This protocol has regard for the HRA guidance and order of content

FULL/LONG TITLE OF THE STUDY

A feasibility and acceptability study of a virtual multimodal intervention delivered by volunteers to improve functional outcomes of frail older adults discharged from hospital

SHORT STUDY TITLE / ACRONYM

Frail2Fit

PROTOCOL VERSION NUMBER AND DATE

Version 1.2 13/03/2024

RESEARCH REFERENCE NUMBERS

IRAS Number:	309521
SPONSORS Number:	RHM MED1860
FUNDERS Number:	GNT0525

SIGNATURE PAGE

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

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

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

For and on behalf of the Study Sponsor:

Signature:
.....

Date:
...../...../.....

Name (please print):
.....

Position:
.....

Chief Investigator:

Signature: 
.....

Date:
13/06/2022

Name: (please print): Dr Stephen Lim
.....

LIST of CONTENTS

KEY STUDY CONTACTS

Chief Investigator	Dr Stephen Lim Consultant Geriatrician Clinical Academic in Geriatric Medicine Academic Geriatric Medicine University of Southampton University Hospital Southampton NHS FT Tremona Road Southampton SO16 6YD Email: s.e.lim@soton.ac.uk Telephone: 02381206131
Sponsor	University Hospital Southampton NHS Foundation Trust sponsor@uhs.nhs.uk
Funder(s)	University Hospital Southampton NHS Foundation Trust Small Grant Scheme Email: researchgrants@uhs.nhs.uk **UHS Grant Reference Number:** GNT0525
Key Protocol Contributors	Professor Helen Roberts Professor of Medicine for Older People, Academic Geriatric Medicine University of Southampton, University Hospital Southampton NHS FT Southampton SO16 6YD Email: h.c.roberts@soton.ac.uk Telephone: 02381 204354 Professor Mike Grocott Professor of Anaesthesia & Critical Care Clinical and Experimental Science University of Southampton University Hospital Southampton NHS FT Southampton SO16 6YD Email: mike.grocott@soton.ac.uk Telephone: 02381 208449 Professor Sandy Jack Consultant Clinical Scientist in Anaesthesia and Critical Care University Hospital Southampton NHS FT Email: s.jack@soton.ac.uk Professor Jane Murphy Professor of Nutrition Faculty of Health and Social Sciences Ageing and Dementia Research Centre – CoDirector Bournemouth University

	Bournemouth Gateway Building. St. Pauls Lane, Bournemouth, BH8 8GP Email: jmurphy@bournemouth.ac.uk Telephone: 07872 048915 Dr Judit Varkonyi-Sepp Chartered Psychologist Manager Behavioural Science Theme NIHR Biomedical Research Centre Clinical and Experimental Science University of Southampton Email: j.varkonyi-sepp@soton.ac.uk Mr Andrew Bates Clinical Academic Intensive Care Nurse and Critical Care Research Manager, Fit4Surgery portfolio University Hospital Southampton NHS FT Email: a.bates@soton.ac.uk Telephone: 07917208867 Dr Chloe Grimmett Senior Research Fellow for Macmillan Survivorship Research Group University Hospital Southampton NHS FT Email: c.grimmett@soton.ac.uk Telephone: 02380 597964 Mrs Cynthia Russell Public patient representative Email: cynthia.russell@btinternet.com Dr Samantha Jane Meredith Research Fellow Academic Geriatric Medicine University of Southampton, University Hospital Southampton NHS FT Southampton SO16 6YD Email: s.j.meredith@soton.ac.uk Telephone: 07825 104783

STUDY SUMMARY

Study Title	A feasibility and acceptability study of a virtual multimodal intervention delivered by volunteers to improve functional outcomes of frail older adults discharged from hospital

Internal ref. no. (or short title)	Frail2Fit
Background	Between 30-60% of older people in hospital lose muscle strength and function (deconditioning) which reduces quality of life and increases their risk of hospital readmission. Physical inactivity is estimated to cost the NHS about £1 billion per year. This can be improved with increasing physical activity and good nutrition. Our team have developed and evaluated a programme using online clinics to successfully support over 600 cancer patients living at home to stay active and eat well with provision of emotional support (SafeFit study). With many older people now using the internet for social connection, we have an opportunity to investigate whether a similar model can improve the health of older people.
Research Question/Aim(s)	Frail2Fit will explore the feasibility of training volunteers to deliver online nutrition, exercise, and behaviour change (supported self-management) to improve the health of older people after discharge from hospital. We also want to know if this supported self-management is acceptable to older people, their family members and/or carers, and the volunteers.
Study Design & Methods	In this mixed methods feasibility study, older adults in hospital and identified as frail, will be recruited from medical wards. Volunteers will be trained using our established methods to support patients to be physically active and eat well. Techniques to support behaviour change will help patients engage with the programme. Volunteers will meet the participants online over a 12-week period. We will report the number of volunteers recruited, trained, and retained. We will also report the number of patients recruited, adherence to the intervention, and any adverse events. To evaluate the benefit of the intervention we will measure participants' physical function, appetite, quality of life and well-being, and the impact on hospital admissions. To explore experiences and views about the intervention we will interview 15 patients and their family member/carers, and 10 volunteers.
Study Participants	Older adults discharged from hospital will be invited to participate in this study. The inclusion criteria are older adults age 65 years and above who are able to provide written consent and have been discharged from UHS, who are identified as frail (Clinical Frailty Scale ≥5) and are 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, and patients who are discharged to rehabilitation units, or care homes, or patients receiving end of life care, will be excluded from the study. Volunteers from UHS patient support hub will be invited to participate in this study to deliver the Frail2Fit intervention. The inclusion criteria are volunteers aged 16 years and

	above, who have completed the generic clearance and training at UHS, who can provide written informed consent, and are able to communicate fluently enough in English. Volunteers that are unable to safely complete the exercises included in the intervention will be excluded from the study.
Planned Size of Sample (if applicable)	A sample size of 23 patients was chosen in line with previous sample size recommendations for feasibility studies of 12-50 participants. This sample size was considered an appropriate number that is pragmatic and achievable within the study timescale and resources available. A sample size of 6 volunteers was chosen to provide sufficient cover to deliver the Frail2Fit intervention to groups of 5-6 older adults with 2 volunteers supporting each group.
Outcomes	Primary outcomes: Feasibility and acceptability Secondary outcomes: physical activity levels (PASE and GENEActiv), physical function (Barthel Index), appetite (SNAQ), well-being (WEMWBS), anxiety and depression (HADS), and self-efficacy for managing chronic disease.
Patient and Public Involvement	We surveyed 92 older adults in the community and care homes. 45% had experience working with volunteers and appreciated their contribution. Our SoMoVe study showed that volunteer-led physical activity intervention in hospital was well received by older adults, and they also enjoyed the social interaction. In our survey in 2020, 47 out of 50 older adults attending social clubs agreed or strongly agreed to have trained volunteers lead exercises. 2 public contributors provided input into this study proposal. They will be invited to join the study management group and be involved from development to dissemination of study findings.
Dissemination	We will develop a toolkit to support knowledge transfer including advice on volunteer recruitment, training, and suggestions for successful implementation. Results will be shared with commissioning services, NHS staff, volunteer organisations and service users via charities e.g. Age UK, supported by our PPI partners. Results will also be shared via publication and conference presentations.
Planned Study Period	Start Date: 01/06/22 End Date: 31/07/23 Years: 1 Months: 1 Days: 30

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
University Hospital Southampton NHS Foundation Trust R&D Department, Southampton General Hospital Level E, Laboratory & Pathology Block, SCBR - MP138 Southampton SO16 6YD researchgrants@uhs.nhs.uk	Funding secured: £51,019 Duration: 1 year, 4 months

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor will take overall responsibility for proportionate, effective arrangements being in place to set up, run and report the research project. The study sponsor will review research protocols and study documents to ensure they meet regulatory requirements. The sponsor will also review IRAS forms before submission for ethical review and will monitor the conduct of the study, including any amendments that need to be made. The sponsor will review annual progress reports and will be involved in the 'close out' of the study.

Funding for this study is provided through the University Hospital Southampton NHS FT Small Grants scheme. The study funder reviewed the protocol before funding was secured to ensure the proposed project aligned with research portfolios within UHS clinical divisions, and/or the UHS/UoS research infrastructure. The funder has provided funding to cover the costs of the study, detailed below:

Summary of costs

Research Fellow	£31729
Tablets and sim card	£6000
Post and packaging	£400
Travel expenses	£240
Conferences	£500
PPI cost	£2000
Open Access publication	£1500
Telephone calls	£200
Interview transcription	£400
Volunteer expenses	£7500
UHS R&D fees	£550
Total	£51019

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

The Principal Investigator (PI), Dr Stephen Lim is responsible for the overall conduct of the study. He has the primary responsibilities of planning and managing the project, ensuring that the project progresses according to schedule.

Prof Helen Roberts, who is a Professor of Medicine for Older People, is a senior academic who has vast experience in research among older people. She will contribute and support the PI with her expertise in the management of the study and with her previous experience of working with volunteers.

Andrew Bates has extensive experience managing clinical trials which aim to optimise patient's metabolic and psychological well-being. Andrew will be involved in the training of volunteers, including competency assessment. He will support the research fellow in developing the training manual and delivering the training for the volunteers and research participants. He will ensure that the study is conducted to time and target, consistent with the highest principles of clinical, data and trial governance.

Dr Chloe Grimmett is a post-doctoral research fellow with research interests in the development of interventions to support self-management, and in psychological and physical optimisation of patients. She is the lead behavioural scientist for the WesFit and SafeFit trials. She will deliver the behavioural change support training for the volunteers.

Professor Sandy Jack is a Consultant Clinical Scientist in Anaesthesia and Critical Care, and has vast research experience and expertise in the development and implementation of exercise interventions. Her expertise will be key to the delivery of a robust physical activity intervention. Her experience in conducting trials will ensure that the study will be conducted to a high standard.

Prof Jane Murphy has a wealth of experience in nutrition and ageing research. Her expertise will ensure that the nutritional aspects of the intervention are robust. She will also support the delivery of the intervention working within University Hospitals Dorset.

Dr Judit Varkonyi-Sepp is Manager for the Behavioural Science Theme at NIHR Biomedical Research Centre (BRC) and a Health Psychologist, Research Psychologist and Coaching Psychologist. Her expertise will ensure the behaviour change aspects of the intervention is robust. She will also support the delivery of the volunteer's behaviour change training.

A research fellow will assist the PI in participant recruitment, data collection and data entry. Weekly meetings will be held with the PI and the research fellow to discuss the day to day running of the study. Monthly project management meetings will be held with the PI, RF and PPI lead to discuss the progress of the study and to monitor the conduct of the study.

Patient and public involvement (PPI)

We surveyed 92 older adults in the community and care homes. 45% had experience working with volunteers and appreciated their contribution. Our SoMoVe study showed that volunteer-led physical activity intervention in hospital was well received by older adults and they also enjoyed the social interaction. In our survey in 2020, 47 out of 50 older adults attending social clubs agreed or strongly agreed to have trained volunteers lead exercises. 2 public contributors provided input into this study proposal. They will be invited to join the study management group and be involved from development to dissemination of study findings.

In this study, the role of PPI includes:

- Reviewing patient-facing materials such as patient information sheet, consent form forms and questionnaires.
- Participating in the study steering group to support the delivery of the study.

- Providing input at every stage of the study to ensure that the focus of the study is primarily on delivering patient benefit.
- Ensuring that the processes of the study such as data collection, and interviews, are not too burdensome for patients.
- Recommending methods or avenues of disseminating research findings to provide a wider reach and ensure that patient and the public are informed of the research findings.

PROTOCOL CONTRIBUTORS

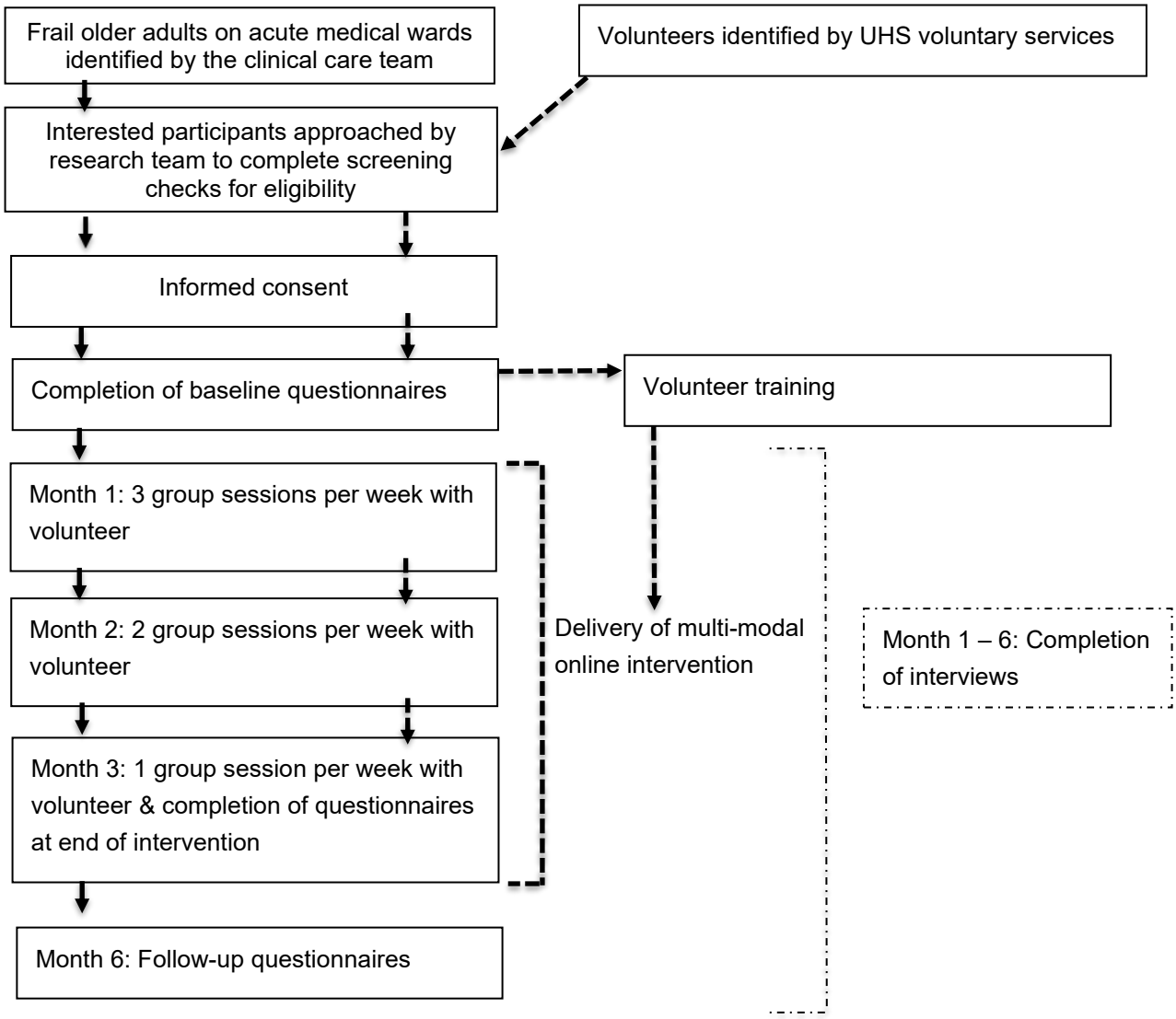
The current protocol has been developed and adapted from the SafeFit trial, SoMoVe and ImPACt studies, steering study procedures and providing an evidence-based training package for volunteers. Public representatives have been involved in the design of the multi-modal volunteer-led intervention and will critique any patient-facing resources, such as participant information sheets, consent forms and training manuals.

