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RESEARCH PROTOCOL

Study Title
The acceptability of exercise snacking to improve leg strength in memory clinic outpatients: a pilot study

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1. Overview

As we age, muscles can become progressively weaker to the point that tasks of daily living cannot be carried out without risk of falls and other injurious events. Prolonged periods of isolation and inactivity in older adults, such as that imposed in response to the global COVID-19 pandemic, can lead to reduced muscle size, force, and activation. However, regular resistance exercise training has been shown to maintain and even increase muscle strength in older adults. Whilst machine- or free-weights-based progressive resistance exercise programmes have been shown to be safe and efficacious in improving strength in older adults, these can be costly, logistically challenging, or not attractive to this population. Moreover, individuals most in need of improving muscle strength are those least likely to undertake resistance exercise, and may already be presenting clinically as being at risk of falling. Previous research has identified a homebased, non-loaded, lower limb only, 'exercise snacking' model that does not require exercise equipment or supervision as a viable alternative exercise strategy with potential to improve leg muscle strength in healthy older adults. We define exercise snacking as the performance of small bursts of strength exercise that require no specialist equipment clothing or settings, at a time to suit the individual. To date, we have shown this approach to be feasible and acceptable to general healthy older adult population, however this approach to exercise focussed on improving strength has not been considered in a clinical population. This research seeks to investigate the acceptability of 28 days of homebased exercise snacking in outpatients attending the memory clinic at the Research Institute for Care of the Elderly (RICE) Centre in Bath, UK. This study will improve understanding of how zero-cost exercise strategies to potentially improve muscle function and delay frailty could be incorporated in daily routines of older adults.

2. Background and Rationale

The ageing process is accompanied by loss of muscle size and strength, with data from longitudinal studies suggesting that muscle size is lost at 0.5-1% per year [1]. Furthermore, muscle strength is lost two to five times more rapidly than would be expected based on the rate of muscle mass loss during ageing, and at twice the rate in the legs compared to the upper body [2, 3]. Eventually the continued loss of muscle strength results in the tasks of daily living becoming too physically strenuous to be managed safely, and independent living becomes untenable, placing a large burden on both the individual and society [4-7]. Frailty is largely caused by this loss of muscle mass and strength, and is associated with increased risk of falls and reduced quality of life [8, 9]. Reduced physical function and the progression to frailty also places older adults at heightened risk of developing cognitive impairment and dementia [10, 11]. Conversely, retaining good physical function into older age helps maintain high self-efficacy and levels of physical activity, helping adults stay physically and socially engaged with their communities which contributes to maintaining cognitive function [12].

In light of the concerning estimated annual loss of 0.5-1% of muscle size and 1-5% of muscle strength in older age [1, 13], recognising means to delay individuals reaching a 'frailty threshold' has been identified as an urgent health care priority [14]. Moreover, action is needed before individuals reach a point where frailty begins to limit capacity to perform activities of daily living, i.e. before recovery of lost muscle strength through exercise is not possible. As such, even modest improvements of a few percent in muscle size or function with an exercise intervention may essentially represent postponement of frailty measurable in years.

Whilst heavy load strength training is no doubt the most effective approach for increasing muscle strength, recent evidence suggests low load resistance training can be efficacious in increasing muscle strength too [15]. Specifically in an older population, Reid, Martin [16] demonstrated increases of 34% and 13% in leg muscle peak power and strength in mobility limited older adults undertaking low load resistance training twice a week for 16 weeks. This increased muscle function was in part attributed to increased neural activity alongside the changes in muscle size, and likely contributed to the improved Short Physical Performance Battery (SPPB) scores achieved.

