Effects of a falls prevention exercise programme on health-related quality of life in older home care recipients: a randomised controlled trial

Bjerk, Maria; Brovold, Therese; Skelton, Dawn A.; Liu-Ambrose, Teresa; Bergland, Astrid

Published in:
Age and Ageing

DOI:
10.1093/ageing/afy192

Publication date:
2019

Document Version
Author accepted manuscript

Effects of a falls prevention exercise programme on health-related quality of life in older home care recipients: A randomised controlled trial

Abstract

Background:
Falls have serious consequences for quality of life (QOL) and contribute substantially to the global burden of disease. Home care is an important arena to address falls prevention and QOL, but this vulnerable group of older adults is underrepresented in health research. This study explores the effects of a falls prevention exercise programme on health-related quality of life (HRQOL), physical function and falls efficacy in older fallers receiving home care.

Methods:
The study design is a parallel-group randomised controlled trial. The intervention group performed a falls prevention programme based on the Otago Exercise Programme (OEP). The control group received usual care. 155 participants were recruited from primary health care in six Norwegian municipalities. Local physiotherapists supervised the programme. The primary outcome, HRQOL, was measured with the Short Form 36 Health Survey (SF-36). Secondary outcomes were Bergs Balance Scale (BBS), Sit to Stand (STS), 4-meter Walk Test, Instrumental Activities of Daily Living, and Falls Efficacy Scale International.

Results:
Intention-to-treat analysis showed that, compared to the control group, the intervention group improved on SF-36's Physical Component Summary as well as BBS. However, the intervention group also demonstrated a decline in the Mental Health subscale of SF-36. Per protocol analyses showed significant improvements in all physical subscales of SF-36, STS and BBS scores in the intervention group compared with the control group.

Conclusion:
A falls prevention exercise programme based on OEP significantly improved physical HRQOL and balance in older adults receiving home care.

Key points

- One of the first studies to explore the effect of a falls prevention programme on HRQOL in older fallers receiving home care
- Home care recipients with falls have low HRQOL, poor physical function and high fear of falling
- A falls prevention exercise intervention can improve physical HRQOL and balance in frailer older people
- The effect of the falls prevention exercise programme increases, if exercises are performed as prescribed
- Future research should explore how falls efficacy can be improved by falls prevention interventions

Trial registration: ClinicalTrials.gov. NCT02374307. First registration, 16/02/2015.

Keywords: health-related quality of life, falls prevention, exercise interventions, home care, balance

Introduction

Falls contribute considerably to the global burden of disease [1]. About 30% of the population of older adults above 65 years experience a fall once a year [2]. Falls have immediate and long-term consequences, both for fallers and their families' quality of life (QOL) and economically for the health care system [3]. Even without injury, falls often cause loss of mobility, confidence and functional independence [4].

Home care is an important arena to address falls prevention interventions for older adults [3]. It is defined as interdisciplinary care provided by health professionals to people in their own homes and covers services like home nursing, practical assistance and safety alarm [5]. In Norway, the community health services are responsible for the delivery. Referrals are typically made by health professionals. Compared with the general population of older adults, those receiving home care have a higher incidence of falls and a lower level of falls efficacy leading to activity restriction [6]. Other characteristics of this group are medically instability, poor physical function, low level of health-related quality of life (HRQOL) and a need for assistance with activities of daily living (ADL) [7], which are similar characteristics that are associated with an increased risk of falling [6, 8].

Home care aims to preserve and increase functional ability, improving QOL and maintaining independence, and making it possible for the person to remain at home [9]. Although ensuring QOL is important in home care, this group is often neglected in health research, particularly in falls prevention [9]. Nevertheless, studies including home care recipients, have found positive effects on QOL [10], Instrumental ADL and walking time [11] following multifactorial interventions incorporating exercise. In the general population of older adults, studies measuring QOL following falls prevention programmes have shown some positive results, although the methods of intervention have varied [12]. Exercise as a single intervention, challenging balance, is effective in reducing falls in this population [2]. A well-known exercise intervention, the Otago Exercise Programme (OEP), reduces falls, improves strength and balance, and maintains confidence in carrying out everyday activities without falling [13].