The study sponsor (UHS) and funders (UHS Small Grants Scheme) were not directly involved in the design of this study. They will review research protocols and study documents to ensure they meet regulatory requirements. This provides the R&D Office with information on the considerations which have been made in the development of the protocol in a number of areas to help assess the level of risk to the Trust and how this can be mitigated. The sponsor will also review IRAS forms before submission for ethical review and will monitor the conduct of the study, including any amendments that need to be made. The sponsor will review annual progress reports and will be involved in the 'close out' of the study.

The study funder reviewed the protocol before funding was secured in order to ensure the proposed project aligned with research portfolios within UHS clinical divisions, and/or the UHS/UoS research infrastructure.

KEY WORDS: Frailty; older adults; volunteer-led exercise; nutrition support; behaviour change; online intervention

STUDY FLOW CHART



STUDY PROTOCOL

A feasibility and acceptability study of a virtual multimodal intervention delivered by volunteers to improve functional outcomes of frail older adults discharged from hospital

1 BACKGROUND

Older people with frailty are at high risk of poor outcomes including increased post-hospitalisation, healthcare use and mortality [1]. Frailty refers to a state of vulnerability to poor resolution of homeostasis after a stressor event and results from a cumulative decline in biological reserves across multiple organ systems [2]. Approximately 11% of community dwelling older adults have frailty [3], compared to around 14% prevalence in English hospitals [4]. As frailty progresses older adult's functional status declines, resulting in disability, increased risk of falls, and long-term care [5]. Moreover, deconditioning during hospital admission is a major concern and impacts significantly on older adult's ability to be independent. Hospitalised older adults are at risk of immobilisation resulting in reductions in muscle mass by 0.5% and muscle strength by 0.3-4.2% per day [6, 7]. Considering these detrimental clinical consequences, identifying vulnerable patients with frailty, and intervening to prevent functional decline is a high-priority patient-centred outcome.

Current evidence suggest that physical activity (PA) and nutrition interventions are key to maintaining independence and improving frailty status among pre-frail and frail older adults [8, 9]. Physical activity is defined as any bodily movement produced by the musculoskeletal system that increases energy expenditure, and exercise is a sub-category of PA which aims to improve or maintain one or more components of physical fitness through planned, structured, repetitive, and purposive programming [10]. PA and exercise are key strategies to preserve or improve the function of multiple physiological systems that are affected by age, including the respiratory, endocrine, cardiovascular and skeletal muscle systems [11]. Maintenance of regular PA supports older adult's ability to remain independent in activities of daily living (ADL), such as bathing, dressing, and mobilising, and promotes independence and quality of life [12]. PA and nutrition have also been advocated as important lifestyle behaviours to combat and prevent frailty progression during infection prevention measures, helping to alleviate risks associated with social isolation, malnutrition, reduced access to care, and increased sedentary time during the pandemic [13]. Low PA levels and increased time spent being sedentary increases older adults' risk of frailty [14]. Hence, public health initiatives, and healthcare professionals are concerned with the promotion of PA and the consideration of the appropriate type, effectiveness, and feasibility of PA interventions to implement in practice [15, 16].

General PA guidelines for older adults age ≥65 years recommend completion of at least 150-300 minutes of moderate-intensity aerobic PA each week (or at least 75-150 minutes of vigorous-intensity PA), and functional balance and muscle-strengthening activities at least three times per week, for health benefits [16]. For older adults with frailty a multicomponent exercise intervention including flexibility, balance, power, strength, and aerobic training is recommended across frailty categories [15, 17, 18]. As patients become more frail, increased strength training has been advocated to improve functional status and reduce further decline, increasing exercise intensity as frailty status improves [17]. In a recent meta-analysis, Lopez et al. [18] found that progressive strength training alone or combined with other training components were effective intervention strategies for increasing physical aspects of frailty, including maximum strength of knee extensors (SMD 1.07, 95% CI – 0.56 to 1.58, I^2 92%, $p<0.001$), gait speed (SMD 1.57, 95% CI – 0.50 to 2.64, I^2 95%, $p<0.001$), and timed-up-and-go (SMD -0.91, 95% CI – -1.45 to -0.36, I^2 90%, $p\leq0.001$). In other research, moderate-vigorous PA assessed via accelerometers helped to reduce frailty levels in older adults, while light PA attenuated frailty in older adults with co-morbidities, highlighting the need to tailor PA volume to suit older adult's

individual needs [19]. However, PA is only one part of the holistic health and broad-based approaches recommended within frailty consensus statements, with existing literature recognising optimal nutrition as a key strategy to augment PA benefits [20].

Malnutrition is common in older adults and is closely associated with frailty, playing a key role in its pathogenesis [21]. According to the European Society for Clinical Nutrition and Metabolism (ESPEN) malnutrition refers to 'a state resulting from a lack of uptake or intake of nutrition leading to altered body composition (decreased fat free mass and body cell mass) leading to diminished physical and mental function and impaired outcome from disease' [22]. In a meta-analysis exploring nutritional status in older adults across healthcare settings, malnutrition was present in 3% among community-dwelling older adults, 8.7% among older people receiving home care services, and 6% among those attending outpatients [23]. The quality of older adult's diet has a close relation with the incidence of frailty [24]. Dorner et al. [25] examined the associations between nutritional status and frailty in acute hospitalised patients and found 76.7% had malnutrition or were at risk of malnutrition. Moreover, findings illustrated that three-quarters of malnourished hospitalised older adults were frail and over 90% of malnourished participants were pre-frail or frail. Considering the prevalence of malnutrition in older people, its close association with frailty and the negative health outcomes linked to these conditions (e.g., increased morbidity and mortality), more attention is needed in discharge management and continuity of care between the hospital setting and post-discharge setting with improved nutritional care management and intervention [25-27].

The causes of malnutrition are multifactorial and therefore a range of practical approaches in the management of malnutrition among frail older people are needed [27]. The ESPEN guideline on clinical nutrition in older people provides evidence-based recommendations in the prevention and treatment of malnutrition and advocates that all older people should be routinely screened for malnutrition to identify an existing risk early [28]. Oral nutrition can be supported by nursing interventions, education, nutritional counselling, food modification and oral nutritional supplements [28]. Moreover, a burgeoning area of research pinpoints the need to routinely assess appetite to prevent unintentional weight loss among older people, in which the effects of ageing on appetite can drive older people towards a state of reduced hunger with negative links to malnutrition and frailty [29, 30]. Recent development in the Patients Association Nutrition Checklist (PANC) has been used for the early identification of malnutrition risk attributed to unintentional weight loss and appetite changes, together with signposting to basic dietary advice and appropriate health and social care support in community-dwelling older adults [31]. Upon discharge, the tool can be used easily within a 'Nutrition Wheel' format by key stakeholders including volunteers and community workers to encourage conversations with frail older adults regarding malnutrition and to provide sources of help for those likely to be at risk [32].

Interventions to identify malnutrition and improve nutrition status, and to enhance PA levels, have been implemented across a range of settings [17, 27]. However, with the restrictions on social activities and social distancing rules, there is an increasing need to explore innovative ways to deliver supportive self-management interventions that encourage older people to eat well and be physically active. In response to the COVID-19 restrictions, healthcare and rehabilitation have increasingly turned to virtual modes of delivery, such as telehealth methods [33]. The increasing use of technology in the daily lives of many allows PA and nutrition interventions to be delivered online [34]. For instance, the SafeFit trial has successfully trained over 40 non-healthcare exercise professionals to deliver an online universal intervention to maintain and improve physical, nutritional, and psychological well-being in vulnerable people with cancer, who are following social distance guidance [35]. This trial was developed in collaboration with Macmillan Cancer Support, CanRehab trust and Wessex Cancer

Alliance. The intervention is consistent with NHS England Long-term plan to promote personalised care and supported self-management. In other research, telephone conversations, tele-monitoring devices, and internet-enabled tablets have also been shown as an effective means to deliver nutrition and PA interventions to older adults [36, 37]. Yamada et al. [38] investigated a combined nutrition and PA intervention through remote delivery for older adults with sarcopenia. Notably, they found that a remote programme of pedometer -based walking and nutritional supplementation (protein and vitamin D) delivered over 6 months enhanced anabolic hormone levels, step count, and skeletal muscle mass index in community-dwelling older adults with frailty. Hence, exploring the feasibility, acceptability and effectiveness of multi-modal telehealth interventions for older adults with frailty is an important research agenda and existing literature indicates the important utility of such delivery modes and interventions within the current health climate to improve routine practice and continued care of older adults with frailty.

In addition to remote online interventions, there is also increased attention towards volunteer-led implementation of PA and nutrition strategies [39-41]. Delivery of interventions in the community by healthcare professionals, dieticians, or exercise trainers may have cost implications. One alternative would be to train volunteers to deliver multi-modal interventions in the community. Volunteering can be defined as an activity that is freely chosen, does not involve remuneration and helps or benefits those beyond an individual's immediate family. Rather than a spontaneous help given to someone in an emergency situation, volunteering is typically proactive rather than reactive and entails some commitment of time and effort [42]. In the Kings Fund report on volunteering in health and care in England, the most common settings for volunteer support were hospices, community settings and hospitals [43]. A recent systematic review explored the impact of PA interventions conducted by trained volunteers on health-related outcomes for community-dwelling older people age ≥65 years [39]. Trained volunteers implemented strength and balance exercises 1-3 times per week, which led to improvements in functional status (e.g., short physical performance battery, Barthel Index), improved frailty status, a reduction in fear of falls, and maintained or improved quality of life [39]. Nevertheless, the review called for more high-quality research to investigate the effects of volunteer-led PA interventions among older people. Similarly, a systematic review and meta-analysis investigating the effectiveness of trained volunteers delivering interventions to individuals at risk of malnutrition highlighted significant improvements in physical performance, fear of falling, lunchtime energy intake and improved patient satisfaction across community and hospital settings [40]. Yet, the findings were based upon low quality evidence and thus the authors recommended more adequately powered research in the area to identify the most effective use of resources to combat malnutrition and frailty.

Recently, the SoMoVe study trained volunteers to deliver PA interventions for hospitalised older people on acute medical wards [44]. The study found that it was feasible to deliver a volunteer-led mobility intervention including the recruitment, training and retention of volunteers. The intervention was safe and acceptable to healthcare professionals and patients, and a commonly cited benefit was the social aspect of the intervention, in which volunteers developed a rapport with patients and encouraged them to mobilise or exercise. Nevertheless, reported key barriers identified included the busy clinical environment and lack of awareness of the intervention among staff. Volunteers have also been shown to reduce frailty and malnutrition risk among community-dwelling older adults [41, 45]. For example, in a randomised controlled trial Luger et al. [41] 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 an improvement in frailty status. Furthermore, an array of existing research has shown improvements in handgrip strength, quality of life, social participation, physical function and frailty status in community-dwelling pre-frail and frail older adults receiving home-based PA and nutrition interventions from lay-volunteers [45-47]. Consequently, a whole society

approach involving multi-sectoral collaborations, such as community volunteers, has been advocated to promote age-friendly communities and healthy ageing [47].

2 RATIONALE

There is strong evidence regarding the health benefits of PA and nutrition to improve frailty for older adults, yet COVID-19 restrictions have presented significant challenges to older adult's lifestyle behaviours and for the effective delivery of routine healthcare and rehabilitation. Early research indicates that volunteer led interventions are potentially feasible and can have positive effects on older adult's health and physical functioning, yet more research is needed to further explore the acceptability, feasibility, and effectiveness of this approach. Building on these studies, the current research will evaluate a multi-modal online volunteer-led nutrition support and PA intervention for older people with frailty, post-hospitalisation. To our knowledge there are currently no studies exploring the use of trained volunteers delivering such interventions online, thus more research is needed to identify the facilitators and barriers of volunteer-led online interventions for frail older people.

3 THEORETICAL FRAMEWORK

In this study, Normalisation Process Theory (NPT) will be used as the theoretical framework which will underpin the development and evaluation of the volunteer-led intervention [48]. The NPT provides a set of sociological tools to understand and explain the social processes through which new or modified practice of thinking, enacting, and organizing work are operationalized in healthcare and other institutional settings. The use of an implementation theory is useful as it helps researchers identify, describe and explain important elements of the implementation process. The three core problems which the theory is concerned with are: implementation (bringing of a practice or practices into action), embedding (routine incorporation of practice or practices into everyday work of individuals and groups) and integration (reproduction and sustainability of a practice or practices among the social matrices of an organization or institution). NPT was used in the development of the study protocol as well as the online physical activity and nutrition intervention. The online NPT toolkit was used to assist in critically thinking through the processes and challenges which may arise in implementing and integrating an intervention in a complex health care setting. NPT was chosen as the framework that underpinned this study as it was systematic in its approach, easy to understand and provided a proven framework to evaluate the implementation process of this study. The online toolkit available for this implementation theory also made the application of NPT at various stages of this study more convenient and practical.

4 RESEARCH QUESTION/AIM(S)

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

4.1 Objectives

The specific objectives include:

1. To develop a training programme for volunteers to support the delivery of an online multimodal intervention.
2. To assess the feasibility of recruiting, training and retaining volunteers to deliver the intervention.
3. To assess the feasibility of recruiting and retaining older adults with frailty to the trial.

4. To determine the acceptability of the intervention and explore barriers and facilitators to the intervention to support future wider implementation.

