BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-069533
Article Type:	Protocol
Date Submitted by the Author:	24-Oct-2022
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Keywords:	GERIATRIC MEDICINE, REHABILITATION MEDICINE, NUTRITION & DIETETICS, PUBLIC HEALTH, QUALITATIVE RESEARCH

The Frail2Fit study protocol: A feasibility and acceptability study of a virtual multimodal intervention delivered by volunteers to improve functional outcomes in older adults with frailty after discharge from hospital

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Keywords: older adult; frailty; nutrition; exercise; volunteer; behaviour change

Word count: 3979

ABSTRACT

Introduction

Physical activity (PA) and replete nutritional status are key to maintaining independence and improving frailty status among frail older adults. In response to the COVID-19 pandemic, healthcare has increasingly turned to virtual modes of delivery and there is interest in the use of trained volunteers to deliver PA and nutrition interventions. We aim to evaluate the feasibility and acceptability of training hospital volunteers to deliver an online intervention, comprising exercise, behaviour change and nutrition support, to older people with frailty after discharge from hospital.

Methods

We will use a quasi-experimental mixed methods approach. Hospital volunteers (n = 6) will be trained to deliver an online, 3-month, multi-modal intervention to frail (clinical Frailty Scale ≥ 5) adults ≥ 65 years (n = 30) after discharge from hospital. Feasibility will be assessed by determining the number of volunteers recruited, trained, and retained at the end of the study; the proportion of intervention sessions delivered; participant recruitment, retention, and adherence to the intervention. To determine the acceptability of the intervention, interviews will be conducted among a purposive sample of older adults, and volunteers. Secondary outcomes will include physical function, appetite, well-being, quality of life, anxiety and depression, self-efficacy for managing chronic disease, and PA. Outcomes will be measured at baseline, 3 months, and 6 months.

Analysis

Descriptive statistics will be used to describe feasibility and adherence to the intervention. Secondary outcomes at baseline will be compared at 3 and 6 months. Interviews will be transcribed verbatim and analysed using thematic analysis.

Ethics and dissemination

Health Research Authority (HRA) ethical approval was obtained on 30th May 2022 (reference: 22/WA/0155). Results will be disseminated through peer-reviewed journal articles, volunteer organisations, NHS communication systems and social media platforms. A toolkit will be developed to facilitate roll out of volunteer training.

Trial registration number: NCT05384730

Article summary

Strengths and limitations of this study

- The intervention addresses the detrimental state of frailty, exploring opportunities to improve older peoples' management of post-discharge frailty.
- This study will evaluate the feasibility of a novel volunteer-led approach to the delivery of online exercise, behaviour change, and nutrition support for frail older adults.
- Lay volunteers will be upskilled using a bespoke training package, including development of healthy conversation skills, use of tools to facilitate nutrition support, and improving exercise knowledge and delivery.
- The intervention is underpinned by behaviour change techniques that seek to empower older people to exercise and eat well.
- A limitation of the study is the exclusion of older adults who are unable to provide consent, and a small sample size, impacting representation and generalisability of findings.

INTRODUCTION

Older people with frailty are at high risk of poor outcomes including increased post-hospitalisation, healthcare use and mortality [1]. Frailty refers to a cumulative decline in biological reserves leading to poor resolution of homeostasis after a stressor event [2]. Approximately 11% of community dwelling older adults have frailty [3], compared to around 14% to 80% in hospitalised older adults [4-7]. Differing cohorts of patients (e.g., age, ward type), and frailty measures (e.g., Edmonton Frail Scale, Cardiovascular Health Study Frailty Index) could explain the range of frailty prevalence reported in hospital. Typically, wards specialising in medicine for older people, and older patients (≥ 85 years) have higher incidence of frailty [4, 6]. As frailty progresses, older adults' functional status declines, resulting in disability, increased risk of falls, and long-term care [8]. Moreover, deconditioning during hospital admission is a major concern and impacts significantly on the ability for older adults to maintain independence [9, 10]. Considering these detrimental clinical consequences there is a need to identify ways to better manage and prevent decline in frailty to improve patient care [11].

Current evidence suggests that physical activity (PA) and nutrition interventions, underpinned with behaviour change support, are key to maintaining independence and improving frailty status among frail older adults [12-14]. Healthcare professionals advocate multi-modal and multi-disciplinary approaches to frailty management, such as consideration of the appropriate type, effectiveness, and feasibility of interventions to implement in practice, including online and volunteer-led approaches [15-19].

In response to the COVID-19 pandemic, healthcare, including frailty management, has increasingly turned to virtual modes of delivery, such as telehealth methods [20, 21]. Moreover, online communication tools have gained popularity among older people to remain socially connected, allowing PA and nutrition interventions to be delivered online [22]. Our research (the SafeFit trial) showed that exercise professionals could be trained to deliver an online intervention to maintain and improve physical, nutritional, and psychological well-being in people with cancer [23]. Telephone conversations, tele-monitoring devices, and internet-enabled tablets have also been shown as an effective means to deliver nutrition and PA interventions to community-dwelling older adults who were inactive or had malnutrition [24, 25]. Nevertheless, there is little evidence on the use of trained volunteers to lead such interventions. Subsequently, research is required to evaluate

the feasibility of volunteer-led online interventions to support older adults with frailty to eat well and remain physically active.

A whole society approach involving multi-sectoral collaborations, such as volunteers, has been advocated to promote age-friendly communities and healthy ageing [26, 27], and there is growing interest in the use of volunteer-led PA and nutrition interventions to support older adults health and well-being [17-19]. A recent systematic review explored the impact of PA interventions conducted by trained volunteers on health-related outcomes for community-dwelling older people (≥65 years) [28]. Volunteers implemented strength and balance exercises 1-3 times per week, which led to improvements in functional status, frailty status, a reduction in fear of falls, and improved quality of life [28]. Nevertheless, the review concluded that more high quality randomised controlled trials (RCT) are needed to investigate the effects of volunteer-led PA interventions among older people. Similarly, more adequately powered research has been recommended to explore volunteer-led nutritional interventions in the community [17].

Existing research suggests that volunteer-led PA and nutrition interventions reduced frailty risk among community-dwelling older adults, and showed improvements in handgrip strength, quality of life, social participation, and physical function [18, 19, 26, 29, 30]. For example, an RCT found that volunteers trained to perform nutrition-related discussions and strength exercises with older adults, resulted in a 25% reduction in prevalence of impaired nutritional status, and improvement in frailty [19]. Nevertheless, more insight is needed on how best to recruit, train, and retain volunteers to deliver PA and nutrition support in the management of frailty. Moreover, the underpinning behaviour change elements of such interventions have been underreported and thus consideration of behavioural support is required in future home-based frailty interventions [14].

Behaviour change support for older people can improve adherence to lifestyle changes [31], impacting on factors that may influence, or predict behaviour, such as physical and social vulnerabilities associated with ageing, achieving social goals, and perceived confidence to engage in behaviours (i.e., self-efficacy) [32, 33]. In a recent systematic review, behavioural interventions that showed value for improving frail older adults' physical function were educational and enablement strategies, including instruction on how to perform a behaviour, and restructuring the physical environment (e.g., modifications to reduce falls risk) [14]. Authors concluded that greater engagement with behavioural science is needed when developing and evaluating home-based health interventions for older adults experiencing frailty. Hence, the current Frail2Fit intervention

will be underpinned by behaviour change strategies to increase participants' confidence and autonomy to engage with PA and nutrition support.

The knowledge gaps this study addresses are three-fold, including how to recruit, train, and retain volunteers through exploring the feasibility and acceptability of a volunteer-led online multimodal intervention; investigation of the facilitators and barriers to online volunteer-led implementation of the intervention; and inclusion of volunteer behavioural change training to underpin exercise and nutrition components with behaviour change support.

Aims

This study aims to explore the feasibility and acceptability of training lay hospital volunteers to deliver an online multi-modal intervention, including exercise, behaviour change and nutrition support, to older people with frailty discharged from hospital. Objectives of this study are to:

1. Develop a training programme for volunteers to support the delivery of an online multimodal intervention.
2. Assess the feasibility of recruiting, training, and retaining volunteers to deliver the intervention.
3. Assess the feasibility of recruiting and retaining older adults with frailty to the trial.
4. Determine the acceptability of the intervention and explore barriers and facilitators to the intervention to support future wider implementation.
5. Determine outcomes to use in a future RCT.

METHODS AND ANALYSIS

Study design and setting

The protocol (v1.0, October 2022) was developed according to the SPIRIT reporting guidelines [34]. This feasibility study will use a quasi-experimental mixed methods approach and will be conducted at an NHS hospital trust in the South of England. Hospital volunteers will be trained to deliver virtual group support for frail older adults discharged from acute medical wards.

Participant recruitment

Older adults on acute medical wards will be informed about the opportunity to participate in the study by ward staff. The clinical care team will identify eligible participants in line with inclusion and exclusion criteria (Box 1) through existing access to medical records.

Box 1. Inclusion and exclusion criteria

Inclusion criteria	**Exclusion criteria**
• Older adults aged ≥65 years • Able to provide written consent • Recently discharged, or soon to be discharged from hospital • Identified as frail (Clinical Frailty Scale ≥5) • Able to walk at least a few steps upon hospital discharge	• Older adults who are not able to safely complete the exercises included in the intervention as advised by the patient's clinician • Patients who are discharged to rehabilitation units, or care homes • Patients receiving end of life care

Participants interested in the study will be approached by the research team who will complete informed consent and a frailty screening check using the clinical frailty scale (CFS) [35]. Participants scoring ≥5 on CFS will be eligible to participate in the study. A sample size of 30 participants was chosen in line with previous sample size recommendations for feasibility studies [36, 37].

Volunteer recruitment

Hospital volunteers aged ≥16 years, who have completed generic hospital volunteer clearance and training will be invited to participate in this study. To lead the group support sessions, volunteers must be physically able to perform the exercises themselves and be able to provide written consent. Volunteers will be identified by hospital voluntary services. Interested volunteers will be approached by the research team to discuss the study and complete informed consent (supplementary material). It is estimated that 6 volunteers will be needed to lead 3 groups of 5-10 participants. See figure 1 for an outline of study processes.

Intervention

The intervention duration will be 3 months. Participants will receive three group sessions per week for 1 month, twice per week for the second month, and once weekly for the last month. The tapered nature of the intervention was chosen to provide suitable support for older adults, with the aim to gradually encourage independence. Volunteers will deliver exercise, nutrition, and behaviour change support from a secure online platform (Microsoft Teams). Group sessions will last 40-60 minutes. The components of the intervention and the training package have been adapted from the SafeFit, SoMoVe, and ImPACt studies [18, 23, 38].

Exercise

Exercise will consist of volunteer-led group resistance training for 20-30 minutes using resistance bands. To align with home-based safety considerations, the exercises will be performed seated. Seated exercise will focus on strengthening 8 major muscle groups, tailored specifically to meet the needs of older adults and to minimise the risks of injury. Participants will be encouraged by volunteers to progress repetitions, to gently improve range of motion, and increase the resistance grade of bands. Intensity will be monitored with the Resistance Intensity Scale for Exercise (RISE) [39] and the Talk Test [40], aiming for a low-moderate intensity. Participants will be encouraged to complete the exercises 2-3 times per week consistent with Chief Medical Office guidelines on PA and strength improvement for older adults [41]. Resources, including resistance bands, exercise booklets, and online exercise videos, will be given to participants before hospital discharge in preparation for the home-based intervention.

Nutrition support

Using the Nutrition Wheel, volunteers will initiate group discussion with participants to raise any nutrition-related concerns [42]. The Nutrition Wheel is an interactive tool developed from the Patients Association Nutrition Checklist and used to engage individuals in conversation about unintentional weight loss and malnutrition [42]. The Nutrition Wheel consists of 4 main questions, including 1) Are you or your family concerned that you may be underweight, or need nutritional advise? 2) Have you lost a lot of weight unintentionally in the past 3-6 months? 3) Have you noticed that your clothes or rings have become loose recently? 4) Have you recently lost your appetite and/or your interest in eating? Based on the participant's answers, they will be directed to further questions and guided to appropriate nutritional advice (e.g., information sheets, national helplines, or if necessary, signposted to their GP/practice nurse). Volunteers will be given suggested weekly

nutrition topics based around the nutrition wheel to facilitate group discussions (Box 2). Importantly, volunteers will not advise the group, instead they will harness the resourcefulness of the group and encourage them to come up with their own solutions.

Box 2. Example of weekly nutrition topics
Snacking – adding calories and protein
Fluids and drinking
Food shopping
Cooking
Fruit and vegetables
Cutting food and chewing

Behaviour change support

Volunteers will receive training in healthy conversation skills (HCS) guided by principles of Making Every Contact Count (MECC) [43, 44]. The MECC approach supports positive behaviour change through encouraging client-centred brief conversations surrounding health and well-being and will support the delivery of the exercise and nutrition components in the current intervention. Training will enable volunteers to have the confidence and competence to deliver healthy lifestyle messages, to help encourage participants to change their behaviour through solution-focused and empowering approaches [45]. Through using HCS in the current intervention volunteers can help to improve participants capability and motivation to be physically active and to eat well, empowering participants to take control of their health behaviours by building self-efficacy [46]. Behaviour change will be monitored by participant diaries, during the intervention phase.

Digital support

To address digital inequality, internet-enabled tablets will be provided. Individuals with low confidence will be supported by the research team to access the teleconferencing platform. They

will be given digital support leaflets and guidance about how to stay safe online. Digital support will be available to participants throughout the study.

Safety during sessions

At the beginning of each session volunteers will complete a pre-session screening checklist to ensure participants are safe to exercise (e.g., safe set-up of a home exercise space; feeling well; no new or worsening symptoms). Volunteers will be given training to encourage participants to exercise at their own pace, to rest when they need to, and to move within a pain-free range of motion, ensuring that participants are working at a tailored intensity. Where possible participants will be encouraged to undertake the sessions with friends or family members at home and they will be asked to keep cameras on during the sessions. Groups will be limited to a maximum of 10 participants.

Volunteers will conduct the online intervention from hospital. If an emergency occurs, such as an acute medical event, volunteers will immediately alert hospital volunteer support. If concerned about collapse, hospital staff will call 999. Staff will have a list of participant's addresses and GPs on file. An 'escalation plan' giving clear steps to follow, depending on the emergency situation, will be given to volunteers and staff. Cases of health concern will be raised with the chief investigator and a decision will be made regarding continuation in the trial based on clinician advice.

Volunteer training programme

Volunteers will receive a bespoke training package adapted from the SafeFit trial [23]. Exercise and nutrition training will be delivered by the research team in-person, and behaviour change support training will be delivered online. Once the 3 training components have been completed, a member of the research team will shadow the volunteers during the first month of intervention delivery. After 4 weeks, volunteers will aim to lead the sessions independently with continued support (including regular supervision meetings) by the trainers.

