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

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ABSTRACT

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

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

Setting: City of Jyväskylä, Central Finland.

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

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

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

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

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

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

INTRODUCTION

In today's society, the high prevalence of disability among older people increases the risk for development of dependency and the use of public health and social services.[1,2] Disability in instrumental activities of daily living (IADL) is defined as difficulty with or inability to perform more complex household tasks and run errands outside the home. Further, cognitive deficits[3] and mobility limitations[1,4] are known predictors for subsequent IADL disability. Interventions for reducing or postponing disability are needed within primary care, but so far few strategies to tackle this current problem have been introduced.[5] In terms of maximal effectiveness, persons in high risk for developing subsequent disability should be targeted, because they are potentially the greatest beneficiaries of such interventions.[1,6,7]

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

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

METHODS

Design and Setting

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

Participants

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

Randomization

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

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

Intervention

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

Study outcome

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

For subgroup analyses persons were stratified according to baseline IADL disability into those with disability (n=308) and those with no disability (n=324) at baseline. In addition, stratification was made according to baseline mobility limitation and cognitive status. Those who reported difficulty or task modification in walking 500 m such as tiredness, reduced pace, longer duration, using walking aids or cutting back on walking the distance were considered to have mobility limitation (n=285) while the rest were considered to have no limitation (n=347).[24] For cognitive status, stratification was done at the mean value of the Mini-Mental State Examination MMSE[21] score, the range being 22 to 30 with cut-off at 27.

Measurements

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

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

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

Statistical Analysis

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

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

The analyses were carried out according to the intention-to-treat principle. A generalized estimating equations (GEE) model[28] was constructed on the IADL variable to test the significance of an interaction term representing the time-related change in the intervention and control groups. The explanatory variables used in this model included a measurement time indicator variable and an intervention group status variable. In the model, the group by time interaction term was used to indicate the effect of the intervention. At the two-year follow-up, there were missing values for 38 persons (6%) in one or more of the eight IADL questions. For these cases with missing values, data were imputed with the multiple imputation procedure implemented in SAS by using information on the other IADL questions and baseline information such as number of chronic diseases, physical activity level, and MMSE and CES-D scores. We did not impute values for persons who died during the follow-up (n=16). Sensitivity analyses performed suggested no significant differences in effects due to imputation. The analyses were carried out using SAS, version 9.1 (GENMOD procedure). Comparisons of discrete baseline characteristics were performed using chi-square test and for continuous variables using independent sample t-test and ANOVA. We analyzed the change in physical activity with repeated measures variance and logistic regression. All significances were at $P<0.05$ level and two-tailed. These analyses were performed using SPSS, version 12.0.

RESULTS

Program Feasibility

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

Treatment Effect on IADL Disability

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

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

Adverse Events

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

DISCUSSION

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

This is the first randomized controlled trial, to the best of our knowledge, to investigate the long-term effect of primary care-based physical activity counseling on IADL disability among community-dwelling sedentary older people. An earlier randomized controlled trial on a home-based physical therapy intervention among older people was able to prevent functional decline over time for moderately frail persons[29] and decline in higher-level measures of physical function such as IADL disability.[30] The relatively intense 6-month program consisted of up to 16 visits and of monthly supportive phone calls over six months carried out by a physical therapist, whereas our physical activity counseling program used existing non-profit exercise classes for older people provided by the municipality, which are available for participants also after the trial.[20]

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

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

The mechanisms underlying the association between physical activity and IADL disability are likely to be complex[16] and it is possible that an increase in physical fitness alone is not enough to improve functional dependence.[34] Factors other than physical fitness, such as individuals' background, beliefs, personal behavior, as well as the physical and social context may determine whether a person is disabled.[32,34] For instance, environmental factors such as a lack of an elevator can prevent a person from walking to a grocery shop independently and thus improvements in physical fitness due to the physical activity counseling intervention may not translate into a reduction in disability in shopping independently because of the underlying environmental obstacle.

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

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

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

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

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

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

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Conflicts of interest:

All authors declare no interest of conflict.

Role of the sponsor:

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

Author Contributions:

E. Heikkinen, T. Rantanen, R. Leinonen originated the study and obtained the funding. M.B. von Bonsdorff and T. Rantanen analyzed and interpreted the data. M.B. von Bonsdorff drafted the paper. T.Rantanen, U.M. Kujala, E. Heikkinen critically revised the paper. M. Hirvensalo and M. Rasinaho were responsible for the physical activity counseling intervention. R. Leinonen, M.B. von Bonsdorff, M. Mänty, and S. Karhula participated in data collection. T. Törmäkangas was the statistical expert. 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	0.25
3) light physical activity 1-2 hours/week	23.6	23.6	1.00
4) moderate physical activity/housework 3 h/week	51.6	48.7	0.47
5) moderate physical activity at least 4 hours/week	24.2	26.2	0.40
	Mean (±SD)	Mean (±SD)	
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