4.2 Outcome

Exploration of the feasibility and acceptability of the intervention will help to determine whether the multi-modal volunteer-led online intervention is appropriate for further evaluation in future research, to determine sample sizes for a controlled trial and to assess whether the ideas and findings can be shaped to be relevant and sustainable. The study will also help to determine suitability of the intervention for a larger roll out of the programme across Wessex.

Through collaborations between University of Southampton, University Hospital Southampton, and Wessex AHSN, the anticipated impacts include:

- Development of training material for wider use and future implementation studies.
- Collaboration with Wessex AHSN and the National Association of Voluntary Services Manager to develop an implementation plan with the aim to roll out the intervention across the Hampshire and Isle of Wight region and nationally at a later stage.
- Dissemination of our research findings through scientific and lay platforms to encourage implementation in other settings.
- Increased participation in PA and improved nutrition support for frail older people post-discharge with potential benefit in health outcomes.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

Study Design

A quasi-experimental mixed methods approach will be used to determine the feasibility and acceptability of implementing a volunteer-led multi-modal intervention for discharged older adults with frailty. This feasibility study will be conducted at the University Hospital Southampton NHS Foundation Trust (UHS), training hospital volunteers to deliver virtual group support for older adults discharged from UHS.

Feasibility studies are used to determine whether an intervention is appropriate for further evaluation, to determine sample sizes for controlled trials and to assess whether the ideas and findings can be shaped to be relevant and sustainable. In this study, the feasibility of training volunteers to deliver a virtual multi-modal intervention to improve older adult's functional outcome post-discharge will be assessed. The acceptability of the intervention will also be examined through qualitative interviews to explore the views and experiences of volunteers, trainers, carers and older adults involved in this study. The impact of the intervention on physical activity levels and functional outcomes will be measured. However, as this is a feasibility study, it is not powered to show any statistical difference in the outcome measure.

Intervention

The intervention duration will be 3 months. Participants will receive three group sessions per week for 1 month (weeks 1-4), twice per week for the second month (weeks 5-8), and once weekly for the last month (weeks 9-12), with a maximum of 24 sessions. The tapered nature of the intervention was chosen to provide suitable support for older adults post-discharge with the aim to gradually encourage increased self-management to foster independence post-intervention. Components of the intervention, including exercise, nutrition support and behaviour change support, will be delivered from an online platform (Zoom). Each group session will last 40-60 minutes, including 20-30 minutes of exercise

followed by 20-30 minutes of nutrition support. The components of the intervention and the training package have been adapted from the SafeFit trial [35] and will be delivered in line with behaviour change principles and emotional support to maximise participant uptake, adherence and lifestyle self-management.

Exercise: The exercise will consist of volunteer-led group progressive resistance exercise training for 20-30 minutes. To align with home-based safety considerations, the exercises will be performed seated. Seated exercise will focus on strengthening upper and lower limbs (8 major muscle groups) and enhancing whole body range of motion and flexibility, tailored specifically to meet the needs of older adults and to minimise the risks of injury. Participants will be encouraged by the volunteers to progress repetitions (aiming for 3 sets of 8 repetitions) and to gently improve range of motion. Elastic resistance bands will be introduced from Week 5 to older adults who are comfortable and ready to progress to using resistance in the exercises. Participants will be encouraged by the volunteers to increase the resistance grade if they are able to carry out the repetitions easily. Intensity will be monitored with the Resistance Intensity Scale for Exercise (RISE) [49] and the Talk Test [50], aiming for a low-moderate difficulty on RISE and 4-6 on the Talk Test. 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 [16]. The exercise programme has been developed and piloted from a previous ARC Wessex study that aimed to improve PA and health in community-dwelling older adults through trained volunteers [51]. Participants will be given an exercise booklet and access to an exercise video to help support engagement with the exercises and encourage un-supervised participation at home.

Nutrition support: Volunteers will work with participants to review their diet and eating habits using the Nutrition Wheel to ensure their nutrition is appropriate and they are not at risk of undernutrition [31]. The Nutrition Wheel is an interactive tool developed from the Patients Association Nutrition Checklist (PANC) and used to engage individuals in conversation about unintentional weight loss and malnutrition. The Nutrition Wheel was developed by Professor Murphy in collaboration with the Wessex AHSN and key stakeholders and charities and identifies whether an older adult may be at risk of undernutrition, providing guidance accordingly. Specifically, the Nutrition Wheel consists of 4 main questions from PANC, 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 advise. Individuals identified as undernourished will be signposted to appropriate information sheets, national helplines, or if necessary, signposted to their GP/practice nurse for further advise and screening.

Behaviour change support: Volunteers will receive training in healthy conversation skills (HCS) guided by principles of Making Every Contact Count (MECC) [52, 53]. The MECC approach supports positive behaviour change through encouraging client-centred brief conversations surrounding health and well-being and will help 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 [54]. The MECC approach is underpinned by behaviour change principles from the COM-B model, highlighting both automatic and reflective processes involved in decision making and action. 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 and a sense of control [55].

Participants will be given the option to choose between the online intervention and telephone consultations. Participants who opt for telephone consultations will be encouraged by volunteers to perform the exercises provided in the booklet and will be given nutritional advice based on the nutrition wheel. The frequency of telephone consultations will be similar to the online intervention.

Training of volunteers

Volunteers will receive a bespoke training package adapted from the SafeFit training guidance [35]. Depending upon current Government recommendations in response to the COVID-19 pandemic the training will either be delivered online by the research team, or in-person at UHS. Once the 3 training components (i.e., exercise, nutrition, and behaviour change) have been completed, volunteers will support and shadow the trainers to deliver the intervention during the first month, aiming for 2 sessions per week to be delivered by the trainers and 1 to be delivered by the volunteers with support from the trainer. After 4 weeks, volunteers will be expected to lead the sessions independently to continue supporting participants in the adherence of the intervention with continued weekly input by the trainers.

Exercise: The exercise training programme will be developed based on clinical expertise from therapists and current evidence including experience from a recently completed study [44] and an ongoing feasibility study [51]. Training will include 2 group sessions each lasting approximately 2 hours. The first training session will include a brief section teaching the theory underpinning the benefits of exercise for older adults, and will include exercise training principles, such as FITT recommendations (frequency; intensity; time; type). The remainder of the first training session will give an overview of the seated exercise content, detail exercise delivery advice (e.g., how to demonstrate and give effective teaching points), and explore exercise safety considerations (e.g., safe set-up before and during exercise, and what to do in an emergency). Volunteers will be given an exercise training manual and links to a video to practice the exercises in their own time. Time for practice (1-2 weeks) will be given before volunteers return for their second group exercise training session. The second session will focus on delivery of the seated exercises allowing volunteers to practice delivering the exercise to their peers and to obtain feedback from the group and trainer. Safety considerations will be revisited at the end of the second session. Volunteers will also receive training on how to document adverse events that occur during the exercise classes.

Following completion of group exercise training, volunteers will be offered one-to-one training and practice sessions to help support their competence and confidence in delivering the seated exercises safely and effectively. Based upon the ImPACt study it is predicted that volunteers might need 1-3 one-to-one exercise training and practice sessions with the trainer. The trainer, Dr Samantha Meredith, is a research fellow and clinical exercise instructor with extensive experience delivering exercise to a range of population groups, including older adults, and within various rehabilitation settings.

Nutrition support: Volunteers will be trained to use the Nutrition Wheel by Dr Samantha Meredith, supported by Prof Jane Murphy, during a 2-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 an opportunity to use the Nutrition Wheel in a role play context.

Behaviour change support: The training, which is based on Healthy Conversation Skills (HCS), will be delivered by a health psychologist (Judit Varkonyi-Sepp). 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 [56]. The training will be 3 hours of in-person interactive learning to support volunteers to deliver exercise and nutrition components in an encouraging, person-centred way, translating MECC principles into practice.

Digital training

To address equality of access, participants can be provided with a tablet with the online teleconferencing platform preloaded. The tablet will contain a SIM card which will enable internet access at home, particularly for participants who do not have internet access. The research fellow will act as a digital champion who will support individuals with low confidence to access the teleconferencing platform. Upon recruitment, participants will be taught how to use the tablet and to access the teleconferencing platform during their hospital stay. They will be given a digital support booklet and will be given guidance about how to stay safe online. Digital support will be available to participants throughout the trial.

Volunteer Support and Fidelity Checks

Throughout the study a peer-supported community will be established through regular online monthly volunteer meetings to discuss experiences and gain feedback from peers and trainers. 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 regular fidelity checks (once per month) to assess the quality of group sessions delivered by volunteers. The volunteers will be observed and assessed against a competency and implementation checklist, including competency checks for the 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 given a training manual to help support their learning and to be used as a resource during delivery of the intervention. Volunteers will also be asked to keep an attendance record during the intervention using session completion logs and will be trained to report any adverse events.

Safety during sessions

Volunteers will be encouraged to 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 taught 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 present and they will be asked to keep cameras on during the

sessions. If a participant feels unwell a Zoom breakout room will enable the participant's well-being to be reviewed in private by a second volunteer.

If an emergency occurs, such as an acute medical event during the session, the volunteer will encourage participants to call their GP, or 111. If concerned about collapse, the volunteer will call 999. Volunteers will have a list of participant's addresses and GPs to hand - in case of collapse. An 'escalation plan' giving clear steps to follow, depending on the emergency situation, will be given to volunteers.

Data Collection

Participant characteristics including age, gender, domicile status, weight, body mass index, malnutrition status (MUST), baseline nutritional status (e.g., use of nutritional supplements and dietician support), co-morbidities (Charlson Co-morbidity Index) [57], cognition (Mini-mental state examination; MMSE) [58] and number of medications will be recorded. Volunteer characteristics recorded will include age, occupation, qualifications, volunteering experience, and employment status.

The primary outcome measures are feasibility and acceptability of the intervention.

Feasibility

The feasibility of implementing a volunteer-led online multi-modal intervention will be assessed by determining the number of volunteers recruited, trained and retained at the end of the study, the number 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.

Acceptability of the intervention

Interviews will be conducted among older adults (N= 6), volunteers (N= 6), and those involved in recruiting participants and training volunteers (N= 3), to determine the acceptability of the intervention and to explore barriers and enablers to the implementation of the intervention. Interviews will be semi-structured to help guide conversation whilst allowing participants the flexibility to elaborate and reflect on any meaningful experiences.

Older adults will be selected by purposive sampling to share their thoughts and views regarding the implementation of the volunteer-led sessions. To ensure a wide range of views are included in the interviews, participants will be selected to ensure equal distribution of male and female patients, ethnicities, and a representative age range. Interviews will also be conducted for volunteers leading the intervention. Discussions among volunteers are likely to generate a wider perspective of the implementation process and may provide insight into the group narrative on their experiences in delivering the intervention and their interaction with the research participants. Interviews will be conducted via telephone and will be audio-recorded for data collection purposes.

The interviews will be semi-structured and consist of several key open-ended questions that will help define the areas explored but allow the interviewer or interviewee to expand and diverge with the aim

of pursuing or developing an idea with more depth. The interview schedules will be underpinned by Normalisation Process Theory (NPT) (see below). The interviews will seek 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 NPT provides a set of sociological tools to understand and explain the social processes through which new or modified practice of thinking, enacting, and organizing work are operationalized in healthcare and other institutional settings. The use of an implementation theory is useful as it helps researchers identify, describe and explain important elements of the implementation process. The three core problems which the theory is concerned with are: implementation (bringing of a practice or practices into action), embedding (routine incorporation of practice or practices into everyday work of individuals and groups) and integration (reproduction and sustainability of a practice or practices among the social matrices of an organization or institution). NPT was used in the development of the study protocol as well as the online physical activity and nutrition intervention. The online NPT toolkit was used to assist in critically thinking through the processes and challenges which may arise in implementing and integrating an intervention in a complex health care setting. NPT was chosen as the framework that underpinned this study as it was systematic in its approach, easy to understand and provided a proven framework to evaluate the implementation process of this study. Determining the acceptability of the intervention through qualitative measures will aid future implementation studies.

Secondary outcome measures: The secondary outcomes will include the measurement of physical activity levels, physical function, appetite, well-being, anxiety and depression, and self-efficacy for managing chronic disease. These measures are detailed below and will be measured at baseline (in hospital), 3 months (via telephone) and 6 months (via telephone).

Physical activity: PA will be measured using the physical activity scale for the elderly (PASE) [59]. The PASE measures a broad spectrum of activities including leisure-time, household, and occupational PA during the previous 7 days, and has good stability and convergent validity within community-dwelling older adults [60].

In addition to the PASE, PA and sleep will be assessed objectively using wrist-worn accelerometers (GENEActiv, Activinsights, Kimbolton, Cambridge, UK). These devices have previously been validated for use in healthy adult populations [61] and are extensively used in clinical studies. 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) [62]. GENEActiv watches will be posted to participants to collect 7 days of objective PA levels upon discharge from hospital (baseline) and at 3 and 6 months. GENEActiv watches will be returned through pre-paid return postage.

Physical function: Barthel Index will be used to measure older adult's functional ability [63]. The Barthel Index consists of ten items and is predominantly used with patient populations and infrequently used for community-dwelling people with reasonable reliability and good responsiveness [64]. The Barthel Index scores 10 items describing ADL and mobility, with a higher number being a reflection of greater ability to function independently following hospital discharge.

Appetite: Appetite will be measured using the Simplified Nutritional Appetite Questionnaire (SNAQ) [65], which has been validated to predict weight loss in community dwelling older adults and used to predict poor health outcomes in hospitalised older people [65-67]. SNAQ is a four-item tool comprising items 1, 2, 4 and 6 of the CNAQ, assessing appetite, satiety, taste of food and number of meals per day respectively. SNAQ has a maximum score of 20, with a score of ≤14 indicating poor appetite.

Well-being: Well-being will be assessed using the Warwick-Edinburgh Well-Being Scale (WEMWBS), which comprises 14 positively worded items relating to different aspects of positive mental health, including positive affect, satisfying interpersonal relationships and positive functioning [68]. Each item is scored on a 5-point Likert scale from 1 (none of the time) to 5 (all of the time), with a higher score indicating a higher level of mental well-being. The WEMWBS is a psychometrically robust scale showing good content validity and popularity in the measurement of well-being in relation to public health [68, 69].

Depression and anxiety: The Hospital Anxiety and Depression Scale (HADS) will be used to assess anxiety and depression [70]. The questionnaire comprises seven questions for anxiety and seven questions for depression, and has been validated across multiple settings and populations [71]. A score of 0-7 is normal, 8-10 borderline abnormal, and 11-21 abnormal.