The literature on falls prevention in the community-dwelling population of older adults is large [2], but research on the more vulnerable group of older home care recipients is lacking [12, 14]. This is an important group where secondary preventative actions can be carried out [9]. The objective of this study is to examine the effects of a falls prevention exercise programme on HRQOL, physical function and falls efficacy in older adults receiving home care.

Methods

Study design

The study was designed as a parallel-group randomised controlled trial. An intervention group performed a falls prevention exercise programme and a control group carried on with activities as usual. Group allocation was at a 1:1 ratio. A study protocol provides more details [14]. Reporting follows the CONSORT 2010 Statement [15].

Setting and participants

Participants were recruited in six municipalities in Eastern Norway. Recruitment was based on home care registers. Assessments and interventions were carried out in the participants' homes.

Inclusion criteria: 67+ years (retirement age), receiving home care, having experienced at least one fall during the last twelve months, able to walk with or without a walking aid and understand Norwegian.

Exclusion criteria: medical contraindications to exercise, life expectancy below one year, a score below 23 on the Mini-Mental State Examination (MMSE) indicating cognitive impairment, and currently participating in other falls prevention programmes or trials.

Intervention

The intervention was a home-based falls prevention exercise programme based on the OEP lasting 12 weeks. The participants received five home visits by a local physiotherapist. They performed individually adjusted exercises for strengthening and balance [13]. The physiotherapist gave information about fall risks, exercise safety, activities in daily life and encouraged adherence. If necessary, the participants received up to four additional home visits. In weeks without home visits, participants received motivational phone calls. Participants were encouraged to carry out exercise on their own at least three times weekly for 30 minutes and walk up to 30 minutes at least two times weekly if safe. Adjustable ankle cuffs and an exercise booklet were distributed. The participants were advised to complete an exercise diary.

The control group received usual care. If an assessment detected a condition that required follow-up by the community health services, e.g. malnutrition, a referral was made to the nurse responsible.

Outcome measures

Assessments were carried out at baseline and following the intervention at three months. Trained research assistants, blinded to the participants' group allocation, performed the assessments.

At baseline global cognitive function was assessed by the Mini-Mental Statement Examination (MMSE) [16]. Demographic and background variables like sex, age, falls history and medications were also collected. To monitor safety, adverse events like falls, cardiovascular events or musculoskeletal injuries when performing exercises were reported by the participants and the physiotherapists in a diary.

Primary outcome measure

HRQOL was measured using the Short Form 36 Health Survey (SF-36) which is validated in Norwegian [17]. The SF-36 summary score is comprised of a physical component summary (PCS) and a mental component summary (MCS), based on subscores from eight domains: physical functioning (PF), role limitations due to physical problems (RP) and due to emotional problems (RE), bodily pain (BP), general health perception (GH), vitality (VT), social functioning (SF) and mental health (MH). The scores range from 0-100 (worst-best).

Secondary outcome measures

To assess physical function measures of balance, leg muscle strength, preferable gait speed and instrumental activities of daily living were included. Static and dynamic balance were measured by Bergs Balance Scale (BBS) [18], lower extremity muscle strength by the 30 seconds sit to stand test (STS) [19], gait speed by 4 meters usual walking speed (4MWT) [20] and IADL by the Lawton IADL scale [21].

Fear of falling was assessed by Falls Efficacy Scale International (FES-I) measuring fear when performing 16 daily activities [22].

Sample size

Sample size was estimated to 150 participants. Anticipated drop-out was 15-20%, based on similar studies [23]. Power was set to $\beta=0.8$ and the level significance to $\alpha=0.05$ to detect a difference of 5 points with a standard deviation of 10 points on the SF-36 summary scales.

Randomisation

A computer-generated permuted block randomisation scheme was employed. Each block contained six subjects of the same sex and municipality. After baseline testing performed by research assistants, the scheme allocated participants according to the sequence of enrolment by a key number concealing the randomisation sequence. MB administered the scheme.

Statistical methods

The statistical analysis was performed using STATA/SE 14.1. Differences between baseline and follow-up were analysed using linear mixed models according to the intention-to-treat (ITT) principle. Missing values were substituted by multiple imputation using a predictive mean matching model with arm, age and sex and baseline values of the imputed variable as predictors.

Additional per-protocol analyses were performed exploring the effect of adherence. Linear regressions (OLS) on adherence to the exercise programme in the intervention group were fitted. A propensity-score matching model was also applied matching participants who performed exercise as prescribed with similar participants in the control group. Matching was performed on baseline scores and sex with one match per observation.