Exercise

The exercise training programme was developed based on clinical expertise and recently completed research of volunteer-led exercise in hospital and the community [18, 38]. Training will include an in-person group session lasting 2 ½ hours, comprising theory underpinning the benefits of exercise for older adults, exercise training principles, seated exercise delivery, and safety considerations. Volunteers will practice delivering exercise to peers and will be given a training manual and links to

training videos developed from previous research [18, 38] and adapted for this specific trial. The lead trainer (SM) is a research fellow and clinical exercise instructor with experience delivering exercise to a range of population groups, including older adults.

Nutrition support

Volunteers will be trained to use the Nutrition Wheel by SM, supported by JM, during a 2 ½ hour session with accompanying support materials. The training will cover principles of healthy eating, information on undernutrition (e.g., prevalence, risk factors, identification, and treatment), details on the Nutrition Wheel, and practicing how to facilitate a Healthy Conversation based on the Nutrition Wheel in a group context. Links to trusted nutrition resources will be provided to volunteers for group signposting and they will be given suggested weekly nutrition topics (Box 2) with supporting questions to facilitate group discussions.

Behaviour change support

The training, which is based on Healthy Conversation Skills (HCS), will be delivered by a health psychologist (JV-S). HCS training develops four key competencies: 1) asking open discovery questions ('how' and 'what' questions), 2) listening instead of making suggestions or giving advice, 3) reflecting on practice, and 4) setting goals using SMARTER (specific, measurable, action-oriented, realistic, timed, evaluated, reviewed) planning [47]. The training will be 3 hours of online interactive learning to support volunteers to deliver exercise and nutrition components in an empowering, person-centred, solution-focused way, translating MECC principles into practice.

Volunteer support

Throughout the study a peer-supported community will be established through online monthly volunteer meetings. The research team will work closely to support volunteers, including listening and providing any emotional support on a group and individual basis. Volunteer feedback will be integral to shaping the support that volunteers will need in delivering the intervention and ensuring volunteer well-being. In addition, trainers will conduct monthly fidelity checks to assess the quality of group sessions delivered by volunteers. The volunteers will be observed and assessed against a competency framework, including checks for exercise, nutrition, and behaviour change components. Based upon fidelity checks and volunteer feedback, extra one-to-one training sessions, emotional and confidence support, will be available if necessary. Volunteers will be asked to keep an

attendance record during the intervention using session completion logs and will be trained to report any adverse events.

Outcome measures

Participant characteristics including age, gender, body mass index, malnutrition status (Malnutrition Universal Screening Tool), cognition (Mini-Mental State Examination) [48] and number of medications will be recorded. Volunteer characteristics recorded will include age, occupation, qualifications, volunteering experience, and employment status.

Primary outcomes

The primary outcome measures are feasibility and acceptability of the intervention. Feasibility will be assessed by determining the number of volunteers recruited, trained and retained at the end of the study, the proportion of intervention sessions delivered, and fidelity of volunteer delivery. Moreover, participant recruitment, retention and adherence to the intervention will be measured, as well as any adverse events. To determine the acceptability of the intervention and to explore barriers and enablers to the implementation of the intervention, interviews will be conducted among older adults (N= 6), volunteers (N= 6), and those involved in recruiting participants (N= 3). Interviews will be conducted via telephone and will be audio-recorded for data collection purposes.

The interviews will be semi-structured, consisting of key open-ended questions to explore the views of older adults, volunteers and trainers on the multi-component sessions, the barriers and facilitators to the intervention and suggestions for future implementation studies. The interview schedules will be underpinned by Normalisation Process Theory (NPT). NPT is an implementation theory providing a framework to identify and explain important elements of the implementation process, thereby understanding the social processes through which new or modified practice is implemented, embedded, and integrated into healthcare settings [49].

Secondary outcomes

The secondary outcomes will include the measurement of PA, physical function, appetite, well-being, quality of life, anxiety and depression, and self-efficacy for managing chronic disease, measured at baseline (in hospital), 3 months (via telephone) and 6 months (via telephone).

PA will be measured using the physical activity scale for the elderly (PASE) [50] and using wrist-worn accelerometers (GENEActiv, Activinsights, Kimbolton, Cambridge, UK). The PASE measures

leisure-time, household, and occupational PA across 7 days, and has good stability and convergent validity within community-dwelling older adults [51]. The GENEActiv accelerometers will measure triaxial movement acceleration in gravity (g) units (1 g = 9.81 m/s^2) at a frequency of 100Hz continuously over a period of 7 days. Previously validated acceleration threshold values (in older adults) will be used to quantify the time (minutes/day) spent on average in each intensity category: total PA, and separately for light, moderate, vigorous intensities and the composite category moderate-vigorous PA (MVPA) [52]. GENEActiv watches will be posted to participants at baseline, 3 and 6 months and returned with a pre-paid return envelope.

The Barthel Index will measure older adult's functional ability across 10 items, with a higher number being a reflection of greater ability to function independently following hospital discharge [53]. The Barthel Index has reasonable reliability and good responsiveness [54].

Appetite will be measured using the Simplified Nutritional Appetite Questionnaire (SNAQ) [55], which has been validated to predict weight loss in community dwelling older adults and used to predict poor health outcomes in hospitalised older people [55-57]. SNAQ is a four-item tool assessing appetite, satiety, taste of food and number of meals per day with a score of ≤14 indicating poor appetite.

Well-being will be assessed using the Warwick-Edinburgh Well-Being Scale (WEMWBS), which comprises 14 items relating to positive affect, satisfying interpersonal relationships and positive functioning [58]. The WEMWBS is a psychometrically robust scale showing good content validity and popularity in the measurement of well-being in relation to public health [58, 59].

The Hospital Anxiety and Depression Scale (HADS) will be used to assess anxiety and depression symptoms [60] and has been validated across multiple settings and populations [61]. Depression and anxiety symptoms are measured on sub-scales where a score of 0-7 is normal, 8-10 borderline abnormal, and 11-21 abnormal.

Quality of life will be measured using the EuroQol (EQ-5D-5L) assessment comprising a short descriptive questionnaire and a visual analogue scale (VAS) [62]. The EQ-5D-5L has been widely used in clinical trials and population studies as a popular measure of health status [63].

The 6-item Lorig scale will be used to assess participant's self-efficacy in managing their chronic disease [64]. The scale contains items developed from the chronic disease self-management study

covering domains, such as symptom control, role function, emotional functioning and communicating with health professionals [64]. Each item is scored on a 10-point Likert scale with higher scores indicating higher self-efficacy.

Data analysis

Quantitative data analysis

Data will be entered into a secured database for analysis. Statistical analysis will be conducted using the statistical software SPSS (v28.0.1.1). Descriptive statistics -median (Interquartile Range [IQR]); mean (standard deviation [SD]); number (%) – will be used to analyse the numbers of volunteers recruited, trained, and retained, as well as patients' adherence to the intervention to assess the feasibility of delivering this intervention. To determine suitability for a future RCT, inferential statistics will be used. Outcome measures recorded at baseline will be compared to measurement at 3 and 6 months to determine if the intervention had an impact on PA measured by PASE and GENEActiv, functional outcomes including functional ability (Barthel), appetite (SNAQ), symptoms of anxiety and/or depression (HADS), wellbeing (WENWBS), self-efficacy (Lorig) and quality of life (EQ-5D-5L). The distribution of each outcome measure will be assessed for normality and described using parametric or non-parametric statistics accordingly. A basic cost-analysis of the training programme will be carried out, costing the time involved in delivering the training.

Qualitative data analysis

Data collected from the interviews will be transcribed verbatim and analysed using thematic analysis (TA). TA is a method for identifying, analysing and reporting patterns or themes within data [65]. There are six phases in the TA process: Phase 1 – familiarising with the data, Phase 2 – generating initial codes, Phase 3 – searching for themes, Phase 4 – reviewing themes, Phase 5 – defining and naming themes, and Phase 6 – producing the report. Analysis of qualitative data will be conducted using Microsoft Word, or NVIVO software (v12), depending on the amount of data collected. SM will analyse codes to generate concepts and ideas to determine the acceptability of the intervention, and to identify facilitators and barriers to the implementation process. From the codes, themes will be developed to reflect the views and experiences of participants and volunteers regarding the online multimodal intervention. SL will code 25% of interviews separately to develop, discuss, and agree on themes with SM through an iterative process.

PATIENT AND PUBLIC INVOLVEMENT

This intervention was developed in line with our previous research [18, 38], which highlighted that volunteer-led PA interventions in hospital and the community were safe, and well received by older adults. In the development of our programme of research older adults in the community and care homes (n = 92) completed a survey, illustrating 45% had experience working with volunteers and appreciated their contribution. A further survey conducted in community social clubs showed that 47 out of 50 older adults agreed or strongly agreed to have trained volunteers lead exercises. A PPI representative led by the PPI lead for the Ageing and Dementia theme within the Wessex Applied Research Collaboration (ARC) is a part of the study management group. As such they provided input into this study proposal, reviewed patient facing materials, and ensured that the processes of the study such as data collection, and interviews, were not too burdensome for participants. They will continue to be involved in the study steering group throughout the research and will be consulted regarding dissemination of research findings.

ETHICS AND DISSEMINATION

Health Research Authority (HRA) ethical approval was obtained on 30th May 2022 (22/WA/0155). The NHS sponsor for this trial will monitor and audit the study in line with their policies and procedures. Any protocol changes will be approved by HRA before implementation. The study steering committee will have oversight of study processes and research personnel have been trained in Good Clinical Practice. Data will be stored on a password protected University database and handled in line with the Data Protection Act 2018 to maintain confidentiality. Access to data will be granted to relevant members of the research team and authorised representatives from the Sponsor for monitoring and/or audit purposes. Results from this study will be disseminated through peer-reviewed journal articles, scientific conferences, volunteer organisations, NHS communication systems and social media. Findings will be translated into a toolkit to support knowledge transfer including advice on volunteer recruitment, training, and suggestions for successful implementation in future trials and wider roll out of the intervention.

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Author contributors

SM drafted the manuscript. All authors were involved in the conception and trial design and provided critical intellectual content. SL is the chief investigator responsible for the overall conduct and management of the study. JM provided nutrition and dietetic expertise, contributing to the design of nutritional components. JV-S provided expertise in Healthy Conversation Skills Training, contributing to the design of the behaviour change components of the intervention. SM will lead the volunteer training and be involved in data collection, and analysis. All authors contributed to the preparation of this article.

Funding statement

The University Hospital Southampton Foundation Trust Small Grants Scheme funded this research (Reference number: GNT0525).

Competing interests

The authors have no competing interests to declare.

Patient consent for publication

Not required

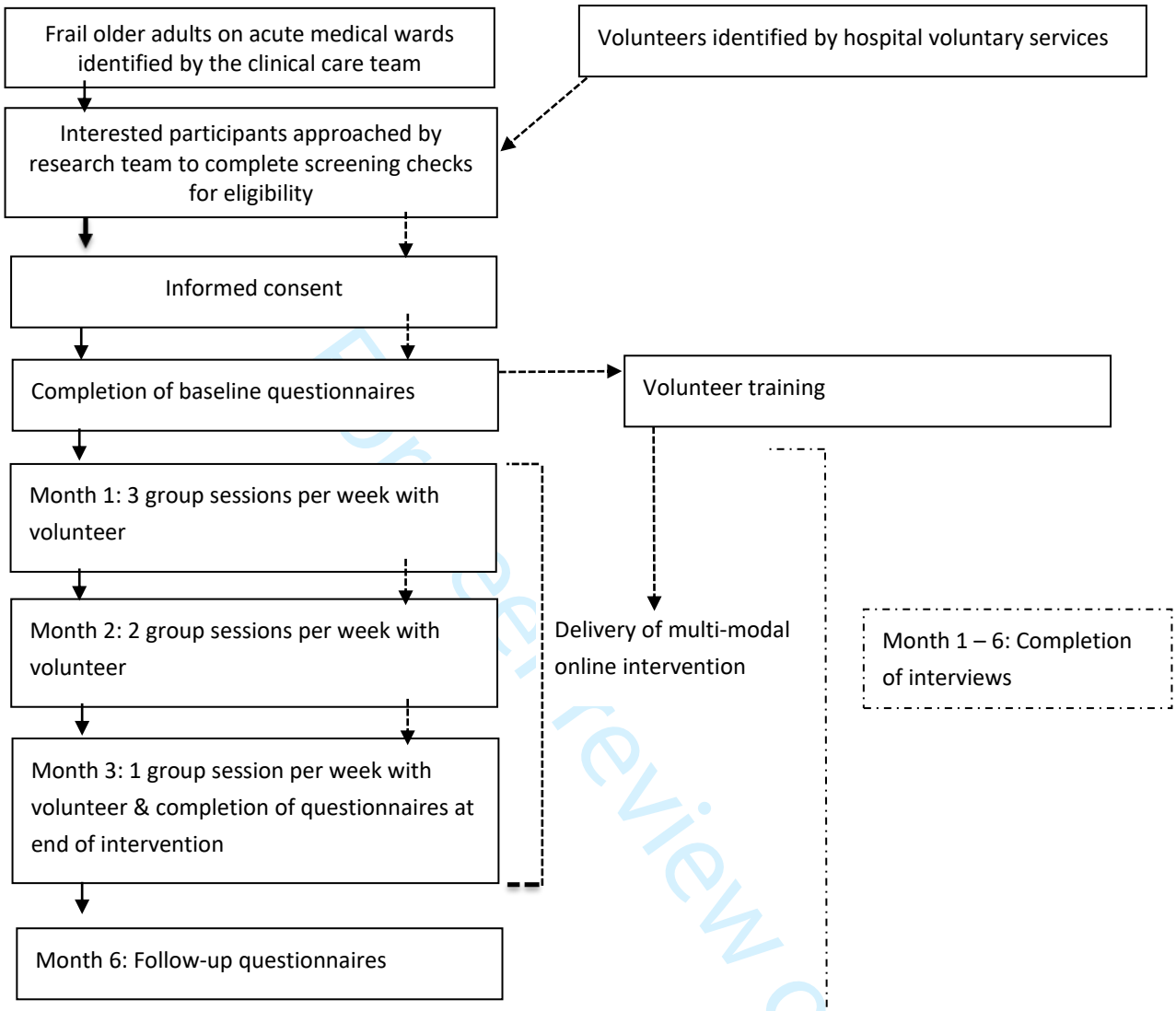


Figure 1. Study flow chart.