Quality of life: Quality of life will be measured using the EuroQol (EQ-5D-5L) assessment comprising a short descriptive questionnaire and a visual analogue scale (VAS) [72]. The questionnaire includes 5 domains (e.g., mobility; self-care; usual activities; pain/discomfort; and anxiety/depression) measured with 5 response levels from ‘no problems’ to ‘extreme problems/unable’. The VAS subjectively rates health from 0 (the worst health you can imagine) to 100 (the best health you can imagine). The EQ-5D-5L has been widely used in clinical trials and population studies as a popular measure of health status [73].

Self-efficacy for managing chronic disease: A 6-item scale will be used to assess participant’s self-efficacy in managing their chronic disease [74]. 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 [74]. Each item is scored on a 10-point Likert scale from 1 (not at all confident) to 10 (totally confident). Higher scores indicate higher self-efficacy.

Data Analysis

Quantitative data analysis

Data collected will be double entered into a secured database for analysis. Statistical analysis will be conducted using the statistical software SPSS. Descriptive statistics -median (IQR); mean (SD); number (%) – will be used to analyse the numbers of volunteers recruited, trained and retained, as well as the type and extent of progression of the resistance exercise, and duration of their activity, and patients’ adherence to the intervention. Analysis of the above outcome measures will be used to develop an assessment of the feasibility of delivering this intervention. To determine suitability for a future, fully-powered effectiveness study of the intervention, outcome measures recorded at baseline will be compared to measurement at 3 and 6 months to determine if the intervention had an impact on physical activity levels measured by PASE and GENEActiv, functional outcomes including Katz, Barthel, SNAQ, HADS, WENWBS, self-efficacy and 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 of clinical staff involved in delivering the training.

Qualitative data analysis

Data collected from the interviews will be transcribed verbatim and analysed using thematic analysis (TA). The audio-recordings will be transcribed by an administrative colleague within the research department who is experienced in transcribing qualitative data. TA is a method for identifying, analysing and reporting patterns or themes within data and is widely used in qualitative research [75]. There are six phases in the process of conducting TA: 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 either Microsoft Word, or with the help of NVIVO, depending on the amount of data collected. Transcribed text will be read and coded separately and then together by two researchers. The codes will be analysed to generate concepts and ideas to determine the acceptability of the intervention, and to identify facilitators and barriers to the implementation process. The codes act as tags or labels to help catalogue key concepts embedded within the raw data. From the codes, themes will be developed to reflect the views and experiences of the community-dwelling older adults and volunteers regarding the community-based PA intervention.

6 STUDY SETTING

This is a single-centre feasibility study taking place at University Hospital Southampton NHS Foundation Trust. Patients on the discharge pathway will be identified and recruited from acute medical wards at UHS and volunteers will be recruited from UHS voluntary services. Volunteers will complete study training at UHS and will deliver the online intervention from UHS. Recruited older adults with frailty will participate in an online intervention from their own home upon discharge from hospital. Interviews will take place on the phone, or an online platform while participants are at home.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

Older adults with frailty discharged from UHS and volunteers from the UHS patient support hub will be invited to participate in this study (see details below).

7.1.1 Inclusion criteria

Patients:

- Older adults aged 65 years and above
- Able to provide written consent
- Discharged from UHS
- Identified as frail (Clinical Frailty Scale ≥5)
- Able to walk at least a few steps upon hospital discharge
- Able to communicate fluently enough in English

Volunteers:

- Established volunteers at UHS patient support hub

- Age 16 years and above
- Completed the generic volunteer clearance and training at UHS
- Able to provide written informed consent
- Able to communicate fluently enough in English

7.1.2 Exclusion criteria

Patients:

- 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:

- Volunteers who are unable to safely complete the exercises included in the intervention will be excluded from the study

7.2 Sampling

Participants will be recruited from UHS using purposive sampling techniques (detailed below).

7.2.1 Size of sample

Patients: A sample size of 23 participants was chosen in line with previous sample size recommendations for feasibility studies of 12-50 participants (Julious, 2005) [76, 77]. This sample size was considered an appropriate number that is pragmatic and achievable within the study timescale and resources available.

Volunteers: A sample size of 6 volunteers was chosen to provide sufficient cover to deliver the Frail2Fit intervention to groups of 5-6 older adults with 2 volunteers supporting each group.

7.2.2 Sampling technique

Purposive sampling will be applied to recruit patients on UHS acute medical wards to participate in the study, who meet the characteristics and eligibility criteria. Purposive sampling of volunteers from the UHS patient support hub will be applied to select appropriate volunteers who meet eligibility criteria for the study.

7.3 Recruitment

Eligible patients will be identified and approached initially by their clinical care team, and volunteers will be identified and approached by the UHS voluntary services manager before being approached by the research team (details below).

7.3.1 Sample identification

Patients: Older adults on acute medical wards at UHS will be informed about the opportunity to participate in the study by ward staff. The clinical care team will identify eligible patients for participation in the research in line with inclusion criteria through existing access to their medical records. Ward staff will liaise closely with the research team to inform them of interested participants. Patients interested in the study will then be approached by the research team who will complete informed consent and additional screening checks to determine their suitability to participate in the study, including the clinical frailty scale (CFS).

The CFS is a judgment-based frailty tool that evaluates specific domains including comorbidity, function and cognition to generate a frailty score on a 9-point scale ranging from 1 (very fit/robust and active) to 9 (terminally ill) [78]. The CFS is a valid and reliable measure of frailty in older people and is associated with a range of clinical outcomes including comorbidity, falls, cognition, function, and mortality [79]. Patients scoring ≥5 on CFS will be eligible to participate in the study.

Volunteers: Volunteers will be identified by hospital voluntary services within the UHS patient support hub, managed by Emma Squires. The patient support hub helps ensure patients with a range of needs are supported in their own homes following discharge from hospital, including providing food parcels, and befriending services. The patient support hub recruits volunteers with an interest in supporting patients post-discharge with practical and emotional support. The research team will liaise closely with the patient support hub in the recruitment and support of volunteers interested in participating in the Frail2Fit study. The support hub team will identify and approach existing patient support hub volunteers to invite them to the study. All volunteers associated with the support hub will have appropriate clearance and training from UHS. Interested volunteers will be approached by the research team with a participant information sheet and if they meet eligibility criteria (i.e., no contraindications to the exercise component) they will complete informed consent. Two volunteers will be matched based upon volunteer experience levels to deliver the Frail2Fit intervention to a group of 5-6 participants (i.e., any newer volunteers will be matched with experienced support hub volunteers).

7.3.2 Consent

The clinical care team, or volunteer services manager will inform the research team of any interested patients and volunteers, respectively. Interested participants will then be approached by the research team to explain the study in more depth and given a participant information sheet. If the participants are still keen to volunteer following response to any of their questions and explanation of the participant information sheet, then they will complete a written consent form.

Participants will be given 2 days to decide if they would like to volunteer in the study. This will give participants time to consider their involvement in the study, to discuss the study with family and to ask any questions, while also enabling recruitment for the study before patients are discharged. All members of the study team are adequately trained in Good Clinical Practice (GCP) and have experience taking informed consent in previous research.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

There are minimal risks involved in this study. This study does not involve any invasive procedure. It is perceived that the benefits of the intervention outweigh potential risks. 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 the study is that volunteers and patients will be taught evidence-based exercises and nutrition advice which will be conducted in group online sessions. Moreover, 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.

Although the risks involved in the study are minimal, common injuries that may occur during exercises include muscle strain and back pain. Nevertheless, these risks will be reduced through various approaches explained below. Hospital volunteers are covered by NHS indemnity insurance in the case of any adverse events.

- Volunteers will complete evidence-based training modules to ensure they are competent to deliver the intervention to frail older adults. All volunteers recruited by voluntary services at the hospital have completed generic safety checks (e.g., criminal record checks) and basic training (e.g., health and safety).
- Volunteers will be taught 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.
- Throughout the study period, fidelity checks will be conducted by the trainers once every 2 weeks to ensure that the volunteers are delivering high quality group sessions. The volunteers will be observed and assessed against a competency and implementation checklist, including competency checks for the exercise, nutrition, and behaviour change components.
- 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).
- Where possible participants will be encouraged to undertake the sessions with friends or family members present and they will be asked to keep cameras on during the sessions.
- If a participant feels unwell a Zoom breakout room will enable the participant's well-being to be reviewed in private by a second volunteer.
- If an emergency occurs, such as an acute medical event during the session, the volunteer will encourage participants to call their GP, or 111. If concerned about collapse, the volunteer will call 999.
- Volunteers will have a list of participant's addresses and GPs to hand - in case of collapse. An 'escalation plan' giving clear steps to follow, depending on the emergency situation, will be given to volunteers.
- Volunteers will be trained to support participants using the nutrition wheel and will not be expected to give participants specialised nutrition advice. Volunteers will be trained to effectively and safely signpost participants to suitable resources and health professional support based upon answers given from the nutrition wheel.

A potential burden for some patients could be issues with learning new technology or having minor difficulties in accessing Zoom from home. To address equality of access, participants will be provided with a tablet with the online teleconferencing platform preloaded. The tablet will contain a SIM card which will enable internet access at home, particularly for participants who do not have internet

access. The research fellow will act as a digital champion who will support individuals with low confidence to access the teleconferencing platform. Upon recruitment, participants will be taught how to use the tablet and to access the teleconferencing platform during their hospital stay. Digital support will be available to participants throughout the trial.

Participants will be given the option to choose between the online intervention and telephone consultations. Participants who opt for telephone consultations will be encouraged by volunteers to perform the exercises provided in the booklet and will be given nutritional advice. The frequency of telephone consultations will be similar to the online intervention.

Previous research (the ImPACt study) has gained feedback from interviews with volunteers and found some volunteers experienced an increased sense of purpose and belonging and improved confidence through leading the health intervention with older adults. Nevertheless, some volunteers described a small burden level, especially if they were volunteering on their own. In response to this feedback, we will ensure that 2 volunteers will be allocated per group of 5-6 participants, so the volunteers can provide support to each other during the sessions and can 'cover' each other if they are unavailable. Two volunteers to each group worked better in previous research (the ImPACt study) and helped to reduce any burdens the volunteers might have felt having to support and lead the group on their own. In addition, the trainer will supervise the volunteers closely during the first month of the intervention to ensure they are adequately supported, confident and competent to deliver the intervention. The trainer will be freely available throughout the study to support volunteers, including provision of extra one-to-one training sessions and regular monthly volunteer catch-up meetings to ensure that the volunteers are flourishing.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

This study will require ethical approval from the Health Research Authority (HRA). We will submit this study for review to the HRA NHS Research Ethics Committee through the Integrated Research Application System.

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Discontinuation/Withdrawal of Participants from Study:

Each participant has the right to withdraw from the study at any time and request that any data collected be deleted. It will not be possible for the participant to withdraw their data once the analysis has started because the data collected will already be pseudonymised and have been used.

Participants can withdraw from the study without giving a reason by contacting the research team.

Regulatory Review & Compliance

Before any site can enrol participants into the study, the Chief Investigator/Principal Investigator will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

For any amendment to the study, the Chief Investigator/Principal Investigator, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator/Principle Investigator will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Amendments also need to be notified to the national coordinating function of the UK country where the lead NHS R&D office is based and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site. Note that some amendments that may be considered to be non-substantial for the purposes of REC still need to be notified to NHS R&D (e.g. a change to the funding arrangements).

The amendment history will be tracked through allocating version numbers and dates to the protocol and any study resources, which will be kept on electronic file by the CI and study sponsors.

8.3 Peer review

The protocol has undergone proportionate review to assess the scientific robustness and clinical safety of the study by 2 independent experts in the field of Academic Geriatric Medicine and the funder from the University Hospital Southampton NHS Foundation Trust. No reviewers have been involved in the development of the protocol.

8.4 Patient & Public Involvement

We have previously gathered the views from 92 older people from lunch clubs (42), care homes (11) and a hospital (39) regarding the use of volunteers in supporting personal care of hospitalised older adults. 45% of the respondents had experience with hospital volunteers and all spoke highly of their contribution. Most participants thought volunteers could be trained to help with mobility.

In the Southampton Mobility Volunteer study (SoMoVe), patients spoke highly of the volunteers and appreciated the motivation and encouragement received to walk or perform exercises [44]. The social interaction with the volunteers was also a positive experience. A recent survey was conducted to gather the views of older adults attending community clubs regarding the use of trained volunteers to deliver group exercises. 47 of the 50 club attendees agreed or strongly agreed to have volunteers lead the group exercises.

Our previous work has shown that older people are keen to work with volunteers and have reported positive experiences in their interaction with them. Wessex Fit 4 Cancer group includes an established patient representation group including sitting members of the board and trial steering groups. They were key contributors to the online trial design and training package.

Two public and patient representatives (PPIR) provided input into this study proposal. They reviewed the plain English summary and study proposal and proposed minor changes. Their input will also be sought in the development of the study protocol. They will review all patient-facing materials to ensure that adequate information is provided to patients and that any written information is understandable and jargon-free. PPIR will also be invited to join the study management group. This group will aim to meet up quarterly to discuss the study progress and PPIR will be involved throughout the study process from development to dissemination of study findings.

8.5 Protocol compliance

Protocol compliance will be managed by the CI, study management team and study sponsor. Accidental protocol deviations can happen at any time. Protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

8.6 Data protection and patient confidentiality

The study staff will ensure that the participants' anonymity is maintained. Data will be identified only by a participant ID number. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with GDPR and the Data Protection Act 2018, which requires data to be anonymised as soon as it is practical to do so.

Participation and all the information collected about participants 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 participant data 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 participant data. All of these people have a duty to keep participant information strictly confidential.

Data collected will be entered electronically on to a 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 the data. In accordance with regulations

we are required to keep participant data secure for 10 years. The data may be used in future studies by our research team. If this happens, participant data will be used anonymously (non-identifiable participant information) so participants cannot be identified. Any new research studies using participant data will be authorised by the local research ethics committee.

All participants will be made aware of the information collected during the research study during processes of informed consent through participant information sheets, discussions with the research team and completion of consent forms.

8.7 Indemnity

University Hospital Southampton NHS FT has a specialist insurance/indemnity policy/scheme in place to:

1. Meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research
2. Meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research
3. Meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research.

The sponsor(s) has not made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises.