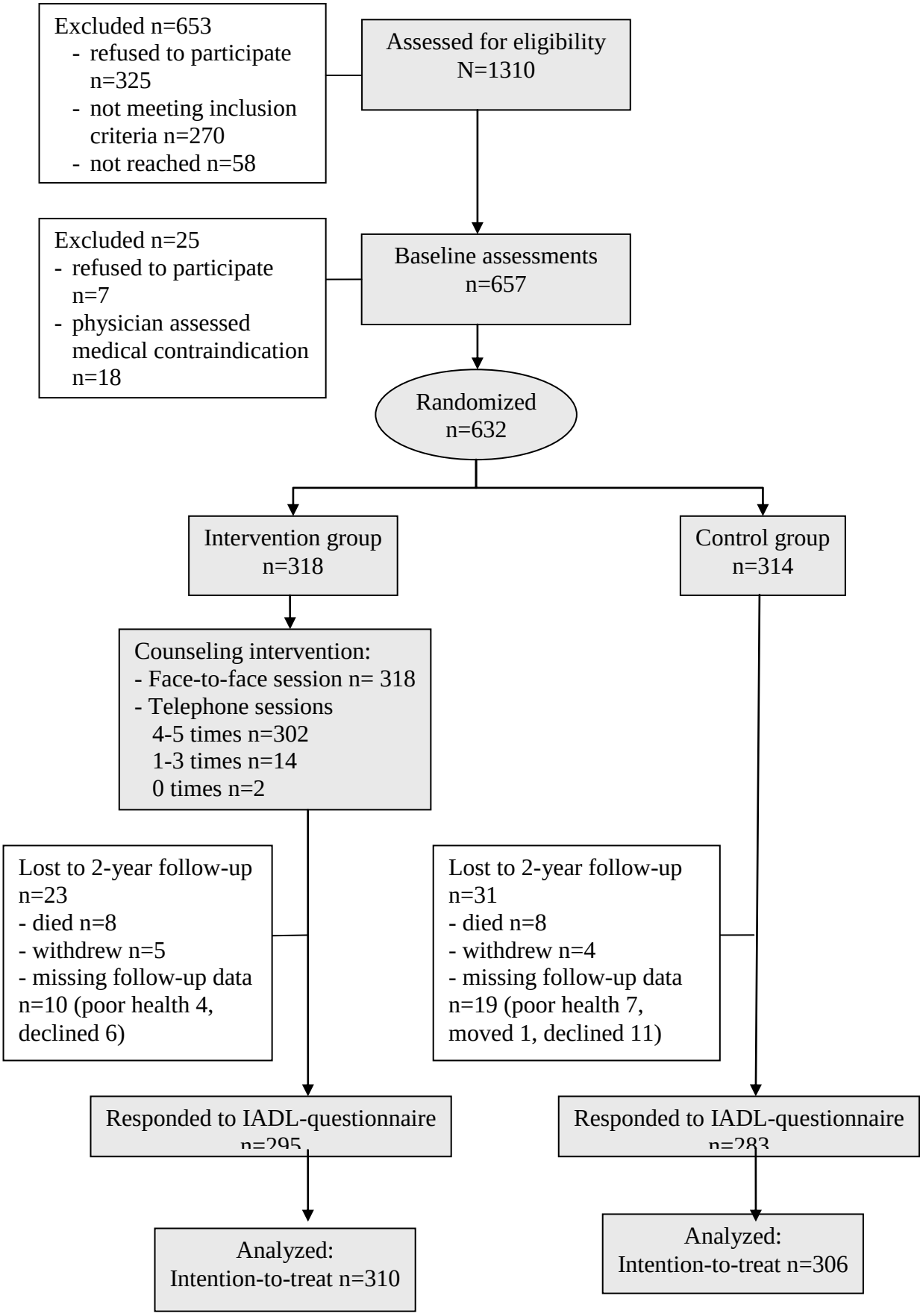
Study groups	**IADL disability**		**Effect in the GEE Model**			
	Baseline Mean (±SD)	Follow-up Mean (±SD)	Group effect p-value	Time effect p-value	Group x Time effect p-value	RR
All participants n=632			0.002	<0.001	0.504	1.07
Intervention group	0.83 (1.16)	1.30 (1.84)				
Control group	1.04 (1.39)	1.81 (2.01)				
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			0.103	0	0	0.84
Intervention group	1.84 (1.05)	2.00 (2.12)				
Control group	1.99 (1.34)	2.48 (2.07)				
No mobility limitations n=347			0.135	<0.001	0.937	1.02
Intervention group	0.44 (0.77)	0.83 (1.46)				
Control group	0.55 (0.86)	1.19 (1.74)				
Mobility limitations n=285			0.013	<0.001	0.358	1.12
Intervention group	1.34 (1.36)	1.93 (2.09)				
Control group	1.59 (1.64)	2.52 (2.07)				
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:


Excluded n=653
- refused to participate n=325
- not meeting inclusion criteria n=270
- not reached n=58
Assessed for eligibility N=1310
Excluded n=25
- refused to participate n=7
- physician assessed medical contraindication n=18
Baseline assessments n=657
Randomized n=632
Intervention group n=318
Control group n=314
Counseling intervention:
- Face-to-face session n= 318
- Telephone sessions
4-5 times n=302
1-3 times n=14
0 times n=2
Lost to 2-year follow-up n=23
- died n=8
- withdrew n=5
- missing follow-up data n=10 (poor health 4, declined 6)
Lost to 2-year follow-up n=31
- died n=8
- withdrew n=4
- missing follow-up data n=19 (poor health 7, moved 1, declined 11)
Responded to IADL-questionnaire n=295
Responded to IADL-questionnaire n=283
Analyzed: Intention-to-treat n=310
Analyzed: Intention-to-treat n=306