The most recent Cochrane Review of resistance type exercise training for improving physical function in older adults presents evidence that multifaceted improvements in health and function are achieved with progressive resistance training [17]. However, of the randomised controlled trials included in this review, more than half included participants already described as frail, suffering a health problem, or functionally limited. As alluded to previously, an opportunity exists to delay sarcopenia in older individuals who are still mobile and capable of a range physical activities, but may be at risk of progressing into frailty [18]. Furthermore, only 10 of the 121 trials included in the review implemented exclusively homebased exercise, with all of those using some form of exercise equipment with either disabled, frail, or mobility limited participants. The rest implemented gym-based training, usually involving supervised high intensity training, with all but two trials using a training frequency of two to three times a week. This may not be an appealing, affordable, or feasible regime for older

individuals to adhere to, and heavy resistance training may not even be necessary to induce strength gains. As such, the current study aims to investigate the acceptability of an exercise regime that fills the gap in the literature for homebased exercise in a clinical population of older adults. Specifically, the exercise snacking model under investigation requires no exercise equipment, is of moderate intensity, and sees 'exercise snacks' performed at a frequency of twice per day.

As this is the first study to examine homebased exercise snacking in outpatients identified as at risk of falling, it is crucial to assess the acceptability of the exercise snacking. As evidenced by Rasinaho, Hirvensalo [19], often adherence to an exercise intervention is accompanied by other more subtle changes in everyday behaviours, such as further changes to non-exercise physical activity patterns. However, there are inevitably challenges to adherence associated with home based exercise that have the potential to undermine the effectiveness of an exercise programme [20]. As such, a qualitative approach lends itself to assessment of subjective ratings of the exercise snacking regime.

3. Aims

The primary aim of this pilot study is to explore the acceptability of a 28-day homebased exercise snacking intervention to improve leg strength in older adults who have attended the memory clinic at the RICE Centre in Bath. The secondary aim is to examine the influence of exercise snacking on measures of physical function relevant to this population and the feasibility of collecting these data.

4. Study Design

4.1 Research Design

This is a single cohort acceptability study. All participants will receive the intervention, and pre- and post-testing.

4.2 Population

Outpatients attending the memory clinic at the RICE Centre in Bath, aged over 65 years who meet the eligibility criteria (section 5), will be invited to participate in this study.

4.3 Sample Size

The novel exercise snacking intervention to improve muscle function has not been studied in a clinical population of older adults before, and as such the acceptability of exercise snacking in this population is unknown. Furthermore, there is a lack of comparable literature to inform a quantitative sample size calculation to assess changes in muscle function as a primary outcome measure in this population, particularly given adherence rates are yet to be established. Therefore, in order to assess the acceptability of the intervention, it is estimated that 20 participants will be required to complete all follow-up assessments. A capped rolling recruitment strategy will be employed whereby if up to 10 participants drop-out of the intervention and do not complete follow-up assessments, they will be replaced. Participants who drop out of the intervention but agree to complete the follow-up assessments will not be replaced. For the sake of pragmatism, no more than 10 additional participants will be recruited.

4.4 Study Procedures

4.4.1 Overview

During clinical consultation with RICE gerontologists, potential participants will be identified and provided with verbal and written study information. Patients willing to participate must then provide consent to be contacted by a member of the research team to arrange a meeting to undertake eligibility screening, and if eligible, baseline assessment, and exercise familiarisation. This screening meeting will include obtaining informed consent for participation in the study. In the same meeting, eligible participants will then undergo baseline assessment of physical function and complete a secondary outcome questionnaire pack comprising instruments to assess attitudes, self-efficacy and motivation towards exercise, cognition, mental health and quality of life. Participants will be instructed on how to perform exercise snacking and be provided with an exercise logbook containing written instructions for the intervention and recording of exercise snacks. The 28-day exercise snacking intervention will begin the day after the baseline assessment. The follow-up assessment will be scheduled for within 5 days of the last day of the intervention. This will include reassessment of physical function, along with secondary outcome questionnaires, a questionnaire on acceptability and a short qualitative interview to provide in-depth feedback on their experience of the intervention. If local lockdown measures are introduced, or the participant is required to self-isolate whilst participants are undertaking the intervention, follow-up assessments of physical function will be completed remotely via video call on ICT provided by the study, as will the interviews.