8.8 Access to the final study dataset

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

9 DISSEMINIATION POLICY

9.1 Dissemination policy

The data arising from the study will be the intellectual property of the University of Southampton. On completion of the study, data will be analysed, and a final study report will be prepared. The study report can be accessed via clinicaltrials.gov and the ARC Wessex website (NIHR Applied Research Collaboration for Wessex). Research findings will be made available to research participants upon request.

The study findings will be presented at national and international scientific meetings. They will also be published in peer-reviewed journals to disseminate findings to the scientific community. Social media platforms such as Twitter, Facebook and blogs will also be used to disseminate research findings, which will achieve a wider reach of scientific and lay communities. Members of PPI in the steering group will also provide input on other dissemination methods and ideas. This feasibility and acceptability study will provide a blueprint for future implementation studies on a larger scale. On completion of this study we will work with Wessex AHSN and the National Association of Voluntary Services Manager to develop an

implementation plan with the aim to roll out the intervention across the Hampshire and Isle of Wight region and nationally at a later stage.

9.2 Authorship eligibility guidelines and any intended use of professional writers

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authorship will be determined per the ICMJE guidelines and other contributors will be acknowledged.

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11. APPENDICIES

11.1 Appendix 1- Required documentation

CV of Chief Investigator

Participant Information Sheet

Participant Consent Form

Consultant Letter

Referee's Report

Letter from Funder

Data Collection Booklet

Interview Schedule

Screening and Escalation Plan

11.2 Appendix 2 – Schedule of Procedures

Procedures	No. received per participant	Time	Who	Location
Written consent (volunteers & patients)	1	5-10 mins	SL & SM	Hospital Wards
Questionnaire pack data collection (patients)	3	30-45 mins	SM	Baseline: on hospital wards. 3 and 6 month Collections: on the telephone with participants at home.
Questionnaire measuring characteristics (volunteer)	1	15-20 mins	SM	Telephone while participant at home
Volunteer training	4	1-2 hours	SM / SL/ Dietician / Psychologist	Depending on covid guidelines the training will either be online (e.g., Zoom, or Teams), or will be in-person at UHS.
Volunteer fidelity check	4-6	1 hour	SM	Observing volunteers online while they deliver intervention.
Group volunteer meeting	3	30-45 mins	SM / SL	Online (Zoom, or Microsoft Teams)
Interview (volunteers and patients)	1	25-45 mins	SM	Telephone, or online.
Physical activity measurement - wearing GENEActiv watch (patients)	3	7 days	SM	Baseline assessment: on the ward at UHS. 3 and 6

				month assessments: participant's home, in which watches will be posted out.
Group exercise and nutrition intervention	24	1 hour	Trained Volunteers	Online (Zoom)

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

Stephen Eu Ruen Lim

Profile

GMC number: 7082136

Job description: Consultant Geriatrician, Clinical Academic in Geriatric Medicine

Current post: University Hospital Southampton NHS FT

Qualifications

Bachelor of Medicine, Bachelor of Surgery,	
University of Southampton	July 2010
MRCP Part 1	October 2011
MRCP Part 2	May 2012
MRCP Paces	July 2013
Speciality Certificate Examination in Geriatric Medicine	April 2016
PhD in Human Development and Health,	
University of Southampton	December 2018

Appointments held

Consultant Geriatrician, University Hospital Southampton NHS FT

NIHR Academic Clinical Lecturer and Honorary Specialist Trainee in Geriatric Medicine, Southampton General Hospital, Salisbury District Hospital, Lymington New Forest Hospital, 2018-21

ST6 in Geriatric Medicine, Queen Alexandra Hospital, 2017-18

NIHR CLAHRC Clinical Research Fellow and Honorary Specialist Trainee in Geriatric Medicine, Southampton General Hospital, 2015-17

NIHR Academic Clinical Fellow and ST3 in Geriatric Medicine, Southampton General Hospital 2014-15

Core Medical Trainee 1 & 2, Queen Alexandra Hospital, 2012-13

Foundation year trainee 1 & 2, Southampton General Hospital, Lymington New Forest Hospital, 2010-12

Fellowships/ Grants

1. NIHR Academic Clinical Fellowship (2014–15)
2. NIHR CLAHRC Wessex. SoMoVe study: **£90,369.00** (2015-17) (Principal investigator)
3. NIHR Academic Clinical Lecturer in Geriatric Medicine (2018–21)
4. British Geriatrics Society Specialist Registrar Grant 2018 : **£1000**
5. NIHR ARC Wessex. ImPACt study: **£82,363.80** (2020-22) (Principal investigator)
6. NIHR ARC Wessex. Implementing Digital Activity study: **£38,000.00** (2021–22) (Co-Investigator)
7. The Burdett Trust for Nursing Pneumo 65 study: **£100,000** (2019-2022) (Co-investigator)
8. University Hospital Southampton NHS Trust. Wessex Frail2fit study: **£51,019** (2021-23 (Lead investigator)
9. University Hospital Southampton Research Leaders' Programme: **£51,735.40** (2022-2025) (Lead applicant)

Awards/ Prizes

1. NIHR Annual Trainees Meeting 2016 – **Poster competition prize winner**
2. University of Southampton Health and Medical research conference 2017 – **Highly Commended award for poster presentation**
3. University of Southampton Faculty of Medicine 3 minute thesis competition 2018 – **Winner**
4. University of Southampton 3 minute thesis grand final 2018 – **People's Choice Winner**
5. Southampton Medical and Health Research Conference 2018 – **3 Minute Oral Presentation Prize Winner**

6. 9th NIHR Infrastructure Doctoral Research Training Camp 2018 – **Highly Commended Poster Award**
7. British Geriatrics Society Autumn Meeting 2018 **Presidential Abstract Round**
8. Royal College of Physician **Turner-Warwick Lecturer** 2019
9. British Geriatrics Society Autumn Meeting 2019 **Presidential Abstract Round**
10. University of Southampton – **Michael Arthur Research Prize** 2020 (for the best research publication by a clinical academic trainee)

Publications

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5. Lim S, Ibrahim K, Dodds R, Purkis A, Strike G, Baxter M, Rogers A, Sayer AA, Roberts HC. *Increased physical activity levels among hospitalised older people: The role of trained volunteers*. Age and Ageing 2019;48(supp 1):i27-i30
6. Lim SER, Cox NJ, Roberts HC. *The effectiveness of volunteer-led physical activity interventions in improving health outcomes for community-dwelling older people: a systematic review*. Age and Ageing 2020; 49(supp 1):i30-i32
7. Cox NJ, Lim SER, Baylis D, Howson F, Sayer AA, Roberts HC. *Poor appetite is common in hospitalised older people and associated with subclinical low mood*. Age and ageing 2020;49(supp 1):i34-i36

Official Functions

1. Trustee for Bethany Care Home (2019 – current)
2. Chair of the British Geriatrics Society Trainees' Council (2017 – 2019)
3. Trustee and director of the British Geriatrics Society (2017 – 2019)
4. Chair-elect of the European Geriatric Medicine Society Geriatric Emergency Medicine Special Interest Group (2021 – current)
5. Committee member of the NICE Advocacy guidance committee (2021 – current)
6. Member of the European Academy for Medicine of Aging (2021 – current)

Roles

1. Personal academic tutor (3 University of Southampton medical students)
2. PhD supervision (1 University of Southampton PhD candidate)
3. Supervision of a post-doctoral research fellow

Membership

1. Royal College of Physicians
2. British Geriatrics Society
3. Medical Protection Society
4. British Medical Association
5. European Geriatric Medicine Society

Scientific Functions

1. Reviewer for Age and Ageing, PLOS One, Frontiers in Medicine, Clinical Medicine, BMC Geriatrics and Journal of Aging and Physical Activity

Invited lectures

1. NIHR Ageing and BGS Wessex meeting: Clinical Academic Training, Southampton, UK, June 2015
2. NIHR CLARHC Wessex Stakeholders Meeting: Southampton Mobility Volunteer study, Southampton ,UK, June 2016
3. NIHR CRN Ageing and BGS Wessex conference: Southampton Mobility Volunteer study, Bournemouth, UK December 2016
4. Helpforce Conference: Southampton Mobility Volunteer study, London, UK, June 2017
5. British Geriatrics Society Autumn Meeting: Deconditioning among hospitalised older people, London, UK, November 2017

6. NIHR CLAHRC Away Day: Delivering the future for Applied Health Research: the role of volunteers, Southampton, UK, January 2018
7. Healthcare Conference UK: Getting patients up, dressed and moving, London, UK, January 2018
8. Healthcare Confrence UK: Getting patients up, dressed and moving, London, UK, May 2018
9. NIHR CLAHRC Celebrating Ageing research conference 2018
10. Wessex Geriatric Medicine Training Day: Sarcopenia in older adults, Basingstoke, UK, Basingstoke, January 2019
11. North West British Geriatrics Society Regional meeting: Sarcopenia, London, UK, September 2019
12. University of Bournemouth Falls Insight workshop, Bournemouth, UK, December 2019
13. NIHR ARC Launch Event: Physical Activity among community-dwelling older adults: The ImPACt study, Basingstoke, UK, October 2019
14. European Geriatric Medicine Society Congress – Geriatric Emergency Medicine symposium. Athens, Greece October 2021

Teaching activities

Undergraduate

1. Supervision of 3rd year medical student BMedSci research project, University of Southampton
2. Examiner of 3rd year medical student research project, University of Southampton
3. 3rd year and final year medical students Objective Structured Clinical Examination (OSCE) examiner
4. Final Year medical students Assessment of Clinical Competence (ACC) examiner, University of Southampton
5. Annual lecture for international transfer students, University of Southampton
6. Formal departmental teaching for medical students attached to the Geriatric Medicine department
7. SBOM lectures and seminars for medical students, University of Southampton

8. Organised national meeting to promote Geriatric Medicine among medical students, Nov 2019

Postgraduate

1. Formal departmental teaching for junior doctors at the Geriatric Medicine department, University Hospital Southampton NHS FT, Queen Alexandra Hospital
2. Teaching for senior house officers preparing for the MRCP PACES examination
3. Organised national meeting on Frailty and Sarcopenia April 2019
4. Teaching session at an international post-graduate course (EAMA) June 2019
5. Teaching session at an international post-graduate course (EAMA) Jan 2020

Research Presentations

1. BGS and NIHR Wessex Ageing 2015 – Oral presentation
2. NIHR Annual Trainee's Meeting 2015 – Poster presentation
3. NIHR CLAHRC Wessex Annual Stakeholder's Event 2016 – Oral presentation
4. University of Southampton Faculty of Medicine Research Conference 2016 - Poster presentation
5. NIHR Trainee's Meeting 2016 – Poster presentation
6. BGS Spring Meeting 2017 – Poster presentation
7. University of Southampton Faculty of Medicine Research Conference 2017 – Poster presentation
8. University Hospital Southampton Quality Improvement conference 2017 – Oral presentation
9. BGS and CRN ageing research meeting 2017 – Oral presentation
10. European Geriatric Medicine Society congress, Nice, France 2017 – Poster presentation
11. Southampton Medical and Health sciences research conference 2018 – Poster and oral presentation
12. Rank Prize symposium on Nutrition – Oral presentation 2018
13. 9th NIHR Infrastructure Doctoral Research Training Camp 2018 – Poster presentation

14. European Geriatric Medicine Society congress, Berlin, Germany 2018 – Poster presentation
15. British Geriatrics Society Autumn meeting 2019 – Poster presentation
16. University of Southampton Faculty of Medicine Research Conference 2020 - Poster presentation
17. University of Southampton Faculty of Medicine Research Conference 2020 – Michael Arthur Research prize- Oral presentation

Conference organisation

1. Geriatrics for Undergraduate, University College London. November 2019

Media

1. NIHR CLAHRC Wessex Media training
2. BBC South Today interview Jan 2018
3. British Geriatrics Society Media training
4. NIHR ARC Launch event Oct 2019
5. Nursing Older People magazine interview

Impact

1. Nomination for UHS Hospital Heroes award, 2017
2. Research presentation with the Minister of Civil Service, 2015

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.

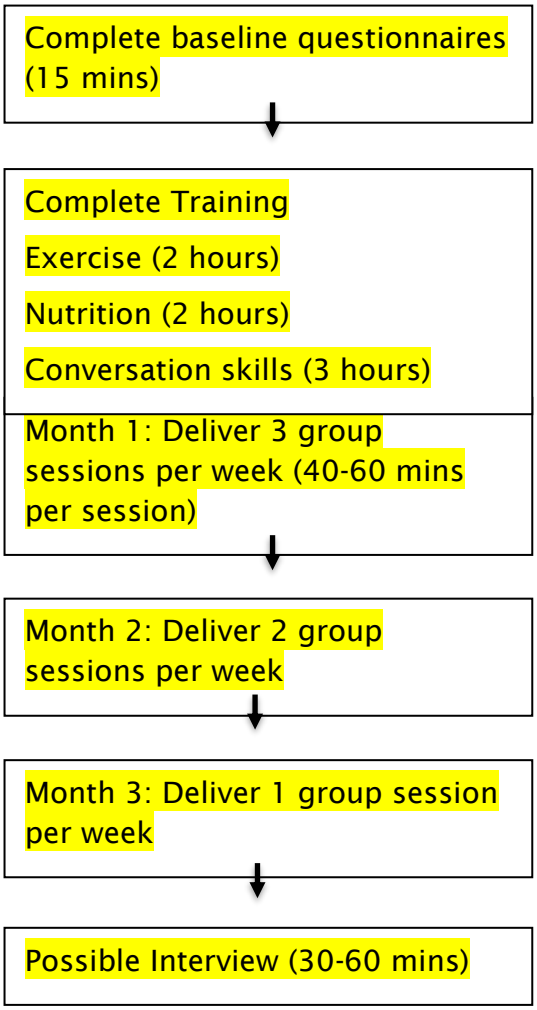
What will happen in case of an emergency?

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 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


Complete baseline questionnaires (15 mins)
Complete Training
Exercise (2 hours)
Nutrition (2 hours)
Conversation skills (3 hours)
Month 1: Deliver 3 group sessions per week (40-60 mins per session)
Month 2: Deliver 2 group sessions per week
Month 3: Deliver 1 group session per week
Possible Interview (30-60 mins)

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.

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 (Family Member/Carer)

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 family member or a carer of an older adult taking part in the online exercise and nutrition programme.

What will happen to me if I take part?

You will be invited to attend an interview to share your views and experiences on physical activity and nutrition support for frail older adults. We would like to find out your opinions on your family member, or client, taking part in the online nutrition and exercise support sessions to see what we can do to improve the delivery of the programme. Interviews will take place over the phone, or online (e.g., Zoom) depending on your personal preference. Interviews will be audio-recorded. 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.

