Effects of a home-based physical rehabilitation program on physical disability after hip fracture: A randomized controlled trial

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Short running head: Effects of home-rehabilitation on disability

Abstract

Background: Less than half of the hip fracture patients will regain the pre-fracture level of physical functioning. This secondary analysis of a randomized controlled trial investigated the effects of a multi-component home-based rehabilitation program (ProMo) on physical disability after hip fracture.

Methods: Population-based clinical sample of over 60-year-old community-dwelling people (n=81) operated for hip fracture were randomized into intervention and control groups. The year-long intervention aimed at restoring mobility. It included evaluation and modification of environmental hazards, guidance for safe walking, pain management, home-exercise, physical activity counseling, and standard care. Physical disability was assessed by a questionnaire at baseline, and three, six and twelve months thereafter. Sum scores were computed for basic (ADL) and instrumental activities of daily living (IADL). A higher score indicated more difficulty. GEE models were constructed to analyze the effect of the intervention.

Results: In the intention-to-treat analysis, no intervention effect was observed for sum scores. For the single disability items, a borderline significant positive effects were observed for preparing food and handling medication (interaction p=0.061 and p=0.061, respectively). In the per-protocol analysis, the mean differences between groups were -0.4 points (S.E. 0.5), -1.7 (0.7), and -1.2 (0.7) at three, six and twelve months for ADL and -1.0 (1.2), -3.2 (1.5), and -2.5 (1.4) for IADL, correspondingly.

Conclusion: The current analyses suggest that home-based rehabilitation may reduce disability among older people after hip fracture. The present results need to be confirmed in a study with larger sample size. Potentially a more task-oriented rehabilitation approach might gain more benefits.

Introduction

Hip fractures are strongly associated with many adverse consequences (1,2) and are typically followed by activity restriction which leads to functional limitations and finally to disability. Moreover, less than half of the hip fracture patients will regain the pre-fracture level of physical functioning (3). Physical disability is defined as difficulty in performing activities of daily living in a social context and thus reflects an imbalance between person's physical functional capacity and the requirements of the environment (4). Activities of daily living can be divided into basic (ADL) (5) and instrumental (IADL) (6) activities.

The search for an optimal rehabilitation model has evoked increasing interest for home rehabilitation after a hip fracture. Right after hospital discharge the hip fracture patients are often weak and tired and thus not able to participate in rehabilitation elsewhere than home on a regular basis. The frail ones are potentially those who would benefit most from home-based rehabilitation. Additionally, when rehabilitation is implemented outside home, it requires equipment, facilities and ability to travel. Based on previous research, home-based rehabilitation programs involving physical rehabilitation may be as beneficial as inpatient rehabilitation programs as long as they are started within four months post fracture (7).

In one recently published study, community-dwelling hip fracture patients participated in a year-long, home-based exercise program including physical exercise, safety assessment, and self-efficacy based motivational component (8,9). This intervention had no effect on several targeted outcomes, including coping with ADL, compared to standard care (9). In another study home rehabilitation focusing on supported discharge improved independence in IADL in community-dwelling older adults after hip fracture (10). Based on earlier contradictory studies, more research is needed to determine the effectiveness of home rehabilitation programs on physical disability after hip fracture. Additionally, Crotty et al. (2010) suggests in their systematic review that patient-reported outcomes (e.g. physical disability and fear of falling) should be established for hip fracture trials because insufficient evidence exists to recommend practice chance for hip fracture rehabilitation (11).

The purpose of this study was to investigate the effects of multi-component home-based rehabilitation program (ProMo) on self-reported physical disability among over 60-year-old community-dwelling men and women with a recent hip fracture. The intervention was planned to support mobility recovery and independent living in the home environment. It took place at the participants' homes and began on average six weeks after the hospital discharge (12).

Material and methods

Study Design

The study protocol of this randomized controlled trial (RCT; ISRCTN53680197) entitled "Promoting Mobility after Hip Fracture" (ProMo) has already been published (12) and is described briefly here. This secondary analysis reports the outcomes related to physical disability which refers to perceived functional capacity. The one year primary outcome of this study was self-reported difficulty in walking, the result of which will be reported elsewhere. Participants in this study were randomly assigned to the intervention (ProMo + standard care) or control (standard care) group after the baseline measurements. All participants were measured at the university laboratory four times; at baseline, and three, six, and twelve months thereafter. Baseline measurements were organized as soon as possible after being discharged to home; on average 70 days after the hip fracture.

Ethics

This RCT was performed in accordance with the Declaration of Helsinki and approved by the Ethics Committee of the Central Finland Health Care District on August 18th, 2007. Participants signed a written informed consent prior to participation. Proxy consent was not permitted. Those who were interested in the study had an opportunity to discuss with a researcher before signing and giving permission to review their medical records. The participants could, at any point, refuse to participate further.

Participant inclusion and exclusion

All consecutive, over 60-year-old, ambulatory and community-dwelling men and women who were living in the city of Jyväskylä or neighboring municipalities and were operated for femoral neck or pertrochanteric fracture (International Classification of Diseases S72.0 or S72.1) were screened for eligibility and informed about the study (n=296). Patients were excluded from the study if they were suffering from severe memory problems (Mini Mental State Examination <18) (13), alcoholism, severe cardiovascular, pulmonary or progressive (i.e neoplasm, amyotrophic lateral sclerosis) disease, para- or tetraplegic or severe depression (Beck Depression Inventory >29) (14).

Sample size

Pretrial power calculations were based on earlier published longitudinal data on mobility recovery after a hip fracture. In the study by Visser et al (2000), 45.3 % of the community-dwelling participants were independent in more demanding mobility tasks (chair rising, walking one block and negotiating stairs) before the fracture (15). Twelve months after a hip fracture less than one third of them (20.7 % of the total sample) had regained their pre-fracture level of mobility. In this study, to detect the expected difference between the study groups in mobility recovery at $\alpha=0.05$ and $\beta=0.20$, a minimum of 44 subjects were needed in each study group (12). Sample size was calculated using an online sample size calculator available from (DSS researcher's toolkit, http://www.dssresearch.com/KnowledgeCenter/toolkitcalculators).

Randomization an blinding

Participants who gave informed consent underwent baseline assessment before randomization. A statistician not involved in recruitment or assessments developed the group allocation schedule using a computer generated random number sequence and stored the list off site. Men and women and those operated with internal fixation or arthroplasty were randomized by blocks which were randomly arranged within blocks of 10. The study group assignment was enclosed in sealed opaque envelopes. The study coordinator performed randomization. This study was single-blinded. To ensure blinding, participants were asked not to disclose group allocation to the assessors and other participants.

