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Physical activity after a hip fracture: effect of a multicomponent home-based rehabilitation program − a secondary analysis of a randomized controlled trial

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Running head: Promotion of physical activity among older people with hip fracture

Physical activity after a hip fracture: effect of a multicomponent home-based rehabilitation program − a secondary analysis of a randomized controlled trial

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Running head: Promotion of physical activity among older people with hip fracture

Physical activity after a hip fracture: effect of a multicomponent home-based rehabilitation program − a secondary analysis of a randomized controlled trial

ABSTRACT

OBJECTIVES: To investigate the effect of a yearlong multicomponent rehabilitation program on the level of physical activity (PA) and the maintenance of the level of PA over one year follow-up among older people recovering from a recent hip fracture.

DESIGN: Secondary analysis of a randomized, controlled, parallel-group trial.

SETTING: Home-based rehabilitation; measurements in university laboratory.

PARTICIPANTS: Community-dwelling people aged 60+ recovering from a hip fracture. Participants were randomly assigned into an intervention (n=40) or control (n=41) group on average 42±23 days after discharge from hospital.

MEASUREMENTS: The outcome was the level of PA, which was assessed with the questionnaire (a modified Grimby scale) at baseline, and 3, 6, 12 and 24 months after baseline. Three PA categories were defined: inactivity, light PA and moderate to heavy PA. Physical function was assessed using the short physical performance battery (SPPB) at baseline. The effects of the intervention were analyzed with generalized estimation equations.

INTERVENTION: A yearlong intervention included evaluation and modification of environmental hazards, guidance for safe walking, non-pharmacological pain management, a progressive home exercise program, PA counseling and Standard Care.

RESULTS: In the intervention group, a significant increase was observed in the level of PA after the intervention (interaction p=0.005) and after one-year follow-up (0.021) compared to the standard care only. The benefit was particularly evident among the participants with a baseline SPPB score seven or above (interaction p<0.001).

CONCLUSION: The 12-month individualized multicomponent rehabilitation program increased PA among older hip fracture patients. The increase was found to be maintained at the one-year follow-up.

28 **Key words**: hip fracture, physical activity, rehabilitation

Hip fracture is a major trauma, which compromises physical activity (PA) of older people.[1] Overall level of physical activity is extremely low in hip fracture patients during the inpatient period[2,3] and for a long time thereafter.[1,4,5]

Physical activity after a hip fracture is important for preventing further falls and disability.[6,7] In addition to beneficial long-term effects of physical activity on the prevention and treatment of several chronic diseases,[8] physical activity has shown to have positive short-term effects on health and mobility recovery after injury or surgery.[9] Walking safely indoors, and even a short distance outdoors, may be crucial and protect from further mobility loss after hip fracture.[10,11] Therefore, more attention should be given to extended rehabilitation programs which concentrate not only on affected leg but also on mobility and physical activity in general. Home-based rehabilitation programs are achievable for people who have recently sustained a hip fracture and who are frail.[12,13] In particular, home-based rehabilitation is important for patients who cannot attend supervised training sessions outside home.

Two earlier studies have shown that supervised home-based training programs have increased the amount of time spent on exercise activities after a hip fracture.[14,15] However, the effect of home-based rehabilitation program with minimal supervision and long-term follow-up on the overall level of PA is not known. The aim of this secondary analysis was to investigate whether an individually tailored multi-component home-based rehabilitation program increases the level of PA and whether it is maintained over a one-year follow-up among community-dwelling persons recovering from a hip fracture.

METHODS

Study design and participants

The Promoting Mobility after Hip Fracture (ProMo) study was a parallel group randomized controlled trial (RCT) investigating the effects of a yearlong individually tailored home-based rehabilitation program on mobility recovery and physical functional capacity in community-dwelling people aged 60 years and older and who had sustained a hip fracture (ISRCTN53680197). The trial was registered retrospectively but before the recruitment was completed. The detailed protocol has been reported earlier.[13] Briefly, staff at the local hospital reviewed the medical records of all 60-year-old and older, ambulatory and community-dwelling men and women arriving for a surgery for a hip fracture (ICD code S72.0 or S72.1) and living in the city of Jyväskylä or one of the neighboring municipality. In total, 269 men and women were informed about the study. Of those, 161 were interested in participating and were further visited by a researcher. Finally, 136 persons were recruited to the study. Patients suffering from severe memory problems (MMSE<18), alcoholism, a severe cardiovascular, pulmonary condition or some other progressive disease, or suffering from severe depression (BDI-II>29) were excluded. In total, 81 patients participated in the study (Figure 1). Random allocation to the intervention (ProMo and Standard Care, n=40) and control (Standard Care only, n=41) groups was performed after the baseline measurements by a statistician blinded to the study participants. Baseline measurements were conducted as soon as possible after discharged from hospital (44 to 239 days post- fracture). Measurements were organized at 3, 6 and 12 months after baseline. Information on level of PA was also collected 24 months after baseline. The researchers who collected the data and built up the data file were blinded to group allocation. All participants signed a written informed consent and gave their permission to review their medical records. The ethical committee of the Central Finland Health Care District approved the study protocol.