Are there any benefits in my taking part?

By taking part in this study, you will help us better understand what we can do to improve the online exercise and nutrition support programme. This is an important step as we look to expand the programme in future studies. You will be contributing towards the improvement of health and care of older people.

Are there any risks involved?

There are minimal risks involved in this study. You will be interviewed by me on the telephone. The interview will be kept confidential, with your details anonymised. This study does not involve any invasive procedure.

What data will be collected?

You will be interviewed to explore your views and experiences about the exercise and nutrition programme. 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.

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 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.

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.

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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 (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.

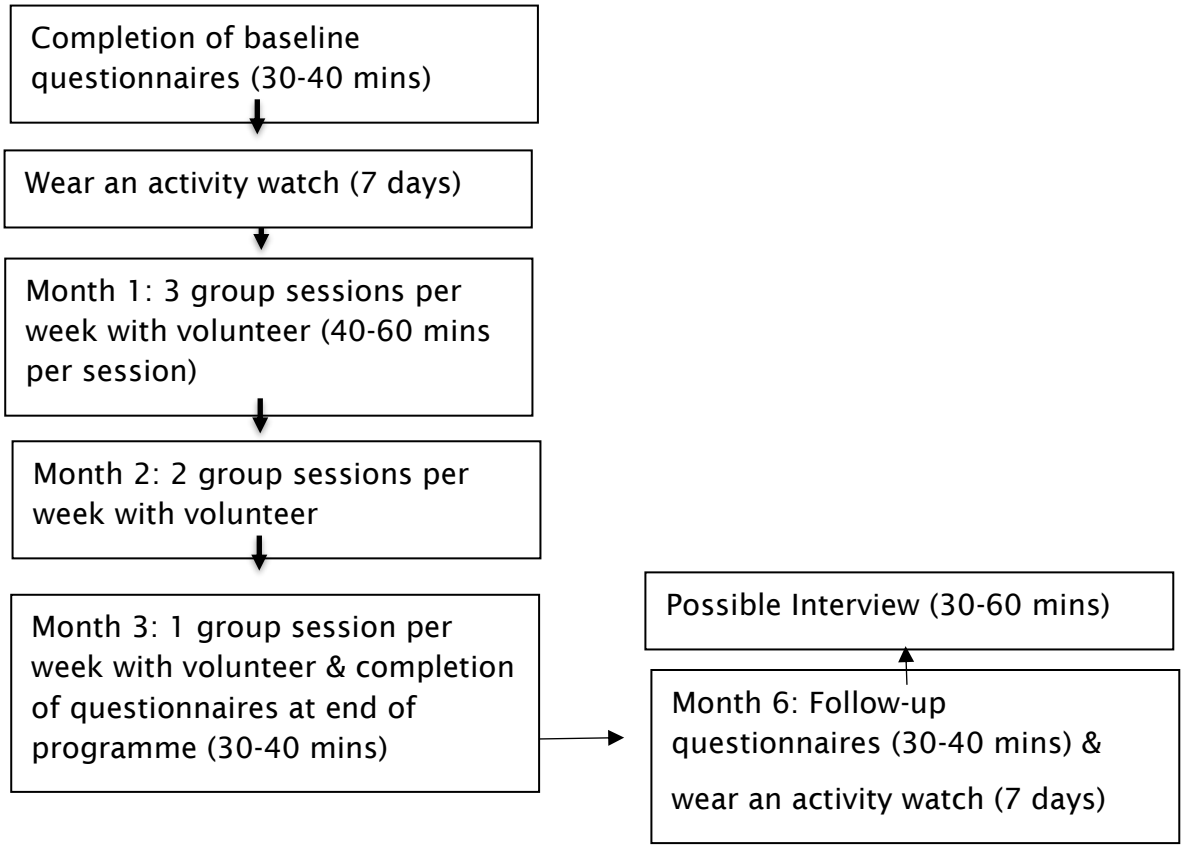
Evaluating the programme

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


Completion of baseline questionnaires (30-40 mins)
Wear an activity watch (7 days)
Month 1: 3 group sessions per week with volunteer (40-60 mins per session)
Month 2: 2 group sessions per week with volunteer
Month 3: 1 group session per week with volunteer & completion of questionnaires at end of programme (30-40 mins)
Month 6: Follow-up questionnaires (30-40 mins) & wear an activity watch (7 days)
Possible Interview (30-60 mins)

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.

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 <u>initial</u> 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]

Clinical Care Team Notification Letter

UHS Frail2Fit Feasibility Study: A feasibility and acceptability study of a virtual multimodal intervention delivered by volunteers to improve functional outcomes of frail older adults discharged from hospital

Dear UHS Clinical Care Team Date: **XXX**

Your patient, **XXX**, has agreed to take part in the above feasibility study. This is a quasi-experimental mixed methods feasibility study co-ordinated by the study management team at the University of Southampton and the research sponsor at University Hospital Southampton NHS Foundation Trust.

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

This study will involve your patient completing a 12-week volunteer-led online intervention, including evidence-based exercise training, nutrition and behaviour change support. We will assess your patient's physical activity, appetite, physical function, well-being, anxiety and depression, and health self-management, using validated questionnaires at baseline, 3 months and 6 months post-intervention. We will also assess objective physical activity levels using an accelerometer for 7 days at baseline, 3 months, and 6 months. Your patient may also be asked for an interview to explore their experiences participating in the intervention.

Your patient has been provided with verbal and written information for the study (copy enclosed) which explains why s/he has been approached to take part in the research, that the participation is entirely voluntary, and emphasises that they are free to withdraw from the study at any time without prejudicing their future medical care.

Should you have any questions or require further information about this research, please do not hesitate to contact the chief investigator in charge of the local study.

Dr Stephen Lim, Consultant Geriatrician, Academic Geriatric Medicine, University Hospital Southampton NHS FT, Tremona Road, Southampton, SO16 6YD Telephone: 02381206131. Email: s.e.lim@soton.ac.uk

Yours sincerely,

Dr Samantha Jane Meredith

Research Fellow
University of Southampton
Academic Geriatric Medicine
s.j.meredith@soton.ac.uk

University Hospital Southampton NHS Foundation Trust

Scientific Peer Review Form

PROJECT TITLE	Frail2Fit
CHIEF INVESTIGATOR	Stephen Lim
STUDENT (if applicable)	

All studies which are requesting sponsorship from University Hospital Southampton NHS Foundation Trust will require **two** supporting peer reviews to assist in the verification of the scientific quality and robustness of the study.

Please note no internal peer review is required for projects where an external body is undertaking a review as part of a funding application but should include confirmation of the funding award with the Sponsorship request.

SCIENTIFIC QUALITY PEER REVIEW	**ASSESSMENT CRITERIA**			
	YES	**NO**	**UNCLEAR**	***N/A***
1. Study Design	☒	☐	☐	☐
Does the research have a clear protocol?	☒	☐	☐	☐
Is the research question or hypothesis clearly stated?	☒	☐	☐	☐
Are the project objectives described?	☒	☐	☐	☐
Are the objectives realistic?	☒	☐	☐	☐
Has other relevant research been reviewed?	☒	☐	☐	☐
Is the methodology appropriate to the research question?	☒	☐	☐	☐
Have the methods of measurement been described?	☒	☐	☐	☐
Has the reliability and validity of measurement been reviewed?	☒	☐	☐	☐

If available, are validated scales of measurement being used?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				
2. Study sample and data analysis	☒	☐	☐	☐
Is the proposed population group appropriately representative?	☒	☐	☐	☐
Is the sample size justified and realistic?	☒	☐	☐	☐
Are the methods of data analysis (statistical or otherwise) described and appropriate?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				
3. Impact and importance	☒	☐	☐	☐
Are the expected values and benefits of the research clear?	☒	☐	☐	☐
Will the research add to current knowledge or have training value?	☒	☐	☐	☐
Is the research generalisable i.e. have potential application beyond the Trust?	☒	☐	☐	☐
Will the findings lead to significant health gains and/or benefit the Trust/ NHS/ population?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				

4. Dissemination	☒	☐	☐	☐
Do the researchers intend to disseminate research findings in an appropriate journal ?	☒	☐	☐	☐
Will the results of the research be made available to research participants?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				
5. Feasibility	☒	☐	☐	☐
Is the research feasible within the local context?	☒	☐	☐	☐
Is the project feasible within the timeframe and resources proposed?	☒	☐	☐	☐
Is the proposed research likely to put the Trust, Trust staff, participants in the research or the applicants at risk, which are such that these should specifically be taken into account when deciding whether or not to support the research?	☐	☒	☐	☐
Where relevant, has a multidisciplinary and multi-professional approach to addressing the research question been adopted?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				
6. Consumer Involvement	☒	☐	☐	☐
Where relevant, have patients or their representatives been involved in this project?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				

OVERALL RATING (Scale of 1-5 were 1 indicates poor, 3 acceptable and 5 excellent)	4

Overall Comments

Please provide comments you may wish to make on the proposal, particularly any suggestions as to how the project could be amended. Your comments will be used to provide feedback to the Principal Investigator.

Very interesting study proposal! It would be useful to perhaps explain further the intervention for each session, i.e. how long is it session, will all components be delivered each session or one component session etc.

REVIEWER RECOMMENDATION	*Approve:* ☒ *Approve with amendments described above:* ☐

	Resubmit after amendments described above: ☐ Reject: ☐
Signature: **(please provide a physical signature and not a copy of a scanned example)**	
Printed Name:	*Dr Qian Yue Tan*
Job Title & Organisation:	*Clinical Research Fellow and Specialty Registrar in Geriatric Medicine, University Hospital Southampton NHS FT*
Date:	*21st February 2022*

University Hospital Southampton NHS
NHS Foundation Trust

University Hospital Southampton NHS Foundation Trust
Scientific Peer Review Form

PROJECT TITLE	Frail2Fit: A feasibility and acceptability study of a virtual multimodal intervention delivered by volunteers to improve functional outcomes of frail older adults discharged from hospital.
CHIEF INVESTIGATOR	Dr Stephen Lim
STUDENT (if applicable)	

All studies which are requesting sponsorship from University Hospital Southampton NHS Foundation Trust will require **two** supporting peer reviews to assist in the verification of the scientific quality and robustness of the study.

Please note no internal peer review is required for projects where an external body is undertaking a review as part of a funding application but should include confirmation of the funding award with the Sponsorship request.

SCIENTIFIC QUALITY PEER REVIEW	ASSESSMENT CRITERIA			
	YES	NO	UNCLEAR	*N/A*
1. Study Design	☐	☐	☐	☐
Does the research have a clear protocol?	☒	☐	☐	☐
Is the research question or hypothesis clearly stated?	☒	☐	☐	☐
Are the project objectives described?	☒	☐	☐	☐
Are the objectives realistic?	☒	☐	☐	☐
Has other relevant research been reviewed?	☒	☐	☐	☐
Is the methodology appropriate to the research question?	☒	☐	☐	☐
Have the methods of measurement been described?	☒	☐	☐	☐
Has the reliability and validity of measurement been reviewed?	☒	☐	☐	☐
If available, are validated scales of measurement being used?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				

2. Study sample and data analysis	☐	☐	☐	☐
Is the proposed population group appropriately representative?	☒	☐	☐	☐
Is the sample size justified and realistic?	☒	☐	☐	☐
Are the methods of data analysis (statistical or otherwise) described and appropriate?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				

3. Impact and importance	☐	☐	☐	☐
Are the expected values and benefits of the research clear?	☒	☐	☐	☐
Will the research add to current knowledge or have training value?	☒	☐	☐	☐
Is the research generalisable i.e. have potential application beyond the Trust?	☒	☐	☐	☐
Will the findings lead to significant health gains and/or benefit the Trust/ NHS/ population?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				

4. Dissemination	☐	☐	☐	☐
Do the researchers intend to disseminate research findings in an appropriate journal ?	☒	☐	☐	☐
Will the results of the research be made available to research participants?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				

5. Feasibility	☐	☐	☐	☐
Is the research feasible within the local context?	☒	☐	☐	☐
Is the project feasible within the timeframe and resources proposed?	☒	☐	☐	☐
Is the proposed research likely to put the Trust, Trust staff, participants in the research or the applicants at risk, which are such that these should specifically be taken into account when deciding whether or not to support the research?	☐	☒	☐	☐
Where relevant, has a multidisciplinary and multi-professional approach to addressing the research question been adopted?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate: No specific risks identified to be taken into account				

6. Consumer Involvement	☐	☐	☐	☐
Where relevant, have patients or their representatives been involved in this project?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				

OVERALL RATING (Scale of 1-5 were 1 indicates poor, 3 acceptable and 5 excellent)	4

Overall Comments

Please provide comments you may wish to make on the proposal, particularly any suggestions as to how the project could be amended. Your comments will be used to provide feedback to the Principal Investigator.

A well designed study with clear outline of appropriate methodology for the research questions and feasible objectives with embedded PPI. The aspects of the intervention are clearly described; I have a minor comment that information on the delivery of these aspects alongside one another to each participant could be strengthened. It is currently a little unclear how the personalised interventions of nutrition-wheel based discussions and client-centred conversations as part of MECC will sit within the regular group online exercise sessions, will these be a breakout one-to-one sessions or the whole group? A clearer outline of the anticipated intervention contact(s) might make this clearer for potential participants for this feasibility and acceptability study.

REVIEWER RECOMMENDATION	Approve: ☒ Approve with amendments described above: ☐ Resubmit after amendments described above: ☐ Reject: ☐
Signature: **(please provide a physical signature and not a copy of a scanned example)**	
Printed Name:	Dr Natalie Cox
Job Title & Organisation:	Clinical Research Fellow NIHR Southampton BRC
Date:	22/2/2022

University Hospital Southampton NHS
NHS Foundation Trust

R&D Department
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Level E, Laboratory & Pathology Block, SCBR - MP138
Southampton
SO16 6YD

UHS Grant Reference Number: GNT0525

26th October 2021

Dear Stephen

Re: Wessex Frail2Fit – a feasibility and acceptability study of a virtual multimodal intervention delivered by volunteers to improve functional outcomes of older people with Covid discharged from hospital

With the agreement of the UHS R&D Joint Strategy Group, I am delighted to inform you that your project has been approved for full funding of £45,019, plus additional request of £6000 for a digital inclusivity feasibility study, within the UHS R&D Small Grants Scheme.