Version 0.1 5th September 2022

Participant Information Sheet (Patient)

Study Title: The Frail2Fit Study: Online Nutrition and Exercise Support for Older Adults with Frailty

Researcher: Dr Stephen Lim

This project has been reviewed by the Wales REC 7 Research Ethics Committee. REC Reference: 22/WA/0155

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

I am a doctor specialising in the Care of Older People with an interest in improving the health of older people. This study aims to see if we can train volunteers to encourage older adults to exercise in a group and to provide them with nutrition support after being discharged from hospital. We also want to know if this is acceptable to them, and their family members. We will see if the exercise and nutrition support have an impact on the health of those taking part. This study is funded by the University Hospital Southampton Research and Development grants

scheme and has been submitted to the NHS Health Research Authority research ethics committee for approval.

Why have I been asked to participate?

You have been asked to take part in this study because you are due to be discharged from the University Hospital Southampton NHS Foundation Trust and you meet the eligibility criteria for this study. The inclusion criteria for this study are: anyone older than age 65, identified as frail, who can participate safely in the exercise programme, are able to walk at least a few steps upon hospital discharge, and are able to give consent.

What will happen to me if I take part?

Online exercise and nutrition support

When you get home, you will be encouraged by volunteers to join in online home-based seated exercise and group nutrition support for twelve weeks. The volunteers delivering the programme have been trained by health professionals. In the first month you will be offered the opportunity to participate in 3 online sessions per week. Over time the number of sessions per week will reduce as you become more independent and learn how to complete the exercises.

The exercises are done seated. They are simple to complete and are designed to maintain or improve your muscle strength. It is important that you move to where you feel comfortable and at your own pace. As you get a bit fitter the volunteers can offer you a resistance band. This is a long elastic band to get your muscles safely working a bit harder. The exercise is done online in a group with your peers.

The nutrition support will involve friendly group discussion about diet and eating. The volunteers are not dieticians but they will be able to offer you direction to information that could help with eating well and feeling good.

If you struggle to access the support online, we have an iPad (computer) you can borrow. We can also show you how to use the iPad and how to access the online sessions. Our research staff will be here to help you throughout the programme. If you do not feel comfortable using the online support then you can opt for telephone support instead.

Evaluating the programme

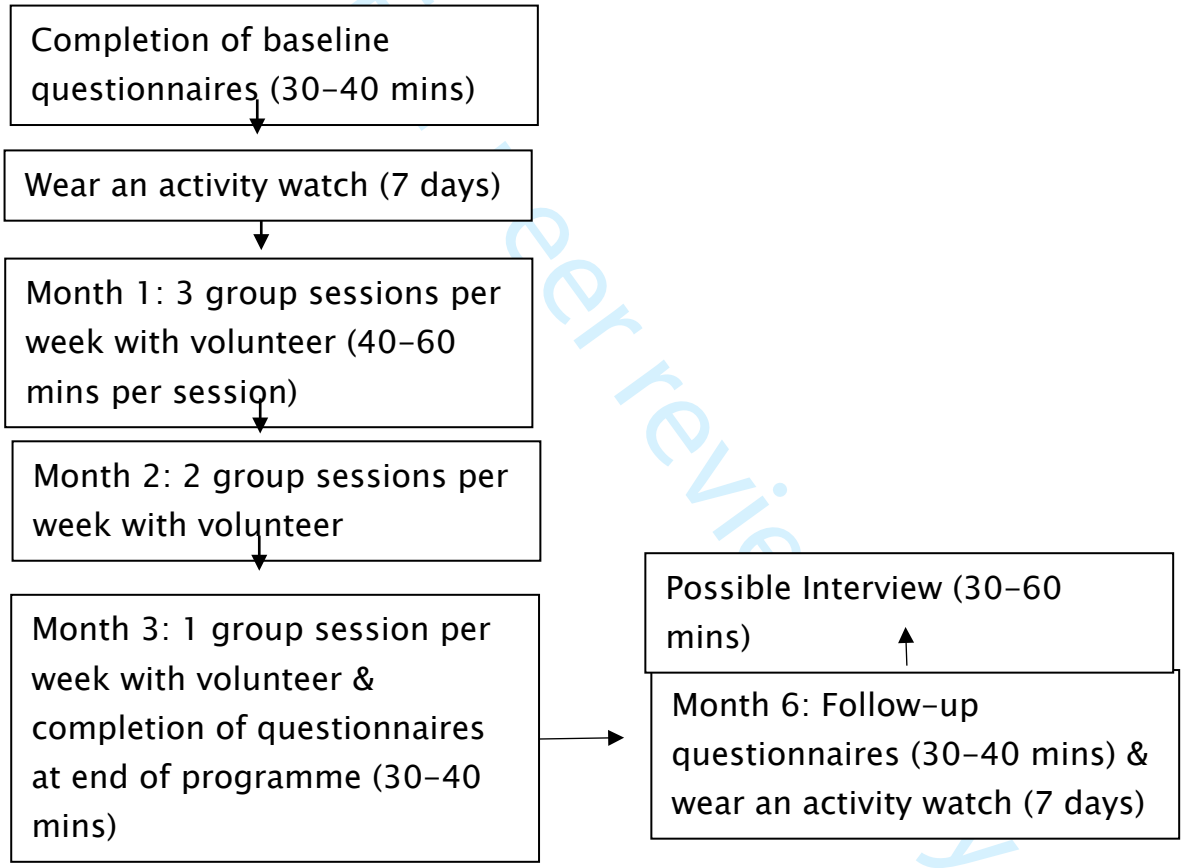
To find out if the online support works, we would like to learn about your health and well-being. We might also ask you some questions about your experiences participating in the programme.

Before you leave hospital a research assistant, who is a healthcare professional, will collect some basic information about you. This will include measurements of your physical health, eating habits and activity levels with questionnaires. You will also be given an activity watch (accelerometer) to wear for 7 days when you get home. This watch will accurately measure your activity levels. After three months and six months, we will contact you again to repeat the measurements to determine the impact of the exercise and nutrition support on your health. The repeat data collection process will be done at your own home over the telephone and activity watches will be posted to you with a return pre-paid envelope.

You may be invited to attend an interview to share your views and experiences on the exercise and nutrition support programme. Interviews will take place over the phone, or online (e.g., Zoom)

depending on your preference. Interviews will be audio-recorded. If you do participate in an interview your details will be anonymised (non-identifiable participant information), which means that no one outside the research team will know your name. People will read about the things you say to us, but they will not know who said those things.

Timeline



Are there any benefits in my taking part?

Studies have shown that exercise training and nutrition support are beneficial in improving physical function of older people. One of the benefits of taking part in this study is that you will be taught evidence-based exercises and nutrition advice which will be conducted in group online sessions. Exercising in an online group can also be a positive experience as the social aspect of group exercises has been shown to be a source of motivation.

By taking part in this study, you will also be contributing to further research to improve the health of older people.

Are there any risks involved?

The risks involved in this study are minimal. Common injuries that may occur during exercises include muscle strain and back pain. To reduce the chances of any injuries you will be encouraged to exercise at your own pace to a level you feel comfortable with. The exercises are gentle seated movements and will be shown to you by friendly volunteers who have been trained by health professionals.

Less commonly, is the risk of falls. However, the exercise programme is likely to help promote improvement in balance and muscle strength, which may help reduce the risk of falling. This study does not involve any invasive procedure.

What will happen in case of an emergency?

The volunteers will be taught how to deliver the support sessions safely. However, in the unlikely event that you require immediate

medical attention (e.g., collapse) the volunteer will contact the emergency services. If you experience an adverse event (e.g., a muscle strain) then the volunteer will let us know (the study team) and we will get in contact with you to escalate the situation further, if required. Feel free to contact us if you have any worries or concerns during the programme.

What data will be collected?

We will collect basic information such as your gender, date of birth, age, physical function status, and cognitive status. Using validated questionnaires, we will measure your physical activity levels, eating habits and well-being. These questionnaires will take approximately 30-40 minutes to complete with assistance from one of the research team. We will also measure your activity levels using an activity watch (accelerometer). These measures are important as it will help determine if the exercise and nutrition programme had a positive impact on your health. You may be invited to an interview to explore your views and experiences about the exercise and nutrition programme. Interviews will be recorded using a digital audio-recorder.

Your contact details will be recorded to allow the research team to contact you at 3 and 6 months to re-do questionnaires. Your address will be recorded in case of an emergency during the exercise session. This will enable volunteers to notify the emergency services of where you are if needed.

Your information will be anonymised (made non-identifiable) during the data analysis process and published data will not include any identifiable participant information.

Will my clinical care team know if I want to participate in the study?

If you decide to volunteer for the study, we will send a letter to your clinical care team to let them know that you are participating in the research if you consent to this in the consent form.

Will the online sessions continue when the study has finished?

The online support sessions will last 12 weeks during the study. There will be no further online support sessions when the study has finished. However, you will be given resources, including booklets and access to online videos to continue with your exercise and nutrition changes at home in your own time.

Will my participation be confidential?

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

Data collected will be entered electronically on the computer and stored on the university's networked storage. Access to this information will be password-protected. Hard copies of participant

information will be stored in a locked filing cabinet in a secure office in our research unit and will be accessible only by the research team. Audio recordings for the interviews will be deleted once they have been transcribed. Codes are allocated to each participant to ensure that the data is anonymised. Only the researchers in this study will have access to your data.

In accordance with the regulations we are required to keep your data secure for 10 years.

Your data may be used in future studies by our research team. If this happens, your data will be used anonymously (non-identifiable participant information) so you cannot be identified. Any new research studies using your data will be authorised by the local research ethics committee.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

Please inform me if you wish to take part in this study and I will be in touch with you to provide you with more information and go through the consent process.

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected. Please inform the volunteer leading the sessions or me if you wish to withdraw from the study.

If you do not wish to carry on with this study, you can withdraw at any time without giving a reason. If you decide to withdraw we would like to retain the use of anonymised (non-identifiable participant information) routine data and any data already collected which would be important for the overall study results.

What happens if I have given consent but then lose capacity to consent during the study?

You and all your identifiable data collected during the study would be withdrawn from the study. Data which is not identifiable to the research team may be retained.

What will happen to the results of the research?

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent. The results of the research will be published in scientific journals. Research staff may also present the results at conferences and local meetings, and on a website where it would be available to members of the public. You will not be identified in any report produced.

If you are interested, when we have finished analysing the study data, the research team will phone you to share the results. We will also place the study findings on a website (https://www.arc-wx.nihr.ac.uk/) and point you to any open access research publications. If you are interested but do not have access to the internet we can post the results upon request.

Where can I get more information?

For further information, please contact me (**Dr Stephen Lim**) at s.e.lim@soton.ac.uk, or by telephone 023 8120 6131.

Or you can contact the research assistant Dr Samantha Meredith at s.j.meredith@soton.ac.uk, or by telephone 078 2510 4783.

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

NHS Indemnity Insurance

The University Hospital Southampton NHS Foundation Trust will act as sponsor for this research study and will provide insurance for the study through the NHS indemnity scheme. The insurance will meet the potential legal liability of the sponsor for harm to participants arising

from the design of the research and the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research. Moreover, volunteers will be insured by The Liabilities to Third Parties Scheme (LTPS) through NHS Resolutions. This will provide volunteers with employer's liability, public liability, products liability, and professional indemnity cover.

How will we use information about you?

We will need to use information from you for this research project. This information will include your:

- Name
- Age
- Address
- Telephone number
- Gender
- Medical status

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. We will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed and stored data will be destroyed. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to sponsor@uhs.nhs.uk, or

by ringing us on +44(0)23 8120 3598.

Thank you for taking the time to read the information sheet and considering taking part in the research.

Participant Information Sheet (Volunteers)

Study Title: The Frail2Fit Study: Online Nutrition and Exercise Support for Older Adults with Frailty

Researcher: Dr Stephen Lim

This project has been reviewed by the Wales REC 7 Research Ethics Committee. REC Reference: 22/WA/0155

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

I am a doctor specialising in the Care of Older People with an interest in improving the health of older people. This study aims to see if we can train volunteers to encourage older adults to exercise in a group and to provide them with nutrition support after being discharged from hospital. We also want to know if this is acceptable to them, and their family members. We will see if the exercise and nutrition support have an impact on the health of those taking part. This study is funded by the University Hospital Southampton Research and Development grants scheme and has been submitted to the NHS Health Research Authority research ethics committee for approval.

Why have I been asked to participate?

You have been asked to take part in this study because you are a patient support hub volunteer at University Hospital Southampton NHS Foundation Trust.

What will happen to me if I take part?

You will be trained to deliver online group exercises and nutrition support for older people with frailty. Below we will outline your training and the online programme.

Volunteer Training

The training will be a combination of in-person and online content led by various health professionals specialising in nutrition and exercise for older adults. You will also be given additional resources to support your training including booklets and online videos. Training will take place for half a day in-person at University Hospital Southampton and 3 hours of online training. Also, we are available for any additional one-to-one training sessions that you would like.

The training will be split into 3 main sections:

1) Exercise Training: We will teach you how to safely deliver seated exercises to older adults online, including use of elastic resistance bands (2 hours).
2) Nutrition Training: We will teach you how to engage older adults in conversations about their nutrition and where to signpost older adults for more information about healthy eating (2 hours).

3) Behaviour Change Training: You will be invited to an online course in 'healthy conversation skills' to help you empower older adults to improve their exercise and nutrition (3 hours).

Online Programme for Older Adults with Frailty

The supportive online sessions that you will be delivering to the older adults will last approximately 45-60 minutes and will include 20-30 minutes of exercise and 15-25 minutes of nutrition support. You will also be taught how to motivate lifestyle changes and how to make sure the exercise and nutrition support are safe and enjoyable.

We would like you to deliver the support sessions for 12 weeks to a small group of older adults.

- In the first month (week 1-4) you will deliver 3 sessions per week.
- In the second month (week 5-8) you will deliver 2 sessions per week.
- And in the last month (week 9-12) you will deliver 1 session per week.

You will be teamed up with another volunteer, so you can support each other in the delivery of the sessions. Also, the trainer will support you throughout the project and will organise regular group volunteer meetings to discuss any concerns or feedback.

You may also be invited to attend an interview to share your views and experiences on delivering the online programme. Your details will be anonymised, which means that no one outside the research team will know your name. People will read about the things you say to us, but they will not know who said those things.

Are there any benefits in my taking part?

Studies have shown that resistance exercise training and nutrition support are beneficial in improving physical function. One of the benefits of taking part in this study is that you will be taught evidence-based exercises and dietary advice which will be conducted in group sessions. By doing the exercises yourself, you are also likely to benefit from it. Exercising in a group can also be a positive experience as the social aspect of group exercises has been shown to be a source of motivation. By taking part in this study, you will also be contributing to further research to improve the health of older people.

Are there any risks involved?

