

**A Randomised Controlled Feasibility Trial Evaluating a Resistance Training Intervention with Frail
Older Adults in Residential Care: The Keeping Active in Residential Elderly (KARE) Trial**

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Abstract

Frailty is associated with negative health outcomes, disability, and mortality. Physical activity is an effective intervention to improve functional health status. However, the effect of resistance training on multi-dimensional health in frail older adults remains unclear. This randomised controlled trial (RCT) was conducted in a UK residential care home to assess feasibility with limited efficacy testing on health and functional outcomes, to inform a future definitive RCT. Eleven frail older adults (>65 years) completed a 6-week machine-based resistance training protocol three times a week. Uptake and retention were greater than 80%. The measures and intervention were found to be acceptable and practicable. Analyses indicated large improvements in functional capacity, frailty and strength in the intervention group compared to controls. These findings support the feasibility of a definitive RCT and reinforce the value of resistance training in this population. This trial was registered with ClinicalTrials.gov: NCT03141879.

Keywords: care home residents, frailty, multi-dimensional health, physical function, strengthening exercise

Frailty is a clinically significant multi-dimensional syndrome associated with adverse outcomes such as falls, hospitalisation, disability, and mortality among older adults (Clegg et al., 2013; Fried et al., 2001; Xue, 2011). It is characterised by diminished strength, mobility, and functional capacity, and increases an individual's vulnerability to external stressors including infection or trauma (Hewitt et al., 2019; Morley et al., 2013). Despite no universally accepted definition of frailty (Fried et al., 2001; Theou et al., 2015) it is of increasing importance as the world's older population continues to grow (United Nations & Social Affairs, 2019), and a rising proportion are spending prolonged periods in ill health. Evidence suggests that health span (the period of life spent in good health) is not keeping pace with lifespan (Whittaker et al., 2019).

Sustained ill health and loss of function in older age is not predetermined, and frailty is not an inevitable consequence of ageing. Frailty is a manageable condition (Morley et al., 2013) and has consistently been shown to be responsive to physical activity intervention. Being physically active is vitally important to optimise healthy ageing and improve function (Bherer et al., 2013; Lazarus & Harridge, 2018). Further, preserving balance and muscle and bone strength is integral to maintaining quality of life by reducing both the fear and the risk of falls, fractures, and frailty (Davies et al., 2019; Fragala et al., 2019; Skelton & Mavroeidi, 2018). Robust evidence supports the beneficial effects of resistance training to improve muscle strength and function, and its ability to mitigate age-related declines in neuromuscular function, rate of force development, bone mineral density, and associated metabolic dysregulation (Fragala et al., 2019; McLeod et al., 2019).

However, despite the mounting evidence that resistance training interventions are effective for combatting age-related physical decline, older adults in residential care are an often-overlooked group. This is potentially due to higher frailty levels, reduced physical independence and functional ability, and the perceived difficulty of providing a feasible regimen of training for individuals with a range of comorbidities and limitations. Additional barriers may include the ability to tolerate testing and training,

health and injury risks, adherence levels, and declines in cognitive function and health status (Ferrucci et al., 2004). Research also suggest that frail older adults may themselves be reticent to engage in physical activity due to fear of falling, comorbidities, injury risk, over-exertion, and changes to habitual routines (Finnegan et al., 2015; Franco et al., 2015).

Approaches to physical activity interventions in residential care have included multi-component exercise (Arrieta et al., 2018; Cadore et al., 2014; Lazowski et al., 1999), functional exercise (Peri et al., 2008), and combined resistance and weight-bearing exercise (Fien et al., 2016). The most commonly utilised exercise protocol is multi-component training, with the inclusion of resistance, balance, aerobic and flexibility activity (Theou et al., 2011) and current guidelines suggest this may be the best strategy to improve gait, balance and strength, and reduce the risk of falls (Fragala et al., 2019). However, the generalisability of these recommendations to address wider health consequences of frail older adults is still to be established. Studies that reported positive changes in physical function included stepping reaction time and timed walking test (Lord et al., 2003); enhanced functional outcomes, muscle strength and power (Cadore et al., 2014); and significant improvement in strength, gait speed and lower limb function (Bastone Ade & Jacob Filho, 2004). Exercise interventions with progressive resistance training as the primary focus are less common in residential care settings and have tended to focus primarily on physical performance outcomes, for example, strength, walking speed, balance, and functional capacity (Hassan et al., 2016; Serra-Rexach et al., 2011).

Delivering strengthening exercise programmes as group-based activity might also be important in a residential care home setting. For example, one study conducting a group multi-component exercise intervention with community-dwelling frail older adults reported a reversal of frailty and improvements in cognitive, emotional, and social networking measures (Tarazona-Santabalbina et al., 2016). This underlines the positive impact that social support and group processes can have on the engagement with, and maintenance of, physical activity behaviour (Shvedko et al., 2018; Smith et al., 2017). What is

not yet clear is the impact of resistance training in a group setting, on multi-dimensional health and wellbeing and physical function in frail older adults in residential care. Consequently, research to assess the feasibility and impact of this is timely and urgent.

Aims and Objectives

The primary aim of this study was to assess the feasibility of a definitive, randomised controlled trial (RCT) using a resistance training intervention with frail older adults in residential care. The secondary aim was to perform limited efficacy testing on measures of multi-dimensional health from pre- to post-intervention compared to the wait-list control. These are intended as the primary dependent variables in the future definitive RCT and include physiological, psychological, cognitive, and emotional health measures, and functional capacity.

The specific objectives arising from these aims were to: (a) evaluate the experiences of the intended recipients, well-being team and care staff (acceptability); (b) determine actual interest, use and adherence levels to the resistance training intervention (demand); (c) evaluate the level of organisational change required including perceived fit into the existing culture, organisation, and structure (integration and adaptation); (d) determine the practicality of the resistance training intervention with frail older adults in residential care (practicality); (e) evaluate the suitability and relevance of the selected measures of multi-dimensional health and wellness (implementation and expansion); and (f) examine changes pre- to post-intervention compared to the wait-list control in measures of multi-dimensional health using mean differences, effect size and meaningful change (limited-efficacy testing). The feasibility aims and objectives were based on the research design framework proposed by Bowen et al. (2009). As this was a feasibility study there were no directional hypotheses.

This research has been reported in line with CONSORT 2010 guidelines for reporting randomised pilot and feasibility trials (Eldridge et al., 2016), Consensus on Exercise Reporting Template (CERT) (Slade

et al., 2016) and Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Schematic Participant Timeline (Chan et al., 2013). Consort 2010 checklist is included as supplementary material.

Method

Participants

The trial site was a care home in Birmingham, UK, initially approached due to management support of healthy ageing and research initiatives, a dedicated well-being team and strong sense of community. Initial recruitment of participants was made by either a direct approach from a staff member, introduction to a member of the research team, or by voluntary attendance at a short introductory talk given by the Principal Investigator and researcher in the care home (February 2019). Participants were screened against the following eligibility criteria: (a) resident in the care home; (b) age ≥ 65 years; (c) having at least three of the five Fried Frailty Phenotype Criteria (Adapted from Fried et al. (2001)); (d) no severe sensory impairments that would profoundly impact upon their ability to participate; (e) ability to speak and read the English language; (f) not currently taking part in any other clinical trial which could potentially affect the results of this study; and (g) with a predicted life expectancy greater than the length of the trial.

Recruitment

All potential participants were offered a summary sheet about the study (a 2-page flyer based on the Participant Information Sheet (PIS) content). The summary sheet detailed the 'who, what, when, where and why' of the study including potential benefits and risks of taking part, research team contact details, and confidentiality and data protection. The summary sheet was produced on the advice of the well-being team who suggested that lengthy documentation may be off-putting for some residents, particularly those with any mild cognitive or sight impairment. All potential participants who expressed further interest in the study were given the full comprehensive PIS, in line with the published protocol (Doody et al., 2019). Potential participants had 10 days to consider whether they would like to

participate and were encouraged to meet with a member of the research team to discuss any queries

Following any further explanation, interested potential participants were provided with an informed consent form. The trial design was inclusive, including those who may have lacked capacity to provide informed consent, and documentation was in place for personal or nominated consultees. All participants had capacity and provided written informed consent before trial commencement and verbal consent before the start of their interview. All were free to withdraw from the study at any time.

Sample size

A convenience sample of $n \approx 48$ participants was suggested by Doody et al. (2019) in the published protocol. Actual sample size for this trial was adjusted following recruitment advice from well-being staff, and in line with recommendations (Hertzog, 2008; O'Cathain et al., 2015). Specific guidance for mixed methods randomised feasibility trials is limited. Hertzog (2008) proposed that samples of 10-15 per group may be adequate depending on the nature of the decision based on the estimate, and that even a few cases will be informative for decisions into acceptability, practicality, and implementation. Sample sizes for qualitative feasibility trials are also typically small, between 5-20 individuals (O'Cathain et al., 2015). An additional week (labelled as week -3, on Figure 1) was allocated for consent and eligibility screening prior to the baseline assessments to allow for broader recruitment. Following the initial level of interest generated by the introductory talk at the care home, and discussions with the well-being team, the researcher aimed for a sample of 20 participants.

Trial design

Ethical approval for this study was provided by London Harrow Research Ethics Committee, REC: 17/LO/1316 Protocol: RG_17-108 IRAS: 219616. The full study protocol has been published elsewhere (Doody et al., 2019). Trial registration: ClinicalTrials.gov: NCT03141879. Registered 5 May 2017. The trial was conducted between February 2019 and July 2019. The study timeline is shown in Figure 1 and represents the overall study duration.

