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

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ABSTRACT

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

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

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

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

STRENGTHS AND LIMITATIONS OF THIS STUDY

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

Trial registration number NCT05384730.

INTRODUCTION

Older people with frailty are at high risk of poor outcomes including increased post-hospitalisation, healthcare use mortality. Frailty refers to a cumulative decline in biological reserves leading to poor resolution of homoeostasis after a stressor event.² Approximately 11% of community dwelling older adults have frailty,³ compared with around 14-80% in hospitalised older adults.⁴⁻⁷ Differing cohorts of patients (eg, age, ward type), and frailty measures (eg, Edmonton Frail Scale, Cardiovascular Health Study Frailty Index) could explain the range of frailty prevalence reported in hospital. Typically, wards specialising in medicine for older people, and older patients (≥85 years) have higher incidence of frailty. 4 6 As frailty





progresses, older adults' functional status declines, resulting in disability, increased risk of falls and long-term care. Moreover, deconditioning during hospital admission is a major concern and impacts significantly on the ability for older adults to maintain independence. Considering these detrimental clinical consequences there is a need to identify ways to better manage and prevent decline in frailty to improve patient care.

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

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

A whole society approach involving multisectoral collaborations, such as volunteers, has been advocated to promote age-friendly communities and healthy ageing. Health practitioners are under increasing time pressures and typically have poor capacity to deliver extra support above and beyond routine services. Hence, volunteer-led interventions could promote organisational benefits, diversifying the health and social care workforce and reducing healthcare costs. Moreover, volunteering provides direct benefits to volunteers' including enhanced well-being and reduced social isolation.

There is growing interest in the use of volunteer-led PA and nutrition interventions to support older adults' health and well-being. PA recent systematic review explored the impact of PA interventions conducted by trained volunteers on health-related outcomes for community-dwelling older people (≥65 years). Volunteers implemented strength and balance exercises one to three times per week, which led to improvements in functional status, frailty status, a reduction in fear of falls and improved quality of life. Nevertheless, the review

concluded that more high quality randomised controlled trials (RCT) are needed to investigate the effects of volunteer-led PA interventions among older people. Similarly, more adequately powered research has been recommended to explore volunteer-led nutritional interventions in the community. ¹⁷

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

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

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



Aims

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

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

METHODS AND ANALYSIS Study design and setting

The protocol was developed according to the Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines (online supplemental file 3).³⁴ This feasibility study will use a quasi-experimental mixed methods approach and will be conducted at a National Health Service (NHS) hospital trust in the South of England. Hospital volunteers will be trained to deliver virtual group support for frail older adults discharged from acute medical wards. The study began recruitment in November 2022.

Participant recruitment

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

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

Volunteer recruitment

Volunteers will be identified by hospital voluntary services in line with inclusion and exclusion criteria (box 1). Interested volunteers will be approached by the research team to discuss the study and complete informed consent (online supplemental material 1). It is estimated that six volunteers will be needed to lead three groups of 5–10 participants. See figure 1 for an outline of study processes.

Box 1 Inclusion and exclusion criteria

Inclusion criteria

Older adults

- ⇒ Older adults aged ≥65 years.
- ⇒ Able to provide written consent.
- > Recently discharged, or soon to be discharged from hospital.
- ⇒ Clinical Frailty Scale ≥5.
- \Rightarrow Able to walk at least a few steps on hospital discharge.

Volunteers

- ⇒ Hospital volunteers aged ≥16 years.
- \Rightarrow Completed generic hospital volunteer clearance checks, including criminal record check.
- ⇒ Completed basic hospital volunteer training, such as health and safety.
- ⇒ Able to provide written consent.

Exclusion criteria

Older adults

- ⇒ Older adults who are not able to safely complete the exercises included in the intervention as advised by the patient's clinician.
- \Rightarrow Patients who are discharged to rehabilitation units, or care homes.
- ⇒ Patients receiving end-of-life care.

Volunteers

- ⇒ Unable to safely complete the seated exercises.
- ⇒ Unable to commit to completing Frail2Fit volunteer training (7 hours).
- ⇒ Unable to commit at least 2 hours to conducting the intervention per week for a minimum of 6 months.

Intervention

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

Exercise

Exercise will consist of volunteer-led group resistance training for 20–30 min using resistance bands. To align with home-based safety considerations, the exercises will be performed seated. The exercise programme was developed by a qualified NHS physiotherapist and used in a previous intervention among community dwelling older adults at social clubs. Seated exercise will focus on strengthening eight major muscle groups, tailored specifically to meet the needs of older adults and to minimise the risks of injury (online supplemental material 2). Participants will be encouraged by volunteers to progress

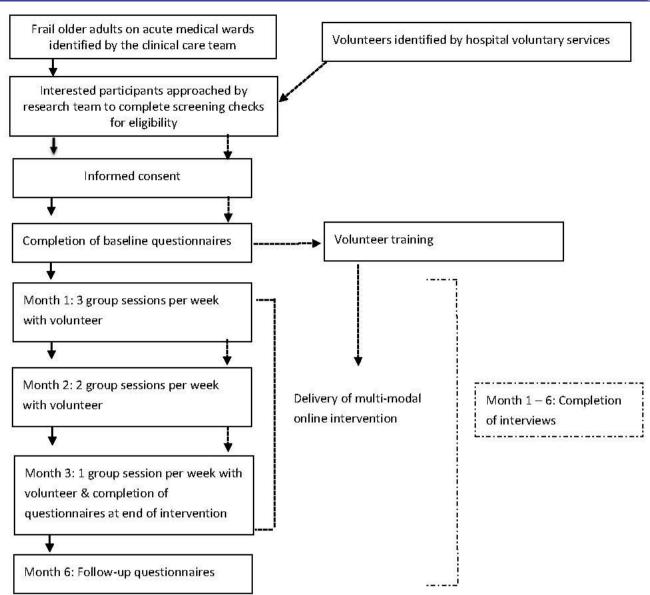


Figure 1 Study flow chart

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

Nutrition support

Using the Nutrition Wheel, volunteers will initiate group discussion with participants to raise any nutrition-related concerns. The Nutrition Wheel is an interactive tool developed from the Patients Association Nutrition Checklist and used to engage individuals in conversation about unintentional weight loss and malnutrition.

