A mixed-methods feasibility study of a sit-to-stand based exercise programme to maintain knee-extension muscle strength for older patients during hospitalisation

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Introduction
Progressive resistance training is known to be effective in improving both muscle strength and functional performance in healthy older adults1, and those with sarcopenia2. Even very modest amounts of exercise have led to considerable strength gains in frail older patients3. There is also evidence of the benefits of exercise programmes for improving functional performance in older patients in acute general medical wards4,5, and, muscle strength in adults admitted with respiratory conditions6. However, previous systematic reviews7-10 have inconsistent findings; furthermore, none of these studies began a progressive strengthening exercise programme within the first 24 hours of admission to hospital. Given that there is evidence that older adults lose an average 6% loss of muscle strength in the first 48 hours of hospitalisation with an average amount of physically ‘active’ time less than 3%11, earlier intervention may be beneficial.

Before addressing the efficacy of exercise interventions during hospitalisation, the present study aimed to determine the acceptability of the exercise programme and to identify barriers and facilitators to compliance with the programme from the participants’ perspective.

Abstract
Objectives: To determine the acceptability of an exercise programme and to identify barriers and facilitators to compliance with the programme from the participants’ perspective. Methods: Patients aged 75 years or older were recruited within the first 36 hours of hospital admission. Participants were randomised to complete two strengthening-based (intervention arm) or stretching-based (control arm) exercise sessions per-day. At hospital discharge, participants were asked to take part in interviews with a member of the research team exploring the barriers and facilitators to adherence to the intervention. Results: 15 participants (7 intervention arm, 8 control arm) were recruited before the trial was stopped due to COVID-19. Both groups showed reductions in knee-extension strength, and improvements in functional mobility at discharge from hospital. A total of 23/60 intervention sessions were classed as ‘complete’, 12/60 as partially complete, and 25/60 were missed entirely. Eight participants took part in interviews. Intrinsic factors that impacted participation in the research, related to current health, health beliefs, and experience of multi-morbidity or functional decline. Staff had both a positive and negative effect on participant adherence to the intervention. Conclusions: The exercise intervention was well received, with most participants describing health benefits, though intervention fidelity was lower than expected.

Keywords: Acceptability, Exercise, Hospital, Older people

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barriers and facilitators to compliance with the exercise programme from the participants’ perspective.

**Materials and methods**

**Setting**

Patients were recruited from the Acute or Geriatric Medicine wards of Cambridge University Hospitals (CUH) NHS Foundation Trust. Every patient admitted to a Geriatric Medicine ward is routinely assessed by a physiotherapist, and the wards’ occupational therapists will review any patient who is referred to them. In a 2016 service evaluation, 58% of patients were assessed by a physiotherapist within the first 24 hours of their hospital admission, and participants received a median of 3 sessions per week. In the same service evaluation, 44% of patients were assessed by an occupational therapist. The Acute Medicine wards have dedicated physiotherapists and occupational therapists, who will review any patients who are referred to them. Follow-up measures were collected in the participants’ residences.

**Study design**

This was a randomised feasibility study. Ethical approval was granted by the Cambridge Central Research Ethics Committee (19/EE/0162). All participants provided written informed consent to participate in the study.

**Patient and Public Involvement (PPI)**

The study design reflects amendments and changes suggested by the PPI panel. The panel also reviewed the final versions of the participant information sheet and consent form.

**Sample**

Patients admitted to CUH between October 2019 and March 2020, aged 75 years or older and expected to be hospitalised for at least 24 hours, were eligible for inclusion. Patients were excluded if they had: been admitted for more than 36 hours (we aimed to recruit within the first 24 hours of a patient’s admission); however if a patient requested more time to consider participation, or consent was delayed by medical procedures or investigations, we still recruited up to 36 hours after admission); unable to provide informed consent (e.g. due to cognitive impairment); receiving end-of-life care; transferred to or from the intensive care unit; bed-bound or requiring a hoist to transfer from bed to chair 2 weeks before hospitalisation; or if the Consultant in charge of the patient had any other clinical concerns regarding participation in a strengthening exercise programme.

Sampling was convenience-based and recruitment took place predominantly Monday to Friday, 08:00 to 18:00. On days when recruitment occurred, all patients aged 75 years and over admitted within the previous 24 hours were consecutively screened by a member of the clinical team. If potentially suitable patients gave permission, their details were passed onto members of the research team who would in turn approach them about participating in the study. Recruitment was limited by the availability of staff to deliver the intervention. Throughout the study period, only 1-2 participants could be recruited to the ‘active’ stage of the study (receiving either the strengthening or stretching intervention in hospital) at any one time, limiting the recruitment rate.

Prior to the study, an independent statistician produced a computer-generated randomisation sequence, which was used to enter the allocated treatment arm description into numbered opaque envelopes. The envelope was opened by the physiotherapy assistant who was to deliver the intervention, after baseline assessment was completed by the primary investigator (PI).

**Sample size**

The target sample size was set at 30 (15 in each arm) based on recommendations of 24 for feasibility studies.

**Procedures**

Both the intervention and the control group received ‘usual care’, including physiotherapy, occupational therapy and nursing interventions as required.

**Intervention**

In addition to usual care, participants were seen twice a day by a physiotherapy assistant who would supervise their exercise programme. A description of the intervention development is provided in Appendix 1. The exercise protocol consisted of six levels of exercise, see Figure 1.

For the easiest level, consisting of ‘bottom lifts’, the participant was asked to lift their bottom a couple of inches off the bed, and then sit back down. The participant could use their upper limbs, and the physiotherapy assistant would provide physical assistance if necessary. The height of the bed was set at the maximum height at which the participant could safely sit. The maximum height of the bed was 80 cm excluding mattress. The hardest level required the participant to stand from the lowest height of the bed (35 cm excluding mattress) without them using their upper limbs to push up from the bed. During the baseline assessment (before randomisation), the initial starting point of the strengthening exercise was determined for each participant by the PI, a qualified physiotherapist.

The aim of each session was to achieve 3 sets of 10 repetitions of the exercise, based on the findings of Borde, Hortobagyi. If the participant was unable to manage a minimum of 2 sets of 7 stands during a session, for the subsequent session the intensity was reduced (either by a whole level, or if working in level 5 by raising the bed by 5 cm). If the participant achieved three sets of nine repetitions in the previous session, the subsequent starting points were increased in difficulty (either by a whole level, or if working in level 5, by lowering the bed by 5 cm). If neither of these
Figure 1. Progression of strengthening exercises.

