Falls prevention to improve health-related quality of life, physical function and falls self-efficacy in older adults receiving home care

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Summary

Background: Falls and fall-related injuries in older adults are associated with great burdens for the individuals, the health care system and society. Although they have a high incidence of falls, a high prevalence of fear of falling and a lower level of health-related quality of life (HRQOL), older adults receiving home care are underrepresented in research on older fallers. Effective interventions to prevent falls and improve HRQOL, physical function and falls self-efficacy in this population is of importance to meet current and future public health challenges.

Aims: The first aim of the thesis was to provide an in-depth background for the study with detailed information on the project procedures. The second aim was to describe the characteristics of the population of home care recipients, including their HRQOL, physical function and falls self-efficacy, and to determine the relationship between these factors. The third aim was to evaluate the short- and longer-term effects of a falls prevention exercise programme on HRQOL, physical function and falls self-efficacy. The final aim was to examine the agreement between the two general measures of HRQOL, SF-6D and EQ-5D, employed when evaluating interventions in home care recipients.

Methods: This thesis consists of five papers in which three different designs are employed. The first paper is a study protocol for the randomised controlled trial (RCT). The second paper presents a study with a cross-sectional observational design. In the third and fourth papers, a single-blinded parallel-group RCT, including a follow-up at 3 months and 6 months is presented. The fifth paper reports on a longitudinal study on the same data. The participants in all studies were 155 older adults receiving home care from six municipality health care services in Eastern Norway. Inclusion criteria were being over 67, receiving home care, having experienced at least on fall during the last 12 months, being able to walk with or without a walking aid and being able to communicate in Norwegian. Exclusion criteria were medical contraindications to exercise, life expectancy below 1 year, a Mini-Mental State Examination (MMSE) score below 23 and currently participating in other falls prevention programmes or trials. The intervention group received an individual home-based falls prevention exercise programme based on the Otago Exercise Programme (OEP) lasting 12 weeks. The control group received usual care. Assessments were carried out at baseline, at the end of the intervention at 3 months and at a 6-month follow-up. The primary outcome, HRQOL, was measured using the Short-Form 36 Health Survey (SF-36). Physical function was measured using the Bergs Balance Scale (BBS), the 30-second sit-to-stand test (STS), the 4-metre walk test (4MWT), instrumental activities of daily living (IADL) and walking habits. Falls self-efficacy was measured using the Falls Efficacy Scale International (FES-I). Nutritional status was measured using the Mini-Nutritional Assessment (MNA). At baseline, MMSE scores, demographic information and background variables were collected. Information on adverse events and exercise adherence was collected at 3 and 6 months.

Results: The sample of older home care recipients included in this project had poor HRQOL, physical function and falls self-efficacy compared to the general older population. Paper II shows that better HRQOL was associated with better physical function and falls self-efficacy, when adjusted for baseline values such as sex, education, living alone and number of falls. Paper III shows that the intervention group improved their physical HRQOL and balance in the short term following a falls prevention exercise intervention. Further analysis revealed that the effects were greater for those who managed to complete the programme as prescribed and showed a negative impact on mental HRQOL for those who did not manage to complete the programme as prescribed. Paper IV shows that the improvement in physical HRQOL was sustained at follow-up. Further analysis demonstrated that the intervention increased the probability of maintaining exercise post-intervention and that this exercise mediated the effect of the intervention on physical HRQOL. Paper V shows that older adults with a higher mean HRQOL and/or better physical function scored higher on EQ-5D, while those with lower mean HRQOL and/or poorer physical function scored higher on SF-6D. EQ-5D was more responsive to changes in physical function compared to SF-6D.

Conclusions: Home care recipients are a frail group of older adults with poor HRQOL, physical function and falls-self efficacy. A falls prevention exercise programme can improve their HRQOL and physical function in the short term and can help sustain their HRQOL in the longer term. SF-6D and EQ-5D are applicable when evaluating interventions in home care, but EQ-5D seems more responsive to changes in physical function. More research on this group is needed, particularly in terms of developing interventions and evaluating the effects of falls prevention programmes on mental HRQOL and falls self-efficacy.

Sammendrag

Bakgrunn: Fall og fallrelaterte skader hos eldre er forbundet med store belastninger, både for eldre, helsevesenet og samfunnet. Selv om eldre som mottar hjemmetjenester har en høy forekomst av fall og frykt for fall samt lavere helserelatert livskvalitet (HRQOL), er denne gruppen underrepresentert i helseforskning. Effektive tiltak for å forebygge fall og forbedre HRQOL, fysisk funksjon og mestringstro i denne befolkningen er av betydning for å møte dagens og fremtidige folkehelseutfordringer.

Formål: Det første målet var å gi en grundig bakgrunn for studien med detaljert informasjon om prosedyrene i prosjektet. Det andre målet med prosjektet var å beskrive egenskapene til hjemmetjenestemottakere, inkludert deres HRQOL, fysiske funksjon og mestringstro, samt å undersøke forholdet mellom disse faktorene. Det tredje målet var å evaluere de kortsiktige og langsiktige effektene av et fallforebyggende treningsprogram på HRQOL, fysisk funksjon og mestringstro. Det siste målet var å undersøke likheter og forskjeller mellom SF-6D og EQ-5D for å kunne evaluere nytteverdien av intervensjoner for hjemmetjenestemottakere.

Metode: Dette PhD-prosjektet inkluderer fem artikler der det benyttes tre ulike design. Den første artikkelen er en studieprotokoll for den randomiserte kontrollerte studien (RCT). I den andre artikkelen presenteres en tverrsnittsstudie. I tredje og fjerde artikkel presenteres en enkeltblindet RCT studie, med en oppfølging etter tre måneder og en etter seks måneder. Den femte artikkelen presenterer en longitudinell studie. Deltakerne i alle studiene var 155 eldre med hjemmetjenester fra seks kommuner i Norge. Inklusjonskriterier var alder 67+, mottaker av hjemmetjenester, opplevd minst ett fall i løpet av de siste 12 månedene, kunne gå med eller uten ganghjelpemiddel og kunne kommunisere på norsk. Eksklusjonskriterier var medisinske kontraindikasjoner for trening, forventet levealder under ett år, en score under 23 på Mini-Mental State Examination (MMSE) og deltakelse i andre fallforebyggende programmer eller forskningsprosjekter. Intervensjonsgruppen mottok et individuelt hjemmebasert fallforebyggende treningsprogram basert på Otago treningsprogram med varighet 12 uker. Kontrollgruppen mottok tjenester som vanlig. Vurderinger ble utført ved oppstart, ved intervensjonsslutt etter tre måneder og ved oppfølging etter seks måneder. Det primære utfallet, HRQOL, ble målt ved Short-Form 36 Health Survey (SF-36). Fysisk funksjon ble målt ved Bergs Balanse Skala (BBS), 30 sekunder reise seg til stående test (STS), 4 meter gang test (4MWT),

instrumentelle daglige aktiviteter (IADL) og gangvaner. Mestringstro ved aktiviteter som innebærer fallrisiko ble målt ved Falls Efficacy Scale International (FES-I). Ernæringsstatus ble målt ved Mini-Nutritional Assessment (MNA). Ved første måletidspunkt ble også MMSE samt bakgrunnsvariabler samlet inn. Informasjon om uheldige hendelser og fysisk aktivitet ble samlet inn ved tre og seks måneder.

Resultater: De eldre hjemmetjenestemottakere inkludert i prosjektet hadde redusert HRQOL, fysisk funksjon og mestringstro sammenlignet med den generelle eldre befolkningen. Artikkel II viser at bedre HRQOL var assosiert med bedre fysisk funksjon og bedre mestringstro, justert for bakgrunnsvariabler som kjønn, utdanning, å bo alene og antall fall. Artikkel III viser at intervensjonsgruppen forbedret deres fysiske HRQOL og balanse ved intervensjonsslutt. Ytterligere analyser viste at for de som klarte å fullføre programmet som foreskrevet, var effektene større, og for de som ikke klarte å fullføre programmet, ble det observert en negativ innvirkning på mental HRQOL. Artikkel IV viser at forbedringen i fysisk HRQOL ble opprettholdt ved oppfølging etter seks måneder. Ytterligere analyser avslørte at intervensjonen økte sannsynligheten for at deltakerne opprettholdt treningen etter intervensjonsslutt og at denne treningen påvirket effekten av intervensjonen på fysisk HRQOL. Artikkel V viser at eldre med høyere gjennomsnittlig HRQOL og/eller bedre fysisk funksjon scorer høyere på EQ-5D, mens de med lavere gjennomsnittlig HRQOL og/eller dårligere fysisk funksjon scorer høyere på SF-6D. EQ-5D var mer sensitiv til endringer i fysisk funksjon sammenlignet med SF-6D.

Konklusjoner: Hjemmetjenestemottakere er en skrøpelig gruppe av eldre med redusert HRQOL, fysisk funksjon og mestringstro. Et fallforebyggende treningsprogram kan forbedre HRQOL og fysisk funksjon på kort sikt og opprettholde HRQOL på lengre sikt. SF-6D og EQ-5D er nyttig når man skal evaluere intervensjoner for hjemmetjenestemottakere, men EQ-5D virker mer sensitiv for endringer i fysisk funksjon. Mer forskning i gruppen av hjemmetjenestemottaker er nødvendig, spesielt for å kunne utvikle intervensjoner og videre evaluere effekter av fallforebyggende programmer med hensikt å bedre mental HRQOL og mestringstro ved aktiviteter som innebærer fallrisiko.

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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; 17(1):559, DOI: **https://dx.doi.org/10.1186/s12913-017-2516-5**.

Paper II

Bjerk M, Brovold T, Skelton DA, Bergland A. Associations between health-related quality of life, physical function and fear of falling in older fallers receiving home care. BMC Geriatrics. 2018; 18(1):253, DOI: **https://dx.doi.org/10.1186/s12877-018-0945-6**.

Paper III

Bjerk M, Brovold T, Skelton DA, Liu-Ambrose T, Bergland A. Effects of a falls prevention exercise programme on health-related quality of life in older home care recipients: a randomised controlled trial. Age and Ageing. 2019; 48(2):213-219, DOI: **https://dx.doi.org/10.1093/ageing/afy192**.

Paper IV

Bjerk M, Brovold T, Davis JC, Skelton DA, Bergland A. Health-related quality of life in home care recipients after a falls prevention intervention: a 6-month follow-up. European Journal of Public Health, Volume 30, Issue 1, February 2020, Pages 64–69, DOI: **https://dx.doi.org/10.1093/eurpub/ckz106**.

Paper V

Bjerk M, Brovold T, Davis JC, Bergland A. Evaluating a falls prevention intervention in older home care recipients: a comparison of SF-6D and EQ-5D. Quality of Life Research. 2019; 28(12):3187-3195, DOI: **https://dx.doi.org/10.1007/s11136-019-02258-x**.

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List of abbreviations

ADL: Activities of Daily Living
BBS: Berg Balance Scale
BP: Bodily Pain
CI: Confidence interval
EQ-5D: EuroQOL EQ-5D-5L
FES-I: Falls Efficacy Scale International
4MWT: 4-Metre Walk Test
GH: General Health
HRQOL: Health-related quality of life
IADL: Instrumental activities of daily living
ICF: International Classification of Functioning, Disability and Health
ITT: Intention-to-treat
MCI: Mild cognitive impairment
MCID: Minimal clinically important difference
MCS: Mental Component Summary
MH: Mental Health
MI: Motivational Interviewing
MMSE: Mini Mental State Examination
MNA: Mini Nutritional Assessment
OEP: Otago Exercise Programme
OR: Odds ratio
PADL: Personal activities of daily living
PCS: Physical Component Summary
PF: Physical Functioning
PROM: Patient centred outcome measure
QOL: Quality of life
RCT: Randomised controlled trial
RE: Role Emotional
RP: Role Physical
SD: Standard deviation
SF: Social Functioning
SF-36: Short Form (36) Health Survey
SF-6D: Short-Form Six-Dimension
STS: Sit-to-stand test
VT: Vitality
WHO: World Health Organization

Definitions of central concepts

Complex interventions: Activities that consist of a number of component parts with the potential for interactions between them that, when applied to the intended target population, produce a range of possible and variable outcomes (3).

Exercise: A sub-category of physical activity that is planned, structured and repetitive and that has as a final or intermediate objective the improvement or maintenance of physical fitness (4).

Fall: An unexpected event where the participant comes to rest on the ground, floor or lower level (2).

Falls prevention: A variety of actions to help reduce the number of accidental falls suffered by older people (2).

Falls self-efficacy: The perceived self-confidence at avoiding falls during essential, relatively non-hazardous activities (5).

Frailty: A state of increased vulnerability to poor resolution of homeostasis after a stress event, which increases the risk of adverse outcomes, including falls, delirium and disability (6).

Health promotion: Health promotion enables people to increase control over their own health. It covers a wide range of social and environmental interventions designed to benefit and protect individual people's health and quality of life by addressing and preventing the root causes of ill health, not just focusing on treatment and cure (7).

Health-related quality of life: A multidomain concept that represents the patient's general perception of the effect of illness and treatment on the physical, psychological and social aspects of life (8).

Healthy ageing: The process of developing and maintaining the functional ability that enables well-being in older age (9).

Malnutrition: A state of nutrition in which a deficiency, an excess or imbalance of energy, protein and other nutrients causes measurable adverse effects on tissue/body form, function and/or clinical outcome (10).

Multifactorial interventions: Where the component interventions are matched to an individual assessment of risk (11).

Multiple component interventions: Where the same component interventions are provided to all people (12, 13).

Physical activity: A bodily movement produced by skeletal muscles that result in energy expenditure. Physical activity encompasses exercise, sports, and physical activities performed as part of daily living, occupation, leisure, or active transportation (4).

Physical function: The individual's ability to perform different activities. It reflects motor function and control, physical fitness, and habitual physical activity (4).

Quality of life: Individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, standards and concerns (14, 15).

Responsiveness: A measure of the association between the change in the observed score and the change in the true value of the construct (16).

1 Introduction

This thesis reports on the results of a randomised controlled trial (RCT) in which the main focus was to improve health-related quality of life (HRQOL) in older home care recipients who had experienced falls. The overall aim of the study was to contribute to evidence-based knowledge on the applicability of falls prevention exercises, by performing a study in a clinical setting and for a group of older adults dependent on professional health care at home. More specifically, the aim was to increase knowledge on the short- and longer-term effectiveness of the Otago Exercise Programme (OEP) in relation to older people's HRQOL, physical function and falls self-efficacy. In addition, this thesis explores the HRQOL of home care recipients, covariates of HRQOL and the applicability of generic HRQOL measures when evaluating interventions. The knowledge acquired in this thesis can be of relevance for people who have experienced falls, health professionals, policy makers and health care researchers.

The increasing number of older adults who live longer poses new challenges to health, long-term care and the welfare system (17). In Norway, the number of older adults over 67 will increase from 0.79 million in 2017 to 1.28 million in 2040 (18). Moreover, the number of adults 80 and older will more than double from 0.22 million in 2017 to 0.47 million in 2040. Preventative actions to maintain the functional abilities of older adults to promote well-being are therefore of great importance (9, 19, 20). Staying active and maintaining quality of life (QOL) in older adults has been emphasised as an important strategy in health policy, nationally and internationally, to prepare for the challenges resulting from the increasing population of older adults (9, 19, 21-25). Even though the expanding ageing population is a global health concern, older adults are underrepresented in clinical research, particularly frail older adults like home care recipients, even when examining conditions affecting this population almost exclusively, such as falls or Alzheimer's disease (26, 27).

The participants in this research project are older home care recipients who have experienced falls. Falls in older adults are an increasingly important public health concern due to the increasing number of older adults and the severe consequences, contributing considerably to the global burden of disease (2, 9, 28, 29). Moreover, falls are among the most frequent causes of unintentional injuries, such as hip fractures, and falling accounts for half of all hospital admissions of older adults (2). Globally, approximately 30% of home-dwelling older adults over

65 experience at least one fall yearly, and this increases to 50% for those over 80 (12). The cost of falls and associated injuries is rising, and it has been estimated to be 1.5% of health care costs in European countries (30). The costs are both direct (fall-related injuries) and indirect (loss of mobility, confidence and functional independence). In addition to affecting the health care system and the person directly, falls also have an immediate and a long-term impact on the QOL of the faller's family (31).

For many older adults, falls and injuries from falls are a starting point for receiving professional health services at home (32, 33). Falls can cause longstanding pain, functional impairment and reduced life satisfaction leading to a downward trend in older adults' health state and resulting in the need for professional health care (28, 34). Home care is defined as health and social care provided by formal health workers in the homes of older adults and can cover different activities, such as assistance with daily activities, safety alarm service or interdisciplinary rehabilitation (33). These services can be important in enabling older adults to remain at home and thus prevent long-term care. In Norway, a large proportion of older adults receive professional home care, particularly those over 80. Approximately 50% of 80-90-year olds and 90% of those 90 and older receive home care (35). Compared to the general population of older adults home care recipients have a higher incidence of falls and a greater fear of falling (36).

Ageing is inevitable, and with age comes the increased risk of falling, illness and declining physical function, which might reduce QOL. Effective interventions in primary care to prevent falls and improve HRQOL are emphasised in public health policy (9). Interventions can alter older people's HRQOL by influencing their perceived physical, mental and social well-being (37). HRQOL is thus an important measure when assessing the effects of interventions and health services on the well-being of older adults and should be included in preventative programmes (38). Assessing HRQOL specifically is essential, as functional improvements or other positive impacts of intervention might not have a direct positive effect on self-perceived HRQOL (39). In addition to assessing the self-perceived QOL of older adults, HRQOL instruments can also be utilised for economic evaluations measuring the effects of health care and policy interventions (40). These evaluations are necessary to inform decision makers on the cost-effectiveness of interventions and further to make evidence-based decisions when prioritising in health care (41, 42).

The overall aim of this PhD project was to explore the effectiveness of an evidence-based falls prevention exercise programme on the HRQOL of older home care recipients. Included in the overall aim were different sub-aims that are addressed in the papers included for this thesis. The first sub-aim was to provide a protocol publication to enhance the transparency of the project (Paper I). The second sub-aim was to provide more knowledge on HRQOL, physical function and falls self-efficacy and the associations between these factors in older home care recipients (Paper II). The third sub-aim was to examine the short- and longer-term effects of the OEP when carried out in a home care setting (Papers III and IV). The final sub-aim was to explore how HRQOL index measures can be used to evaluate interventions in this population (Paper V).

2 Background

This chapter includes a literature review of the studies highly relevant to this thesis, particularly those focusing on falls and HRQOL. It also discusses falls prevention interventions to improve the HRQOL of vulnerable older adults as home care recipients. The scope of the literature review was broad, including literature published both before and after the study started. First, to provide the context for this research study, health care services for older adults will be presented, looking closely at primary health care, home care and falls (2.1). Second, the function of community-dwelling older adults will be examined, and the International Classification of Functioning, Disability and Health (ICF) will be presented as a theoretical framework to evaluate function in older adults (2.2). Physical and mental function, falls-self efficacy and frailty in older adults will be explored. Third, HRQOL will be discussed, including the definition, HRQOL in older adults and associations with physical function and falls self-efficacy (2.3). Fourth, interventions to prevent falls, both multifactorial interventions and the OEP, and interventions to improve HRQOL will be presented (2.4). Finally, the evaluation of falls prevention interventions will be explored, specifically focusing on HRQOL measures (2.5).

The literature in this review was identified by searching PubMed and Medline databases, in addition to Google Scholar using the appropriate search terms. In addition, the author's extensive database of relevant literature collected during the project was employed. The search criteria were broad.

2.1 Health services for older adults

Health services are delivered in a range of sectors, and funding and administrative systems differ across and within countries. In the following paragraphs, the context of this research project will be introduced, looking at primary health care from both an international and a national perspective. Home care services in Norway will be described, and falls as a challenge for the health services of older adults will be discussed.

2.1.1 Primary health care

Both costs and consumer preferences have led to a shift from the long-term institutional care of older adults to care based at home or in the community, also known as primary care (43). Primary care has been defined as the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community (44). Providing health services where people live and incorporating them into everyday life is important to enable older adults to remain in their own homes, which in recent years has been emphasised in health policy (24, 45). Primary care contributes to preventing illness and death and is associated with a more equitable distribution of health in various populations (46). Effective interventions for older adults in primary care are emphasised in public health policy to increase the number of years in good health (47). Moreover, effective services in primary care can help reduce the costs of other health care services, such as long-term care (17, 47). Often, older adults start receiving primary health care due to a decline in capacity. In Europe, it is calculated that approximately 15%-35% of people above 75 need some assistance with activities of daily living (ADL) or instrumental activities of daily living (IADL) (48). At this point, it is important to ensure that older adults engage in healthy behaviours to prevent, slow or partly reverse the process of becoming frail or more dependent on care (9). The focus of these interventions can be everything from reducing risk factors to carrying out actions that can help maintain or reverse the loss of intrinsic capacity, which can be defined as the composite of all physical and mental capacities of a person.

