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1 **Running head:** Home-based exercise after hip fracture

2

3 **Effects of home-based physical exercise on days at home, healthcare utilization and functional**
4 **independence among patients with hip fractures: a randomized controlled trial**

5

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37

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39

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47

48 Reprints are not available.

49 **ABSTRACT**

50

51 **Objective** To evaluate the effects of a physical exercise program on days lived at home, the use
52 and costs of healthcare and social services mortality and functional independence among patients
53 with hip fractures.

54

55 **Design** Randomized controlled trial with parallel two-group design, consisting of a 12-month
56 intervention and 12-month registry follow-up.

57

58 **Setting** Home-based intervention.

59

60 **Participants** Patients with operated hip fracture, living at home, aged ≥ 60 years, randomized into
61 physical-exercise (n=61) or usual-care (n=60) groups.

62

63 **Intervention** Supervised physical exercise twice a week.

64

65 **Main Outcome Measures** The primary outcome was the number of days lived at home over 24
66 months. Secondary outcomes were the use and costs of healthcare and social services and
67 mortality over 24 months, and Functional Independence Measure (FIM) over 12 months.

68

69 **Results** Over 24 months there was no significant difference between the groups in terms of days
70 lived at home (Incidence Rate Ratio [IRR] 1.01 [95% CI 0.90–1.14]) or mortality (Hazard Ratio [HR]
71 1.01 [95% CI 0.42–2.43]). The mean total costs of healthcare and social services did not differ
72 between the groups: over 12 months the costs per person-year were 1.26-fold (95% CI 0.87–1.86)

73 and over 24 months 1.08-fold (95% CI 0.77–1.70) greater in the physical-exercise than in the usual-
74 care group. The mean difference between the change in FIM of the groups over 12 months was
75 4.5 points (95% CI 0.5–8.5, $p=0.029$) in favor of the physical-exercise group.

76

77 **Conclusions** Long-term home-based physical exercise had no effect on the number of days lived at
78 home over 24 months among patients with hip fractures. The intervention was cost neutral over
79 these 24 months. The FIM scores improved in both groups over 12 months, but significantly more
80 in the physical-exercise group than in the usual-care group.

81

82 **Key Words:** Hip Fractures, Exercise, Rehabilitation, Aged, Functional Status, Health Services, Cost
83 Analysis

84

85 **List of Abbreviations:** ADL (Activities of Daily Living), IADL (Instrumental Activities of Daily Living),
86 FIM (Functional Independence Measure), HR (Hazard Ratio), ICD (International Statistical
87 Classification of Diseases and Related Health Problems), IRR (Incidence Rate Ratio), MMSE (Mini-
88 Mental State Examination), NYHA (New York Heart Association), RR (Risk Ratio)

89

90 Hip fractures diminish older peoples' functional capacity,¹⁻³ health and quality-of-life,^{4, 5} and
91 increase the risk of mortality.⁶⁻⁸ They pose an economic burden on societies^{9, 10} by increasing the
92 use and costs of healthcare and social services,¹¹⁻¹³ especially nursing home (24-hour) care.^{3, 14, 15}
93 Increased service use is due to patients' poor pre-fracture functioning^{13, 16} and poor recovery of
94 functional capacity after a hip fracture.¹⁻³ Multicomponent, individual, progressive, supervised and
95 long-term exercise interventions after hospital discharge have prevented the loss of functional
96 capacity of patients with hip fractures.¹⁷⁻²⁴ However, there is no consensus on optimal exercise
97 content or duration,^{19, 25} or the best settings for exercise regimens.^{17, 26}

98
99 Evidence on the effects of long-term, supervised home-based physical exercise on days lived at
100 home among patients with hip fractures is lacking. Previous studies have mainly focused on the
101 effects of outpatient exercise programs on nursing home admissions¹⁸, re-hospitalization²⁷ and
102 overall healthcare costs²⁸. Regarding healthcare and social service utilization, home-based exercise
103 regimens with relatively short intervention periods and with a few supervised exercise sessions
104 have shown to be cost-neutral²⁹ and probably cost-effective³⁰. Further investigations are needed
105 to clarify whether home-based exercise interventions could increase the number of days at home
106 among patients with hip fractures and also be cost-effective.

107
108 The aim of this randomized controlled trial was to study the effects of a year-long home-based
109 physical-exercise program among patients with operated hip fractures on the number of days lived
110 at home over 24 months. In addition, we evaluated the effects of the exercise program on the use
111 and costs of healthcare and social services and on mortality over 24 months, and on functional
112 independence over 12 months.

113

114

115 METHODS

116

117 Study design

118

119

120 This parallel-group, randomized controlled trial with physical-exercise and usual-care arms was

121 conducted in accordance with the Helsinki declaration in one social and healthcare district (133

122 000 inhabitants) in Finland between 12/2014 and 12/2019. The study protocol has been reported

123 earlier.³¹ The study received ethical approval from the relevant ethics committee in Finland in

124 November 2014 and was registered at ClinicalTrials.gov in December 2014.

125

126 Participants

127

128

129 Between 10/2014 and 12/2017, 541 patients with hip fractures were operated on at the district's

130 main hospital, from which they moved primarily to the adjacent rehabilitation hospital, or in some

131 cases to primary care hospital wards or straight home. Overall, we contacted 338 patients at the

132 rehabilitation hospital for whom discharge was planned. Of these, 144 were interested and

133 granted their permission for our home visit after discharge to assess their eligibility. Of these, 121

134 were eligible and willing to participate, and signed an informed consent document (Figure 1). The

135 main inclusion criteria were: age of 60 or over, living at home, being able to walk indoors (walking

136 aid allowed), a Mini-Mental State Examination (MMSE)³² score of ≥ 12 , first-operated femoral-neck

137 (ICD code S72.0), pertrochanteric (S72.1) or subtrochanteric (S72.2) fracture of the femur, and no

138 contraindications as regards physical exercise (e.g. Class III or IV of NYHA [New York Heart
139 Association Functional Classification] or severe neurological disease). Exclusion criteria were living
140 in a nursing home or life expectancy of <2 years. The original inclusion criteria of age (≥ 65 years),
141 and MMSE (≥ 17) were lowered in April 2015, in order to increase the number of eligible
142 participants because recruitment rates were low.

143

144 After baseline assessments, the participants were randomized into a physical-exercise group
145 (n=61) or a usual-care control group (n=60), using a computer-generated random sequence
146 allocation program with randomly varying block sizes of two to ten without stratification. The
147 program was generated by a statistician who had no other role in the trial. The project manager of
148 the trial used the randomization program and informed the participants of the randomization
149 result.

150

151 **Outcomes**

152

153

154 The main outcome was the number of days lived at home over 24 months (730 days). Days in
155 hospital wards, long-term wards, nursing homes, and days after death up to the end of the 24-
156 month follow-up were counted as days not lived at home. The information on all the randomized
157 participants was gathered from the electronic medical records of the social and healthcare district
158 by a business intelligence analyst blinded to allocation.

159

160 We report three secondary outcomes (healthcare and social service utilization, mortality and
161 functional independence) of our trial in this article. Information on all the randomized

162 participant's healthcare and social service utilization and mortality over 24-months was acquired
163 from medical records. All contacts between the participants and primary care, specialized medical
164 care and home-care, as well as days in hospitals and nursing homes, and the physical exercise
165 sessions of our intervention were included in the analyses. Costs (in euros) were calculated from
166 the social and healthcare provider's perspective, by multiplying the number of service units used
167 by national mean unit costs in 2011,³³ and correcting them to the 2018 level according to the
168 inflation rate based on the cost-of-living index. Pharmaceutical costs incurred outside the hospital
169 were not included. The cost of one physical exercise session in the patients' homes varied from 60
170 to 130 euros (€) and included the physiotherapist's travel expenses. The mean cost of the
171 intervention was calculated by multiplying the mean cost of one session (86.50€) by the number of
172 completed sessions. The used services and their costs were calculated per person-year.

173

174 Functional independence was assessed using the Functional Independence Measure (FIM), which
175 includes motor and cognitive components.³⁴ During the assessment visits to the participant's homes
176 at baseline, and at three, six and 12 months, the study physiotherapist or the study nurse, not
177 blinded to the allocation, interviewed and observed the participant and evaluated 18 tasks using
178 scores from 1 (total assistance) to 7 (complete independence).

179

180 Background information on age, sex, and living arrangements were acquired through interviews,
181 and information on illnesses and medications, and the details of the hip-fracture surgery were
182 drawn from medical records. Data on participation in and the adverse effects of the intervention
183 were acquired from the physiotherapists' monthly reports.

184

185 **Physical exercise intervention**

186

187

188 Our 12-month supervised, structured, and progressive physical exercise program was executed as
189 one-hour sessions twice a week at the participant's home, starting approximately within two
190 weeks of discharge from the rehabilitation hospital.³¹ The intervention contained strength,
191 balance, mobility and functional exercises, counselling on physical activity, and brief advice on
192 nutrition. Exercises were individually tailored according to the participant's health status and
193 goals, and their intensity was increased gradually to ensure progression. If acute illnesses or
194 hospitalization led to temporary suspension of the intervention, the program continued after
195 recovery. The participants in the physical-exercise group could also use any necessary healthcare
196 or social services, including rehabilitation, over the 24-month study period. A detailed description
197 of the intervention has been presented earlier.³¹

198

199 **Usual care**

200

201

202 The participants in the usual-care group received no exercise intervention. In accordance with the
203 local guideline on hip fractures, the need for home-based rehabilitation was evaluated at the time
204 of discharge from the rehabilitation hospital. Patients were either instructed to continue exercises
205 by themselves, or received short-term, supervised home-based rehabilitation. Over 24 months,
206 the participants in the usual-care group could use any healthcare or social services they needed.

207

208 **Statistical analyses**

209

210

211 Power calculations were based on data from the PERFECT study,³⁵ from which data on the
212 proportion of patients living at home one year after the hip fracture were available. A sample size
213 of 182 (91 per research arm) persons was needed to detect the hypothesized difference ($\alpha=0.05$,
214 power=80%) of 180 (SD 431) days in the days lived at home over 24 months of the physical-
215 exercise and usual-care arms. To allow for discontinuation (15%) and death (20%), our target was
216 300 participants.

217

218 The baseline characteristics of the participants in the randomization groups are reported as means
219 with SDs or as frequencies with percentages. The groups were compared using the t-test or
220 bootstrap type t-test, for continuous variables, and Pearson's chi-square test or Fisher's exact test
221 for categorical variables.

222

223 The main outcome, the number of days lived at home over 24 months, and the amount of use of
224 healthcare and social services (secondary outcome; visits or days) were analyzed using a
225 generalized linear model with appropriate distribution (Poisson or binomial) and log-link
226 function. The results are reported as days or visits, and incidence rate ratios (IRR) or risk ratios (RR)
227 with 95% confidence intervals (CIs based on a Poisson distribution). Poisson regression is similar to
228 multivariate regression (OLS), in which the number of days and visits is followed using the Poisson
229 distribution and observed as a dependent (count data) variable.³⁷

230

231 Cost analyses were performed using a generalized linear regression model with log-link and
232 gamma-variance functions. The variance function was selected on the basis of the Park test and
233 Akaike's information criterion. The bootstrapping (bias-corrected) technique was used in

234 connection with the cost analyses (1000 replicates). Changes in FIM scores and differences
235 between the changes in the groups at three, six and 12 months were analyzed using mixed-effects
236 models, with an unstructured covariance matrix (Kenward–Roger method to calculate degrees of
237 freedom). The repeated measurements were taken at different time points, including baseline,
238 three, six and 12 months. Mixed models enabled analyses of unbalanced datasets without
239 imputation; therefore, we analyzed all the available data with the full analysis set. Differences in
240 costs per person-year in relation to baseline FIM scores were analyzed using a four-knot restricted
241 cubic spline generalized linear regression model with log-link and gamma-variance functions. We
242 used the Kaplan–Meier method to estimate cumulative mortality using asymptotic variance
243 confidence intervals. Regarding mortality, we also used the Cox proportional hazards model to
244 calculate adjusted hazard ratios (HRs) with 95% CIs. The normality of the variables was evaluated
245 graphically and using the Shapiro–Wilk *W* test. The analyses were adjusted for sex and age and
246 carried out according to the intention-to-treat principle. Statistical analyses were performed using
247 the Stata 16.1, StataCorp LP (College Station, TX, USA) statistical package.

248

249

250 **RESULTS**

251

252

253 At baseline, the participants' mean age was 81.5 and 75% were female. The participants in the
254 physical-exercise group were slightly older than those in the usual-care group (83 [SD 6] years vs.
255 80 [SD 7] years, and there were slightly more female participants in the physical-exercise group
256 than in the usual-care group (82% vs. 68%), respectively (Table 1). Sixty percent of all the
257 participants lived alone, and 48% received home-care services.

258

259 The mean participation rate of the exercise sessions was 82% (mean number of sessions 85,
260 median 96, range 1–104) per participant. No serious adverse effects were observed during the
261 sessions. Seventy-four percent of the participants reported mild transient musculoskeletal
262 problems, of which 24% were related to known illnesses, such as osteoarthritis. Shortness of
263 breath was reported by 41%, and six people experienced a fall during exercise but had no need for
264 medical care.

265

266 **Main Outcome**

267

268

269 The main outcome, the mean number of days lived at home over 24 months, was 625 days (95% CI
270 578–673) in the physical-exercise group and 616 (95% CI 563–670) in the usual-care group (age-
271 and sex-adjusted IRR 1.01 [95% CI 0.90–1.14]). Twenty-eight people (46%) in the physical-exercise
272 group and 18 people (30%) in the usual-care group lived at home for the full 730 days (age- and
273 sex-adjusted RR 1.53 [95% CI 0.94–2.48], $p=0.088$).

274

275 Two people (3%) in the physical-exercise group and three people (5%) in the usual-care group
276 were permanently placed in nursing homes ($p=0.69$) during the 24-month period. Five people in
277 the physical-exercise group and six in the usual-care group died over the initial 12-month period,
278 and six and four persons over the next 12 months, respectively (Figure 1). Two-year survival in the
279 physical-exercise group was 82% (95% CI 70–90%) and in the usual-care group 83% (95% CI 71–
280 91%); age- and sex-adjusted HR 1.01 (95% CI 0.42–2.43).

281

282 **Secondary outcomes**

283

284

285 The mean total costs of all healthcare and social services per person-year over 12 months were
286 1.26-fold (95% CI 0.87–1.86) greater in the physical-exercise group (40 722 € [SE 3942]) than in the
287 usual-care group (33 180 € [SE 5808]). Over 24 months, in the physical-exercise group, the mean
288 total costs per person-year (34 159 € [SE 3857]) were 1.08-fold (95% CI 0.77–1.70) greater than in
289 the usual-care group (31 848 € [SE 5663]) (Table 2).

290

291 The mean change of total FIM scores over 12 months was 6.0 (95% CI 3.3–8.8) points in the
292 physical-exercise group and 1.6 (95% CI -1.2–4.4) points in the usual-care group (Figure 2). The
293 sex- and age-adjusted mean difference between the changes of total FIM scores of the groups was
294 4.5 points (95% CI 0.5–8.5, $p=0.029$). Among the participants in the physical-exercise group who
295 had baseline FIM scores above 100, the total costs of healthcare and social services per person-
296 year over 24 months were 9000 € higher than among those with a baseline FIM score of >100 in
297 the usual-care group (Figure 3).

298

299

300 **DISCUSSION**

301

302

303 This randomized controlled trial of a year-long, supervised, home-based physical-exercise program
304 for patients with hip fractures revealed no significant differences in the number of days lived at
305 home or in mortality over 24 months between the physical-exercise and usual-care groups.

306 However, functional independence improved more in the physical-exercise group than in the
307 usual-care group over the 12-month training period. This improvement was gained cost-neutrally
308 in terms of all the healthcare and social services used.

309

310 Days lived at home after operated hip fracture has not been a specified outcome in previous
311 home-based exercise studies, but rehabilitation has been reported to have effects on hip-fracture
312 patients' nursing home admittance and mortality. Of our participants, 46% in the physical-exercise
313 group, and 30% in the usual-care group lived at home for the full 24 months without any
314 intermittent inpatient care, while 3% and 5% were permanently admitted to nursing-homes, and
315 18% and 17% died, respectively. The low rate of nursing home admittance in our trial could be the
316 result of recent policies that favor home-based services in Finland and in other European
317 countries.^{38, 39} In contrast to our result, another supervised progressive outpatient resistance-
318 training and multidisciplinary intervention program reduced the odds of requiring admittance to a
319 nursing home and the risk of mortality over 12 months in comparison to standard care.

320

321 In our trial, the mean use and costs of all healthcare and social services per person-year of the
322 physical-exercise and the usual-care groups did not differ over 12 or 24 months. A meta-analysis
323 found no effects of home-based rehabilitation on emergency department visits,²⁴ and 10-week
324 multidisciplinary home rehabilitation did not reduce hospital days⁴⁰ over 12 months after a hip
325 fracture. Furthermore, another study with a 12-month home-based exercise program showed no
326 effects on service use or costs after hospital discharge among older adults with falls or joint
327 replacement procedures.⁴¹

328

329 According to our analyses, long-term and progressive home-based exercise programs should focus
330 on patients with hip fractures who have total FIM scores under 100 at the time of discharge.
331 Among these, the costs of rehabilitation were more likely to be balanced by reduced utilization of
332 other healthcare and social services. Rehabilitation (including the physical-exercise intervention)
333 was the main reason for the higher costs in the physical-exercise group than those in the usual-
334 care group over 24 months. Future trials should concentrate on finding new ways to implement
335 home-based rehabilitation; for example, using remote technologies or implementing more
336 exercise training in a more systematic way in home-care services to enhance functional
337 independence and reduce overall rehabilitation costs.

338

339 In our trial, functional independence improved more in the physical-exercise group than in the
340 usual-care group over 12 months. This improvement in FIM was gained cost neutrally in terms of
341 all the healthcare and social services used. The 4.5-point mean difference between the changes in
342 total FIM scores of the groups indicates less need for assistance in daily activities and might be
343 considered clinically meaningful.⁴² To our knowledge, our trial is the first to report on the effects
344 of home-based rehabilitation on FIM scores among patients with hip fractures. Previous studies
345 have reported contradictory results for ADL (activities of daily living)^{21,43} or IADL (instrumental
346 activities of daily living)²¹. Edgren et al. (2015)²¹ found that a 12-month home-based physical-
347 exercise program may reduce disability, but Orwig et al. (2011)⁴³ found no effect on physical
348 functioning among people with hip fractures.

349

350 A rigorous randomized design, successful randomization (except for age and sex, which were
351 taken into account in the analyses), and a relatively small loss to follow-up are strengths of our
352 trial. The information on days lived at home and on all use of healthcare and social services was

353 complete as it was gathered from electronic medical records, and the use of private healthcare
354 and social services was rare. Furthermore, adherence to our supervised intervention was good,
355 and no serious adverse events occurred. Supervision enables more individualized and safer
356 training.⁴⁴

357

358 **Study Limitations**

359

360

361 The first limitation is the size of recruited sample (n=121) which is below the power calculations
362 (n=182), as many patients refused to participate due to poor perceived health. Widening the two
363 inclusion criteria (age and MMSE) had no effect on the recruitment rate. Our study could have
364 been underpowered for detecting a 180-day difference between the groups in terms of their days
365 lived at home, as used in the power analysis. Secondly, the hypothesized difference between the
366 groups in our study's main outcome may have been overestimated. Thirdly, the FIM assessments
367 involve a risk of bias because the assessors were not blinded to the allocation result. Finally, we
368 were unable to study the effects of our intervention on FIM over 24 months, as we had data
369 planned the assessments to cover a 12-month period.

370

371

372 **CONCLUSION**

373

374

375 Our 12-month, physiotherapist-supervised, home-based physical exercise trial had no effect on
376 the number of days lived at home or on mortality over 24 months among patients with hip

377 fractures. The intervention was cost neutral, and there was no difference between the groups’
378 total public healthcare and social service costs over 12 or over 24 months. Our intervention
379 improved functional independence to a greater extent in the physical-exercise group than in the
380 usual-care group over 12 months.

381

382 Table 1. Baseline characteristics of the participants in the physical-exercise and usual-care groups.

383 Frequencies (%) or means (SD) are shown.

Characteristics	Physical-exercise n=61	Usual-care n=60
Age, mean (SD)	83 (6)	80 (7)
Women, n (%)	50 (82)	41 (68)
Education <9 years, n (%)	38 (62)	39 (65)
Living, n (%)		
Alone	37 (61)	35 (58)
With spouse	16 (26)	19 (32)
With another person	8 (13)	6 (10)
Home-care services, n (%)		
0 times/week	28 (46)	35 (58)
1–7 times/week	13 (21)	13 (22)
>7 times/week	20 (33)	12 (20)
Number of regular medications, mean (SD)	8.8 (3.4)	8.7 (3.0)
Physician-diagnosed diseases or disorders, n (%)		
Coronary heart disease	27 (44)	27 (45)
Stroke or Transient Ischemic Attack (TIA)	14 (23)	19 (32)
Hypertension	44 (72)	43 (72)
Diabetes	16 (26)	12 (20)
Osteoporosis	27 (44)	24 (40)
Alzheimer's disease	11 (18)	10 (17)

Body Mass Index (BMI) (kg/m ²), mean (SD)	26.4 (4.4)	25.9 (4.4)	384
MMSE, mean (SD)	23.1 (4.7)	22.7 (4.2)	385
Fracture type (ICD code), n (%)			386
Femoral-neck (S72.0)	39 (64)	35 (58)	387
Petrochanteric (S72.1)	17 (28)	21 (35)	388
Subtrochanteric (S72.2)	5 (8)	4 (7)	389
Type of surgery (NOMESCO* codes) ³⁶			390
Total hip arthroplasty [†]	2 (3)	0 (0)	391
Hemiarthroplasty [‡]	31 (52)	36 (59)	392
Internal fixation [§]	27 (45)	25 (41)	393
Hospital care, days, mean (SD)			394
From the fracture event to surgery	1.4 (1.5)	1.1 (1.4)	395
Stay in the surgical ward	4.9 (2.5)	4.7 (2.6)	396
Stay in the rehabilitation hospital	23.2 (12.4)	25.3 (16.5)	397
From hospital admission to discharge	28.1 (12.1)	30.0 (17.1)	398
FIM, mean (SD)			399
Total	97.2 (13.1)	98.0 (15.0)	400
Motor	67.4 (10.3)	68.1 (11.2)	401
Cognition	29.6 (4.2)	29.1 (5.0)	402
			403

409 * NOMESCO (Nordic Medico-Statistical Committee Classification of Surgical Procedures)³⁶

410 † including hybrid total hip arthroplasty and cemented primary total hip arthroplasty

411 ‡ including cemented hemiarthroplasty

- 412 § including internal fixation of fracture of neck of femur with nail or screw, internal fixation of
- 413 fracture of upper femur with screws and side plate, internal fixation of fracture of upper femur
- 414 with intramedullary nail, and other internal fixation of other parts of femur

415

416 Table 2. Use (visits or days) and costs (€) of healthcare and social services per person-year in physical-exercise and usual-care groups over 0—

417 12 and 0—24 months.

	Use of healthcare and social services			Costs (€) of healthcare and social services		
	Physical-exercise (n=61) Mean (SE)*	Usual-care (n=60) Mean (SE)*	IRR [†] (95% CI)	Physical-exercise (n=61) Mean (SE) [‡]	Usual-care (n=60) Mean (SE) [‡]	Mean ratio [§] (95% CI)
0—12 months						
Home care, visits	234.0 (45.8)	212.5 (53.9)	1.02 (0.57 to 1.83)	10 560 (2 018)	9 777 (2 403)	1.00 (0.31 to 1.69)
Primary care						
General practitioner, visits	12.7 (2.0)	9.4 (1.1)	1.32 (0.91 to 1.92)	1 637 (273)	1 135 (126)	1.45 (0.93 to 2.22)
Nurse, visits	21.8 (2.9)	22.9 (2.7)	0.93 (0.64 to 1.36)	1 112 (148)	1 245 (157)	0.89 (0.60 to 1.27)
Rehabilitation , visits	94.8 (2.6)	18.2 (2.7)	5.32 (3.94 to 7.19)	8 812 (252)	3 568 (524)	2.55 (1.88 to 3.39)
Hospital wards, days	8.4 (3.6)	6.5 (2.3)	1.20 (0.44 to 3.22)	2 959 (1 299)	2 260 (812)	1.20 (0.31 to 3.55)
Home healthcare, visits	3.9 (0.9)	3.5 (0.6)	1.09 (0.58 to 2.06)	470 (102)	412 (73)	1.15 (0.63 to 2.29)
Specialized medical care						
Physician, visits	2.0 (0.4)	2.9 (0.5)	0.80 (0.50 to 1.30)	631 (137)	946 (186)	0.77 (0.45 to 1.30)

Nurse, visits	0.8 (0.3)	1.2 (0.3)	0.77 (0.35 to 1.71)	51 (20)	56 (13)	0.99 (0.36 to 2.56)
Emergency department, visits	1.8 (0.4)	1.7 (0.3)	1.18 (0.65 to 2.13)	626 (154)	676 (174)	1.04 (0.53 to 2.09)
Hospital wards, days	2.1 (0.7)	4.3 (0.9)	0.55 (0.23 to 1.28)	2 093 (820)	7 047 (3 652)	0.40 (0.14 to 1.25)
Nursing home, days	16.1 (8.6)	13.8 (9.1)	1.29 (0.25 to 6.68)	2 960 (1 515)	2 490 (1 532)	1.36 (0.05 to 15.55)
Total costs				40 722 (3 947)	33 180 (5 808)	1.26 (0.87 to 1.86)

0—24 months

Home care, visits	201.3 (41.5)	248.0 (64.3)	0.73 (0.39 to 1.37)	9 354 (1858)	11 472 (2846)	0.73 (0.38 to 1.43)
Primary care						
General practitioner, visits	11.0 (1.4)	9.5 (1.0)	1.12 (0.80 to 1.57)	1 540 (263)	1 151 (120)	1.34 (0.89 to 1.90)
Nurse, visits	21.4 (2.7)	20.8 (2.5)	1.02 (0.69 to 1.50)	1 074 (131)	1 130 (149)	0.97 (0.65 to 1.38)
Rehabilitation ^{II} , visits	53.0 (1.8)	11.7 (1.5)	4.59 (3.51 to 5.99)	5 547 (290)	2 556 (401)	2.23 (1.61 to 3.13)
Hospital wards, days	7.9 (2.6)	4.6 (1.3)	1.54 (0.68 to 3.51)	3 531 (1 354)	1 761 (625)	1.74 (0.61 to 4.39)
Home healthcare, visits	3.6 (0.7)	3.9 (0.6)	0.96 (0.56 to 1.63)	452 (85)	454 (70)	1.05 (0.66 to 1.85)
Specialized medical care						
Physician, visits	1.9 (0.3)	2.2 (0.3)	0.97 (0.64 to 1.48)	643 (132)	777 (165)	0.94 (0.56 to 1.63)
Nurse, visits	0.9 (0.3)	1.4 (0.4)	0.72 (0.30 to 1.72)	60 (22)	65 (18)	1.01 (0.36 to 2.58)

Emergency department, visits	1.3 (0.3)	1.2 (0.2)	1.11 (0.65 to 1.91)	545 (140)	558 (159)	1.11 (0.57 to 2.34)
Hospital wards, days	3.3 (0.8)	4.4 (0.9)	0.76 (0.40 to 1.47)	3 430 (895)	7 314 (3 643)	0.56 (0.23 to 1.40)
Nursing home, days	12.9 (5.9)	11.3 (7.1)	1.30 (0.30 to 5.58)	2 434 (1 035)	2 053 (1 167)	1.45 (0.32 to 14.30)
Total costs				34 159 (3 857)	31 848 (5 663)	1.08 (0.77 to 1.70)

418 * use of healthcare and social services (Poisson rates per person-year)

419 † adjusted (age and sex) Incidence Rate Ratio, the physical-exercise group over the usual-care group

420 ‡ costs of healthcare and social services (mean costs per person-year)

421 § adjusted (age and sex) mean ratio, the physical-exercise group over the usual-care group, bootstrap (bias-corrected) with 95% confidence intervals

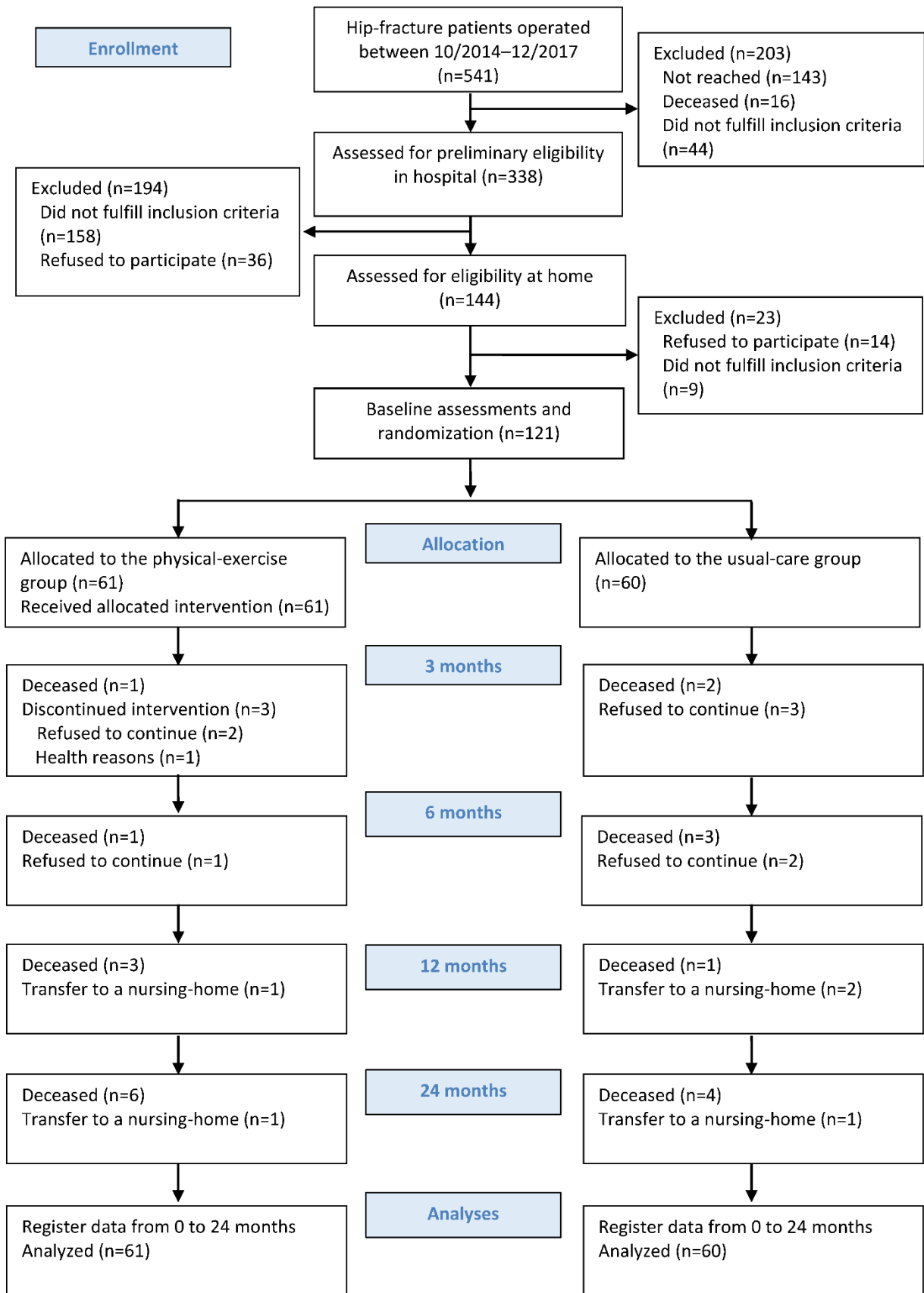
423 || including physiotherapy, occupational therapy, speech therapy and trial intervention (physiotherapist-supervised, home-based physical exercise)

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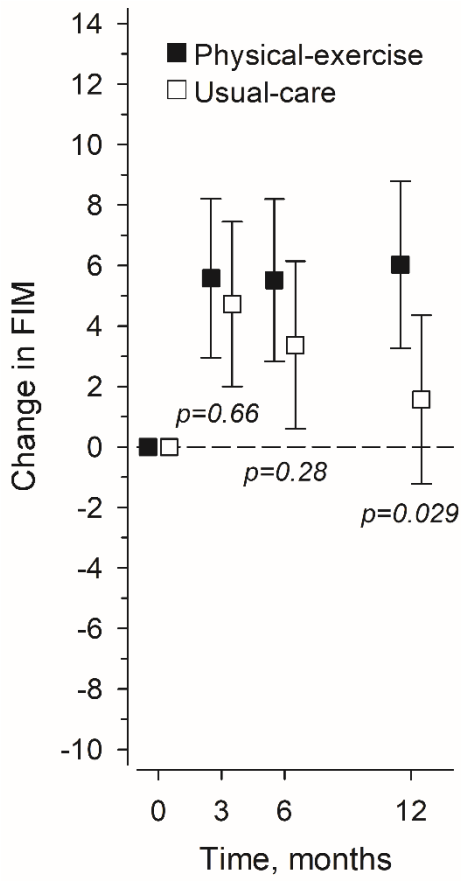
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428 Figure 1. Flowchart of the study.



430 Figure 2. Changes from baseline in total FIM scores over 12 months in the physical-exercise group
431 and the usual-care group. Means and 95% CI; age and sex adjusted.

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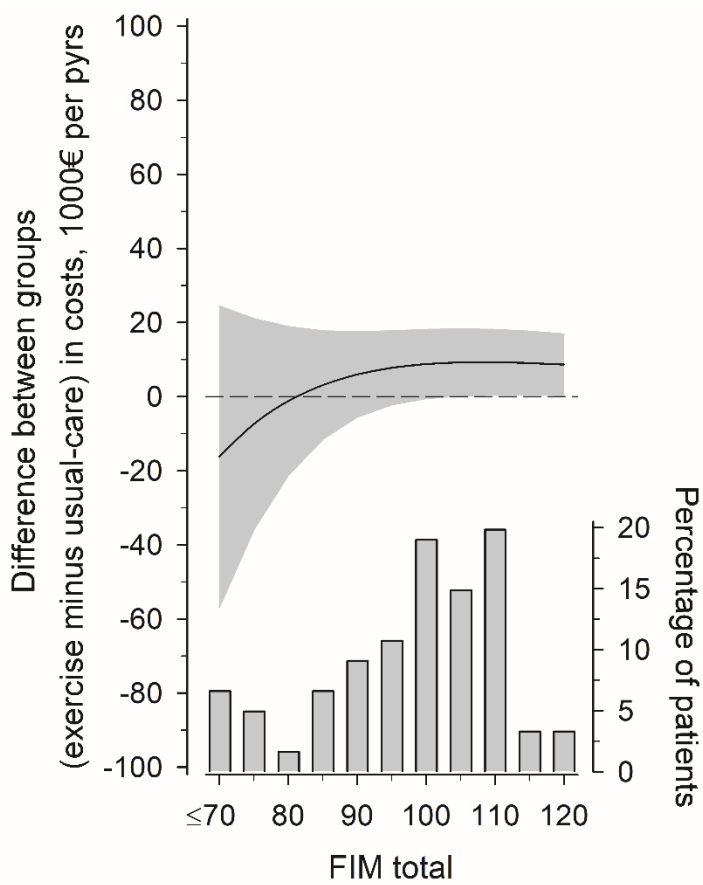
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441 Figure 3. Differences between the costs per person-year (pyrs) over 24 months in the physical-
 442 exercise and usual-care groups according to total FIM scores at baseline. The grey area represents
 443 the 95% confidence interval. The curve was derived from a four-knot restricted cubic spline
 444 generalized linear regression model adjusted for age and sex.

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