The sham intervention was carried out in either a seated or lying position depending on the participant’s position when the physiotherapy assistant arrived for the session. The stretches were targeted at the deltoid, pectoral, hamstring, and gastrocnemius (Figure 2) at a low intensity (gentle stretch). During the baseline assessment, the physiotherapist assessed that participants had the necessary pain-free range of motion to complete the exercise. If pain-free range of motion was restricted, or if there were any other reasons the stretch could not be completed, the relevant stretch was either adapted or removed from their protocol. The participants were asked to hold the stretch for two minutes, completing two stretches on each muscle group. The sham intervention was designed to appear exercise-based to the participant but provide minimal benefit in terms of lower limb strengthening. This exercise-based appearance was designed to minimise incidences of ‘unblinding’ in a future study of efficacy (i.e. where patients would refer to ‘having done their exercises’, as opposed to a non-exercise-based control). As
with the intervention group, the control group received two supervised sessions a day. Fidelity to the control programme was recorded by the physiotherapy assistant, including total number of sessions, number of sessions terminated early, and reason for missed sessions or early termination.

**Measurements**

The outcome measures taken were planned to be used in a future study of the clinical and cost effectiveness of a strengthening intervention. Knee-extension strength and grip strength were measured using hand-held dynamometry (using methodology described elsewhere 11). Knee-extension strength, grip strength and the de Morton Mobility Index (DEMMI), a 100-point ordinal scale for the assessment of mobility in older acute medical patients 15, were measured at baseline assessment, discharge and follow-up. The Barthel Index was used as a measure of functional independence with basic activities of daily living 16 and measured at baseline and follow-up assessment. At baseline assessment participants were asked to report their answers for the Barthel Index based on their functional ability two weeks before admission. The Survey of Health, Ageing and Retirement in Europe Frailty Instrument (SHARE-FI) tool was used to measure physical frailty 17. Cognition was measured using the Mini Addenbrooke’s Cognitive Examination (Mini-ACE) 18, and falls efficacy using the Falls Efficacy Scale - International (FES-I) 19. The SHARE-FI, Mini-ACE, FES-I were measured at baseline and follow-up assessment. Length of hospital stay, level of activity during hospitalisation, care needs on discharge and new institutionalisation were also collected.

The objective level of in-hospital physical activity was recorded using wearable accelerometers (AX3, Activity, Newcastle upon Tyne, UK) attached with an adhesive dressing to their legs. Using validated methodology, one was attached to the mid-thigh 20. Data collected included the amount of time in a lying position or sitting position versus time spent in a standing position or walking 20. The accelerometer was removed after the last measures of functional mobility and muscle strength were taken on day 7 (or day of discharge if earlier).

For descriptive purposes, the following measures were collected: age, sex, weight, Charlson Comorbidity Index (CCI) 21, Malnutrition Universal Screening Tool (MUST) 22, the number of falls and hospital admissions in previous 12 months, admission principal diagnosis, C-reactive protein levels on admission as a measure of illness severity, and the Clinical Frailty Scale (CFS).

Semi-structured topic-guided interviews with individual patients were performed to assess their experience of the intervention, any physical or communication barriers to exercise, and any changes in their mobility requiring adjustments of the programme.

Figure 2. Stretches performed by control group.
Table 1. Timepoints at which measures were taken during the study.

| Measure                          | Admission | Day 7 (or day of discharge if earlier) | Follow-up (4-6 weeks) |
|----------------------------------|-----------|----------------------------------------|-----------------------|
| HHD (Knee extension + grip strength) | Y         | Y                                      | Y                     |
| DEMMI                            | Y         | Y                                      | Y                     |
| Barthel Index                    | Y         | -                                      | Y                     |
| Demographics                     | Y         | Y                                      | Y                     |
| SHARE-FI                         | Y         | -                                      | Y                     |
| Mini-ACE                         | Y         | -                                      | Y                     |
| FES-I                            | Y         | -                                      | Y                     |
| CFS                              | Y         | -                                      | -                     |
| CCI                              | Y         | -                                      | -                     |
| NEWS                             | Y         | -                                      | -                     |
| MUST                             | Y         | -                                      | -                     |
| Activity                         | Y         | -                                      | -                     |
| Semi-structured interview        | -         | Y                                      | -                     |

CCI = Charlson Co-Morbidity Index, CFS = Clinical Frailty Scale, FES = Falls Efficacy Scale, HHD = hand-held dynamometry, Mini-ACE = Mini Addenbrookes Cognitive Examination, MUST = Malnutrition Universal Screening Tool, NEWS = National Early Warning Score.

Figure 3. Flow chart.
Participants following the collection of outcome data at discharge (or day 7 in hospital if earlier) were conducted. Interviews were conducted in private rooms so as not to be overheard. Interviews explored the acceptability of the interventions, barriers and facilitators to compliance with the intervention, and the perceived and observed benefits of the intervention. PH or the research nurse recruiting the participant to the study attempted to systematically recruit all participants for interview, though agreeing to interview was not a pre-requisite for recruitment to the study. The interview topic guide is presented in Appendix 2.

All measurements were taken by the PI, and a full description of which measurements were taken at each timepoint is provided in Table 1. As the PI also conducted the semi-structured interviews, they were not considered blinded to outcome or follow-up assessments.

**Protocol amendments**

As with many research studies, in March 2020 due to COVID-19 decision had to be made to terminate the study early. This was made both for safety reasons and to allow researchers to return to clinical practice. Due to COVID-19 and the time constraints of the doctoral fellowship for which this study was conducted, the study could not be restarted. The study did not therefore reach the recruitment target, and at the time of termination only 15 participants had been recruited.