[Insert Figure 1 about here]

All study participants completed initial screening (week -2) and baseline measures (weeks -1 and 0) prior to confirmation of group allocation. The six-week resistance training programme was scheduled weeks 1-6 for the intervention group, and weeks 9-14 for the wait-list control group. Both groups completed post-intervention testing weeks 7-8, with follow-up testing scheduled weeks 13-14 and weeks 15-16 for the intervention and wait-list control group, respectively. This staggered approach ensured that follow-up testing was completed six weeks after the end of the group exercise sessions. Participants were advised to avoid strenuous physical activity or resistance training for at least 24 hours prior to any measures of strength or functional capacity, or blood samples. Due to the comprehensive test battery, and to avoid participant fatigue, assessments were scheduled over multiple days/visits (see Figure 2).

Randomisation

The Principal Investigator conducted the randomisation and allocation independent of the identification, consent, screening, and baseline assessments. The researcher enrolled participants, conducted eligibility screening, baseline testing and informed participants of group allocation. Permuted block randomisation (1:1) was used to randomise participants. Randomisation was conducted using a computer-generated random number generator (www.randomizer.org). Group allocation was not revealed until after consent, eligibility screening and baseline measures had been completed ensuring allocation concealment and minimising selection bias. Due to the nature of the intervention and the researcher's dual role (intervention delivery and tester) further blinding was not possible. Trial participants, care staff and well-being team members were also aware of group allocation. All post-intervention and follow-up testing were completed un-blinded by the researcher. Minimisation of conscious bias was upheld by strict adherence to standardised test protocols, timing of tests and consistency of encouragement across all assessments.

Important changes to trial design after the protocol was published

The published protocol (Doody et al., 2019) advised the use of a concurrent control group design for the feasibility trial and utilisation of a wait-list control group within the subsequent future RCT. After discussion with the care home management, this was amended to a wait-list control. to ensure that all participants would have access to potential beneficial effects of the intervention, as well as nullifying the negative psychological impact of being interested in exercise for better health and then being randomised to no treatment. Both groups had continued access to regular on-site well-being activities independent from this study. Utilisation of the wait-list control group allowed more insight into the acceptability and implementation of the proposed RCT. Due to the small size and the proposed number of covariates (frailty score and age) block randomisation was adopted rather than the stratified-block method in the published protocol. Stratified-block randomisation would be a consideration for a future RCT to control for baseline covariate imbalance, reduce bias in statistical analysis and increase the power of the study.

Measures

Feasibility Outcomes

The primary aim of the study was to assess the feasibility of conducting a definitive RCT. The feasibility outcome measures are defined in Table 1 and address all key focus areas for feasibility trials (Bowen et al., 2009). All semi-structured interviews and focus groups were conducted by the researcher who had previous experience of interviewing and facilitating group discussions. The researcher had established professional relationships with all participants and staff throughout the study. Interviews took place either in the communal lounge area outside of scheduled activities or in participant's rooms to ensure a quiet, private space. Two separate focus groups were conducted in a private room. Audio from interviews and focus groups was digitally recorded using IBM ThinkPad X1 Laptop, Voice Recorder App

(Microsoft 2018) and iGOKU USB Microphone. The researcher also kept comprehensive written field notes and a reflexive diary.. Full detail of data collection is given in the trial protocol (Doody et al., 2019).

[Insert Table 1 about here]

Health and Functional Outcomes

Measures of multi-dimensional health are outlined in Figure 2, Participants Timeline, below and in the trial protocol (Doody et al., 2019). These measures were categorised into physiological, psychological, cognitive, and emotional health measures, social support, and functional capacity. Physiological measures were inflammatory cytokines, C-reactive protein, cortisol, and dehydroepiandrosterone-sulphate (DHEAS) from blood serum. Psychological and emotional measures comprised the Geriatric Depression Scale (GDS) (Yesavage et al., 1983), the Hospital Anxiety Depression Scale (HADS) (Zigmond & Snaith, 1983) and the Perceived Stress Scale (PSS) (Cohen et al., 1994). Cognitive assessment was via the Standardised Mini-Mental State Examination (SMMSE) (Molloy et al., 1991), and social support was measured through the Interpersonal Support Evaluation List (ISEL-12) (Cohen et al., 1985). Finally, functional capacity was assessed using the Activities of Daily Living (ADL) scale (Katz et al., 1970), the Short Physical Performance Battery (SPPB) (Guralnik et al., 1994) and leg strength. The Fried Frailty Phenotype (Fried et al., 2001) and SMMSE (Molloy et al., 1991) were also used as part of eligibility screening (see Figure 2). Qualitative data for each participant were recorded on an individual Case Report Form.

[Insert Figure 2 about here]

Important changes to health and functional outcome assessments after the protocol was published

The original protocol (Doody et al., 2019) specified assessment of leg strength and power output, and one repetition maximum (1RM) testing (Sheppard and Triplett (2016) p.453. The 1RM would be subsequently used for assignment of training loads. This testing methodology was amended

due to consideration of safety, appropriateness, relevance, and validity (Conlon et al., 2018; Zourdos et al., 2016). Whilst maximal strength testing *per se* is safe and acceptable for older adults (Alcazar et al., 2018) the researcher used professional judgement to select a maximal isometric strength testing protocol for lower limb only, including knee extensors, knee flexors, hip adductors, and hip abductors. This was justified on the basis that Moir (2012) proposes isometric tests to require little movement skill, be relatively easy to administer and provide additional Rate of Force Development (RFD) data. RFD has shown direct association with the ability to contract muscles rapidly and maximally, related to falls risk (Fragala et al., 2019). Further, guidelines advise that maximal strength testing may be contraindicated for adults with severe osteoporosis (ACSM, 2018) but acknowledge that no specific criteria are recommended.

Isometric maximal strength testing was performed using Performance Recorder Software Suite User Manual test protocol (13.8.2010) and HUR Rehab Line Equipment Measurement Instructions, and in line with previous research using HUR equipment (Borg et al., 2008; Mård et al., 2008). The Performance Recorder (PR1) is a reliable tool to assess isometric strength, and to monitor change in strength over time (Neil et al., 2013). Subsequent discussions with the equipment manufacturers confirmed that the 1RM test data would be reliable as an outcome measure but not appropriate for accurate training load prescription (Newton et al., 2011).

Attendance and adherence

Attendance was reported as a percentage of attended exercise sessions. Adherence to exercise prescription was measured and reported as the percentage of total repetitions completed at prescribed load. Exercise adherence data (including attendance, exercises performed, sets, reps and loads) was automatically recorded by the SmartTouch software incorporated into the exercise machines and verified by the researcher. Any technical issues which compromised accurate record keeping using

SmartTouch, including wi-fi connectivity or log-in and recognition problems, were reported and noted alongside attendance records to ensure data reliability.

Resistance Training Intervention

Equipment

The resistance training intervention utilised specialised, pneumatic, strength training equipment with SmartTouch web-based software and radio-frequency identification (RFID) user log-in systems with smart cards from the premium line of HUR SmartTouch (4th Generation) (HUR Ltd., Finland). The ergonomically designed machines were specially designed for use in active ageing programmes. The touch screens on each machine displayed participants names on log-in and sign-out, overall programme, sets, repetitions, and load.

All machines were set-up and used according to the manufacturer's guidelines. Range of motion limiters, seat heights and lever arm lengths were set, stored on individual RFID cards, and checked prior to each session. Participants were encouraged to work through full range of joint movement (unless limited by pain, or specific joint or medical problems) and with proper technique including handgrip, body and limb positioning, breathing patterns, range of movement and speed. The researcher assisted with transferring from machines to any assisted walking devices; manually modified load, if required; and offered feedback and assisted with any technology issues i.e., card recognition or wi-fi connectivity. Participants with sight, hearing or movement limitations were supported with individual attention, as needed. All RFID cards were kept in a card storage box next to the machine compressor unit and only accessed by the researcher or the participant.

Five separate, free-standing machines were used: leg press, leg extension/leg curl, chest press, hip abduction/adduction, and optimal rhomboid. The leg extension/leg curl and hip abduction/adduction machines had dual functionality, and exercise programme prescription included all seven exercises. All machines (except for hip abduction/adduction) had unilateral and bilateral

capability. The exercise equipment was installed in the main meeting room (lounge) at the care home with adequate space between machines to allow direct access from walking frames and wheelchairs.

Delivery

All exercise sessions were supervised by the researcher who was a qualified strength and conditioning coach with over 25 years of experience. Programme-specific training with HUR equipment (including isometric strength testing with PR1 and HUR Labs Performance Recorder PC software) was undertaken prior to programme commencement, with additional support available throughout the trial duration.

The sessions were run as a group-based activity with a total of five participants attending each time.. Participants wore their usual day clothes. While no specific or structured motivation strategies were used, the researcher, members of the well-being team and care-home management were supportive and encouraging throughout the intervention. Participants were actively encouraged to attend all scheduled assessment and exercise sessions. This could include a verbal reminder of the day/time of the session, and/or physical assistance in moving to the lounge. While adherence was keenly promoted, participants were assured that attendance and engagement were voluntary.