Floor- and ceiling effects were considered when more than 20% of the participants achieved the lowest or highest possible score.

Results

Flow of participants

Screening (February 2016-February 2017) identified 320 older adults with falls and 167 consented to baseline testing, of whom 155 met the inclusion criteria. Recruitment stopped when the sample size target was reached. 77 participants were allocated to the intervention group and 78 to the control group. Eight participants in the intervention group and nine participants in the control group were lost to follow-up. A flow diagram provides more details (Appendix 1). No falls or other serious incidences were reported when exercising. Three participants reported musculoskeletal pain/discomfort after using the ankle cuffs.

Participant characteristics

Sample characteristics are presented in table 1. At baseline all differences between the groups or between the drop-outs and the rest of the sample were not statistically significant.

Mean age was 82.7 years with 79.3% women and a mean number of falls of 2.7. On SF-36, PCS was 38.3. The physical subscales scores ranged from 38.3 to 57.6. MCS was 49.4. The mental subscales ranged from 66.9 to 75.80. Secondary outcomes, showed a mean STS value of 5.1, a mean 4MWT of 0.62 m/sec and a mean BBS score of 39.1. The participants had a mean FES-I score of 30.7.

Table 1: Baseline characteristics. Descriptive statistics of the sample at baseline.

	Total (N=155)	Treatment (N=77)	Control (N=78)
Characteristics			
Age, mean (SD)	82.7 (6.7)	83.1 (6.7)	82.2 (6.7)
Sex, males, %	20.7	20.8	20.5
Living alone, %	84.5	83.1	85.9
Higher education (>12 years), %	36.1	32.5	39.7
No. of medications weekly, mean (SD)	5.3 (3.4)	5.1 (3.7)	5.4 (3.2)
Primary health care services			
Practical assistance, %	69.7	64.9	74.4
Nursing, %	30.3	26.0	34.6
Safety alarm service, %	75.5	79.2	71.8
Walking aid %	73.6	77.9	69.2
Falls the last 12 months			
No., mean (SD)	2.7 (3.7)	2.5 (3.3)	2.9 (4.0)
Injuries from falls:			
Minor injuries %	45.5	45.5	45.5
Serious injuries, hospitalisation %	35.1	32.8	37.7
Mini-Mental State Examination			
MMSE, mean (SD)	27.4 (2.2)	27.4 (2.2)	27.4 (2.2)
Falls Efficacy			
FES-I, mean (SD)	30.7 (9.8)	30.2 (10.1)	31.1 (9.6)
Physical function			
IADL, Lawton and Brody. >6, %	56.1	54.6	57.7
Sit to stand, mean (SD)	5.1 (4.1)	5.5 (3.8)	4.7 (4.4)
4-meter walk test m/sec, mean (SD)	0.62 (0.21)	0.61 (0.18)	0.63 (0.24)
Berg Balance Scale, mean (SD)	39.1 (11.3)	39.1 (11.1)	39.1 (11.6)
Mini Nutritional Assessment			
Risk of or malnourished %	24.5	26.0	23.1
Health-related quality of life			
SF-36 scores, mean (SD)			
Physical function	44.6 (23.1)	44.6 (21.9)	44.7 (24.4)
Role physical	51.7 (29.7)	53.2 (30.1)	50.2 (29.4)
Body pain	53.8 (32.2)	53.8 (28.9)	53.8 (35.2)
General health	57.6 (23.3)	58.8 (22.7)	56.5 (23.9)
Vitality	38.3 (21.5)	39.0 (21.7)	37.5 (21.3)
Social function	66.9 (31.2)	67.7 (29.1)	66.0 (33.2)
Role emotional	75.8 (28.5)	78.0 (27.7)	73.6 (29.3)
Mental health	72.1 (17.4)	74.0 (16.8)	70.1 (17.8)
Physical component summary	38.3 (9.0)	38.2 (9.0)	38.4 (9.1)
Mental component summary	49.4 (10.3)	50.4 (9.9)	48.4 (10.6)

SD, Standard deviation; N, number of individuals; MMSE, Mini-Mental State Examination; FES-I, Falls Efficacy Scale International; IADL, Instrumental Activities of Daily Living; STS, Sit to stand; 4MWT, 4-meter walk test; BBS, Bergs Balance Scale; MNA, Mini Nutritional Assessment; SF-36, 36-Item Short Form Survey

Intention-to-treat analysis

Table 2 presents the ITT analysis. After three months, both groups improved substantially on the mental components of SF-36. MCS was 3.8 points (p<0.001) higher at follow-up. Compared to the controls, the intervention group had generally higher scores at the physical components at follow-up. The estimated intervention effect on PCS was 4.0 (p<0.001). The MH subscore declined relatively by 6.7 points (p=0.009).