**Analysis**

To determine the acceptability of the exercise programme and to identify barriers and facilitators to compliance with the exercise programme from a participant perspective, both quantitative and qualitative methods were used. The

|                          | Intervention | Control |
|--------------------------|--------------|---------|
| n                        | 7            | 8       |
| Female                   | 4 (57.1%)    | 4 (50.0%)|
| Age                      | 80.0 (75.0-91.0) | 91.5 (75.0-96.0) |
| CCI                      | 3.0 (1.0-4.0) | 2.5 (0.0-4.0) |
| CFS (0 - 9)              | 4.0 (2.0-6.0) | 5.0 (3.0-6.0) |
| Weight (kg)              | 61.6 (57.0-103.8) | 75.7 (55.2-97.0) |
| SHARE FI                 | 2.4 (0.9-4.5) | 4.4 (0.4-6.0) |
| Non-fragile              | 1 (14.3%)    | 1 (12.5%)|
| Pre-fragile              | 3 (42.9%)    | 0 (0%)   |
| Frail                    | 3 (42.9%)    | 7 (87.5%)|
| Admissions in previous 12 months | 1.0 (0.0-7.0) | 1.0 (0.0-4.0) |
| Falls in previous 12 months | 0.0 (0.0-8.0) | 0.0 (0.0-6.0) |
| Admission CRP (mg/L)     | 19.2 (0.0-159.2) | 9.9 (0.0-94.9) |
| Barthel Index (0 - 100)  | 100.0 (65.0-100.0) | 75.0 (40.0-100.0) |
| DEMMI (0 - 100)          | 44.0 (15.0-85.0) | 33.0 (20.0-85.0) |
| MUST (0 - 2)             | 0.0 (0.0-2.0) | 0.0 (0.0-1.0) |
| Grip strength (kg)       | 21.0 (12.0-36.0) | 13.2 (4.0-41.0) |
| Knee torque (Nm)         | 53.6 (39.9-70.4) | 38.5 (19.2-111.3) |
| FES-I (16 - 64)          | 36.0 (17.0-64.0) | 49.0 (18.0-61.0) |
| Mini ACE (0 - 30)        | 27.0 (23.0-30.0) | 26.0 (20.0-30.0) |

Data presented as median (range) or count (percentage). Abbreviations: CCI = Charlson Co-Morbidity Index, CFS = Clinical Frailty Scale, SHARE-FI = Survey of Health, Ageing and Retirement in Europe Frailty Instrument, CRP = C-reactive protein, DEMMI = de Morton Mobility Index, MUST = Malnutrition Universal Screening Tool, FES-I = Falls Efficacy Scale - International, Mini ACE = Mini Addenbrookes Cognitive Examination. Higher CCI score represents a greater comorbidity burden. Higher CFS or SHARE-FI score represents a higher degree of frailty. Higher scores for BI, DEMMI and Mini-ACE represent better functional ability. Higher MUST score represents higher risk of malnutrition. Higher FES score represents a lower falls-efficacy.

Table 2. Baseline characteristics.
following analyses were conducted:
- comparisons of the number of intervention sessions completed with the number of sessions planned, and the number of sessions terminated early (i.e. fewer than two sets of seven stands during a session);
- an analysis of the reasons for missing treatment sessions and for terminating treatment sessions early;
- analysis of the recorded topic-guided interview of participants at discharge from hospital after outcome measures were taken.

The qualitative analysis followed thematic analysis principles as described by Braun and Clarke23. Analysis primarily used a deductive or theoretical approach; that is, data was coded with reference to the study objectives of assessing acceptability, barriers and facilitators. Themes were identified at a semantic level. PH generated descriptive initial codes of the transcriptions, which were then discussed with RRO and CD, who had read the transcripts. Once all data were re-coded, codes were grouped into broader themes using memos to record the process. Through an iterative process with all authors and after re-analysing the data and relevant literature, codes and themes were re-written and re-sorted. The software NVivo was used to assist with data management of the interview transcripts.

Results

15 participants were recruited before the trial was stopped due to the COVID-19 outbreak. Of these, 10 were followed up, and 8 were interviewed before discharge from hospital (Figure 3). Baseline characteristics are presented in Table 2. The intervention group had a lower median age of 80 compared to 91.5 in the control group (though a similar age range), and had a higher level of baseline function (e.g. grip strength 21 kg vs. 13.2 kg; knee extension strength 53.6Nm vs. 38.5Nm; DEMMI 44 vs 33). Admission diagnoses are summarised in Table 3. Outcome measurements are presented in Table 4. From admission to discharge, there was little difference in the change in strength or functional mobility between the two groups (Table 4). At discharge from hospital, based on grip strength 2/7 of the intervention group and 6/8 of the control group met the European Working Group On Sarcopenia In Older People’s (EWGSOP) suggested cut-offs for probable sarcopenia (<27 kg for men, <16 kg for women). Both groups experienced a reduction in knee-extension strength, minimal change in grip strength, and small improvement in functional mobility. The control group spent a median 6.1 days (range: 2.2 days - 20.2 days) in hospital, and the intervention group 5.5 days (range: 1.8 days - 8.1 days). From the baseline to discharge assessment, the intervention group spent 2.9% (range: 0.9% - 5.5%) of the time standing or walking, compared to 2.5% (range: 0.4% - 6.8%) in the control group.

The median starting level for the intervention was level 5 (range 1-6). Of the four participants who started at level 5, none reached level 6, though they progressed in terms of the bed height. One participant started at the maximum level of difficulty.

Adherence

A total of 60 intervention (strengthening) sessions were prescribed, of which 23 were classed as ‘complete’ i.e. at least seven out of ten stands in two sets, 12 as partially complete, and 25 were missed entirely. The reasons for incomplete sessions were fatigue (14/17), fatigue and nausea (2/17) and nausea (1/17). The reason for missed sessions are presented in Table 5. One individual missed all nine of their sessions, five due to medical contraindication as advised by the medical team.

A total of 65 control (stretching) sessions were prescribed, of which 55 sessions were completed in full, three sessions partially completed (stopped early due to discomfort), and seven sessions were missed.
Qualitative findings

The interviews were conducted with five members of the intervention group and with three members of the control group. The median age of interviewees was 83 years, and five were female. The median length of stay was seven days (range 2 to 8 days). All participants lived in their own homes, five lived on their own, and two had experienced falls in the past 12 months. The findings of the interviews were separated into three themes, namely intrinsic factors, extrinsic factors, and exercise dose. The interviews aimed to elucidate barriers and facilitators to compliance with the intervention; however, most interviews also identified barriers and facilitators to physical activity in hospital in general. Given the relevance of the latter to the topic, these results are also included here.

