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Author(s): Turunen, Katri; Salpakoski, Anu; Edgren, Johanna; Törmäkangas, Timo; Arkela, Marja; Kallinen, Mauri; Pesola, Maija; Hartikainen, Sirpa; Nikander, Riku; Sipilä, Sarianna

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

Year: 2017

Version:

Please cite the original version:

Turunen, K., Salpakoski, A., Edgren, J., Törmäkangas, T., Arkela, M., Kallinen, M., Pesola, M., Hartikainen, S., Nikander, R., & Sipilä, S. (2017). Physical activity after a hip fracture : effect of a multicomponent home-based rehabilitation program - a secondary analysis of a randomized controlled trial. *Archives of Physical Medicine and Rehabilitation*, 98(5), 981-988. <https://doi.org/10.1016/j.apmr.2017.01.004>

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Accepted Manuscript



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

Katri Turunen, PhD, Anu Salpakoski, PhD, Johanna Edgren, PhD, Timo Törmäkangas, PhD, Marja Arkela, PhD, Mauri Kallinen, MD, Maija Pesola, MD, Sirpa Hartikainen, MD, Riku Nikander, PhD, Sarianna Sipilä, PhD

PII: S0003-9993(17)30034-5

DOI: [10.1016/j.apmr.2017.01.004](https://doi.org/10.1016/j.apmr.2017.01.004)

Reference: YAPMR 56783

To appear in: *ARCHIVES OF PHYSICAL MEDICINE AND REHABILITATION*

Received Date: 25 April 2016

Revised Date: 4 January 2017

Accepted Date: 6 January 2017

Please cite this article as: Turunen K, Salpakoski A, Edgren J, Törmäkangas T, Arkela M, Kallinen M, Pesola M, Hartikainen S, Nikander R, Sipilä S, Physical activity after a hip fracture: effect of a multicomponent home-based rehabilitation program – a secondary analysis of a randomized controlled trial, *ARCHIVES OF PHYSICAL MEDICINE AND REHABILITATION* (2017), doi: 10.1016/j.apmr.2017.01.004.

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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

Katri Turunen, PhD,^{1,9} Anu Salpakoski, PhD,^{2*} Johanna Edgren, PhD,^{1*} Timo Törmäkangas, PhD,¹ Marja Arkela, PhD,³ Mauri Kallinen, MD,^{4,5} Maija Pesola, MD,⁶ Sirpa Hartikainen, MD,^{7,8} Riku Nikander, PhD,^{1,9,10} Sarianna Sipilä, PhD,¹ * contributed equally.

¹ University of Jyväskylä, Gerontology Research Center and Faculty of Sport and Health Sciences, Jyväskylä, Finland, ² Research and Development, Mikkeli University of Applied Sciences, Mikkeli, Finland, ³ Department of Physiotherapy, Central Hospital of Central Finland, Jyväskylä, Finland, ⁴ Department of Medical Rehabilitation, Oulu University Hospital, Oulu, Finland, ⁵ Center for Life Course Epidemiology Research, University of Oulu, Finland, ⁶ Department of Orthopedics and Traumatology, Central Hospital of Central Finland, Jyväskylä, Finland, ⁷ Kuopio Research Centre of Geriatric Care, University of Eastern Finland, Kuopio, Finland, ⁸ School of Pharmacy, University of Eastern Finland, Kuopio, Finland, ⁹ GeroCenter Foundation for Aging Research and Development, Jyväskylä, Finland, ¹⁰ Research & Education, Central Hospital of Central Finland, Jyväskylä, Finland.

ACKNOWLEDGMENTS

We thank the physiotherapists at the Central Finland Health Care District for the valuable work in the recruitment of the participants and data collection. We are also thankful to all those persons who assisted in data collection.

Funding Source: ProMo was funded by the Ministry of Education and Culture and Kela - The Social Insurance Institution of Finland. The funding agencies played no role in the design, conduct, data management, analysis or manuscript preparation related to this article.

Conflicts of interest: none

Corresponding author: Katri Turunen

mailing address: University of Jyväskylä, Department of Health Sciences, Gerontology Research Center, P.O. Box 35, FI-40014 University of Jyväskylä, Finland

e-mail address: katri.m.turunen@jyu.fi

telephone: +358505316520

fax number: +358 14 260 4600

Alternate Corresponding Author: Sarianna Sipilä

email address: sarianna.sipila@jyu.fi

Funding sources: the Ministry of Education and Culture and Kela - The Social Insurance Institution of Finland.