4.4.2 Screening

All potential participants will undergo a face-to-face screening meeting with a member of the research team at the RICE Centre, to assess eligibility based on criteria described in Section 5 before proceeding. If the participant has a carer, then they may also attend the session. Potential participants will be asked to wear clothes in which it is comfortable to complete simple movement tasks. Before commencing any assessment, the screening and study procedures will be verbally described to the potential participant by the researcher, and they will be given the opportunity to ask questions about the study. If the potential participant is happy to continue with the screening and the study, subject to meeting eligibility criteria, they will be asked to sign an informed consent form.

A stadiometer and balance scales will be used to determine the potential participant's height and weight for calculation of Body Mass Index (BMI). Potential participants will complete a bespoke health screening questionnaire based on study exclusion criteria, and mini-mental state examination (MMSE) [21]. Those identified as meeting any exclusion criteria or with an MMSE score of <20 will be excluded from the study at that point.

Potential participants will then undertake an objective assessment of physical function (Short Physical Performance Battery; SPPB [22]) in which simple tests of walking speed, ability to repeatedly rise from a chair, and simple standing balance are scored based on set criteria. Only participants scoring over three and no more than eight out of twelve, without scoring zero on any element of the test will be eligible to continue the

screening. The upper limit to the SPPB eligibility criteria is to deliberately target a cohort who demonstrate some degree of compromised strength and balance.

Participants will receive a thorough demonstration of the exercise snacking movements. They will be asked to demonstrate their ability to safely carry out the movement themselves to the satisfaction of the researcher, who may then provide further guidance and opportunity for the participant to practice the movements if required. If the participant is unable to safely complete the exercises without loss of balance or experiencing acute joint pain whilst performing the movements, or the participant, their carer, or researcher feels that the participant would be placed in undue risk by undertaking exercise snacking in the home unsupervised, then they will be excluded from the study.

Eligible participants who successfully pass the aforementioned screening tests will be invited to continue in the study, and those wishing to do so will then undertake the baseline assessment during the same visit.

4.4.3 Baseline assessment

Baseline questionnaires and cognitive tests will be completed (paper form). The questionnaires will include brief measures of attitudes- (Outcome Expectancy for Exercise Questionnaire), self-confidence- (barrier self-efficacy scale), and psychological need satisfaction- (PNSE) for exercise, and a series of questionnaires designed to evaluate current mental health (Patient Health Questionnaire, Generalised Anxiety Disorder Assessment and Subjective Vitality Index), General Health (Short Form Health Survey) and Quality of Life (Life Satisfaction Scale, Global Quality of Life Scale). Measures of health and wellbeing will include a researcher led cognitive test (Montreal Cognitive Assessment), the Gronigen Frailty Indicator (GFI) [23].

As a collective measure of physical function, the SPPB score from the screening will be used, with the additional assessment of physical function described herein only undertaken with participants that have passed the screening and chosen to enrol in the study

Lower limb functional capacity will be assessed by a 60-second sit-to-stand test (STS-60) from a standardised, firm seated chair. For this assessment, as many sit-to-stand repetitions as possible will be completed, with the participant initially sitting fully on the chair, and rising to a full standing height with knees extended, without the use of arms for assistance with movement. Arm movement to maintain balance will be permitted, however the participant will be encouraged to minimise use of the arms to push off from the chair during the movement, rather the legs should initiate the movement. Whilst timing and counting the number repetitions performed, the researcher will be at all times vigilant to any potential loss of balance, and will stop the test if they feel the participant is unduly stressed or at risk of falling. The chair seat height will be 45 cm (the height of a standard kitchen chair). Participants will not be able to see the time remaining on the test, and no verbal encouragement will be provided. Immediately after completing the STS-60, participants will be asked to provide a rating of perceived exertion for the test using the 7-20 Borg scale [24].