The risks involved in this study are minimal. Common injuries that may occur during exercises include muscle strain and back pain. Less commonly, is the risk of falls. However, the exercise programme is likely to help promote improvement in balance and muscle strength, which may help reduce the risk of falling. This study does not involve any invasive procedure.

What will happen in case of an emergency?

You will be taught how to deliver the support sessions safely. However, in the unlikely event that a participant in your group requires immediate medical attention (e.g., collapse) you will need to call for help (staff will be available in the Patient Support Hub), or contact the emergency services. If a participant experiences an adverse event (e.g., a muscle strain) then you will need to let us know (the study team) and we will get in contact with them to escalate the situation further, if required.

What data will be collected?

We will be collecting basic information such as your gender, age and ethnicity. You may be interviewed to explore your views and experiences about the exercise programme. Interviews will take place on the telephone, or online (e.g., Zoom) depending on your personal preference. Interviews will be recorded using a digital audio-recorder. Participant information will be anonymised (non-identifiable participant information) during the data analysis process and published data will not include any identifiable participant information.

Timeline

Will the online sessions continue when the study has finished?

The online support sessions will last 12 weeks during the study. There will be no further online support sessions when the study has finished. However, participants will be given resources, including booklets and access to online videos to continue their exercise and nutrition changes at home in their own time.

Will my participation be confidential?

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

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Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

Please inform the researcher if you wish to take part and the research team will be in touch with you to provide you with more information and go through the consent process.

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected. Please inform the researcher if you wish to withdraw from the study.

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Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent. The results of the research will be published in scientific journals. Research staff may also present the results at conferences and local meetings, and on a website where it would be available to members of the public. You will not be identified in any report produced.

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Or you can contact the research assistant Dr Samantha Meredith at s.j.meredith@soton.ac.uk, or by telephone 078 2510 4783.

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions.
If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

NHS Indemnity Insurance

The University Hospital Southampton NHS Foundation Trust will act as sponsor for this research study and will provide insurance for the study through the NHS indemnity scheme. The insurance will meet the potential legal liability of the sponsor for harm to participants arising from the design of the research and the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research. Moreover, volunteers will be insured by The Liabilities to Third Parties Scheme (LTPS) through NHS Resolutions. This will provide volunteers with employer's liability, public liability, products liability, and professional indemnity cover.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your:

- Name
- Age
- Address
- Telephone number
- Gender
- Medical status

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. We will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed and stored data will be destroyed. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to sponsor@uhs.nhs.uk, or
- by ringing us on +44(0)23 8120 3598.

Thank you for taking the time to read the information sheet and considering taking part in the research.

CONSENT FORM

Study title: The Frail2Fit Study: Online Nutrition and Exercise Support for Older Adults with Frailty

Researcher name: Stephen Lim **REC Reference**: 22/WA/0155

Participant Identification Number:

Please initial the box(es) if you agree with the statement(s):

I have read and understood the information sheet version _____ dated _____ and have had the opportunity to ask questions about the study.	
I agree to take part in this research project and agree for my data to be used for the purpose of this study.	
I understand my participation is voluntary and I may withdraw (at any time) for any reason without my participation rights being affected.	

I understand that should I withdraw from the study then the information collected about me up to this point may still be used for the purposes of research only.	
I agree to take part in the interview for the purposes set out in the participation information sheet and understand that these will be recorded using video or audio recording.	
I understand that my confidentiality as a participant in this study will remain secure and that the transcript of the interview will not contain my name or identifiable information. I agree for my data to be stored anonymously and that any published quotations or extracts from the research will maintain my confidentiality.	
I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from University of Southampton study team, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
I understand that my personal information collected about me such as my name or where I live will not be shared beyond the study team.	
I agree that anonymised data collected in this study may be used for future research by the study team.	
I would like my clinical care team to be notified that I am participating in this research.	

Name of participant (print name) .....

Signature of participant ……

Date ……

Name of researcher (print name) ……

Signature of researcher ……

Date ……

.

[1 copy for the participant, 1 copy for the file]

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

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		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	6
Funding	#4	Sources and types of financial, material, and other support	19
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	19
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	15
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	15

Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	15
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	N/A – This is a feasibility study with a quasi-experimental design and no comparison groups
Objectives	#7	Specific objectives or hypotheses	6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	6

Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-12
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	10
Interventions: adherence	#11c	Strategies to improve adherence to intervention protocols, and any procedures	12-13

		for monitoring adherence (eg, drug tablet return; laboratory tests)	
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-14
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8 and see Figure 1.
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7

Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A – quasi-experimental design – feasibility study
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care	N/A

		providers, outcome assessors, data analysts), and how	
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-14
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12

Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further	N/A – feasibility study

		details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A – feasibility study
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	11-12
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	15
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	15
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant	15

		parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7 and see supplementary material
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	15
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	15
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A

Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	15
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	19
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	19
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary material
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

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BMJ Open

The Frail2Fit study protocol: A feasibility and acceptability study of a virtual multimodal intervention delivered by volunteers to improve functional outcomes in older adults with frailty after discharge from hospital

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-069533.R1
Article Type:	Protocol
Date Submitted by the Author:	15-Feb-2023
Complete List of Authors:	Meredith, Samantha; University of Southampton Faculty of Medicine, Academic Geriatric Medicine Roberts, Helen; University of Southampton Faculty of Medicine, Faculty of Medicine Grocott, Michael P. W.; University of Southampton, Jack, Sandy; University of Southampton Faculty of Medicine, Murphy, Jane; Bournemouth University, Humans Sciences & Public Health Varkonyi-Sepp, Judit; University Hospital Southampton NHS Foundation Trust, NIHR Southampton Biomedical Research Centre Bates, Andrew; University Hospital Southampton NHS Foundation Trust, NIHR Southampton Biomedical Research Centre Lim, Stephen; University of Southampton, Academic Geriatric Medicine
Primary Subject Heading:	Geriatric medicine
Secondary Subject Heading:	Health services research, Qualitative research, Rehabilitation medicine, Sports and exercise medicine
Keywords:	GERIATRIC MEDICINE, REHABILITATION MEDICINE, NUTRITION & DIETETICS, PUBLIC HEALTH, QUALITATIVE RESEARCH

The Frail2Fit study protocol: A feasibility and acceptability study of a virtual multimodal intervention delivered by volunteers to improve functional outcomes in older adults with frailty after discharge from hospital

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Keywords: older adult; frailty; nutrition; exercise; volunteer; behaviour change

Word count: 4242

ABSTRACT

Introduction

Physical activity (PA) and replete nutritional status are key to maintaining independence and improving frailty status among frail older adults. In response to the COVID-19 pandemic, healthcare has increasingly turned to virtual modes of delivery and there is interest in the use of trained volunteers to deliver PA and nutrition interventions. We aim to evaluate the feasibility and acceptability of training hospital volunteers to deliver an online intervention, comprising exercise, behaviour change and nutrition support, to older people with frailty after discharge from hospital.

Methods

We will use a quasi-experimental mixed methods approach. Hospital volunteers (n = 6) will be trained to deliver an online, 3-month, multi-modal intervention to frail (clinical Frailty Scale ≥ 5) adults ≥ 65 years (n = 30) after discharge from hospital. Feasibility will be assessed by determining the number of volunteers recruited, trained, and retained at the end of the study; the proportion of intervention sessions delivered; participant recruitment, retention, and adherence to the intervention. To determine the acceptability of the intervention, interviews will be conducted among a purposive sample of older adults, and volunteers. Secondary outcomes will include physical function, appetite, well-being, quality of life, anxiety and depression, self-efficacy for managing chronic disease, and PA. Outcomes will be measured at baseline, 3 months, and 6 months.

Analysis

Descriptive statistics will be used to describe feasibility and adherence to the intervention. Secondary outcomes at baseline will be compared at 3 and 6 months. Interviews will be transcribed verbatim and analysed using thematic analysis.

Ethics and dissemination

Health Research Authority (HRA) ethical approval was obtained on 30th May 2022 (reference: 22/WA/0155). Results will be disseminated through peer-reviewed journal articles, volunteer organisations, NHS communication systems and social media platforms. A toolkit will be developed to facilitate roll out of volunteer training.

Trial registration number: NCT05384730

Article summary

Strengths and limitations of this study

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- A strength of the study design is the mixed methods approach, allowing in-depth qualitative understanding of the implementation processes, and quantitative measures to reveal impacts on health outcomes.
- Lay volunteers will be upskilled using a bespoke training package, including development of healthy conversation skills, use of tools to facilitate nutrition support, and improving exercise knowledge and delivery.
- A limitation of the study is the exclusion of older adults who are unable to provide consent, and a small sample size, impacting representation and generalisability of findings.

INTRODUCTION

Older people with frailty are at high risk of poor outcomes including increased post-hospitalisation, healthcare use and mortality [1]. Frailty refers to a cumulative decline in biological reserves leading to poor resolution of homeostasis after a stressor event [2]. Approximately 11% of community dwelling older adults have frailty [3], compared to around 14% to 80% in hospitalised older adults [4-

7]. Differing cohorts of patients (e.g., age, ward type), and frailty measures (e.g., Edmonton Frail Scale, Cardiovascular Health Study Frailty Index) could explain the range of frailty prevalence reported in hospital. Typically, wards specialising in medicine for older people, and older patients (≥ 85 years) have higher incidence of frailty [4, 6]. As frailty progresses, older adults' functional status declines, resulting in disability, increased risk of falls, and long-term care [8]. Moreover, deconditioning during hospital admission is a major concern and impacts significantly on the ability for older adults to maintain independence [9, 10]. Considering these detrimental clinical consequences there is a need to identify ways to better manage and prevent decline in frailty to improve patient care [11].

Current evidence suggests that physical activity (PA) and nutrition interventions, underpinned with behaviour change support, are key to maintaining independence and improving frailty status among frail older adults [12-14]. Healthcare professionals advocate multi-modal and multi-disciplinary approaches to frailty management, such as consideration of the appropriate type, effectiveness, and feasibility of interventions to implement in practice, including online and volunteer-led approaches [15-19].

In response to the COVID-19 pandemic, healthcare, including frailty management, has increasingly turned to virtual modes of delivery, such as telehealth methods [20, 21]. Moreover, online communication tools have gained popularity among older people to remain socially connected, allowing PA and nutrition interventions to be delivered online [22]. Our research (the SafeFit trial) showed that exercise professionals could be trained to deliver an online intervention to maintain and improve physical, nutritional, and psychological well-being in people with cancer [23]. Telephone conversations, tele-monitoring devices, and internet-enabled tablets have also been shown as an effective means to deliver nutrition and PA interventions to community-dwelling older adults who were inactive or had malnutrition [24, 25]. Nevertheless, there is little evidence on the use of trained volunteers to lead such interventions. Subsequently, research is required to evaluate the feasibility of volunteer-led online interventions to support older adults with frailty to eat well and remain physically active.

A whole society approach involving multi-sectoral collaborations, such as volunteers, has been advocated to promote age-friendly communities and healthy ageing [26, 27]. Health practitioners are under increasing time pressures and typically have poor capacity to deliver extra support above and beyond routine services. Hence, volunteer-led interventions could promote organisational

benefits, diversifying the health and social care workforce, and reducing health care costs [27]. Moreover, volunteering provides direct benefits to volunteers' including enhanced wellbeing and reduced social isolation [27].

There is growing interest in the use of volunteer-led PA and nutrition interventions to support older adults' health and well-being [17-19]. A recent systematic review explored the impact of PA interventions conducted by trained volunteers on health-related outcomes for community-dwelling older people (≥65 years) [28]. Volunteers implemented strength and balance exercises 1-3 times per week, which led to improvements in functional status, frailty status, a reduction in fear of falls, and improved quality of life [28]. Nevertheless, the review concluded that more high quality randomised controlled trials (RCT) are needed to investigate the effects of volunteer-led PA interventions among older people. Similarly, more adequately powered research has been recommended to explore volunteer-led nutritional interventions in the community [17].

Existing research suggests that volunteer-led PA and nutrition interventions reduced frailty risk among community-dwelling older adults, and showed improvements in handgrip strength, quality of life, social participation, and physical function [18, 19, 26, 29, 30]. For example, an RCT found that volunteers trained to perform nutrition-related discussions and strength exercises with older adults, resulted in a 25% reduction in prevalence of impaired nutritional status, and improvement in frailty [19]. Nevertheless, more insight is needed on how best to recruit, train, and retain volunteers to deliver PA and nutrition support in the management of frailty, and to explore the barriers and facilitators to such interventions. For example, a previous volunteer-led intervention to improve PA in hospitalised older adults found social aspects and perceived health benefits as key facilitators, and a busy clinical environment and lack of awareness of the intervention among staff as key barriers to the intervention [18]. Moreover, the underpinning behaviour change elements of such interventions have been underreported and thus consideration of behavioural support is required in future home-based frailty interventions [14].

Behaviour change support for older people can improve adherence to lifestyle changes [31], impacting on factors that may influence, or predict behaviour, such as physical and social vulnerabilities associated with ageing, achieving social goals, and perceived confidence to engage in behaviours (i.e., self-efficacy) [32, 33]. In a recent systematic review, behavioural interventions that showed value for improving frail older adults' physical function were educational and enablement strategies, including instruction on how to perform a behaviour, and restructuring the physical

environment (e.g., modifications to reduce falls risk) [14]. Authors concluded that greater engagement with behavioural science is needed when developing and evaluating home-based health interventions for older adults experiencing frailty. Hence, the current Frail2Fit intervention will be underpinned by behaviour change strategies to increase participants' confidence and autonomy to engage with PA and nutrition support.

The knowledge gaps this study addresses are three-fold, including how to recruit, train, and retain volunteers through exploring the feasibility and acceptability of a volunteer-led online multimodal intervention; investigation of the facilitators and barriers to online volunteer-led implementation of the intervention; and inclusion of volunteer behavioural change training to underpin exercise and nutrition components with behaviour change support.

Aims

This study aims to explore the feasibility and acceptability of training lay hospital volunteers to deliver an online multi-modal intervention, including exercise, behaviour change and nutrition support, to older people with frailty discharged from hospital. Objectives of this study are to:

1. Develop a training programme for volunteers to support the delivery of an online multimodal intervention.
2. Assess the feasibility of recruiting, training, and retaining volunteers to deliver the intervention.
3. Assess the feasibility of recruiting and retaining older adults with frailty to the trial.
4. Determine the acceptability of the intervention and explore barriers and facilitators to the intervention to support future wider implementation.
5. Determine outcomes to use in a future RCT.

METHODS AND ANALYSIS

Study design and setting

The protocol was developed according to the SPIRIT reporting guidelines [34]. This feasibility study will use a quasi-experimental mixed methods approach and will be conducted at an NHS hospital

trust in the South of England. Hospital volunteers will be trained to deliver virtual group support for frail older adults discharged from acute medical wards. The study began recruitment November 2022.