Clinical trial registration number: Current Controlled Trials ISRCTN53680197

- 1 **Running head:** Promotion of physical activity among older people with hip fracture
- 2 **Physical activity after a hip fracture: effect of a multicomponent home-based rehabilitation**
- 3 **program – a secondary analysis of a randomized controlled trial**

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4 ABSTRACT

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

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

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

10 **PARTICIPANTS:** Community-dwelling people aged 60+ recovering from a hip fracture.

11 Participants were randomly assigned into an intervention (n=40) or control (n=41) group on
12 average 42±23 days after discharge from hospital.

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

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

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

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

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

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30 Hip fracture is a major trauma, which compromises physical activity (PA) of older people.¹

31 Overall level of physical activity is extremely low in hip fracture patients during the inpatient
32 period^{2,3} and for a long time thereafter.^{1,4,5}

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

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

50 **METHODS**

51 **Study design and participants**

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

74

75 **Measurements**

76 *Health and fracture status*

77 The presence of chronic conditions, use of prescribed medication, fracture date and status, and
78 date of surgery were confirmed according to a pre-structured questionnaire, current prescriptions
79 and medical records. Baseline cognitive status was assessed with the MMSE¹⁶ and depressive
80 mood with the BDI.¹⁷ Body height and weight were measured and body mass index (BMI)
81 calculated.

82 *Level of physical activity*

83 The level of PA during the preceding month was assessed with a modified version of the Grimby
84 scale including seven categories.¹⁸ The categories are 1) mainly resting, 2) most activities
85 performed in a sitting position, 3) light PA twice a week at most, 4) moderate PA or housework
86 about 3 hours a week, 5) moderate PA or housework at least 4 hours/week or heavy PA \leq 4 hours
87 a week, 6) physical exercise or heavy leisure time PA several times a week, and 7) competitive
88 sports several times a week. The scale was re-categorized for analyses as: inactivity (categories
89 1-2), light PA (category 3), and moderate to heavy PA (categories 4-7). A modified Grimby scale
90 with 6 response options reported moderate levels of retest reliability in older men ($r=.634$) and
91 women ($r=.655$).¹⁹ A recent study by Portegijs et al²⁰ showed that the PA scale with 7 response
92 options correlated with mobility ($R_s = 0.40-0.61$) and with 7 days accelerometer data ($R_s = -$
93 $0.28- 0.49$).

94

95 *Physical function and mobility*

96 Physical function was measured at baseline using the Short Physical Performance Battery
97 (SPPB) with a total score from 0 to 12.²¹ A higher score indicates better physical performance.
98 Information on the use of walking aids outdoors and perceived difficulty in walking outdoors
99 during the previous year before the fracture and at baseline were collected using a
100 questionnaire.¹³ Mobility limitation was assessed with a question on perceived difficulty in
101 walking outdoors. Response categories were; 1) able to manage without difficulty, 2) able to
102 manage with some difficulty, 3) able to manage with a great deal of difficulty, 4) able to manage
103 only with the help of another person, and 5) unable to manage even with help.¹³ Participants
104 reporting need for help of another person or inability were categorized as having mobility
105 limitation.

106 **ProMo intervention and Standard care**

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

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

117 arose from a guideline on fall and fracture prevention²² and two RCTs that were successful in
118 preventing functional decline among community-dwelling older people.^{23, 24} Rehabilitation
119 began on average within one week of the baseline measurements and included five to six home
120 visits supervised by a physiotherapist.

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

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

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

142 **Statistical methods**

143 Pretrial power calculation was performed for the primary outcome, mobility, according to the
144 mobility recovery rate reported by Visser et al.²⁵ which showed that 45% of the community-
145 dwelling participants were independent in walking before the hip fracture but one year after
146 fracture only 21% of the total sample had regained their pre-fracture level of mobility. To detect
147 the expected difference (based on percentages 45 and 21) between the study groups in mobility
148 recovery at $\alpha = 0.05$ and $\beta = 0.20$, a minimum of 44 subjects was needed in each study group.

149 Sample size was calculated using an online sample size calculator available from (DSS
150 researcher's toolkit,

151 <http://www.dssresearch.com/KnowledgeCenter/toolkitcalculators/samplesizecalculators.aspx>).

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

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

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167 **RESULTS**

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

173 **Compliance**

174 The adherence to the home exercises and PA counseling have been reported previously.¹³
175 Briefly, compliance with the home-based physical exercises was fair: strengthening 61 %,
176 stretching 53%, balance 65%, and functional exercises 69% during the first 6 months. Thereafter,
177 the values for the strengthening, stretching and balance exercises were 39%, 37%, and 43 %,
178 respectively. Compliance with the face-to-face PA counseling session was 98%, and 88 to 90%
179 in the following contacts. At the end of the 12-month intervention, three participants had
180 withdrawn and one participant had died for medical reasons unrelated to the intervention. At the
181 one year follow-up, 57 (74%) participants responded to the PA questionnaire (Figure 1). Loss to
182 follow up was predicted by lower baseline MMSE (24.5 for drop outs vs. 26.4 for those who
183 continued; OR=1.24, $p=0.044$) and SPPB (5.2 vs. 6.7 ; OR 1.33, $p= 0.042$) scores, $\chi^2(4) =14.04$,
184 $p=0.007$, but not by age (OR 1.03, $p=0.473$), gender (3.55, 0.090) or baseline PA (1.96, 0.375).

185 **Level of physical activity**

186 A statistically significant group by time interaction indicated that the number of participants who
187 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 $SPPB \geq 7$. 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

204 **DISCUSSION**

205 This study showed that, compared to standard care, the yearlong multicomponent home-based
206 rehabilitation program significantly increased the level of PA among older people recovering
207 from a hip fracture. The benefits of the intervention were maintained over one-year follow-up.
208 The beneficial effect of the intervention was evident among those with higher physical function
209 at baseline whereas in the lower physical function subgroup the results were less clear. The
210 findings of this study are supported by the findings of the main study, which showed that the
211 ProMo -program reduced perceived difficulties in mobility compared to Standard Care only.¹³
212 Increase in the level of PA by ProMo -intervention was substantial and gained with minimal
213 efforts. In this study, in total five to six home visits were implemented over the first six-month
214 period during which a physiotherapist instructed home exercise program and gave motivational
215 counseling to increase the level of self-oriented PA. This type of PA counseling have been
216 proven to be effective in earlier studies involving older sedentary people.^{24, 26} In other
217 comparable studies, exercise interventions have been implemented with close supervision and
218 frequent weekly visits^{14,15} or with supportive equipment such as DVD players.¹² In addition,
219 these programs have included a self-efficacy based motivational component aiming to optimize
220 training adherence throughout the intervention and enhance the positive attitudes and beliefs
221 related to exercise.^{14,15,12} Highly supervised home-based training programs have increased the
222 time spent on exercise activities after a hip fracture.^{14,15}

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

227 impairment already prior to the hip fracture. Therefore, they may not have had sufficient capacity
228 to perform home exercises or to go outdoors and engage in out-of-home physical activities
229 independently. To support engagement in daily physical activities and participation in the
230 community, they would most likely need more supervision and care such as included in a
231 comprehensive geriatric assessment and intervention. In fact, recent studies have reported that
232 hip fracture patients participating in a comprehensive orthogeriatric care were more physically
233 active during the first postoperative days², had better mobility²⁷ and physical function²⁸ several
234 months after surgery than patients who received traditional orthopedic care and physiotherapy.
235 A previous study²⁹ also showed that a comprehensive geriatric assessment and intervention had a
236 positive effect on mobility, especially among older people suffering from pain which is typical
237 after a hip fracture.³⁰ It should be noted that, owing to the recent fracture, also the participant's
238 with better physical function at baseline had still compromised physical performance. Older
239 people with a SPPB score of 10 or less are at increased risk for mobility disability and those with
240 a score of 7 or less are likely to have incident mobility disability.³¹

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

247 Study limitations

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

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

255 The PA scale with seven response options used in the current study has not been validated
256 among older clinical populations. It and also other versions of the same scale do, however, show
257 moderate levels of reliability¹⁹ and validity²⁰ in community-dwelling older people. A recall bias
258 for the self-reported PA level during the previous month is probably minimal but may exist. Self-
259 reports have proven less robust in measuring light or moderate activity than intense activity.³³ It
260 is known that the level of overall activity is low in hip fracture patients.⁵ Thus, an objective
261 measurement of PA, e.g. with an accelerometer, could have added information on different facets
262 of physical activity.

263 **CONCLUSIONS**

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

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355 Figure legends

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

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

	Intervention		Control	
	n		n	
Demographics and health				
Age, y, mean \pm SD	40	80.9 \pm 7.7	41	79.1 \pm 6.4
Women, n (%)	40	31 (78)	41	32 (78)
Body mass index, kg/m ² , mean	40	25.3 \pm 3.6	40	25.6 \pm 3.9
MMSE, score, mean \pm SD	39	25.7 \pm 2.9	41	26.0 \pm 2.8
BDI-II, score, mean \pm SD	39	9.4 \pm 5.7	41	8.2 \pm 5.7
Number of chronic diseases, mean \pm SD	40	3 \pm 2	41	3 \pm 2
Time from surgery to baseline, wks, mean \pm SD	40	9.3 \pm 2.3	41	9.2 \pm 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 \pm SD	40	5.8 \pm 2.5	41	6.6 \pm 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 p-value
	Inactivity n (%)	Light activity n (%)	Moderate to heavy activity n (%)	Inactivity n (%)	Light activity n (%)	Moderate to heavy activity n (%)	
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.

	<u>Intervention</u>		<u>Control</u>		<u>Intervention-Control</u>	
	OR	95 % CI	OR	95 % CI	χ^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.

Time point	Short Physical Performance Battery sum score ≥ 7						p	Short Physical Performance Battery sum score < 7						p
	Intervention			Control				Intervention			Control			
	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

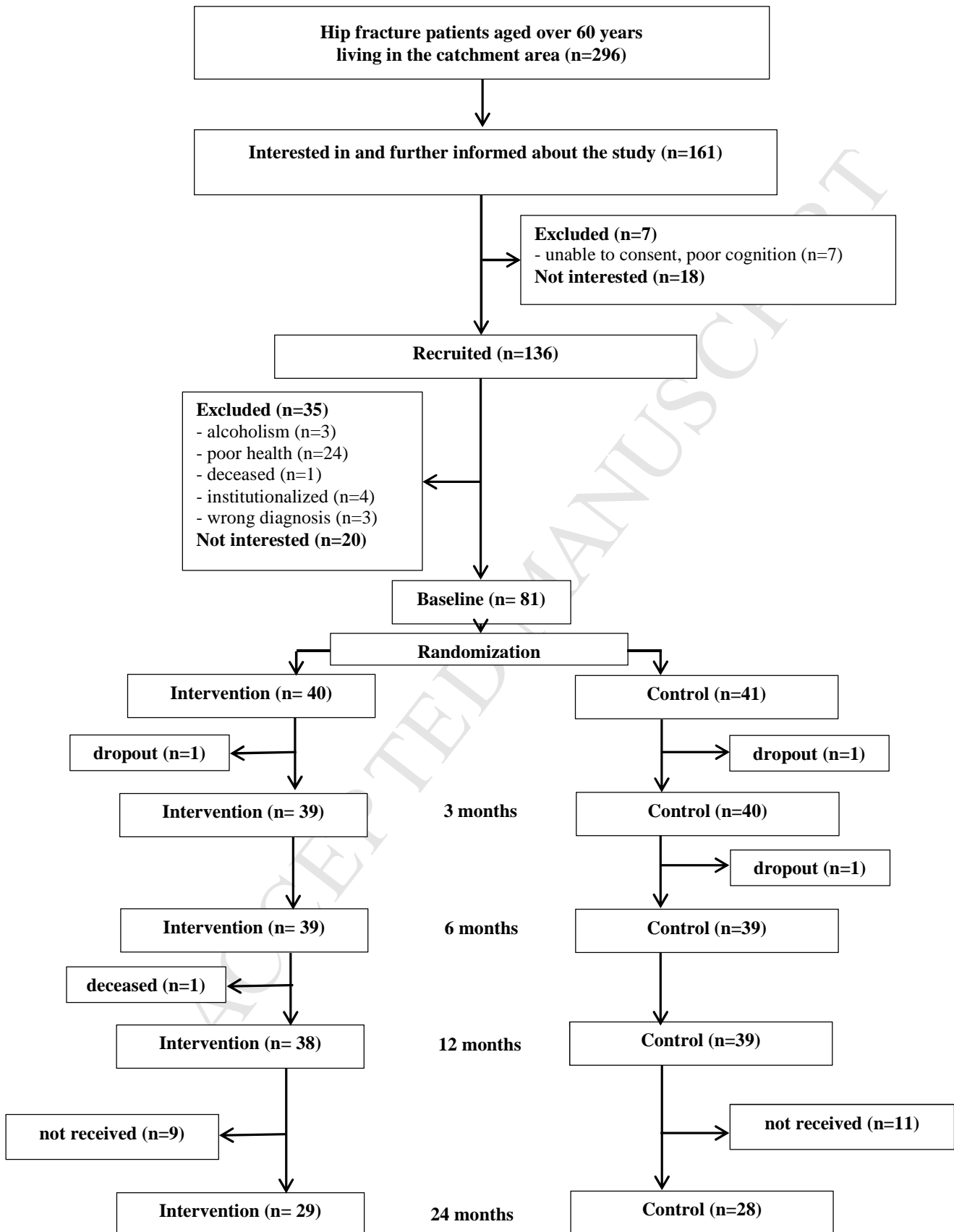


Figure 1. Flow chart of the study.

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