Measurements

Health and fracture status

The presence of chronic conditions, use of prescribed medication, fracture date and status, and date of surgery were confirmed according to a pre-structured questionnaire, current prescriptions and medical records. Baseline cognitive status was assessed with the MMSE[16] and depressive mood with the BDI.[17] Body height and weight were measured and body mass index (BMI) calculated.

Level of physical activity

The level of PA during the preceding month was assessed with a modified version of the Grimby scale including seven categories.[18] The categories are 1) mainly resting, 2) most activities performed in a sitting position, 3) light PA twice a week at most, 4) moderate PA or housework about 3 hours a week, 5) moderate PA or housework at least 4 hours/week or heavy PA $\leq$ 4 hours a week, 6) physical exercise or heavy leisure time PA several times a week, and 7) competitive sports several times a week. The scale was re-categorized for analyses as: inactivity (categories 1-2), light PA (category 3), and moderate to heavy PA (categories 4-7). A modified Grimby scale with 6 response options reported moderate levels of retest reliability in older men (r=.634) and women (r=.655).[19] A recent study by Portegijs et al[20] showed that the PA scale with 7 response options correlated with mobility (Rs = 0.40-0.61) and with 7 days accelerometer data (Rs = -0.28- 0.49).

Physical function and mobility

Physical function was measured at baseline using the Short Physical Performance Battery (SPPB) with a total score from 0 to 12.[21] A higher score indicates better physical performance. Information on the use of walking aids outdoors and perceived difficulty in walking outdoors during the previous year before the fracture and at baseline were collected using a questionnaire.[13] Mobility limitation was assessed with a question on perceived difficulty in walking outdoors. Response categories were; 1) able to manage without difficulty, 2) able to manage with some difficulty, 3) able to manage with a great deal of difficulty, 4) able to manage only with the help of another person, and 5) unable to manage even with help.[13] Participants reporting need for help of another person or inability were categorized as having mobility limitation.

ProMo intervention and Standard care

Information on Standard Care after the hip fracture was collected with an interview. Standard care included written information on home exercises given by a physiotherapist. In total, 68 % of the intervention and 71 % of the standard care controls (p=0.813) reported receiving home exercise program from a physiotherapist before discharge to home. Typically, the program included exercises for the lower extremities without additional resistance. Participants in the control group received Standard Care only.

Participants in the intervention group received both Standard Care and the ProMo -intervention, the aim being to restore mobility and physical functional capacity after hip fracture. ProMo has been described in detail earlier.[13] Briefly, ProMo was an individually tailored 12-month physical activity and rehabilitation intervention implemented in the participants' homes. The basis for it

arose from a guideline on fall and fracture prevention[22] and two RCTs that were successful in preventing functional decline among community-dwelling older people.[23, 24] Rehabilitation began on average within one week of the baseline measurements and included five to six home visits supervised by a physiotherapist.

ProMo started with an evaluation of environmental hazards, with modifications when necessary, and guidance for safe walking. In addition, participants' fall related self-efficacy, satisfaction with walking aids and pain management strategies were discussed. The individual home exercise program was implemented during the second home visit and was upgraded four to five times. It included strengthening and stretching exercises for the lower limb muscles, balance training, and functional exercises. Progression of the strengthening exercises was increased with resistance bands. The standing balance exercises included weight shifting from one leg to the other, stepping in different directions, and standing on one leg. The level of challenge was increased by reducing the manual support and narrowing the base of support. The functional exercises, including walking, reaching/turning different directions, and stair climbing, were to be performed for the first twelve weeks only. The strengthening and stretching exercises were advised to be done three times a week on the same day and the balance and functional exercises two to three times a week on the same day. All participants kept an exercise diary.