The results on BP should be interpreted with caution as 20.6% in both groups reached the maximum value of 100 after intervention. This ceiling effect occurred also in SF and RE after intervention.

On the secondary outcomes, both groups improved on STS, 4MWT and BBS at follow-up. The only significant intervention effect was found on BBS, where a relatively higher score of 2.4 points (p=0.047) was achieved. BBS mediated some of the intervention effect (Appendix 2).

Table 2: Intention to treat analysis. Coefficients from linear mixed models including indicator variables for arm, follow-up and interaction of these. The arm coefficient measures the difference at baseline. The follow-up coefficient measures the general improvement in both groups over time and the interaction term captures the additional improvement at follow-up of being treated. Standard errors (SE) in parentheses.

	Difference Intervention – Control at baseline		General improvement at follow-up – both groups		Additional improvement at follow-up – Intervention gr.	
SF-36 scores, mean diff. (SE)						
Physical function	-0.1	(3.9)	2.7	(2.3)	5.2	(3.2)
Role physical	3.1	(4.9)	7.4	(4.2)	4.0	(5.9)
Bodily pain	0.0	(5.1)	-2.9	(2.7)	8.0*	(3.9)
General health	2.3	(3.8)	1.4	(2.1)	2.6	(2.9)
Vitality	1.5	(3.6)	0.3	(2.2)	1.8	(3.1)
Social function	1.7	(4.7)	10.0**	(3.7)	5.0	(5.1)
Role emotional	4.4	(4.3)	11.0**	(3.5)	-5.8	(5.0)
Mental health	3.9	(3.0)	4.6*	(1.8)	-6.7**	(2.6)
Physical component summary	-0.1	(1.6)	-0.3	(0.9)	4.0***	(1.2)
Mental component summary	2.0	(1.7)	3.8***	(1.1)	-3.1	(1.6)
Physical measures, mean diff. (SE)						
FES-I	-0.9	(1.5)	-2.3	(1.2)	0.6	(1.7)
Sit to stand	0.8	(0.7)	0.8*	(0.4)	0.4	(0.6)
4-meter walk test m/sec	-0.02	(0.04)	0.06**	(0.02)	-0.00	(0.03)
Berg Balance Scale	0.1	(1.8)	3.1***	(0.8)	2.4*	(1.2)

* p<0.05, ** p<0.01, *** p<0.001

Per protocol analyses

Table 3 reports two per protocol analyses with respect to adherence to the exercise programme. Fifty (73.5%) of the participants performed the programme as prescribed, which is defined as receiving home visits, telephone follow-ups and completing independent exercise according to OEP. In the intervention group, 18 (26.5%) of the participants could not complete the OEP as prescribed due to hospitalisation, sudden disease or loss of spouse. The regression analysis showed that those performing less exercise score considerably lower compared to those performing exercise as prescribed. In particular, MH was substantially lower (-12.4, p=0.001). Among those who performed exercise as prescribed, a significant improvement was found in PCS (5.8, p<0.001), PF (10.0, p=0.004), BP (12.3, p=0.005), and BBS (3.3, p=0.01).

The propensity score models, where those performing exercise as prescribed (N=50) were fitted with participants in the control group (N=68), showed that exercising as prescribed, or more, significantly improved PCS (6.3, p<0.001), PF (9.7, p=0.02), RP (10.6, p=0.04), GH (7.6, p=0.02) and VT (8.2, p=0.02). On the secondary outcomes, STS improved by 1.4 (p=0.02) and BBS by 4.3 (p<0.001).

Table 3: Per protocol analyses. Linear regressions (OLS) on adherence to the exercise programme in the intervention group, compared to outcomes in the control group. Propensity-score matching of those performing exercise as prescribed with participants in the control group. Standard errors (SE) in parentheses.