As a measure of static standing balance, participants will be asked to complete simple tests of standing balance lasting a maximum of 60 seconds. Tests will consist of feet in

semi-tandem stance, full-tandem stance, and single leg standing, with each leg tested in the single leg balance test. The aim of each test is to maintain balance for as long as possible, up to 60 seconds. Each configuration of feet position will be tested twice, with the highest score of the two taken. The first point in time at which either feet or arms are moved substantially (i.e. loss of balance has occurred) will conclude that attempt. The researcher will stand close to the participant to provide physical support if the participant appears to be losing balance, and it will be explained to the participant that they should move from the given stance being tested to prevent falling if necessary

As a measure of functional mobility, participants will be asked to complete a timed-up-and-go test (TUG), in which participants rise from a chair, walk 3 meters, turn around, walk back to the chair, and return to a seated position [25]. This test will also be completed twice, with the fasted time taken.

To assess habitual physical activity levels during the first week of the intervention, participants will then be instructed in the use of, and given a wearable physical activity monitor (ActivPAL). They will be asked to wear the ActivPAL for seven consecutive 24-hour days, and will be provided with a pre-paid and addressed envelope in which to return the device. The ActivPAL provides data on sit-to-stand transitions, and thus will also act as an intervention compliance assessment tool.

Participants will be given an exercise snacking logbook containing full written instructions on how to complete a bout of exercise snacking, and also be given verbal instruction and opportunity to ask questions on its use. The logbook includes space in which to record notes about each exercise snack that may be useful to the researcher or the participant. With the logbook for reference, the participant will perform a bout of exercise snacking as a familiarisation before leaving. The 28-day intervention period will begin the day after the screening and baseline assessment takes place.

4.4.4 Follow-up assessment

Follow-up assessment will take place within 5 days of the final day of the 28-day intervention. The follow-up assessment is planned to take place at the RICE Centre. However, due to the uncertainty of the ongoing COVID-19 pandemic, there is the possibility of future lockdowns being implemented, or the participant being required to self-isolate whilst enrolled in the study. As the exercise snacking intervention is deliberately intended to be performed in the home the intervention should be able to continue uninterrupted, provided that the participant will not be alone when performing the exercise bouts. In the event that participants are not able to attend the testing facility for follow up assessment, this may be conducted remotely using video calling. This approach was successfully implemented in a recent study conducted whilst older adults were following government guidance to ‘shield’ during March to June 2020 [26]. However, in the aforementioned study, older adults without physical access to the information and communications technology (ICT) capable of video calling or lacking the digital literacy to use video calling software, were not able to take part in the study. To address this in the present study, tablets with pre-paid sim card/wifi dongles will be provided, along with written instructions for use of a GDPR compliant video calling software. The questionnaire-based assessments will still be completed on paper forms during the follow-up assessment video call, and they will be delivered with the tablet.

Questionnaires will be completed in the same order as the baseline assessment, but preceded by an additional questionnaire based on the theoretical framework of acceptability (TFA), which contains 8 items measuring general acceptability and the 7 distinct components of the framework [27] to assess acceptability of the exercise snacking intervention. Participants will repeat the same tests of physical function as completed in the baseline assessment (including the SPPB previously completed in the screening), under the same conditions as previously.

To complete the physical function tests remotely participants must be accompanied at all times by someone else (e.g. carer or another member of the household). Researchers will instruct the participant on where to place the tablet and chair for the SPPB chair test and STS-60 for a view that allows the test to be carried out as in the baseline assessment. For the balance measures of the SPPB and static standing balance measures, the participant will be reminded that they can position a stable item nearby in case they feel at risk of losing balance. The 2.4 m walk element of the SPPB and the TUG will be omitted in cases where the follow-up testing is completed remotely.