Increasing longevity is definitively valuable, but dependent on good health (48). The World Health Organization (WHO) has defined healthy ageing as the process of developing and maintaining the functional ability that enables well-being in older age (48). Healthy ageing can be ensured through the provision of effective health care services. Actions to enhance healthy ageing by maximising functional ability are seen as important, not just preventing losses but also reinforcing resilience and psychosocial growth. At the population level, there is also a need for actions to improve overall levels and to pay extra attention to those with low capacity. A recent paper based on the WHO World report on ageing and health stated four actions that are important for healthy ageing (48). These are to provide health care that addresses multidimensional demands and not specific diseases independently; to develop long-term care that aims to maintain functional ability in older adults who have or are at high risk of substantial loss of capacity; to help older adults be able to live in an age-friendly environment that enables them to age safely in a place that is right for them, to continue to develop personally and to contribute to their community; and to emphasise the importance of monitoring and measuring to overcome the major knowledge and research gaps that currently exist (43, 49). At the moment, there are only very few and mostly small studies that include older adults, even on the conditions that almost exclusively affect this population (26). Additionally, primary health care is an understudied research area within health research (50).

Globally, countries have different systems for organising primary health care (50, 51). The services can be delivered in a range of sectors, including public health (national, state, county or district), social services and private for-profit or non-profit organisations (43). The funding and administrative systems through which services are delivered differ across and within countries. In Norway, there has been a shift in political health care reforms in the distribution of resources and responsibility, from specialist health care to primary health care (23, 24). This shift has posed challenges for the primary care health sector, and innovative development of the services has been necessary. Preventative interventions and health promotion have been emphasised to a larger degree as a central part of health and social services in the community. Home care is one service that the municipal health service is responsible for providing. These services strive to offer the 'lowest level of effective care', and home care is defined as the lowest level in Norway (52). The municipality determines the type of service and the amount of care that older adults require. Home care refers to care given by professional health workers at home, covering a wide range of activities, from short-term rehabilitation to long-term assistance with daily activities. Example of services are day care, home visits, allied health, home maintenance, home nursing and house cleaning. These services provided by the municipality aim to maintain independence, contribute to functional health status and QOL (33). By maintaining functional ability and well-being, home care is an important contributor to healthy ageing and enabling older adults to remain at home (33), which is also a central aim in the present study.

2.1.2 Home care for older adults

The participants in this PhD project comprised older home care recipients. In Norway, approximately 12% of the population aged 67-79, 50% of those aged 80-90 and 90% of those 90 and older receive home care (35). Home care recipients have reported poor functional ability; poor perceived health; and challenges with ADL and IADL tasks and items related to pain and illness, rest, sleep and psychosocial well-being (53-55). For instance, geriatric major depression is twice as common in home care recipients as in the general population of older adults (56). The challenges in personal activities of daily living (PADL) and IADL have been shown to worsen over time. This downward spiral is associated with lower Mini Mental State Examination (MMSE) scores, diagnosed mild cognitive impairment (MCI) and dementia, poor medical health and neuropsychiatric symptoms (57). Moreover, a lower level of QOL has been reported in the population of home care recipients. In a study of Swedish home care services, approximately 20%-40% of older adults reported a limited ability to be alone, and approximately 30% reported low or very low QOL (53). The number of illnesses, the limited ability to be alone, living alone and age were significantly associated with a lower level of QOL, and having a social network was associated with higher QOL (58). It has been suggested that who the helpers are does not influence the level of QOL; rather, it is the extent of help with ADLs that influences QOL negatively and the extent of the social network that influences QOL positively (58).

There seems to be differences in those receiving formal and informal care, which is also connected to the amount of help provided. Those receiving help from formal caregivers generally had fewer children, were single and were living alone compared to those receiving informal care (59, 60). Public services at home seems to be preferably given to those living with a spouse or who are able to stay alone at home, while those without relatives might not be able to remain at home when their need for help increases. Among older adults living alone, dementia, functional limitations and depressive symptoms have been shown to predict the use of home care and institutionalisation (61). Among those who were non-demented and cohabiting, depressive symptoms and dependency in ADL increased the likelihood of both home care and institutionalisation. Both dependency in ADL and IADL and cognitive impairments have been shown to be the strongest predictors of the amount of home care received (62). Even though more females than males receive home care, the gender differences in receiving home care disappear when controlling for co-residence (60).

2.1.3 Falls in older adults – incidence, risk factors and consequences

In the WHO Global Report on Falls Prevention in Older Age, a fall is defined as 'inadvertently coming to rest on the ground, floor or other lower level, excluding intentional change in position to rest in furniture, wall or other objects' (2). Giving a definition when conducting falls prevention studies is important because the definition might differ from that used by older adults. For instance, older adults describe a fall as loss of balance, while health care professionals often define it as something that leads to an injury or ill health (63). Different studies have examined the incidence of falls and have found that globally, approximately 30% of older adults over 65 experience at least one fall yearly (29, 64, 65). The incidence increases with age and level of frailty (2). For those over 80 the incidence increases to above 50% (12).

Home care recipients report falls more often than the general population of older adults. In a study carried out in Australia, 58% of home care recipients had experienced a fall in the previous 12 months, and 26% had fallen twice or more (66). A study of home care services carried out in Norwegian municipalities showed that 17% of the participants had experienced at least one fall in a 3-month period and 34% had injuries from the fall, ranging from bruises to fractures that required hospitalisation (67). In Canada, a study measuring falls in a 3-month period showed that 27% of the participants had experienced one or more falls and 10% had experienced multiple falls (two or more) (68). The discrepancy in incidence could be explained by differences in the populations receiving home care. The population of home care recipients in Canada might be frailer.

Falls occur most often because of complex interactions between different risk factors. There might potentially be hundreds of risk factors for falls. These can be categorised in different ways, but they can broadly be divided into intrinsic and extrinsic causes (69). Figure 1 shows the interplay between the different risk factors—behavioural, biological, environmental and socioeconomic—and falls and falls-related injuries (2). In a recent systematic review, impaired balance and walking, polypharmacy and a history of previous falls were identified as the major risk factors (30). Other risk factors reported in the study were advancing age, female sex, visual impairments, cognitive decline (especially attention and executive dysfunction), and environmental factors.

In older home care recipients, the incidence of falls correlates with the amount of services an older adult receives (70). Home care receivers who have experienced falls are characterised

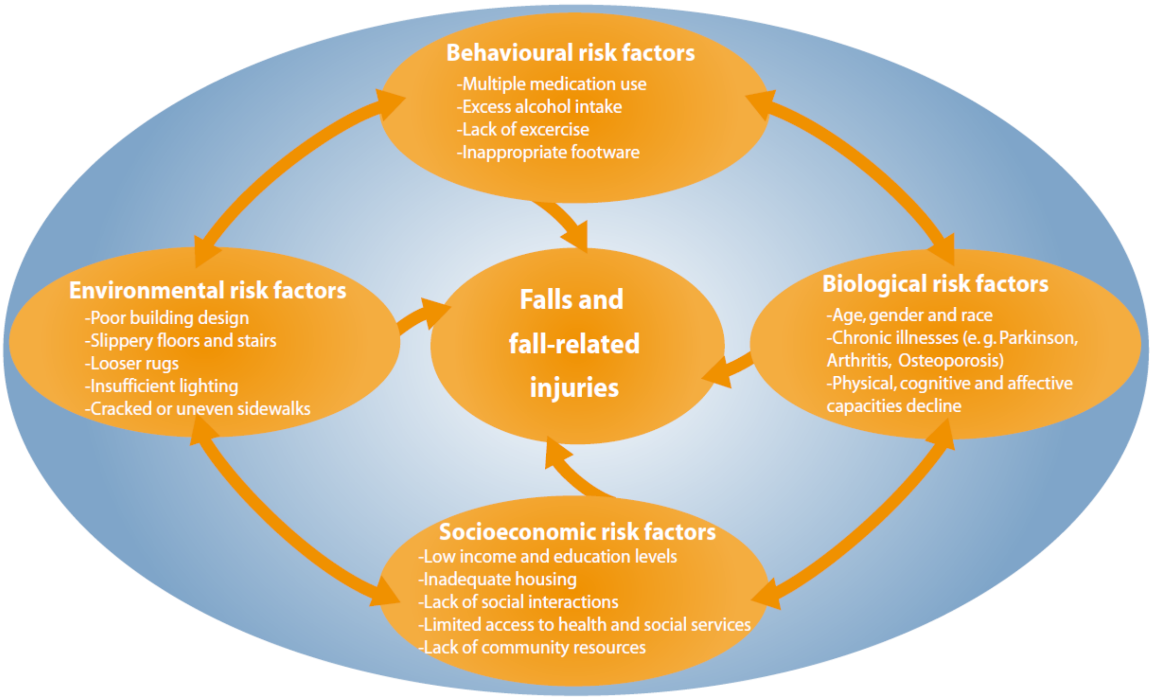

Figure 1. Risk factor model for falls in older adults (2)

by having comorbidities of neurological and cardiovascular impairment, having more medications prescribed, and having experienced almost three times the number of falls prior to home care admission compared to those without falls (71). In addition, requiring functional assistance (66) and reporting a higher level of fear of falling leading to activity restrictions (36) are falls risks in this population. In a study conducted in Sweden, which included people living in senior citizens apartments, most of the falls reported occurred indoors in the residents' own apartments and when they were engaged in activities such as walking, standing or rising/sitting down (72). It is likely that impairments related to ADL difficulties and the need for home care are also connected to the risk of falls.

Falls have serious consequences, contribute significantly to the global burden of disease (73), and impose a substantial burden on health and social services (74, 75). The mean cost of falls has been calculated to be US $3,476 per faller, US $10,749 per injurious fall and US $26,483 per fall requiring hospitalisation (76). Falls lead to 20%-30% of mild to severe injuries and are an underlying cause of 10%-15% of all emergency room visits (32, 75). In a study of home-dwelling older adults in Norway, falls resulted in a fracture in 13.4% of the women and in 16.2% of the men (77). Of the hospital admissions due to falls, 89% were due to fractures, with half of those fractures being a hip fracture (78). Community-dwelling older fallers who present in the emergency room also have a high risk of future falls and fractures (79). Furthermore, falls have longer-term economic consequences, leading to inpatient rehabilitation (32, 80) and causing up to 40% of all nursing home admissions (81).

In addition to the consequences for the health care system and for society, there are also considerable consequences for the faller and the faller's family. Older fallers appear to have markedly increased mortality compared to non-fallers (82). Moreover, falls are one of the main causes of longstanding pain, functional impairment, disability and reduced life satisfaction in older adults (28, 34). Even without causing an injury, falls can cause loss of mobility, confidence and functional independence (30). Finally, falls and the fear of falling have a strong negative influence on QOL and HRQOL, both for the faller and the faller's relatives (34, 66, 83, 84). Caregivers of home care recipients at risk of falling have reported a high care burden, depression, multiple health problems and reduced QOL (66).

2.2 Function in community-dwelling older adults

In the following paragraphs, the terms physical function, mental health, falls self-efficacy and frailty in older adults will be explored. The ICF will be introduced as a theoretical framework for determining the functioning of older adults. This framework is relevant to both older adults in general and to fallers and home care recipients, which is the focus in this research project. Falls and ageing are complex and multidimensional health conditions affecting all factors included in the ICF (85). Due to the lack of literature specifically focusing on older home care recipients and fallers, literature including the general population of community-dwelling older adults has also been included.

2.2.1 The International Classification of Functioning, Disability and Health

The ICF is a framework that can be used to organise and document information on functioning and disability (1, 86). This model is presented in Figure 2. In the context of healthy ageing, this framework has been acknowledged as an appropriate tool to facilitate disease prevention and health promotion for older adults (87). In ICF, functioning is conceptualised as dynamic interactions between a person's health condition, environmental factors and personal factors (1, 86). ICF is thus a multidimensional model with a biopsychosocial grounding. According to ICF, functioning and disability include body functions, body structures, activity and participation. Body functions are defined as the physiological and psychological functions of body systems,

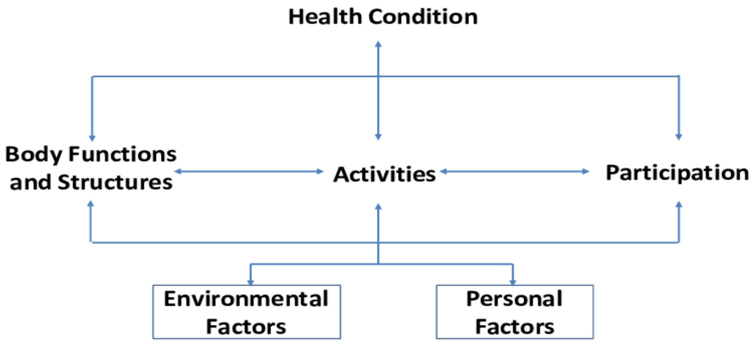

Figure 2. ICF model showing the interactions between the different factors (1)

and body structures are defined as the anatomical parts of the body. Activity is defined as the execution of a task or action, and participation is defined as involvement in life situations. In addition, there are environmental and personal factors that are influenced by and that influence the factors mentioned above. Environmental factors constitute both the physical, social and attitudinal environment in which people live, and personal factors constitute the influences on functioning that are specifically related to a person. The ICF can be used in both a clinical setting to set goals or to evaluate the outcomes of interventions and in health policy to facilitate planning, monitoring and resource allocation (88).

Since the development of the ICF, the model has been evaluated for use in different populations and in different settings. ICF can be utilised for all age groups and has been acknowledged as a useful model when working with older adults (89, 90) and when dealing with falls (91-93). Ageing is a complex health condition potentially demanding cooperation between various professions, and this model constitutes 'a unified language' that enables the sharing of health information across professions and across the different levels of the health care system (94-96). In physiotherapy practice and research, the ICF has been recognised as a useful tool in the whole process of patient management to be able to provide holistic treatment in cooperation with other health care providers (97, 98). One of the recognised positive aspects of this model, is the change in focus when it comes to disability, where the focus is on how people live with their condition rather than on the disease or mortality (99). However, one challenging element, especially when working with frailer older adults, might be that there are many prerequisites to be able to benefit from enabling environments (100). For instance, benefiting from an enabling environment might demand good cognition or good vision, which many older adults with disabilities do not have. Another element of discussion is that this tool facilitates what clinicians and researchers are supposed to measure, but it does not facilitate how to measure the different factors (101). The ICF was used to categorise the different outcomes applied in this research project, which are presented in Table 5.

2.2.2 Physical function in older adults

In this PhD thesis, older home care recipients experience the impact of changes in physical function in the course of ageing. Physical function is a broad term that can be defined as the capacity of an individual to carry out the physical activities of daily living, and it reflects motor control, physical fitness and habitual physical activity (4). In the present study, outcome measures encompassing walking speed, muscle strength, balance, ADL function and level of physical activity were included to assess the physical function of the participants. Nutrition was also assessed due to the importance of this factor in relation to exercise in older adults.

The ageing process can lead to a reduction in functional fitness, muscle strength, balance, walking speed, physical activity level and ADL functioning (102-105). These physical factors are important for mobility, typically defined as the ability to perform functional tasks, such as walking, climbing stairs or rising from a chair (106). Mobility is essential for older adults to live actively and independently and is further linked to health status and QOL (107). The decline in physical function leading to functional impairments, such as the reduced ability to walk, balance abnormalities and low activity level, are also the main causes for falls in older adults (108). Preventing decline and maintaining physical function in older adults is therefore of great importance (109).

The ability to walk is essential for recreational and domestic activities, and walking can be classified as both activity and participation in the ICF categories (1). Walking is one of the most recommended, preferred and prevalent activities and is easy to incorporate into everyday life and to keep up into old age (110). Both recreational and utilitarian walking have been widely recommended to older adults to improve balance, muscle strength and general health and thus to reduce the risk of falling (111, 112). Walking and balance disorders are common in older adults and are predictors of morbidity and mortality, as well as a reduced level of function (103). Walking speed decreases with age, and the maximum walking speed more than the usual walking speed (113). Assessing walking speed is therefore relevant to monitor functional status and overall health and to further estimate the future risk of hospitalisation for older adults (114-116).

Maintaining muscle strength and balance is essential to improve walking ability and prevent falls in older adults (117, 118). Balance is an important predictor of long-term well-being in older adults (119). A decline in balance can be due to different factors, such as degeneration of the visual or vestibular sensory systems, degeneration of proprioception, impairments of central processing or a combination of these factors (120). Several studies have shown that lower extremity muscle strength is an essential factor associated with balance impairments in older fallers (121). Muscle weakness and asymmetry is prevalent in older adults, with and without a history of falls (104). The reduction in maximal strength in older age is a result of a combination of loss in muscle mass and neural control (122). Maintaining lower extremity muscle strength is important to prevent and delay the onset of disability, frailty and dependency in older age (123). Assessing muscle strength in this population is therefore of importance to be able to predict disability (124).

Both physical activity level and ADL function decline with age (102, 105). The reduction in physical activity level seems to be equal for both men and women, and the difference in the level between the youngest (60-69) and the oldest (70-80) members of the older adult population seems to be caused by a reduction in muscle strength, flexibility, agility and endurance (102). When it comes to physical function related to ADL, it has been shown that across Europe IADL limitations are becoming more apparent in older adults (105). Although there is an improvement in health with respect to a decrease in ADL limitations, the level of IADL has not improved over the years.

In addition to muscle strength, nutrition plays an important role in maintaining muscle mass when older adults experience a decline in muscle mass (125). The prevalence of malnutrition is generally high in older adults, but it depends on the population studied (126). Globally, the general prevalence has been shown to be 22.8%, but there were differences between settings. The prevalence was 50.5% in a rehabilitation setting, 22.8% in a hospital setting, 13.8% in a nursing home setting and 5.8% in the community. A study carried out in Finland showed that in a group of home care recipients aged 75-94, 3% were malnourished and 48% were at risk of malnourishment, according to Mini Nutritional Assessment (MNA) scores (127). A similarly high prevalence was found in a population of home care recipients in Australia, which highlights the vulnerability of this group and the need for nutritional screening and interventions to address nutritional issues (128).

2.2.3 Mental health and falls self-efficacy in older adults

Mental health is related to mental well-being, and is an integral part of overall health (129). Our ability to think, express ourselves, interact with other people and appreciate life is based on mental health, and therefore it is essential to promote mental well-being in all groups in society. At all ages, mental health is determined by biological, psychological and social factors. In this PhD project, older adults with cognitive decline, indicated by an MMSE score below 23, were excluded from the study due to safety reasons. The term cognition includes general intellectual ability, memory, language, visual-spatial skills, perception and complex problem solving (130). A certain level of ability in these skills was necessary to be able to safely perform the self-training exercise programme described in this study. Therefore, considering mental health is important when dealing with older adults who have experienced falls. Cognitive impairments have been identified as important risk factors in falling, and an MMSE total score below 26 (global cognitive impairment) indicates a moderate to high risk of serious fall-related injuries (131). Moreover, this frail older population has a risk of developing future cognitive impairments. In the general population of older adults, cognitive impairments (including dementia) represent a growing worldwide public health problem, and the prevalence found in studies including older adults is 10%-22% (132, 133). Performing physical activity can prevent a decline in cognitive function, and moderate to high physical activity level has been associated with a reduction in the incidence of cognitive impairment (134). In older adults, improving physical activity and fitness has been shown to enhance brain health and cognition (135).

Fear of falling or low falls self-efficacy is another element which has been shown to have a large impact on both the risk of falling and activity level in older adults (36, 136). Fear of falling is referred to as a person's loss of confidence in his or her ability to balance, and falls self-efficacy or being afraid of falling is generally used in the literature to describe this concept (137). Older adults with a fall history have a lower degree of falls self-efficacy (138). Moreover, older adults with poor fall-related self-efficacy experience a greater decline in the ability to perform ADL and have a lower level of HRQOL (136, 139). The feared consequences of falling are loss of functional independence and damage to identity, which are associated with the avoidance of activity in both the short and longer term (140). This underlines the importance of the relationship between falls self-efficacy and physical function, where low falls self-efficacy often leads to the avoidance of activities, which in turn can have a negative impact in terms of increasing physical frailty and the risk of falling in older adults (141).

2.2.4 Frailty in older adults

The terms 'frail', 'frailty' and 'pre-frail' are often used in literature on home care recipients, fallers and other vulnerable older adults. These terms have also been used in this PhD project. Frailty can be defined as a state of increased vulnerability to poor resolution of homoeostasis after a stressor event, which increases the risk of adverse outcomes, including falls, delirium and disability (6). Physical frailty, specifically, is defined as a medical syndrome with multiple causes and contributors that is characterised by diminished strength and endurance and reduced physiologic function that further increase an individual's vulnerability to developing increased dependency and/or death (142). Frailty is a long-established clinical expression that implies a concern about an older adult's vulnerability (143). In older adults over 65, the prevalence of frailty has been shown to range from 7%-16.3% (144). Frailty is increasingly seen as an important factor in ageing, and clinicians and researchers are currently employing multiple instruments; however, there needs to be standardisation (145). In light of the high prevalence of frailty and its potential reversibility, it is important to make reducing disability in this population a clinical priority (144).

2.3 Health-related quality of life

HRQOL represents those elements of QOL that directly relate to an individual's health (146, 147). The use of this concept is fundamental in health care in that it recognises the effects of illness (148), evaluates treatment (149) and facilitates resource decisions (150). HRQOL is a sub-set of the overall concept of QOL, and these two concepts are closely related (151). HRQOL in older adults has increasingly been emphasised as an important focus and outcome in public health policy and research (9, 25). In this research project, HRQOL has been selected as the main outcome. The definition HRQOL is explained in the paragraphs below. Further, HRQOL as a measure for older adults and the anticipated relationships between HRQOL, physical function and falls self-efficacy in older adults are explored.