Important changes to equipment and delivery after the protocol was published

The published protocol (Doody et al., 2019) proposed using six separate machines for all participants. However, current recommendations advise that the inclusion of specific exercises, and the volume of exercise per session, needs to be tailored to individual fitness and physical function (Fragala et al., 2019; Ribeiro et al., 2020). In alignment with this, and other professional guidelines, the researcher used professional judgement to modify exercise selection for any participants, as required. This feasibility exercise intervention was subsequently amended to include only five machines (7 exercises) by exclusion of the abdominal crunch machine, directly based on guidelines for any clinical diagnosis for osteoporosis or frailty (ACSM, 2018) and extensive strength and conditioning and

biomechanics literature (McGill, 2006, 2010, 2015; Verkhoshansky & Siff, 2009) discouraging repetitive loaded spinal flexion patterns in deconditioned or weak individuals. Specific guidance for individuals with osteoporosis (Skelton & Mavroei, 2018) further recommends spine-sparing exercises and an avoidance of repetitive, weighted, loaded flexion patterns.

The proposed intervention (Doody et al., 2019) was a group exercise circuit but was subsequently modified to allow individual progression through the training prescription if required, in line with UK CMO's recommendations (Davies et al., 2019).

Exercise Prescription

The resistance training intervention was based on published recommendations for strength training for older adults including, but not limited to, ACSM Guidelines for Exercise Testing and Prescription (ACSM, 2018), NSCA Programme Design for Resistance Training (2016) and UK CMO 2019 Physical Activity Guidelines for Older Adults (Davies et al., 2019), and NSCA Resistance for Older Adults (Fragala et al., 2019). These included detailed guidance on number and frequency of sessions, structure, duration, loading, sets, reps, total volume load, rest intervals and progression.

The sessions were performed 3 times per week for 6 weeks, on Monday, Wednesday, and Friday mornings (0930-1030) allowing a minimum of 48 hours recovery between sessions. All participants were scheduled to attend 18 sessions in total throughout the 6-week intervention. Once established, total session duration, was 35-40 min, including warm-up and cool-down. Initial sessions (week one) were slightly longer in duration (45-50 min) due to participant unfamiliarity with warm-up exercises, machines and log-in systems, individual machine set-up, and establishing appropriate individual starting loads.

The short warm-up routine (~5 mins) was completed immediately prior to the resistance training programme, either sitting or standing depending on the individual participant. It included a range of low-intensity, simple movement patterns primarily aimed at increasing blood flow, joint fluid viscosity and range of movement, including shoulder rolls (forwards and backwards), across body

reaches, overhead reaches, punching patterns, marching on the spot and calf raises. The sequencing of the exercises was not strictly standardised but did follow a basic progressive format with a focus on movement quality, posture, and technique. As all participants had either walked aided or un-aided to the lounge area they had already completed ~5 min of physical activity prior to the structured session. The warm-up time was also a time for social interaction and feedback between the researcher and the participants. Post-exercise session, participants were encouraged to perform ~ 5 mins of light stretching exercises and similar mobility patterns to the warm-up sequence. All exercise sessions were supervised by the researcher ensuring high levels of fidelity around consistency of delivery, coaching technical guidance, motivation, and observation. The intervention was delivered as planned and the programme prescription is shown in Table 2.

[Insert Table 2 about here]

Although the resistance training programme exercise selection was standardised for all participants and unchanged for the study intervention, there was flexibility to individualise this design by order or movement pattern. The sequence of completion could be influenced by practical issues of transferring between machines (requiring additional time and/or assistance from the researcher), use by another group member or individual preference. All bilateral had built-in repetition recording sensors ensuring that a consistent number of repetitions were completed on each limb. Any consistent preference and sequencing were recorded in researchers field notes.

The starting loads for each participant were confirmed during the first exercise session and as part of initial familiarisation. All the participants were beginners and with no prior experience of resistance training. The concept of progressive overload and appropriate intensity were explained and consistently reinforced throughout the intervention. The OMNI resistance exercise scale (OMNI-RES) (Gearhart Jr et al., 2009) and 'reps in reserve' (RIR) (Helms et al., 2016) were used to describe to participants the appropriate loading and progression. Whilst not a key criterion of the feasibility study,

loading progression was achieved by programmed micro-adjustments on each machine: when more than 14 repetitions of a given exercise could be completed with good form, the load was automatically increased by 5% for upper limb and 10% for lower limb on the subsequent training session (Sheppard & Triplett, 2016). All loads were modifiable manually by the participant or researcher intra-session, if required, and immediate feedback was given on the machine screen to confirm whether the volume load (reps x sets x load) had been achieved. Participants were encouraged to hit their targets and gradually increase loading, but the focus was on a clear, simple message about consistency and overall session enjoyment

Initial loading was conservative and designed to improve participants confidence, orientation, and skill acquisition with secondary focus on progressive overload (Conlon et al., 2018). Load progressions were guided by the '5% and 10% increments' rather than ruled by them and subjective feedback from participants and the researcher's professional judgement were prioritised.

All participants were requested to follow the resistance training programme as prescribed and not make any substantial changes to any other physical activity for the duration of the intervention. There were no other non-exercise components in the study i.e., lifestyle coaching or specific education.

Important changes to exercise prescription after the protocol was published

The original protocol (Doody et al., 2019) suggested three-four sessions per week totalling 21 sessions over six weeks with an alternating pattern of three sessions one week, and four sessions the next. Following early discussions with the well-being team this was not considered feasible: the lounge area was often used for other routine activities, including religious services on Sundays, and a changing schedule would be disruptive to both staff and residents. It was also advised that a regular routine at a consistent timeslot would be more acceptable to potential participants, minimise interference with other activities, and increase the likely adherence and successful implementation

The original protocol (Doody et al., 2019) proposed that the prescription of training loads for the study intervention would be based on percentages of 1RM tests on each machine. This is a traditional and accepted tool within Strength and Conditioning (S&C), but is not without flaws (Sheppard & Triplett, 2016), and a considerable time requirement. Deconditioned and inexperienced participants in any resistance training programme will benefit from an orientation phase with a progressive increase in training volume load (sets x reps x load) allowing time for musculotendinous adaptations before 1RM testing. 1RM testing beginners with little/no experience of resistance training on each exercise may not be accurate and representative of actual strength levels: initial increases in strength are often attributed to improvements in neuromuscular coordination and skill rather than strength alone (Newton et al., 2011). Older adults may have existing health conditions including arthritis and joint pain or mild cognitive impairment, require a more subjective-feedback approach. Training loads were subsequently prescribed based on professional expertise and participants' subjective feedback.

Exercise prescription in the original protocol (Doody et al., 2019) proposed '2 sets of 5 reps at 80% 1RM (Repetition Maximum)'. This was modified to '2 sets of 12 reps at Rating of Perceived Exertion (RPE) light/moderate intensity' in line with current guidelines (Fragala et al., 2019). All exercises, sets, loads and reps were modifiable intra-sessions to allow for daily fluctuation and subjective feedback (Sheppard & Triplett, 2016; Verkhoshansky & Siff, 2009).

Data Analysis

All quantitative data from individual Case Report Forms were inputted into IBM SPSS Statistics for Windows, version 25.0 (IBM Corp.). Qualitative data from interviews and focus groups was transcribed verbatim into Microsoft Word and uploaded into NVivo 12 for thematic analysis. The researcher's reflective journal and additional field notes were also uploaded as supporting data.

Feasibility Outcome Measures

Thematic analysis (Braun & Clarke, 2006) was used to identify, analyse, organise, and communicate themes in the qualitative data. The researcher reviewed the audio recordings and field notes after each interview and documented additional reflections in a reflexive diary. After transcribing the interviews, the researcher read and re-read the transcripts alongside the supporting field notes and journal entries to ensure immersion in the data. Initial themes (codes) were developed deductively based on the feasibility outcomes, key areas of interest, interview questions, and used to build a coding framework in NVivo 12. Sub-themes were subsequently refined and developed inductively from analysis of theme frequencies, patterns, and occurrences in the data set. The researcher documented any initial observations to clarify coding decisions, keep track of evolving ideas and theories, and improve trustworthiness of the data by providing an audit trail (Nowell et al., 2017). Reviewing and refinement of themes, including any recoding and renaming, was completed by the authors before the final write-up and analysis.

Attendance and adherence data were analysed for both groups for the duration of their respective six-week exercise intervention (weeks 1-6 and weeks 9-14, as detailed in Figure 1) to provide further insight into feasibility, demand, and acceptability with this population.

Health and Functional Outcome Measures

Limited efficacy testing was completed on all measures.

Descriptive statistics were used to report participant characteristics, recruitment, adherence, and participation rates. Intention-to-treat analysis was applied for all variables where participant data was missing due to missing assessments or dropping out of the study: the last measure taken was carried forward. Intervention effect was calculated using mean difference (95% Confidence Intervals) pre- to post-intervention. Effect size evaluation was performed using Hedges' g and interpreted as small ($d = 0.2$), medium ($d = 0.5$), and large ($d = 0.8$) based on Cohen (1988). Analysis was pre- to post- intervention compared to the wait-list control. In line

with recommendations from Schober et al. (2018) evaluation of minimally clinically relevant changes and smallest meaningful change (Perera et al., 2006) were also reported if reliable thresholds were available. **Results**

Participants

Of those who were contacted (n=18), 15 consented to eligibility screening giving an uptake of 83.3% (see Figure 3 Consort Diagram). Four were excluded through not meeting the Fried Frailty criteria. All the eligible participants randomised to the study (n=11) completed the full baseline assessments. Six participants (54.5%) were allocated to the intervention group and five (45.5%) to the wait-list control group. One participant in the intervention group was unable to join the training intervention due to unrelated health complications and changes in medication but did not wish to withdraw. This participant remained positive that they would be able to re-join in due course and completed post- and follow-up assessments. Subsequently, all data were included in intention-to-treat analysis, (ITT). All participants (100%) were assessed for every feasibility and health and functional outcome.