Individual motivational face-to-face physical activity counselling with a personalized PA plan took place after three months in the participants' homes. The topics covered during the session were pre-fracture and present PA level, the participant's interest in returning to his/her previous activities, possibility for starting a new type of PA or exercise, and guidance on how to be active in everyday chores. The problem-solving method was used to address perceived obstacles to PA. The participants were also given written information on the physical activity courses and

facilities offered by the municipality. Counselling was a one-off session followed by phone calls at four and eight months, and a face-to-face meeting at six months.

Statistical methods

Pretrial power calculation was performed for the primary outcome, mobility, according to the mobility recovery rate reported by Visser et al.[25] which showed that 45% of the community-dwelling participants were independent in walking before the hip fracture but one year after fracture only 21% of the total sample had regained their pre-fracture level of mobility. To detect the expected difference (based on percentages 45 and 21) between the study groups in mobility recovery at a = 0.05 and b = 0.20, a minimum of 44 subjects was needed in each study group. Sample size was calculated using an online sample size calculator available from (DSS researcher's toolkit, http://www.dssresearch.com/KnowledgeCenter/toolkitcalculators/samplesizecalculators.aspx).

The effect of the intervention on PA level was analyzed using a general estimating equations (GEE) model with interaction term using IBM SPSS Statistics for Windows (version 22; IBM Corporation, Armonk, NY). The GEE model was also used to assess the effect of the intervention in subgroups categorized by a SPPB score of ≥ 7 and < 7 at baseline. Score below 7 indicates high risk for disability.[21] In a case of missing data, the GEE methodology uses maximum-likelihood estimation. R-program was used to compute odds ratios (OR) and 95 % confidence intervals (CI) for average changes in PA level at each time point relative to baseline. Change parameters from baseline to each time point were calculated based on the GEE model coefficients. A chi-squared distributed test statistic was computed to compare the average change parameters across the intervention and the control group. The test statistic was based on the

multi-parameter delta-method involving the GEE model parameters and their robust covariance matrix. A binary logistic regression analysis was performed to test whether participation in the one year follow-up measurements versus drop out from the follow-up was predicted by age, gender, SPPB score, MMSE score and PA level at baseline.

RESULTS

Baseline characteristics are presented in Table 1. At baseline, the subgroup analysis revealed that the participants with a SPPB score of < 7 had significantly lower MMSE score than those with a SPPB score of ≥ 7 (25.2 ± 3.1 vs. 26.5 ± 2.3, p =0.040). In addition, the participants with SPPB score of < 7 were more likely to have outdoor mobility limitation (p=0.050) and physical inactivity (p=0.033) compared to those with SPPB score of ≥ 7.

Compliance

The adherence to the home exercises and PA counseling have been reported previously.[13] Briefly, compliance with the home-based physical exercises was fair: strengthening 61 %, stretching 53%, balance 65%, and functional exercises 69% during the first 6 months. Thereafter, the values for the strengthening, stretching and balance exercises were 39%, 37%, and 43 %, respectively. Compliance with the face-to-face PA counseling session was 98%, and 88 to 90% in the following contacts. At the end of the 12-month intervention, three participants had withdrawn and one participant had died for medical reasons unrelated to the intervention. At the one year follow-up, 57 (74%) participants responded to the PA questionnaire (Figure 1). Loss to follow up was predicted by lower baseline MMSE (24.5 for drop outs vs. 26.4 for those who continued; OR=1.24, p=0.044) and SPPB (5.2 vs. 6.7; OR 1.33, p= 0.042) scores, $\chi^2(4) = 14.04$, p=0.007, but not by age (OR 1.03, p=0.473), gender (3.55, 0.090) or baseline PA (1.96, 0.375).

Level of physical activity

A statistically significant group by time interaction indicated that the number of participants who engaged in moderate to heavy PA increased more in the intervention than in the control group

188 during the 12-month intervention (Tables 2-3). The number of inactive participants decreased
189 more in the intervention group than in the control group during the intervention. Moreover, the
190 likelihood for the change to a higher level of PA relative to the baseline was significantly greater
191 in the intervention than control group throughout the intervention (Table 2).

192 The intervention effect was attenuated during the follow-up but remained significant (Tables 2-
193 3). At 24 months, over half (52%) of the participants in the intervention group engaged in
194 moderate to heavy PA, whereas the corresponding proportion in the controls was 36%.
195 Moreover, 17% of the participants in the intervention and 28% of the participants in the control
196 group were physically inactive. Although the proportion of active participants remained higher in
197 the intervention than control group, there was no between-group difference in the likelihood of a
198 change to a higher level of PA relative to the baseline category (p= 0.262; Table 2).