Interventions

Standard Care

At baseline, information on standard care after the hip fracture was collected by interviewing all participants (12). Of all participants, 70% obtained a written home exercise program from the hospital or health care center with no difference between the intervention and control group (68% vs. 71%, p=0.813). Typically the program included 5–7 exercises with no additional resistance. There was no follow-up or update for the home exercises. Twelve participants received a referral to physiotherapy (five in the intervention and seven in the control group).

Promo-intervention

The intervention included standard care and the ProMo rehabilitation program (12). ProMo was an individually tailored year-long rehabilitation intervention taking place at participants' homes. It aimed at restoring mobility after hip fracture and began on average within one week after the

baseline measurements. The program included 5–6 home visits by an experienced physiotherapist. Tailored written materials were provided for each participant on assistive devices, hip protectors, safe footwear, home exercises, and local physical exercise facilities.

During the first face-to-face session ***evaluation and modification of environmental hazards and guidance for safe walking*** took place according to the guidelines by the National Public Health Institute of Finland (16). Participants' concerns regarding fear of falling, satisfaction with assistive devices for physical functioning and usage of hip protectors were also considered. An individual ***non-pharmacological pain management*** evaluation took place in the second face-to-face session and was repeated at three (fourth home visit) and six months (fifth home visit). Pain management sessions included structured interview. In addition, knowledge on pain relief strategies were discussed (17). The purpose of the first and second home visits was to prepare the ground for the physical activity and exercise.

Also the ***individual progressive home exercise program*** was launched during the second home visit. It comprised strengthening exercises for lower limb muscles, balance training as well as stretching, and functional exercises. Functional exercises included walking, reaching/turning different directions, and stair climbing. Strengthening and stretching exercises were advised to be done on the same day three times a week. Balance, walking and functional exercises were advised to be done on the same day two to three times a week (different than strengthening and stretching exercises). The duration of one exercise session was approximately 30 minutes. (More detailed in **Supplementary Table 1.)**

The home exercise program was updated 4–5 times with a more intensive and demanding protocol. The first update occurred after one week (third home visit) and subsequently after one **(**fourth home visit), three (fifth home visit), six (sixth home visit), and nine months (phone call). For eleven participants only five home visits were scheduled. Four participants went on holiday during the intervention period and the face-to-face meeting was replaced by a phone call. Additionally, six participants received two updated programs during the third home visit and were contacted by telephone after one month for further support. During the intervention, the progression for the strengthening exercises was increased with resistance bands of three different strengths. All participants kept daily exercise diary in which they marked the exercises they performed and the Borg Scale for each exercise. Participants were asked to mail their exercise diaries to the research physiotherapist monthly. If diaries were not returned in time the physiotherapist called to the participant and reminded him/her.

Individual motivational face-to-face ***physical activity counseling*** (18) took place after three months (fourth home visit) at subjects' homes. Counseling was a onetime session followed by phone calls at four and eight months and a face-to-face meeting at six (sixth home visit) months to promote and encourage subjects to physical activity. In addition, an extra motivational conversation was provided at twelve months after the final laboratory measurements.

Outcome Assessments

Review of medical data and health status

Medical data and health status was assessed at baseline, during a medical examination performed by a nurse practitioner and a physician (12) (**Supplementary Table 2**). To ascertain safe participation in the measurements and intervention, the physician evaluated contraindications according to American College of Sports Medicine guidelines (19). Indoor and outdoor falls and need for emergency room services after the previous assessment were self-reported at three, six and twelve months with a questionnaire.

Physical disability

Physical disability was assessed by a validated questionnaire (20) estimating perceived difficulties in six basic activities of daily living (ADL): eating, transferring from/to bed, dressing, bathing, cutting toe nails, and toileting (5,20) and eighth instrumental activities of daily living (IADL): preparing meals, doing laundry, coping with light housework, coping with heavy housework, handling medication, using the telephone, using public transportation, and handling finances (6,20) (**Supplementary Table 2**). Both scales are commonly used and shown to be valid predictors of functional capacity among older people (21). Test-retest reliability is high for both scales (22). For the statistical analysis, two sum scores were composed: ADL score (ranging from 0 to 30) and IADL score (ranging from 0 to 40). Higher score indicates more difficulty. Additionally, three-graded categorical variables were computed for each individual item: 1) No difficulty, 2) Some difficulty, and 3) Major difficulty.

Covariates

The presence of chronic conditions was confirmed according to a pre-structured questionnaire and medical records obtained from the local hospital and health care centers during the medical examination carried out by physician and research nurse. Balance confidence (Activities-specific Balance Confidence Scale), functional balance (Berg Balance Scale), pain on the fractured side (questionnaire), use of walking aids outdoors (questionnaire), and average temperature of the month (monthly temperature data) were assessed (**Supplementary Table 2**).

Statistical methods

Normality of the distributions was tested with Kolmogorov-Smirnov test. Means, standard deviations (SD), medians and frequencies for the baseline characteristics were calculated. The significance of differences between the groups at baseline was tested by Pearson Chi-Square tests for discrete variables, by Independent Samples t-test for normally distributed data, and by Mann-Whitney U-test for non-normally distributed continuous data. All significances were two tailed and set at a p-value < 0.05.

The intention-to-treat (ITT) principle was followed to assess the effect of the intervention on our primary outcome; physical disability. To analyze the effect of the intervention generalized estimating equation (GEE) models were constructed. Since the ADL and IADL scores were not normally distributed, square root transformations were applied and used in the GEE models. The GEE methodology allowed us to analyze whether the participants in the intervention group had a lower prevalence or higher recovery from physical disability compared with the control group. In a case of missing data (max eight cases missing at one time point) the GEE methodology uses maximum-likelihood estimation which provides estimates for the model's parameters by finding particular parametric values that make the observed results the most probable. We adjusted the GEE models for age and additionally one of the following at a time: number of chronic diseases, time since fracture, pain of the fractured limb, balance confidence, functional balance, and the average temperature of the month. In the per-protocol analyses those who were suspended from training by the physician or exercising with low frequency (performed less than 45% of the expected exercises) were excluded (altogether 14 non-compliant intervention group members) but only at issuing time-point. The GEE models of the single ADL/IADL items did not withstand adjusting for potential confounders because there were too few observations in some of the categories. However, we calculated corrected p-values for single ADL/IADL items using the FDRTOOL-package in R version 2.15.2 to avoid false positive results in multiple comparisons (23).