[Insert Figure 3 about here]

Participants were mainly female (63%) with a mean age of 86.09 (7.18); the age range was 73-95 years. All participants were White British. Most participants had secondary or degree/diploma education (64%), had been resident at the care home for 54.00 (55.65, range: 5-156) months and reported on average 2.36 (1.36) medical conditions. Fried Frailty score was 3.27 (\pm 0.47) with SPBB scores ranging from one to eight indicating the presence of frailty and functional limitations. The Katz ADL score was 5.18 (0.98) indicating partial dependency. Calculated gait speed from the SPBB walking test was 0.48 (0.21) m·s⁻¹ suggesting increased likelihood of poor health and function, but the SMMSE score of 27.00 (4.17) indicated normal cognitive function. Baseline descriptive characteristics are summarised by group in Table 3. This also shows no significant socio-demographic or screening measure

score differences between the intervention and control group, although cognitive function was marginally higher in the intervention group.

[Insert Table 3 about here]

The primary outcomes were concerned with feasibility; quantitative feasibility statistics are shown in Table 4. Overall uptake and retention were over 80%. Attendance and adherence, in the intervention but not the control group, were consistent with previous findings (Martin & Sinden, 2001) and exceeded 80% in all cases. Table 5 presents a breakdown of adherence by participant, detailing total reps, reps at prescribed load and those meeting the adherence criteria. Most striking are the differences in adherence criteria: in the intervention group, excluding ITT, completion in all cases was over 95% and met the adherence criteria, while the control group recorded less than 50% in all cases with none meeting the criteria. All participants engaged in interviews except one person from the control group due to illness. Interview duration ranged from 8-37 minutes. Care home management and well-being staff focus groups were both 36 minutes duration.

[Insert Tables 4 and 5 about here]

Feasibility Outcomes

Qualitative findings from the focus groups and interviews established several themes for each of the feasibility issues examined. These are outlined in Figure 4 for illustrative purposes.

[Insert Figure 4 about here]

Acceptability

Two themes were identified: 'Appropriateness of Intervention' and 'Participant Experience'. As regards 'Appropriateness of Intervention', discussions were focused on the suitability of the equipment and exercise prescription, the relevance of the assessments, and engagement with the research team. Staff explained that despite some initial reservations it had fitted in well with high levels of engagement

and interest. Limited capacity to support more residents, particularly those with cognitive impairment, was reported as the only negative feature. Comments from most participants were that the exercise prescription was “reasonable”, “manageable”, and “beneficial.” One participant, commenting on the suitability, said, “I’ve just been quite happy doing the exercises and coming along. I’ve felt it’s not been too hard, too onerous, too exacting. I can quite easily cope with it and I’ve found it quite pleasant” (Mary, participant, wait-list control). Opinion about the assessments, including the overall number, requirement for multiple re-assessments and some of the questionnaires, were more divergent. For example, whilst some participants spoke of enjoying the detail and “thought-provoking” nature of the questions, others said that they were “pretty useless”, “a bit out of this world” and lacking relevance. Participants spoke positively about the practical relevance of the functional capacity tests, considered it to be “pretty obvious” that physical tests were going to be useful, and, despite it being a novel experience, took a keen interest in strength measures. Participants talked candidly about the new challenges: “getting on those machines.... grrr... and testing to your limits... phew, you know, and that’s coz I’m not used to it, you see” (William, participant, wait-list control).

In terms of ‘Participant Experience’, most participants described their experience of the intervention as having been physically, mentally, and socially beneficial, and recognised that doing more exercise positively impacted general health. Participants spoke about improvements in leg strength, balance, and movement confidence. Feedback to staff from one participant’s family had been that of astonishment such were the improvements in walking speed and capacity on a family holiday.

Commenting on their experience, one participant explained:

My balance. My walking. I do have a three-wheeler walker but even so when I first starting using it, I was zigzag on the corridor but now... and I can speed up my walking a little bit. Mentally it’s given me the confidence to do things that I couldn’t.

(Betty, participant, intervention)

Participants placed value on regular social interaction, involvement, and purpose. They spoke about enjoying talking to the researchers, the mental and physical stimulus of the intervention, and the opportunity to connect with fellow residents. One participant stated that “I think it has helped bring the five of us out that are residents in the home... I think it’s helped us relax and be able to communicate” (Betty, participant, intervention).

Demand

The feasibility outcome of Demand generated two themes of ‘Attendance and Adherence’ and ‘Interest and Reasons for Involvement’. Regarding ‘Attendance and Adherence’, participants suggested that three days a week was “not excessive” and “just about right.” One participant with full attendance noted, “Well, I think this is the sort of thing, once you start you’ve got to keep it going. To be most effective” (James, participant, intervention). Staff members expressed surprise at the commitment and adherence of participants and explained that this was contrary to their initial expectations. Reflecting on why attendance had exceeded expectations, staff were candid about the need for routine, structure, consistency, and encouragement when working with older adults in residential care.:

Recorded levels of attendance and adherence were notably lower in the wait-list control group. Staff suggested that individual levels of motivation, group cohesion and physical proximity to the exercise equipment may have made a difference.

‘Interest and Reasons for Involvement’ was identified as a theme with several participants enthusiastically embracing the opportunity to take part. Participants spoke about enjoying the physical challenge, mental stimulation, self-reflection, and opportunity to benchmark their functional ability. For example, one participant said, with laughter:

I know I’m 80 and things do wear out but what’s the point? If you’ve got the help to do something to improve your health both physically and mentally, and it’s free, then why not benefit... make use of it? (Betty, participant, intervention)

Staff discussed a “can-do attitude” towards research in the residential care home and were upbeat about the physical activity intervention and potential impact. Participants spoke about “being useful”, “helpful”, creating more knowledge and a feeling that others may benefit from the findings: “Does it mean that I’m helping people? Now, if I’m helping anybody, good, tick me off please, and I’ll step into that one quite freely” (Joyce, participant, wait-list control).

Implementation

Two themes were developed here: ‘Location and Space Considerations’ and ‘Timetabling Issues’. Regarding ‘Timetabling Issues’, staff and participants felt that working within and respecting the existing daily routines of the care home had minimised any negative impact and meant that the intervention “fitted in” well. ‘Location and Social Space Considerations’ was a more contentious theme. Some staff members felt strongly that installing and using the exercise equipment in the lounge area was detrimental:

It restricts a lot of space and loads of people don’t like it which then creates actually more negative feeling about it rather than creating a positive ‘oh, I would get involved’... they don’t want it in their space, it’s getting in the way... in an ideal world I don’t think anyone would want it there permanently. (Jessica, staff member)

Others maintained that any negative issues were minor with the benefits outweighing any perceived disadvantage. One staff member, for example, expressed an opinion that high visibility and accessibility had been advantageous:

I think a lot of it has been to do due with the fact that it is so visible. It’s kept it in their thoughts... ‘oh, yes we’re doing that’.... and then other people have asked them questions and they like the fact that they can say, ‘I’m involved in this that and the other’... and doing this... so helps to generate it because they’ve got a talking point

1 whereas if it's away in a cupboard people aren't going to say, 'what's that all about?'

2 because they don't see it. (Linda, staff member)

3 ***Practicality***

4 For Practicality, 'Demands on Staff Time' and 'Intervention Suitability in Residential Care Setting'

5 themes emerged. 'Demands on Staff Time' was a theme for both staff and participants. Overall, staff felt

6 positively about their time input and how it had changed over the project duration: more help was

7 needed in the early stages including assistance with local knowledge, promotion, and recruitment

8 whereas latter stages required less direct involvement. The need to request additional help from staff to

9 access the equipment, for example, was a concern for some less able participants: "I was a bit

10 concerned that two people had to lift me off that one machine, well helped with a lift up. I don't like to

11 involve the staff, you see" (William, participant, wait-list control).

12 In terms of 'Intervention Suitability in Residential Care Setting', it became clear that there were

13 important practical considerations around scheduling and space demands. Staff pointed out that

14 minimising changes to pre-existing schedules and creating a routine would be important for any future

15 research. The demands on space in residential care homes was recognised as a practical issue of

16 "impact" and "restriction", and experienced care staff saw this is a potential barrier: "They [care homes]

17 weren't designed with certain things in mind as care has progressed on so it's not just a problem in that

18 room in this instance, it's a general problem" (Linda, staff member).

19 ***Integration***

20 Regarding Integration, two themes were explored: 'Perceived Fit of Exercise into Existing

21 Culture' and 'Long-term Sustainability'. For 'Perceived Fit in to Existing Culture', staff noted that exercise

22 was already an accepted, regular, and popular feature on the well-being timetable in the form of a

23 seated 'Music and Movement' class. However, it was discussed that although this was "fantastic" for

frail and wheelchair-bound people the training intervention had been a “real outlet”, and a good fit for those who wanted to participate in more challenging exercise options.