199 The subgroup analyses indicated that the intervention effect was statistically significant at both
200 12 and 24 months among the participants with a higher baseline SPPB≥7. Those with SPPB<7
201 showed a trend in the same direction, but it did not reach statistical significance (p=0.282 at 12-
202 month and 0.481 at 24-month; Table 4).

203

DISCUSSION

This study showed that, compared to standard care, the yearlong multicomponent home-based rehabilitation program significantly increased the level of PA among older people recovering from a hip fracture. The benefits of the intervention were maintained over one-year follow-up. The beneficial effect of the intervention was evident among those with higher physical function at baseline whereas in the lower physical function subgroup the results were less clear. The findings of this study are supported by the findings of the main study, which showed that the ProMo -program reduced perceived difficulties in mobility compared to Standard Care only.[13]

Increase in the level of PA by ProMo –intervention was substantial and gained with minimal efforts. In this study, in total five to six home visits were implemented over the first six-month period during which a physiotherapist instructed home exercise program and gave motivational counseling to increase the level of self-oriented PA. This type of PA counseling have been proven to be effective in earlier studies involving older sedentary people.[24, 26] In other comparable studies, exercise interventions have been implemented with close supervision and frequent weekly visits[14,15] or with supportive equipment such as DVD players.[12] In addition, these programs have included a self-efficacy based motivational component aiming to optimize training adherence throughout the intervention and enhance the positive attitudes and beliefs related to exercise.[14,15,12] Highly supervised home-based training programs have increased the time spent on exercise activities after a hip fracture.[14,15]

It is not fully clear why the participants with poor physical function did not benefit from this rehabilitation program. In addition to the lower SPPB score, they had lower MMSE score and many of them suffered from outdoor mobility limitation at baseline. It may be that the participants with poor physical function suffered from muscle weakness and mobility

impairment already prior to the hip fracture. Therefore, they may not have had sufficient capacity to perform home exercises or to go outdoors and engage in out-of-home physical activities independently. To support engagement in daily physical activities and participation in the community, they would most likely need more supervision and care such as included in a comprehensive geriatric assessment and intervention. In fact, recent studies have reported that hip fracture patients participating in a comprehensive orthogeriatric care were more physically active during the first postoperative days[2], had better mobility[27] and physical function[28] several months after surgery than patients who received traditional orthopedic care and physiotherapy. A previous study[29] also showed that a comprehensive geriatric assessment and intervention had a positive effect on mobility, especially among older people suffering from pain which is typical after a hip fracture.[30] It should be noted that, owing to the recent fracture, also the participant's with better physical function at baseline had still compromised physical performance. Older people with a SPPB score of 10 or less are at increased risk for mobility disability and those with a score of 7 or less are likely to have incident mobility disability.[31]

The strengths of this study include the study design, a multicomponent rehabilitation program, and the findings that have high societal and clinical relevance. Our rehabilitation program was designed to be easy to carry out and was implemented with minimal number of home visits. The intervention was well tolerated.[13] Adherence rate to home exercises closely resembled that achieved in other similar studies.[12,32] In addition, compliance with the PA counseling was excellent.

Study limitations

The trial was registered after the first participant was recruited but, however, before the recruitment was completed. This study reports a secondary outcome of a RCT. Moreover, the

subgroup analysis with SPPB cut point 7, which is widely used in comparable studies, was not defined prior to the beginning of the study. Thus, our findings should be interpreted as hypothesis generating rather than hypothesis testing. At the follow-up some selection bias may have been present. More studies are needed to assess the long-term effects of rehabilitation programs on the level of PA after hip fracture.

The PA scale with seven response options used in the current study has not been validated among older clinical populations. It and also other versions of the same scale do, however, show moderate levels of reliability[19] and validity[20] in community-dwelling older people. A recall bias for the self-reported PA level during the previous month is probably minimal but may exist. Self-reports have proven less robust in measuring light or moderate activity than intense activity.[33] It is known that the level of overall activity is low in hip fracture patients.[5] Thus, an objective measurement of PA, e.g. with an accelerometer, could have added information on different facets of physical activity.