The mean changes in ADL and IADL scores between baseline and different follow-up assessments were calculated as [follow-up–baseline]. Differences in the mean changes (effect) between the study groups and standard errors (S.E.) were also calculated. Compliance with the exercises was calculated as [number of performed exercises]:[expected number of exercises]×100%. All the analyses, except p-value correction, were done using IBM SPSS Statistics 19 software.

Results

Participant flow

A flow chart of the study is presented in **Figure 1**. We recruited participants between 1.3.2008 and 31.12.2010. All patients fulfilling the inclusion criteria (n=296) received an information letter. Of them, 161 expressed initial interest in the study and were further informed during the inpatient period. Finally, 136 persons were recruited. Eighteen men and 63 women (total 81; average age 79 years, time since fracture 70 days) were eligible and were randomized into intervention (n=40) and control (n=41) groups. Three women dropped out after the baseline measurements, one from the intervention and two from the control group, all due to personal reasons. One participant in the intervention group died before the twelve-month measurements because of cardiac failure (not related to the intervention). At baseline, the study groups did not differ in demographics, chronic diseases, time elapsed since fracture, operation type, pain, usage of assistive devices, postural balance, balance confidence or physical disability (**Supplementary Table 2**).

Feasibility

The intervention was well tolerated and no intervention related adverse events occurred. Of the 40 participant in the intervention group, nine were suspended by a physician for medical reasons. During the first six months four participants were suspended. Two of them returned to the intervention (revision operation and femoral fracture: International Classification of Diseases S72.4) and two never returned (pulmonary embolism and pneumonia + new hip fracture). In addition, five participants were permanently suspended during the final six months (pubic bone fracture, urinary tract infection, cerebral infarction, cardiac failure, and sacrum strain fracture). In the control group there were four revision operations but no new hip fractures.

During the one-year study, the number of participants who had sustained a fall after the previous assessment varied between 26–33% (no difference between groups). During the first three months, 3% on the participants in the intervention group and 13% of those in the control group needed emergency room services. Thereafter, respectively 8% and 20% reported using emergency room services from three to six months (no difference between groups).

The number of performed exercises and compliance are presented in **Supplementary Table 1.** In general, the compliance was higher during the first six months compared to the final six months. The overall compliance for all exercises was 61% during the first six months, 40%

during the final six months, and 54% when counted for the whole twelve month period. Five participants were considered exercising with low frequency (total number of all exercises less than 45% of the expected).

Effects of the intervention on physical disability

The mean ADL score was 4.7 (SD=3.2) in the intervention group and 3.9 (3.0) in control group. Respective values for IADL score were 9.4 (7.7) and 7.8 (6.5). In the ITT analyses no significant intervention effects were observed in ADL or IADL scores. For ADL score the mean differences between groups at three, six and twelve months were -0.3 points (S.E 0.5), -1.1 (0.7), and -0.1 (0.8); interaction p=0.436 in the crude GEE model. Corresponding values for IADL were: -0.9 (1.1), -2.6 (1.3), and -1.7 (1.3); p=0.920 (**Table 1; Figure 2A&2B**). When single items were analyzed with the ITT principle, we observed a positive, though not significant, intervention effect in preparing meals and handling medication (interaction p=0.061 and p=0.061, respectively (**Figure 3, Supplementary Tables 3&4**).

In the per-protocol analysis, a greater difference between groups was observed in ADL an IADL. The mean differences between groups at three, six and twelve months were -0.4 points (S.E. 0.5), -1.7 (0.7), and -1.2 (0.7); p=0.190 for ADL and -1.0 (1.2), -3.2 (1.5), and -2.5 (1.4); p=0.651 for IADL, correspondingly (**Figure 2C&2D**). The results for adjusted sum score models remained similar.

Discussion

This randomized controlled trial investigated the effects of an individually tailored multi-component home-rehabilitation program on physical disability in community-dwelling older people who had sustained a hip fracture. Physical disability was assessed by a questionnaire assessing perceived difficulty in ADL and IADL. In the intention-to-treat analyses, the ProMo intervention had no wide ranging effect on physical disability. In more detailed analyses we found out, however, that the intervention tended to reduce difficulty in two IADL tasks, preparing meals and handling medication. Additionally, in the per-protocol analyses a greater, though not significant, difference between groups was observed in both ADL and IADL.

The results of this study are consistent with earlier findings (1,24,25) indicating that the consequences of a hip fracture are substantial. A large number of the participants had some or major difficulty in ADL and IADL after the hip fracture. Similar to the other studies most of the recovery in physical functioning occurred within the first three months after hospital discharge

(10,26). Some of this recuperation is presumably natural and may occur without any intervention. Only few RCTs have investigated individually tailored multi-component home-based rehabilitation programs aiming to improve independence in daily activities among older people who have sustained a hip fracture and the results have been conflicting. Tinetti et al. (1999) studied the effects of physical and functional therapy (27). Orwig et al. (2011) investigated the intervention which comprised an exercise module and a self-efficacy based motivational module (9). Both studies included a twelve-month home-intervention. Researchers found no significant advantage over usual care. The results of our study are partly similar to the foregoing. Even though the ProMo intervention had no wide-ranging effect on disability, we found a borderline significant intervention effect in two IADL tasks: preparing meals and handling medication.

The improvement seen in two separate IADL items in our study is encouraging. Preparing meals is important and a necessary daily activity. Progress in it may have occurred because of improvement in balance due to balance training resulting in better standing position and freedom from assistive devices inside home. This makes operating in kitchen more fluent and effortless. Additionally, handling medication is an inevitable skill for most community-dwelling older people. Checking out the dosage and sufficiency of the pain medication during the intervention may have resulted in easiness of handling other medication also. Independence in preparing meals and handling medication reduces the need for home care services and provides financial and instrumental savings. Thus, the result can be considered clinically meaningful.

To our knowledge, previously only two RCTs have indicated that individually tailored multi-component home-based rehabilitation program has improved independence in daily activities after a hip fracture (10,28). Anyhow, in these studies the interventions started when the participants were staying at geriatric wards and hospital staff was involved. The interventions focused on supported discharge and enhancing self-efficacy. Additionally, they comprised home visits by both physical and occupational therapist. In the study by Crotty et al. (2003) also speech pathologist and social worker visited the participants. The ProMo intervention started on average six weeks after the hospital discharge, took place at participants' homes, and included visits and phone calls by a physiotherapist. The hospital staff or occupational therapist was not involved with the delivery of the intervention. Consequently, contrasting between the designs and interventions may partly explain the different results.