2.3.1 Defining health-related quality of life

The term HRQOL is broadly discussed, and many definitions do not sufficiently differentiate the term from QOL (152). One definition refers to HRQOL as how health impacts an individual's ability to function and his or her perceived well-being in the physical, mental and social domains of life (153). Another way of defining HRQOL is that the term encompasses the impact of health, illness and treatment on QOL and excludes aspects that are unrelated to health, such as cultural, political and societal factors (154). HRQOL is a measure of the self-perceived health status of a person, and it combines objective functioning with subjective well-being (15, 152). This outcome has increasingly been utilised in evaluating medical treatments and preventative interventions, to describe populations and in clinical practice (155).

2.3.2 Health-related quality of life in older adults

Measuring HRQOL in older adults with chronic conditions can be helpful to support user management and to evaluate the services for this group (156, 157). More specifically, HRQOL is relevant to assess disease progression, satisfaction with care, the quality of services, the effect of treatment and the appraisal of health (158). Assessing HRQOL in older adults can help predict hospitalisation and mortality (159). However, there is an issue with this measure when assessing changes over time, namely the response shift phenomenon, which involves changing internal standards, values and the conceptualisation of QOL with time (160). When assessing changes in QOL , a person's QOL rating can respond to changes in illness and the treatment of other sudden life events (158). In an intervention study, for instance, other mechanisms than those directly connected to the intervention might influence a person's perceived QOL at a certain time point, further impacting the outcome of the study.

Older adults with chronic conditions or who have experienced falls generally report a lower level of HRQOL compared to healthy older adults (34, 161, 162). Pain, depression and a decline in physical function have been acknowledged as contributing factors to a decrease in HRQOL in older adults at risk of falls (161). In fallers, the decline in physical HRQOL has also been shown in the longer term when measured over a period of 6 years (34). A recent Norwegian cohort study of the general population of older adults aged 70-80, showed a decline in all the elements of HRQOL compared to younger age groups (163). However, the level of HRQOL in this age group has remained relatively stable over the past two decades, which might be due to an increase in healthy life years or the emphasised focus on health promotion in community-dwelling older adults (45, 164). Some factors have been shown to be important in improving QOL in older adults. These factors are having social relationships, living at home, engaging in leisure activities, having a role in society, having good health and mobility, retaining independence and control over one's life and having a positive psychological outlook (165).

2.3.3 Associations between health-related quality of life, physical function and falls self-efficacy

Older adults who have experienced falls have lower HRQOL compared to non-fallers (83, 139, 166). Multimorbidity, which is common among older adults and fallers, also has a negative impact on HRQOL (167). Both physical and mental health have been shown to be associated with the level of HRQOL in different populations of older adults (161, 168, 169).

HRQOL is influenced by different aspects related to physical functions including mobility, the level of physical activity and physical fitness (170-172). Several cross-sectional studies have shown a consistently positive association between self-reported physical activity and HRQOL (168). Attaining the recommended levels of physical activity seems to be of importance for HRQOL independent of age, race or sex (173, 174). More specifically, doing leisure-time physical activity is related to better scores on The Short Form 36 Health Survey (SF-36) in terms of physical functioning, social functioning and mental health, while the number of hours in sedentariness is related to lower scores (170). When it comes to mobility, having good balance, strength (119, 169) and walking ability (175) seems to affect HRQOL positively. Even in frailer older adults recently discharged from hospital, engaging in physical activity and having higher levels of physical fitness have been shown to be vital for their HRQOL (171).

Mental health, including the fear of falling, influence the level of HRQOL in older adults (139, 176). Older adults with higher levels of fear of falling most likely have poorer HRQOL (177). In a systematic review including cross-sectional studies, most studies found an association between fear of falling and HRQOL, and this association was independent of the conceptualisation of fear of falling (176). When exploring falls-related self-efficacy and its relationship to HRQOL in more detail, it seems to have a particular impact on the sub-scales of SF-36 concerning physical function and bodily pain (136). However, even though the association is independent of other important variables, there might be additional factors, such as risk-taking behaviour and psychological aspects, that can partly explain the association (178). Having acceptable physical and mental health is critical for older adults to be able to live independently in the community, and any decrease in this ability has a great impact on their HRQOL (179). Therefore, health care interventions with the aim of maintaining or improving physical and mental health in older adults are of great importance for HRQOL (9). Finally, studies including cross-sectional data exploring associations, such as presented in this section, are limited by their design, and causal relationships cannot be established (16).

2.4 Interventions to prevent falls and improve health-related quality of life in older adults

Older adults who are receiving home care and who have experienced falls commonly have health conditions requiring complex interventions. Complex interventions have been conceptualised as activities with components that might interact and produce a range of possible and variable outcomes in a target population (3, 180). Planning, designing and implementing complex interventions is highly demanding, and if some important stages are neglected, the overall effect of the intervention on the outcome might be limited (181). To improve the quality of falls research, international researchers have reached a consensus in recommending a common set of measures that can be used in clinical trials for older adults (13). In the following paragraphs, selected recent systematic reviews evaluating multifactorial and multiple component falls prevention interventions, are presented. Moreover, as the focus in this research project is on the application of the OEP and on the effects on HRQOL, the literature investigating these specific topics will be explored in more depth.

2.4.1 Multifactorial and multiple component interventions to prevent falls

Several systematic reviews and policy guidelines recommending and evaluating falls prevention interventions have been published in recent years. An overview of selected systematic reviews and meta-analyses is presented in Table 1. This selection was motivated by the high quality of the material and its relevance for this PhD project. In addition to reviews of quantitative studies examining effectiveness, there are also a vast number of qualitative reviews looking at both the implementation of falls prevention interventions and the experiences of older adults and clinicians. These were not included in this specific section due to the overall aim of this PhD thesis, which was primarily to study the effectiveness of a falls prevention exercise intervention on HRQOL. However, some qualitative clinical studies and reviews have been included in the discussion chapter. The literature on falls prevention for older adults is comprehensive, and it has been suggested that the evidence base is changing faster than guidelines can be developed. Guidelines can rapidly become out of date (182). Nevertheless, building awareness of the importance of falls prevention and evidence-based interventions is important to reduce the number of falls in older adults (2).

Multifactorial interventions comprising, for example exercise, home safety adjustments and medication evaluation can be beneficial in reducing the number of falls and the risk of falling compared to usual care or attention control (11, 183-186). However, exercise as a single intervention seems to be the most effective in preventing falls in older adults and also from a cost-efficiency and public health perspective (187, 188). Exercise can reduce the risk of all falls (both less severe and injurious falls) resulting in medical care (189). Falls prevention focusing on exercise can also lead to improvements in physical activity, balance, mobility and muscle strength (190). Moreover, to be able to reduce the fear of falling it seems to be necessary to design the exercise interventions specifically to improve falls self-efficacy (191, 192). However, a systematic review by Zijlstra and colleagues (193) suggested that falls prevention interventions not necessarily aimed at fall self-efficacy could also result in a reduction of the fear of falling. One explanation for the relationship between exercise and falls self-efficacy might be found in the social cognitive theory by Bandura (194-196). This theory states that the beliefs in personal efficacy affects emotional, cognitive and behavioural patterns in several domains of psychosocial and physical functioning. Participating in a falls prevention exercise programme could therefore improve the feeling of mastering when performing activities with a risk of falling and further decrease the level of fear of falling.

Table 1. Selected systematic reviews and meta-analyses reporting falls prevention recommendations for community-dwelling older adults

Reference	Aim(s)	Population	No. included Studies	Outcomes	Recommendations/ Conclusion
Gates et al, 2008	To evaluate the effectiveness of multifactorial assessment and intervention programmes in preventing falls and injuries	Older adults in primary care, community or emergency care settings	19 trials 6397 participants	Falls rate Injuries from falls	Evidence of benefit from multifactorial risk assessment and targeted intervention for falls in primary care, community or emergency care settings was limited and reductions in the number of fallers may be smaller than thought.
Petridou et al, 2009	To compare and quantify the effectiveness of multifactorial versus exercise-alone interventions in reducing recurrent falls	Community-dwelling older adults	10 trials 2549	Falls rate Risk of falls	Interventions aiming to increase muscle strength, balance and mobility through physical exercise can be equally or even more effective compared to more complicated and long-lasting multifactorial interventions.
Thomas et al, 2010	To evaluate the effect of the OEP on the risk of death and fall rates and to explore levels of compliance with the OEP	Community-dwelling older adults	7 trials 1503 participants	Risk of death Falls rate	OEP reduces the risk of death and falling. Significant results were achieved with compliance to the programme two times per week.
Gillespie et al, 2012 Cochrane	To assess the effects of interventions designed to reduce the incidence of falls	Community-dwelling older adults	159 RCTs 79193 participants	Falls rate Risk of falls	Group and home-based exercise programmes and home safety interventions reduce the rate of falls and the risk of falling.
Sherrington et al, 2016	To assess the effect of exercise on falls prevention	Community-dwelling older adults	88 trials 19478	Falls rate	Exercise as a single

	and to explore whether the characteristics of the trial design, sample or intervention are associated with greater fall prevention effects				intervention can prevent falls in community-dwelling older people. Exercise programmes that challenge balance and are of a higher dose have larger effects.
Hopewell et al, 2018	To assess the effects (benefits and harms) of multifactorial interventions and multiple-component interventions on preventing falls in older people living in the community	Community-dwelling older adults >65	62 trials 19935	Falls rate	Multifactorial interventions may reduce the rate of falls compared with usual care or attention control. There may be little or no effect on other fall-related outcomes. Multiple- component interventions, usually including exercise, may reduce the rate of falls and the risk of falling compared with usual care or attention control.
Sherrington et al, 2019	To assess the effects (benefits and harm) of exercise interventions in preventing falls	Community-dwelling older adults >60	108 RCTs (23407 participants)	Falls rate Number of people experiencing falls	Exercise programmes that reduce falls primarily involve balance and functional exercises

Exercise programmes aiming at preventing falls should incorporate balance and functional strengthening tasks, which are challenging and have a higher dose regarding intensity and frequency (117, 187, 197). Walking training can also be included, but brisk walking should not be recommended for high-risk individuals (198). In Cochrane reviews published before the start of the PhD project, a dose of at least two hours weekly was recommended (198). However, in recent reviews from 2016 and 2019, a dose of at least three hours weekly is recommended (117, 187). The exercises could be carried out in a home setting or in a group setting and should be targeted both at the general community and at those with an increased risk of falling (12, 198). Importantly, the exercises seem to be safe, as the adverse events most commonly reported are non-serious (117). In frailer older adults, the main focus of exercise programmes aiming at preventing falls, should be on maintaining the activity level in the longer term to prevent any decline in physical function (199-201). Studies have shown that exercise interventions can have positive effects on balance, mobility and falls frequency in frailer older adults in the longer term (202-204). More research is needed on the effect of exercise as a single intervention in the frailer group of older adults, such as people receiving care or living in care facilities (187), and on the implementation of exercise recommendations in clinical practice (121). In the next paragraphs, the OEP will be introduced and discussed, as this was the intervention evaluated in this PhD project.

2.4.2 Otago Exercise Programme

The Otago Exercise Programme is a result of several years of research about identifying falls risk factors and testing potential interventions, and it was designed specifically to prevent falls in older adults (205). The programme consists of exercises for leg muscle strength and balance that progress in difficulty and a walking plan. A trained instructor individually prescribes all exercises during five home visits. An overview of important clinical studies evaluating the OEP is presented in Table 2. More details on the intervention are described in the methods section in Chapter 3.

Table 2. Clinical studies testing the effect of Otago Exercise Programme in community-dwelling older adults

Study	Participants	Trial design	Follow-up (months)	Main outcome measures	Effects between groups
Campbell et al, 1997	N = 233 Females only Primary care >80 years	RCT Home-based exercise Usual care	12	Falls Injuries from falls Muscle strength Balance	Yes Yes Yes, in one of the tests Yes
Campbell et al, 1999	N = 93 Taking psychotropic medications >65 years	RCT two interventions Taking medications/gradual withdrawal Home-based exercise/no exercise	10	Falls Falls risk	Yes, gradual withdrawal medication No, exercise
Robertson et al, 2001	N= 240 >75 years	RCT Home-based exercise Usual care	12	Falls Injuries Costs of implementing the programme Hospital costs	Yes Yes Yes Yes
Robertson et al, 2001	N = 450 >80 years	Controlled trial Home-based exercise (nurse delivered) Usual care	12	Falls Injuries Costs of implementing the programme Hospital costs	Yes Yes Yes Yes
Campbell et al, 2005	N = 391 Severe visual impairment >75 years	RCT (four arms) Home safety programme Home-based exercise programme and vitamin D supplement Both interventions Social visits	12	Falls Injuries Costs of implementing the programme	Yes, home safety No, exercise Yes, home safety
Liu-Ambrose et al, 2008	N= 59 Falls clinic	RCT Home-based exercise	6	Falls risk Mobility	No No

	>70 years	Usual care		Executive function	Yes
Kyrdalen et al, 2014	N = 125 Falls clinic >65 years	RCT Home-based exercise Group exercise	6	Balance	Yes, group exercise
Lliffe et al, 2014	N = 1256 Primary care >65 years	Cluster RCT FaME group exercise OEP, home-based Usual care	6	Reaching recommended PA level (150 minutes weekly) 12 months after cessation	Yes, in FaME group

N: number; RCT: randomised controlled trial; OEP: Otago Exercise Programme; FaME: Falls Management Exercise

Several studies have tested the OEP with different durations and participants. A systematic review including seven trials of the OEP showed that this programme reduces the risk of death and falling in community-dwelling older adults (206). The programme was also effective in improving physical function and reducing falls and injuries when tested in women 80 and older over a 12-month period (207). However, the benefit was greater in those who fell more often. This result was confirmed in a later study that showed the programme was most effective in reducing falls-related injuries in those aged 80 or older and in those with a history of falls (208). It also showed that the programme was equally effective for women and men. Strict adherence to the exercise programme has proved to be important to reduce the number of falls (209). In addition, conducted as a 3- or 6-month intervention the programme has shown to be effective in improving some functions in older adults (210-212). Liu-Ambrose and colleagues (210) carried out an intervention lasting six months and showed that the OEP improved executive function in older adults referred to an outpatient falls clinic. In another study, the programme was carried out for 3 months, and the participants performing the OEP at home improved their HRQOL and walking speed (212). Additional group training had greater effects on mental health. A study by Kyrdalen and colleagues (211) showed that group training did not have a greater effect on mental health and falls self-efficacy compared to home exercise. Nevertheless, those performing group exercises had greater improvements in functional balance, muscle strength and physical health. Finally, the programme has been cost-effective both when conducted by physiotherapists and by trained nurses for community-dwelling older adults (213).

Other studies have compared the OEP to alternative interventions and have been unable to show an effect of the OEP. When compared to the gradual withdrawal of psychotropic medication, performing exercises did not influence the risk of falls (214). However, the number of participants in this study was small and the results must be interpreted with caution. Compared to a home safety programme, the OEP was less cost-effective and less effective in reducing falls (209). The target population was older adults with poor vision, and the self-management design of the OEP might have been too demanding for this group, thus resulting in reduced adherence. When compared to another falls prevention intervention Falls Management Exercise (FaME), OEP was less effective in reducing falls in the longer term (215). However, in this study the sample was older adults who were functionally more able and the OEP might have been too easy to be able to cause any difference. Nevertheless, both falls prevention interventions appears to be safe, with no significant differences in adverse events (216).

2.4.3 Interventions to improve health-related quality of life

The results of studies investigating the effects of falls prevention interventions and exercise on HRQOL and QOL in older adults are inconclusive. In a systematic review including 12 studies, six showed positive effects of falls prevention interventions on some domains of QOL, namely physical function, social function, vitality and mental health (38). Similar results were demonstrated in a study exploring the effects of falls preventative exercise compared to other interventions in older people who had recently fallen (217). When looking at sex differences, men in particular seem to benefit from falls prevention when the outcome is HRQOL (218). Other studies have conducted exercise interventions for older adults who were recently hospitalised or who were in a rehabilitation setting and showed positive changes in QOL following group exercise (219, 220). However, studies evaluating the impact of exercise interventions on QOL in a group of frail older adults have not shown any positive changes (201, 221). Even though improvements in some physical functions were demonstrated, the level of HRQOL did not change (222). If gains in HRQOL have been shown following exercise, most often they are in the physical sub-domains of HRQOL (223, 224). The different results might be partly due to the measurement tools used to assess QOL or HRQOL, which can have insufficient responsiveness when employed in the different study populations.

An important aim of home care is to improve or prevent a decline in HRQOL to enable older adults to remain at home, and effective interventions are of great importance (33, 47). There is limited literature exploring the effect of falls prevention exercise interventions on HRQOL in older home care recipients. However, one RCT study comprised a multifactorial falls prevention intervention for older home care recipients and showed improvements in QOL, especially in emotional health (225). Another study that explored the effects of a self-management exercise intervention for older home care recipients did demonstrate positive gains in ADL and walking speed, especially among good compliers (226). Even though they did not measure HRQOL specifically, improvements in ADL further enabling the older adults to manage their everyday lives could have positive effects on HRQOL (59). Similarly, the characteristics of the exercise programme emphasising self-management and mastering could lead to gains in QOL

(227). Finally, tailoring the interventions to meet older adults' needs is important to help them live independently at home with good QOL (228).

There are different ways of explaining why exercise may improve HRQOL. Understanding what may cause changes in HRQOL has important implications when designing, implementing and promoting exercise programmes (229). Exercise can affect HRQOL through mediators, which can be defined as intervening causal factors (230). The mediating factors can be either physiological, such as balance or strength, or psychological, such as falls self-efficacy (231). Other mechanisms are moderators helping us understand for whom the intervention is beneficial (231). The characteristics of a person or group, such as the participants' health, or the characteristics of the exercise procedure, such as exercise intensity, could moderate the effect of exercise on HRQOL.

2.5 Evaluating falls prevention interventions in older home care recipients

When conducting studies where interventions for older adults are carried out, it is important to evaluate the effect or the efficiency of the intervention to inform clinicians, health managers and policy makers (232). HRQOL is a patient-centred outcome measure (PROM) that can be used to develop data on health status and to conduct cost-benefit or cost-effectiveness (or cost-utility) analyses (233). In the following paragraphs, the applicability of two common HRQOL utility measures, the Short-Form Six-Dimension (SF-6D) and the EuroQol- EQ-5D-5L (EQ-5D), employed when performing economic evaluations, will be introduced, as this was the final focus in this PhD project. The intention behind performing economic evaluations of falls prevention interventions will be discussed first.

2.5.1 Economic evaluation of falls prevention interventions

Falls have major consequences for older adults and society and contribute considerably to the global burden of disease (9, 28, 34). The costs for the health care system are extensive and derive directly from injurious falls in those at high risk and from rehabilitation for those at moderate or lower risk (32, 80, 234). Davis and colleagues even suggest that the economic cost of falls is greater than policy makers acknowledge (76). Falls, fractures and the fear of falling have a negative effect on HRQOL, which in turn impacts the use of health care resources (84). Effective interventions to prevent falls and improve HRQOL in older adults are therefore of importance, and evaluating the effectiveness of the interventions is essential. Several studies have shown that well-designed community-based falls prevention interventions for older adults are highly cost-effective (235, 236). The reduction in costs is even greater than the costs of implementing and conducting such programmes in health care system (237). However, other studies have not been able to show that falls prevention interventions are cost-effective, at least not for all older adults (238, 239). Including an economic evaluation in falls prevention research studies is therefore necessary to be able to inform health policy when planning health services for older adults. If the interventions are evaluated as effective, it would be important to implement these services to decrease the incidence of falls and to decrease health care costs (74).

2.5.2 Health-related quality of life measures evaluating the effectiveness of interventions

HRQOL is an important outcome in evaluations assessing the effects of health care and policy interventions for older adults (40). The SF-36 and the EQ-5D are two of the most commonly used generic measures of HRQOL (240). These assessments are both PROMs, which are standardised and validated questionnaires completed by patients to measure their perceptions on their functional status and well-being (241, 242). The purpose of PROMS is to assess effectiveness of treatments and to assess patients' perspective of care outcomes (243). In previous research, PROMs have been associated with improved symptom control and patient satisfaction (244).

Preference-based utility indexes of SF-6D and EQ-6D can be calculated based on the SF-36 and EQ-5D questionnaires, and these can be employed in economic evaluations (245). Because these utility indexes are based on the questionnaires, the psychometric properties of SF-36 and EQ-5D are of importance to secure internal validity. There is good evidence for both SF-36 and EQ-5D in terms of reliability, validity and responsiveness in older adults (240, 246). However, EQ-5D is recommended when a briefer assessment is required, while SF-36 is recommended when a more detailed assessment is required (240). The brief design of EQ-5D might explain why the response rate has been shown to be higher for this instrument compared to SF-36, especially among those who are older and who have co-morbidities (247). However, the focus on mental health is not as great in EQ-5D as in SF-36 (248). Moreover, SF-36 seems to have an advantage in terms of sensitivity, especially in the lower levels of morbidity (249).

