Progressive strength training in older patients after hip fracture: a randomized controlled trial

Running head: Strength training after hip fracture.

Keywords: hip fracture, progressive strength training, balance and physical function

Abstract

Objective: the aim of this study was to assess the effect of a 3-month strength-training program on functional performance and self-rated health in a group of home dwelling older hip fracture patients.

Design: randomized, controlled; single-blind parallel-group trial.

Setting: intervention at outpatient's clinic.

Subjects: 150 patients with surgical fixation for a hip fracture.

Methods: strength training was integrated into all stages of the program. The program comprised four exercises, half of them in a standing position, performed at 80% of maximum. Measurements were taken after the 3-month intervention. The primary outcome measurement was the Berg Balance Scale. Secondary outcomes were results of the sit-to-stand test, Timed Up-and-Go test, maximal gait speed, 6-minute walk test, Nottingham Extended Activities of Daily Living scale, and the SF-12 health status questionnaire

Results: at baseline, there were no significant between-group differences. At follow-up, the intervention group showed highly significant improvements both in the primary end-point (Berg Balance Scale, mean difference 4.7 points) and in secondary end-points of tapping strength, mobility, and instrumental activities of daily living

Conclusion: home dwelling hip fracture patients can benefit from an extended supervised strength-training program in a rehabilitation setting. These patients are capable of high-intensity strength training, which should optimize gains in physical function, strength and balance. Resistance exercise training seems to influence functional performance adaptation.

Introduction

Hip fractures are common among older adults and can have a devastating impact on their ability to remain independent [1, 2]. This injury is associated with an excess mortality of 5–20% the first year post fracture, a costly hospitalization of the patient and lengthy rehabilitation procedures [3, 4]. Between 22% and 75% of patients do not recover their previous ambulatory or functional status 6–12 months after the event, and a significant functional decline has been documented even among individuals who were functioning at a high level before the fracture [5]. Hip fracture patients are often frail older adults with a fall history, weight loss, sarcopenia, low physical activity, cognitive decline and depression [6].

Immobilization after major surgery and during hospitalization can cause a severe decline in muscle strength and muscle functioning, and physical training seems to improve strength and functional performance in hip fracture patients [7]. However, a recent systematic review [2] indicates that the evidence is insufficient with respect to best practices in rehabilitating hip fracture in older adults. The patient group is a heterogeneous one, and, consequently, rehabilitational efforts need to be individualised [2]. There is a particular need for more studies to determine the type and amount of exercise intervention necessary to maintain or enhance strength and function in these patients [1, 8]. No studies have focused only on progressive strength training as an intervention for hip fracture patients. The aim of this study was to assess the effect upon balance, strength, mobility, instrumental activities of daily living (iADL), and self-rated health of a 3-month strength-training program of progressive resistance exercise training, in older home-dwelling hip fracture patients.

Methods

Study design

This was a randomized, controlled, single-blind parallel-group trial involving hip fracture patients, starting at 12 weeks after a fracture. Patients were approached during their acute stay in hospital and were followed without any extra intervention for the first 12 weeks, after which they were randomized in a 2:1 manner to either an intervention or a control group for the next 12 weeks. The study reported here is the first part of a long-term study. The 2:1 allocation was used because the members of the intervention group were to be randomized to further intervention or control groups for an additional 12 weeks, and this allocation will allow further studies on the intervention group. The follow-up study will be published later.

Study population

Patients of both sexes, aged 65 years or older who were admitted to Ullevål University Hospital or Diakonhjemmet Hospital in Oslo, Norway, with a femoral neck fracture or a trochanteric fracture between June 2007 and December 2008 were eligible for the study. Patients were recruited during the hospital stay (figure 1) and 467 were registered in the acute phase (figure 1).

Patients were not included if they had been permanently institutionalized before the hip fracture, had metastatic cancer as presumed reason for the fracture, if their expected remaining lifetime was less than six months, or if the hip fracture was part of a multitrauma, which left 181 eligible for inclusion. Those who had been registered in the acute phase but died, moved or were institutionalized during the first 3 months or did not return for the 3-month follow-up, were not eligible for randomization.