Under ‘Long-term Sustainability’, staff remarked that there was additional demand for the equipment above and beyond the feasibility trial, and that even residents who were not involved in the trial had expressed interest. One staff member felt strongly that it was viable and would provide an opportunity to reinforce education surrounding long-term quality of life:

I have seen frail people become a lot better. And I think that the education... just because you’re old, isn’t an excuse for poor quality of life, because you can get better. You can improve your quality of life, until you die. (Lauren, staff member)

Most study participants were also supportive of long-term possibilities: “I think it’s been a great idea and I only hope that they’ll keep the equipment, quite frankly.” (Arthur, participant, intervention)

Adaptation

Two key themes were established here: ‘Changes to Session Frequency’ and ‘Modifications to Equipment’. While staff and participants were open to considering changes to the frequency of sessions there was overall support for the original format (three times per week). Some staff members talked positively about increasing the availability of sessions so long as this could be maintained within a regular structure and routine: “I think that people really like routine here and if you can build it into a routine, you could even get it more frequently really” (Jessica, staff member).

Under ‘Modifications to Equipment’, most staff comments were positive and included praise for the specific design functions for older people, ability to individualise loading and progression, and ease of installation. Feedback from participants was more nuanced: some participants considered it lacked broader accessibility and had presented challenges including physically “getting on” to the machines. Several participants were, however, undaunted by any additional physical demands. As one particularly upbeat interviewee laughingly explained:

Well, out of 4 machines there was one where... well I called it 'The Beast'... because you had to put your legs under these rollers, and I did find that difficult, but we laughed about it and I was helped. (Betty, participant, intervention)

Expansion

Two key themes emerged from the feasibility outcome of Expansion 'Impact on Budget, Resources and Staffing' and 'Effect on Residential Care Home Environment'. AStaff felt that any further expansion would be a "huge commitment and cost", were concerned about "cost effectiveness" and whether use would be sustained long-term. Staff explained that the equipment alone would not be enough, and having a specialist, trained and motivating individual on-site with an ability to understand older people "makes a difference":

I don't think you could put it in a room aside from anything else. I think you've got to build something else in. So, whether you have a person who oversees the whole lot and spurs people on, it's encouragement, I think, really. I think you've got to have that particular person who's motivating enough to do it. (Susan, staff member)

'Effect on Residential Care Home Environment' was identified as an issue for further expansion, especially in care facilities that were not purpose built, with the equipment viewed as "taking up a lot of space." However, there were differing perspectives within the staff:

I find there to be a big benefit with exercise so I would out-weigh the benefit with the fact that it is in the room because I know the benefit of exercise, I put a lot of stock into it. Yes, I would be quite happy to have it stay there regardless of the fact that it is in the way or not, but I understand that it might not be ideal, but I think it's good. (Lauren, staff member)

Limited Efficacy Testing

Two key themes were established: here ‘Meaningful Impact on Functional Capacity’ and ‘Satisfaction with Intervention’. In terms of ‘Meaningful Impact on Functional Capacity’ it became clear that improvements in strength, walking speed, and balance were recognised and valued by both staff and participants. Participants described feeling “much firmer on my feet”, healthier, and strong enough to get out of chairs without using their arms:

Well, overall, I found it very beneficial physically and also mentally because I’ve been diagnosed with vascular dementia and having various buttons to press, when and whatever, I have found it very beneficial. But physically I am doing things that I haven’t been able to do, for you know. (Betty, participant, intervention)

However, some participants were more reserved with their judgements, and felt that it had not “made a great deal of difference”, “achieved a limited objective” and that while it had “built things up somewhat”, it was too soon to assess the impact.

In relation to ‘Satisfaction with Intervention’ both staff and participants felt that overall, the intervention had been a positive experience: staff spoke about it as having been “a great success”, “better than we anticipated” and “really good.” It was suggested that it had been a “social interaction” and facilitated a “joining together of the group.” One staff member commented on the social aspect of the group intervention: “I think it’s good to keep this generation of people as busy as possible because it fights loneliness and fights all sorts of other things, so I think that it has been really positive time” (Lauren, staff member). Participants talked in terms of having been “very happy” and “pleased”, and “enjoying” the intervention: “Yes, I’m just sorry that it’s come to an end and just hope and pray that these machines can be here a bit longer. Sorry to see them go whenever” (Betty, participant, intervention). And another reflected that “in a way, it’s given us a little bit more purpose in living. It feels as though perhaps you might be, you can still be a little bit useful, even though you are old” (Mary, participant, wait-list control).

Health and Functional Outcomes

Analyses of pre-intervention to post-intervention compared to wait-list control indicated significant differences in some variables, however, due to the feasibility nature of this study, mean differences, 95% CI and effect sizes are also presented (see Table 6). Changes that are most notable are shown in Table 6. These included differences in some measures of strength and functional capacity: peak torque measures for right knee extension ($p = .03$, effect size = 1.47) and hip abduction ($p = .04$, effect size = 1.36), and Fried Frailty walk time ($p = 0.04$, effect size = -1.34), walk test speed ($p = 0.00$, effect size = 2.35), and total score ($p = 0.00$, effect size = -2.07). Changes over time in some measures of functional capacity also indicated clinically important change (Kwon et al., 2009): mean difference in SPPB gait speed ($0.24 \text{ m}\cdot\text{s}^{-1}$) and SPPB total score (1.50).

[Insert Table 6 about here]

Measures showing improvement, as described above, are shown in Figures 5-9. The follow-up timepoint is also shown for the sake of completeness. Variables which did not seem to differ in any way between the groups over time were cytokines, stress hormones, and psychological/emotional (GDS, HADS, PSS), cognitive (SMMSE), and social support measures (ISEL).

[Insert Figures 5-9 about here]

Harms

There were no reported adverse events during the feasibility trial.

Discussion

This study has shown that a resistance training intervention designed to improve multi-dimensional health and functional capacity of frail older adults in residential care is feasible. The results of this trial support the development of a definitive RCT, and provide relevant feedback in terms of acceptability, demand, integration, adaptation, practicality, implementation, and expansion. With respect to the secondary aim of performing limited efficacy testing on measures of health and functional

capacity, the results indicate large effect size values, positive trends and meaningful improvements in frailty, strength, and functional capacity. No meaningful change was found in terms of psychological, cognitive, and emotional health, physiological and social support measures.

Acceptability

Acceptability of the intervention was evident, with positive feedback on the trial structure, equipment, and exercise prescription.. Levels of interest, uptake, and retention suggest that recruitment and screening processes were effective and appropriate. The recruitment rates were similar or higher than other resistance training studies with older adults in residential care (Fien et al., 2016; Johnen & Schott, 2018), and drop-out rates lower than those reported in RCTs examining exercise programmes in older adults (Martin & Sinden, 2001; Paw et al., 2008) with no adverse effects reported. The number and range of assessments were well tolerated by all participants, with perceived or measurable changes in strength and functional ability considered as most relevant and interesting. In line with work by Dionigi and Cannon (2009), these actual and perceived changes appeared to contribute to increased feelings of achievement, confidence, and satisfaction. Despite no meaningful change in social support measures, participants reported enjoying the social interaction, engagement with other residents and staff, and gaining a sense of purpose. This finding is consistent with Devereux-Fitzgerald et al. (2016) who found perceived value, enjoyment and social interaction to be key factors relating to older adults' acceptability of physical activity interventions.

Demand

Levels of attendance and adherence were comparable with or higher than previous studies of older adults in long term care (Ferreira et al., 2018; Finnegan et al., 2015; Forster et al., 2010), and an exercise frequency of three times per week was considered appropriate. This supports earlier findings from group resistance training interventions (Hruda et al., 2003; Lazowski et al., 1999; Sahin et al., 2018) and is consistent with current exercise guidelines for older adults (Davies et al., 2019; Fragala et al.,

2019). Clear differences were identified between the groups for adherence and attendance. Although the magnitude of this difference was surprising, challenges and barriers relating to retention, adherence, and participation are not uncommon. Previous research highlighted the complex multi-dimensional nature of frailty (Ferrucci et al., 2004; Provencher et al., 2014) and identified several barriers including poor health, pain and fatigue (Burton et al., 2017; Hassan et al., 2016). In the present study, these differences could be attributed to two likely factors that occurred when the wait-list control received their intervention. First, there was lower one-to-one support during this time due to unforeseen reduced availability of the researcher. Second, there was unanticipated disruption to the schedule due to timetabling conflicts, a period of restricted access due to infection control measures and bank holidays. Interest and willingness to be involved was evident with reported reasons for involvement spanning enjoyment, interaction, improvements in physical function, and a desire to help others by contributing to research. These results match those of previous studies where participants cited keenness to contribute to society or knowledge (Lui et al., 2009), and enjoyment of social interaction (Devereux-Fitzgerald et al., 2016).

Implementation

The trial was ably supported by the care staff and management team. Consistent with the literature, supportive partnerships with on-site carers and allied health professionals, and enthusiastic backing from welfare activity coordinators and instructors may have been influential in the success of the intervention (Finnegan et al., 2015; Hawley-Hague et al., 2016; Provencher et al., 2014). Using a busy communal area for the equipment, however, remained a somewhat contentious issue throughout. Nonetheless, deliberately creating a high level of visibility in the home may have had a positive influence on levels of adherence, interest and long-term sustainability (Fien et al., 2016; Fien et al., 2019; Mulasso et al., 2015).

Implementation of all multi-dimensional health measures presented some challenges including scheduling, equipment availability, time commitment, and energy levels. However, participants did willingly take part with only limited numbers requiring rescheduling due to unanticipated illness or fatigue. Several participants questioned the requirement for such comprehensive measures and reported finding them repetitive and tiring. These findings correspond with previous observations which suggest that respondent burden (Ferrucci et al., 2004) and unfavourable benefit-burden ratio (Mody et al., 2008) may negatively impact recruitment and retention rates of older adults. Given this, and that the meaningful effects here were shown for measures of physical function and frailty, fewer assessments of psychosocial factors should be included in the definitive trial, or briefer versions could be considered.