The original purpose was to design the ProMo intervention easy to carry out in order that it could be launched into communal health care without large investments or resources. The rehabilitation program was organized with a minimal number of home visits. It was well

tolerated, and no intervention related adverse events occurred. The compliance with the home exercises was good (on average 54%) compared to other similar rehabilitation protocols (27,29). This indicates that for most participants the exercises were convenient to perform independently.

Generalizing the study results to older hip fracture patients should be done cautiously since the frailest ones were excluded from our study. However, those in poor condition would have likely benefitted more from rehabilitation. Thus our results may underestimate the training effect. One potential limitation of the study is that the power calculations were initially carried out to detect expected difference between the study groups in mobility limitation (the main outcome of the ProMo study). Based on the calculations, a minimum of 44 subjects was needed in each study group. Despite of the extended recruitment period we were able to recruit only 81 applicable hip fracture patients to the RCT. Thus the power of the study may have been too weak to show a more explicit training effect on physical disability which may be more a more complex outcome than mobility limitation is. Anyhow, the drop-out rate in our study was very low. Only three participants dropped out and just one of them was from the intervention group.

Per-protocol analysis carried out in this study should be interpreted with caution since it loses the balances of randomization and may thus lead to attrition bias. However, per-protocol analysis usually gives better comprehension of the efficacy of the intervention under optimal conditions. It should also be noted that when single disability items are separated from a multi-item measure the reliability and validity of the single items has not been established similarly as those of the sum scores calculated from the disability scales. Although single item analysis may not be the optimal method for analyzing the disability scales, inspection of the single items provides valuable additional information on the effects of the intervention on different domains of ADL/IADL.

In future, more research is required concerning what kind of rehabilitation would be effective in different subgroups e.g. those in good vs. poor physical condition or cognitively impaired. It is also worthwhile to consider how these different subgroups can be identified before discharge to home. Usage of a more sensitive disability scale, such as Functional Status Questionnaire (30), may be considered to conquer the ceiling effect.

Conclusion

Multi-component home-based rehabilitation had positive, though not significant, effect on physical disability. Additionally, the secondary analyses of the ProMo trial showed that multi-component home-based rehabilitation tended to reduce difficulty in two IADL tasks: preparing meals and handling medication among community-dwelling older people recovering from hip fracture. Managing these two IADL tasks reduces need for home care services and provides financial and instrumental savings. Results of the ProMo trial also suggest that multi-component home-based rehabilitation may reduce ADL and IADL disability extensively. The current hypothesis needs to be confirmed in a study with sufficient power. Possibly a more task-oriented rehabilitation might gain more benefits for disability outcomes.

Abbreviations

ADL: Activities of Daily Living; GEE: Generalized Estimation Equation; IADL: Instrumental Activities of Daily Living; SD: Standard deviation; S.E. Standard error

Competing interests

Authors declare that they have no competing interests.

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See Supplementary material.

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Table 1.

		Intervention (n=40)			Control (n=41)				
Category	**Time point**	**n**	**Sum Score[§] (SD)**	**Change[#] (S.E.)**	**n**	**Sum Score[§] (SD)**	**Change[#] (S.E.)**	**p[*]**	**Difference Between Groups (S.E.)**
ADL	Baseline	40	4.7 (3.2)		41	3.9 (3.0)		0.436	
	3 month	36	3.4 (3.2)	-1.5 (0.3)	39	3.0 (3.0)	-1.2 (0.3)		-0.3 (0.5)
	6 month	38	3.0 (3.2)	-1.7 (0.5)	39	3.4 (3.7)	-0.6 (0.5)		-1.1 (0.7)
	12 month	36	3.6 (4.1)	-1.1 (0.7)	39	3.0 (3.7)	-1.1 (0.5)		-0.1 (0.8)
IADL	Baseline	40	9.4 (7.7)		41	7.8 (6.5)		0.920	
	3 month	36	7.1 (7.1)	-2.8 (0.7)	39	5.5 (6.0)	-1.9 (0.8)		-0.9 (1.1)
	6 month	38	6.4 (6.6)	-3.1 (0.8)	39	7.2 (7.8)	-0.5 (1.0)		-2.6 (1.3)
	12 month	36	6.8 (7.7)	-2.8 (1.0)	39	6.5 (7.1)	-1.1 (0.9)		-1.7 (1.3)