To be eligible for randomization, patients had to meet the following criteria 12 weeks after the operation: (1) age 65 years or older; (2) living at home; (3) able to undergo physical therapy for the hip fracture; and (4) scoring 23 or more (out of 30) on the Mini-Mental State Examination (MMSE) [9].

After inclusion and baseline measurements, patients were assigned randomly by a computer-generated list to the intervention or the control group. Research assistants not involved in the study performed the randomization using lots in sealed opaque envelopes. Patients were randomized in blocks of eight.

Measurements

Demographic data such as age, sex, living conditions, pre-fracture self-rated health, falls before the index injury, pre-fracture use of walking aids indoors and outdoors, and score on the MMSE were collected by the investigator during the acute stay. Self-reported pre-fracture functioning in personal activities of daily living (pADL) was assessed by the Barthel Index, which includes 10 activities that focus on the patient’s dependency on help. The scores range from 0 (completely dependent) to 20 (independent) [10].

The primary outcome was the Berg Balance Scale (BBS) score registered after the 12-week training period (24 weeks after the fracture). Secondary outcomes were the results of seven different outcomes. Strength was measured by the sit-to-stand test and maximum step high test. , Mobility was measured by the Timed Up-and-Go test, maximum gait speed, and 6-minute walk test. In addition, Nottingham Extended Activities of Daily Living scale (NEADL), measuring IADL, and the SF-12 questionnaire, measuring self-rated health, were used. All assessments were made by an examiner who was blinded to the group allocation and who was not involved in any part of the treatment or rehabilitation.

Berg Balance Scale: The BBS measures functional balance, which has three dimensions: maintenance of a position, postural adjustment to voluntary movements, and reaction to external disturbance; it is scored from 0 to 56 [11].

Sit-to-stand test: The patient sat on a 46-cm high hardback chair without armrests, with the arms folded, and was instructed to rise to a straight standing position as fast as possible without using the arms. The investigator measured the time to rise 10 times [12].

The Timed Up-and-Go test: The patient was timed as he or she rose from an armchair, walked 3 m, turned, walked back, and sat down again. The test was applied as described by Podsiadlo and Richardson [13].

Maximal gait speed test: Subjects walked 10 m from a stationary position, and the time in seconds was registered. The command was, “Walk as fast as you can without feeling unsafe and without running” [14].

Maximum step height test: As a test of climbing stairs, the ability to mount boxes of increasing heights (10, 20, 30, 40, 50, 60, and 70 cm) without support was measured [15]. The height of the highest box mounted was recorded.

Six-minute walk test: The patients walked for 6 minutes indoors, along a flat, straight enclosed corridor [16].

The Nottingham Extended Activities of Daily Living score (NEADL): This comprises 22 activities, and the sum score ranges from 0 to 66. A higher score indicates better functioning in iADL [17]. The scorings were based on self-report.

The Short Form-12 test: This was based upon self-report and was used as a measurement of the participant's self-rated health. We used the summary measures PCS-12 (physical domain of SF-12, scores ranging from 0 to 100) and MCS-12 (mental domain of SF-12, scores ranging from 0 to 100) [18].

Intervention

Exercises during the 3-month phase (3–6 months after the fracture) were conducted by a physiotherapist using a combination of group and individual sessions. One-repetition maximum (1-RM) voluntary strength was measured for two different exercises (knee flexion and knee extension). Before testing, all patients exercised on a stationary bicycle or a treadmill as a warm-up for 10–15 minutes. The treadmill speed or bicycle resistance was set at the highest comfortable setting that was acceptable for the participant. Exercise sessions lasted 45 to 60 minutes, depending on the participant's ability and tolerance. Initially, the participant performed three sets of 15 repetitions of each exercise at 70% of his or her 1-RM. The 1-RM measurements were repeated every third week and used to increase the exercise prescription progressively. After the first 3 weeks, the resistance was increased to 80% of the 1-RM, and every third week the number of repetitions was reduced from 12 to 10, while maintaining at least eight repetitions. The resistance was modified by the physiotherapist every third week and more often if the participant was able to perform at that load, which was based on the 1-RM measurements. Patients completed four exercises: standing knee flexion, lunge (pass forward), sitting knee extension and leg extension.