	Regression analysis				Propensity-score matching	
	Exercise less than prescribed		Exercise as prescribed		Average treatment effect	
SF-36 scores, mean diff. (SE)						
Physical function	-8.7	(4.8)	10.0**	(3.4)	9.7*	(4.0)
Role physical	-4.7	(9.5)	7.2	(6.6)	10.6*	(5.1)
Bodily pain	-3.5	(6.1)	12.3**	(4.3)	13.0***	(3.7)
General health	-7.5	(4.5)	5.8	(3.1)	7.6*	(3.3)
Vitality	-8.2	(4.8)	5.6	(3.4)	8.2*	(3.5)
Social function	4.1	(8.0)	3.5	(5.6)	3.0	(4.5)
Role emotional	-3.6	(7.8)	-5.2	(5.5)	-0.7	(3.9)
Mental health	-12.4**	(3.8)	-4.8	(2.7)	-3.2	(2.7)
Physical component summary	-1.8	(1.7)	5.8***	(1.2)	6.3***	(1.6)
Mental component summary	-3.1	(2.4)	-2.9	(1.7)	-3.0	(1.6)
Physical measures, mean diff. (SE)						
FES-I	4.5	(2.6)	-0.5	(1.8)	-1.1	(1.7)
Sit to stand	-0.8	(0.9)	0.9	(0.6)	1.4*	(0.6)
4-meter walk test m/sec	-0.06	(0.05)	0.02	(0.03)	0.01	(0.03)
Berg Balance Scale	-0.4	(1.9)	3.3**	(1.3)	4.3***	(1.1)

* p<0.05, ** p<.01, *** p<0.001

Discussion

Results from this study showed that a falls prevention exercise programme can improve physical HRQOL in addition to balance in home care recipients. The controls also improved on most outcomes dampening the net effect of the intervention. Improvements in controls have been shown previously [10], and participating in a research study and receiving test visits may explain these results. Per protocol analyses showed that those who performed exercises as prescribed seem to improve significantly in all domains of SF-36, as well as balance and lower extremity strength. Not being able to perform the intervention, was associated with a decline in mental HRQOL and reduced positive effects to other outcomes.

This study adds to previous research suggesting that exercise can be beneficial in the population of older home care recipients. Positive results of exercise on QOL, ADL and walking time have been found in this group following multifactorial interventions [10, 11]. However, the effect of exercise as a single intervention on HRQOL is not known in this group. In this study, participants in the intervention group improved their physical HRQOL. The improvement on PCS ranged from 4.0 in the ITT analysis to 6.3 in the propensity-score matching. These results are of clinical relevance. On BBS, an improvement of 2.4 in the ITT analysis and 4.3 in the propensity-score matching might not be sufficient to achieve a true change [24]. The pragmatic intervention of three months might be too short, and stronger effects could potentially be expected with a longer duration [12]. Nonetheless, maintaining physical function and reducing decline is vital in this vulnerable group of older adults [25]. Even though the subjects were frail, 73.5% managed to complete the falls prevention exercise programme as prescribed.

On the primary outcome HRQOL, the sample had generally low scores at baseline, compared to a normative sample of older adults aged 70-80 [26]. Their physical function was poor, with an average preferable walking speed of 0.62 m/s, close to the cut off at 0.6 m/s [27]. They also had impaired balance, with an average sum score of 39.1 on BBS [28]. Moreover, the sample reported a high level of concern about falls, measured by FES-I, with an average of 30.7 [22]. These factors increase the risk for future falls [4]. Targeting this vulnerable group of older adults in falls prevention is, thus, of importance in order to maintain their independence and HRQOL.

Interestingly, in the ITT analysis, MH declined in the intervention group. The per protocol analyses revealed that this result can be explained by their ability to accomplish the exercise programme. Hospitalisation, sudden disease or loss of spouse made it challenging or impossible for several participants to complete the intervention. Not being able to improve in the exercise programme as expected may have negatively impacted mental HRQOL. Another interesting finding is that falls efficacy was not impacted by the programme. This is in contrary to previous literature, where home-based exercise reduced fear of falling in community-dwelling older adults [29]. However, the sample in the present study was frailer, and more follow-up specifically directed on their fear of falling could be necessary to improve their falls efficacy. From previous studies falls efficacy has shown to be an important predictor of HRQOL [30]. The lack of effect on falls efficacy might explain why HRQOL did not improve to a larger degree. This should be explored more systematically in future research.