[§] Higher score indicates more difficulty

[#] Negative values indicate reduction in ADL/IADL disability

*General Estimation Equations, crude model, interaction p-value

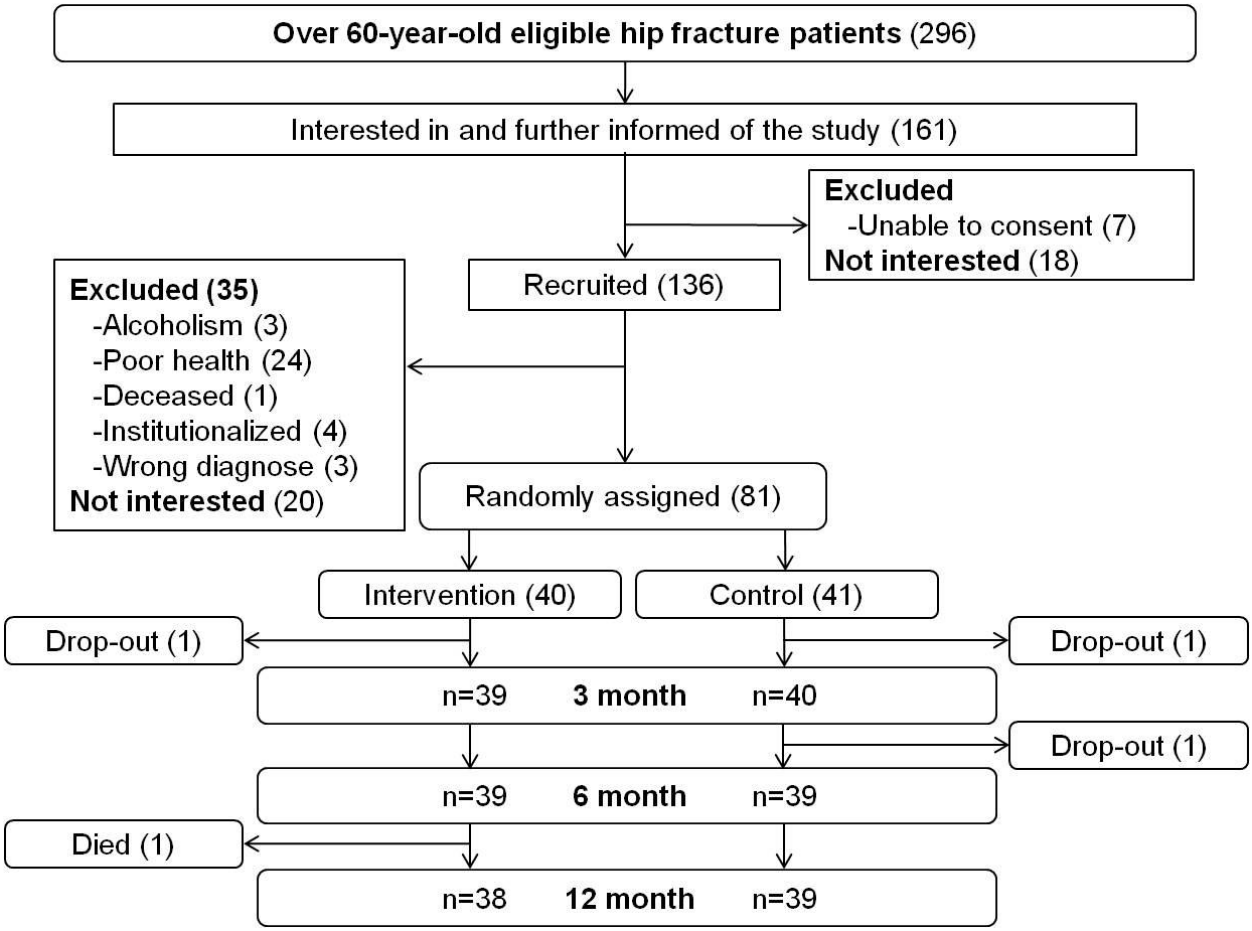
Over 60-year-old eligible hip fracture patients (296)
Interested in and further informed of the study (161)
Excluded
-Unable to consent (7)
Not interested (18)
Recruited (136)
Excluded (35)
-Alcoholism (3)
-Poor health (24)
-Deceased (1)
-Institutionalized (4)
-Wrong diagnose (3)
Not interested (20)
Randomly assigned (81)
Intervention (40)
Control (41)
Drop-out (1)
Drop-out (1)
n=39 3 month n=40
Drop-out (1)
n=39 6 month n=39
Died (1)
n=38 12 month n=39

Figure 1.

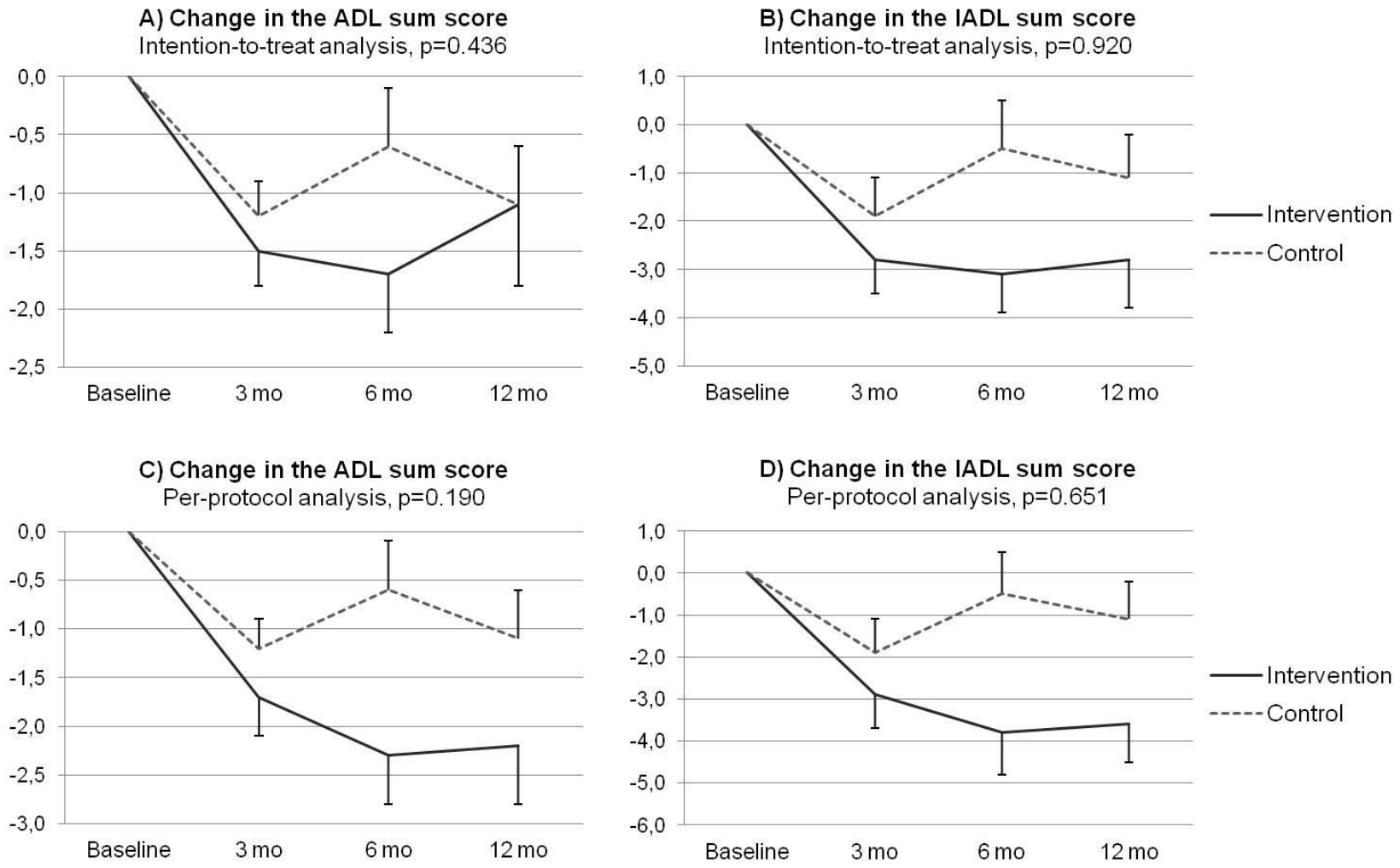
A) Change in the ADL sum score
Intention-to-treat analysis, p=0.436
0,0
-0,5
-1,0
-1,5
-2,0
-2,5
Baseline
3 mo
6 mo
12 mo
B) Change in the IADL sum score
Intention-to-treat analysis, p=0.920
1,0
0,0
-1,0
-2,0
-3,0
-4,0
-5,0
Baseline
3 mo
6 mo
12 mo
Intervention
Control
C) Change in the ADL sum score
Per-protocol analysis, p=0.190
0,0
-0,5
-1,0
-1,5
-2,0
-2,5
-3,0
Baseline
3 mo
6 mo
12 mo
D) Change in the IADL sum score
Per-protocol analysis, p=0.651
1,0
0,0
-1,0
-2,0
-3,0
-4,0
-5,0
-6,0
Baseline
3 mo
6 mo
12 mo
Intervention
Control

Figure 2.