Each participant was required to attend exercise sessions twice per week and to complete a home training program once a week. Patients who missed an exercise session because of illness or brief vacation were allowed to return to training if the absence was 2 weeks or less. The home exercise protocol included two exercises in the standing position: standing knee flexion and lunge (pass forward), a warm-up session were not required. The patients borrowed weight belts, which could be loaded from 0.5 to 12 kg. If they were able to, the patients were advised to walk about 30 minutes every day.

Control group

Subjects in the control group were asked to maintain their current lifestyle. No restrictions were placed on their exercise activities.

Ethics

The Eastern Norway Regional Ethics Committee for Medical Research approved the study. Oral and written information about the studies was given. Informed consent was given by all patients, at time of fracture, through methods approved by the Data Protection Officer. At start of intervention the patients were reassured that they were free to withdraw from the study if they wanted. A physiotherapist always monitored the exercise sessions and attended the safety. No patients fell during the sessions.

Statistical analysis

The sample size was estimated for a long-term follow-up study based on the intervention group from the present study, which gave the 2:1 ratio for distribution. We estimated that a total sample of 90 subjects (45 in each group) would provide an 80% probability of detecting differences between group means for the BBS, assuming a mean difference of 2.5 (SD 4.2) We assumed an alpha of 0.05, taking account of a possible drop-out rate of 15–20%. Analysis was on an intention-to-treat basis. Missing data for subjects who did not complete the programme were replaced by baseline test values (last observation carried forward). Between-group comparisons of measurements at a single time point were performed using unpaired *t* tests (continuous variables) or χ^2 tests (categorical variables), unless specified otherwise. Paired *t* tests were used to analyse within-group differences.

Results

One hundred and fifty patients with hip fracture (27 men and 123 women) were randomized at 3 months after their fracture. The patient flow is illustrated in Figure 1. Socio-demographic variables and pADL score at baselinepatients are presented in Table 1,and did not differ between the groups. Twelve patients (8%, seven controls and five from the intervention group) withdrew from the study but still provided some follow-up data. Those who withdrew did not differ from those who completed with respect to age, sex, fracture type, method of surgical repair, or baseline scores (data not shown).

Table 2 shows the differences between the intervention and the control groups at the 3-

month evaluation (6 months after the injury) and the within-group differences. At baseline, there were no significant between-group differences. At follow-up, the score on the BBS (primary end-point, mean difference 4.7 points) improved significantly in the intervention group but not in the controls. The secondary end-points: strength, mobility, and instrumental ADL (mean 48.1) also improved significantly in the intervention group. The improvements in instrumental ADL were related to mobility items, especially outdoor mobility. However, the secondary outcomes maximal walking speed and the SF-12 sub domains self-rated health did not improve significantly in either group (Table 2) and did not differ between the groups at baseline or at follow up (Table 2).

Discussion

We found pronounced effects of progressive strength training on balance (primary outcome) and on secondary outcomes of strength, gait distance, and functional performance in hip fracture patients. The improvements were highly significant. Half of the exercises in our program were performed in the standing position, and previous reports have indicated that the relationship between strength and functional balance in frail older persons is most pronounced if training is performed when standing [19]. Only a few controlled studies of exercise training after hip fracture have been reported. Significant improvements in strength were achieved in an uncontrolled study using methods that were difficult to standardize [20] or in a study that compared weight-bearing with non-weight-bearing exercises [21]. To our knowledge, ours is the first study to show that strength training at a relatively high intensity with only a few exercises is feasible and effective in this patient group.