This study has a pragmatic design with local physiotherapists conducting a feasible intervention in the participants' homes. Such an approach has both strengths and limitations. Generalisability to a clinical setting improves. Well-known measurement tools were employed, but some were self-reported introducing additional uncertainty. Recruitment from home-care service registers was active and outreaching, and drop-outs were few. This could have limited selection bias and increased the representativeness by providing a clinical relevant sample. The sample had a large percentage of

women and the mean age was high, which is typical in the population of home care recipients. On the other hand, due to the high age and level of frailty, this sample was more heterogeneous and medically unstable. Different subgroups of home care recipients could benefit differently from the falls intervention, which could not be tested in this limited sample. Future research could narrow the inclusion criteria or increase the sample size substantially to allow for systematic subgroup analyses.

Conclusion

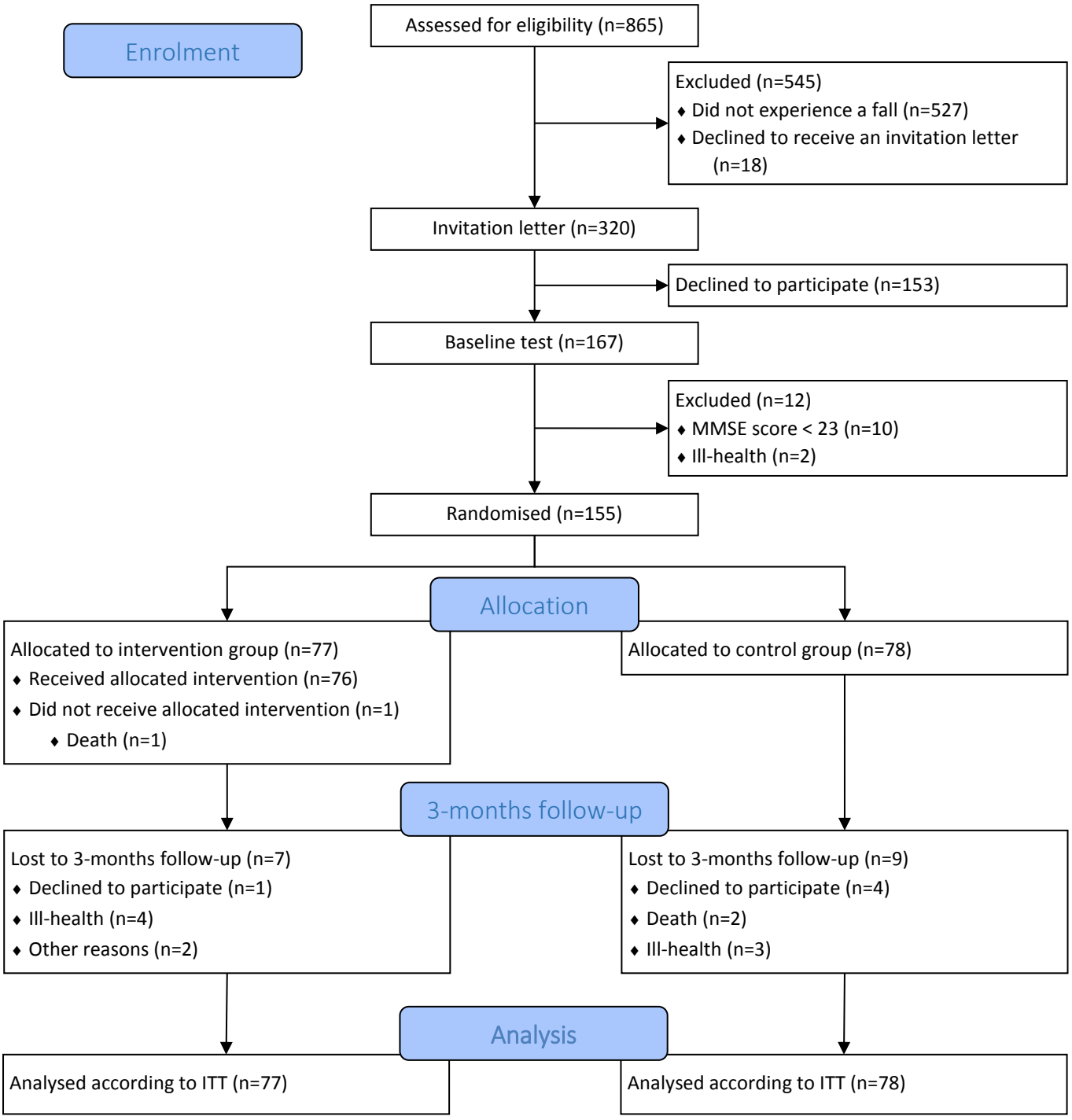
A falls prevention exercise programme based on OEP improved physical HRQOL and balance in older adults receiving home care. For those managing to complete the exercise programme as prescribed, this effect seems to be greater. For those not managing to complete the programme, a negative impact on mental HRQOL was observed. This study found no effect on falls efficacy.