This project was originally submitted to the Southampton Hospitals Charity in early 2021 for consideration by NHS Charities Together of proposals seeking to address the impact of COVID-19 in vulnerable groups, focussing on themes of prevention, intervention or recovery. It was peer reviewed by a panel of experts from UHS and the University of Southampton and recommended for funding. After a change in eligibility criteria, NHS Charities Together rejected the recommendation.

UHS recognises the importance of supporting early career researchers and has made the strategic decision to fund some of the projects recommended to NHS Charities Together. You have confirmed that the proposal presented in January 2021 remains valid, is unfunded by other sources, and aligns with the strategic priorities of the UHS-UoS research infrastructure.

Upon confirmation of your acceptance of this award, a grant cost centre will be set up within UHS R&D for management by the UHS R&D grants team. Funds will be available from 1 November 2021. You are expected to proceed with the study in the timeframe described in your proposal, i.e. 16 months from commencement.

You are required to provide a report to the UHS R&D Small Grants Scheme both on completion of the project and 12 months later, detailing outcomes and next steps.

On behalf of the UHS R&D Director, I would like to offer our congratulations on securing this funding and wish you every success with the project.

Yours sincerely,

Dr Karen Underwood
Interim Director of Research & Development
University Hospital Southampton NHS
Foundation Trust

Professor Christopher Kipps
Clinical Director of Research & Development
University Hospital Southampton NHS
Foundation Trust

Section 1 (to be completed with volunteers)

1. Do you have any previous volunteering experience? Yes ☐ No ☐
   a. and if so how many years? _____

2. Do you have any previous experience delivering group exercises? Yes ☐ No ☐
   a. and if so how many years? _____

3. Why did you choose to become a Frail2Fit volunteer?

4. Gender: Male ☐ Female ☐ Other ☐
5. Ethnicity:
   ……
6. Marital status: Single ☐ Married ☐ Divorced/Separated ☐
   Widowed ☐ Cohabiting ☐
7. DOB:
   ……
8. Employment status: Employed: Part-time ☐ Full-time ☐ Unemployed ☐
   Retired ☐ Student ☐ Other ☐
   .....

Section 2 (to be completed by Research staff)

1. Date attended training:
   ……
2. Date competencies achieved:
   ……
3. Date started as Frail2Fit volunteer
   :……

Supervision required for confidence: Minimal ☐ Moderate ☐ Constant ☐

Supervision required for safety: Minimal ☐ Moderate ☐ Constant ☐

4. Number of interventions conducted:……
5. Date ceased as Frail2Fit volunteer:
   ……
6. Reasons for leaving:
   ……

Collection sheet completed by:
   ……

Date completed:
   ……

Date Information Collected: | | | | | | | (d d m m y y)

Gender: Male = 0 Female = 1 | |

Date of Birth: | | | | | | | (d d m m y y)

SOCIAL CIRCUMSTANCES

Marital status: Single = 1, Married = 2, Divorced or separated = 3, Widowed = 4, Cohabiting = 5 | |

Usual Residence: Private home living alone = 1, Private home living with friends or relatives = 2, Sheltered accommodation = 3, Residential/Rest Home = 4, Nursing Home = 5 | |

Care provision:

- **No care required = 0**
- **Informal provision = 1**
- **Formal provision = 2**

| |

Tobacco and alcohol consumption:

Smoking Never = 1 Ex = 2 Current = 3 | |

Cigarette pack years | | | |

Alcohol units per week | | |

Clinical Frailty Scale

Frailty Score:
≥5 for study inclusion ☐

Clinical Frailty Scale*

1 **Very Fit** – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.

2 **Well** – People who have **no active disease symptoms** but are less fit than category 1. Often, they exercise or are very **active occasionally**, e.g. seasonally.

3 **Managing Well** – People whose **medical problems are well controlled,** but are **not regularly active** beyond routine walking.

4 **Vulnerable** – While **not dependent** on others for daily help, often **symptoms limit activities.** A common complaint is being "slowed up", and/or being tired during the day.

5 **Mildly Frail** – These people often have **more evident slowing,** and need help in **high order IADLs** (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.

6 **Moderately Frail** – People need help with **all outside activities** and with **keeping house**. Inside, they often have problems with stairs and need **help with bathing** and might need minimal assistance (cuing, standby) with dressing.

7 **Severely Frail** – **Completely dependent for personal care**, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).

8 **Very Severely Frail** – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.

9. **Terminally Ill** - Approaching the end of life. This category applies to people with **a life expectancy <6 months**, who are **not otherwise evidently frail**

Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In **severe dementia**, they cannot do personal care without help.

* 1. Canadian Study on Health & Aging, Revised 2008.
2. K. Rockwood et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005;173:489-495.

DALHOUSIE UNIVERSITY *Inspiring Minds*

EuroQol EQ-5D-5L

Under each heading, please tick the ONE box that best describes your health TODAY

Mobility

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

Self-Care

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

Usual Activities *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

Pain / Discomfort

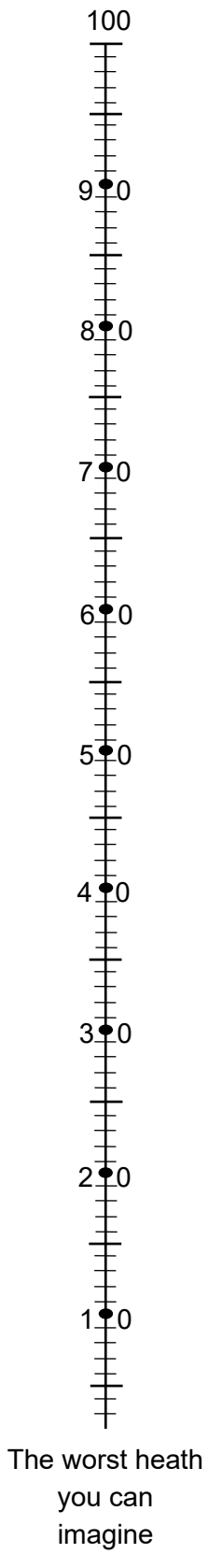
I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

Anxiety / Depression

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY
- The scale is numbered from 0 to 100
- 100 means the best health you can imagine
- 0 means the worst health you can imagine
- Mark an X on the scale to indicate how your health is TODAY
- Now, please write the number you marked on the scale in the box below

YOUR HEALTH TODAY = ☐



Mini Mental State Examination

ORIENTATION

Year	Month	Day	Date	Time	__/5
Country	Town	District	Hospital	Ward	__/5

REGISTRATION

Examiner names 3 objects (eg apple, table, penny)
Patient asked to repeat (1 point for each correct)
THEN patient to learn the 3 names repeating until correct __/3

ATTENTION AND CALCULATION

Subtract 7 from 100, then repeat from result.
Continue 5 times: 100 93 86 79 72 65
Alternative: spell "WORLD" backwards - dlrow. __/5

RECALL

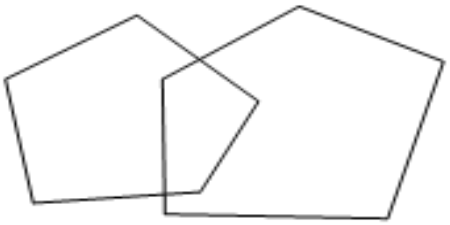
Ask for names of 3 objects learned earlier. __/3

LANGUAGE

Name a pencil and a watch __/2
Repeat “No ifs, ands or buts” __/1
Give a 3 stage command. Score 1 for each stage.
Eg. "Place index finger of right hand on your nose and then on your left ear". __/3
Ask patient to read and obey a written command on a piece of paper stating "Close your eyes". __/1
Ask the patient to write a sentence. Score if it is sensible and has a subject and a verb. __/1

COPY

Ask the patient to copy a pair of intersecting pentagons:



__/1

Total: __/30

Charlson Co-morbidity Index
Score '0' if the disease is not present.

Active co- morbidities	**Score**
Myocardial infarction (+1)	
Congestive Cardiac Failure (+1)	
Peripheral vascular disease (+1)	
Cerebrovascular accident or Transient Ischaemic Attack (+1)	
Dementia (+1)	
Chronic Obstructive Pulmonary Disease (+1)	
Connective tissue disease (+1)	
Peptic ulcer disease	
Liver disease • None (0) • Mild (+1) • Moderate to severe (+3)	
Diabetes mellitus • None or diet-controlled (0) • Uncomplicated (+1) • End-organ damage (+2)	
Hemiplegia (+2)	
Moderate to severe Chronic Kidney Disease (moderate = creatinine > 265 micromol/L (+2)	
Solid tumour • None (0) • Localised (2) • Metastatic (6)	
Leukeamia (+2)	
Lymphoma (+2)	
AIDS (+6)	
Age • < 50 years (0) • 50-59 years (+1) • 60-69 years (+2) • 70-79 years(+3) • ≥ 80 years (+4)	
Total score	

Number of medications: ☐

NUTRITIONAL INDICES (self-reported)
Height, Weight and Body Mass Index

Date Measured: | | | | | | | (d d m m y y)

Height (cm) | | | |

Weight (kg) | | | | • | |

BMI (kgm^{-2}) | | | • | |

MUST Score:

ACCELEROMETER

Date of device applied :

Date of device removed : | | | | | | | (d d m m y y)

Total number of days : | |

Reason for early removal of device:

No. of Hospital Readmissions: | |

Barthel Index

Bowels incontinent (or needs to be given enema) occasional accident (once/week) continent	 **0** **1** **2**
Bladder incontinent, or catheterized and unable to manage occasional accident (max. once per 24 hours) continent (for over 7 days)	 **0** **1** **2**
Grooming needs help with personal care independent face/hair/teeth/shaving (implements provided)	 **0** **1**
Toilet Use dependent needs some help, but can do something alone independent (on and off, dressing, wiping)	 **0** **1** **2**
Feeding unable needs help cutting, spreading butter, etc. 2 = independent (food provided within reach)	 **0** **1**
Transfer unable – no sitting balance major help (one or two people, physical), can sit minor help (verbal or physical) independent	 **0** **1** **2** **3**
Mobility Immobile wheelchair independent, including corners, etc. walks with help of one person (verbal or physical) independent (but may use any aid)	 **0** **1** **2** **3**
Dressing dependent needs help, but can do about half unaided independent (including buttons, zips, laces etc)	 **0** **1** **2**
Stairs unable needs help (verbal, physical, carrying aid) independent up and down	 **0** **1** **2**
Bathing dependent independent (or in shower)	 **0** **1**
Total Score:	

PASE
Leisure Time Activity

1. Over the past 7 days, how often did you participate in sitting activities such as reading, watching TV, or doing handcrafts?

0) Never (go to question 2)
1) Seldom (1-2 days) (go to question 1a and 1b)
2) Sometimes (3-4 days) (go to question 1a and 1b)
3) Often (5-7 days) (go to question 1a and 1b)

1a. What were these activities ?

1b. On average, how many hours did you engage in these sitting activities ?

0) Less than 1 hour
1) 1-1.9 hours
2) 2-4 hours
3) >4 hours

2. Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc

0) Never (go to question 3)
1) Seldom (1-2 days) (go to question 2a)
2) Sometimes (3-4 days) (go to question 2a)
3) Often (5-7 days) (go to question 2a)

2a. On average, how many hours per day did you spend walking ?

0) Less than 1 hour
1) 1-1.9 hours
2) 2-4 hours
3) >4 hours

3. Over the past 7 days, how often did you engage in light sport or recreational activities such as bowling, golf with a cart, shuffleboard, fishing from a boat or pier or other similar activities?

0) Never (go to question 4)
1) Seldom (1-2 days) (go to question 3a and 3b)
2) Sometimes (3-4 days) (go to question 3a and 3b)
3) Often (5-7 days) (go to question 3a and 3b)

3a. What were these activities ?
3b. On average, how many hours did you engage in these light sport or recreational activities?

0) Less than 1 hour
1) 1-1.9 hours

2) 2-4 hours
3) >4 hours

4. Over the past 7 days, how often did you engage in moderate sport and recreational activities such as doubles tennis, ballroom dancing, hunting, ice skating, golf without a cart, softball or other similar activities?

0) Never (go to question 5)
1) Seldom (1-2 days) (go to question 4a and 4b)
2) Sometimes (3-4 days) (go to question 4a and 4b)
3) Often (5-7 days) (go to question 4a and 4b)

4a. What were these activities ?

4b. On average, how many hours did you engage in these moderate sports or recreational activities ?

0) Less than 1 hour
1) 1-1.9 hours
2) 2-4 hours
3) >4 hours

5. Over the past 7 days, how often did you engage in strenuous sport and recreational activities such as jogging, swimming, cycling, singles tennis, aerobic dance, skiing (downhill or cross-country) or other similar activities?

0) Never (go to question 6)
1) Seldom (1-2 days) (go to question 5a and 5b)
2) Sometimes (3-4 days) (go to question 5a and 5b)
3) Often (5-7 days) (go to question 5a and 5b)

5a. What were these activities?

5b. On average, how many hours did you engage in these strenuous sport or recreational activities?

0) Less than 1 hour
1) 1-1.9 hours
2) 2-4 hours
3) >4 hours

6. Over the past 7 days, how often did you do any exercises specifically to increase muscle strength and endurance, such as lifting weights or pushups, etc.?

0) Never (go to question 7)
1) Seldom (1-2 days) (go to question 6a and 6b)
2) Sometimes (3-4 days) (go to question 6a and 6b)
3) Often (5-7 days) (go to question 6a and 6b)

6a. What were these activities ?

6b. On average, how many hours did you engage in these exercises to increase muscle strength ?

0) Less than 1 hour
1) 1-1.9 hours
2) 2-4 hours
3) >4 hours

Household Activity

7. During the past 7 days, have you done any light housework, such as dusting or washing dishes?

1) No
2) Yes

8. During the past 7 days, have you done any heavy housework or chores, such as vacuuming, scrubbing floors, washing windows, or carrying wood?

1) No
2) Yes

9. During the past 7 days, did you engage in any of the following activities? Please answer YES or NO for each item.

a) Home repairs like painting, wallpapering, electrical work, etc.
b) Lawn work or yard care, including snow or leaf removal, wood chopping, etc.
c) Outdoor gardening
d) Caring for another person, such as children, dependent spouse, or another adult

Work-Related Activity

10. During the past 7 days, did you work for pay or as a volunteer?

1) NO
2) YES (go to questions 10a and 10b)

10a. How many hours per week did you work for pay and or as a volunteer? ____ hours

10b. Which of the following categories best describes the amount of physical activity required on your job and or volunteer work?