The performances improved significantly in all the motor tasks related to the risk of functional disability and dependence, such as balance [22], chair rise [23], timed up-and-go [24] and step height [15]. A score on Bergs Balance Scale below 45 (out of 56) is considered to be an indicator of fall risk [11]. In our study, the intervention group changed their mean score from below to abowe the cut off during the intervention, indicating that the improvement was clinically relevant. Performance on the 6-minute walk test (6MWT) also improved significantly in the intervention group, indicating better walking ability and greater confidence while walking [25]. As 6MWT measure sub-maximal aerobic capacity and functional limitations among mobility-limited elders [25], the progress in 6MWT may also indicate an improvement in endurance and functional performance. This is also supported by the IADL measures found in our study. Older persons adapt their walking patterns in order to enhance stability at the cost of less-effective forward propulsion [23], which may explain why we did not find improvement in maximal walking speed. The improved balance and strength were also reflected in a significant improvement in instrumental ADL, which is importance for the patient's future independence.

We found no effect on self-rated healththe physical or mental subdomains of SF-12, which contrasts with the results of Binder *et al*. [26]. The achieved gain in muscle strength may improve walking distance, stair climbing and balance, but may be insufficient to cause significant favourable effects on subjectiveself-rated health status in this patient group [27]. The results accord with those of Ruhland and Shields [28], indicating that an individual's perception of health-related quality of life may be strongly associated with impaired maximal walking speed [28]. Subjective health outcomes in this patient group may be difficult to change with exercise alone [8] because they are likely to be affected by psychosocial and environmental factors as well as by physical ability.

Our clinical trial was designed and implemented according to a strict experimental protocol. The sample size was adequate, with a very low drop-out rate and good compliance with the exercise program. Another strength of our study is the use of standardized, validated instruments for all assessments and the involvement of a blinded examiner.

Our study has some limitations. The intervention group may have had greater social contact than the controls, and it is possible that improvements could have resulted from a “placebo effect” and additional contact rather than from the exercises. Exercise intervention studies appeal to healthier and more motivated individuals [29]. Exercises, other kinds of interventions or levels of physical activity for the control group, were not registered. Another limitation is the inclusion criteria, which restrict our findings to older people living on their own without moderate and severe cognitive symptoms. The frailest hip fracture patients were not included. Conclusions about the training results may not be extended beyond older hip fracture populations living at home.

Conclusion

Home dwelling hip fracture patients can benefit by extending their rehabilitation in a supervised exercise setting and by performing strength-training exercising at high intensities to optimize gains in physical function, strength and balance. The resistance exercise training program seemed to induce adaptations in functional performance. Hip fracture patients represent a large population, and these findings are relevant for clinical practices that treat such patients.

Key points

- Progressive strength training is safe and effective for home dwelling older patients with hip fracture.
- Strength, balance and physical function are improved by physical training.
- Resistance exercise training seems to improve functional performance adaptation in hip fracture patients.

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Table 1. Baseline characteristics

Variables	Intervention (*n*=100)	Control (*n*=50)	*P*
Age, mean (SD), (range)	82.1 (6.5), (65.0–96.3)	82.9 (5.8), (66.5–94.6)	0.448
Women, *n* (%)	85 (85.0)	40 (75.5)	0.124
Living alone, *n* (%)	50 (50.0)	28 (52.8)	0.786
Fall in the past 6 months[a] yes, *n* (%)	21 (21.0)	13 (24.5)	0.687
Use of walking aid indoor, *n* (%)	43 (43.0)	19 (35.8)	0.848
Use of walking aid outdoor, *n* (%)	47 (47.0)	26 (49.1)	0.375
Mini-Mental State Examination, mean (SD),(range)	28.7 (2.6) (23–30)	29.3 (2.4) (23–30)	0.398
Barthel Index sum score, median (IQR)	19.5 (18, 20)	20 (19, 20)	0.067