Previous research has demonstrated both similarities and differences between EQ-5D and SF-6D in various populations. The differences and similarities between the two measures should be considered, as the choice of instrument may influence the health care decisions made (172, 250). Both EQ-5D and SF-6D seems to be valid preference-based measures and are able to discriminate between severity sub-groups and to capture changes in health over time (251-253). However, when comparing EQ-5D and SF-6D across seven patient groups, the SF-6D had a smaller range and lower variance in values (254). SF-6D has also proved to be generally less sensitive compared to EQ-5D, especially in relation to physical chronic conditions (255). When evaluated in various populations, SF-6D had floor effects and EQ-5D had ceiling effects (247, 254, 256). Regarding the incremental QALYs estimated from EQ-5D and SF-6D, some studies have shown that the utility gain estimated from SF-6D is substantially greater compared to that estimated from EQ-5D (172, 257). One important factor to explain this difference might be the inclusion of the items 'vitality' and 'social functioning' in SF-6D, which is not explicitly included in EQ-5D (257). However, other studies have found the opposite, where the EQ-5D resulted in higher change scores, greater health gains and a more favourable cost-effectiveness ratio (252, 258). This discrepancy could be due to the characteristics of the population included. It has been suggested that acceptance of the incremental cost utility ratio might differ due to health conditions, where in groups with mild conditions the acceptance of the incremental cost utility ratio was higher when using EQ-5D and in groups with worse conditions the same was applicable when using SF-6D (259, 260). Nevertheless, the impact that this uncertainty regarding the health state values has on the economic evaluations of interventions should be acknowledged in order to provide insight into the policy implications of preference measurement (258).

2.6 Rationale for the thesis

The body of literature on falls prevention for community-dwelling older adults is large and supports exercise interventions as effective ways to prevent falls and improve physical health (12, 117). However, research including the more vulnerable group of older home care recipients and focusing on the impact of evidence-based falls prevention exercise interventions on HRQOL is lacking (26, 38). Knowledge on both the characteristics of this group and effective interventions to improve HRQOL is lacking. Nevertheless, in this increasing population, preventative actions improving HRQOL are of importance to facilitate the healthy ageing of older adults and increase their ability to remain at home.

The health challenges in the group of older fallers receiving home care are typically complex and persistent, and providing them effective interventions while keeping the costs reasonable is challenging for those planning and delivering primary health care services. To ensure healthy ageing for this population, health services should focus on maintaining functional ability to promote QOL both in the short and longer terms (9). However, the literature on interventions promoting HRQOL and knowledge on measures to evaluate these interventions in frailer older adults is limited.

Due to the lack of research on effective falls prevention interventions to improve HRQOL, physical function and falls self-efficacy in vulnerable older home care recipients with falls, this was the main focus of this PhD project. First, the PhD project intended to acquire more knowledge on the characteristics of this group and on the interactions between different characteristics as HRQOL, physical function and falls self-efficacy. A second goal was to explore if a widely used and well-documented falls prevention intervention could benefit this population in terms of improving their HRQOL, physical function and falls-self efficacy both on shorter and longer term. Third, the PhD project explored if the measures used to assess HRQOL were applicable when evaluating falls-prevention interventions in this population. The information from this research project is expected to be of great relevance to clinicians in planning, developing and implementing falls prevention interventions for home care recipients. In addition, the knowledge can be applied by health managers and health policy makers when setting priorities and developing guidelines in primary care.

3 Aims of the thesis

The overall aim of this research project was to develop new knowledge on falls prevention for older adults receiving home care as a strategy to enable them to remain at home longer. This encompasses competence development of health professionals and providing useful tools for both clinicians and users in falls prevention. More specifically, the aim of this project was to study the effects of a falls prevention intervention on HRQOL, physical function and falls self-efficacy in older home care recipients who had experienced falls. Below follow the aims of each paper.

3.1 Paper I

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; 17(1):559, DOI: **https://dx.doi.org/10.1186/s12913-017-2516-5**.

The aim of this paper was to give an in-depth background to provide a foundation for the development of this research project. Another aim was to give detailed information on the procedures in the project, for instance on assessment and intervention.

3.2 Paper II

Bjerk M, Brovold T, Skelton DA, Bergland A. Associations between health-related quality of life, physical function and fear of falling in older fallers receiving home care. BMC Geriatrics. 2018; 18(1):253, DOI: **https://dx.doi.org/10.1186/s12877-018-0945-6**.

The aim of this study was to describe the baseline characteristics of this population of older home care recipients and fallers. A second aim was to explore the relationships between HRQOL and physical function as well as fear of falling in this population.

3.3 Paper III

Bjerk M, Brovold T, Skelton DA, Liu-Ambrose T, Bergland A. Effects of a falls prevention exercise programme on health-related quality of life in older home care recipients: a randomised controlled trial. Age and Ageing. 2019; 48(2):213-219, doi: **https://dx.doi.org/10.1093/ageing/afy192**.

The primary aim of this study was to examine the short-term effects of a falls prevention exercise programme on HRQOL, physical function and falls self-efficacy in older home care recipients. The secondary aim was to assess the impact of adherence to the falls prevention programme on the possible effects on HRQOL, physical function and falls self-efficacy.

3.4 Paper IV

Bjerk M, Brovold T, Davis JC, Skelton DA, Bergland A. Health-related quality of life in home care recipients after a falls prevention intervention: a 6-month follow-up. European Journal of Public Health, Volume 30, Issue 1, February 2020, Pages 64–69, DOI: **https://dx.doi.org/10.1093/eurpub/ckz106**.

The primary aim of this study was to explore the prolonged effect of a falls prevention exercise programme as a strategy to improve HRQOL, physical function and falls self-efficacy in older home care recipients. The secondary aim was to explore the relative importance of maintain-ing exercise to improve HRQOL, physical function and falls self-efficacy in the longer term.

3.5 Paper V

Bjerk M, Brovold T, Davis JC, Bergland A. Evaluating a falls prevention intervention in older home care recipients: a comparison of SF-6D and EQ-5D. Quality of Life Research. 2019; 28(12):3187-3195, DOI: **https://dx.doi.org/10.1007/s11136-019-02258-x**.

The main aim of this paper was to examine the agreement between EQ-5D and SF-6D when evaluating interventions for older home care recipients. Other aims were to assess the differences and similarities in HRQOL domains covered by the instruments and to assess the instru-ments' responsiveness to changes in physical function over time.

4 Design and methods

In this chapter, the design and methods of all studies included for the thesis are presented and critically evaluated. First, the participants, settings and randomisation procedures will be introduced. Second, the different elements in the intervention and the assessment procedures will be explained. Finally, the statistical procedures and ethical considerations will be described. Table 3 provides an overview of the different papers, the designs and the data collection.

4.1 Design

Paper I

The first paper is a study protocol describing the background, outcomes and intervention in the RCT. Study protocols can be written for both proposed and ongoing clinical research and can reduce publication bias and improve reproducibility (261). The SPIRIT checklist was used when preparing the protocol (262). This protocol paper was published in BMC Health Services Research, a fully citable open-access journal, publicly available to clinicians and researchers.

Paper II

The second paper employed cross-sectional data from baseline measurements of the RCT. The aim was to explore the associations between HRQOL, fear of falling and physical function in older home care recipients. Although interesting associations can be discovered using a cross-sectional design, causal relationships cannot be identified unless all confounding factors are accounted for. Since the sample comprised participants recruited for an RCT potentially performing a falls prevention intervention, these participants might also be different from the general population of older home care recipients. Older home care recipients are, however, an understudied population, and information on their characteristics can be valuable to plan interventions in primary health care. The STROBE guideline was followed to report on the design, analyses and presentation of data (263).

Papers III and IV

The design for these two papers is a single-blinded parallel-group RCT, measuring the short-term effect at the end of the intervention at 3 months and the longer-term effect at a 6-month follow-up. The intervention group performed a falls prevention programme and the control group received health services as usual. The RCT is the gold standard for research experiments and the only design which under reasonable assumptions can establish causal relations (264). The random allocation limits the risk of confounding and increases internal validity (16). In addition, the pre- and post-testing controls for time-related threats to the validity. However, achieving a natural setting is often difficult in RCTs. In most falls prevention research carried out up to today, the design has been more exploratory, where efficacy is measured under ideal conditions. Because the aim in the present study was to evaluate the effectiveness of an evidence-based falls prevention intervention in a clinical setting, the design was more pragmatic. This means that it measures the effectiveness in routine clinical practice as opposed to explanatory RCTs, which measure effectiveness under ideal conditions (265). Recent literature has emphasised the importance of performing falls prevention studies in 'real life' settings to enable implementation (117, 266). Adapting the design according to clinical practice is necessary, for instance, regarding the duration of the intervention and the measurements selected. Reporting followed the CONSORT 2010 statement (261).

Paper V

The design of this study is based on secondary analysis of longitudinal data from the RCT. The analysis can also be categorised as a panel data analysis, as it employs repeated measures from the same sample at different time points (16). The aim was to compare the preference-based utility measures SF-6D and EQ-5D to provide knowledge on the applicability of these two outcomes when measuring HRQOL at certain time points and when measuring changes over time. Reporting followed the STROBE guidelines (263).

Table 3. Overview of the papers included for the thesis

Paper	Design	Data collection
I. 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	Protocol describing background and procedures in depth	No data Description of procedures Information from a pilot of the intervention and assessments, and conversations with physiotherapists, users and managers
II. Associations between health-related quality of life, physical function and fear of falling in older fallers receiving home care	Cross-sectional	Baseline - 155 participants
III. Effects of a falls prevention exercise programme on health-related quality of life in older home care recipients: a randomised controlled trial	Randomised controlled trial with two arms	Baseline - 155 participants 3 months - 138 participants
IV. Health-related quality of life in home car recipients after a falls prevention intervention: a six months follow-up	Randomised controlled trial with two arms, follow-up study	Baseline - 155 participants 6 months - 135 participants
V. Evaluating a falls prevention intervention in older home care recipients – a comparison of SF-6D and EQ-5D	Cross-sectional, longitudinal with three time points	Baseline - 155 participants 3 months - 138 participants 6 months - 135 participants

4.2 Setting

The data collection for the PhD project started in February 2016 and lasted until September 2017. The participants were recruited from home care services in six municipalities in Eastern Norway. Home care was defined as services provided by health professionals to older adults in their own home, such as home nursing, practical assistance or safety alarm services (33, 52). In Norway, the municipalities are responsible for providing home care for older adults. Home nursing and assistance with personal care are free of charge, while practical assistance and safety alarm services have deductibles. Approximately 12% of the Norwegian population in the 67-79 age group receive home care services (35). This increases to 50% in the 80-90-year-old age group and to 90% for those over 90.

The managers in the municipalities were contacted before project start-up, and meetings were held to agree on the conditions for participation, such as the timeline and economic costs. It was agreed that the timeline for the whole project would be 1.5 years and that the project group should cover the expenses for equipment. Further, a small pilot study involving three older home care recipients was conducted to explore the applicability of the exercises and outcome measures. Those participants were not included in the RCT.

4.3 Recruitment

Recruitment was performed by the PhD student and a research assistant in collaboration with managers and coordinators in the health care services. To limit the selection bias of choosing older adults who were more fit and to improve generalisability, the recruitment was done via the telephone using lists of people receiving home care (home nursing, practical assistance or safety alarm service). In the first telephone call, participants were asked if they would like to receive an invitation letter with information about the project. If they agreed, the PhD student or research assistant called them again after approximately one week. The older adults could then ask questions and agree to a home visit for assessment. Written informed consent was obtained at the baseline assessment.

4.4 Participants

The inclusion criteria for the study were receiving home care services, age over 67 (retirement age), having experienced at least one fall in the previous 12 months, able to walk with or without a walking aid and able to communicate in Norwegian. The exclusion criteria were medical contraindications to exercise, life expectancy less than 1 year, an MMSE score below 23 indicating cognitive decline and participation in another falls prevention programme or research trial.

The flow of participants in the RCT is presented in Figure 3. Eight hundred and sixty-five older adults were initially assessed for eligibility. Approximately a third of these people had experienced a fall in the last 12 months, which is in line with previous literature on falls (12). Three hundred and twenty received an invitation letter, and approximately half of those agreed to participate in the study. One hundred and sixty-seven were assessed at baseline and 12 were excluded due to cognitive decline determined by the MMSE. One hundred and fifty-five participants were included in the RCT. The number of participants from each municipality ranged from 19-38. One hundred and twenty-three participants were female and 32 were males.

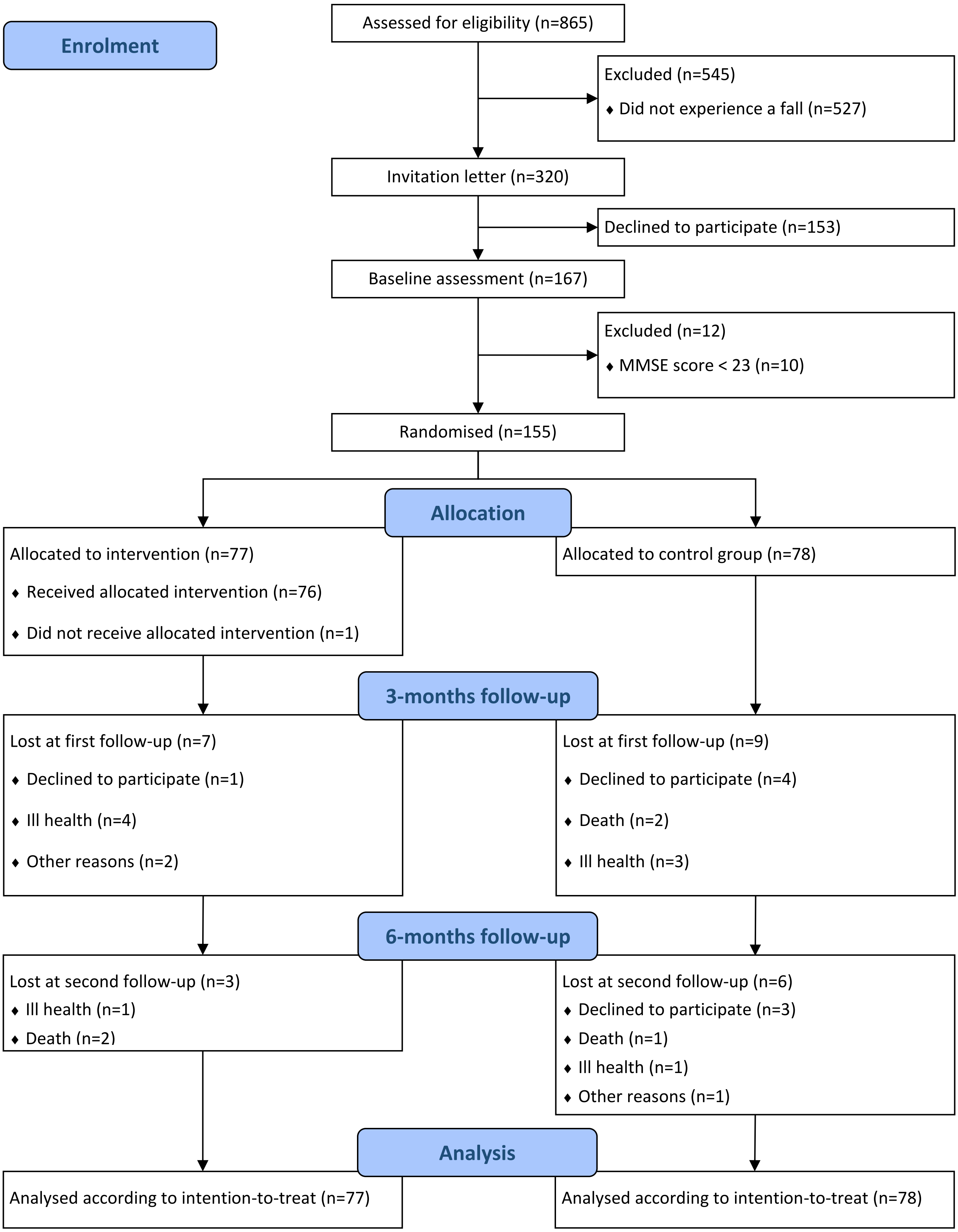

Figure 3. Flow of participants in the RCT; n: number

Seventy-seven participants were allocated to the intervention group and 78 to the control group. After 3 months, seven participants were lost in the intervention group and nine in the control group. Even though some participants missed the assessment at 3 months they were contacted again for assessment at the 6-month follow-up. At 6 months, another three participants were lost in the intervention group and six in the control group. Among the reasons for dropping out were death and ill health. Intention-to-treat (ITT) analyses were performed at 3 and 6 months, and 155 participants were included in the analyses for Papers III and IV. In Paper V, complete case analyses were conducted for the HRQOL outcome measures; 138 completed the assessments at 3 months and 135 at 6 months.

4.5 Randomisation procedure

A computer-generated permuted block randomisation scheme prepared by a statistician was employed to randomise the participants into the intervention group or the control group. Each block contained six subjects of the same sex from the same municipality. The participants were recruited on different days in different municipalities that differed in size. A block randomisation ensured a more balanced distribution of participants from these municipalities into the intervention group and the control group. The research assistants who performed the baseline testing enrolled the participants. The scheme then allocated the participants according to the sequence of enrolment by a double key number concealing the randomisation sequence. Due to practical reasons, the PhD student administered this scheme. A written randomisation manual describing the procedure was distributed to all physiotherapists and assessors participating in the project.

4.6 Intervention

4.6.1 The intervention group

Participants in the intervention group undertook a falls prevention exercise programme based on the OEP (205). Seventeen physiotherapists working for six different home care services conducted the intervention in the participants' homes. The intervention consisted of five home visits where the physiotherapists instructed the participants as to how to perform the exercises for balance and strength and as to the appropriate level and progression of each exercise. The balance exercises comprised tasks such as tandem stance, walking backwards and stair walking. For strengthening exercises, ankle weight cuffs were used to strengthen hip extension and abduction, knee flexion and extension and ankle plantar and dorsiflexion. The programme also included warm-up exercises, such as neck and shoulder movements. Images showing examples of the exercises are shown in Figure 4.

In addition to guiding the exercises, the physiotherapists gave information on falls risks, everyday activity and safety at the first home visit. The participants were expected to perform exercises on their own between the supervised sessions at least three times weekly for at least 30 minutes. If they could not perform exercises for 30 minutes, they could divide the sessions into 10-minute bouts, for instance. The participants were also advised to walk for 30 minutes at least two times weekly if safe. Walking could be carried out indoors or outdoors, depending on the participants' level of frailty, and an appropriate walking aid could be used. The walking sessions could also be divided in shorter bouts. The participants were encouraged to complete an exercise diary reporting the self-training and a falls diary reporting any falls or other adverse events. The physiotherapists assisted them if needed and guided the participants in how they could incorporate the exercises into their everyday lives. Ankle cuff weights, a booklet with the exercises and an exercise diary were provided for each participant. In the weeks between the home visits, the physiotherapists made motivational telephone calls to improve adherence, give guidance and answer questions. The OEP manual does not describe in detail how to motivate the participants or how to conduct the telephone calls; this was up to the physiotherapists to decide. If the participants experienced sudden events, such as hospitalisation or illness, they received up to four extra visits or extra telephone calls. At the end of the intervention, the participants were encouraged to continue exercising until the follow-up assessment at 6 months. If requested, the participants received information on activities in their municipality. An overview of the programme is shown in Table 4. The progression of the exercises is shown in Table 5.

Figure 4. Examples of exercises from the Otago Exercise Programme

Table 4. Content of the falls prevention exercise programme

Week	Activity
1	Home visit Information on falls risk, safety and everyday activity Exercise diary Plan of exercises until next visit
2	Home visit Progression of exercises Exercise diary Plan of exercises until next visit
3	Motivational telephone call
4	Home visit Progression of exercises Exercise diary Plan of exercises until next visit
5	Motivational telephone call
6	Motivational telephone call
7	Motivational telephone call
8	Home visit Progression of exercises Exercise diary Plan of exercises until next visit
9	Motivational telephone call
10	Home visit Progression of exercises Exercise diary Plan of exercises
11	Motivational telephone call
12	Motivational telephone call

Table 5. Progression of exercises

Exercises	Progression
Strengthening	5 repetitions without weight
	5-10 repetitions with weight
	10 repetitions, add weight
	5-10 repetitions
	10 repetitions, add weight
Balance	5-10 seconds hold, with support
	Add another set
	5-10 seconds hold, with reduced support
	Add another set
	5-10 seconds hold, without support
	Add another set

4.6.2 The control group

The control group received usual care from the primary care services. They performed activities and exercises as usual and were recommended to stay active. For instance, if they received treatment from a physiotherapist or participated in an exercise group they continued this activity. However, they could not participate in a falls prevention programme or another falls prevention research trial in the project period. At the end of the intervention at 3 months, the control group was encouraged to stay active until the follow-up assessment at 6 months. If requested, the participants received information on activities in their municipality.

4.6.3 Treatment fidelity

Adherence to the OEP is important to achieve positive effects for the older adults participating (206, 209). Treatment fidelity was important to achieve the best possible compliance to the programme, meaning that the consistency of the intervention was enhanced to ensure it was implemented as planned. In the present study, various efforts were made to ensure treatment fidelity. Meetings were held in each municipality at least once monthly to ensure the flow of the project. Challenges were brought up and the physiotherapists could ask questions. To ensure the quality of the treatment, each physiotherapist completed a fidelity checklist for each participant at the home visits with details on the content of each home visit and the progression of the exercises (see Table 4 and Table 5). For each participant, progression and challenges were discussed at the monthly meetings or if necessary, on the telephone between meetings. The researcher was available via telephone and email, if there were any difficulties that had to be handled instantly.