Intrinsic factors

Several intrinsic factors that impacted participation in the research and attitudes to research were identified. These related to current health, health beliefs, experience of multi-morbidity or functional decline, and the perceived benefit of participation. There was also a sub-theme relating to altruistic motives.

Current health

Poor health, particularly fatigue, lack of sleep and general feeling of sickness were given as barriers to adherence with the exercise.

> “...when your colleague and [name of physiotherapy assistant] came, I was so tired having been awake most of the night that I said, ‘oh later on, please, I’ll do them later on’
and unfortunately she was tied up later on so I haven't been able to see her.” [Participant 9 Intervention Group (IG)]

> “Well, I wasn’t very well that evening with that one and I just didn’t feel strong enough, if you like, to do the exercises. Not that they’re particularly strenuous because, you know, but just...” [Participant 5 Control Group (CG)]

Health beliefs

Most participants appeared to have a belief or awareness of negative connotations of bed rest.

> “Well, he [Participant’s GP] told me that one day’s bed rest with your feet up and not taking any exercise causes 15%, you could lose 15% of your mobility, and I don’t know how true that statistic is or whether he reached up and got it out of the sky.” [Participant 9 IG]

This comment from the same participant who was quoted previously as describing themselves as being too tired for exercise suggests that awareness of negative effects of bed rest would not necessarily overcome fatigue when it came to adherence with the exercise programme.

Experience of multi-morbidity or functional decline

Many participants perceived the experience of hospital-associated functional decline or deconditioning.

> “I feel as if I’m wasting away almost.” [Participant 10 CG]

Attitudes towards the experience of loss of function or strength were divided into two camps. Some participants were defeatist, often assuming loss of function and independence with being an inevitable part of ageing:

> “I’ve just lost all power. But I suppose you can’t expect to go forever.” [Participant 6 CG]

These participants had also described multi-morbidity and pre-hospital functional decline or deconditioning. Others saw their loss of function as a temporary setback that would resolve over time.

> “Yes, I think so at the moment, I could probably do more when I get my strength back.” [Participant 9 IG]

> “No, I don’t think so. I mean, they’re kindly going to put this care in place for six weeks, and by then, I hope, I’m more or less back to normal.” [Participant 5 CG]

This was often associated with strong determination to triumph, and a belief that this was within their own power to achieve.

> “Not right now but I will be. I’ll get my confidence back. I’m not a quitter.” [Participant 9 IG]

> “Yes, I’m quite a strong personality, you know, I will conquer it...” [Participant 5 CG]

Perceived benefit of participation

Most participants reported they felt that they had benefited from and enjoyed participating in the study, both in terms of physical improvement such as strengthening, reducing stiffness and improving walking, and in terms of improving their confidence. Perhaps surprisingly, this was also apparent in the control group, though this was in part linked to the social element of having the physiotherapy assistant visit them.

> “I thoroughly enjoyed it [...] and I feel that I have benefitted from it by getting more, back to number 1 [...] I think they sort of got the strength back in me legs.” [Participant 4 IG]

> [Asked whether the conversations with the PTA was an important part of the intervention] “Oh I think so, I think so, yes definitely, almost definitely, yes. Someone coming along who didn’t say anything, you wouldn’t... you wouldn’t be gripped by it. I know the conversation about Canada will ran out [laughter], but you know, when you can talk to someone about one thing, you can probably talk to them about anything.” [Participant 10 CG]

Altruistic motives

Despite the perceived benefit and enjoyment in participating, altruistic motives appeared to overshadow those factors when it came to the reasons for participation in the research and adherence to the interventions.

> “I said I’d take part in the research because I’m one of these, you’ve all helped me and I think if you’re in a research and you can help somebody else, I think you’re repaying you know, what they’ve done for you.” [Participant 3 IG]

Similar motives, however, may also have had a negative impact on participation, as two individuals were worried that poor adherence or dropping out would be ‘letting down’ the research team.

> “I wouldn’t like to start it [exercise programme at home] and then let you down in the middle.” [Participant 6 CG]

Extrinsic Factors

Staff had both a positive and negative effect on participant adherence to the exercise programme.

> “...her making her journey to see me I couldn’t say no you know, she’s stood there and sort of pleaded, you’re going to do it [participant name] and that, and what made me laugh in this last 2 or 3 days was we’ve been doing this one, pushing up from off the bed and standing upright and going like that and she’d stare me right in the face and she’d burst out laughing, so we have a good laugh about it and that, but never a dull moment, and I would do it again tomorrow.” [Participant 4 IG]

The following comment from the same participant also illustrates the negative effect of staff. It refers to a staff member unfamiliar to the participant. It may therefore also relate to the importance of trust, and the patient-clinician relationship.

> “And they were just the opposite to [the usual physiotherapy assistant], they wanted to push, I said look, I said, it’s my life, I said, I want to lead my life the way I do.” [Participant 4 IG]

This theme was also present in relation to other hospital physical activity.
> “Mind you one of the nurses helped me [...] I said, “can I have the commode please?” He said, “no,” he said, “you’d be better off on the toilet,” he said, “I’ll push you there on the commode,” and he did, and then you know that got me going, then I decided, ‘well if he can push me, I can walk’, so I walked there then, I can walk to the toilet now.” [Participant 3 IG]

It also appeared that the rigidity of hospital processes of care in some cases caused both frustration and reduced activity.

> “...nurse tells me, when I wanted to wash up yesterday evening, ‘I want to have a wash,’ and he said, ‘No, most people wash in the morning’, ‘Yeah, but so what?’ you know, this kind of thing, having, being a bit bossed around, and he tried to guide me back to my bed.” [Participant 11 IG]

This comment was mirrored in others talking about their loss of control and dislike of institutionalisation.

Other hospital processes of care such as attachments were identified as barriers to physical activity.

> “When you’re tied up with tubes, you have to proceed very slowly and make sure you don’t pull anything.” [Participant 1 IG]

### Exercise dose

In terms of the acceptability of the interventions, most considered the intensity and frequency of the exercises appropriate.