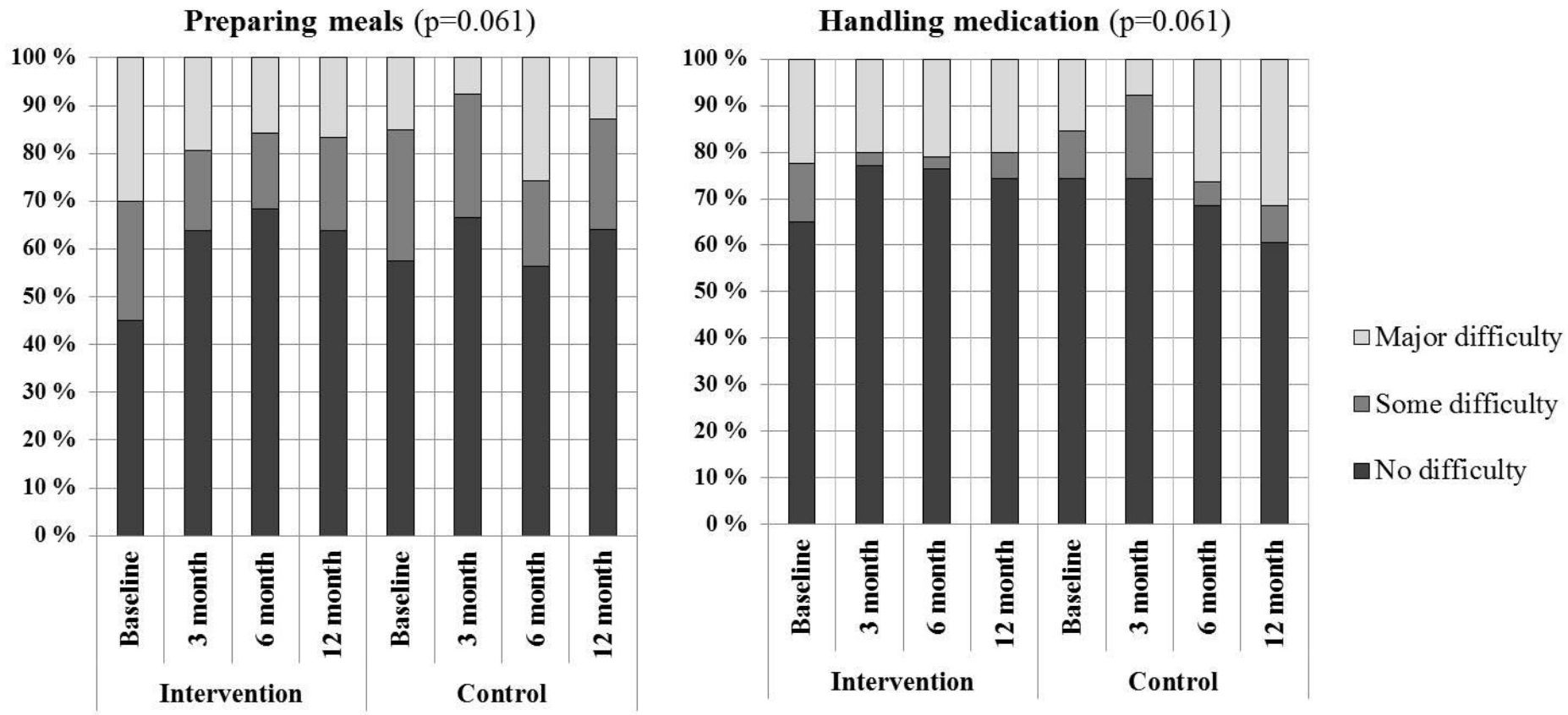
Preparing meals (p=0.061)
Handling medication (p=0.061)
100 %
90 %
80 %
70 %
60 %
50 %
40 %
30 %
20 %
10 %
0 %
Baseline
3 month
6 month
12 month
Intervention
Control
Major difficulty
Some difficulty
No difficulty

Figure 3.

Captions for table and figures

Table 1. ADL and IADL sum score values, absolute changes, and differences between groups

Figure 1. Flow chart of the randomized controlled trial

Figure 2. Mean changes, standard errors (S.E.), and interaction p-values for the ADL and IADL sum scores; **a)** All participants included; **b)** Participants who were suspended or exercising with low frequency were excluded from the analysis at issuing time point

Figure 3. Change in self-reported difficulty in preparing meals and handling medication and interaction p-values in the crude GEE model

Supplementary material

Supplementary Table 1. The mean number of performed exercises, standard deviations, and compliance with the exercises

	1-5 months			6-12 months			1-12 months		
	Mean (SD)	**Expected[#]**	**Compliance[§]**	**Mean (SD)**	**Expected[#]**	**Compliance[§]**	**Mean (SD)**	**Expected[#]**	**Compliance[§]**
Strengthening exercises	47.9 (34.0)	78	61.4	30.1 (32.5)	78	38.6	78.0 (62.7)	156	50.0
Stretching exercises	41.2 (35.1)	78	52.8	29.2 (32.8)	78	37.4	70.4 (64.6)	156	45.1
Balance exercises	43.6 (29.8)	65	67.1	39.2 (30.7)	65	60.3	72.4 (56.4)	130	55.7
Functional exercises*	20.8 (16.6)	30	69.3	~	~	~	~	~	~
Total[**]	152.3 (109.6)	251	60.7	87.4 (96.3)	221	39.5	239.8 (195.2)	442	54.3

[#]For strengthening and stretching exercises the expected total number of exercise sessions during the one-year intervention was on average 156 (three times a week, 52 weeks in a year) and for balance exercises 130 (two to three times a week, 52 weeks in a year). For functional exercises, which were performed only for the first twelve weeks two to three times a week, the equivalent number was 30.