Qualitative assessment of experience of the protocols: Following the intervention participants will be invited to take part in an interview to provide qualitative feedback on their experience of the intervention. Interviews will take place in person or via video calling accordingly, will be digitally recorded, transcribed verbatim and anonymized on completion. The interview schedule will cover; (i) participants' perceptions of the impact of exercise snacking on mood, appetite, vitality, sleep, and other participant-generated concerns, (ii) adherence to the study protocol, i.e., if and how participants adapted the prescribed regimes, and factors they suggest would make the protocol easier to adopt, and (iii) the perceived barriers and facilitators, and costs and benefits of exercise-snacking. Transcripts will be analysed systematically using framework analysis to highlight key themes within and across participants, and the results used to facilitate participant input into the feasibility analysis and protocol amendments.

4.5 Exercise snacking intervention

The exercise snacking requires only a stable kitchen chair to perform. During all exercise snacking bouts, there must be a carer or a member of the household with functional capacity to request immediate assistance if required. Participants will be asked to perform five exercises, each for one minute followed by one minute of rest. In that minute of exercise, the participant will perform as many controlled repetitions of the given exercise as they can. Participants will be asked to perform the exercise snacks twice daily, ideally once in the morning and once in the afternoon close to mealtimes and separated by at least two hours where possible. The exercises are: sit-to-stand from a chair, seated arm raises to overhead, marching on the spot (holding a chair if necessary), seated arm crossing, and seated calf raises. Participants will be asked to always perform the sit-to-stand exercise first and record the number of repetitions completed in the minute, and thereafter may alternate the order of exercises, but will be asked to record the order in a logbook provided. During the demonstration, participants will be reminded that the aim is to complete as many repetitions as possible during each bout, and that use of the logbook serves to provide the participant with objective feedback on their progress.

4.5 Data Analyses

Primary aim: Acceptability of a 28-day exercise snacking intervention in outpatients attending the RICE memory clinic in Bath.

Secondary aims: Changes from pre- to post- exercise-snacking intervention in 1) attitudes to exercise (Outcome Expectancy for Exercise Questionnaire) 2) self-confidence for exercise (Barrier Self-efficacy Scale), 3) psychological need satisfaction- for exercise (PNSE)) 4) current mental health (Patient Health Questionnaire, Generalised Anxiety Disorder Assessment and Subjective Vitality Index), 5) general health (Short Form Health Survey) 6) quality of life (Life Satisfaction Scale, Global Quality of Life Scale 7) cognitive assessment (MOCA and GFI), and 8) physical function assessments of (SPPB, STS-60, RPE for STS-60,standing balance scores, and TUG).

Statistical analyses: The primary outcome of acceptability of the exercise snacking intervention will be assessed qualitatively using reflexive thematic analysis, and descriptively based on the scores from the TFA questionnaire. Together this information will highlight aspects of the programme that may pose a challenge to implementation or warrants further consideration as to how to optimise engagement and utility for the users. Student's T-test will be used to identify changes in secondary aims, i.e. change in questionnaire scores and functional outcomes from pre-to-post-intervention. Statistical significance will be accepted at $P<0.05$. Effect sizes will also be calculated according to Cohen [28], with $d>0.08$ considered a large effect.

5. Inclusion / Exclusion Criteria

5.1 Inclusion Criteria

In order to participate in this study, volunteers must satisfy all of the following criteria:

- Aged >65 years
- Have attended the Memory Clinic at the RICE Centre in Bath
- Mini-mental state examination (MMSE) score of ≥20 [21]
- Short Physical Performance Battery (SPPB) [22] score 3-8 and not scoring 0 on any component of the test
- Capability to safely perform the exercise snacking movements, assessed by a researcher during screening, and be able to have someone present in the home who could call for help if required during all exercise snacks.
- Not regularly engaging in recreational sports or structured exercise (once a week or more).
- Have a foreseeable clear period of 28 consecutive days in which to perform the exercise snacking protocol (i.e. no planned holidays or hospitalisation)

5.2 Exclusion Criteria

Participants will not be able to take part in this study if they meet any one of the following criteria:

- Co-morbidity preventing participation (e.g. severe breathlessness, pain, psychosis, Parkinson's, Dementia with Lewy Bodies, or other severe neurological disease)
- Individuals with a history of bone, joint or neuromuscular problems or a current musculoskeletal injury ascertained through preliminary screening *that would prevent exercise snacking or be made worse by performing exercise snacking*.
- Individuals with contraindications to exercise including chest pain, dizziness, or loss of consciousness, or who have been instructed by their doctor to only do physical activity recommended by them.