Participant recruitment

Older adults on acute medical wards will be informed about the opportunity to participate in the study by ward staff. The clinical care team will identify eligible participants in line with inclusion and exclusion criteria (Box 1) through existing access to medical records.

Box 1. Inclusion and exclusion criteria

Inclusion criteria	**Exclusion criteria**
Older adults • Older adults aged ≥65 years • Able to provide written consent • Recently discharged, or soon to be discharged from hospital • Clinical Frailty Scale ≥5 • Able to walk at least a few steps upon hospital discharge	**Older adults** • Older adults who are not able to safely complete the exercises included in the intervention as advised by the patient's clinician • Patients who are discharged to rehabilitation units, or care homes • Patients receiving end of life care
Volunteers • Hospital volunteers aged ≥ 16 years • Completed generic hospital volunteer clearance checks, including criminal record check • Completed basic hospital volunteer training, such as health and safety • Able to provide written consent	**Volunteers** • Unable to safely complete the seated exercises • Unable to commit to completing Frail2Fit volunteer training (7 hours) • Unable to commit at least 2 hours to conducting the intervention per week for a minimum of 6 months

Participants interested in the study will be approached by the research team who will complete informed consent and a frailty screening check using the clinical frailty scale (CFS) [35]. Participants scoring ≥5 on CFS will be eligible to participate in the study. A sample size of 30 participants was chosen in line with previous sample size recommendations for feasibility studies [36, 37]. Thirty participants is considered a practical, ethical, and suitable sample size for feasibility studies, which are used to determine whether an intervention is appropriate for further evaluation, and to understand if interventions can be shaped to be relevant and sustainable [38, 39].

Volunteer recruitment

Volunteers will be identified by hospital voluntary services in line with inclusion and exclusion criteria (Box 1). Interested volunteers will be approached by the research team to discuss the study and complete informed consent (Supplementary Material 1). It is estimated that 6 volunteers will be needed to lead 3 groups of 5-10 participants. See figure 1 for an outline of study processes.

Intervention

The intervention duration will be 3 months. Participants will receive three group sessions per week for 1 month, twice per week for the second month, and once weekly for the last month. The tapered nature of the intervention was chosen to provide suitable support for older adults, with the aim to gradually encourage independence. The intervention will take place Monday, Wednesday, and Friday with a choice of morning and afternoon sessions, depending on participant preference. Volunteers will be assigned to days and times that fit their schedule and encouraged to commit to these times to maintain group consistency. Volunteers will deliver exercise, nutrition, and behaviour change support from a secure online platform (Zoom). Group sessions will last 40-60 minutes. The components of the intervention and the training package have been adapted from the SafeFit, SoMoVe, and ImPACt studies [18, 23, 40].

Exercise

Exercise will consist of volunteer-led group resistance training for 20-30 minutes using resistance bands. To align with home-based safety considerations, the exercises will be performed seated. The exercise programme was developed by a qualified NHS physiotherapist and utilised in a previous intervention among community dwelling older adults at social clubs [40]. Seated exercise will focus on strengthening 8 major muscle groups, tailored specifically to meet the needs of older adults and

to minimise the risks of injury (Supplementary Material 2). Participants will be encouraged by volunteers to progress repetitions, to gently improve range of motion, and increase the resistance grade of bands. Intensity will be monitored with the Resistance Intensity Scale for Exercise (RISE) [41] and the Talk Test [42], aiming for a low-moderate intensity. Participants will be encouraged to complete the exercises 2-3 times per week consistent with Chief Medical Office guidelines on PA and strength improvement for older adults [43]. Resources, including resistance bands, exercise booklets, and online exercise videos, will be given to participants before hospital discharge in preparation for the home-based intervention.

Nutrition support

Using the Nutrition Wheel, volunteers will initiate group discussion with participants to raise any nutrition-related concerns [44]. The Nutrition Wheel is an interactive tool developed from the Patients Association Nutrition Checklist and used to engage individuals in conversation about unintentional weight loss and malnutrition [44]. The Nutrition Wheel consists of 4 main questions, including 1) Are you or your family concerned that you may be underweight, or need nutritional advise? 2) Have you lost a lot of weight unintentionally in the past 3-6 months? 3) Have you noticed that your clothes or rings have become loose recently? 4) Have you recently lost your appetite and/or your interest in eating? Based on the participant's answers, they will be directed to further questions and guided to appropriate nutritional advice (e.g., information sheets, national helplines, or if necessary, signposted to their GP/practice nurse). Volunteers will be given suggested weekly nutrition topics based around the nutrition wheel to facilitate group discussions (Box 2). Importantly, volunteers will not advise the group, instead they will harness the resourcefulness of the group and encourage them to come up with their own solutions.

Box 2. Example of weekly nutrition topics
Snacking – adding calories and protein
Fluids and drinking
Food shopping
Cooking

Fruit and vegetables Cutting food and chewing

Behaviour change support

Volunteers will receive training in healthy conversation skills (HCS) guided by principles of Making Every Contact Count (MECC) [45, 46]. The MECC approach supports positive behaviour change through encouraging client-centred brief conversations surrounding health and well-being and will support the delivery of the exercise and nutrition components in the current intervention. Training will enable volunteers to have the confidence and competence to deliver healthy lifestyle messages, to help encourage participants to change their behaviour through solution-focused and empowering approaches [47]. Through using HCS in the current intervention volunteers can help to improve participants capability and motivation to be physically active and to eat well, empowering participants to take control of their health behaviours by building self-efficacy [48]. Behaviour change will be monitored by participant diaries, during the intervention phase.

Digital support

The online platform 'Zoom' will be used to deliver the intervention. In a recent scoping review, including 17 studies, online exercise programming among older adults was feasible and delivered through a variety of platforms, including Zoom and Facebook Live [49]. Adherence rates to the online programmes ranged from 43-90% [49]. Dagenais and colleagues highlighted the need to overcome barriers, such as poor access to technology, and fear of using online software. In the current study, to address digital inequality, internet-enabled tablets will be provided. Individuals with low confidence will be supported by the research team to access the teleconferencing platform. They will be given digital support leaflets and guidance about how to stay safe online. Digital support will be available to participants throughout the study.

Safety during sessions

At the beginning of each session volunteers will complete a pre-session screening checklist to ensure participants are safe to exercise (e.g., safe set-up of a home exercise space; feeling well; no new or worsening symptoms). Volunteers will be given training to encourage participants to exercise at their own pace, to rest when they need to, and to move within a pain-free range of motion, ensuring

that participants are working at a tailored intensity. Where possible participants will be encouraged to undertake the sessions with friends or family members at home and they will be asked to keep cameras on during the sessions. Groups will be limited to a maximum of 10 participants.

Volunteers will conduct the online intervention from hospital. If an emergency occurs, such as an acute medical event, volunteers will immediately alert hospital volunteer support. If concerned about collapse, hospital staff will call 999. Staff will have a list of participant's addresses and GPs on file. An 'escalation plan' giving clear steps to follow, depending on the emergency situation, will be given to volunteers and staff. Cases of health concern will be raised with the chief investigator and a decision will be made regarding continuation in the trial based on clinician advice.

Volunteer training programme

Volunteers will receive a bespoke training package adapted from the SafeFit trial [23]. Exercise and nutrition training will be delivered by the research team in-person, and behaviour change support training will be delivered online. Once the 3 training components have been completed, a member of the research team will shadow the volunteers during the first month of intervention delivery. After 4 weeks, volunteers will aim to lead the sessions independently with continued support (including regular supervision meetings) by the trainers.

Exercise

The exercise training programme was developed based on clinical expertise and recently completed research of volunteer-led exercise in hospital and the community [18, 40]. Training will include an in-person group session lasting 2 ½ hours, comprising theory underpinning the benefits of exercise for older adults, exercise training principles, seated exercise delivery, and safety considerations. Volunteers will practice delivering exercise to peers and will be given a training manual and links to training videos developed from previous research [18, 40] and adapted for this specific trial. The lead trainer (SM) is a research fellow and clinical exercise instructor with experience delivering exercise to a range of population groups, including older adults.

Nutrition support

Volunteers will be trained to use the Nutrition Wheel by SM, supported by JM, during a 2 ½ hour session with accompanying support materials. The training will cover principles of healthy eating, information on undernutrition (e.g., prevalence, risk factors, identification, and treatment), details

on the Nutrition Wheel, and practicing how to facilitate a Healthy Conversation based on the Nutrition Wheel in a group context. Links to trusted nutrition resources will be provided to volunteers for group signposting and they will be given suggested weekly nutrition topics (Box 2) with supporting questions to facilitate group discussions.

Behaviour change support

The training, which is based on Healthy Conversation Skills (HCS), will be delivered by a health psychologist (JV-S). HCS training develops four key competencies: 1) asking open discovery questions ('how' and 'what' questions), 2) listening instead of making suggestions or giving advice, 3) reflecting on practice, and 4) setting goals using SMARTER (specific, measurable, action-oriented, realistic, timed, evaluated, reviewed) planning [50]. The training will be 3 hours of online interactive learning to support volunteers to deliver exercise and nutrition components in an empowering, person-centred, solution-focused way, translating MECC principles into practice.

Volunteer support

Throughout the study a peer-supported community will be established through online monthly volunteer meetings. The research team will work closely to support volunteers, including listening and providing any emotional support on a group and individual basis. Volunteer feedback will be integral to shaping the support that volunteers will need in delivering the intervention and ensuring volunteer well-being. In addition, trainers will conduct monthly fidelity checks to assess the quality of group sessions delivered by volunteers. The volunteers will be observed and assessed against a competency framework, including checks for exercise, nutrition, and behaviour change components. Based upon fidelity checks and volunteer feedback, extra one-to-one training sessions, emotional and confidence support, will be available if necessary. Volunteers will be asked to keep an attendance record during the intervention using session completion logs and will be trained to report any adverse events.

Outcome measures

Participant characteristics including age, gender, body mass index, malnutrition status (Malnutrition Universal Screening Tool), cognition (Mini-Mental State Examination) [51] and number of medications will be recorded. Volunteer characteristics recorded will include age, occupation, qualifications, volunteering experience, and employment status.

Primary outcomes

The primary outcome measures are feasibility and acceptability of the intervention. Feasibility will be assessed by determining the number of volunteers recruited, trained and retained at the end of the study, the proportion of intervention sessions delivered, and fidelity of volunteer delivery. Moreover, participant recruitment, retention and adherence to the intervention will be measured, as well as any adverse events. To determine the acceptability of the intervention and to explore barriers and enablers to the implementation of the intervention, interviews will be conducted among older adults (N= 6), volunteers (N= 6), and those involved in recruiting participants (N= 3). Interviews will be conducted via telephone and will be audio-recorded for data collection purposes.

The interviews will be semi-structured, consisting of key open-ended questions to explore the views of older adults, volunteers and trainers on the multi-component sessions, the barriers and facilitators to the intervention and suggestions for future implementation studies. The interview schedules will be underpinned by Normalisation Process Theory (NPT). NPT is an implementation theory providing a framework to identify and explain important elements of the implementation process, thereby understanding the social processes through which new or modified practice is implemented, embedded, and integrated into healthcare settings [52].

Secondary outcomes

The secondary outcomes will include the measurement of PA, physical function, appetite, well-being, quality of life, anxiety and depression, and self-efficacy for managing chronic disease, measured at baseline (in hospital), 3 months (via telephone) and 6 months (via telephone).

PA will be measured using the physical activity scale for the elderly (PASE) [53] and using wrist-worn accelerometers (GENEActiv, Activinsights, Kimbolton, Cambridge, UK). The PASE measures leisure-time, household, and occupational PA across 7 days, and has good stability and convergent validity within community-dwelling older adults [54]. The GENEActiv accelerometers will measure triaxial movement acceleration in gravity (g) units (1 g = 9.81 m/s^2) at a frequency of 100Hz continuously over a period of 7 days. Previously validated acceleration threshold values (in older adults) will be used to quantify the time (minutes/day) spent on average in each intensity category: total PA, and separately for light, moderate, vigorous intensities and the composite category moderate-vigorous PA (MVPA) [55]. GENEActiv watches will be posted to participants at baseline, 3 and 6 months and returned with a pre-paid return envelope.

The Barthel Index will measure older adult's functional ability across 10 items, with a higher number being a reflection of greater ability to function independently following hospital discharge [56]. The Barthel Index has reasonable reliability and good responsiveness [57].

Appetite will be measured using the Simplified Nutritional Appetite Questionnaire (SNAQ) [58], which has been validated to predict weight loss in community dwelling older adults and used to predict poor health outcomes in hospitalised older people [58-60]. SNAQ is a four-item tool assessing appetite, satiety, taste of food and number of meals per day with a score of ≤14 indicating poor appetite.

Well-being will be assessed using the Warwick-Edinburgh Well-Being Scale (WEMWBS), which comprises 14 items relating to positive affect, satisfying interpersonal relationships and positive functioning [61]. The WEMWBS is a psychometrically robust scale showing good content validity and popularity in the measurement of well-being in relation to public health [61, 62].

The Hospital Anxiety and Depression Scale (HADS) will be used to assess anxiety and depression symptoms [63] and has been validated across multiple settings and populations [64]. Depression and anxiety symptoms are measured on sub-scales where a score of 0-7 is normal, 8-10 borderline abnormal, and 11-21 abnormal.

Quality of life will be measured using the EuroQol (EQ-5D-5L) assessment comprising a short descriptive questionnaire and a visual analogue scale (VAS) [65]. The EQ-5D-5L has been widely used in clinical trials and population studies as a popular measure of health status [66].

The 6-item Lorig scale will be used to assess participant's self-efficacy in managing their chronic disease [67]. The scale contains items developed from the chronic disease self-management study covering domains, such as symptom control, role function, emotional functioning and communicating with health professionals [67]. Each item is scored on a 10-point Likert scale with higher scores indicating higher self-efficacy.

Data analysis

Quantitative data analysis

Data will be entered into a secured database for analysis. Statistical analysis will be conducted using the statistical software SPSS (v28.0.1.1). Descriptive statistics -median (Interquartile Range [IQR]); mean (standard deviation [SD]); number (%) – will be used to analyse the numbers of volunteers

recruited, trained, and retained, as well as patients' adherence to the intervention to assess the feasibility of delivering this intervention. To determine suitability for a future RCT, inferential statistics will be used. Outcome measures recorded at baseline will be compared to measurement at 3 and 6 months to determine if the intervention had an impact on PA measured by PASE and GENEActiv, functional outcomes including functional ability (Barthel), appetite (SNAQ), symptoms of anxiety and/or depression (HADS), wellbeing (WENWBS), self-efficacy (Lorig) and quality of life (EQ-5D-5L). The distribution of each outcome measure will be assessed for normality and described using parametric or non-parametric statistics accordingly. A basic cost-analysis of the training programme will be carried out, costing the time involved in delivering the training.