[§]Compliance = [number of performed exercises]:[expected number of exercises]×100%

*Functional exercises were performed only during the first 12 weeks

In general, the ***compliance with physical exercises* was higher during the first six months being 61% with strengthening, 53% with stretching, 65% with balance, and 69% with functional exercises. During the final six months the corresponding values were respectively 39%, 37%, and 43% (functional exercises were instructed to do only during the first twelve weeks). The overall compliance for all exercises was 61% during the first six months, 40% during the final six months, and 54% when counted for the whole twelve month period. Five participants were considered exercising with low frequency (i.e. total number of all exercises less than 45% of the expected). Two of them reported no exercises at all during the one-year intervention. ***Compliance with the physical activity counseling,*** which was part of the intervention, was excellent. One participant, who was suspended from week 13 onwards, did not receive any counseling session. All others received at least the first face-to-face counseling. Thus, compliance with the first face to face session was 98% and with the following sessions as follows: 90% (first phone contact), 88% (second face to face), and 88% (second phone contact), and 83% (third phone contact).

Supplementary Table 2. Baseline characteristics of the ProMo study in the intervention and control groups

	Intervention (n=40)	**Control** (n=41)	**p***
	Mean (SD); n (%)	Mean (SD); n (%)	
Age (years)	80.4 (7.8)	78.5 (6.4)	0.251[§]
Gender: women	31 (49)	32 (51)	0.953[#]
Chronic diseases[**]	3 (1)	3 (2)	0.462
Time since fracture (days)[**]	62.5	59.0	0.379
Operation type[**]			0.917[#]
Internal fixation	19 (50)	19 (50)	
Arthroplasty	21 (49)	22 (51)	
Offending pain, fractured limb[†]	19 (50)	19 (50)	0.917[#]
Use of walking aids outdoors	29 (74)	34 (87)	0.054[#]
Berg Balance Scale, total score[{] (range 0-56)	40.5 (10.4)	43.6 (8.5)	0.311
ABC Scale, total score[¤] (range 16-160)	89.5 (32.5)	87.2 (28.9)	0.734[§]
Baseline ADL sum score[‡] (range 0-30)	4.7 (3.2)	3.9 (3.0)	0.316
Baseline IADL sum score[‡] (range 0-40)	9.4 (7.7)	7.8 (6.5)	0.421

*Mann Whitney U-test, except: [§] Independent samples t-test; [#] Pearson Chi-Square test

[**]The presence of chronic conditions, fracture status and date, type and date of surgery were confirmed according to a pre-structured questionnaire, current prescriptions and medical records obtained from the local hospital and health care centers during the ***medical examination*** carried out by physician and research nurse.

[†]***Pain*** on the fractured side was assessed by two questions "Have you experienced pain daily during the last month in the lower back, hip, knee, ankle or foot on your left/right side? Has the pain compromised your mobility?" The response alternatives were 1) No, 2) Yes, but it is not offending, 3) Yes, and it is offending. A new variable "offending pain of the lower body on the fractured side" was composed based on the answers.

[{]***Functional balance*** was assessed by the Berg Balance Scale (1)

[¤]A modified Finnish version of the Activities-specific Balance Confidence Scale (2,3) was used to assess confidence in performing specific activities without becoming unsteady. ***Balance confidence*** can be regarded as a surrogate for fear of falling and falls-related self-efficacy.

[‡]There were five response categories for each ADL/IADL item: 1) Able to manage without difficulty, 2) Able to manage with some difficulty, 3) Able to manage with major difficulty, 4) Able to manage only with the help of another person, and 5) Unable to manage even with help. For the supplementary analyses, the categorical variables were re-coded into thee-graded: 1) No difficulty (category 1), 2) Some difficulty (categories 2 and 3), and 3) Major difficulty (categories 4 and 5).

Additionally, the ***average temperature*** of the month in which the respective assessment took place was derived from average monthly temperature data, collected in the years 1981-2010 daily at 12 O'clock at a local weather station in Jyväskylä (4).

Supplementary references

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4. Pirinen P, Simola H, Aalto J, Kaukoranta J, Karlsson P, Ruuhela R. Tilastoja suomen ilmastosta 1981-2010 - climatological statistics of finland 1981-2010. Helsinki: Ilmatieteen laitos (Finnish Meteorological Institute); 2012.

Supplementary Table 3. Number and proportions of participants who reported difficulty in ADL

		Intervention (n=40)				**Control** (n=41)				
Task[#]	**Time point**	**n**	**No**	**Some**	**Lots of**	**n**	**No**	**Some**	**Lots of**	**p**[§]
Eating	Baseline	40	35 (88)	4 (10)	1 (3)	41	34 (83)	6 (15)	1 (2)	0.193
	3 month	40	30 (83)	4 (11)	2 (6)	41	36 (92)	3 (8)	0	
	6 month	38	32 (84)	5 (13)	1 (3)	39	32 (82)	6 (15)	1 (3)	
	12 month	36	32 (89)	4 (11)	0	39	31 (80)	6 (15)	2 (5)	
Getting to/out of bed	Baseline	40	25 (63)	13 (33)	2 (5)	41	24 (59)	16 (39)	1 (2)	0.517
	3 month	40	25 (69)	11 (31)	0	41	28 (72)	10 (26)	1 (3)	
	6 month	38	27 (71)	9 (24)	2 (5)	39	27 (69)	10 (26)	2 (5)	
	12 month	35	26 (74)	6 (17)	3 (9)	39	31 (80)	8 (21)	0	
Dressing	Baseline	40	19 (48)	18 (45)	3 (8)	41	22 (54)	19 (46)	0	0.193
	3 month	40	25 (69)	10 (28)	1 (3)	41	25 (63)	14 (35)	1 (3)	
	6 month	38	26 (68)	10 (26)	2 (5)	39	23 (59)	13 (33)	3 (8)	
	12 month	36	25 (69)	7 (19)	4 (11)	39	24 (62)	12 (31)	3 (3)	
Bathing	Baseline	40	18 (45)	14 (35)	8 (20)	41	20 (49)	13 (32)	8 (20)	0.193
	3 month	40	24 (67)	5 (14)	7 (19)	41	24 (63)	8 (21)	6 (16)	
	6 month	38	27 (71)	8 (21)	3 (8)	39	23 (59)	10 (26)	6 (15)	
	12 month	36	25 (69)	4 (11)	7 (19)	39	25 (64)	8 (21)	6 (15)	
Toileting	Baseline	40	30 (75)	5 (13)	5 (13)	41	28 (68)	13 (32)	0	0.513
	3 month	40	29 (81)	6 (17)	1 (3)	41	34 (87)	5 (13)	0	
	6 month	38	32 (84)	5 (13)	1 (3)	39	33(85)	5 (13)	1 (3)	
	12 month	36	28 (78)	6 (17)	2 (6)	39	33 (85)	5 (13)	1 (3)	
Cutting toe nails	Baseline	40	5 (13)	7 (18)	28 (70)	41	6 (15)	17 (42)	18 (44)	0.334
	3 month	40	7 (19)	11 (31)	18 (50)	41	13 (33)	11 (28)	15 (39)	
	6 month	37	8 (22)	16 (43)	13 (35)	39	13 (33)	10 (26)	16 (41)	
	12 month	36	7 (19)	13 (36)	16 (44)	39	15 (39)	14 (36)	10 (26)	