Another important factor to ensure compliance was education sessions for the physiotherapists conducting the intervention. The physiotherapists' understanding of the structure of OEP, including the progression and individualisation of exercises, was of importance. Before the start of the project, the physiotherapists completed one full-day workshop on falls prevention and the OEP. In addition, during the 1.5 years the project lasted, six workshops were conducted in which topics relating to older adults were presented. In these workshops, there was also time to exchange experiences and common challenges. An overview of the content of the workshops is presented in Table 6.

Table 6. Overview of the workshops

Workshops	Time	Content
1	February 2016	Falls in older adults, recent research on falls risks, assessments and interventions. Theoretical introduction and practical session on OEP.
2	May 2016	Topic presented: Dizziness in older adults Discussion on project issues: recruitment, workload, introducing the OEP for the participants.
3	October 2016	Topic presented: Health communication Discussion and practical session on teamwork
4	February 2017	Presentation on the progress of the project until now Topic presented: Pain in older adults Topic presented: Osteoporosis and exercise
5	May 2017	Presentation of results from baseline data (Paper II) Presentation of the experiences of the participants in the study – results from a Master thesis
6	November 2018	Presenting the results from the RCT at the end of the intervention (Paper III) and follow-up (Paper IV) Presenting outcome measures of HRQOL (Paper V) Presenting qualitative data on the experiences of the physiotherapists on conducting OEP for home care recipients (upcoming papers) This workshop was presented for clinicians and health care managers in the six participating municipalities

OEP: Otago Exercise Programme; RCT: randomised controlled trial; HRQOL: health-related quality of life

4.7 Assessment procedures

Outcome measures were selected based on both theoretical and practical reasons. The assessments employed had established reliability and validity, as recommended by the CONSORT group (261). Reliability can be assessed by determining the internal consistency of the measure or by examining the stability of scale scores over time or in different settings (16). Validity is defined as the extent to which a scale measures the construct that it intends to measure. In addition, responsiveness and sensitivity to change are two important factors to consider when selecting assessment tools. Sensitivity to change is the ability of an instrument detecting a change regardless of its clinical relevance (statistical significance), while responsiveness refers to the detection of change that is clinically meaningful (minimal clinically important difference or MCID) (16, 267).

The outcomes were also selected based on literature identifying a standard set of measurements in falls prevention programmes (13, 268). These measurements are commonly used in clinical practice and represent the full range of health gains, which is important considering the pragmatic design of the study (265). The measurements were conducted in the participants' homes, and considerations concerning equipment and space had to be made. Both the measurements and their order were selected to avoid the physical and mental fatigue of the participants. First, the MMSE was conducted due to its function as an exclusion criterion. All participants with a score less than 23, indicating cognitive decline, were excluded (269). The reason for excluding older adults with cognitive decline was the level of self-training demanded. The participants had to be aware of their physical limitations when performing balance tasks and needed to be able to remember the instructions given by the physiotherapists. Second, baseline characteristics and questionnaires on physical function were collected. Third, the physical tests were performed, and finally the questionnaires on falls self-efficacy and HRQOL were conducted.

The outcomes measures applied in the PhD project are presented in Table 7, including the ICF classification. Assessments were carried out at baseline, at the end of the intervention at 3 months and at the 6 month follow-up. One hundred and fifty-five participants were tested at baseline, 138 at 3 months and 136 at 6 months. For the final study, Paper IV, complete data for EQ-5D and SF-6D was included. For EQ-5D, there was complete data for 155 participants at baseline, 135 at 3 months and 135 at 6 months. For SF-6D, there was complete data for 155 participants at baseline, 136 at 3 months and 133 at 6 months.

The assessors were four physiotherapists working as research assistants on the project. A workshop was arranged before project start-up in which all measurement tools were explained and practiced. All assessors were blinded to the group allocation of the participants. The assessors did not perform the OEP intervention in the municipalities participating in the project.

Table 7. Outcome measures included.

Instrument	Function measured	ICF factors	Sum Score
Mini Mental State Examination (MMSE)	Cognitive function	Body function	0-30 (worst-best)
Short Form 36 Health Survey (SF-36)	Health-related quality of life	Body function Activity Participation Personal factors	0-100 (worst-best)
SF-6D	Health utility index		0.29-1 (worst-best)
EuroQOL EQ-5D-5L (EQ-5D)	Health-related quality of life	Body function Activity Personal factors	5-25 (best-worst) for each scale
EuroQOL EQ-5D-5L (EQ-5D)	Health utility index		0-1 (worst-best)
The Bergs Balance Scale	Balance	Body Function Activity	0-56 (worst-best)
4-metre walk test	Usual walking speed	Body Function Activity	Time, metre per second
30-second sit-to-stand test	Leg muscle strength	Body function Activity	Number of raises in 30 seconds
Lawton and Brody Instrumental Activities of Daily Living	Instrumental activities of daily living	Activity Participation	0-8 (worst-best)
Falls Efficacy Scale International (FES-I)	Falls self-efficacy	Body function Activity Participation	16-64 (best-worst)
The walking habits questionnaire	Physical activity level	Activity Participation	Minutes per week
Mini Nutritional Assessment (MNA)	Nutritional status	Body function Activity	0-14 (worst-best)

ICF: International Classification of Functioning, Disability and Health.

4.7.1 Outcomes assessing health-related quality of life

HRQOL, measured by SF-36 version 2, was the primary outcome of the RCT (270). SF-36 is a generic and validated questionnaire and has been translated to Norwegian (271). The 36 items in SF-36 are grouped into eight health status scales; physical functioning (PF), role limitations due to physical problems (RP) and due to emotional problems (RE), bodily pain (BP), general health perceptions (GH), vitality (VT), social functioning (SF) and mental health (MH). Based on the scores of these eight scales, a physical component summary (PCS) and a mental component summary (MCS) are calculated. The sum scores range from 0-100 (worst-best). Previous research has shown that SF-36 has good psychometric properties when applied to older adults, with high reliability, validity and sensitivity to changes (240, 272). A systematic review indicates that the minimal clinically important change score is in the range of 3-5 points for both summary scales (273). The sample in the present study was compared to a Norwegian reference study for which data was collected in 2015 for 398 older adults aged 70-80 (163).

Another measurement tool commonly employed for HRQOL is EQ-5D. This measurement tool is a generic and validated questionnaire that describes five dimensions of HRQOL—mobility, self-care, usual activities, pain/discomfort and anxiety/depression —on a five-point scale (274-277). EQ-5D is much shorter and less time-consuming than SF-36. It was therefore of clinical relevance to study the differences in the applicability and sensitivity of the two common outcome measures when evaluating interventions, and EQ-5D was included as a secondary outcome. Each of the dimensions can take one of five responses at five levels of severity (no problems/slight problems/moderate problems/severe problems/extreme problems). Scores range from 1-5, where 1 is good and 5 is worse. EQ-5D has been acknowledged as a tool with high validity, reliability and responsiveness when assessing HRQOL in older adults in different settings, such as primary care, the community and in rehabilitation (240). Both SF-36 and EQ-5D were conducted as interviews to increase the response and completion rate in this population of older home care recipients (240).

Outcome measures to assess HRQOL are applicable when conducting economic evaluations of interventions. SF-6D utility indexes can be derived based on SF-36 and is composed of six multi-level dimensions of health. The utility indexes for EQ-5D and SF-6D can be employed to produce quality adjusted life years (QALYs), which in turn can be used for economic evaluations (245, 254). QALYs are defined as the benefit of a health intervention in terms of time in a series of quality-weighted health states in which the quality weights reflect the desirability of living in the particular health state (278). As there are no Norwegian values sets, the published algorithm with the parametric preference weight for United Kingdom were employed (254, 274). SF-6D is based on the domains physical functioning, role participation, social functioning, pain, mental health and vitality with scores ranging from 0.29-1. The corresponding utilities in EQ-5D range from 0-1 (252). Both SF-6D and EQ-5D have been validated extensively in the population of older adults, across a wide range of conditions and countries (279).

4.7.2 Outcomes assessing physical function

The Bergs Balance Scale (BBS) assesses static and dynamic balance and is validated for older adults (280). This test measures performance on 14 different tasks on a 5-point scale from 0 (cannot perform) to 4 (normal performance). The sum score of the 14 different items ranges from 0-56, where a score below 45 indicates a higher risk of falling. The Norwegian version of this assessment tool has proved to have excellent inter-rater reliability and high internal consistency in the population of older adults (281). An alternative to the Bergs Balance Scale is the Mini-Best test; however, it was not applicable for this study due to the level of difficulty and the equipment necessary (282).

The 4-metre walk test (4MWT) measures usual walking speed and functional mobility. Usual walking speed is based on the time required to walk 4 metres using any familiar walking aid and is expressed in metres per second (283). Walking speed is a valid and reliable measure for assessing and monitoring functional status and overall health (114). Walking less than 0.8 m/s implies that an older adult has limited community ambulation and the person can be identified as frail (143). Longer distances, such as 10 metres or 6 metres, could also have been applied; however, this was not feasible because the assessments were performed in the participants' homes.

The 30-second sit-to-stand test (STS) was used to measure lower limb muscle strength and transfer skills (284). In this test, the number of times a person rises from a chair within 30 seconds is recorded (123). This test is applicable when the aim is to detect early decline in functional independence in older adults (285).

The Walking Habits questionnaire is recognised as a valid tool used to measure walking habits and physical activity in frailer older adults (175, 286). In the present study, it was used as a measure of the level of physical activity. This questionnaire assesses general walking behaviour, such as how long and how often one walks. The questions asked are "Do you take a daily walk?" (yes/no), "If you do not take a daily walk, how many times per week do you take a walk?" (never/almost never/1-2 days/3-4 days/almost daily) and "How long does your walk generally last?" (0-15 min/15-30 min/30-60 min/1h-2h/more than 2 h). Walking time in minutes per week is calculated by taking the lowest level of minutes for each response alternative. Other instruments to measure physical activity, such as the Incidental and Planned Activity Questionnaire (IPAQ) (287), were also considered, but many of the questions were not relevant for this group of frail older adults.

The Norwegian version of the Lawton and Brody IADL scale was used to measure instrumental ADL (288). This is a valid and reliable measure of a person's self-reported ability to perform complex ADL, such as cooking, shopping and doing housework. This tool assesses eight areas of function and the summary scores range from 0 (low function) to 8 (high function). Few studies have tested the psychometric properties of this assessment tool, even though it has been used for many years in clinical practice. However, it has been considered as appropriate for community-dwelling older adults with less severe dysfunctions (289).

4.7.3 Outcomes assessing mental health and falls self-efficacy

MMSE is a sensitive, valid and reliable instrument used in both clinical and research settings to measure global cognitive function in older adults (269, 290). This tool consists of 11 cognition tasks, and the scale ranges from 0-30. A score below 23 indicates cognitive impairment (269). In this study, MMSE was carried out at baseline to exclude older adults with a cognitive decline. This was done due to the risk of falls, as the programme demanded a lot of self-training.

Falls self-efficacy was assessed using the Norwegian version of the Falls Efficacy Scale - International (FES-I) (291). This assessment tool is a self-reported questionnaire containing 16 items relating to daily activities and the level of fear of falling when carrying out these activities (292). The four-point scale ranges from 1 (not concerned) to 4 (very concerned) and has a sum score ranging from 16-64; 16-19 indicates low concern, 20-27 moderate concern and 28-64 high concern. This scale has shown good reliability and validity when measuring older adults, and it is recommended for both clinical practice and research (292, 293).

4.7.4 Outcome assessing nutrition

Nutritional status was included as an outcome in the PhD project due to its correlation with the risk of falling (294). It was measured using the MNA form (295-297). The first part consisting of six questions on the decline in food intake, involuntary weight loss, mobility, psychological stress or acute disease in the past 3 months, neuropsychological problems and body mass index was employed. This short version has been shown to be valid in the population of home-dwelling older adults, and it is a helpful tool to identify those who are malnourished or at risk of malnutrition (297). A score of 12-14 indicates normal nutritional status, a score of 8-11 points indicates risk of malnutrition and a score below 8 indicates malnutrition. If the participants were malnourished, it would be necessary to implement other interventions, such as nutritional support, before starting the exercise intervention.

4.7.5 Other information collected at the different assessment time-points

In addition to standardised outcome measures, it was also necessary to gather other information at the different time points. This information was collected through questionnaires made by the researcher.

Demographic and background variables were assessed at baseline. These were age, sex, living alone, education (primary and lower secondary school/upper secondary school/university 1-4 years/university more than 4 years), medical history including mediations, walking aid use, type of home care provided (home nursing, practical assistance, safety alarm service) and history of falls.

Adherence to the intervention was assessed at the end of the intervention at 3 months using the information on fidelity provided by the physiotherapists and the information in the exercise diaries completed by the older adults. Adherence was defined as receiving all home visits and telephone calls and performing two or more self-training sessions each week.

Exercise in the follow-up period was assessed at 6 months. The participants were asked about their level of exercise since the assessment at 3 months. Possible answers were performing individual exercises, group exercises, both individual and group exercises or none.

To monitor safety, adverse events such as falls, cardiovascular events or musculoskeletal injuries when performing the exercises were reported by the participants and physiotherapists in the falls diary. Falls were also reported by the participants in the follow-up period; however, at that point the physiotherapists were not able to assist them. Information on adverse events was collected at 3 and 6 months.

4.8 Statistical procedures

4.8.1 Sample size calculation

The sample size was estimated based on the primary outcome, HRQOL, measured by SF-36. A sample of 150 participants was needed to detect a significant difference of at least five points on the summary scales (PCS, MCS) with a standard deviation (SD) of 10 points. The power was set at 80% and the level of significance at 0.05. This implies a moderate effect size (298), which could be expected because previous research has shown substantial effects on different outcomes following the OEP (206). The anticipated dropout rate was 15-20% based on experiences in previous research involving similar populations (39, 220).

4.8.2 Data analyses

Some processes of the statistical analyses were common for all papers in this PhD project. Statistical analyses were conducted using STATA/SE 14. Descriptive statistics on the study population were included in Papers II, III, IV and V. Percentages were used to describe categorical data, and the mean and SD were used to report continuous data. Skewness was examined by comparing mean and median values. Differences between sexes and between the intervention and control groups at baseline were examined using t-tests and chi square tests. Coefficients with p-values above 0.05 were considered statistically significant. Floor and ceiling effects were considered when more than 20% of the participants achieved the lowest or highest score (240, 299). If this was the case, a logistic regression was fitted. More information on the data analyses can be found in the appendix in Papers II-V.

Paper II

The objective of Paper II was to assess the associations between different variables in this specific population. Due to the linear relationship, Pearson correlation coefficients were used to show the associations between HRQOL, physical function and fear of falling (300). The strength of the correlation was interpreted according to Cohen, where 0.1-0.29 is weak, 0.3-0.49 is moderate and 0.5 to 1.0 is strong (301). A multivariate regression model with adjustments for sex, age, education, living alone, risk of or being malnourished, >3 falls during the previous 12 months and the number of medications was used.

Paper III and IV

In Papers III and IV, the objectives were to explore the short-term effects of the falls prevention intervention at 3 months and on the longer-term effects at 6 months. Differences between the groups at baseline, 3 months and 6 months were analysed using linear mixed regression models.

ITT analyses were performed in which all randomised participants were included, even though some did not receive the complete intervention, there were deviations from the protocol or some withdrew from the study (302). The first purpose for using this method is to limit the potential confounders between treatment groups when including all participants who are randomised (303). The second purpose is pragmatic; the results should reflect what could happen in clinical practice. In the real world, interventions are not always well tolerated, and participants often do not complete or continue with their prescribed treatment. As recommended, sensitivity analyses were performed to explore the effect of departures from the assumption made in the main analyses (304).

Due to sudden events, such as hospitalisation, illness and the loss of a spouse there was missing data. This issue was handled in different ways. Generally, it is important to minimise the amount of missing data. This can be done by carefully choosing the design and managing the trial well (304). In the present study, all the participants received follow-up, with the exception of those who withdrew from the trial. Participants who did not wish to perform the intervention were asked to go through the assessments anyway. If it was not possible to assess participants at 3 months, they were included at 6 months. To avoid missing data, the research assistants made every effort to accommodate the participants, for instance they were very flexible regarding time. In some cases, the participants could not perform some physical tests due to exhaustion or illness, but they could complete the questionnaires and the other physical tests.

In Papers III and IV, 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. Replacing missing values using multiple imputation is an approach where a regression model is used to predict missing values (305). This method is widely believed to be the preferred approach to missing data (304). Another method called 'last observation carried forward' could have been employed, but this method is generally not recommended (305). In addition to performing multiple imputation, complete case analyses were carried out, where only those participants who completed the intervention and all assessments were included. However, these analyses provided similar results, and multiple imputation was the method chosen for both papers.

Per-protocol analyses were performed to explore the results of the ITT more thoroughly. In per-protocol analyses, those participants who do not complete the intervention are ignored. It is argued that this method is able to reflect the treatment differences more clearly (306).

However, it is not as pragmatic as ITT, where the real effect of the intervention is shown. Therefore, both ITT and per-protocol analyses were conducted. In Paper III, per-protocol analyses were performed to explore the effect of adherence on the outcome of the intervention. Linear regression (OLS) on adherence to the exercise programme in the intervention group was fitted to be able to study the association between different levels of adherence and the effect of the intervention. The analyses divided the results into those in the intervention group who exercised as prescribed and those who exercised less than prescribed. A propensity score matching model was also used, matching participants who conducted exercises as prescribed with similar participants in the control group. Propensity score matching is widely used when estimating causal treatment effects in studies matching one group of individuals receiving an intervention with individuals from a control group not receiving an intervention (307). This is a partially parametric method matching the groups on the closest predicted mean (308). Matching was performed on baseline scores and sex, with one match per observation.

In Paper IV, the differences in exercise level between groups were described using percentages and odds ratios (ORs). An OR is the ratio of the odds of a disease or event in two groups (16). To explore differences in characteristics between those continuing exercise and those who discontinued exercise, two-sample t-tests were used. To explore the mediating factors of the effect on the PCS, regression models and structural equation models (SEMs) were fitted. A SEM is an appropriate tool for representing dependency relations in multivariate data (309). The SEM in this study included one direct path and one indirect path through a mediator from the intervention to the PCS.

Paper V

In Paper V, the aim was to examine the agreement between EQ-5D and SF-6D using longitudinal data on older home care recipients. Other aims were to explore differences and similarities in HRQOL domains covered by the instruments and the responsiveness of these two instruments to changes in physical function.

For this paper, complete case analyses were conducted and only SF-36 and EQ-5D questionnaires that were fully completed were included when transforming the scores to SF-6D and EQ-5D utility scales. With many missing scores in the questionnaire, calculating an index score is difficult.

To illustrate the agreement between EQ-5D and SF-6D, Bland-Altman Plots were utilised (310). This is an appropriate method when the aim is to define the intervals of agreements between two outcomes (311). A fitted regression line and boundaries of agreement were used to give a better illustration of the relationship. Plots were drawn for absolute values and changes at different time points. Outliers were checked for characteristics, but not excluded.

As most of the data was ordinal, Spearman rank correlations were used to explore the associations between the different sub-domains of SF-6D and EQ-5D and the physical outcome measures. The strength of these correlations was interpreted according to Cohen (301).

A challenge when studying the responsiveness of SF-6D and EQ-5D related to measures of physical function was the different units in the measurement scales. To solve this issue, elasticities were calculated, where the units are transformed into percentages, which again makes it easier to compare the responsiveness of the scales (312). The elasticities were calculated from a linear mixed regression model with individual-specific effects. An elasticity of an outcome variable y with respect to a predictor variable x was calculated such that it equals approximately the proportional change in y for a proportional change in x. The elasticities were calculated at the mean level of x and can conveniently be interpreted as the percentage change in y in response to a one percentage change in x at this level. This statistical method is most commonly used in economics when studying how one economic variable responds to change in another, but this method can also apply to other fields (312).

4.9 Ethical considerations

This research project was approved by The Regional Committee for Medical Research Ethics in Southeast Norway (Ref. 2014/2051). It is registered in Clinical Trials (NCT02374307), with first registration on 16 February 2015. The project was conducted according to the World Medical Association Declaration of Helsinki. Written informed consent was obtained from all participants included.

There are several ethical challenges with including frail older adults in clinical trials. Previous research has mentioned comorbidity, exhaustion and respondent burden as common reasons for dropping out in experimental studies. This is one reason why frail older adults are often excluded from research trials (26, 39, 313, 314). To prevent negative experiences for the participants and to limit the number of dropouts, several actions were planned and performed during the trial. Before giving informed consent, the participants were provided thorough information, both spoken and written, at different time points to ensure they understood what they were joining. In many cases, the researcher went on a home visit to give more information before the participants consented. All four research assistants performing the assessments and the 17 physiotherapists conducting the intervention had experience working with this group of older adults and had knowledge on making adjustments according to their physical and mental state. The duration and intensity of the intervention and assessments were chosen to reduce the exhaustion and burden.

Due to the level of frailty in this group of older adults, close collaboration with health personnel in the primary health care service was necessary. If there were any incidences or health issues detected by the research assistants at baseline assessments or at any other time point, they consulted the health personnel. For instance, if a participant had a low MNA score, the nurse responsible was contacted, and this person contacted the general practitioner if necessary. Because all participants were at risk of falls, the people in the control group were also invited to join falls preventative exercise groups or other interventions following the trial. In addition, they could carry on activities as usual in the intervention period, even if that included general exercise or general physiotherapy treatment.