Qualitative data analysis

Data collected from the interviews will be transcribed verbatim and analysed using thematic analysis (TA). TA is a method for identifying, analysing and reporting patterns or themes within data [68]. There are six phases in the TA process: Phase 1 – familiarising with the data, Phase 2 – generating initial codes, Phase 3 – searching for themes, Phase 4 – reviewing themes, Phase 5 – defining and naming themes, and Phase 6 – producing the report. Analysis of qualitative data will be conducted using Microsoft Word, or NVIVO software (v12), depending on the amount of data collected. SM will analyse codes to generate concepts and ideas to determine the acceptability of the intervention, and to identify facilitators and barriers to the implementation process. From the codes, themes will be developed to reflect the views and experiences of participants and volunteers regarding the online multimodal intervention. SL will code 25% of interviews separately to develop, discuss, and agree on themes with SM through an iterative process.

PATIENT AND PUBLIC INVOLVEMENT

This intervention was developed in line with our previous research [18, 40], which highlighted that volunteer-led PA interventions in hospital and the community were safe, and well received by older adults. In the development of our programme of research older adults in the community and care homes (n = 92) completed a survey, illustrating 45% had experience working with volunteers and appreciated their contribution. A further survey conducted in community social clubs showed that 47 out of 50 older adults agreed or strongly agreed to have trained volunteers lead exercises. A PPI representative led by the PPI lead for the Ageing and Dementia theme within the Wessex Applied

Research Collaboration (ARC) is a part of the study management group. As such they provided input into this study proposal, reviewed patient facing materials, and ensured that the processes of the study such as data collection, and interviews, were not too burdensome for participants. They will continue to be involved in the study steering group throughout the research and will be consulted regarding dissemination of research findings.

ETHICS AND DISSEMINATION

Health Research Authority (HRA) ethical approval was obtained on 30th May 2022 (22/WA/0155). The NHS sponsor for this trial will monitor and audit the study in line with their policies and procedures. Any protocol changes will be approved by HRA before implementation. The study steering committee will have oversight of study processes and research personnel have been trained in Good Clinical Practice. Data will be stored on a password protected University database and handled in line with the Data Protection Act 2018 to maintain confidentiality. Access to data will be granted to relevant members of the research team and authorised representatives from the Sponsor for monitoring and/or audit purposes. Results from this study will be disseminated through peer-reviewed journal articles, scientific conferences, volunteer organisations, NHS communication systems and social media. Findings will be translated into a toolkit to support knowledge transfer including advice on volunteer recruitment, training, and suggestions for successful implementation in future trials and wider roll out of the intervention.

Author contributors

SM drafted the manuscript. All authors, SM, HR, MG, SJ, JM, JV-S, AB, and SL were involved in the conception and trial design and provided critical intellectual content. SL is the chief investigator responsible for the overall conduct and management of the study. JM provided nutrition and dietetic expertise, contributing to the design of nutritional components. JV-S provided expertise in Healthy Conversation Skills Training, contributing to the design of the behaviour change components of the intervention. SM will lead the volunteer training and be involved in data collection, and analysis. All authors contributed to the preparation of this article.

Funding statement

The University Hospital Southampton Foundation Trust Small Grants Scheme funded this research (Reference number: GNT0525).

Competing interests

The authors have no competing interests to declare.

Patient consent for publication

Not required

License statement

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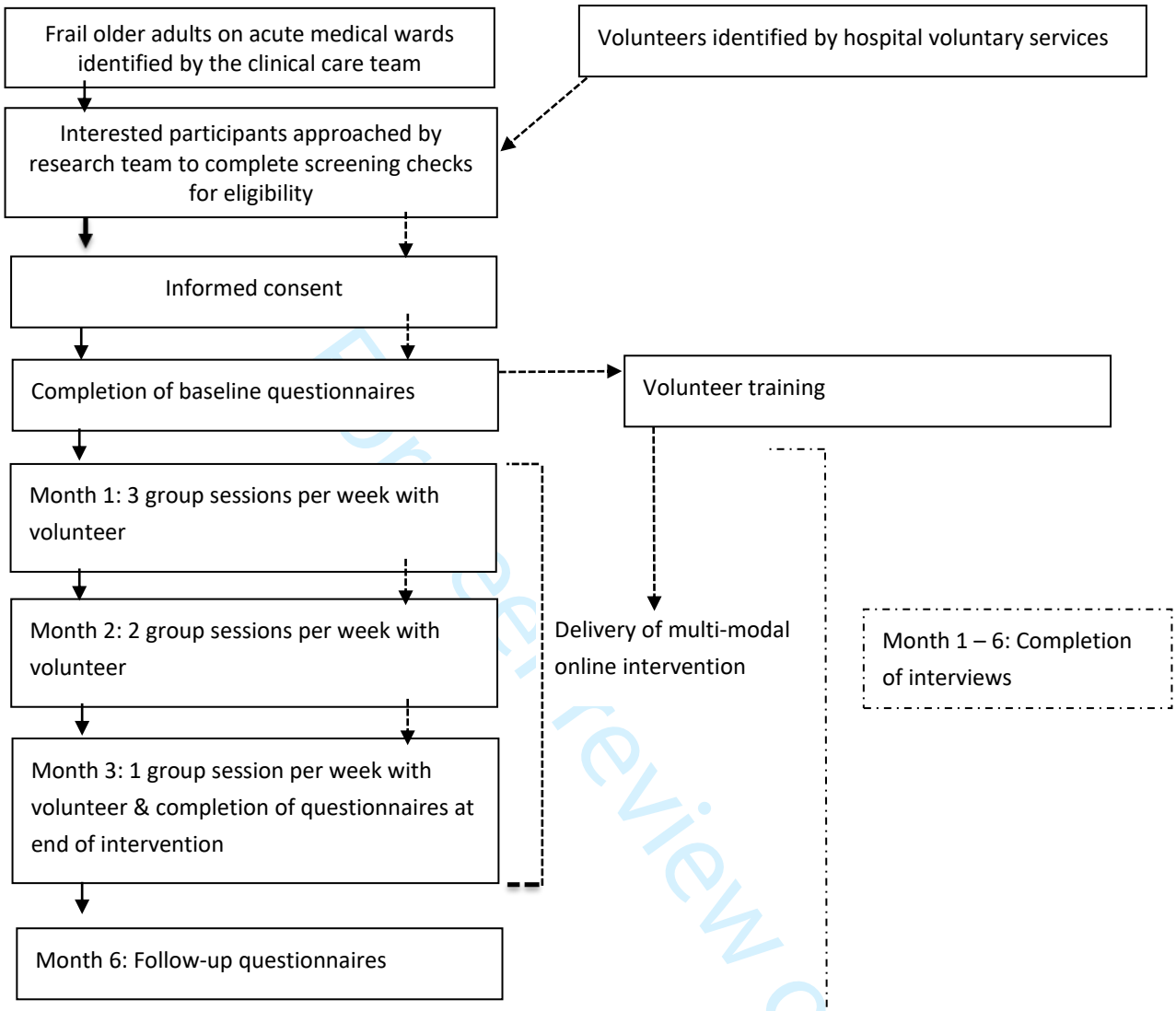


Figure 1. Study flow chart.

Version 0.1 5th September 2022

University of Southampton

Participant Information Sheet (Patient)

Study Title: The Frail2Fit Study: Online Nutrition and Exercise Support for Older Adults with Frailty

Researcher: Dr Stephen Lim

This project has been reviewed by the Wales REC 7 Research Ethics Committee. REC Reference: 22/WA/0155

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

I am a doctor specialising in the Care of Older People with an interest in improving the health of older people. This study aims to see if we can train volunteers to encourage older adults to exercise in a group and to provide them with nutrition support after being discharged from hospital. We also want to know if this is acceptable to them, and their family members. We will see if the exercise and nutrition support have an impact on the health of those taking part. This study is funded by the University Hospital Southampton Research and Development grants scheme and has been submitted to the NHS Health Research Authority research ethics committee for approval.

Why have I been asked to participate?

You have been asked to take part in this study because you are due to be discharged from the University Hospital Southampton NHS Foundation Trust and you meet the eligibility criteria for this study. The inclusion criteria for this study are: anyone older than age 65, identified as frail,

who can participate safely in the exercise programme, are able to walk at least a few steps upon hospital discharge, and are able to give consent.

What will happen to me if I take part?

Online exercise and nutrition support

When you get home, you will be encouraged by volunteers to join in online home-based seated exercise and group nutrition support for twelve weeks. The volunteers delivering the programme have been trained by health professionals. In the first month you will be offered the opportunity to participate in 3 online sessions per week. Over time the number of sessions per week will reduce as you become more independent and learn how to complete the exercises.

The exercises are done seated. They are simple to complete and are designed to maintain or improve your muscle strength. It is important that you move to where you feel comfortable and at your own pace. As you get a bit fitter the volunteers can offer you a resistance band. This is a long elastic band to get your muscles safely working a bit harder. The exercise is done online in a group with your peers.

The nutrition support will involve friendly group discussion about diet and eating. The volunteers are not dieticians but they will be able to offer you direction to information that could help with eating well and feeling good.

If you struggle to access the support online, we have an iPad (computer) you can borrow. We can also show you how to use the iPad and how to access the online sessions. Our research staff will be here to help you throughout the programme. If you do not feel comfortable using the online support then you can opt for telephone support instead.

Evaluating the programme

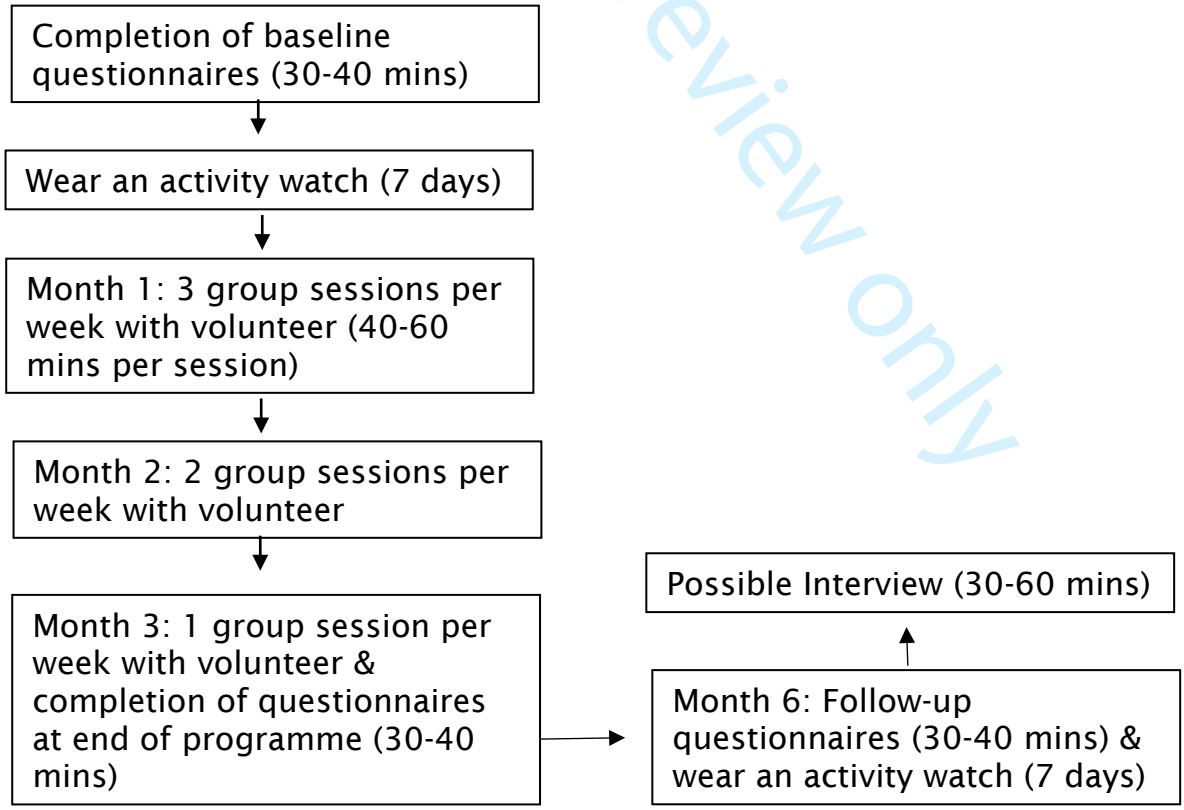
To find out if the online support works, we would like to learn about your health and well-being. We might also ask you some questions about your experiences participating in the programme.

Before you leave hospital a research assistant, who is a healthcare professional, will collect some basic information about you. This will include measurements of your physical health, eating habits and activity levels with questionnaires. You will also be given an activity watch

(accelerometer) to wear for 7 days when you get home. This watch will accurately measure your activity levels. After three months and six months, we will contact you again to repeat the measurements to determine the impact of the exercise and nutrition support on your health. The repeat data collection process will be done at your own home over the telephone and activity watches will be posted to you with a return pre-paid envelope.

You may be invited to attend an interview to share your views and experiences on the exercise and nutrition support programme. Interviews will take place over the phone, or online (e.g., Zoom) depending on your preference. Interviews will be audio-recorded. If you do participate in an interview your details will be anonymised (non-identifiable participant information), which means that no one outside the research team will know your name. People will read about the things you say to us, but they will not know who said those things.

Timeline



Are there any benefits in my taking part?

Studies have shown that exercise training and nutrition support are beneficial in improving physical function of older people. One of the benefits of taking part in this study is that you will be taught evidence-based exercises and nutrition advice which will be conducted in group online sessions. Exercising in an online group can also be a positive experience as the social aspect of group exercises has been shown to be a source of motivation.

By taking part in this study, you will also be contributing to further research to improve the health of older people.

Are there any risks involved?

The risks involved in this study are minimal. Common injuries that may occur during exercises include muscle strain and back pain. To reduce the chances of any injuries you will be encouraged to exercise at your own pace to a level you feel comfortable with. The exercises are gentle seated movements and will be shown to you by friendly volunteers who have been trained by health professionals.

Less commonly, is the risk of falls. However, the exercise programme is likely to help promote improvement in balance and muscle strength, which may help reduce the risk of falling. This study does not involve any invasive procedure.

What will happen in case of an emergency?

The volunteers will be taught how to deliver the support sessions safely. However, in the unlikely event that you require immediate medical attention (e.g., collapse) the volunteer will contact the emergency services. If you experience an adverse event (e.g., a muscle strain) then the volunteer will let us know (the study team) and we will get in contact with you to escalate the situation further, if required. Feel free to contact us if you have any worries or concerns during the programme.