CONCLUSIONS

This study was performed among a vulnerable group of older people who had recently sustained a hip fracture. The results showed that a 12-month home-based multicomponent rehabilitation program increased the level of PA over Standard Care, and that the increase was maintained over one-year follow-up. Our subgroup analysis indicated that the program had greater impact on PA among people with higher physical function. In turn, those with low physical function may benefit from more comprehensive geriatric rehabilitation and care.

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355 Figure legeds

356 **Figure 1.** Flow chart of the study.

357

358

Table 1. Baseline Characteristics of the Intervention and Control Groups.

	Intervention		Control	
	n		n	
Demographics and health				
Age, y, mean ± SD	40	80.9 ± 7.7	41	79.1 ± 6.4
Women, n (%)	40	31 (78)	41	32 (78)
Body mass index, kg/m^2, mean	40	25.3 ± 3.6	40	25.6 ± 3.9
MMSE, score, mean ± SD	39	25.7 ± 2.9	41	26.0 ± 2.8
BDI-II, score, mean ± SD	39	9.4 ± 5.7	41	8.2 ± 5.7
Number of chronic diseases, mean ±SD	40	3 ± 2	41	3 ± 2
Time from surgery to baseline, wks, mean ±SD	40	9.3 ± 2.3	41	9.2 ± 3.6
Type of surgery, n (%)	40		41	
Internal fixation		19 (48)		19 (46)
Hemiarthroplasty		15 (38)		18 (44)
Total hip replacement		6 (15)		4 (10)
Mobility				
Before fracture				
Walking aid, outdoors, n (%)	37	21 (57)	41	18 (44)
Perceived limitation in walking outdoors, n (%)	38	15 (39)	41	12 (29)
At baseline				
Walking aid, outdoors, n (%)	40	30 (75)	39	35 (85)
SPPB, score, mean ± SD	40	5.8 ± 2.5	41	6.6 ±2.2
SPPB score < 7, n (%)		23 (57)		19 (46)

SPPB score ≥ 7, n (%)		17 (42)		22 (53)
Perceived limitation in walking outdoors, n (%)		36 (90)	41	33 (81)
Level of physical activity at baseline, n (%)	40		41	
Inactivity		15 (38)		12 (29)
Light activity		23 (57)		25 (61)
Moderate to heavy activity		2 (5)		4 (10)

MMSE= Mini Mental State Examination, BDI= the Beck Depression Inventory, SPPB = Short Physical Performance Battery.

Table 2. Prevalence of reported level of physical activity by category in the intervention and control groups at baseline), and at 3, 6, 12 and 24 months. IA= interaction.

Time point	Intervention			Control			Group x Time IA
	Inactivity n (%)	Light activity n (%)	Moderate to heavy activity n (%)	Inactivity n (%)	Light activity n (%)	Moderate to heavy activity n (%)	p-value
Baseline	15 (38)	23 (57)	2 (5)	12 (30)	25 (61)	4 (9)	
3 months	5 (14)	17 (47)	14 (39)	8 (20)	22 (55)	10 (25)	
6 months	3 (8)	19 (50)	16 (42)	8 (21)	21 (54)	10 (25)	
12 months	6 (17)	11 (30)	19 (53)	10 (26)	19 (50)	9 (24)	0.005
24 months	5 (17)	9 (36)	15 (52)	8 (28)	10 (36)	10 (36)	0.021

Table 3. Odds Ratios [OR] and 95 % Confidence Intervals [CI] for Changes in the Level of Physical Activity in Relation to the Baseline Measurement in the Intervention and the Control Groups and between the Groups.

	Intervention		Control		Intervention-Control	
	OR	95 % CI	OR	95 % CI	$\chi 2$ (df = 1)	P-Value
Baseline-3 months	5.94	2.76-12.78	1.80	1.05-3.05	6.81	0.009
Baseline-6 months	5.74	1.97-16.72	1.55	0.82-2.95	4.62	0.032
Baseline-12 months	6.28	2.54-15.54	1.64	0.93-2.89	5.78	0.016
Baseline-24 months	4.44	1.60-12.31	2.19	1.02-4.69	1.26	0.262

Table 4. Number of participants on each level of physical activity in the subgroups according to physical function at baseline (BL), and at 3, 6, 12 and 24 months (Mo). P-value for group x time interaction at 12 and 24 months.