In this trial, older adults with a cognitive decline were excluded due to ethical reasons. The intervention demanded a high level of self-training and progression of exercises. If people with cognitive decline were included in the intervention group, doing high-risk exercises could be harmful if they could not evaluate the level of safety. For this group of older adults, a closer follow-up by a physiotherapist would have been necessary to avoid adverse events.

5 Results

In this chapter, the aims and methods are introduced briefly and then summaries of the results from each paper are presented. Finally, a summary of the results from all papers where the studies are connected to each other is presented. The results from Paper I, the study protocol, are not presented because the aim of this paper is not to provide results but rather to describe and discuss methods for the trial. Detailed information on the results can be found in the papers included in the appendix.

5.1 Characteristics of the population of home care recipients

The overall aim of Paper II was to provide information on the baseline characteristics, HRQOL, physical function and falls self-efficacy in the population of home care receivers experiencing falls. Another aim was to determine relationships between HRQOL, physical function and falls self-efficacy in this population. Cross-sectional data from baseline measurements in the RCT was employed for the statistical analyses.

This study included 123 females and 32 males. Men and women differed significantly in the number of falls. Men had a higher number of falls at 4.9 compared to women at 2.1 ($p<0.001$). Another significant difference was in safety alarm service use, where 79.7% of women used the services compared to 59.4% of men ($p=0.017$). The mean age was 82.7 years, and the mean number of falls was 2.7. The participants were all appointed different home care services, and the majority received practical assistance or safety alarm service. When measuring SF-36, the mean score of PCS at baseline was 38.3. The physical sub-scale scores ranged from 38.3-57.6. The mean score of MCS at baseline was 49.4. The mental sub-scale scores ranged from 66.9-75.8. Secondary outcomes showed a mean STS value of 5.1, a mean 4MWT of 0.62 m/s, a mean BBS score of 39.1 and a mean FES-I score of 30.7. More information on baseline characteristics can be found in Table 8.

Table 8. Characteristics of the study population

	Total (N=155)	Female (N=123)	Male (N=32)
Characteristics			
Age, mean (SD)	82.7 (6.7)	83.0 (6.7)	81.3 (6.7)
Living alone, %	84.5	87.0	75.0
Higher education (>12 years), %	36.1	35.0	40.6
No. of medications weekly, mean (SD)	5.3 (3.4)	5.1 (3.4)	6.0 (3.6)
Primary health care services			
Practical assistance, %	69.7	68.3	75.0
Nursing, %	30.3	27.6	40.6
Safety alarm service, %	75.5	79.7	59.4
Walking aid %	73.5	74.0	71.9
Falls in the last 12 months			
N, mean (SD)	2.7 (3.7)	2.1 (2.5)	4.9 (6.0)
Location falls			
Indoor, %	47.4	49.6	38.7
Outdoor, %	18.8	19.5	16.1
Both, %	33.8	30.9	45.2
Injuries from falls			
Minor injuries %	45.5	45.5	45.2
Serious injuries, hospitalisation %	35.1	37.4	25.8
Mini-Mental State Examination			
MMSE, mean (SD)	27.4 (2.2)	27.5 (2.2)	27.2 (2.2)
Falls Self-Efficacy			
FES-I, mean (SD)	30.7 (9.8)	31.0 (9.9)	29.4 (9.5)
Physical function			
IADL, Lawton and Brody. >6, %	56.1	56.1	56.3
Sit to stand, mean (SD)	5.1 (4.1)	5.1 (4.2)	4.8 (3.7)
4-metre walk test m/s, mean (SD)	0.62 (0.21)	0.62 (0.22)	0.61 (0.18)
Berg Balance Scale, mean (SD)	39.1 (11.3)	39.6 (11.4)	37.2 (10.8)
Mini Nutritional Assessment			
Risk of malnourishment or malnourished %	24.4	27.6	12.5
Health-related quality of life SF-36 scores, mean (SD)			
Physical component summary	38.3 (9.0)	38.0 (9.2)	39.4 (8.4)
Mental component summary	49.4 (10.3)	49.0 (10.6)	50.9 (9.1)
Physical function	44.6 (23.1)	44.5 (23.0)	45.2 (23.8)
Role physical	51.7 (29.7)	50.9 (30.1)	54.9 (28.3)
Body pain	53.8 (32.2)	51.8 (32.4)	61.4 (30.7)
General health	57.6 (23.3)	57.6 (23.5)	57.6 (22.7)
Vitality	38.3 (21.5)	36.7 (28.8)	44.2 (19.1)
Social function	66.9 (31.2)	66.1 (31.3)	69.9 (30.8)
Role emotional	75.8 (28.5)	75.6 (28.1)	76.6 (30.6)
Mental health	72.1 (17.4)	71.1 (17.8)	75.6 (15.6)

Means, standard deviations (SD) and percentages

Table 9. Regression of SF-36 on measures on demographics, physical measures, cognition and fear of falling

	Physical comp. sum.	Mental comp. sum.	Physical Function	Role Physical	Bodily Pain	General Health	Vitality	Social Function	Role Emo-tional	Mental Health
Age (years ≥ 67)	0.19 (0.10)	0.31* (0.13)	0.49* (0.23)	0.58 (0.37)	0.80 (0.42)	0.74** (0.28)	0.04 (0.28)	0.70 (0.42)	0.02 (0.03)	0.64** (0.22)
≥ 3 falls in last 12 months	2.48 (1.56)	-4.23* (1.99)	4.57 (3.51)	1.43 (5.49)	3.90 (6.36)	1.06 (4.17)	-4.37 (4.22)	-9.02 (6.28)	-0.27 (0.46)	-4.64 (3.27)
No. medications weekly	-0.72*** (0.19)	0.16 (0.24)	-0.74 (0.42)	-1.02 (0.66)	-1.10 (0.77)	-2.65*** (0.50)	-0.58 (0.51)	0.43 (0.76)	0.06 (0.06)	-0.33 (0.39)
4-metre walk test, m/s	8.28* (3.84)	-1.03 (4.88)	21.12* (8.61)	15.30 (13.47)	23.88 (15.62)	-0.24 (10.24)	16.53 (10.35)	-1.26 (15.43)	0.12 (1.18)	4.37 (8.03)
Berg Balance Scale	0.14 (0.08)	0.00 (0.10)	0.80*** (0.18)	0.31 (0.27)	-0.12 (0.32)	0.18 (0.21)	-0.23 (0.21)	0.33 (0.31)	0.03 (0.02)	-0.00 (0.16)
Instrumental Activities of Daily Living	0.50 (0.51)	-0.11 (0.65)	3.16** (1.15)	2.01 (1.80)	-1.48 (2.08)	-0.96 (1.37)	0.16 (1.38)	2.36 (2.06)	0.02 (0.15)	-0.85 (1.07)
Falls Efficacy Scale – In-ternational	-0.18* (0.07)	-0.30** (0.09)	-0.37* (0.16)	-0.73** (0.25)	-0.55 (0.29)	-0.55** (0.19)	-0.63** (0.19)	-0.46 (0.29)	-0.09 *** (0.02)	-0.52*** (0.15)
Mini-Mental State Exami-nation (score ≥ 23)	-0.26 (0.29)	0.45 (0.37)	-0.11 (0.66)	-0.38 (1.03)	-1.42 (1.19)	0.70 (0.78)	0.78 (0.79)	0.44 (1.18)	-0.03 (0.09)	1.25* (0.61)
R^2 adj.	0.32	0.15	0.47	0.21	0.08	0.27	0.10	0.07		0.20

Adjusted for sex, education, living alone, risk of or being malnourished. Ordinary least squares (OLS) regressions, except on role emotional, where a logistic regression is fitted. Unstandardised regression coefficients, standard error (SE) in parentheses. Model fit reported by R^2-adjusted. N=151.

* p<0.05; **p<0.01; ***p<0.00

Table 9 presents the results of multivariate regressions of the scales of SF-36 and background variables of physical function and falls self-efficacy. The analyses show that having a lower score on FES-I was associated with achieving higher scores on all sub-scales of SF-36, except for BP and SF. Having a higher score on the sub-scale PF was associated with higher scores on the 4MWT, BBS and IADL. Higher age was associated with better MCS, PF, GH and MH scores. Taking fewer medications was associated with higher PCS and GH scores. A higher score on the MMSE was associated with a higher MH score. These associations were independent of other physical measures, number of falls, cognition and key background characteristics, such as age, sex and education.

The results from Paper II show that the population of home care recipients has a low level of HRQOL, poor physical function and a low level of falls self-efficacy. Further, it shows that having a higher level of HRQOL is associated with better physical function and better falls self-efficacy. Interventions to improve HRQOL are therefore essential in this population, leading to the next study in Paper III.

5.2 Short-term effects of a falls prevention exercise programme on health-related quality of life

The aim of Paper III was to examine the short-term effects of a falls prevention exercise programme on HRQOL, physical function and falls self-efficacy in the population of older home care recipients. The design was a parallel-group RCT, and the effect on HRQOL, physical function and falls self-efficacy was measured at the end of intervention at 3 months.

At the end of intervention, both groups had improved substantially on the mental components of SF-36. The MCS was 3.8 points higher at the 3-month assessment. Compared to the control group, the intervention group improved their PCS by 4.0 points ($p<0.001$). The MH sub-score declined relatively by 6.7 points ($p=0.009$). Regarding the measures of physical function, both groups improved in the STS, 4MWT and BBS at the end-of-intervention assessment. The intervention group improved significantly on BBS, achieving a relatively higher score of 2.4 points ($p=0.047$). The results of the ITT-analysis can be found in Table 10.

Table 10. Intention to treat analysis

	Difference Intervention – Control at baseline		General improvement at the 3 month follow-up – both groups		Additional improvement at the 3 month follow-up – Intervention group	
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)						
Falls Efficacy Scale International	-0.9	(1.5)	-2.3	(1.2)	0.6	(1.7)
Sit-to-stand test	0.8	(0.7)	0.8*	(0.4)	0.4	(0.6)
4-metre 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)

Coefficients from linear mixed models including indicator variables for arm, follow-up and the 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.

* $p<0.05$; ** $p<0.01$; *** $p<0.001$

To investigate the results of the ITT-analyses in more depth, per-protocol analyses were performed looking at the effect of the participants' adherence to the programme. Of all participants, 73.5% performed the OEP as prescribed (receiving home visits and telephone calls and completing self-training), while 26.5% could not complete the OEP due to sudden events, such as hospitalisation or the loss of a spouse. The participants who could not complete the programme scored significantly lower on MH with -12.4 points (p=0.001) compared to those who could complete the programme. The participants who could complete the programme improved significantly in the PCS score by 5.8 points (p<0.001), in PF by 10.0 points (p=0.004), in BP by 12.3 points (0.005) and in the BBS score by 3.3 points (p=0.01). When matching those performing the exercises as prescribed (N=50) with the control group participants (N=68), even greater improvements were shown in those who exercised as prescribed. For instance, they improved in the PCS score by 6.3 points (p<0.001) and in the BBS score by 4.3 points (p<0.001). No falls or other serious incidences were reported by the physiotherapists or the participants when exercising. Three participants reported musculoskeletal pain/discomfort after using the ankle cuffs.

The results of Paper III exploring the short-term effects of the falls prevention exercise programme showed that the intervention group participants improved their physical HRQOL and balance compared to the control group participants. This effect was even more evident when the exercise programme was carried out as prescribed. The next question asked was if this effect persisted following the intervention period when receiving usual care only. In the next paper, the aim was therefore to explore longer-term effects measured at the 6-month follow-up.

5.3 Longer-term effects of a falls prevention exercise programme on health-related quality of life

The aim of Paper IV was to explore the longer-term benefits of the falls prevention exercise programme. A further aim of this paper was to examine the relative importance of maintaining exercise to improve HRQOL. The design in this paper was a parallel-group RCT, as in the previous paper. However, the study considered effects measured at the 6-month follow-up.

The results of the ITT analyses showed that at the 6-month follow-up the differences in HRQOL between the intervention group and the control group were similar to those measured at the end of the intervention at 3 months. The intervention group improved significantly in the PCS score by 3.0 points (CI=0.4, 5.6) compared to the control group, and the sub-scale MH was substantially lower in the intervention group by -6.8 points (CI= -11.9, -1.7). Both groups improved in some scales, for instance RP, where the intervention group increased their score by 17.5 points (CI=9.8, 25.1) and the control group increased their score by 13.6 points (CI=6.3, 20.9). Regarding falls, there were significantly fewer participants in the intervention group who experienced falls since the previous assessment, with an OR of 0.4 (CI=0.2, 0.9). No other harms or unintended effects were reported in the follow-up period.

The intervention group participants were more likely to perform exercises either individually or in a group or both in the follow-up period, with an OR of = 2.3 (CI = 1.1, 5.1). Those who performed exercises post-intervention, irrespective of group allocation, generally had higher

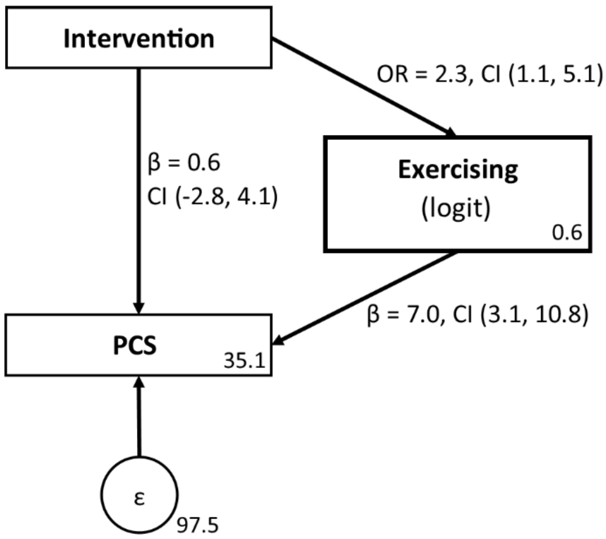

Figure 5. Structural equation model showing the effect of the mediating factor of exercising post-intervention on PCS at 6-month follow-up. A latent error component (ε) is included in the PCS. β = regression coefficients, OR: odds ratio, CI: 95% confidence interval.

PCS, PF, RP, BP and GH scores. They also scored significantly higher on the physical measures of BBS and STS.

A further aim was to explore how the exercise performed post-intervention mediated the effect of the intervention on PCS at the 6-month follow-up. This relationship is illustrated in a structural equation model in Figure 5. The model shows that exercising post-intervention was a mediating factor, increasing PCS by 7 points (CI = 3.1, 10.8).

5.4 Evaluating a falls prevention intervention using SF-6D and EQ-5D

In Papers II-IV, the level of HRQOL and important associations concerning HRQOL and the effect of a falls prevention intervention on HRQOL, were studied in the population of home care recipients. In Paper V, the aim was to study how HRQOL can be measured in this population, especially when utilised for evaluations. More specifically, this paper examined the agreement between EQ-5D and SF-6D and further assessed differences and similarities in domains covered by the instruments and the responsiveness of the measures. Longitudinal data from three time points, baseline, 3 months and 6 months were employed for this study.

First, the distributions of SF-6D and EQ-5D were examined. EQ-5D has a larger percentage of scores in the higher levels of each sub-scale compared to SF-6D and very few responses within the lowest level. Second, a comparison was made between SF-6D and EQ-5D utility scores for selected groups of baseline characteristics. There is a larger spread of EQ-5D utility scores compared to SF-6D utility scores between those with higher/lower age and better/worse physical function. Having lower scores on physical measures was associated with relatively higher scores on SF-6D compared to EQ-5D, and having higher scores on physical measures was associated with relatively higher scores on EQ-5D compared to SF-6D.

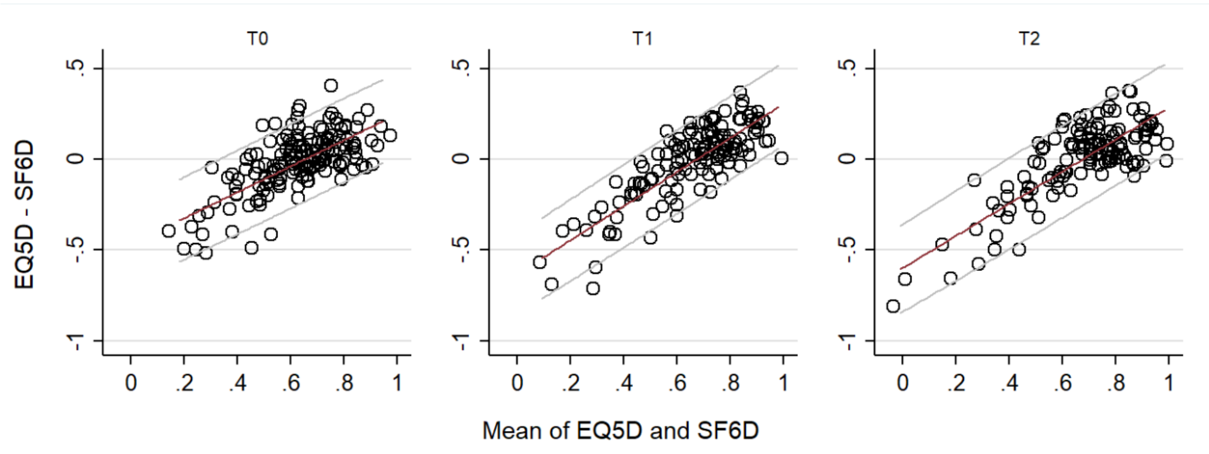

Figure 6. Bland-Altman plot showing the agreement between EQ-5D and SF-6D at time points T0, T1 and T2.

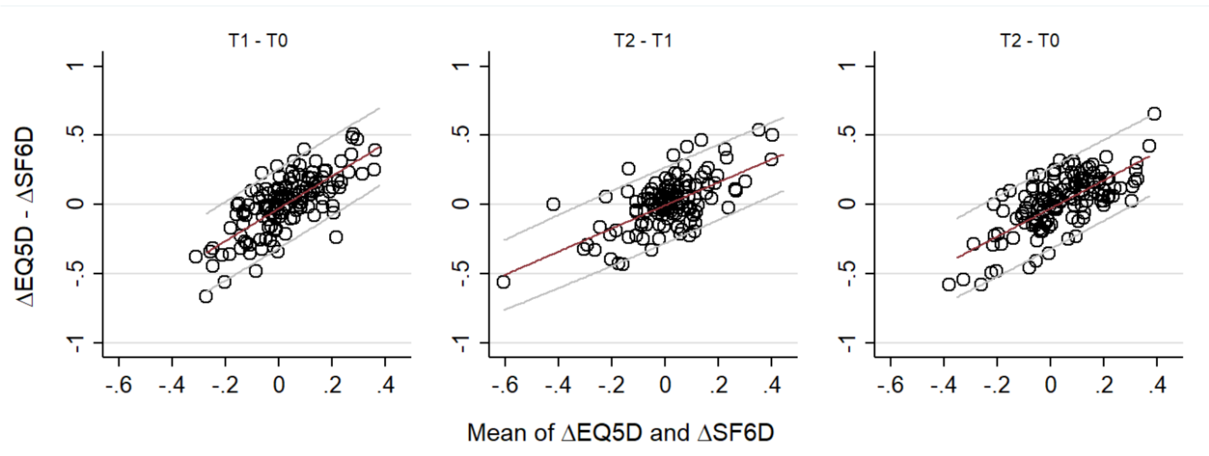

Figure 7. Bland-Altman plot showing the agreement between EQ-5D and SF-6D in terms of changes from T0 to T1, T1 to T2 and T0 to T2.

The Bland-Altman plots in Figure 6 and Figure 7 show there is agreement between EQ-5D and SF-6D both at different time points and in capturing changes from one time point to another. Figure 6 shows that participants with a higher mean HRQOL generally have lower scores on EQ-5D compared to SF-6D and that the participants with a lower mean HRQOL generally have lower scores on EQ-5D compared to SF-6D. Figure 7 illustrates a similar finding, where the participants with a positive change in mean HRQOL generally have stronger positive changes in EQ-5D than in SF-6D, while those with negative changes in mean HRQOL generally have stronger negative changes in EQ-5D than in SF-6D.

The responsiveness of SF-6D and EQ-5D to changes in physical function was assessed by elasticities, where the changes in percentages for the dependent variables are calculated. The elasticities are presented in Table 11. Changes in the physical outcomes assessed for this study had a greater impact on changes in HRQOL measured by EQ-5D compared to SF-6D. For instance, a 10% increase in BBS score led to an increase in EQ-5D by 5.4% (p<0.001) and an increase in SF-6D by 1.8% (p<0.001).

Table 11. Elasticities from linear mixed regressions with individual specific effects

Physical measures	HRQOL	Elasticity	SE	p-value
Berg Balance Scale	EQ-5D	0.54	0.11	0.000
	SF-6D	0.18	0.06	0.002
30-second sit-to-stand test	EQ-5D	0.09	0.04	0.010
	SF-6D	0.02	0.02	0.194
4-metre walk test	EQ-5D	0.20	0.08	0.013
	SF-6D	0.06	0.04	0.118
Falls Efficacy Scale International	EQ-5D	-0.24	0.07	0.001
	SF-6D	-0.13	0.03	0.000

SE: Standard error

5.5 Summary of results

The aim of this PhD project was to obtain further knowledge on HRQOL and interventions to improve HRQOL in the population of older fallers receiving home care. The results of this project are summarised in five papers. Paper I concluded that home care recipients are a growing, diverse and understudied group requiring more attention in clinical research. HRQOL assessment, effective exercise interventions to improve HRQOL and the mechanisms behind the relationship between falls prevention and HRQOL in this population need to be addressed. Paper II established that the level of HRQOL is generally low in home care recipients and that physical function and falls self-efficacy is important for HRQOL. Papers III and IV explored the short- and longer-term effects of a falls prevention intervention on HRQOL. Paper III concluded that a falls prevention exercise programme based on OEP improved both physical HRQOL and balance in home care recipients who had experienced falls. Paper IV showed that the effect on physical HRQOL was sustained in the longer term. The intervention also led to positive changes in exercise behaviour and a reduction in the probability of experiencing falls in the longer term. Paper V concluded that both EQ-5D and SF-6D can be used for evaluative purposes in this population of home care recipients; however, EQ-5D seems more responsive to changes in physical function.