> “Not difficult. Easy to do rather than not difficult I would say, obviously physically difficult but that was easier to do. Easy to do and standing up off the bed’s easy to do, so.” [Participant 1 IG]

One participant (from the control group) suggested that once a day would have been enough. A member of the intervention group suggested that lower doses in the first couple of sessions would have been more appropriate. Similarly, a member of the control group reported that the exercise was too much during the first days of hospitalisation:

> “It was, yes, it was too much, in fact the next day I declined, I didn’t do, but the third day I decided I would have another go, and I was fine.” [Participant 5 CG]

Pride in achieving a certain number of stands or in seeing progression with the intervention was evident in three participants.

> “I am really proud of myself, I have really achieved something.” [Participant 4 IG, comment recorded by physiotherapy assistant at the end of their last session]

One participant though, suggested a minimum duration of a week would have been needed to see improvement from the exercise.

> “Oh no, that couldn’t have been achieved in a couple of days, I’d have to stay for a week or more but like every busy hospital it needs the beds.” [Participant 9 IG]

### Discussion

#### Summary of findings

Despite the limitations caused by COVID-19, this study provides useful information about the acceptability of the twice daily exercise programme and identified barriers and facilitators to compliance with the exercise programme from the participants’ perspective.

The participants who were interviewed were willing to participate in the research for both altruistic reasons and an interest in their own health. The interventions were overall well received, both in terms of perceived physical benefit, and in some cases also due to a feeling of achievement. Due to feelings of fatigue and sickness, flexibility regarding dose and frequency of sessions was required. To change hospital activity in general, staff behaviour can have a significant effect, and flexibility with hospital processes of care is required to positively influence this.

#### Acceptability of the exercise programme

Adherence to the strengthening arm of the trial was particularly poor, with only 60% of sessions being attempted. Most of the missed sessions were explained by either a medical contraindication (7/25), the participant declining due to fatigue (7/25), or being unavailable (5/25). Medical contraindication refers to the participant’s medical team advising the research team that the patient was not well enough to participate.

The qualitative analysis of the semi-structured interviews identified the need for flexibility in terms of the time and dose of exercise. This need for flexibility was not explicitly identified in three qualitative studies evaluating in-hospital exercise interventions\textsuperscript{24-26}, though it does mirror the varied expectations of participants in Cattanach, Sheedy\textsuperscript{27} with regard to physical activity in hospital. In this study, nine participants felt that they should rest in bed until well, 13 thought they should do light activity until well and two to keep active.

Adherence varies considerably in studies of additional exercise for older adults during an acute hospitalisation. McCullagh, O’Connell\textsuperscript{8} reported that the majority of participants recruited completed more than 75% of sessions, Martinez-Velilla, Casas-Herrero\textsuperscript{4} reported an impressive adherence of 96% to their morning supervised sessions, and perhaps even more impressively, an adherence of 83% to afternoon unsupervised sessions. On the other end of the spectrum, McGowan, Ong\textsuperscript{28} asked participants to pedal unsupervised for five minutes three times a day, and reported that despite an average length of stay in hospital of five days, a median total pedal time of five minutes was recorded during the entire study period. The success of Martinez-Velilla, Casas-Herrero\textsuperscript{4} may speak to the importance of a systems approach aimed at changing the
culture of both staff and patients. A systems approach takes a holistic view of a system, defining all the elements and interconnections, to ensure that the whole system performs as required.

Barriers and facilitators to adherence to the exercise

Participants who were interviewed were willing to participate in the research both for altruistic reasons and with an interest in their own health. Similar findings were made by O’Hare, Savage and Pierluissi.

> “Because I wanted to help […] Help myself I suppose and help her.” (Quotation from Participant K in O’Hare, Savage)

The authors hypothesised that participants were motivated to participate in order to assist the physiotherapy student delivering the exercise intervention, but also from positive outcome expectations. Other factors facilitating and motivating participants to exercise were improved strength, reduced stiffness, improved gait and improved confidence as benefits of participation. Similarly, we concluded from the interviews that in general, the interventions were well received, and participants were in part motivated by perceived physical and mental benefit. Lim, Ibrahim reported that both patients and volunteers showed an understanding of the benefits of being active in hospital. This was also reported by So and Pierluissi, who reported that 14% of participants were motivated by a belief that exercise would help them feel better, and 50% believed it would speed their recovery. Interestingly, they described these motivations as contrasting (as opposed to homogeneous motivations) with a larger proportion of participants who were motivated by avoiding the negative effects of bed rest. In summary, both in this study and in similar studies, intrinsic motivations included both altruistic motives and expected health benefits.

The major extrinsic facilitator to exercise identified in this study was the influence of both ward and research staff. So and Pierluissi reported that 3/28 participants cited ward staff asking them to exercise as the motivating factor for their in-hospital exercise. O’Hare, Savage reported that the perception by participants of the physiotherapy student delivering their exercise intervention, as a professional and as an authority figure appeared to influence their engagement:

> “When you see a physiotherapist […] you know what you’re going to do, you’re going to move about physically but anyone else saying it to you it wouldn’t have the same effect would it? No it wouldn’t. They wouldn’t have the same authority.” (Quotation from Participant B in O’Hare, Savage)

Intrinsic barriers to participation included fatigue and general feelings of sickness. Similarly, three participants in the study by O’Hare, Savage reported fatigue and respiratory or gastric problems as limiting their engagement, though interestingly these prevented engagement on only one occasion. Both So and Pierluissi and Brown, Williams reported that patient symptoms such as weakness and fatigue were the most commonly mentioned barrier to exercise:

> “No, no. I can’t exercise now because I hardly walk, and I already feel tired. It tires my heart, and I have to sit down.” (Quotation from participant in So and Pierluissi)

The extrinsic barriers identified in this study and in the literature focus on staff, and hospital structure and processes of care. Patients spoke about a desire for control and flexibility that was at odds with the hospital routine. Brown, Williams identified lack of staffing and the need for assistance as a barrier. Although this was not identified in our feasibility study, it does accord with our findings in a previous study, as well as with the findings of So and Pierluissi. So and Pierluissi also describe active discouragement by nurses or doctors:

> “I’ve been confined because they frown on my trotting up and down the hall and would have hysteria if I got on the staircase.” (Quotation from participant in So and Pierluissi)

Reservations about physical activity caused by fears of patients falling were described by Brown, Williams and So and Pierluissi. In Brown, Williams these reservations were most commonly reported by physicians but were also reported by patients and nurses. In one quotation, however, the fear of a patient falling is secondary to reducing workload, suggesting again that lack of staffing is a significant barrier:

> “While they are in bed they are not giving trouble to anyone. It is less work and, second, because of liability issues in terms of patients falling and hurting themselves while they are in hospital. I think everybody is very concerned with that, but I think mainly because it is less work.” (Quotation from physician in Brown, Williams)

This quotation again speaks to the need for systems approaches (including protection of staff) to increasing in-hospital physical activity and adherence to exercise programmes.

Limitations

The target of 30 participants (15 in each arm) was not met, which significantly limits the study findings. Although most of the qualitative findings appear credible in that they mirror findings in similar studies, the small sample of participants interviewed cannot be said to be representative of all participants, and most certainly not representative of all patients. Further interviews would also have allowed the testing of the reliability of the coding and themes. The sample size of interviewees was also believed to be too small to detect differences between groups in terms of the barriers and facilitators to exercise. Greater insight into the barriers and facilitators of in-hospital exercise may have been gained by interviewing staff, including the physiotherapy assistants who delivered the intervention.

The aims of the feasibility study did not include exploratory analysis of outcome or follow-up data, and the
lower-than-expected sample size precludes any meaningful analysis. However, the initial direction of change in functional outcomes at discharge from hospital in both groups were the same as in a previous observational study. Knee-extension strength was reduced, grip strength showed minimal change, and there was a small improvement in functional mobility. The amount of time spent upright (2.9% in the intervention group, 2.5% in the control group) is similar to the 3.8% observed in the aforementioned observational study.

Nineteen sessions were incomplete due to fatigue or fatigue/nausea. The physiotherapy assistants were not asked to record if the fatigue was thought to be a consequence of the intervention, and this is a recognised limitation of the design. However, 2 participants declined their first 3 and 4 sessions due to fatigue before attempting any exercise, eliminating the possibility that the intervention influenced their fatigue. Of the other 12 sessions, the intervention may well have contributed to the fatigue.

An important element of exercise progression was the lowering of the bed to increase the effort required to achieve a stand. At a lower bed height, the hip and knee extensor muscles work through a larger range of motion and need to produce higher torque to achieve the movement due to the increased moment arms. Resistance training through a full range of motion compared to a partial range of motion (e.g. higher bed height) is expected to have greater effects on muscle adaptations. Further, strength adaptations are thought to be specific to the range of movement that the training is conducted in. Thus, training from a high bed height may not translate to improvements in the initial movement of standing from a standard chair height. We believe this limitation was mitigated by the inbuilt progression in the programme. Finally, given that 1/7 participants started at the maximum level of difficulty, further development of the intervention is warranted to include higher levels of difficulty.

**Conclusion**

This feasibility study found that the exercise intervention was well received, with most participants describing health benefits, though intervention fidelity was lower than expected. Intrinsic and extrinsic factors influenced fidelity to the protocol, and it is hypothesised that a systems approach is required to maximise adherence through cultural change toward the benefits of physical activity in patients and staff. For this reason, exercise interventions are complex interventions as they rely upon changes in practice and culture, and development and evaluation of these interventions require ongoing process evaluation.

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**References**

1. Liu CJ, Latham NK. Progressive resistance strength training for improving physical function in older adults. Cochrane Database Syst Rev 2009 Jul 08(3):CD002759.
2. Cruz-Jentoft AJ, Landi F, Schneider SM, Zuniga C, Arahi H, Boirie Y, et al. Prevalence of and interventions for sarcopenia in ageing adults: a systematic review. Report of the International Sarcopenia Initiative (EWGSOP and IWGS). Age Ageing 2014;43(6):748-59.
3. Fiatarone MA, Marks EC, Ryan ND, Meredith CN, Lippsitz LA, Evans WJ. High-intensity strength training in nonagenarians. Effects on skeletal muscle. JAMA 1990;263(22):3029-34.
4. Martinez-Velilla N, Casas-Herrero A, Zambon-Ferraresi F, Saez de Asteasu ML, Lucia A, Galbete A, et al. Effect of Exercise Intervention on Functional Decline in Very Elderly Patients. During Acute Hospitalization: A Randomized Clinical Trial. JAMA Intern Med 2019;179(1):28-36.
5. McCullagh R, O’Connell E, O’Meara S, Daly H, O’Reilly E, O’Connor K, et al. Augmented exercise in hospital improves physical performance and reduces negative post hospitalization events: a randomized controlled trial. BMC Geriatr 2020;20(1):46.
6. Hartley P, Costello P, Fennor R, Gibbins N, Quinn E, Kuhn I, et al. Change in skeletal muscle associated with unplanned hospital admissions in adult patients: A systematic review and meta-analysis. PLOS ONE 2019;14(1):e0210186.
7. De Morton NA, Jones CT, Keating JL, BertoIwitz D, MacGregor L, Lim WK, et al. The effect of exercise on outcomes for hospitalised older acute medical patients: an individual patient data meta-analysis. Age Ageing 2007;36(2):219-22.
8. Martinez-Velilla N, Cadore EL, Casas-Herrero A, Idoate-Saralegui F, Izquierdo M. Physical Activity and Early Rehabilitation in Hospitalized Elderly Medical Patients: Systematic Review of Randomized Clinical Trials. J Nutr Health Aging 2016;20(7):738-51.
9. Valenzuela PL, Morales JS, Castillo-Garcia A, Mayordomo-Cava J, Garcia-Hermoso A, Izquierdo M, et al. Effects of exercise interventions on the functional status of acutely hospitalised older adults: A systematic review and meta-analysis. Ageing Res Rev 2020;61:101076.
10. Kosse NM, Dutmer AL, Dasenbrock L, Bauer JM, Lamoth CJ. Effectiveness and feasibility of early physical rehabilitation programs for geriatric hospitalized patients: a systematic review. BMC Geriatr 2013;13:107.
11. Hartley P, Romero-Ortuno R, Wellwood I, Deaton C. Changes in muscle strength and physical function in older patients during and after hospitalisation: a prospective repeated-measures cohort study. Age Ageing 2021;50(1):153-60.
12. Hartley PJ, Keevil VL, Alushi L, Charles RL, Conroy EB, Costello PM, et al. Earlier Physical Therapy Input Is Associated With a Reduced Length of Hospital Stay and Reduced Care Needs on Discharge in Frail Older Inpatients: An Observational Study. J Geriatr Phys Ther 2019;42(2):E7-E14.
13. Julious SA. Sample size of 12 per group rule of thumb for a pilot study. Pharmaceutical Statistics 2005;4:287-91.
14. Borde R, Hortobagyi T, Granacher U. Dose-Response Relationships of Resistance Training in Healthy Old Adults: A Systematic Review and Meta-Analysis. Sports Med 2015;45(12):1693-720.
15. de Morton NA, Davidson M, Keating JL. The de Morton Mobility Index (DEMMI): an essential health index for an ageing world. Health Qual Life Outcomes 2008;6:63.
16. Mahoney FI, Barthel DW. Functional Evaluation: The Barthel Index. Md State Med J 1965;14:61-5.
17. Romero-Ortuno R, Walsh CD, Laviol BA, Kenny RA, A. Frailty...
Instrument for primary care: findings from the Survey of Health, Ageing and Retirement in Europe (SHARE). BMC Geriatrics [journal article] 2010;10(1):1-12.