1) Mainly sitting with some slight arm movement (Examples: office worker, watchmaker, seated assembly line worker, bus driver, etc.)
2) Sitting or standing with some walking (Examples: cashier, general office worker, light tool and machinery worker)
3) Walking with some handling of materials generally weighing less than 50 pounds (Examples: mailman, waiter/waitress, construction worker, heavy tool and machinery worker)
4) Walking and heavy manual work often requiring handling of materials weighting over 50 pounds (Ex: lumberjack, stone mason, farm or general labourer)

Short Nutritional Assessment Questionnaire (SNAQ)

1. My appetite is:
   a. Very Poor
   b. Poor
   c. Average
   d. Good
   e. Very Good

2. When I eat:
   a. I feel full after eating only a few mouthfuls
   b. I feel full after eating about a third of a meal
   c. I feel full after eating over half a meal
   d. I feel full after eating most of the meal
   e. I hardly ever feel full

3. Food tastes:
   a. Very bad
   b. Bad
   c. Average
   d. Good
   e. Very good

4. Normally I eat:
   a. Less than one meal a day
   b. One meal a day
   c. Two meals a day
   d. Three meals a day
   e. More than three meals a day

Total Score: _____/20

Warwick-Edinburgh Well-Being Scale (WEMWBS)

	None of the time	Rarely	Some of the time	Often	All of the time
I've been feeling optimistic about the future	**1**	**2**	**3**	**4**	**5**
I've been feeling useful	**1**	**2**	**3**	**4**	**5**
I've been feeling relaxed	**1**	**2**	**3**	**4**	**5**
I've been feeling interested in other people	**1**	**2**	**3**	**4**	**5**
I've had energy to spare	**1**	**2**	**3**	**4**	**5**
I've been dealing with problems well	**1**	**2**	**3**	**4**	**5**
I've been thinking clearly	**1**	**2**	**3**	**4**	**5**
I've been feeling good about myself	**1**	**2**	**3**	**4**	**5**
I've been feeling close to other people	**1**	**2**	**3**	**4**	**5**
I've been feeling confident	**1**	**2**	**3**	**4**	**5**
I've been able to make up my own mind about things	**1**	**2**	**3**	**4**	**5**
I've been feeling loved	**1**	**2**	**3**	**4**	**5**
I've been interested in new things	**1**	**2**	**3**	**4**	**5**
I've been feeling cheerful	**1**	**2**	**3**	**4**	**5**

Hospital Anxiety and Depression Scale (HADS)

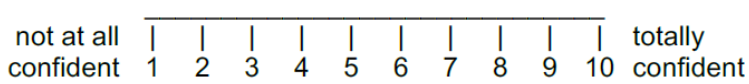
D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Total Score: Depression (D) _____
Anxiety (A) _____

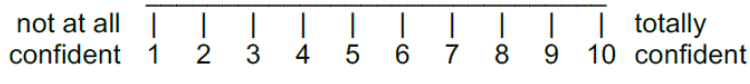
Self-efficacy for managing chronic disease

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

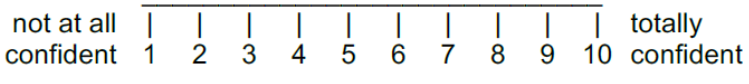
1. How confident do you feel that you can keep the fatigue caused by your disease from interfering with the things you want to do?



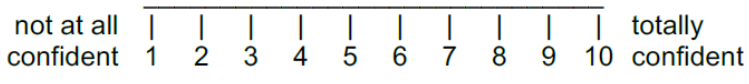
2. How confident do you feel that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?



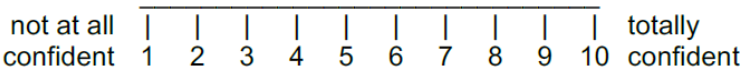
3. How confident do you feel that you can keep the emotional distress caused by your disease from interfering with the things you want to do?



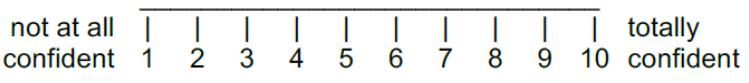
4. How confident do you feel that you can keep any other symptoms or health problems you have from interfering with the things you want to do?



5. How confident do you feel that you can do the different tasks and activities
needed to manage your health condition so as to reduce your need to see a doctor?



6. How confident do you feel that you can do things other than just taking medication to reduce how much your illness affects your everyday life?



SCORE _____

Frail2Fit study

Semi-structured interview schedule for volunteers

1. Tell me your views about being physically active in general.
    a. Explore general perception on physical activity
    b. What are the potential benefits?
    c. Any potential harm?

2. In your view, what are the things/factors that could discourage older people to be more active?
    a. Explore environmental factors, motivation, cost, accessibility, fear of injury/falls and any other additional factors

3. What are the things/factors that could encourage older people to be more active?
    a. Explore environment, social support, interest, accessibility and any other additional factors
    b. Explore types of physical activity which older people are more likely to engage with, including frequency, and duration.

4. What are your general views about diet / nutrition for older people?
    a. Explore general perception on nutrition and eating
    b. What are the potential benefits for older adults following a healthy eating pattern?
    c. Are there any drawbacks, or disadvantages from altering diet / nutrition?

5. In your view what are the things that could encourage older people to eat healthily?
    a. Explore food acquisition and preparation
    b. Explore nutritional knowledge, environment, social support, interest
    c. Explore types of foods that older people may prefer to eat

6. In your view what discourages older people from eating healthily?
    a. Explore social and environmental factors e.g., cost of food, lack of help in preparing meals
    b. Explore appetite, taste preferences and dietary habits

7. What motivated you to volunteer for the role?

8. What are your views on the use of trained volunteers to deliver group exercise and nutrition support to older people in the community?
    a. Can you describe your experience with these classes? Any advantages or disadvantages?

   b. What was good about these groups? And what things do you think need improvement?
   c. What were the benefits?
   d. Were there negative experiences?

9. In your view, what has it been like as a volunteer encouraging participants to be more active?
   a. Explore if it worked for some but not others, including reasons for this.

10. In your view, what has it been like as a volunteer delivering the nutrition wheel and encouraging participants to eat healthily?
   a. Explore if it worked for some but not others, including reasons for this.

11. What were your experiences with the volunteer training?
   a. Explore training content and timing
   b. Explore opinions regarding training resources, such as booklets and videos
   c. Explore if any improvements are needed for volunteer training
   d. Explore their perceptions of available support e.g., support given, impact on confidence levels, availability of peer support

12. Do you have any suggestions or comments about the intervention?
   a. Explore things that went well
   b. Explore things that could be improved

13. What were your experiences with delivering the support online?
   a. Explore any barriers to accessing, or using the online intervention e.g., tech knowledge, general perceptions of using technology, any misconceptions regarding online platforms, visibility and sound during sessions
   b. Explore the things that helped / facilitated use of online tech

14. In your opinion, how could these volunteer-led sessions be continued and extended to other clubs?
   a. Explore participants views on barriers and facilitators to the implementation of the intervention in other settings

15. How can we improve the volunteering experience for future volunteers in this intervention?
   a. Explore factors to aid retention and recruitment of others

Frail2Fit study

Semi-structured interview schedule for patients

1. Since being discharged from hospital how have things been going for you at home?
   a. Could you explain what a typical day is like for you? (Build rapport and understand what life is like for them)
   b. Explore functional capacity
   c. Explore meaningful activities and general day to day motivation
   d. Explore any concerns or barriers to recovery post-discharge

2. Tell me your views about being physically active in general.
   b. Explore general perception on physical activity
   c. What are the potential benefits?
   d. Any potential harm?

3. In your view, what are the things/factors that could discourage older people to be more active?

   a. Explore environmental factors, motivation, cost, accessibility, fear of injury/falls

4. What are the things/factors that could encourage older people to be more active?
   a. Explore environment, social support, interest, accessibility
   b. Explore types of physical activity which older people are more likely to engage with, including frequency, and duration.

5. What are your general views about diet / nutrition? What is your eating and diet like?
   d. Explore general perception on nutrition and eating
   e. What are the potential benefits of following a healthy eating pattern?
   f. Are there any drawbacks, or disadvantages from altering diet / nutrition?

6. In your view what are the things that could encourage older people to eat healthily? What helps you to eat more healthily?
   d. Explore food acquisition and preparation
   e. Explore nutritional knowledge, environment, social support, interest
   f. Explore types of foods that older people may prefer to eat

7. In your view what discourages older people to eat healthily? What stops you eating more healthily?
   c. Explore social and environmental factors e.g., cost of food, lack of help in preparing meals
   d. Explore appetite, taste preferences and dietary habits

8. What are your views on the use of trained volunteers to deliver group exercise and nutrition support to older people in the community?
    a. Can you describe your experience with these exercise and nutrition sessions? Any advantages or disadvantages?
    b. What was good about these groups? And what things do you think need improvement?
    c. What were the benefits?
    d. Were there negative experiences?

9. In your view, how effective were the trained volunteers at delivering the exercises and encouraging participants to be more active?

10. In your view, how effective were the trained volunteers at delivering the nutrition wheel and encouraging participants to eat healthily?

11. Do you have any suggestions or comments about the intervention?
    a. Explore things that went well
    b. Explore things that could be improved

12. What were your experiences with using the device and receiving the support online?
    c. Explore any barriers to accessing, or using the online intervention e.g., tech knowledge, general perceptions of using technology, any misconceptions regarding online platforms, visibility and sound during sessions
    d. Explore the things that helped / facilitated use of online tech

13. In your opinion, how could these volunteer-led sessions be continued and extended to other clubs?
    c. Explore participants views on barriers and facilitators to the implementation of the intervention in other settings

Frail2Fit study

Semi-structured interview schedule for family members

1. Since being discharged from hospital how have things been going for your family member at home?
   e. Could you explain what a typical day is like for them? (Build rapport and understand what life is like for them)
   f. Explore functional capacity
   g. Explore meaningful activities and general day to day motivation
   h. Explore any concerns or barriers to recovery post-discharge

2. Tell me your views about being physically active in general.
   e. Explore general perception on physical activity
   f. What are the potential benefits?
   g. Any potential harm?

3. In your view, what are the things/factors that could discourage older people to be more active?

   a. Explore environmental factors, motivation, cost, accessibility, fear of injury/falls

4. What are the things/factors that could encourage older people to be more active?
   c. Explore environment, social support, interest, accessibility
   d. Explore types of physical activity which older people are more likely to engage with, including frequency, and duration.

5. What are your general views about diet / nutrition? What is your family member's eating and diet like?
   g. Explore general perception on nutrition and eating
   h. What are the potential benefits of following a healthy eating pattern?
   i. Are there any drawbacks, or disadvantages from altering diet / nutrition?

6. In your view what are the things that could encourage older people to eat healthily? What helps your family member to eat more healthily?
   g. Explore food acquisition and preparation
   h. Explore nutritional knowledge, environment, social support, interest
   i. Explore types of foods that older people may prefer to eat

7. In your view what discourages older people to eat healthily? What stops your family member eating more healthily?

e. Explore social and environmental factors e.g., cost of food, lack of help in preparing meals
f. Explore appetite, taste preferences and dietary habits

8. What are your views on the use of trained volunteers to deliver group exercise and nutrition support to older people in the community?
    e. Can you describe your family member's experience with these exercise and nutrition sessions? Any advantages or disadvantages?
    f. What was good about these groups? And what things do you think need improvement?
    g. What were the benefits?
    h. Were there negative experiences?

9. In your view, how effective were the trained volunteers at delivering the exercises and encouraging your family member to be more active?
    a. Explore impact of the exercise programme on family members health and activity levels.
    b. Explore positive and negative experiences of the intervention.

10. In your view, how effective were the trained volunteers at delivering the nutrition wheel and encouraging your family member to eat healthily?
    a. Explore impact of the nutrition programme on family members health and eating behaviours.
    b. Explore positive and negative experiences of the intervention.

11. Do you have any suggestions or comments about the intervention?
    d. Explore things that went well
    e. Explore things that could be improved

12. What are your views on your family member using online tech to access the intervention?
    e. Explore any barriers to accessing, or using the online intervention e.g., tech knowledge, general perceptions of using technology, any misconceptions regarding online platforms, visibility and sound during sessions
    f. Explore the things that helped / facilitated use of online tech

13. In your opinion, how could these volunteer-led sessions be continued and extended to other clubs?
    a. Explore participants views on barriers and facilitators to the implementation of the intervention in other settings

Screening and Escalation Plan

Screening at the start of each support session
(5 – 10 minutes)

- **Exercise:** It is essential to use Table 1 (Exercise Screening at each Session)to identify any changes in participant-specific considerations (or comorbidities)and if necessary, to take the appropriate action defined in Figure 1 (Escalation Process). Please also report any actions taken or concerns to the Frail2Fit team on (insert number here), or (insert email here).
- **Nutrition:** Any marked change in appetite, eating habits (including change inability to eat or drink) and perceived unintended weight loss: Do not exercise and notify trial team on (insert number and email here).
- **Medications:** If participant has started any new medications, report this to the Frail2Fit team. Ensure patient has taken prescribed medications as normal. If they haven't contact the Frail2Fit team on (insert number and email here).

If a concern arises please refer to the **SAFETY ESCALATION PROCESS** outlined in Figure 1.

Table 1. Exercise Screening at each Session

Has the participant been experiencing any of the following? Delayed onset muscle soreness **If yes, observe and modify exercises accordingly**
Has the participant experienced any of the following? Contacted GP Visited A&E Been admitted to hospital? **If yes, please contact Frail2Fit trial team before delivering the exercise support session.**
Has the participant experienced any of the following? Fever or infection Nausea, vomiting or diarrhea Recent dizziness or fainting

Any new or worsening of symptoms (e.g., pain) **If yes, no exercise – alert trial team**
<u>Emergency Scenario</u> **Chest, arm or jaw pain Dial 999** **Anything that the instructor feel's is an emergency** **When appropriate please alert the Frail2Fit team**

Safety Escalation

Based on your screening results you may need to escalate to the trial team for further advice before proceeding with your session – if this is the case please record this in your session completion log.
There may also be circumstances where you need to escalate during or after your session as outlined in Figure 1.

Patient safety is our highest priority, so if you have any concerns or doubts, please just call us.

KEY REMINDER: Please remember to alert the trial team to **any changes** in the participants' status such as:

- New medical diagnosis or co-morbidity
- Start of new medication and removal of a medication
- Admission to hospital or visit to A&E or GP
- New investigations that have been arranged
- New onset of symptoms or worsening of previous symptoms
- Change in known co-morbidities

Figure 1. Safety Escalation Process