References

1. Hay SI, Abajobir AA, Abate KH, Abbafati C, Abbas KM, Abd-Allah F, et al. Global, regional, and national disability-adjusted life-years (DALYs) for 333 diseases and injuries and healthy life expectancy (HALE) for 195 countries and territories, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet. 2017;390(10100):1260-344.
2. Gillespie LD, Robertson MC, Gillespie WJ, Sherrington C, Gates S, Clemson LM, et al. Interventions for preventing falls in older people living in the community. Cochrane Database of Systematic Reviews. 2012;9(11).
3. Vieira ER, Palmer RC, Chaves PH. Prevention of falls in older people living in the community. BMJ. 2016;353:i1419.
4. Ambrose AF, Paul G, Hausdorff JM. Risk factors for falls among older adults: a review of the literature. Maturitas. 2013;75(1):51-61.
5. Thome B, Dykes AK, Hallberg IR. Home care with regard to definition, care recipients, content and outcome: systematic literature review. Journal of Clinical Nursing. 2003 Nov;12(6):860-72.
6. Fletcher PC, Hirdes JP. Restriction in activity associated with fear of falling among community-based seniors using home care services. Age and Ageing. 2004;33(3):273-9.
7. Scott VJ, Votova K, Gallagher E. Falls prevention training for community health workers: strategies and actions for independent living (SAIL). Journal of Gerontological Nursing. 2006;32(10):48-56.
8. Stenhagen M, Ekstrom H, Nordell E, Elmstahl S. Accidental falls, health-related quality of life and life satisfaction: a prospective study of the general elderly population. Archives of Gerontology and Geriatrics. 2014 Jan-Feb;58(1):95-100.
9. Genet N, Boerma WG, Kringos DS, Bouman A, Francke AL, Fagerstrom C, et al. Home care in Europe: a systematic literature review. BMC Health Services Research. 2011 Aug 30;11:207.
10. Markle-Reid M, Browne G, Gafni A, Roberts J, Weir R, Thabane L, et al. The effects and costs of a multifactorial and interdisciplinary team approach to falls prevention for older home care clients 'at risk'for falling: a randomized controlled trial. Canadian Journal on Aging/La Revue canadienne du vieillissement. 2010;29(01):139-61.
11. Bonnefoy M, Boutitie F, Mercier C, Gueyffier F, Carre C, Guetemme G, et al. Efficacy of a home-based intervention programme on the physical activity level and functional ability of older people using domestic services: a randomised study. The Journal of Nutrition, Health & Aging. 2012;16(4):370-7.
12. Vaapio SS, Salminen MJ, Ojanlatva A, Kivelä S-L. Quality of life as an outcome of fall prevention interventions among the aged: a systematic review. The European Journal of Public Health. 2009;19(1):7-15.
13. Campbell AJ, Robertson C. Otago Exercise Programme to prevent falls in older adults. In: School OM, editor. Wellington, N.Z.2003.
14. Bjerk M, Brovold T, Skelton DA, Bergland A. A falls prevention programme to improve quality of life, physical function and falls efficacy in older people receiving home help services: study protocol for a randomised controlled trial. BMC Health Services Research. 2017 aug;17(1).
15. Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC Medicine. 2010;8(1):1.
16. Tombaugh TN, McIntyre NJ. The Mini-Mental State Examination: a comprehensive review. Journal of the American Geriatrics Society. 1992;40(9):922-35.
17. Loge JH, Kaasa S. Short Form 36 (SF-36) health survey: normative data from the general Norwegian population. Scandinavian Journal of Public Health. 1998;26(4):250-8.
18. Halsaa KE, Brovold T, Graver V, Sandvik L, Bergland A. Assessments of interrater reliability and internal consistency of the Norwegian version of the Berg Balance Scale. Archives of Physical Medicine and Rehabilitation. 2007;88(1):94-8.