What data will be collected?

We will collect basic information such as your gender, date of birth, age, physical function status, and cognitive status. Using validated questionnaires, we will measure your physical activity levels, eating habits and well-being. These questionnaires will take approximately 30-40 minutes to complete with assistance from one of the research team. We will also measure your activity levels using an activity watch (accelerometer). These measures are important as it will help determine if the exercise and nutrition programme had a positive impact on your health. You may be invited to an interview to explore your views and experiences about the exercise and nutrition programme. Interviews will be recorded using a digital audio-recorder.

Your contact details will be recorded to allow the research team to contact you at 3 and 6 months to re-do questionnaires. Your address will be recorded in case of an emergency during the exercise session. This will enable volunteers to notify the emergency services of where you are if needed.

Your information will be anonymised (made non-identifiable) during the data analysis process and published data will not include any identifiable participant information.

Will my clinical care team know if I want to participate in the study?

If you decide to volunteer for the study, we will send a letter to your clinical care team to let them know that you are participating in the research if you consent to this in the consent form.

Will the online sessions continue when the study has finished?

The online support sessions will last 12 weeks during the study. There will be no further online support sessions when the study has finished. However, you will be given resources, including booklets and access to online videos to continue with your exercise and nutrition changes at home in your own time.

Will my participation be confidential?

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

Data collected will be entered electronically on the computer and stored on the university's networked storage. Access to this information will be password-protected. Hard copies of participant information will be stored in a locked filing cabinet in a secure office in our research unit and will be accessible only by the research team. Audio recordings for the interviews will be deleted once they have been transcribed. Codes are allocated to each participant to ensure that the data is anonymised. Only the researchers in this study will have access to your data.

In accordance with the regulations we are required to keep your data secure for 10 years.

Your data may be used in future studies by our research team. If this happens, your data will be used anonymously (non-identifiable participant information) so you cannot be identified. Any new research studies using your data will be authorised by the local research ethics committee.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

Please inform me if you wish to take part in this study and I will be in touch with you to provide you with more information and go through the consent process.

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected. Please inform the volunteer leading the sessions or me if you wish to withdraw from the study.

If you do not wish to carry on with this study, you can withdraw at any time without giving a reason. If you decide to withdraw we would like to retain the use of anonymised (non-identifiable participant information) routine data and any data already collected which would be important for the overall study results.

What happens if I have given consent but then lose capacity to consent during the study?

You and all your identifiable data collected during the study would be withdrawn from the study. Data which is not identifiable to the research team may be retained.

What will happen to the results of the research?

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent. The results of the research will be published in scientific journals. Research staff may also present the results at conferences and local meetings, and on a website where it would be available to members of the public. You will not be identified in any report produced.

If you are interested, when we have finished analysing the study data, the research team will phone you to share the results. We will also place the study findings on a website (https://www.arc-wx.nihr.ac.uk/) and point you to any open access research publications. If you are interested but do not have access to the internet we can post the results upon request.

Where can I get more information?

For further information, please contact me (**Dr Stephen Lim)** at s.e.lim@soton.ac.uk, or by telephone 023 8120 6131.

Or you can contact the research assistant Dr Samantha Meredith at s.j.meredith@soton.ac.uk, or by telephone 078 2510 4783.

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

NHS Indemnity Insurance

The University Hospital Southampton NHS Foundation Trust will act as sponsor for this research study and will provide insurance for the study through the NHS indemnity scheme. The insurance will meet the potential legal liability of the sponsor for harm to participants arising from the design of the research and the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research. Moreover, volunteers will be insured by The Liabilities to Third Parties Scheme (LTPS) through NHS Resolutions. This will provide volunteers with employer's liability, public liability, products liability, and professional indemnity cover.

How will we use information about you?

We will need to use information from you for this research project. This information will include your:

- Name
- Age
- Address
- Telephone number
- Gender
- Medical status

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. We will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed and stored data will be destroyed. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to sponsor@uhs.nhs.uk, or

by ringing us on +44(0)23 8120 3598.

Thank you for taking the time to read the information sheet and considering taking part in the research.

University of Southampton

Participant Information Sheet (Volunteers)

Study Title: The Frail2Fit Study: Online Nutrition and Exercise Support for Older Adults with Frailty

Researcher: Dr Stephen Lim

This project has been reviewed by the Wales REC 7 Research Ethics Committee. REC Reference: 22/WA/0155

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

I am a doctor specialising in the Care of Older People with an interest in improving the health of older people. This study aims to see if we can train volunteers to encourage older adults to exercise in a group and to provide them with nutrition support after being discharged from hospital. We also want to know if this is acceptable to them, and their family members. We will see if the exercise and nutrition support have an impact on the health of those taking part. This study is funded by the University Hospital Southampton Research and Development grants scheme and has been submitted to the NHS Health Research Authority research ethics committee for approval.

Why have I been asked to participate?

You have been asked to take part in this study because you are a patient support hub volunteer at University Hospital Southampton NHS Foundation Trust.

What will happen to me if I take part?

You will be trained to deliver online group exercises and nutrition support for older people with frailty. Below we will outline your training and the online programme.

Volunteer Training

The training will be a combination of in-person and online content led by various health professionals specialising in nutrition and exercise for older adults. You will also be given additional resources to support your training including booklets and online videos. Training will take place for half a day in-person at University Hospital Southampton and 3 hours of online training. Also, we are available for any additional one-to-one training sessions that you would like.

The training will be split into 3 main sections:

1) Exercise Training: We will teach you how to safely deliver seated exercises to older adults online, including use of elastic resistance bands (2 hours).
2) Nutrition Training: We will teach you how to engage older adults in conversations about their nutrition and where to signpost older adults for more information about healthy eating (2 hours).
3) Behaviour Change Training: You will be invited to an online course in 'healthy conversation skills' to help you empower older adults to improve their exercise and nutrition (3 hours).

Online Programme for Older Adults with Frailty

The supportive online sessions that you will be delivering to the older adults will last approximately 45-60 minutes and will include 20-30 minutes of exercise and 15-25 minutes of nutrition support. You will also be taught how to motivate lifestyle changes and how to make sure the exercise and nutrition support are safe and enjoyable.

We would like you to deliver the support sessions for 12 weeks to a small group of older adults.

- In the first month (week 1-4) you will deliver 3 sessions per week.
- In the second month (week 5-8) you will deliver 2 sessions per week.

- And in the last month (week 9-12) you will deliver 1 session per week.

You will be teamed up with another volunteer, so you can support each other in the delivery of the sessions. Also, the trainer will support you throughout the project and will organise regular group volunteer meetings to discuss any concerns or feedback.

You may also be invited to attend an interview to share your views and experiences on delivering the online programme. Your details will be anonymised, which means that no one outside the research team will know your name. People will read about the things you say to us, but they will not know who said those things.

Are there any benefits in my taking part?

Studies have shown that resistance exercise training and nutrition support are beneficial in improving physical function. One of the benefits of taking part in this study is that you will be taught evidence-based exercises and dietary advice which will be conducted in group sessions. By doing the exercises yourself, you are also likely to benefit from it. Exercising in a group can also be a positive experience as the social aspect of group exercises has been shown to be a source of motivation. By taking part in this study, you will also be contributing to further research to improve the health of older people.

Are there any risks involved?

The risks involved in this study are minimal. Common injuries that may occur during exercises include muscle strain and back pain. Less commonly, is the risk of falls. However, the exercise programme is likely to help promote improvement in balance and muscle strength, which may help reduce the risk of falling. This study does not involve any invasive procedure.

What will happen in case of an emergency?

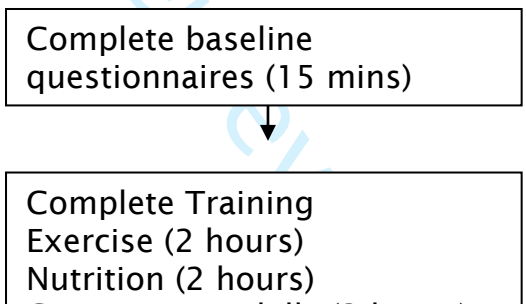
You will be taught how to deliver the support sessions safely. However, in the unlikely event that a participant in your group requires immediate medical attention (e.g., collapse) you will need to call for help (staff will be available in the Patient Support Hub), or contact the emergency services. If a participant experiences an adverse event (e.g.,

a muscle strain) then you will need to let us know (the study team) and we will get in contact with them to escalate the situation further, if required.

What data will be collected?

We will be collecting basic information such as your gender, age and ethnicity. You may be interviewed to explore your views and experiences about the exercise programme. Interviews will take place on the telephone, or online (e.g., Zoom) depending on your personal preference. Interviews will be recorded using a digital audio-recorder. Participant information will be anonymised (non-identifiable participant information) during the data analysis process and published data will not include any identifiable participant information.

Timeline



Will the online sessions continue when the study has finished?

The online support sessions will last 12 weeks during the study. There will be no further online support sessions when the study has finished. However, participants will be given resources, including booklets and access to online videos to continue their exercise and nutrition changes at home in their own time.

Will my participation be confidential?

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

Data collected will be entered electronically on the computer and stored on the university's networked storage. Access to this information will be password-protected. Hard copies of participant information will be stored in a locked filing cabinet in a secure office in our research unit and will be accessible only by the research team. Audio recordings for the interviews will be deleted once they have been transcribed. Codes are allocated to each participant to ensure that the data is anonymised. Only the researchers in this study will have access to your data.

In accordance with the regulations we are required to keep your data secure for 10 years.

Your data may be used in future studies by our research team. If this happens, your data will be used anonymously (non-identifiable participant information) so you cannot be identified. Any new research studies using your data will be authorised by the local research ethics committee.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

Please inform the researcher if you wish to take part and the research team will be in touch with you to provide you with more information and go through the consent process.

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected. Please inform the researcher if you wish to withdraw from the study.

If you do not wish to carry on with this study, you can withdraw at any time without giving a reason. If you decide to withdraw we would like to retain the use of anonymised (non-identifiable participant information) routine data and any data already collected which would be important for the overall study results.

What happens if I have given consent but then lose capacity to consent during the study?

You and all your identifiable data collected during the study would be withdrawn from the study. Data which is not identifiable to the research team may be retained.

What will happen to the results of the research?

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent. The results of the research will be published in scientific journals. Research staff may also present the results at conferences and local meetings, and on a website where it would be available to members of the public. You will not be identified in any report produced.

If you are interested, when we have finished analysing the study data, the research team will phone you to share the results. We will also place the study findings on a website (https://www.arc-wx.nihr.ac.uk/) and point you to any open access research publications. If you are interested but do not have access to the internet we can post the results upon request.

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Or you can contact the research assistant Dr Samantha Meredith at s.j.meredith@soton.ac.uk, or by telephone 078 2510 4783.

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NHS Indemnity Insurance

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How will we use information about you?

We will need to use information from you for this research project.

This information will include your:

- Name
- Age
- Address
- Telephone number
- Gender
- Medical status

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. We will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed and stored data will be destroyed. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to sponsor@uhs.nhs.uk, or
- by ringing us on +44(0)23 8120 3598.

Thank you for taking the time to read the information sheet and considering taking part in the research.

University of Southampton

CONSENT FORM

Study title: The Frail2Fit Study: Online Nutrition and Exercise Support for Older Adults with Frailty

Researcher name: Stephen Lim **REC Reference:** 22/WA/0155

Participant Identification Number:

Please initial the box(es) if you agree with the statement(s):

I have read and understood the information sheet version _____ dated _____ and have had the opportunity to ask questions about the study.	
I agree to take part in this research project and agree for my data to be used for the purpose of this study.	
I understand my participation is voluntary and I may withdraw (at any time) for any reason without my participation rights being affected.	
I understand that should I withdraw from the study then the information collected about me up to this point may still be used for the purposes of research only.	
I agree to take part in the interview for the purposes set out in the participation information sheet and understand that these will be recorded using video or audio recording.	
I understand that my confidentiality as a participant in this study will remain secure and that the transcript of the interview will not contain my name or identifiable information. I agree for my data to be stored anonymously and that any published quotations or extracts from the research will maintain my confidentiality.	
I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from University of Southampton study team, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	

I understand that my personal information collected about me such as my name or where I live will not be shared beyond the study team.	
I agree that anonymised data collected in this study may be used for future research by the study team.	
I would like my clinical care team to be notified that I am participating in this research.	

Name of participant (print name) .....

Signature of participant .....

Date .....

Name of researcher (print name) .....

Signature of researcher .....

Date .....

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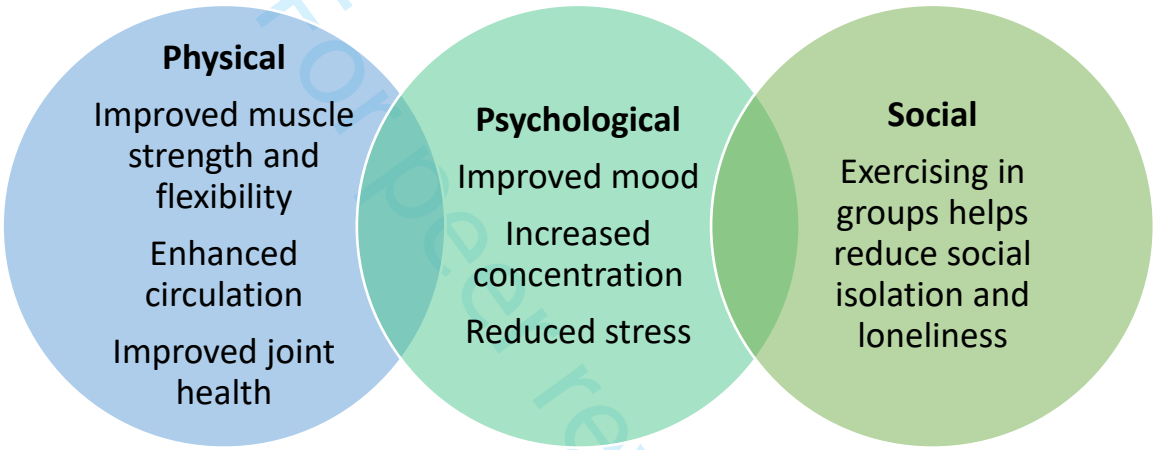
[1 copy for the participant, 1 copy for the file]

5. Exercise Training

5.1 Background and theory

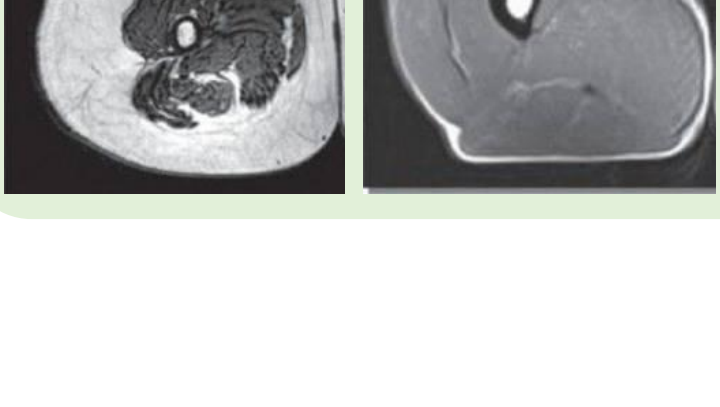
Benefits

Regular physical activity can help improve the way your body functions, and the way you feel. The diagrams below show some examples of physical, psychological (mental), and social benefits from moving.