18. Hsieh S, McGrory S, Leslie F, Dawson K, Ahmed S, Butler CR, et al. The Mini-Addenbrooke’s Cognitive Examination: a new assessment tool for dementia. Dement Geriatr Cogn Disord 2015;39(1-2):1-11.

19. Yardley L, Beyer N, Hauer K, Kempen G, Plot-Zieger C, Todd C. Development and initial validation of the Falls Efficacy Scale-International (FES-I). Age Ageing 2005;34(6):614-9.

20. Hartley P, Keevil VL, Westgate K, White T, Brage S, Romero-Ortuno R, et al. Using Accelerometers to Measure Physical Activity in Older Patients Admitted to Hospital. Curr Gerontol Geriatr Res 2018;2018:3260240.

21. Charlson ME, Pompei P, Ales KL, MacKenze CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis 1987;40(5):373-83.

22. Elia M. Screening for Malnutrition: A Multidisciplinary Responsibility. Development and Use of the Malnutrition Universal Screening Tool (‘MUST’) for Adults. Redditch: BAPEN: 2003.

23. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology 2006;3(2):77-101.

24. O’Hare L, Savage E, McCullagh R, Bantry White E, Fitzgerald E, Timmons S. Frail older adults’ perceptions of an in-hospital structured exercise intervention. Physiotherapy 2017;103(4):78-84.

25. So C, Pierluissi E. Attitudes and expectations regarding exercise in the hospital of hospitalized older adults: a qualitative study. J Am Geriatr Soc 2012;60(4):713-8.

26. Lim S, Ibrahim K, Dodds R, Purkis A, Baxter M, Rogers A, et al. Physical mobility during hospitalization from the perspectives of older patients and patients’ expectations of physical activity during acute general medical admission. Int J Rehabil Res 2014;44(1):50-1.

27. Wall BT, Collins J, Hamer M, van der Meer M, White M, Prigerson H, et al. The feasibility and acceptability of training volunteer mealtime assistants to help older acute hospital inpatients: the Southampton Mealtime Assistance Study. J Clin Nurs 2014;23(12-22):3240-9.

28. Wall BT, Collins J, Hamer M, van der Meer M, White M, Prigerson H, et al. The feasibility and acceptability of training volunteer mealtime assistants to help older acute hospital inpatients: the Southampton Mealtime Assistance Study. J Clin Nurs 2014;23(12-22):3240-9.

29. Brown CJ, Foley KT, Lowman JD Jr, MacLennan PA, Razjouyan J, Najafi B, et al. Comparison of Posthospitalization Function and Community Mobility in Hospital Mobility Program and Usual Care Patients: A Randomized Clinical Trial. JAMA Intern Med 2016;176(7):921-7.

30. Pedersen MM, Petersen J, Bean JF, Damkjaer L, Juul-Larsen HG, Andersen O, et al. Feasibility of progressive sit-to-stand training among older hospitalized patients. PeerJ 2015;3:e1500.

31. Brown CJ, Peel C, Barnman MM, Allman RM. Exercise program implementation proves not feasible during acute care hospitalization. J Rehabil Res Dev 2006;43(7):939-46.

32. Janssen WG, Bussmann HB, Stam HJ. Determinants of the sit-to-stand movement: a review. Phys Ther 2002;82(9):866-79.

33. Bloomquist K, Langberg H, Karlsen S, Madsgaard S, Boesen M, Raastad T. Effect of range of motion in heavy load squatting on muscle and tendon adaptations. Eur J Appl Physiol 2013;113(8):2133-42.

34. Schoenfeld BJ, Grgic J. Effects of range of motion on muscle development during resistance training interventions: A systematic review. SAGE Open Med 2020;8:2050312120901559.

35. Weiss LW, Frx AC, Wood LE, Relyea GE, Melton C. Comparative Effects of Deep Versus Shallow Squat and Leg-Press Training on Vertical Jumping Ability and Related Factors. Journal of Strength and Conditioning Research 2000;14(3):241-7.

36. Torres-Sanchez I, Valenza MC, Saez-Roca G, Cabrera-Martos I, Lopez-Irizarri M, Rodriguez-Torres J. Results of a Multimodal Program During Hospitalization in Obese COPD Exacerbated Patients. COPD 2016;13(1):1-10.

37. Borges RC, Carvalho CR. Impact of resistance training in chronic obstructive pulmonary disease patients during periods of acute exacerbation. Archives of Physical Medicine and Rehabilitation 2014;95(9):1638-45.

38. José A, Dal Corso S. Inpatient rehabilitation improves functional capacity, peripheral muscle strength and quality of life in patients with community-acquired pneumonia: a randomised trial. Journal of Physiotherapy (Elsevier) 2016;62(2):96-102.

39. Brown CJ, Foley KT, Lowman JD Jr, MacLennan PA, Razjouyan J, Najafi B, et al. Comparison of Posthospitalization Function and Community Mobility in Hospital Mobility Program and Usual Care Patients: A Randomized Clinical Trial. JAMA Intern Med 2016;176(7):921-7.