6 Discussion

The overall aim of this thesis was to contribute to evidence-based knowledge on falls prevention by implementing the evidence-based OEP for older home care recipients in a clinical setting to improve their HRQOL, physical function and falls self-efficacy. In the process of conducting this PhD project, several issues concerning methodology and results have arisen. The methodological choices (6.1) and results (6.2) of the PhD project are discussed in this chapter. The strengths and limitations of the different studies included in the thesis will be discussed throughout this chapter. The discussion in the different papers presented in the appendix also contribute to the discussion.

6.1 Methodological considerations

The methodological considerations include a discussion on internal and external validity (6.1.1). Next, the choices regarding the intervention (6.1.2) and outcome measures (6.1.3) are considered. Finally, the statistical methods employed are discussed (6.1.4).

6.1.1 Internal and external validity

Validity is a complex concept important to consider when designing a PhD project. In an experiment, internal validity implies that the results obtained are due to the influence of the experimental variable (16, 315). Examples of methodological factors that may influence internal validity in a pragmatic RCT include random allocation, blinding, outcome measures, sample size and drop-outs (315). Biases influencing these factors can occur, thus challenging internal validity. The most important biases appear when choosing the design, selecting the study population, collecting the data and deciding on the relationships between the different determinants of an effect (316). When biases occur, incorrect conclusions about the association between the exposure and the effect can be made, thus threatening the internal validity of the study (317). Therefore, in this PhD project, the planning stage of the RCT where methodological factors were thoroughly considered was important to improve the internal validity.

External validity refers to the generalisability of the results to the wider population or setting (16, 318). According to Rothwell (319), the extent to which a result can be extrapolated into clinical practise relates to its external validity. Furthermore, it refers to the degree to which the results can be generalised to groups of people who did not participate in the study and to other situations and settings (320, 321). External validity requires internal validity, but internal validity is not sufficient for external validity (316). Most often, threats to both internal and external validity depend on details in the design, and there seems not to be any trade-offs between internal and external validity in experiments (322). In the following paragraphs, common factors influencing internal and external validity are discussed. Because these two concepts are closely related, any further discussion will not focus on them separately, but in conjunction with each other.

Selection bias is an error influencing the internal validity where the study population does not represent the target population (323). In this project, several decisions were made to avoid selection bias. There was a risk of getting a sample of more fit older adults, because recruitment was for an exercise-based falls prevention intervention. Therefore, the recruitment process was active and outward reaching, where telephone calls were made based on lists of people receiving home care. Other recruitment strategies were not employed. An advert in the newspaper, for instance, would probably attract a more active fraction of the older population.

Another important factor affecting selection bias are the criteria for the inclusion and exclusion of participants. The study sample is defined by its inclusion and exclusion criteria and gives an approximate guide for generalisability (324). Here, these criteria were quite broad, including home care recipients who had experienced at least one fall in the previous year, who could walk with or without a walking aid and who could communicate in Norwegian. The choice of inclusion and exclusion criteria entails a trade-off. Having broad inclusion criteria can give quite a heterogenous sample, thus requiring a larger sample for statistical inference, in particular for sub-group analyses. However, narrowing the inclusion criteria to achieve a more homogenous sample would reduce the representativeness. The population of home care recipients is indeed very heterogenous (47). Hence, generalisability, or external validity, would be reduced if the inclusion criteria were very strict. The exclusion of older adults with cognitive decline has been criticised in previous literature (325, 326). Excluding older adults with cognitive decline might have limited the generalisability to the general population of home care recipients. However, including older adults with cognitive decline was not feasible due to safety concerns when performing self-training. Moreover, efforts were made to limit the dropout rate, for instance of the frailest in the sample, to ensure that the sample was representative of the population. To increase the knowledge on the population recruited, thorough information regarding those who did not wish to or were unable to participate could have been collected. However, studying subjects who do not wish to participate is considered unethical (327).

Information bias happens when information is measured, collected or interpreted inaccurately. This limits the internal validity (316). Detection bias is a type of information bias with systematic differences in how outcomes are determined. One way of reducing this risk is to blind assessors to which group the participants belong. In the present study, all assessors were blinded to group allocation. Enrolment and randomisation were conducted following baseline testing, and the assessors performing the measurements at 3 and 6 months did not have any group allocation information. However, there was a risk that the participants would reveal their group allocation on the home visits. To limit the likeliness of this, a warning message about revealing group allocation was included on the first page in the assessment folder. Moreover, to avoid bias in data collection and to ensure test-retest reliability, only well-known clinical outcome measures having shown good psychometric properties were applied in the present study. All assessors participated in a theoretical and practical workshop to perform the assessments as described in the protocols.

Another example of information bias is reporting bias. In this study, the participants might have been underreporting, for instance on medication use, or overreporting on physical activity level. There was also a risk of recall bias, as the number of falls was reported retrospectively. To avoid recall bias at the 3- and 6-month assessments, a falls calendar with weekly notes on falls was completed by the participants.

Blinding the participants to the intervention could have improved the internal validity of the study. Due to the pragmatic design, a blinded placebo group could not be established. The aim of pragmatic trials is to help clinicians decide between usual care and a new treatment; thus, the treatment response is the total difference between the two, including both treatment and associated placebo effects (265, 315). This reflects clinical practice and improves generalisability and external validity.

Internal validity can also be challenged by confounding, where both the independent variable and the dependent variable can be influenced (316). A key characteristic of an RCT is random allocation, where every participant has an equal chance of being allocated to each group (16). Both groups will most likely have similar baseline characteristics, minimising the risk of confounding (328). Concealed allocation is a strategy that can be used to ensure true random allocation. In the present study, a computer-generated permuted block randomisation scheme was employed, stratifying on municipality and sex. This scheme allocated the participants according to the sequence of enrolment by a double key number concealing the randomisation sequence. In addition to differences in baseline characteristics, there can also be systematic differences between those who do not complete the trial and those who complete the trial; called attrition bias (328). To reduce attrition bias, close follow-up of the participants to reduce the drop-out rate is important. In this trial, small adjustments to the programme were made when, for instance, participants experienced illness or hospitalisation, and an extra home visit or telephone call were often provided. This procedure is also common in clinical practice, increasing the external validity of the project. Additionally, the assessors made great efforts and were very flexible in terms of completing the assessments of all participants included.

An RCT has the ability to determine causal relationships (264). One critique is that the external validity is limited because the estimates only apply for the sample recruited for the trial or the setting where the trial was conducted. This, makes it difficult to extend the results to other groups (329). Conducting pragmatic trials, where the effectiveness is measured in usual practice, can improve the generalisability of the results to samples and settings beyond the trial (330). The RCT conducted in this PhD project was pragmatic, where the intervention was performed in clinical care in six municipalities' health care services in Norway. Physiotherapists with different backgrounds and experience performed the intervention as part of their daily practice. All measurements and interventions were conducted in the participants' homes, as is common in clinical practice. The delivery of the intervention was flexible due to several instances of illness or hospitalisation, and up to four extra home visits or telephone calls were provided. Performing active and outward-reaching recruitment and being flexible in the provision of the intervention to ensure a low drop-out rate might have increased the representativeness by providing a clinically relevant sample of home care recipients. These procedures might have improved the generalisability of the results to other home care settings in Norway.

However, home care services are organised in different ways (50, 51). The different organisation of the services with various settings and recipients can limit the applicability of the results from the present study to usual practice in other health care settings. Hence, a protocol paper was published (Paper I) to improve the transparency of the procedures to further inform about the applicability to different settings.

The choice of outcome measures might have had an impact on both the internal and the external validity of the project. To avoid biases related to the instruments, such as lack of sensitivity, ceiling and floor effects and lack of reliability (16), outcome measures were selected based on previous literature considering psychometric properties in similar populations. Because the present study was pragmatic and to further improve external validity, mostly well-known assessment tools routinely applied in clinical practice were used. Additionally, the assessment tools selected were recommended in guidelines for falls prevention studies in older adults (13). To ensure the relevance of the outcomes to the participants of home care recipients, a small pilot was performed in which older adults could express their thoughts on the usefulness of the measures. One factor which might have limited the applicability of the results to clinical settings is the choice of SF-36 version 2 as the primary outcome to measure HRQOL. This assessment tool is commonly used in research; however, because this instrument is license-based it is not frequently used in clinical practice. In most municipality health care settings, both in Norway and globally, the economic costs would prevent the use of such an instrument. An alternative to SF-36 version 2 is the RAND 36-item health survey, which is free to use both in clinical practice and research (155).

6.1.2 Considerations regarding the intervention

Due to the pragmatic design of this research project, where the intervention was performed in a real-life setting, several decisions had to be made concerning the design of the study. Meetings were held with health managers, clinicians and older adults in the planning period of the project to make adjustments that would fit the clinical practice. One of the questions raised was on the duration of the intervention. In previous studies, the OEP has mostly been performed with a duration of either 12 months or 6 months (207, 210). In a study by Kyrdalen and colleagues (211), the OEP was carried out in a 3 month period; but they compared a group exercise programme to a home-based programme. The duration of 3 months in the present study is shorter than the 6 months previously recommended for home-based exercises (187).

The rationale for this duration is both theoretical and pragmatic. The participants in this project were frail older adults receiving home care services. Previous research has shown that this population experiences more falls and has a higher level of fear of falling, poorer physical function and a lower level of HRQOL than the general population of older adults (36, 68, 331). These factors are all barriers to adherence to exercise in older adults (332). A duration of 1 year was considered too long by the clinicians and older adults consulted before the project began. In addition, physiotherapy treatment is most commonly provided within 3 months in primary care, and the duration was thus related to real-life practice.

Another topic for discussion was the frequency of home visits and telephone calls conducted by the physiotherapists, as well as the dose and intensity of the exercises. According to the OEP, only five home visits are performed, but we allowed for up to four extra visits, if needed. The extra visits were often conducted to provide support and assist the older adults to restart exercise after a hospital stay or after a longer period of illness. Nevertheless, this number of visits is lower than what is normally provided by physiotherapists in primary care service, and in some cases, it could be too few to provide enough support for self-training. Previous research has shown that the sufficiency of care was rated significantly lower by health professionals compared to older adults (333). On the other hand, other research has shown that exercise programmes with a moderate level of home visit support, defined as less than one home visit or telephone call per month and more than two home visits in total, are more beneficial for adherence to exercise programmes in older adults compared to higher or lower levels of support (334). In older adults, exercise interventions which are too demanding have even resulted in a negative impact on QOL (218). However, a dose of a minimum 50 hours of exercise over a period of 6-9 months has been recommended to prevent falls in older adults (335). Some of the older adults in the present study might not have reached this dose, but the follow-up period was only 6 months and the participants were frail home care recipients and not part of the general population of community-dwelling older adults. Moreover, the primary aim in the present study was not to reduce the number of falls but to improve HRQOL, and the dose-effect relationship might be different. In addition to the dose of exercises, the progression of the balance and strengthening exercises is essential to achieve an effect of the falls prevention programme (198). To ensure progression and treatment fidelity in the present trial, this topic was emphasised in the workshops and meetings, and forms for each participant including details on progression were completed by the physiotherapists.

Interventions for older home care recipients rarely focus on preventative or rehabilitative approaches, such as self-care activities, risk prevention and actions to preserve social activities and functional ability (336). In recent policy documents actions to prevent decline in function and to promote health in older adults in primary care have been increasingly emphasised (9, 19). In this PhD project, the aim was to promote HRQOL and to prevent falls in a group of frailer older adults. Therefore, some decisions had to be made concerning the choice of mode of the intervention. A recent systematic review has recommended exercise to prevent falls, and the exercises can be performed either individually or in a group (117). In the preparation stage of the project, several of the older adults expressed that they would only participate if the intervention was conducted in their own home. Transportation and the social aspect were barriers for the participants to attend a group session. The benefits of home-based programmes are that they can encourage participants who are reluctant or unable to attend group sessions and they can be individually tailored (337). However, these home-based programmes often provide less supervision and opportunity to socialise. Nevertheless, several of the participants in the present study attended group sessions following the intervention period of individual sessions.

In the PhD project, the paper-version of the OEP were used to guide the participants. Innovative technology, such as apps, sensors that provide feedback (338) and exergames (339, 340) could have been utilised to stimulate physical activity in this group of older adults. Using exergames for exercise could provide additional benefits in terms of the cognitive function of older adults (341). However, including technical equipment was not feasible in the home care setting due to the lack of funding for equipment and the lack of personnel for supervision and follow-up. Another element that could have been focused on to a larger degree is motivational interviewing (MI). MI is an intervention performed in client-centred counselling to achieve behavioural change, and this method could be applicable for older adults with different health challenges (342, 343). In the present project, motivational telephone calls were performed; but not all the physiotherapists had training in MI. In a previous study including older adults and care recipients, positive within-group changes in physical performance, falls self-efficacy, physical activity level and hand-grip strength occurred after receiving both OEP and MI for a period of 3 months (344). Finally, when evaluating the intervention carried out, one factor that could be a limitation is the lack of education for the physiotherapists, specifically on the OEP. There was no funding to provide a complete OEP course for all the physiotherapists included. Nevertheless, as this study was pragmatic and should be applicable to clinical practice, all the physiotherapists were provided a 1-day course in falls prevention and OEP in addition to follow-up workshops, which is a common educational procedure in primary health care in Norway.

6.1.3 Considerations regarding the outcome measures

Guidelines, taxonomies and recommendations have been made stating which outcome measures are important to include in falls prevention studies for community-dwelling populations (13, 268, 345, 346). When conducting falls prevention studies, it has been recommended to include measures assessing physiological and psychological domains in the test battery in addition to HRQOL (13, 346). Recommendations on specific outcome measures have also been made for the population of older adults in general, for whom falls are a major concern (347). To further ensure a relevant and holistic assessment of the older participants in the present project, ICF was used as a theoretical framework to organise the outcome measures selected. Moreover, an element to consider when planning assessments in the population of older adults is their level of frailty. Screening should be performed to exclude those who are too healthy and those who are too sick to benefit from the intervention (39). However, at the same time the inclusion criteria should not be too strict. Oftentimes frail older adults receiving home care are excluded from research or clinical interventions based on the preconception that they will not be able to tolerate the assessment or achieve any benefits from the intervention (39, 346). The recommendations mentioned in this paragraph were utilised when planning the assessments in this project. In addition, practical issues, such as equipment, the setting and the participants' well-being, were taken into consideration.

Maintaining and improving HRQOL in older adults is a central aim in public health policy, both nationally and internationally (9, 24). Measuring HRQOL in older adults with chronic conditions in primary care settings can facilitate patient management and interventions and further contribute to the evaluation of health care services (156). Therefore, the primary outcome selected for this PhD project was HRQOL, and a measure on generic HRQOL was employed. When measuring HRQOL in people with comorbidities or when evaluating interventions with several components, generic scales are recommended (348). Compared to disease-specific scales, generic scales have shown similar or better responsiveness to change (349-351). However, other literature has stated that by only including generic tools when assessing older adults some important aspects might be neglected (352). One alternative could be to combine general and disease-specific tools. For instance, when measuring HRQOL in older adults, the age-specific tool The World Health Organization Quality of Life measure for older adults (WHOQOL-OLD), including dimensions relevant to older adults such as sensory abilities and autonomy, could also have been conducted (352). When using the HRQOL measures to perform economic evaluations, including the age-specific ICEpop CAPability measure for older people (ICECAP-O) or the Adult Social Care Outcomes Toolkit (ASCOT) as a supplement to EQ-5D or SF-6D has been recommended (279). Nevertheless, the aim in Paper V was to compare the applicability of EQ-5D and SF-6D in relation to each other, and therefore age-specific tools were not included.

Secondary outcomes in this PhD project were measures on physical function and falls self-efficacy. Alternative measures of physical function could also have been used in this project. The Short Physical Performance Battery (SPPB) is an objective tool measuring lower extremity physical performance status and is frequently used in research and clinical practice (353, 354). Elements of the SPPB are used in this project, such as the 4MWT and STS. In SPPB, the five repetition STS test is included, while here the 30-second STS was applied. Both instruments have shown good psychometric properties (355), but when measuring older adults with mobility difficulties and poor balance the 30-second STS has been recommended when assessing changes over time (356). When selecting an instrument to assess balance, BBS, which assesses static and dynamic balance more thoroughly compared to SPPB, was included because the OEP is highly focused on balance exercises. BBS does not include dual tasks in which balance and cognition is assessed in conjunction, which could have been a valuable addition as many daily activities demand this skill (357, 358). Another instrument to measure physical function that could have been conducted is the handgrip strength test using a dynamometer. This has shown to be a useful tool for older adults to indicate general muscle strength (359) and to identify those at risk of mobility limitations (360). Using a dynamometer was not applicable to the home setting for practical reasons, such as economic costs and transportation. To assess the level of physical activity, a pedometer could have been used. The participants in the project had an overall low usual walking speed, and many had to use walking aids either indoors or outdoors. Previous research has shown that slow walking speed and walking disorders limit the applicability of pedometers when measuring physical activity in frail older adults (361). In addition, using pedometers to assess walking would demand close follow-up due to practical and technical issues. Unfortunately, it was not possible to provide such follow-up within the framework of this project.

Self-reporting, both when utilising questionnaires and other formats, can result in some challenges and limitations for research studies. In previous studies, using self-report questionnaires to evaluate physical activity, challenges such as overestimating time performing physical activity and recalling physical activity level have been mentioned (362, 363). On the other hand, self-report questionnaires might be more practical and less resource-demanding compared to objective assessment tools. They could also provide other insights for the evaluation (363). In the PhD project, questionnaires were used to assess HRQOL, falls self-efficacy, level of physical activity and nutrition, and forms were used to assess the number of falls and adherence to the exercise intervention. The questionnaires focusing on HRQOL were conducted as interviews, as this is recommended for older adults to improve the response and completion rate (240, 249, 364). Conducting interviews might have provided different answers than if the older adults completed the questionnaires by themselves. Hence, questionnaires were performed as interviews for all participants included.

Guidelines on falls registration by the Prevention of Falls Network Europe (ProFaNe) group have recommended prospective daily recording and a notification system with a minimum of monthly reporting (13). In the present study, falls calendars were used to report falls weekly, and these were completed by the participants in collaboration with the physiotherapists. However, many of the participants experienced challenges filling out the form on a weekly basis, and often the information ended up being collected retrospectively by the physiotherapists at the home visits or by the assessors at the different assessment time points. To improve the response rate in the falls calendars, providing follow-up more often, for instance weekly via telephone, could have been done (13). Here, this was not feasible due to personnel resources. Another element to consider when reporting falls is the definition of the term itself, which can vary from person to person (345). The definition of a fall was explained to the participants at the initial recruitment stage, at baseline assessment and at the start of the intervention. Some of the participants might have chosen not to report falls to protect their identity of being physically competent (365).

Adherence to the OEP was self-reported in an exercise diary. For our purposes, adherence can be defined as maintaining exercise; but there is little consensus on how adherence should be defined specifically, for instance, in terms of attendance, duration and intensity (366). Nevertheless, in falls prevention, all these factors are important to indicate whether the older adults receive the adequate dose of exercises to prevent falls (12). When it comes to home-based exercises, well-designed measures to capture self-reported adherence are lacking (367). Developing an applicable diary for the participants providing us relevant data was a challenge. A specific challenge was that some participants felt the exercise diary was too demanding and refused to complete it. To overcome this issue, the researcher made a simplified version of the exercise diary. The participants did not have to fill out detailed written information on the exercises and physical activity but only had to report the number of days and the time spent performing the exercises. However, this simplification limited the amount of data. To provide more information on the level of exercise necessary to achieve longer-term effects on HRQOL, more details on the intensity and frequency of the exercises performed in the follow-up period could have been collected.

6.1.4 Statistical considerations

Some statistical considerations in this PhD project were similar for all papers included. Reporting on the analyses and study designs followed recommended guidelines, such as the SPIRIT guideline (262) for Paper I, the CONSORT 2010 Statement (261) for Papers III and IV and the STROBE guidelines (263) for Papers II and V. These guidelines were also used in the preparation stage of the overall project (330, 368). To ensure transparency, all outcomes were specified before starting the data collection, both in Clinical Trials and in a separate protocol paper (Paper I). This study protocol was followed subsequently to prevent any bias and spurious conclusions (369).