6. Possible Risks/Discomforts

The study involves participation in small bouts of exercise that the participants may find demanding. However, feelings of tiredness associated with the exercise are transient and will pass quickly. The researchers will be at all times vigilant in their observations of participants performing under the prescribed exercise conditions and are ready to end any testing session should the participant report, or even appear to be unduly stressed. The physical function tests are specifically designed to mimic ambulatory activities of daily living and are therefore movement patterns that the participants will be used to completing and will not find challenging.

Undertaking exercise in the home poses a risk of falling in this population, and as such participants should not perform the exercise snacks alone in the home and should at all times during exercise snacking bouts be in the presence of a carer or member of the household with functional capacity to request immediate assistance. Moreover, whilst participants are encouraged to complete as many repetitions of each exercise as possible in a minute, emphasis is placed on those repetitions being completed safely and in a controlled manner. This is to ensure that balance and movement control throughout the range of movement is mildly challenged so as to stimulate improvement, but within the remit of simple, everyday movements. Furthermore, should the participant feel that there is a risk of losing balance, they may hold onto a chair or stable object (doorframe) during the exercises as a precautionary measure. The exercise bouts are deliberately very brief with structured rest intervals, and should not cause muscle soreness or compromised function after a bout.

All of the above will be explained to the potential participant verbally and in the participant information sheet to ensure that they are fully informed before giving consent. The exercise snacking logbook will have emergency contact numbers for participants should the need arise.

7. Recruitment and Screening

Potentially eligible patients will be identified by RICE gerontologists, based on their clinical judgement. Written information about the study will be provided to the potential participant, and they will be asked to provide consent to be contacted by a member of the study team. During an initial phone contact with a potential participant, a member of the study team will provide a verbal overview of the study, and ask if the participant believes they meet all of the inclusion criteria and none of the exclusion criteria based on the written information provided. If this is the case, potential participants will invited to arrange a screening meeting at RICE. During this meeting, potential participants will

be asked to sign an informed consent form stating their willingness to participate in the study and undergo the eligibility screening with a member of the research team. Eligible participants will be invited to take part in rest of the study, and one of the researchers will describe the study verbally to them again and provide the opportunity for potential participants to gain clarification on any aspect of the study.

8. Informed Consent

It is the responsibility of a researcher to obtain written (signed and dated by the participant and researcher) informed consent before undertaking eligibility screening and enrolling a participant in the study. This must be undertaken after adequate explanation of the aims, methods, objectives and potential hazards of the study. The researcher will also explain to the participants that they are completely free to refuse to enter the study or to withdraw from it at any time without any repercussions. Should the researcher feel that the participant does not fully understand what is being asked of them for the study, that participant will not be eligible to participate in the study. Should the participant lose capacity to consent during the study, they will be withdrawn from the study.

9. Confidentiality

A single password protected Excel data sheet maintained on a RICE computer will be used to record participant names and relevant contact information associated with a given participant ID code. This will exist for logistical purposes of running the study, and only the designated researchers will have access to this identifying information. All other non-identifying participant information and results will be stored on Excel data sheets with the participant ID code only.

For participants that opt it, an audio recording of a qualitative interview undertaken at the second visit to RICE will be taken. The information provided will be transcribed and analysed later with all identifying information removed. The audio file will be deleted once the information has been transcribed.

Any results published from this study will be anonymous and include no identifiable information.

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