SD=standard deviation, IQR=inter-quartile range, *P*=0.05

[a]Fall apart from the injuring fall

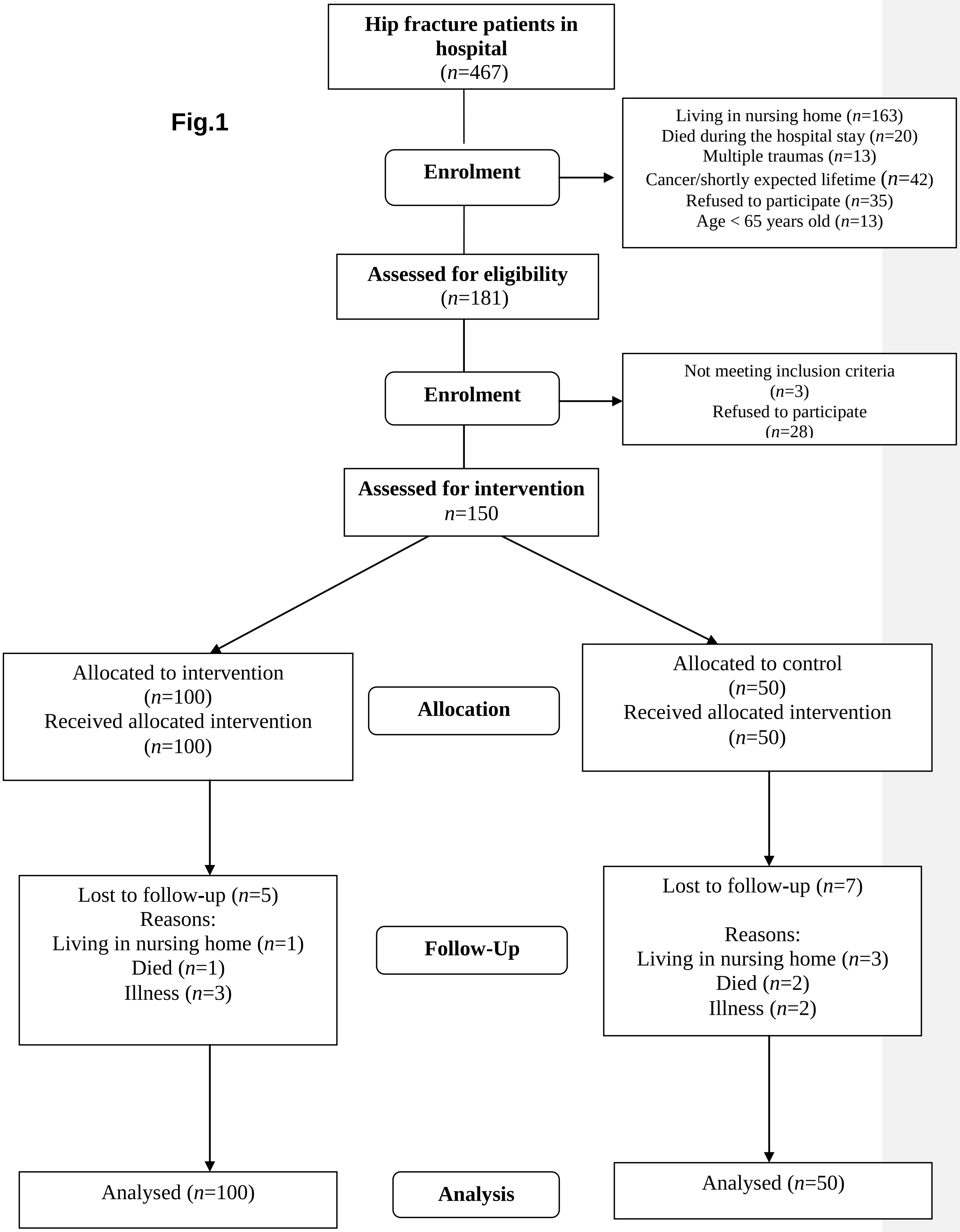
Table 2. Between-group differences at baseline and mean changes after the 3-month intervention