19. Jones CJ, Rikli RE, Beam WC. A 30-s chair-stand test as a measure of lower body strength in community-residing older adults. Research Quarterly for Exercise and Sport. 1999;70(2):113-9.
20. Peters DM, Fritz SL, Krotish DE. Assessing the reliability and validity of a shorter walk test compared with the 10-meter walk test for measurements of gait speed in healthy, older adults. Journal of Geriatric Physical Therapy. 2013;36(1):24-30.
21. Graf C. The Lawton Instrumental Activities of Daily Living (IADL) Scale. The American Journal of Nursing. 2009 Sep-Oct;18(5):315-6.
22. Helbostad JL, Taraldsen K, Granbo R, Yardley L, Todd CJ, Sletvold O. Validation of the Falls Efficacy Scale-International in fall-prone older persons. Age and Ageing. 2010 Mar;39(2):259.
23. Brovold T, Skelton DA, Bergland A. Older Adults Recently Discharged from the Hospital: Effect of Aerobic Interval Exercise on Health-Related Quality of Life, Physical Fitness, and Physical Activity. Journal of the American Geriatrics Society. 2013;61(9):1580-5.
24. Donoghue D, Stokes EK. How much change is true change? The minimum detectable change of the Berg Balance Scale in elderly people. Journal of Rehabilitation Medicine. 2009;41(5):343-6.
25. Manini TM, Pahor M. Physical activity and maintaining physical function in older adults. British Journal of Sports Medicine. 2009;43(1):28-31.
26. Jacobsen EL, Bye A, Aass N, Fossa SD, Grotmol KS, Kaasa S, et al. Norwegian reference values for the Short-Form Health Survey 36: development over time. Quality of Life Research. 2017 Aug 14.
27. Studenski S, Perera S, Patel K, Rosano C, Faulkner K, Inzitari M, et al. Gait speed and survival in older adults. JAMA. 2011;305(1):50-8.
28. Muir SW, Berg K, Chesworth B, Speechley M. Use of the Berg Balance Scale for predicting multiple falls in community-dwelling elderly people: a prospective study. Physical Therapy. 2008;88(4):449-59.
29. Zijlstra G, Van Haastregt J, Van Rossum E, Van Eijk JTM, Yardley L, Kempen GI. Interventions to reduce fear of falling in community-living older people: a systematic review. Journal of the American Geriatrics Society. 2007;55(4):603-15.
30. Davis JC, Bryan S, Li LC, Best JR, Hsu CL, Gomez C, et al. Mobility and cognition are associated with wellbeing and health related quality of life among older adults: a cross-sectional analysis of the Vancouver Falls Prevention Cohort. BMC Geriatrics. 2015 Jul 05;15:75.

Appendix 1: Flow Diagram



Appendix 2: Mediation analysis – Berg Balance Scale

Linear mixed model regressions measuring the change from baseline to follow-up. The models for BBS and PCS in the first two columns are identical to those fitted in the ITT analysis (Table 2). The last regression on PCS also includes BBS as an additional explanatory variable. Missing values were substituted using multiple imputation. Standard errors (SE) in parentheses.

	Bergs Balance Scale	Physical component summary	Physical component summary
Intervention effect	2.4*	4.0***	3.4**
	(1.2)	(1.2)	(1.2)
Bergs Balance Scale			0.3***
			(0.1)

* p<0.05, ** p<.01, *** p<0.001

The results show that compared to the control group, the intervention group had significantly improved BBS scores (2.4, p=0.047). Including BBS in the regression of PCS decreases also the coefficient on the intervention indicator from 4.0 to 3.4. The coefficient on BBS is 0.3 and statistically significant (p<0.001). This confirms that BSB mediated some of the intervention effect on PCS.