Practicality

The intervention placed some additional demand on staff and management time, and resources. This was most apparent during equipment installation, recruitment, scheduling, and assessment periods. However, the requirement for extra support declined during the exercise intervention phases as routines became established, and participants became increasingly confident and familiar with the programme and equipment.. These results suggests that initial financial outlay on specialised resistance machines may pay off longer term with ease of use, and individualised progressive programmes... Previous research lends support to the use of technology with Valenzuela et al. (2018) suggesting that an under-used advantage of technology-based exercise programmes with older adults is the provision of automatically recorded exercise sessions, load progression, and real-time feedback. Work by Bossers et al. (2014) with older, institutionalised adults with dementia, and Johnen and Schott (2018) with nursing home residents, also identified the ability to start individualised, progressive programmes from a low baseline intensity as a contributor to higher adherence rates. Concerns about space for the equipment and appropriate location and timetabling of group sessions, highlighted some potential barriers. . These findings are in line with Lazowski et al. (1999) who drew attention to the challenges of intervention

delivery, location, and competing appointment times with other activities in long-term care facilities, and Benjamin et al. (2009) who reported space constraints and limited designated space for exercise.

Integration

The exercise intervention was perceived to fit in well to the existing culture and, once established, it quickly became recognised as part of the care home's broader commitment to wellness and health. A positive attitude towards research from management and well-being staff was critical to this level of integration. These results broadly support earlier findings citing the positive impact of motivated, enthusiastic staff on attendance of group exercise in nursing homes (Finnegan et al., 2015), and the social influence of health care workers, health professionals and physicians on physical activity in older adults (Burton et al., 2017; Rhodes et al., 1999; Wilson & Spink, 2006). Longer-term sustainability in this setting appeared viable with participants continuing to use the equipment after the trial completion, additional requests to use the equipment, and a keen interest in future research. This result agrees with Bastone Ade and Jacob Filho (2004) who, after a six-month exercise intervention with nursing home residents, reported an expressed hope from participants for the programme continuation. However, this would need formal longitudinal assessment to establish longer term adherence rates.

Adaptation

Potential modifications to the existing intervention were considered, and although there was no firmly identified need for amendments, there was interest to increase the number and availability of exercise sessions. This was somewhat contrary to expectations given the age, frailty, and low levels of physical activity of the participants and may be explained by the reported high levels of enjoyment, social interaction, and achievement. It is encouraging to compare these findings with work by Rydeskog et al. (2009) and Dionigi and Cannon (2009) who reported a rich variety of positive feedback from older adults' experiences of resistance training including increased zest for life, confidence, enhanced feelings of self-esteem and competency. The requirement to modify one exercise machine that required

stepping backwards to exit was evaluated in the light of risk of injury and concerns by staff regarding less able participants. This finding agrees with previous work highlighting potential barriers for older adults participating in resistance training including a lack of age-appropriate training programmes, equipment, and facilities (Burton et al., 2017), and concerns about pain and falling (Franco et al., 2015; Freiburger et al., 2016). However, some participants revelled in mastering this task, and in agreement with Lazowski et al. (1999) this demonstrates the requirement for appropriately challenging individualised programmes.

Expansion

Further expansion of the programme raised budgetary concerns from staff relating to the cost of the equipment, maintenance, and training. A requirement for more dedicated space to house equipment and run group sessions was also seen as a potential obstacle. This fits with previous studies that found although administrators spoke positively about the benefits of physical activity, they identified substantial staffing and funding constraints, limited space, and a lack of dedicated rooms as barriers to provision in long term care homes (Baert et al., 2016; Benjamin et al., 2009; Kalinowski et al., 2012). In fact, the home has retained three of the five machines.

Limited Efficacy Testing

With respect to the feasibility outcome of limited efficacy testing on measures of multi-dimensional health and functional capacity, the results indicated meaningful change and large effect sizes across some but not all measures. Consistent with the literature on progressive resistance training for frail, older adults, this study indicated positive change in strength and functional capacity (Fragala et al., 2019; Latham et al., 2004; Liu & Latham, 2009; Maestroni et al., 2020; Paw et al., 2008; Valenzuela, 2012) and reduction of frailty (Arrieta et al., 2019; Binder et al., 2002; Ferreira et al., 2018). Interestingly, no evidence was found for changes to other multi-dimensional health measures. These findings are contrary to earlier research that identified overall improved mood and cognitive function, lower state

and trait anxiety, and increased IGF-1 levels in older men after 24 weeks of high intensity resistance training (Cassilhas et al., 2010; Cassilhas et al., 2007), and a meta-analysis indicating that physical activity and exercise can be effective in improving mental wellbeing in older adults aged 65 and over (Windle et al., 2010). A possible explanation for these findings is that the six-week exercise intervention was too short to effect significant change in these measures. It is also possible that the supportive, faith-based community within the residential care home positively impacted on the stability of measures of psychological, emotional, and social support status. The qualitative analysis identified a positive meaningful impact on self-reported functional capacity, and high levels of enjoyment and satisfaction with the intervention. Similarly, previous qualitative studies with older adults engaged in regular resistance training reported enhanced appetite for life, calm, self-esteem, and physical confidence (Dionigi & Cannon, 2009; Rydeskog et al., 2009).

Limitations

The present feasibility study had several limitations. First, the short duration of the resistance training intervention may have influenced levels of uptake and attendance, and might not accurately represent dropout and adherence rates for a longer duration RCT. This may also have impacted physiological adaptations, and affected the lack of measurable changes in other markers of multi-dimensional health due to a lack of sensitivity to subtle change over a short time course. Second, the specialised equipment utilised in this study may not be accessible or affordable for larger or multicentre trials, consequently limiting broader expansion. Third, the current study was based on a small sample size thus limiting statistical power; however, as the primary aim of the study was to investigate feasibility, this was deliberate.

Recommendations and Future Directions

Based on the findings discussed above, we would make the following recommendations for the definitive RCT.. To reduce potential bias, where possible, all assessments should be carried out by a

researcher who is blinded to group allocation. The exercise sessions should run for at least 12 weeks, with fewer and/or more sensitive questionnaire measures. Ideally, an experienced, enthusiastic instructor should be present at all sessions to ensure consistency of delivery and support. The intervention should also be run in a visible setting and in a group for the positive effects that this brings. Additional help with, and reminders about, session attendance should be provided for participants with disability or mobility limitations, or cognitive impairment. Additionally, facilitating wider use of the equipment by care home residents who are not study participants, staff and families should be actively encouraged.

As well as the future RCT, future research could usefully explore whether there is any measurable impact on markers of multi-dimensional health over a longer follow-up, and to determine longer-term attendance and adherence. It could also be valuable to assess the impact of moving towards independent exercising as this may be important for longer term adherence, sustainability and expansion. It would also need to examine whether such programmes are economically viable. Research is also needed to investigate the effects of resistance training on frail, older adults with cognitive impairment and dementia, which, although included in this study was not the focus. Prevention of the progression to frailty would also be interesting to examine, by testing the intervention in pre-frail older adults in residential care and/or supported housing. Our next project addresses this latter question.

Conclusion

The KARE feasibility trial was found to be feasible in terms of acceptability, demand, integration, adaptation, practicality, implementation, and expansion. Some modifications are recommended to reduce potential assessor bias and ensure consistency of exercise delivery and support. These could be addressed with minor changes to the study design and additional support from residential care staff. Limited efficacy testing indicated that a resistance training intervention with frail, older adults may positively impact measures of frailty, strength, and functional capacity. Qualitative feedback suggested

that enjoyment, social interaction, achievement and gaining a sense of purpose were key motivators. Participants also reported a meaningful impact on self-reported functional capacity and physical confidence. Collectively these findings support the feasibility of a definitive, RCT using a resistance training intervention with frail older adults in residential care. The study findings reinforce the value of resistance training interventions with improvements in strength and functional capacity contributing to a reduction of frailty.

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Table 1*Feasibility Trial Outcomes, Objectives, and Assessments*

Area of Focus	Objectives	Assessment or measure
1. Acceptability	<ul style="list-style-type: none"> • To assess screening and eligibility criteria • To evaluate recruitment, retention, and adherence rates • To evaluate participant experience, feedback, and perceived appropriateness • To investigate the views and opinions of management, care, and support staff 	<ul style="list-style-type: none"> • Participant uptake analysis • Semi-structured interviews with participants • Focus groups with well-being team staff, care staff and management
2. Demand	<ul style="list-style-type: none"> • To determine level of interest, actual use, and adherence • To investigate staff opinion of trial suitability and proposed, definitive RCT 	<ul style="list-style-type: none"> • Analysis of uptake rates • Exercise intervention adherence rates • Focus groups with well-being team staff, care staff and management
3. Implementation	<ul style="list-style-type: none"> • To determine factors affecting ease, difficulty, or quality of implementation in this setting • To evaluate the applicability of the selected measures of multi-dimensional health and wellness • To determine any logistical issues which may require consideration or amendment prior to RCT 	<ul style="list-style-type: none"> • Semi-structured interviews with study participants • Focus group with well-being team staff, care staff and management
4. Practicality	<ul style="list-style-type: none"> • To determine time-cost, burden and benefit for researcher, participants, staff, and broader support team • To evaluate any practical constraints around required resources, time, or commitment • To assess the quality and suitability of the intervention in this setting 	<ul style="list-style-type: none"> • Semi-structured interviews with study participants • Focus groups with well-being team staff, care staff and management
5. Integration	<ul style="list-style-type: none"> • To assess integration into the existing culture, protocols, and procedures within the care home • To investigate perceived fit and longer-term sustainability in this setting 	<ul style="list-style-type: none"> • Focus groups with well-being team staff, care staff and management