40. Siebens H, Aronow H, Edwards D, Ghasemi Z. A Randomized Controlled Trial of Exercise to Improve Outcomes of Acute Hospitalization in Older Adults. Journal of the American Geriatrics Society 2000;48(12):1545-52.

41. Pedersen MM, Petersen J, Bean JF, Damkjaer L, Juul-Larsen HG, Andersen O, et al. Feasibility of progressive sit-to-stand training among older hospitalized patients. PeerJ 2015;3:e1500.

42. Brown CJ, Peel C, Barnman MM, Allman RM. Exercise program implementation proves not feasible during acute care hospitalization. J Rehabil Res Dev 2006;43(7):939-46.

43. Wall BT, Collins J, Hamer M, van der Meer M, White M, Prigerson H, et al. The feasibility and acceptability of training volunteer mealtime assistants to help older acute hospital inpatients: the Southampton Mealtime Assistance Study. J Clin Nurs 2014;23(12-22):3240-9.

44. Roberts HC, De Wet S, Porter K, Rood G, Diaper N, Robison J, et al. The feasibility and acceptability of training volunteer mealtime assistants to help older acute hospital inpatients: the Southampton Mealtime Assistance Study. J Clin Nurs 2014;23(12-22):3240-9.
### APPENDIX 1.

#### Intervention development

In designing the intervention three aims were considered:

- improve lower-limb muscle strength;
- be feasible during a period of acute illness in frail older adults;
- minimise costs by not requiring either the supervision of a qualified physiotherapist or any more equipment or space than already available on a hospital ward.

The basics of the intervention were initially drafted based on the PI’s (physiotherapist with over 10 years of clinical practice) clinical experience. The evidence regarding exercise intensity, need for supervision, exercise dose and exercise frequency was then reviewed, and the design refined. Finally, the PPI group were asked for their opinions and feedback on the intervention, and further refinements were made. A summary of the decisions made, the reviewed evidence, and modifications informed by the PPI group is provided below.

#### Intervention frequency

The maximum number of intervention sessions per day was two in a scoping review of trials providing exercise interventions to acutely hospitalised older adults\(^2\,^{36-41}\). The PPI group agreed that 3 sessions would likely be overly burdensome on participants, but felt that 2 sessions per day was a reasonable number. The initial plan of a morning and afternoon session was modified by the PPI group, and instead the two sessions could be any time during the day, as long as they were spaced a minimum of 2 hours apart to avoid fatigue. The change was to provide participants with greater flexibility, for example should they wish to avoid an afternoon session so as not to be too tired when visitors arrive.

#### Intervention supervision

There is consensus that for good compliance with exercise, it needs to be supervised\(^22\,^{43}\). For this reason, the patient’s exercise was supervised by a physiotherapy assistant, who was to monitor the patient, provide assistance when needed and record fidelity to the intervention and achievement. As stated above, an aim in the design of the intervention was to minimise costs.

The use of volunteers was considered in delivering the intervention. A body of work led by Professor Helen Roberts has demonstrated that the use of volunteers to provide meal-time assistance in hospitalised older adults in the NHS is both sustainable and valued\(^44\), and these findings have subsequently been replicated in a volunteer-led mobility intervention\(^26\). However, as in Cambridge University Hospitals NHS Foundation Trust, the volunteers providing the mobility intervention in Lim, Ibrahim 2020\(^26\) were not allowed to provide physical assistance. For the purposes of this study, the handling restrictions of volunteers were felt to unduly limit the potential eligibility criteria and the type of intervention being delivered, and physiotherapy assistants were preferred. Physiotherapy assistants are employed throughout the NHS, and supervising or assisting with exercise programmes is usually a key part of their role. An intervention that could be provided by a physiotherapy assistant as opposed to a qualified physiotherapist was predicted to be more feasible in practice, due to the cost savings.

#### Intervention intensity

There is consensus that high intensity strength training in older adults has a larger effect on muscle strength than low or moderate intensity training\(^1,\,^{14,\,45,\,46}\). Definitions of ‘high intensity’ vary, but usually fall within a range of 70-90% of a maximum voluntary contraction (MVC) i.e. a one-repetition maximum\(^1,\,^{14,\,45,\,46}\). In healthy older adults, standing from a chair has been shown to require approximately 80% of an MVC\(^47\). Standing from a seated position would therefore meet the criterion of being considered ‘high intensity’, with raising or lowering of the seated platform adjusting the intensity. It also fulfils requirements of being straightforward and not requiring additional equipment. Furthermore, an exercise programme based on standing from a chair has been found to be feasible in older, hospitalised patients in Denmark\(^41\).

#### Intervention dose

The evidence to support number of repetitions or sets is weaker. Borde, Hortobagyi\(^14\) conducted a meta-regression of 25 studies investigating exercise training in older adults and concluded that two to three sets per exercise and seven to nine repetitions resulted in the largest improvements. This is in line with the protocol of Pedersen et al.\(^41\) who prescribed three sets of 12 repetitions at 60-70% of an MVC. The PPI group debated the number of repetitions and sets. They were concerned that participants could be demotivated if unable to complete the requested number of stands. However, the group also thought it would be advantageous for the assistant to have a target number of stands. The group decided that the assistant should aim to complete up to three sets of 10 stands but should encourage the participant to do ‘as many as possible’ rather than instructing the patient to complete a certain number.
APPENDIX 2.
Participant interview template

1. As you are aware, you are currently part of a research project looking at providing an additional physiotherapy exercise programme to people whilst they are in hospital. Can you tell me what it has been like to take part?
   Prompts: How did you find the exercises? What are the positives and negatives of taking part?
2. Were there any things about taking part in the study that you found difficult?
   Prompts: Were you able to overcome these difficulties? What helped you overcome these difficulties? What would have helped you overcome these difficulties? Is there anything we could have done differently?
3. What do you think about the exercises you were asked to perform?
   Prompts: Can you tell me how difficult you found the exercises? What do you think about the amount of exercise you were asked to perform?
4. How did taking part in the study affect your health?
   Prompts: Are there any changes in your physical condition that you would put down to exercise programme?
5. How would you feel about taking part in a similar study in the future?
   Prompts: What would affect your decision?
6. Thinking about the things you need to do at home, how confident are you now that you can manage?
   Prompts: [If not fully confident] What would improve your confidence?
7. Is there anything else you want to talk about in relation to the study?