Variables	Intervention group (*n*=100)			Control group (*n*=50)			Between-group differences Mean (95% CI)	
	Baseline Mean (SD)	Follow-up Mean (SD)	Change Mean (95% CI)	Baseline Mean (SD)	Follow-up Mean (SD)	Change Mean (95% CI)	Baseline	Follow-up
Berg Balance Scale (0–56)	41.0 (5.1)	47.2 (6.5)	6.2 (4.8, 7.6)	39.2 (6.0)	42.5 (6.1)	3.3 (1.4, 5.3)	1.8 (0.0, 3.6)	4.7 (2.5, 6.8)
Sit-to-stand test (s)	40.2 (12.2)	18.6 (8.4)	–21.7 (–24.7, –17.7)	37.3 (12.1)	34.4 (7.7)	–2.9 (–0.8, 6.6)	2.9 (–1.1, 7.1)	–15.8 (–18.6, –13.1)
Six-minute walk test (m)	216.4 (88.7)	297.2 (120.8)	80.9 (57.6, 104.1)	223.1 (83.6)	240.7 (80.7)	17.6 (12.7, 28.0)	–6.7 (–36.1, 22.6)	56.5 (19.9, 93.1)
Maximum gait speed, 10 m (m/s)	0.42 (0.2)	0.58 (0.3)	0.16 (–1.8, 2.1)	0.43 (0.2)	0.51 (0.3)	0.08 (–1.3, 1.5)	0.01 (–4.2, 5.5)	–0.07 (–1.5, 1.5)
Timed up-and-go test (s)	21.4 (9.2)	13.3 (4.8)	–8.1 (–10.2, –6.1)	20.6 (8.0)	19.8 (10.3)	–0.8 (–4.3, –2.6)	0.8 (–2.2, 3.8)	–6.5 (–9.0, –4.1)
Step height (cm)	8.7 (12.4)	19.6 (13.4)	10.9	8.0 (13.0)	10.6 (10.6)	2.6	0.7 (–9.0, 4.1)	9.0 (4.8, 13.2)

			(7.8, 14.1)			(2.2, 7.3)		
NEADL sum score (0–66)	43.4 (10.8)	48.1 (13.1)	4.8	45.2 (9.1)	43.2 (13.0)	–2.0	–1.8 (–5.3, 1.6)	4.9 (0.6, 9.4)
			(1.7, 7.8)			(–2.3, 6.4)		
PCS-12	49.7 (6.2)	45.6 (5.9)	–4.1	49.4 (6.7)	45.5 (5.4)	–3.9	0.2 (–1.9, 2.4)	0.1 (–1.8, 2.1)
			(–5.9, 2.6)			(–6.2, 1.8)		
MCS-1)	49.8 (7.3)	51.5 (8.4)	1.7	52.3 (7.9)	52.5 (9.1)	0.2	–1.1 (–3.5, 1.4)	1.1 (–1.7, 2.6)
			(0.3, 3.4)			(2.0, 2.4)		

CI=confidence interval; NEADL=Nottingham Extended Activities of Daily Living score; self-rated health PCS-12=physical domain of the Short Form-12 questionnaire; MCS-12=mental domain of Short Form-12 questionnaire

Fig.1



Hip fracture patients in hospital
(n=467)
Enrolment
Living in nursing home (n=163)
Died during the hospital stay (n=20)
Multiple traumas (n=13)
Cancer/shortly expected lifetime (n=42)
Refused to participate (n=35)
Age < 65 years old (n=13)
Assessed for eligibility
(n=181)
Enrolment
Not meeting inclusion criteria
(n=3)
Refused to participate
(n=28)
Assessed for intervention
n=150
Allocated to intervention
(n=100)
Received allocated intervention
(n=100)
Allocation
Allocated to control
(n=50)
Received allocated intervention
(n=50)
Lost to follow-up (n=5)
Reasons:
Living in nursing home (n=1)
Died (n=1)
Illness (n=3)
Follow-Up
Lost to follow-up (n=7)
Reasons:
Living in nursing home (n=3)
Died (n=2)
Illness (n=2)
Analysed (n=100)
Analysis
Analysed (n=50)