6. Adaptation	<ul style="list-style-type: none"> • To evaluate the requirement for any modification or amendments to the existing intervention 	<ul style="list-style-type: none"> • Focus groups with well-being team staff, care staff and management • Semi-structured interviews with study participants
7. Expansion	<ul style="list-style-type: none"> • To investigate any potential disruption, positive or negative effects on environment, organisation, or culture from potential programme expansion • To assess any budget and/or resource requirements for further expansion 	<ul style="list-style-type: none"> • Focus groups with well-being team staff, care staff and management • Semi-structured interviews with study participants
8. Limited-efficacy testing	<ul style="list-style-type: none"> • To examine the potential positive meaningful impact of a moderately intensive 6-week resistance training intervention on markers of multi-dimensional health in frail, older adults • To assess the efficacy of the intervention on the health and functional variables (identified as primary dependent variables of a proposed future RCT) 	<ul style="list-style-type: none"> • Analysis of the health and functional variables • Analysis of uptake and adherence rates • Analysis of the level of satisfaction with the interventions through interviews and focus groups

Note. RCT = Randomised controlled trial

Table 2

Programme prescription including sets, reps, inter-set recovery interval and intensity (load)

Exercise	Sets	Reps	Inter-set recovery (s)	Speed of movement	Load
Optimal Rhomboid	2	12	120	Concentric: as	Progression from 'light-
Hip Adduction	2	12	120	rapidly as possible	moderate' intensity
Hip Abduction	2	12	120	while maintaining	(RPE 5-6) to 'moderate-
Chest Press	2	12	120	sound technique.	hard' (RPE 7-8)
Leg Extension	2	12	120	Eccentric: controlled	(Equivalent OMNI-RES 4-6 progressing to 6-8, with 2-4 RIR)
Leg Curl	2	12	120	(1-2 sec)	
Leg Press	2	12	120		

Note. RPE = Rating of Perceived Exertion, OMNI-RES = OMNI-Resistance Exercise Scale, RIR = Repetitions in Reserve

Table 3*Baseline Sociodemographic, Anthropometric, and Health-related Characteristics of Sample*

Variable		Mean (SD) / n (%)		p
		Intervention (n=6)	Wait-list Control (n=5)	
Age (years)		85.83 (7.83)	86.40 (7.20)	.90
Range (years)		73-93	79-95	
Gender	Female	3 (50.0)	4 (80.0)	.30
BMI (kg/m ²)		25.22 (4.87)	27.83(1.75)	.29
Medical conditions		3.00 (1.55)	1.60 (0.55)	.09
Education	Primary	1 (16.7)	3 (60.0)	.27
	Secondary	4 (66.7)	2 (40.0)	
	Degree/Diploma	1 (16.7)	0 (0)	
Education years		10.67 (1.03)	9.40 (0.89)	.06
Occupation	Manual	2 (33.3)	2 (40.0)	.82
Marital status	Never	1 (16.7)	2 (40.0)	.33
	Married	2 (33.3)	0 (0.0)	
	Separated/divorced	0 (0.0)	1 (20.0)	
	Widowed	3 (50.0)	2 (40.0)	
Length of stay (months)		46.7 (57.5)	62.8 (58.6)	.66
Fried Frailty score		3.33 (0.52)	3.20 (0.45)	.66
SPPB score		5.83 (1.94)	3.60 (3.13)	.18
SPPB Gait Speed (m·s ⁻¹)		0.55 (0.20)	0.39 (0.21)	.23
Katz ADL		5.50 (0.84)	4.80 (1.10)	.26
SMMSE		29.17 (1.17)	24.40 (5.13)	.05*

Note. * $p \leq 0.05$, ** $p \leq 0.01$, *** $p \leq 0.01$, differences indicated by independent t-tests, or chi-squared for categorical variables. ADL = Activities of Daily Living, BMI = Body Mass Index, SMMSE = Standardised Mini Mental State Examination, SPPB = Short Physical Performance Battery

Table 4*Overall Feasibility Statistics*

Statistic		Group	Percentage
Study uptake		Both	83.3
Retention rate		Both	100.0
Session attendance ^a			
	All allocated participants (n=6)	Intervention	82.4
	Excluding ITT participant (n=5)	Intervention	98.9
	All allocated participants (n=5)	Wait-list Control	34.4
Session adherence ^b			
	All allocated participants (n=6)	Intervention	83.05
	Excluding ITT participant (n=5)	Intervention	99.66
	All allocated participants (n=5)	Wait-list Control	24.68

Note. ITT = Intention-to-Treat

^anumber of scheduled sessions attended, reported as a percentage of total available sessions.

Intervention group = 18 total sessions (6 weeks x 3 wk⁻¹); control group = 12 total sessions (six scheduled sessions cancelled by facility due to room timetable clashes and norovirus outbreak containment procedures). ^b adherence to intervention exercise prescription (calculated as percentage of total reps completed at prescribed load)

Table 5*Session Adherence by Participant*

Participant ID	Group	Adjusted reps (total reps - reps at < prescribed load)	Actual reps completed	Prescribed reps completed	Adherence criteria met
			(% of total prescription)		(Y/N)
01	Intervention	2972	98.28	98.28	Y
09	Intervention	3097	102.41	100.00	Y
10	Intervention	3565	117.89	100.00	Y
14	Intervention ^a	0	0.00	0.00	N
15	Intervention	3099	102.48	100.00	Y
17	Intervention	3911	129.33	100.00	Y
05	Wait-list Control	290	9.59	9.59	N
06	Wait-list Control	366	12.10	12.10	N
07	Wait-list Control	1116	36.90	36.90	N
11	Wait-list Control	1462	48.35	48.35	N
13	Wait-list Control	498	16.47	16.47	N

Note. Adjusted reps includes all optimally and overperformed reps, as reported by the SmartTouch software, and in line with the progressive loading prescription. Adherence criteria is detailed in the published protocol (Doody et al., 2019)

^aIntention-to-Treat (ITT) participant

Table 6*Effects Table: within and between-group changes from baseline to follow-up*

Outcome Measure	Intervention					Wait-list Control					Mean difference in changes between groups		
	n	Pre mean (SD)	Post mean (SD)	Mean Difference (95% CI)	p	n	Pre mean (SD)	Post mean (SD)	Mean Difference (95% CI)	p	Mean Difference (95% CI)	p	Effect size (Hedges' g)
Knee ext. left, peak torque (Nm)	6	79.44 (33.77)	92.93 (43.13)	13.49 (-0.24, 27.21)	.05*	4	49.34 (21.28)	43.51 (15.14)	-5.83 (-22.64, 10.98)	.45	19.31 (-2.39, 41.02)	.07	1.20
Knee ext. right, peak torque (Nm)	6	79.86 (33.28)	92.13 (41.68)	12.27 (4.03, 20.50)	.01**	5	52.13 (17.19)	50.04 (12.33)	-2.09 (-14.03, 9.86)	.70	14.35 (2.14, 26.57)	.03*	1.47
Knee flex. left, peak torque (Nm)	6	35.82 (17.96)	44.25 (18.38)	8.44 (0.50, 16.38)	.04*	5	28.75 (7.44)	27.24 (6.05)	-1.51 (-10.21, 7.19)	.70	9.95 (-1.81, 21.70)	.08	1.06
Knee flex. right, peak torque (Nm)	6	44.70 (20.59)	51.73 (22.74)	7.03 (1.78, 12.27)	.01**	5	29.35 (11.96)	28.77 (11.39)	-0.58 (-6.32, 5.17)	.83	7.60 (-0.33, 15.53)	.06	1.22
Hip adduction, peak torque (Nm)	6	94.74 (36.95)	105.41 (42.05)	10.68 (90.28, 21.07)	.05*	5	74.50 (23.25)	72.93 (15.46)	-1.57 (-12.96, 9.82)	.76	12.25 (-3.17, 27.66)	.11	1.00
Hip abduction, peak torque (Nm)	6	61.81 (20.19)	69.22 (20.55)	7.42 (1.23, 13.61)	.02*	5	63.42 (13.56)	60.89 (8.99)	-2.53 (-9.31, 4.26)	.42	9.94 (0.76, 19.13)	.04*	1.36
SPPB Balance test (0-4)	6	3.17 (0.75)	3.17 (0.75)	0.00 (-0.70, 0.70)	1.00	5	1.80 (2.05)	1.40 (1.95)	-0.40 (-1.17, 0.37)	.27	0.40 (-0.64, 1.44)	.41	0.48
SPPB Gait speed (0-4)	6	2.00 (0.89)	3.17 (0.98)	1.17 (0.12, 2.22)	.03*	5	1.40 (0.55)	1.60 (.089)	0.20 (-0.95, 1.35)	.70	0.97 (-0.58, 2.51)	.18	0.78
SPPB Gait speed (m·s ⁻¹)	6	0.55 (0.20)	0.79 (0.19)	0.24 (0.07-0.40)	.01**	5	0.39 (0.21)	0.46 (0.27)	0.07 (-0.12-0.25)	.43	0.17 (-0.07-0.42)	.14	0.88
SPPB Chair stand (0-4)	6	0.67 (0.52)	1.00 (1.10)	0.33 (-0.23, 0.90)	.21	5	0.40 (0.55)	0.40 (0.55)	0.00 (-0.62, 0.62)	1.00	0.33 (-0.52, 1.19)	.36	0.50
SPPB Total points (0-12)	6	5.83 (1.94)	7.33 (2.25)	1.50 (-0.02, 3.02)	.05*	5	3.60 (3.13)	3.40 (3.29)	-0.20 (-1.86, 1.46)	.79	1.70 (-0.57, 3.97)	.11	0.95
Katz ADL (0-6)	6	5.50 (0.84)	5.17 (0.98)	-0.33 (-0.96, 0.29)	.26	5	4.80 (1.10)	4.60 (1.34)	-0.20 (-0.89-0.49)	.53	-0.13 (-1.06, 0.79)	.75	-0.18
Fried Frailty, weight loss (0-1)	6	0.17 (0.41)	0.00 (0.00)	-0.17 (-0.45, 0.11)	.21	5	0.00 (0.00)	0.00 (0.00)	0.00 (-0.31, 0.31)	1.00	-0.17 (-0.60, 0.26)	.36	-0.50