	Short Physical Performance Battery sum score ≥ 7							**Short Physical Performance Battery sum score < 7**						
	Intervention			Control			p	Intervention			Control			p
Time point	In-activity	Light activity	Moderate to heavy activity	In-activity	Light activity	Moderate to heavy activity		In-activity	Light activity	Moderate to heavy activity	In-activity	Light activity	Moderate to heavy activity	
BL	5	11	1	3	15	4		10	12	1	9	10	0	
3 Mo	0	5	9	0	13	8		5	12	5	8	9	2	
6 Mo	0	8	8	3	13	6		3	11	8	5	8	4	
12 Mo	0	3	13	4	9	8	<.001	6	8	6	6	10	1	.282
24 Mo	1	4	10	2	5	10	<.001	4	5	5	6	5	0	.481

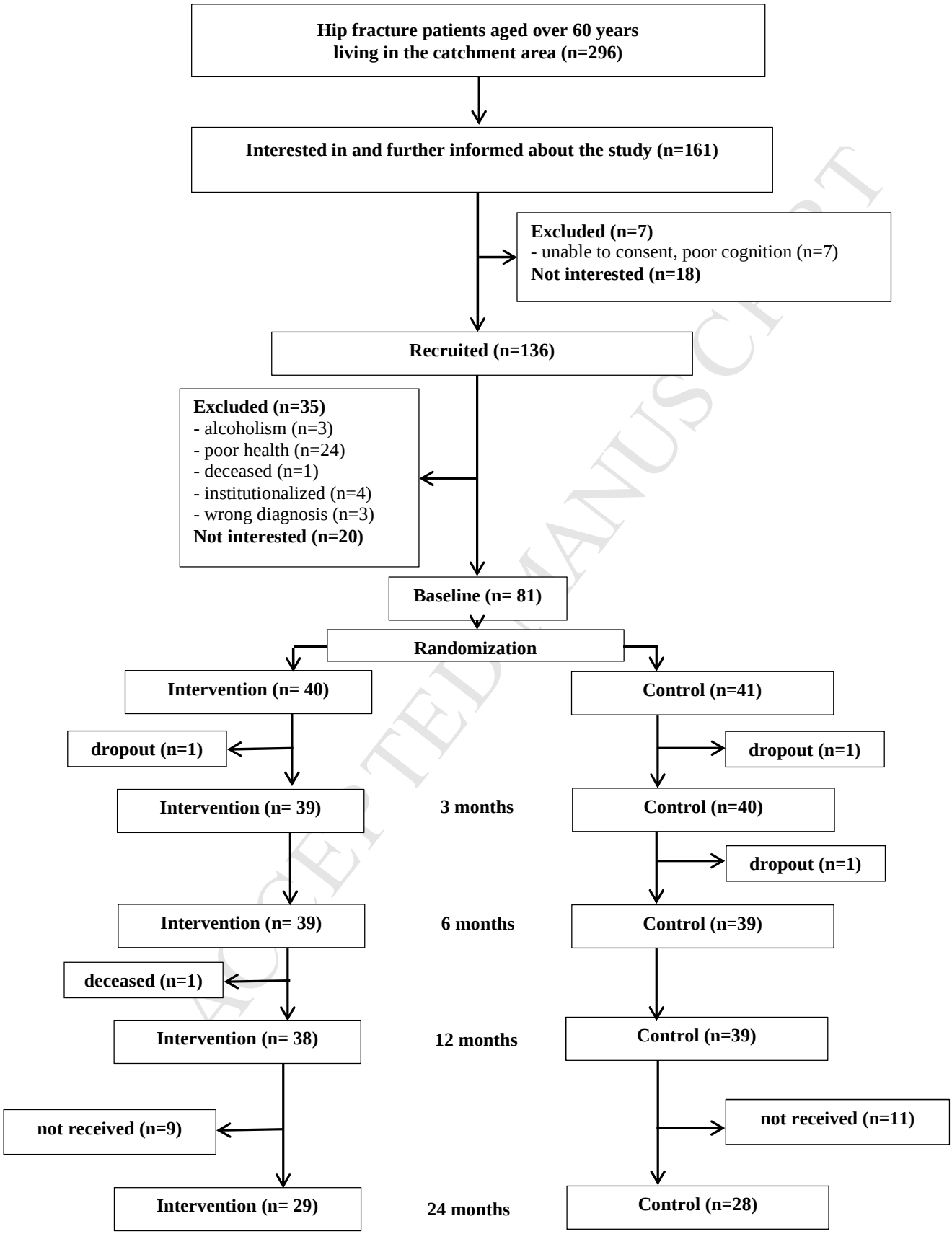

Figure 1. Flow chart of the study.