Exercise is also a key strategy in the management of frailty and can help promote independence in your activities of daily living, such as bathing, dressing, and mobilising.

Even when we reach our 60s, 70s, 80s and 90s we can still gain these benefits from physical activity.



This is an MRI scan showing a cross section of the upper leg from an inactive 70 year old male (left) and an active 70 year old male (right). Can you notice the differences between the amount of muscle, bone and fat (adipose tissue) in each picture?

The FITT Principle

A good way to start designing an exercise programme is to consider the acronym **F I T T**

Frequency How often do you exercise per week?

Intensity How much effort should you put in e.g., light, moderate, or vigorous?

Time How long should we exercise for?

Type What type of exercise should we do e.g., cardiovascular, balance, strength?

For instance, government guidelines suggest we complete 30 minutes of cardiovascular exercise (e.g., walking, cycling, dancing) to get us breathing a bit harder (moderate intensity) 5 times per week. For most people this might be a daunting task. That is why the next concept is important when we are thinking about physical activity to improve health; individualisation.

Individualisation

We need to tailor our movements and the FITT principle to **suit our own needs.** Beginning with 10 minutes of light activity every other day is a great start. **It is all about you**. Starting off at a comfortable volume of activity that is both **enjoyable** and beneficial is key.

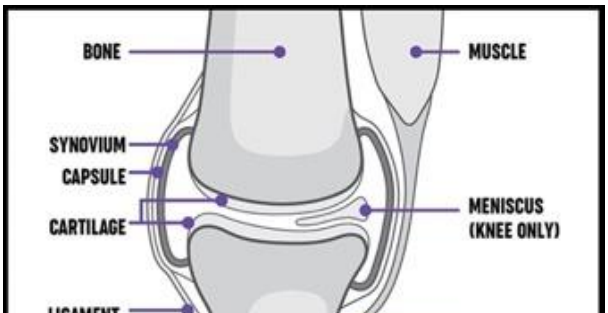
5.2. Exercise Content

We can now apply the FITT principle to the exercise programme you will be doing as a part of the Frail2Fit project.

The Frail2Fit programme focuses on improving your **strength** with evidence based seated exercises. Strength is the amount of force your muscles can exert, or their ability to overcome resistance, such as picking up a shopping bag, or digging in the garden.

Frequency: 1-3 classes per week
Intensity: Light – Moderate
Time: 20 - 30 minutes
Type: Strength

There are 14 seated exercises that focus on mobilising and strengthening your main muscle groups. The exercise class is split into a warm up, the main strengthening component and a cool down.



Why do we need to warm up?

A low intensity warm up gradually increases the body's temperature, heart rate and blood flow, which helps prevent muscles from straining. Warming up also helps to lubricate the joints through the release of synovial fluid. This is like the joints natural oil.

Why do we need to cool down?

The cool down is done at the end of the class to gradually return the heart rate to within resting levels. The cool down is also a good opportunity to stretch out the shortened muscles while the muscles are warm from exercise. Stretching can help to improve flexibility.

Resistance Band Exercise

Resistance bands are large elastic bands that can help to strengthen different areas of your body. They are easy to use and can be added into your weekly exercise to help challenge your muscles safely. There are different band tensions available to suit you:

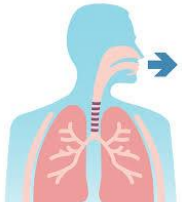
Easy Beginner Intermediate Advanced

Muscle-strengthening exercise, such as using resistance bands, will make your muscles feel warmer and you may feel you get a 'wobble', or 'shake' during the activity. It is normal for your muscles to feel a little achy the next day; the muscles will feel like they have been used. If the exercises are too difficult using a band, then you can complete them without.

Seated Exercise Diagrams

Warm Up

1. Deep Relaxing Breaths



Take 3 deep breaths in and out to help invigorate and energise your body.

2. Heel Lifts & Toe Lifts

Lift both heels off the floor.
Now lift both toes off the floor.
Alternate between heel and toe lifts 10 times.

3. Shoulder Rolls

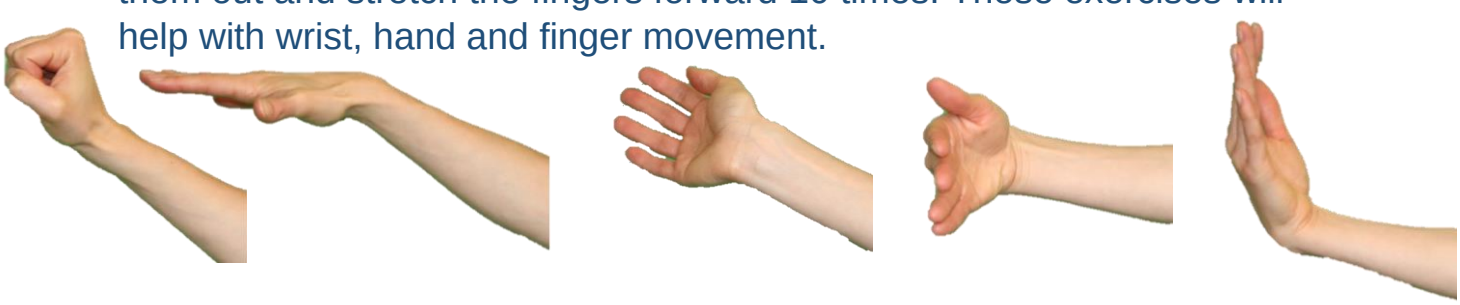
Roll your shoulders forwards slowly 5 times. Then roll your shoulders backwards slowly 5 times. This will help warm the shoulder joints and muscles.

4. Ankle Rotations

Lift and circle one foot round 5 times in one direction then 5 times in the opposite direction. Repeat on the other foot. This will help loosen the ankle joint.

5. Wrist Rotations & Finger Flicks

Rotate your wrists round 5 times in one direction then 5 times in the opposite direction. Next, scrunch your hands into a fist and then open them out and stretch the fingers forward 10 times. These exercises will help with wrist, hand and finger movement.



6. Overhead Arm Stretch

Sit tall in your chair. Lift your arms out to the side and stretch them slowly above your head. Aim to complete 4-8 times. Move to where you feel comfortable. This exercise stretches through the upper body and warms into the shoulder joints.

Main Strength Component

7. Bicep Curl (with band)

Place the band under both feet, holding the band firmly in both hands. Place your elbows against your sides. Turn your palms up. Now curl your arms up towards you. Complete 4-8 times, slow and controlled.

8. Chest Press (with band)

Sit tall, place the band behind your back and under your arm pits. Now press your arms forward slowly stretching out the band. Repeat 4-8 times. This exercise is good for your arm strength.

9. Single Leg Press (with band)

Sit tall at the back of your chair. Place the band under one foot. Now, lift the foot off the floor with your knee bent. Press your foot into the band straightening your leg forwards slowly. Pause with your leg straight, then control the movement back into a knee bend. Complete 4-8 times, then repeat on the other leg. Slow and controlled movements. This exercise is great for strengthening your legs, helping with standing and walking.

10. Marching & Punches (with band)

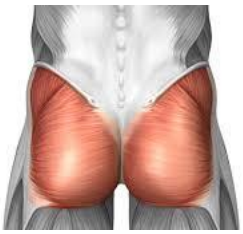
March your feet and lift your knees, alternating sides slowly. For an extra challenge place the band behind your back and under your arm pits. Now, alternate punching arms, stretching the band forwards. Try lifting the opposite knee to the opposite arm. Repeat 4-8 times at a comfortable pace and range of movement for you.

11. Side Steps (with band)

Wrap the band around the tops of your thighs. Lift one leg out to the side against the band. Pause with your leg out to the side then slowly lift the leg back to centre. Repeat the opposite side. Aim to complete 4-8 times, alternating at a slow controlled speed. This exercise is great to strengthen and mobilise the hips.

12. Bottom Squeezes

Clench your bottom cheeks and hold for 3 seconds. Release and repeat 4-8 times. This exercise helps to improve the strength of your gluteals (bottom muscles), which are important for standing and walking.



Cool Down

13. Hamstring Stretch

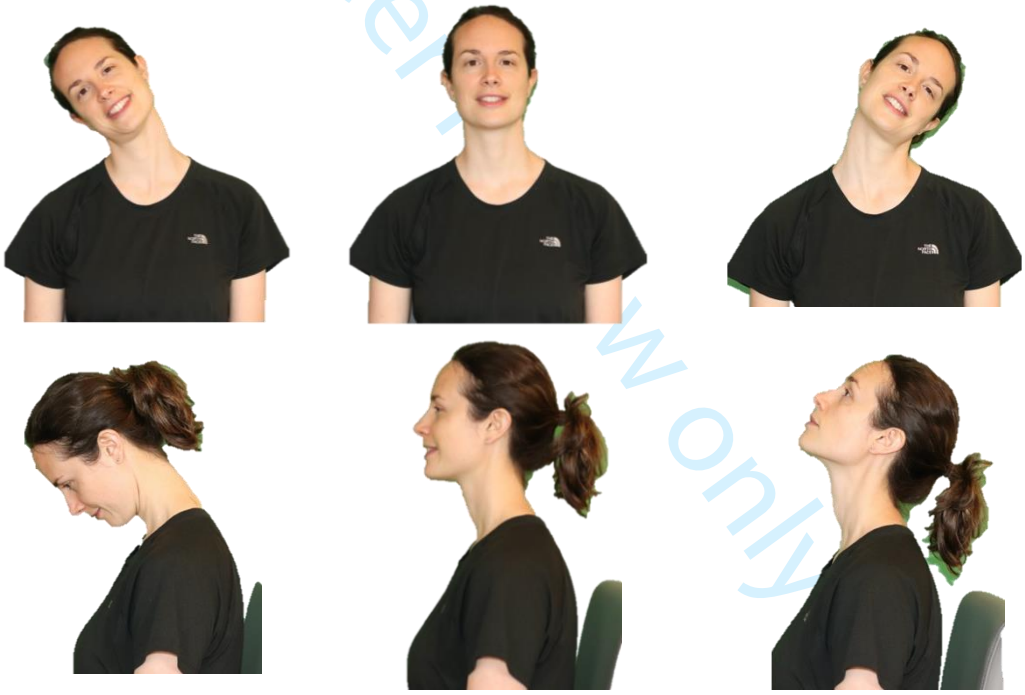
Sit towards the front of your chair. Straighten one leg in front of you and rest your heel on the floor. Lift your toes and gently lean forward into the stretch. Hold the stretch for 20 seconds. This exercise improves the flexibility into the back of the legs.

14. Chest Stretch

Sit towards the front of your chair. Reach back with your hands to touch the back of your chair. Stick your chest out and squeeze your shoulder blades together. Hold the stretch for 20 seconds. Remember to breathe. This exercise is great to prevent hunched shoulders.

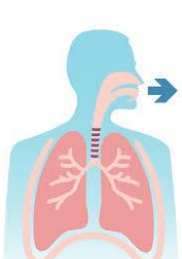
15. Neck Stretches

Slowly tilt your head over to one side and hold for 10 seconds. Bring your head back to the centre and then repeat the opposite side. Next, tilt your head forwards bringing your chin towards your chest and hold. Slowly bring the head back to centre and then slowly lift your head up tilting your chin towards the sky.



16. Deep Relaxing Breaths

Take 3 deep breaths in and out to help invigorate and relax your body.



Progression

We need to be exposed to greater stress for changes to occur in the body. When you have reached a plateau, where you are able to complete the exercises easily, then the intensity or duration can be increased gradually to bring about further changes.

For instance, we can progress our strength exercises by increasing the amount of repetitions we complete on each exercise, or we can add in resistance by using weights, or resistance bands.

Aim to progress to:

- 3 sets of 8 repetitions
- Weights (start with 0.5-1.5kg)
- Resistance band (start with easy tension)

STOP the exercise or reduce intensity/duration if there are signs of over exertion (e.g., muscle soreness lasting longer than 2 days).

Important Resistance Band Considerations

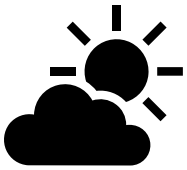
- Perform the exercises without the resistance band until you are comfortable.
- Perform all exercises in a slow and controlled manner, controlling the movement in both directions, and not allowing the band to 'ping'.
- The band should be tight enough to get the muscle 'firing' properly. Holding the band further towards the ends will make the movement easier. We are aiming to feel mild fatigue in the muscles after using the band.
- Try to breathe normally. If it helps you can inhale before starting a repetition and exhale on the contraction.
- Consider your body alignment – good tall seated position with your joints comfortably in alignment.

Resistance Band Safety Tips

1. Do not stretch the band too far
2. Never let go of the band while under tension (i.e., stretched out)
3. Inspect bands before use (they can break down over time due to normal 'wear and tear')

Looking After Your Band

1. Clean bands by wiping with a damp cloth.
2. Do not use soap or any cleaning products to clean bands as these can deteriorate the strength of the band.
3. Avoid storing bands near direct sunlight.
4. Keep stored bands away from heat sources.
5. Bands should not be stored outside or in cold environments.



Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	6
Funding	#4	Sources and types of financial, material, and other support	19
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	19
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	15
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	15

Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	15
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	N/A – This is a feasibility study with a quasi-experimental design and no comparison groups
Objectives	#7	Specific objectives or hypotheses	6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	6

Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-12
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	10
Interventions: adherence	#11c	Strategies to improve adherence to intervention protocols, and any procedures	12-13

		for monitoring adherence (eg, drug tablet return; laboratory tests)	
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-14
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8 and see Figure 1.
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7

Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A – quasi-experimental design – feasibility study
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care	N/A

		providers, outcome assessors, data analysts), and how	
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-14
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12

Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further	N/A – feasibility study

		details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A – feasibility study
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	11-12
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	15
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	15
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant	15

		parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7 and see supplementary material
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	15
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	15
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A

Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	15
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	19
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	19
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary material
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai