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Effect of Physical Activity Counseling on Disability among Older People: A 2-year RCT

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1 **ABSTRACT**

2 **Objective:** To study the effect of a physical activity counseling intervention on Instrumental
3 Activities of Daily Living (IADL) disability.

4 **Design:** Primary care-based, single-blinded, randomized controlled trial.

5 **Setting:** City of Jyväskylä, Central Finland.

6 **Participants:** Six hundred and thirty-two 75-81-year-old participants who were able to walk 500 m
7 without assistance, were at most moderately physically active, had a Mini-Mental State Examination
8 score >21, had no medical contraindications for physical activity, and gave informed consent for
9 participation.

10 **Intervention:** A single individualized physical activity counseling session with supportive phone
11 calls by a physiotherapist every four months for 2 years and annual lectures on physical activity.
12 Control group received no intervention.

13 **Measurements:** The outcome was IADL disability defined as having difficulties in or inability to
14 perform IADL tasks. Analyses were carried out according to baseline IADL disability, mobility
15 limitation and cognitive status.

16 **Results:** At the end of the follow-up, IADL disability had increased in both groups ($P<0.001$) and
17 was lower in the intervention group, but the group by time interaction effect did not reach statistical
18 significance. Subgroup analyses revealed that the intervention prevented incident disability among
19 those without disability at baseline (risk ratio=0.68, 95% confidence interval 0.47-0.97), but had no
20 effect on recovery from disability.

21 **Conclusions:** The physical activity counseling intervention had no effect on older sedentary
22 community-dwelling persons with a wide range of IADL disability, however it prevented incident
23 IADL disability. The results warrant further investigation to explore the benefits of a primary care-
24 based physical activity counseling program on decreasing and postponing IADL disability.

25

26 **Keywords:** physical activity, counseling, IADL disability, aging, primary care

27 **INTRODUCTION**

28 In today's society, the high prevalence of disability among older people increases the risk for
29 development of dependency and the use of public health and social services.^{1,2} Disability in
30 instrumental activities of daily living (IADL) is defined as difficulty with or inability to perform
31 more complex household tasks and run errands outside the home. Further, cognitive deficits³ and
32 mobility limitations^{1,4} are known predictors for subsequent IADL disability. Interventions for
33 reducing or postponing disability are needed within primary care, but so far few strategies to tackle
34 this current problem have been introduced.⁵ In terms of maximal effectiveness, persons in high risk
35 for developing subsequent disability should be targeted, because they are potentially the greatest
36 beneficiaries of such interventions.^{1,6,7}

37
38 Randomized controlled trials (RCT) have shown that physical activity counseling for older persons
39 increases physical activity in short-term, however the long-term effects are unclear.⁸⁻¹¹ There have
40 been positive effects reported for physical activity interventions on decreasing functional
41 limitations.^{12,13} We found in an earlier study that physical activity counseling reduced mobility
42 limitations among older people.¹⁴ Observational studies have shown that physical activity is
43 associated with a reduced risk for disability,^{15,16} but the effects are inconsistent among randomized,
44 controlled trials.¹⁷⁻¹⁹ There is limited information about the effects of physical activity counseling on
45 disability in older adults.

46
47 Our hypothesis was that physical activity counseling increases physical activity and overall activity
48 level, which reduces functional limitations, and that the effect is reflected in decreased disability.
49 The aim of this study was to evaluate the effects of a physical activity counseling intervention,
50 consisting of a single counseling session with subsequent periodic phone contacts over two years, on
51 IADL disability in community-dwelling sedentary older adults.

52

53 **METHODS**

54

55 **Design and Setting**

56 The design and methodology of the Screening and Counseling for Physical Activity and Mobility
57 (SCAMOB) project has been reported in detail elsewhere and is summarized briefly here.²⁰
58 SCAMOB was a 2-year, single-blinded, randomized controlled trial on the effects of individualized
59 physical activity counseling on older sedentary people. The intervention took place in the City of
60 Jyväskylä located in Central Finland with a population of 82 000 inhabitants, of whom 6.1% were
61 aged 75 years and older. The Ethical Committee of the Central Finland Health Care District
62 approved the study. ISRCTN is 07330512.

63

64 **Participants**

65 The target population consisted of all 75-81-year-old registered residents of the City of Jyväskylä,
66 Finland living in the city centre area in March 2003 (N=1310). The contact information of the target
67 population was obtained from the Finnish population register. The flow of the study is presented in
68 figure 1. After a four-phased screening and data collection process 632 persons (75% women) were
69 found to be eligible for the study. To be eligible for randomization, persons had to be able to walk
70 500 meters without assistance, be only moderately physically active or sedentary (at most 4 hours of
71 walking or 2 hours of other exercise weekly), have a Mini-Mental State Examination (MMSE)²¹
72 score >21, have no severe medical contraindications for physical activity (assessed by the study
73 nurse and when necessary ascertained by a physician) and sign an informed consent to participate in
74 a RCT.²⁰

75

76 **Randomization**

77 Participants were randomly assigned to a physical activity counseling intervention group (n=318) or
78 a control group (n=314) as follows. Each week after the completion of baseline assessments,

79 participants were allocated to groups in blocks of 40-50 persons, using a randomization ratio of 1:1,
80 by drawing lots. Randomization allocation was undertaken by a trial administrator. Allocation
81 concealment was achieved by drawing names from opaque envelopes for 40-50 persons at the same
82 time. The study nurses and interviewers who collected the data as well as the assistants who
83 recorded the data were blinded to group allocation and were unaware of the study hypotheses.

84

85 **Intervention**

86 The intervention group received approximately two weeks after randomization a single one hour
87 individual motivational face-to-face physical activity counseling session by one physiotherapist
88 specifically trained for the task.²⁰ The counseling approach was based on the social cognitive theory
89 and motivational interviewing technique.²² Topics covered during the session included present
90 physical activity level, persons' interest in maintaining or increasing physical exercise, performing
91 every day activities such as walking to the grocery store and participating in inexpensive exercise
92 classes organized by the municipality. To increase physical activity, the physiotherapist and the
93 participant together designed a personal physical activity plan based on the participant's interests.
94 The counseling session was followed up by telephone contact to support compliance and behavior
95 change every four months for two years. Telephone calls were planned to take place every three
96 months, but for practical reasons, such as not being able to reach the participant, they took place
97 every four months during two years. In addition to the face-to-face counseling session, the
98 intervention group was invited to participate in two voluntary lectures on topics such as home
99 calisthenics and disability prevention. The control group received no intervention but continued to
100 receive advice on healthy living habits as usual when visiting health and social service providers and
101 had access to all exercise facilities.

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105 **Study outcome**

106 The outcome of this study, IADL disability which included persons with IADL difficulties or
107 inability to perform IADL tasks, was measured at baseline and in 2-year follow-up. Self-reported
108 information was collected in face-to-face interviews with regard to eight IADL tasks: preparing
109 meals, washing clothes, shopping, coping with heavy housework, administering and taking
110 medications, using the telephone, using public transport, and handling finances.²³ For each
111 individual IADL task, we categorized persons into those with no disability (independent without
112 difficulty) and those with disability (task difficulty, need of assistance or unable to perform the task).
113 For the statistical models we used a summary score of the eight IADL tasks, with a range of 0 (no
114 disability in any of the IADL tasks) to 8 (disability in all eight IADL tasks).

115
116 For subgroup analyses persons were stratified according to baseline IADL disability into those with
117 disability (n=308) and those with no disability (n=324) at baseline. In addition, stratification was
118 made according to baseline mobility limitation and cognitive status. Those who reported difficulty or
119 task modification in walking 500 m such as tiredness, reduced pace, longer duration, using walking
120 aids or cutting back on walking the distance were considered to have mobility limitation (n=285)
121 while the rest were considered to have no limitation (n=347).²⁴ For cognitive status, stratification
122 was done at the mean value of the Mini-Mental State Examination MMSE²¹ score, the range being
123 22 to 30 with cut-off at 27.

124

125 **Measurements**

126 In addition to outcome data, demographic, socioeconomic and living habit information was collected
127 at baseline and in follow-up face-to-face interview and clinical examination. Habitual physical
128 activity was assessed with a previously validated seven-point scale,²⁵ on which the persons
129 belonging to the five first categories were included in the study: mainly resting; most activities
130 performed sitting down; light physical activity 1-2 hours/week; moderate physical activity or

131 housework 3 hours/week; and moderate physical activity at least 4 hours/week. Persons belonging to
132 the two highest activity categories, who reported doing physical exercise or competitive sports
133 several times a week, were excluded from the study before randomization because they would not
134 have benefited from our physical activity counseling intervention. To study the changes in the
135 habitual physical activity from baseline to 2-year follow-up we categorized persons into 1) those
136 whose activity level remained moderate or above or who increased their activity level from
137 sedentary (light physical activity 1-2 hours/week at the most) to at least moderate 2) those who
138 remained sedentary or reduced the activity level from being at least moderately physically active to
139 sedentary.

140

141 Morbidity was measured as the number of self-reported physician-diagnosed chronic conditions
142 lasting over three months. The number of chronic diseases was first inquired at the face-to-face
143 interview and later double-checked at the nurses' clinical examination. Participants were inquired
144 about the use of informal care given by a spouse, relatives or friends. Depression was measured with
145 Centre for Epidemiologic Studies Depression Scale (CES-D).²⁶ In addition, adverse events were
146 assessed by asking the participants whether they had had injuries in the previous year and had the
147 injuries required medical treatment.

148

149 **Statistical Analysis**

150 Based on our pilot sample, we estimated that about 60% of the target population was suffering from
151 or were at an increased risk for mobility limitation. The significance level was set at 5% and power
152 at 80%. A within-person correlation of 0.4 was assumed. To allow for 10% attrition, the total sample
153 size needed was about 630. For the IADL disability outcome, using the sample size calculation of
154 Rochon,²⁷ we calculated that assuming exchangeable working correlation between measurements
155 and a within-person correlation of 0.4 the sample size was sufficient for detecting a 40% change in

156 the odds ratio in favor of the intervention group at the two-tailed significance level of 5% and power
157 of 80%.

158
159 The analyses were carried out according to the intention-to-treat principle. A generalized estimating
160 equations (GEE) model²⁸ was constructed on the IADL variable to test the significance of an
161 interaction term representing the time-related change in the intervention and control groups. The
162 explanatory variables used in this model included a measurement time indicator variable and an
163 intervention group status variable. In the model, the group by time interaction term was used to
164 indicate the effect of the intervention. At the two-year follow-up, there were missing values for 38
165 persons (6%) in one or more of the eight IADL questions. For these cases with missing values, data
166 were imputed with the multiple imputation procedure implemented in SAS by using information on
167 the other IADL questions and baseline information such as number of chronic diseases, physical
168 activity level, and MMSE and CES-D scores. We did not impute values for persons who died during
169 the follow-up (n=16). Sensitivity analyses performed suggested no significant differences in effects
170 due to imputation. The analyses were carried out using SAS, version 9.1 (GENMOD procedure).
171 Comparisons of discrete baseline characteristics were performed using chi-square test and for
172 continuous variables using independent sample t-test and ANOVA. We analyzed the change in
173 physical activity with repeated measures variance and logistic regression. All significances were at
174 $P<0.05$ level and two-tailed. These analyses were performed using SPSS, version 12.0.

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182 **RESULTS**

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184 **Program Feasibility**

185 At 2-year follow-up, 295 (93%) participants of the intervention group and 283 (90%) of the control
186 group completed the IADL questionnaire. After randomization, 16 participants had died
187 (intervention group n=8 and control group n=8) and 9 withdrew from the study (intervention group
188 n=5 and control group n=4). Data was missing for the IADL disability outcome in the intervention
189 group for 10 persons (poor health 4 and declined 6) and for the control group for 19 (poor health 7,
190 declined 11 and moved 1) (see Figure 1). The baseline characteristics of the intervention and control
191 groups were comparable (see Table 1). Physical activity counseling increased physical activity
192 significantly during the intervention in the intervention group compared to the control group (group
193 by time $P=0.009$). The physical activity level decreased for 16% in the intervention and for 22% in
194 the control group, increased for 38% in the intervention and 32% in the control group and remained
195 the same for 46% in the intervention and 45% in the control group. The proportion of participants
196 who increased their activity level from sedentary to at least moderate or remained moderately active
197 during the 2-year intervention was significantly higher in the intervention compared to the control
198 group (83 % vs. 72%, odds ratio [OR] = 2.0, 95% confidence interval [CI] 1.3-3.0). Similarly, the
199 proportion of those who reduced their physical activity level from at least moderate to sedentary or
200 remained sedentary was lower in the intervention than in the control group (17 % vs. 28 %, OR 0.51
201 95 % CI 0.3-0.8).

202

203 **Treatment Effect on IADL Disability**

204 At baseline 143 persons in the intervention group and 165 in the control group were suffering from
205 IADL disability and at follow-up 160 and 200, respectively. The IADL disability score was 0.83 (SD
206 1.16) for the intervention and 1.04 (SD 1.39) for the control group (Table 3). At follow-up IADL
207 disability had increased in both groups ($P<0.001$) but was lower in the intervention group, 1.30 (SD

208 1.84) vs. 1.81 (SD 2.01) $P = 0.002$. However the group by time interaction effect did not reach
209 statistical significance (risk ratio [RR] = 1.07, 95% CI 0.87-1.32). After this, subgroup analyses were
210 made according to baseline IADL status. The incidence of IADL disability for those with no IADL
211 disability at baseline was 36.4% for the intervention group and 46.2% for the control group
212 ($p=0.077$). Among those with IADL disability at baseline, 73.0% from the intervention group and
213 82.6% from the control group ($p=0.045$) suffered from IADL disability at the 2-year follow-up.
214 Among those with no IADL disability at baseline, the intervention prevented IADL disability over
215 time (RR = 0.68, 95% CI 0.47-0.97). For those with IADL disability at baseline, there were no
216 statistically significant differences in recovery from IADL disability at follow-up. There were no
217 statistically significant differences in the treatment effect over time according to presence of mobility
218 limitations or cognitive status at baseline. Investigating individual IADL tasks separately showed
219 similar results (data not shown).

220

221 **Adverse Events**

222 At baseline, about 30% of the intervention group and 28% of the control group reported some form
223 of injury in the previous year. At follow-up, the numbers had stayed similar in both groups. This
224 indicates that the intervention did not cause excessive adverse events.

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234 **DISCUSSION**

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236 In our study, IADL disability increased during the trial and changes did not differ between
237 intervention and control groups. However, subgroup analyses revealed that physical activity
238 counseling prevented new disability among those without IADL disability at baseline, but had no
239 effect on the recovery from disability among those with baseline disability. No differences in the
240 changes were observed between study groups in subgroup analyses according to mobility limitation
241 or cognitive capacity.

242

243 This is the first randomized controlled trial, to the best of our knowledge, to investigate the long-
244 term effect of primary care-based physical activity counseling on IADL disability among
245 community-dwelling sedentary older people. An earlier randomized controlled trial on a home-based
246 physical therapy intervention among older people was able to prevent functional decline over time
247 for moderately frail persons²⁹ and decline in higher-level measures of physical function such as
248 IADL disability.³⁰ The relatively intense 6-month program consisted of up to 16 visits and of
249 monthly supportive phone calls over six months carried out by a physical therapist, whereas our
250 physical activity counseling program used existing non-profit exercise classes for older people
251 provided by the municipality, which are available for participants also after the trial.²⁰

252

253 Our hypothesis was that physical activity counseling increases physical activity, which in turn
254 decreases mobility difficulties, and as a result decreases and postpones disability. In previous
255 analyses of the current data published elsewhere,^{31,14} we found that as a result of the intervention the
256 level of physical activity increased, depressive mood reduced among those with minor depressive
257 symptoms, and the intervention prevented development of mobility limitation. However, the increase
258 in the level of physical activity was not directly reflected in the more complex and multifaceted
259 IADL disability. Moreover, it is hard to measure accurately the benefit that the intervention had on

260 reducing IADL disability, because currently there is no agreement on what can be considered to be
261 meaningful and consequently we have to rely on self-report regarding disability. Nonetheless, the
262 10% benefit in intervention group for both incidence and recovery of IADL disability suggests that
263 the intervention was meaningful from a public health perspective in tackling IADL disability, which
264 is crucial for maintaining independency in old age.

265

266 The mechanisms underlying the association between physical activity and IADL disability are likely
267 to be complex¹⁶ and it is possible that an increase in physical fitness alone is not enough to improve
268 functional dependence.³⁴ Factors other than physical fitness, such as individuals' background,
269 beliefs, personal behavior, as well as the physical and social context may determine whether a
270 person is disabled.^{32,34} For instance, environmental factors such as a lack of an elevator can prevent a
271 person from walking to a grocery shop independently and thus improvements in physical fitness due
272 to the physical activity counseling intervention may not translate into a reduction in disability in
273 shopping independently because of the underlying environmental obstacle.

274

275 The current findings of subgroup analyses help hypotheses building for future studies. In our study,
276 physical activity counseling prevented incident disability among those with no disability at baseline.
277 This suggests that physical activity counseling may be efficacious in high functioning older people
278 in preventing more complex disability. The IADL tasks where difficulty develops first, namely
279 coping with heavy housework and using public transport, require physical vigor and good mobility.
280 It is intuitive that physical activity counseling might postpone emergence of difficulty in these
281 physical tasks but not in tasks such as using the telephone or handling finances, where underlying
282 factors are presumably predominantly cognitive or require specific fine motor skills. However,
283 evidence on the positive effects of physical activity on cognitive capacity is emerging.³⁵
284 Consequently, improving IADL skills might require not only physical exercise but also some form

285 of occupational therapy to cause behavior change especially for those with IADL disability who are
286 most likely to experience greater barriers to motivation and adherence to physical activity.

287

288 Strengths of the study included a relatively big sample size with register-based recruiting to
289 minimize the effect of volunteering participants who tend to be more motivated to behavior change
290 such as increasing physical activity.¹¹ We excluded persons with a MMSE score of 21 and less,
291 which further strengthened the reliability of our data, given that persons with more severe cognitive
292 problems may not be able to provide accurate reports of their engagement in physical activity and
293 functional status.¹⁶ In addition, the intervention time was long when compared to some other
294 physical activity counseling interventions^{8,9,33} and adherence to the physical activity counseling
295 program was high.

296

297 There are some limitations to the study that need to be considered. First, the IADL disability
298 outcome was self-report, susceptible to reporting bias. It is possible that motivational counseling
299 with emphasis on self-efficacy for more active behavior^{20,22} could have direct effects such as a
300 psychological stimulating effect and thus influence the self-report. However, we do not believe that
301 reporting bias following increased confidence in one's abilities would solely explain the result.
302 Moreover, biannual telephone interviews on topics such as physical activity and mobility were
303 carried out for all participants during the intervention, which could have further stimulated both the
304 intervention and control group. In the test-retest conducted to a small number of participants
305 Kendall's tau-b ranged between 0.491 and 1.00 for IADL tasks.²⁰ Physical activity was measured
306 with a self-report scale,²⁵ while a more specific measure on activity such as a pedometer could have
307 been useful. However, the classes in the activity scale were wide and thus it is likely that the increase
308 in physical activity was underestimated. Second, the results of the subgroup analyses need to be
309 considered with caution, since the effect of randomization is uncertain. Third, the content of our
310 intervention focused foremost on increasing the level of physical activity and decreasing mobility

311 limitations. This might have deflated the effect of the intervention on IADL disability. Some
312 additional counseling, focusing on topics such as coping with daily tasks, could have been included
313 to reduce or postpone the development of IADL disabilities.^{30,32,34} In addition, the power of the data
314 could have been insufficient for conducting the IADL subgroup analyses.

315
316 More research is needed on the usefulness of primary care-based physical activity counseling in
317 postponing IADL disability. This is supported by the results of our subgroup analyses, which
318 indicated that physical activity counseling might postpone disability among older, sedentary
319 community-dwelling persons with no IADL disability.

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338

339 **Conflicts of interest:**

340 All authors declare no interest of conflict.

341

342 **Role of the sponsor:**

343 The funding sources of the study had no role in the design, implementation or analyses of the data or
344 in the preparation of the manuscript for publication.

345

346 **Author Contributions:**

347 E. Heikkinen, T. Rantanen, R. Leinonen originated the study and obtained the funding. M.B. von
348 Bonsdorff and T. Rantanen analyzed and interpreted the data. M.B. von Bonsdorff drafted the paper.
349 T.Rantanen, U.M. Kujala, E. Heikkinen critically revised the paper. M. Hirvensalo and M. Rasinaho
350 were responsible for the physical activity counseling intervention. R. Leinonen, M.B. von Bonsdorff,
351 M. Mänty, and S. Karhula participated in data collection. T. Törmäkangas was the statistical expert.
352 All authors contributed to the intellectual content of the paper and approved the final version.

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Table 1 Baseline Characteristics by Randomization Group

Characteristics	Intervention (n=318)	Control (n=314)	P-values*
	%	%	
Women	74.5	75.2	0.86
Married	39.6	45.5	0.13
Use of informal care	14.5	19.1	0.12
CES-D score ≥ 16	19.4	20.0	0.86
Ability to walk 2 km without difficulties	66.2	68.1	0.63
Disability in one or more IADL tasks	45.0	52.5	0.06
Disability in individual IADL tasks:			
Washing clothes	9.1	11.5	0.33
Shopping	14.2	14.6	0.86
Coping with heavy housework	33.3	41.7	0.03
Preparing food	5.7	9.2	0.09
Using public transport	15.1	19.4	0.15
Administering and taking medication	1.9	1.6	0.78
Using the telephone	1.9	1.0	0.32
Handling finances	1.6	5.4	0.008
Physical activity			
1) mainly resting	0	0	
2) most activities performed sitting down	0.6	1.6	<u>0.25</u>
3) light physical activity 1-2 hours/week	23.6	23.6	<u>1.00</u>
4) moderate physical activity/housework 3 h/week	51.6	48.7	<u>0.47</u>
5) moderate physical activity at least 4 hours/week	24.2	26.2	<u>0.40</u>
	Mean (\pmSD)	Mean (\pmSD)	
Age	77.6 (1.9)	77.6 (1.9)	0.80
Number of chronic diseases	3.0 (2.0)	3.0 (2.0)	0.08
Years of education	9.1 (4.0)	9.3 (4.4)	0.56
MMSE score	27.1 (2.0)	27.0 (2.2)	0.50

* Discrete variables analyzed with chi-square test, continuous variables with independent sample t-test and ANOVA

CES-D=Centre for Epidemiologic Studies Depression Scale, score ≥ 16 indicating possible depression; IADL= Instrumental Activities of Daily Living; MMSE=Mini-Mental State Examination, score range 22-30, with higher score indicating better cognitive capacity

Table 2 IADL Disability, Mean Score, Standard Deviations, and Effects in the GEE Model for the Intervention and Control Groups for All Participants and Subgroups According to IADL Disability, Mobility Limitation and Cognitive Status at Baseline

Study groups	IADL disability		Effect in the GEE Model			
	Baseline Mean (\pm SD)	Follow-up Mean (\pm SD)	Group effect p-value	Time effect p-value	Group x Time effect p-value	RR
All participants n=632	0.83 (1.16)	1.30 (1.84)	0.002	<0.001	0.504	1.07
Intervention group	1.04 (1.39)	1.81 (2.01)				
Control group						
No IADL disability n=324			0.036	0	0	0.68
Intervention group	0	0.75 (1.35)				
Control group	0	1.07 (1.66)				
IADL disability n=308	1.84 (1.05)	2.00 (2.12)	0.103	0	0	0.84
Intervention group	1.99 (1.34)	2.48 (2.07)				
Control group						
No mobility limitations n=347	0.44 (0.77)	0.83 (1.46)	0.135	<0.001	0.937	1.02
Intervention group	0.55 (0.86)	1.19 (1.74)				
Control group						
Mobility limitations n=285	1.34 (1.36)	1.93 (2.09)	0.013	<0.001	0.358	1.12
Intervention group	1.59 (1.64)	2.52 (2.07)				
Control group						
Intact cognition n=299 (MMSE score 28-30)			0.084	<0.001	0.161	1.28
Intervention group	0.78 (1.15)	0.99 (1.41)				
Control group	0.80 (1.11)	1.33 (1.76)				
Mild cognitive problems n=332 (MMSE score 22-27)			0.014	<0.001	0.689	0.95
Intervention group	0.88 (1.17)	1.60 (2.14)				
Control group	1.26 (1.57)	2.24 (2.13)				

Note. IADL= Instrumental Activities of Daily Living; MMSE=Mini-Mental State Examination

Legend for Figure 1:

Study flow chart

Figure 1:

