y, Nassis GP, et al. Prevalence of Insufficient Physical Activity, Sedentary Screen Time and Emotional Well-Being During the Early Days of the 2019 Novel Coronavirus (COVID-19) Outbreak in China: A National Cross-Sectional Study. *Lancet.* 2020.

27. Medical Research Council. Developing and evaluating complex interventions: new guidance. 2019.

28. Rockwood K, Song X, MacKnight C, et al. A global clinical measure of fitness and frailty in elderly people. *Canadian Medical Association Journal.* 2005;173(5):489-495.

29. Mehrholz J, Wagner K, Rutte K, et al. Predictive validity and responsiveness of the functional ambulation category in hemiparetic patients after stroke. *Arch Phys Med Rehabil.* 2007;88(10):1314-1319.

30. Brooke P, Bullock R. Validation of a 6 item cognitive impairment test with a view to primary care usage. *Int J Geriatr Psychiatry.* 1999;14(11):936-940.

31. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *Journal of Clinical Epidemiology.* 2012;65(3):301-308.

32. Julious SA. Sample size of 12 per group rule of thumb for a pilot study. *Pharmaceutical Statistics.* 2005;4(4):287-291.

33. Michie S, Ashford S, Sniehotta FF, et al. A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: the CALO-RE taxonomy. *Psychol Health.* 2011;26(11):1479-1498.

34. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Ann Behav Med.* 2013;46(1):81-95.

35. Compernolle S, De Cocker K, Cardon G, et al. Older Adults' Perceptions of Sedentary Behavior: A Systematic Review and Thematic Synthesis of Qualitative Studies. *Gerontologist.* 2019.

36. Munir F, Biddle SJH, Davies MJ, et al. Stand More AT Work (SMArT Work): using the behaviour change wheel to develop an intervention to reduce sitting time in the workplace. *BMC Public Health.* 2018;18(1):319.

37. Edwardson CL, Yates T, Biddle SJH, et al. Effectiveness of the Stand More AT (SMArT) Work intervention: cluster randomised controlled trial. *BMJ.* 2018;363:k3870.

38. Healy GN, Eakin EG, Owen N, et al. A Cluster Randomized Controlled Trial to Reduce Office Workers' Sitting Time: Effect on Activity Outcomes. *Medicine and Science in Sports and Exercise.* 2016;48(9):1787-1797.

39. Ojo SO, Bailey DP, Brierley ML, et al. Breaking barriers: using the behavior change wheel to develop a tailored intervention to overcome workplace inhibitors to breaking up sitting time. *BMC Public Health.* 2019;19(1):1126.

40. Howlett N, Jones A, Bain L, et al. How effective is community physical activity promotion in areas of deprivation for inactive adults with cardiovascular disease risk and/or mental health concerns? Study protocol for a pragmatic observational evaluation of the ’Active Herts' physical activity programme. *BMJ Open.* 2017;7(11):e017783.

41. Public Health England. Achieving behaviour change: A guide for national government. Available at: <https://www.gov.uk/government/publications/behaviour-change-guide-for-local-government-and-partners> (Accessed 25 January 2021). 2020.

42. Stockwell S, Schofield P, Fisher A, et al. Digital behavior change interventions to promote physical activity and/or reduce sedentary behavior in older adults: A systematic review and meta-analysis. *Exp Gerontol.* 2019;120:68-87.

43. Whitmore J. *Coaching for Performance: GROWing People, Performance and Purpose.* London: Nicholas Brealey Publishing; 2002.

44. Cruz-Jentoft AJ, Bahat G, Bauer J, et al. Sarcopenia: revised European consensus on definition and diagnosis. *Age Ageing.* 2019;48(1):16-31.

45. Incel NA, Ceceli E, Durukan PB, et al. Grip strength: effect of hand dominance. *Singapore Med J.* 2002;43(5):234-237.

46. Kyle UG, Bosaeus I, De Lorenzo AD, et al. Bioelectrical impedance analysis--part I: review of principles and methods. *Clin Nutr.* 2004;23(5):1226-1243.

47. Guralnik JM, Simonsick EM, Ferrucci L, et al. A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. *J Gerontol.* 1994;49(2):M85-94.

48. Morley JE, Anker SD, von Haehling S. Prevalence, incidence, and clinical impact of sarcopenia: facts, numbers, and epidemiology-update 2014. *J Cachexia Sarcopenia Muscle.* 2014;5(4):253-259.

49. Kempen GI, Miedema I, Ormel J, et al. The assessment of disability with the Groningen Activity Restriction Scale. Conceptual framework and psychometric properties. *Soc Sci Med.* 1996;43(11):1601-1610.

50. Lyden K, Kozey Keadle SL, Staudenmayer JW, et al. Validity of two wearable monitors to estimate breaks from sedentary time. *Medicine and Science in Sports and Exercise.* 2012;44(11):2243-2252.

51. Grant PM, Ryan CG, Tigbe WW, et al. The validation of a novel activity monitor in the measurement of posture and motion during everyday activities. *British Journal of Sports Medicine.* 2006;40(12):992-997.

52. Beaudart C, Biver E, Reginster JY, et al. Validation of the SarQoL(R), a specific health-related quality of life questionnaire for Sarcopenia. *J Cachexia Sarcopenia Muscle.* 2017;8(2):238-244.

53. Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: the PANAS scales. *J Pers Soc Psychol.* 1988;54(6):1063-1070.

54. Office for National Statistics. Analysis of Experimental Subjective Well-being Data from the Annual Population Survey, April to September 2011. Available at [https://webarchive.nationalarchives.gov.uk/20160105232634/http://www.ons.gov.uk/ons/rel/wellbeing/measuring-subjective-wellbeing-in-the-uk/analysis-of-experimental-subjective-well-being-data-from-the-annual-population-survey--april---september-2011/report-april-to-september-2011.html](https://webarchive.nationalarchives.gov.uk/20160105232634/http%3A//www.ons.gov.uk/ons/rel/wellbeing/measuring-subjective-wellbeing-in-the-uk/analysis-of-experimental-subjective-well-being-data-from-the-annual-population-survey--april---september-2011/report-april-to-september-2011.html) (accessed 14 April 2020). 2011.

55. Kelly AM. Does the clinically significant difference in visual analog scale pain scores vary with gender, age, or cause of pain? *Acad Emerg Med.* 1998;5(11):1086-1090.

56. Valko PO, Bassetti CL, Bloch KE, et al. Validation of the fatigue severity scale in a Swiss cohort. *Sleep.* 2008;31(11):1601-1607.

57. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ.* 2015;350:h1258.

58. Francis JJ, Johnston M, Robertson C, et al. What is an adequate sample size? Operationalising data saturation for theory-based interview studies. *Psychol Health.* 2010;25(10):1229-1245.

59. Gale NK, Heath G, Cameron E, et al. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology.* 2013;13(1):117.