Outcome Measure	Intervention					Wait-list Control					Mean difference in changes between groups		
	n	Pre mean (SD)	Post mean (SD)	Mean Difference (95% CI)	p	n	Pre mean (SD)	Post mean (SD)	Mean Difference (95% CI)	p	Mean Difference (95% CI)	p	Effect size (Hedges' g)
Fried Frailty 2a, depression (0-3)	6	1.33 (1.21)	1.00 (0.89)	-0.33 (-1.59, 0.92)	.56	5	1.00 (0.71)	1.60 (1.14)	0.60 (-0.77, 1.97)	.35	-0.93 (-2.79, 0.92)	.28	-0.63
Fried Frailty 2b, depression (0-3)	6	1.00 (1.10)	0.50 (0.55)	-0.50 (-1.34, 0.34)	.21	5	1.20 (1.30)	1.20 (1.30)	0.00 (-0.92, 0.92)	1.00	-0.50 (-1.75, 0.75)	.39	-0.50
Fried Frailty, grip strength (kg)	6	21.82 (6.39)	24.55 (7.44)	2.73 (0.82, 4.65)	.01**	5	15.78 (2.96)	16.48 (3.23)	0.70 (-1.39, 2.79)	.47	2.03 (-0.75, 4.82)	.13	0.90
Fried Frailty, walk test (s)	6	9.03 (4.48)	5.80 (1.31)	-3.23 (-5.90, -0.56)	.02*	5	16.06 (12.25)	17.07 (12.77)	1.01 (-1.91, 3.93)	.45	-4.24 (-8.19, -0.28)	.04*	-1.34
Fried Frailty, walk test speed (m·s ⁻¹)	6	0.60 (0.24)	0.82 (0.17)	0.22 (0.13-0.31)	.00***	5	0.44 (0.29)	0.40 (0.27)	-0.03 (-0.13-0.07)	.46	0.25 (0.12-0.39)	.00***	2.35
Fried MLTAQ (kcal·wk ⁻¹)	6	75.61 (89.54)	76.89 (63.88)	1.28 (-72.57, 75.13)	.97	5	32.47 (32.49)	8.55 (16.08)	-23.92 (-104.81, 56.98)	.52	25.20 (-84.34, 134.73)	.62	0.29
Fried Frailty Total (0-5)	6	3.33 (0.52)	2.00 (0.89)	-1.33 (-1.96, -0.71)	.00***	5	3.20 (0.45)	3.40 (0.55)	0.20 (-0.49, 0.89)	.53	-1.53 (-2.46, -0.61)	.00***	-2.07
GDS total (0-30)	6	5.67 (3.20)	5.33 (3.67)	-0.09 (-74.85, 74.67)	.87	5	6.20 (1.92)	4.80 (3.03)	-1.40 (-3.75, 0.95)	.21	-2.11 (4.25, 0.47)	.47	0.42
HADS anxiety (0-7)	6	2.33 (2.66)	2.83 (3.31)	0.50 (-2.13, 3.13)	.67	4	3.75 (2.06)	3.25 (3.30)	-0.50 (-3.72, 2.72)	.73	1.00 (-3.16, 5.16)	.60	0.32
HADS depression (0-7)	6	4.67 (2.80)	4.33 (3.08)	-0.33 (-1.79, 1.13)	.62	5	2.40 (2.07)	3.80 (3.42)	1.40 (-0.20, 3.00)	.08	-1.73 (-4.56, 1.10)	.17	-1.02
PSS total (0-40)	6	10.33 (6.62)	10.67 (7.58)	0.33 (-4.35, 5.02)	.88	5	14.00 (9.57)	10.00 (7.68)	-4.00 (-9.13, 1.13)	.11	4.33 (-2.61, 11.28)	.19	0.78
SMMSE total (0-30)	6	29.17 (1.17)	29.00 (1.10)	-0.17 (-2.39, 2.05)	.87	5	24.40 (5.13)	24.80 (7.73)	0.40 (-2.03, 2.83)	.72	-0.57 (-3.86, 2.73)	.71	-0.22
ISEL appraisal (0-12)	6	6.67 (3.08)	7.67 (2.07)	1.00 (-1.01, 3.01)	.29	5	7.40 (2.30)	7.20 (1.79)	-0.20 (-2.41, 2.01)	.84	1.20 (-1.79, 4.19)	.39	0.50
ISEL belonging (0-12)	6	5.33 (2.16)	6.17 (2.14)	0.83 (-0.74, 2.40)	.26	5	7.20 (2.28)	6.60 (0.89)	-0.60 (-2.32, 1.12)	.45	1.43 (-0.90, 3.76)	.20	0.77
ISEL tangible (0-12)	6	7.83 (0.98)	8.00 (0.63)	0.17 (-0.97, 1.30)	.75	5	6.00 (1.73)	7.20 (1.10)	1.20 (-0.05, 2.45)	.06	-1.03 (-2.72, 0.65)	.20	-0.77

Outcome Measure	Intervention					Wait-list Control					Mean difference in changes between groups		
	n	Pre mean (SD)	Post mean (SD)	Mean Difference (95% CI)	p	n	Pre mean (SD)	Post mean (SD)	Mean Difference (95% CI)	p	Mean Difference (95% CI)	p	Effect size (Hedges' g)
MNA total (0-14)	6	12.67 (1.51)	11.50 (2.59)	-1.17 (-3.38, 1.05)	.26	5	12.40 (1.82)	11.60 (1.67)	-0.80 (-3.22, 1.62)	.47	-0.37 (-3.65, 2.91)	.81	-0.14
IL-6 (pg/mL)	6	0.60 (1.20)	0.33 (0.36)	-0.27 (-0.89, 0.35)	.35	5	0.44 (0.37)	0.18 (0.14)	0.26 (-0.94, 0.43)	.42	-0.01 (-0.94, 0.91)	.97	-0.02
IL-8 (pg/mL)	6	37.43 (41.22)	20.34 (18.79)	-17.09 (-57.74, 23.55)	.37	5	57.05 (51.57)	18.49 (13.02)	-38.57 (-83.09, 5.96)	.08	21.47 (-38.81, 81.76)	.44	0.45
TNF α (pg/mL)	6	0.99 (0.70)	1.00 (0.53)	0.02 (-0.43, 0.47)	.93	5	1.00 (0.52)	1.08 (0.64)	0.08 (-0.41, 0.57)	.71	-0.06 (-0.73, 0.60)	.83	-0.12
IFN γ (pg/mL)	6	0.06 (0.13)	0.03 (0.04)	-0.03 (-0.14, 0.07)	.49	5	0.01 (0.01)	0.01 (0.03)	0.01 (-0.11, 0.12)	.91	-0.04 (-0.20, 0.12)	.58	-0.32
Cortisol (ng/mL)	6	121.44 (24.93)	150.45 (37.01)	29.01 (-3.53, 61.54)	.07	5	130.89 (38.64)	142.84 (46.42)	11.95 (-23.69, 47.59)	.47	17.06 (-31.14, 65.25)	.42	0.44
DHEAs (ng/mL)	6	409.73 (249.48)	394.37 (225.05)	-15.37 (-85.31, 54.58)	.63	5	600.53 (500.22)	582.49 (432.77)	-18.04 (-94.66, 58.58)	.61	2.67 (-101.07, 106.42)	.95	0.03
Cortisol:DHEAs	6	0.39 (0.19)	0.52 (0.34)	0.14 (-0.02, 0.29)	.08	5	0.71 (1.07)	0.66 (0.92)	-0.05 (-0.22, 0.12)	.50	0.19 (-0.04, 0.42)	.10	1.03

Note. * $p \leq 0.05$, ** $p \leq 0.01$, *** $p \leq 0.001$, differences indicated by independent t-tests. ADL = Activities of Daily Living, DHEAS =

Dehydroepiandrosterone Sulphate, Ext. = Extension, Flex = Flexion, GDS = Geriatric Depression Scale, HADS = Hospital Anxiety and Depression

Scale, IFN γ = Interferon gamma, IL = Interleukin, ISEL = Interpersonal Support Evaluation List, MLTAQ = Minnesota Leisure Time Activity

Questionnaire Shortened Version, MNA = Mini Nutritional Assessment, PSS = Perceived Stress Scale, SMMSE = Standardised Mini Mental State

Examination, SPPB = Short Physical Performance Battery, TNF α = Tumour Necrosis Factor alpha.