Data presented as: n (%)

[§]General Estimation Equations, crude model, corrected interaction p-value

[#]In general, less than 10% experienced major difficulty in the following ADL: eating, getting to/out of bed, dressing, and toileting. However, 20% of the participants faced major difficulty in bathing and 57% in cutting toe nails.

Supplementary Table 4. Number and proportions of participants who reported difficulty in IADL

		Intervention (n=40)				**Control** (n=41)				
Task[#]	**Time point**	**n**	**No**	**Some**	**Lots of**	**n**	**No**	**Some**	**Lots of**	**p**[§]
Preparing food	Baseline	40	18 (45)	10 (25)	12 (30)	40	23 (58)	11 (28)	6 (15)	**0.061**
	3 month	40	23 (64)	6 (17)	7 (19)	40	26 (67)	10 (26)	3 (8)	
	6 month	38	26 (68)	6 (16)	6 (16)	39	2 (56)	7 (18)	10 (26)	
	12 month	36	23 (64)	7 (19)	6 (17)	39	25 (64)	9 (23)	5 (13)	
Doing laundry	Baseline	40	19 (48)	8 (20)	13 (33)	40	21 (53)	8 (20)	11 (28)	0.112
	3 month	40	23 (66)	5 (14)	7 (20)	40	25 (63)	10 (25)	5 (13)	
	6 month	38	28 (74)	2 (5)	8 (21)	39	23 (59)	3 (8)	13 (33)	
	12 month	36	26 (72)	0	10 (28)	39	26 (67)	7 (18)	6 (15)	
Light housework	Baseline	40	15 (38)	11 (28)	14 (35)	40	16 (40)	12 (30)	12 (30)	0.121
	3 month	40	20 (56)	10 (28)	6 (17)	40	25 (63)	8 (20)	7 (18)	
	6 month	38	26 (68)	8 (21)	4 (11)	38	21 (55)	9 (24)	8 (21)	
	12 month	35	24 (69)	4 (11)	7 (20)	39	21 (54)	11 (28)	7 (18)	
Heavy housework	Baseline	40	3 (8)	11 (28)	26 (65)	40	5 (13)	12 (30)	23 (58)	0.233
	3 month	40	6 (17)	13 (36)	17 (47)	40	9(23)	12 (30)	19 (48)	
	6 month	38	6 (16)	14 (67)	18 (47)	39	11 (28)	7 (18)	21 (54)	
	12 month	36	8 (22)	9 (25)	19 (53)	39	12 (31)	8 (21)	19 (49)	
Handling medication	Baseline	40	26 (65)	5 (13)	9 (23)	39	29 (74)	4 (10)	6 (15)	**0.061**
	3 month	40	27 (77)	1 (3)	7 (20)	39	29 (74)	7 (18)	3 (8)	
	6 month	38	29 (76)	1 (3)	8 (21)	38	26 (68)	2 (5)	10 (26)	
	12 month	35	26 (74)	2 (6)	7 (20)	38	23 (61)	3 (8)	12 (32)	
Using the telephone	Baseline	40	38 (95)	1 (3)	1 83)	41	33 (81)	7 (17)	1 (2)	0.119
	3 month	40	31 (86)	5 (14)	0	41	33 (85)	4 (10)	2 (5)	
	6 month	38	33 (87)	5 (13)	0	38	34 (90)	3 (8)	1 (3)	
	12 month	36	34 (94)	1 (3)	1 (3)	39	36 (92)	3 (8)	0	
Public transportation	Baseline	39	13 (33)	7 (18)	19 (49)	36	6 (17)	13 (36)	17 (47)	0.122
	3 month	39	11 (32)	8 (24)	15 (44)	36	14 (37)	12 (32)	12 (32)	
	6 month	36	14 (39)	9 (25)	13 (36)	37	19 (51)	7 (19)	11 (30)	
	12 month	33	13 (39)	9 (27)	11 (33)	38	18 (47)	7 (18)	13 (34)	
Handling finances	Baseline	40	25 (63)	7 (18)	8 (20)	41	25 (63)	7 (18)	8 (20)	0.274
	3 month	40	24 (67)	4 (11)	8 (22)	41	24 (67)	4 (11)	8 (22)	
	6 month	38	30 (79)	1 (3)	7 (18)	39	30 (79)	1 (3)	7 (18)	
	12 month	36	29 (81)	0	7 (19)	39	29 (81)	0	7 (19)	

Data presented as: n (%)

[§] General Estimation Equations, crude model, corrected interaction p-value

*Statistically significant difference

[#]Coping with heavy housework was found as the most difficult IADL task with 60% of the participants reporting major difficulty. The next challenging IADL were doing laundry (30% of the participants reported major difficulty), coping with light housework (32%) and using public transportation (44%). In preparing meals, handling medication and handling finances approximately 20% experienced major difficulty. Least difficulty was reported in using the telephone (2%).

Additional supplementary material

Author contributions

JE collected and analyzed the data, carried out the ProMo intervention, interpreted results, and wrote the paper. AS recruited participants, collected data, and wrote the paper. SES collected data, and wrote the paper. EP interpreted results and wrote the paper. MK conceived the idea of the study, recruited participants, collected data, and wrote the paper. MA conceived the idea of the study, recruited participants, and wrote the paper. PJ recruited the participants and wrote the paper. JV recruited participants and wrote the paper. MP conceived the idea of the study, recruited participants, and wrote the paper. TR conceived the idea of the study, interpreted results, and wrote the paper. AH conceived the idea of the study, interpreted results, and wrote the paper. SS developed the idea of conducting the study, recruited participants, collected data, interpreted results, and wrote the paper. All authors read and approved the final manuscript.

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