The Nutrition Wheel consists of four main questions, including (1) Are you or your family concerned that you may be underweight, or need nutritional advise? (2) Have you lost a lot of weight unintentionally in the past 3-6 months? (3) Have you noticed that your clothes or rings have become loose recently? (4) Have you recently lost your appetite and/or your interest in eating? Based on the participant's answers, they will be directed to further questions and guided to appropriate nutritional advice (eg, information sheets, national helplines or, if necessary, signposted to their general practitioner (GP)/practice nurse). Volunteers will be given suggested weekly nutrition topics based around the nutrition wheel to facilitate group discussions (box 2). Importantly, volunteers will not advise the group, instead they will harness the resourcefulness of the group and encourage them to come up with their own solutions.



Box 2 Example of weekly nutrition topics

- ⇒ Snacking—adding calories and protein.
- ⇒ Fluids and drinking.
- \Rightarrow Food shopping.
- \Rightarrow Cooking.
- ⇒ Fruit and vegetables.
- ⇒ Cutting food and chewing.

Behaviour change support

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

Digital support

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

Safety during sessions

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

they will be asked to keep cameras on during the sessions. Groups will be limited to a maximum of 10 participants.

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

Volunteer training programme

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

Exercise

The exercise training programme was developed based on clinical expertise and recently completed research of volunteer-led exercise in hospital and the community. Training will include an in-person group session lasting 2½ hours, comprising theory underpinning the benefits of exercise for older adults, exercise training principles, seated exercise delivery and safety considerations. Volunteers will practice delivering exercise to peers and will be given a training manual and links to training videos developed from previous research and adapted for this specific trial. The lead trainer (SJM) is a research fellow and clinical exercise instructor with experience delivering exercise to a range of population groups, including older adults.

Nutrition support

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

Behaviour change support

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

Volunteer support

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

Outcome measures

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

Primary outcomes

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

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

Secondary outcomes

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

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

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

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

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

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



Quality of life will be measured using the EuroQol-5Dimensions-5Levels (EQ-5D-5L) questionnaire comprising 5 health areas (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) assessed with 5 response levels (e.g., no problems, slight, moderate, severe, or unable), and a Visual Analogue Scale. The EQ-5D-5L has been widely used in clinical trials and population studies as a popular measure of health status.

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

Data analysis

Quantitative data analysis

Data will be entered into a secured database for analysis. Statistical analysis will be conducted using the statistical software SPSS (V.28.0.1.1). Descriptive statistics-median (IQR; mean (SD); number (%)—will be used to analyse the numbers of volunteers recruited, trained and retained, as well as patients' adherence to the intervention to assess the feasibility of delivering this intervention. To determine suitability for a future RCT, inferential statistics will be used. Outcome measures recorded at baseline will be compared with measurement at 3 and 6 months to determine if the intervention had an impact on PA measured by PASE and GENEActiv, functional outcomes including functional ability (Barthel), appetite (SNAQ), symptoms of anxiety and/or depression (HADS), wellbeing (WENWBS), self-efficacy (Lorig) and quality of life (EQ-5D-5L). The distribution of each outcome measure will be assessed for normality and described using parametric or non-parametric statistics accordingly. A basic cost-analysis of the training programme will be carried out, costing the time involved in delivering the training.

Qualitative data analysis

Data collected from the interviews will be transcribed verbatim and analysed using thematic analysis (TA). TA is a method for identifying, analysing and reporting patterns or themes within data.⁶⁸ There are six phases in the TA process: Phase 1—familiarising with the data, Phase 2—generating initial codes, Phase 3—searching for themes, Phase 4—reviewing themes, Phase 5—defining and naming themes and Phase 6—producing the report. Analysis of qualitative data will be conducted using Microsoft Word, or NVivo software (V.12), depending on the amount of data collected. SJM will analyse codes to generate concepts and ideas to determine the acceptability of the intervention, and to identify facilitators and barriers to the implementation process. From the codes, themes will be developed to reflect the views and experiences of participants and volunteers regarding the online multimodal intervention. SERL will code 25% of interviews separately to develop, discuss and agree on themes with SJM through an iterative process.

Patient and public involvement

This intervention was developed in line with our previous research, 18 40 which highlighted that volunteer-led PA interventions in hospitals and the community were safe, and well received by older adults. In the development of our programme of research older adults in the community and care homes (n=92) completed a survey, illustrating 45% had experience working with volunteers and appreciated their contribution. A further survey conducted in community social clubs showed that 47 out of 50 older adults agreed or strongly agreed to have trained volunteers lead exercises. A patient and public involvement (PPI) representative led by the PPI lead for the Ageing and Dementia theme within the Wessex Applied Research Collaboration is a part of the study management group. As such they provided input into this study proposal, reviewed patient facing materials and ensured that the processes of the study such as data collection, and interviews, were not too burdensome for participants. They will continue to be involved in the study steering group throughout the research and will be consulted regarding dissemination of research findings.

Ethics and dissemination

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

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

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