Normally in RCTs, the primary outcome is a single measure. SF-36, the primary outcome in the PhD project, is a comprehensive measure comprising two summary scores, PCS and MCS. The SF-36 manual does not recommend combining them into one single measure of HRQOL, such as a global score. Consequently, both summary scores were included (370). Other studies recruiting from a comparable population have used a similar presentation when SF-36 was the primary outcome (220, 371). Power was calculated based on this primary outcome, and a sample of 150 had to be recruited to state whether the effect or having no effect was due to the intervention (300). A total of 155 participants were recruited so that the analyses had sufficient statistical power. In other studies evaluating falls prevention interventions in older adults, the number of falls or injuries from falls is often included as the primary outcome (12, 117). Incorporating falls as an outcome in the present study would have required a much larger sample size and a longer follow-up period. However, this was not within the scope of the research study, as there is already a substantial amount of literature showing a reduction in the number of falls following an exercise intervention (117).

Data was analysed according to the ITT principle in Papers III and IV. Performing analyses according to ITT requires that all subjects randomised are included in the analyses, regardless of protocol deviations, participant compliance or withdrawal (303). By including all the subjects randomised, potential confounding between treatment groups is minimised if the sample is large enough according to power calculation. Another advantage is that it reflects clinical practice, as interventions are not always carried out or completed as intended. For instance, in the present trial, the participants could not always complete all self-training and home visits due to sudden illness, hospitalisation or other events. Nevertheless, these participants were always included in the statistical analyses to create results applicable to a clinical setting. Even though all participants were included, strategies to handle missing data were necessary because there were assessments that could not be completed. Having a certain amount of missing data can lead to an unbalanced dataset, can reduce the efficiency of the study or can introduce biases (372). How to handle missing data in RCTs has been widely discussed, and there seems to be more than one solution (373). Multiple imputations have been recommended previously (372). This method imputes the missing values using a set of sampled values based on models for the missing data conditional on all relevant observed data, thus accounting for the underlying uncertainty. Nevertheless, preventing missing data in the phase of designing and conducting the study is the best strategy (304, 373). In the present study, efforts were made to carry out all follow-up assessments even if some of the participants withdrew from the allocated intervention. If a participant could not carry out all the physical measures due to fatigue, at least the questionnaires were completed.

Additional statistical analyses were conducted to examine the results in more depth. For instance, for Paper III, per-protocol analyses were performed to assess the effect of adherence. A propensity score matching model was applied to match the participants who performed the intervention as prescribed with similar participants in the control group (307). When including only those participants who complied with the intervention, the per- protocol analyses reflects the effect of the intervention unaffected by deviations, thus representing a more ideal condition (374). However, as the aim of these analyses was to further explore the differences in benefits of the intervention between those who were able to complete the intervention and those who were not, performing per-protocol analyses was relevant. One important aspect of these analyses is that the effects shown might be due to differences at baseline rather than to the different treatments (375). To reduce the variability in characteristics between groups, matching was performed based on similar baseline scores and sex, including one match per observation. The random allocation into groups, already conducted for the RCT, might also have reduced the selection bias further, which often is a critique of per-protocol analyses.

Another analytical method applied to assess the results in more depth was to report effects in elasticities. This analysis was included in Paper V to assess the responsiveness of SF-6D and EQ-5D. The challenge when assessing the responsiveness of the two measures was the differences in the range of the scales. Applying elasticities enabled comparison between the measures, as elasticities could be quantified as the ratio of the percentage change in one variable to the percentage change in another, removing the unit of measurement (312).

6.2 Discussion of the results

In this section, common issues from the five papers are reviewed based on the overall results of this project. The primary focus of the discussion is on the main outcomes—HRQOL, physical function and falls self-efficacy (6.2.1, 6.2.2, 6.2.3). Establishing longer-term exercise behaviour (6.2.4), evaluating interventions (6.2.5) and implementing falls prevention in clinical practice (6.2.6) are also discussed.

6.2.1 Health-related quality of life, physical function and falls self-efficacy in home care recipients and fallers

In this PhD project, the participants were older adults aged 67-96 receiving home care services and who had experienced at least one fall in the previous 12 months. This group of frailer older adults is often excluded in clinical studies (26, 187), which is discussed in Paper I. This is an important group to evaluate, because it is a transitional group between those living independently in the community and those living in an institution (376). As shown in Paper II, their HRQOL, physical function and falls self-efficacy were different from other groups of older adults. The results support the suggestion that there is a need for a shift in health care delivery to older adults from more hospital-based care to a more accessible service closer to their homes (47). All participants received professional health care at home, and these services can contribute to improving the independence of older adults so they can live at home longer and further prevent hospitalisation and institutionalisation (17, 377). In Norway, there has recently been increased pressure on primary health care services to handle health challenges for older adults (24). To provide better health services for older home care recipients, we need information on their health status, such as their HRQOL, physical function and falls self-efficacy, and on the relationship between these factors (Paper II).

Even though there is a lack of research including home care recipients and fallers, the results of Paper II are in line with the existing literature. In the sample studied in this PhD project, the participants had a mean number of falls of 2.7 in the last 12 months, which is equivalent to a study showing a high incidence of falls in home care recipients compared to the general population of older adults (68). The sample had a high percentage of women (79.3%), and the mean age was high (82.7 years), which is typical for the population of home care recipients in Norway (35). Previous literature including older home care recipients has demonstrated a low level of falls self-efficacy (36) and QOL (378) and a high level of activity restrictions (36) and functional challenges (66). Here, we showed that the HRQOL, physical function and falls self-efficacy of the participants were, on average, poor. For instance, the mean usual walking speed was 0.62 m/s, which is close to the cut-off of 0.6 m/s, indicating an increased likelihood of poor health and function (114, 116, 379). The participants also had impaired balance, with a mean sum score of 39.1 on the BBS; this is below the cut-off score of 45, indicating an increased risk of future multiple falls (380). In addition to having an increased risk of future falls based on poor physical function, the sample showed a high level of fear of falling. The participants in our study achieved a mean score of 30.7 on the FES-I; this is above the cut-off score of 28, indicating a high level of concern about falling when performing different daily activities (292). All these factors contribute to an increased risk of future falls (30). When it comes to HRQOL, the sample had generally low scores at baseline, compared to a normative sample of Norwegian older adults aged 70-80 (163). This might be explained by the link between physical function and HRQOL (169) and the general population of older adults might have better function compared to home care recipients. Several of the characteristics of the home care recipients mentioned above also apply to the general group of fallers, such as impaired balance and walking ability (30), reduced falls self-efficacy (381) and low QOL (83). Hence, older adults who receive home care and who have experienced falls pose health challenges that primary health care needs to address.

In the present PhD project, associations between HRQOL, physical function and falls self-efficacy were explored in the population of older fallers receiving home care (Paper II). Higher HRQOL was associated with better falls self-efficacy. Previous studies have demonstrated a similar relationship in the general population of older adults (139, 178). However, in the previous studies the samples included both fallers and non-fallers, and it might not be possible to generalise the results to the frailer sample in the present study. Moreover, previous studies on older adults have shown associations between IADL limitations (382), reduced walking speed (175), reduced physical fitness (171) and a lower level of HRQOL. The samples in these studies are older adults over 75 or frailer older adults recently discharged from hospital, which is comparable to the sample in our study. Moreover, our study showed that better scores on measures of balance, walking speed and IADL were associated with better scores on the physical sub-scale of SF-36. On the other hand, there were no relationships with the other sub-scales, and a small sample size might be the explanation. In studies specifically including home care recipients, the level of QOL has been negatively associated with IADL limitations and positively associated with having a social network (58). QOL is a broader concept than HRQOL, which might limit this comparison (151). In the PhD project having a social network was not assessed specifically, which could have been an important factor influencing HRQOL in this sample.

A surprising and interesting result was that several of the scales of SF-36, for instance MCS and MH, were positively associated with higher age. Similar findings were obtained in a previous study examining normative scores of SF-36 in different age groups in the Norwegian population (163). Older adults aged 70-80 had slightly higher mental sub-scores compared to the younger older adults in the sample. Possibly, those who were older and who received home care were more satisfied with their own situation compared to those who were younger. A similar tendency has been shown when studying the concept of well-being. When examining well-being in different generations, a U-shaped relationship between well-being and age has been demonstrated, where those in older age have better well-being (383). Nevertheless, well-being is a different concept than HRQOL, which might explain why some of the sub-scales of SF-36 do not have a positive relationship with age. Subjective well-being is normally assessed as satisfaction with life in combination with a balance between positive and negative emotions (384). In the concept of HRQOL, physical health has a stronger focus compared to the concept of well-being, which might have contributed to the limited association between higher age and the PCS score of SF-36.

6.2.2 Effects of a falls prevention exercise intervention on health-related quality of life

In the previous section, it was shown that the sample in the PhD project on average had a low level of HRQOL, and interventions to improve HRQOL are thus of importance. In this section, the focus is on the short- and longer-term effects of an evidence-based falls prevention exercise intervention on HRQOL. Based on research published before the start of the research project, the intervention chosen for testing in this sample was the OEP (205). The OEP encompasses exercise, motivational conversations and risk evaluation and can thus be conceptualised as a complex intervention. In complex interventions, several behaviours are required of those delivering and receiving the intervention (180). For instance, in this project the physiotherapists needed comprehensive knowledge on different factors related to falls prevention, such as the ability to evaluate the risk of falling and the ability to motivate the participants. Moreover, in complex interventions there are often several and variable outcomes included. The primary outcome of this study was HRQOL, but several assessments of physical function, I-ADL, falls self-efficacy and nutrition were also incorporated to provide a holistic evaluation of the programme in this group of older adults. There is no sharp boundary between simple and complex interventions, but few interventions are truly simple, and the number of components might vary widely (180). However, in simple interventions, the dose is at an optimal level and the intervention is delivered in the same way, which do not apply to the pragmatic design of the RCT conducted in the PhD project (385).

The short-term effect of this falls prevention intervention on HRQOL was measured at the end of the intervention at 3 months. The longer-term effect was measured at the 6-month follow-up. An improvement in physical HRQOL was shown at the end of the intervention, with changes in PCS ranging from 4.0 points in the ITT analysis to 6.3 points in the propensity score matching analysis. On assessment at the 6-month follow-up, the improvement in physical HRQOL had been sustained, and there was a change of 3.0 points in PCS. Even though the change in scores is not extensive, these results are within the MCID range of 3-5 points for SF-36 summary scales (273), which is of clinical importance (386). Previous research has shown mixed results when measuring the effects of exercise on HRQOL (201, 219, 221, 223, 387). A study with a similar design to the present study measuring the effect of an exercise intervention on HRQOL at 3 and 6 months in older adults attending a falls outpatient clinic found similar positive changes in physical HRQOL. These results were limited to a comparison between individual and group exercise (211).

In a systematic review evaluating the effect of falls prevention programmes on QOL, 6 of the 12 studies included showed positive effects on QOL (38). The participants in the studies included for that review were mostly female and within the same age range as those in our study, but they were either independent community dwellers, or were hospitalised or institutionalised and not home care recipients. The interventions ranged from exercise to information-based interventions to comprehensive geriatric assessment, which might have different characteristics from the intervention in the present study. Additionally, HRQOL was most often included as a secondary outcome, which might have impacted on the effect shown, as power calculation is based on the primary outcome (300). There are only a few studies in which exercise interventions have been evaluated in older home care recipients and in which QOL or HRQOL have been measured. These studies have shown that exercise interventions can have positive effects on QOL in this group of frail older adults in need of professional assistance with daily activities (225, 226).

When evaluating the effect of the programme on mental HRQOL, one interesting finding was that the intervention group had a decline in the MH sub-scale relative to the control group, both upon assessment at 3 months and at 6 months. This aspect was investigated further in the per-protocol analyses, where those who adhered to the intervention were compared to those who could not adhere due to, for example, hospitalisation or sudden illness. One explanation for this finding might be that the intervention group participants had higher expectations than the control group participants regarding improvements as they were not blinded to group allocation. When these expectations were not met, it might have had a negative impact on their mental HRQOL. A second explanation could be what is defined in the literature as response shift, where there is a change in the evaluation of internal standards and values (160, 388). Possibly, some of the participants experienced a change in their evaluation of their HRQOL and this might have had an impact on the result. A third explanation that might have led to a limited difference in mental HRQOL between the groups could be the home visits performed by the assessors, which were conducted for participants in both the control and intervention groups. These visits might have had a positive impact on the mental HRQOL of the participants. Simply participating in a research study and receiving home visits might explain the dampening of the net effect of the intervention (228).

Designing interventions for the group of frail older adults to improve their HRQOL is challenging. This group is often excluded from clinical studies, based on the assumption that they cannot tolerate the assessments or that they will not benefit from the intervention (39, 346). In this PhD project, a small pilot was conducted in which older adults were asked about the design of the intervention and what would be suitable. The choice of a 3-month duration and a 6-month follow-up was preferred and thus implemented. However, the duration of the intervention and the follow-up might have been too short to improve HRQOL substantially, and stronger effects could potentially have been achieved with a longer duration and follow-up (38). Previous literature has pointed out that showing effects in HRQOL after home-based exercise interventions can be challenging, especially in frail older adults (38). In home-exercise programmes, the intensity might be too low. Nevertheless, frequent bouts of physical activity performed at low-to-moderate intensity might be better suited to enhance HRQOL in frail older adults compared to vigorous exercise performed less frequently (229). At the same time, providing exercise at home can be of great importance for this group, as this might be the only feasible option due to, for instance, transportation barriers (389). Finally, in the group of frail older adults, the aim should be to maintain physical function and reduce the decline in HRQOL rather than on achieving large improvements (109).

6.2.3 Effects of a falls prevention exercise interventions on physical function and falls self-efficacy

In the following section, the short- and longer-term effects of the falls prevention exercise programme in relation to the secondary outcomes will be discussed. The secondary outcomes in this PhD project were falls self-efficacy and physical function, assessing balance, leg muscle strength, usual walking speed and I-ADL. On the BBS, assessing static and dynamic balance, the intervention group achieved a relative improvement of 2.4 points in the ITT analysis and 4.3 points in the propensity score matching analysis when measured at the end of the intervention. According to Donoghue and colleagues (390), the MCID is 4 points if one's score is 45-56 initially, 5 points if one's score is 35-44 and 7 points if one's score is 25-34. The mean BBS score for the sample at baseline was 39.1 points, and a change in score of 5 points would be clinically meaningful on average. Hence, the improvement in the BBS score in the intervention group might not have been enough to achieve a change of clinical relevance (390). On the other hand, as mentioned previously, maintaining physical function and preventing its decline should be the primary aim in this group of frail older adults, as most of them will experience a decline in physical function dependent on their ageing (109). Both groups achieved improvements on STS, assessing leg muscle strength, when measured at the 6-month follow-up. A large percentage of the participants in the control group also performed exercises in the post-intervention period, which might have contributed to the positive changes seen in both groups. In the PhD project, there were no significant changes between groups in I-ADL and walking speed, contrary to a previous study of a multicomponent exercise intervention for home care recipients (226). Differences in the characteristics of the intervention and outcome measures might have influenced this discrepancy in findings.

Interestingly, falls self-efficacy was not affected by the falls prevention exercise programme in this group of older adults. Previous research studying the effect of falls prevention exercise interventions on falls self-efficacy have shown mixed results. Some studies have shown positive results (193, 391), while others have not shown any positive effects (344, 392). A recent systematic review demonstrated small to moderate effects of exercise interventions on reducing the fear of falling in older adults (393). These discrepancies in results might be due to the population studied, varying from older adults diagnosed with osteoporosis or stroke to community-dwelling older adults without a specific diagnosis, or to the characteristics of the intervention, varying from multifactorial programmes to exercises based on tai chi. The sample in the present study was frail, and follow-up specifically directed at their fear of falling, for instance behavioural techniques to reduce the fear in different situations, might be necessary to improve their falls self-efficacy. Another factor that might explain the lack of effect could be the assessment performed to evaluate the effect. In FES-I, older adults are asked about their fear of falling when performing different activities. Possibly, they became more aware of their fear from assessment at baseline to the next assessment at 3 months and therefore did not improve their score upon the second assessment. Furthermore, the lack of effect of the programme on falls self-efficacy might explain why mental HRQOL did not improve, as falls self-efficacy has been shown to be an important predictor of HRQOL (178). A recent study carried out an intervention involving cognitive-behavioural therapy for older adults to reduce their level of fear of falling and achieved positive results (394). By combining exercise and cognitive-behavioural therapy, falls prevention interventions might possibly influence mental health to a larger degree.

Importantly, the present PhD project showed that the falls prevention exercise programme applied to frail older adults receiving home care seems to be safe, and adverse events were limited. There were no falls or other serious incidents reported when exercising. However, three participants reported musculoskeletal pain/discomfort after using ankle cuffs. The present study is in line with recent reviews of the literature. In a systematic review by El-Khoury and colleagues (189), including 17 studies and 4305 participants, a total of eight participants in two studies reported temporary musculoskeletal discomfort related to exercise. No fall-related injuries occurred during the exercise sessions in any of the included studies. However, only six of the trials specifically reported adverse reactions. Similar results were shown in the systematic review by Sherrington and colleagues (117), where only two serious events were reported; any other events were non-serious and were mostly musculoskeletal in nature. The focus on exercise safety (especially on the first home visit) as part of the OEP might have prevented adverse events in the intervention group.

6.2.4 Establishing longer term exercise behaviour

Both Papers III and IV showed that establishing longer-term exercise behaviour in older home care recipients is important to sustain or improve their HRQOL, physical function and falls self-efficacy and to prevent falls. Previous research has also shown that longer-term exercise can prevent or postpone a decline of functional performance and QOL (201, 395). Adherence to falls prevention exercise programmes to establish longer-term exercise behaviour is the focus in this section. Promoting physical activity over time with the aim of changing exercise behaviour is different in older adults compared to the general adult population (396). When evaluating interventions for older adults, a higher degree of participation has been shown in interventions including balance and walking exercises, moderate home visit support and physiotherapist-led delivery (334). In falls prevention, factors facilitating participation have included social support, low intensity exercise and involvement in decision making, while factors limiting participation have been under-estimation of the risk of falling, fear of falling and the stigma associated with programmes targeted at older adults (397). About 50% of community-dwelling older people are likely to adhere to falls prevention interventions after 12 months (398). In the present study, 80.3% of the participants in the intervention group continued to exercise following the intervention period, either individually or in a group. Continuing exercising in the follow-up period was shown to mediate the effect of the intervention on physical HRQOL, which is in line with previous research showing that staying physically active can improve physical HRQOL in the long run (223). Social interactions have a key role in supporting the continuation of home exercise over time (399). In the present study, the relationship to the physiotherapist, family, friends or others developed in the intervention period might have influenced the high level of adherence in the follow-up period.

Adherence to exercise interventions depends on the characteristics of the programme and of the participants (334, 400, 401). In this project, 73.5% managed to complete the exercise programme as prescribed, receiving all home visits and telephone calls and performing two or more self-training sessions each week. Previous research has shown that those who are the best adherers have better self-rated health, physical function, cognitive function and higher exercise self-efficacy (400, 402, 403). In people with limited mobility, poor health, fear, negative experiences, lack of company and unsuitable environments have more often been mentioned as barriers to adhering to exercise than in those having no mobility limitations (404).

Similar findings were shown in this study. The participants who stayed active had better physical HRQOL, strength and balance compared to the non-active participants. However, 26.5% of the intervention group participants could not adhere fully to the programme, for instance performing less self-training for a period due to sudden illness or hospitalisation. This is in line with previous findings stating that a change in health status is the primary reason for poor adherence to exercise (332). Even though a proportion of the sample could not complete the intervention as planned for various reasons, it seems that they were able to start exercising again in the follow-up period. The flexible and individualised structure of the programme focusing on self-management with limited home visits and including motivational telephone calls and self-training might further explain the high degree of physical activity in the follow-up period (405). Previous research has shown that low-cost self-management programmes can be beneficial in improving health status and reducing health care costs in populations of older adults with chronic diseases (406, 407).

In addition to ensuring longer-term adherence to exercise interventions, recruiting older adults who are not physically active or who have limited their level of physical activity is of importance in public health policy (9). Recruiting older adults to falls prevention interventions can be challenging, in particular frail older adults. Here, about half of the older adults eligible for the study and who received an invitation letter agreed to participate. One explanation for why some did not wish to participate might be their identification as a faller, which represents a potential threat to their identity and autonomy (408). In younger older adults, the denial of the risk of falling and not seeing the necessity of preventing falls can limit participation in falls prevention (409). In higher-risk groups, individual beliefs, such as their personal need for falls prevention, and structural and social factors, are important to improve participation (410). In the project, many of the older adults had mobility difficulties or did not wish to attend group activities. Therefore, an individual home-based programme was provided to improve recruitment from this group of frailer older adults. Finally, falls prevention programmes can be promoted more effectively by better emphasising and presenting their multiple positive benefits, such as increased well-being, health and independence (411, 412).

6.2.5 Evaluating interventions in older home care recipients

In falls prevention studies including community-dwelling older adults, the falls rate is most often the primary outcome when evaluating the efficiency of an intervention (117). Even though this was not the primary outcome, a reduction in the number of participants experiencing falls was shown in the intervention group relative to the control group at the 6-month follow-up. However, it is questionable, if the rate of falls is always the most suitable outcome of exercise interventions, as previous research has shown that increased physically activity is associated with an increased number of falls (413). Other outcomes of falls prevention are possibly of greater importance. Here, the aim was rather to evaluate the effect on HRQOL, as this is an understudied aspect in research on older home care recipients and falls prevention (11, 38). HRQOL is a useful measure when evaluating interventions for older adults, both in terms of assessing their QOL and calculating the cost effectiveness (240). In this project, SF-36 and EQ-5D were used to measure HRQOL, and Paper V explores the applicability of the utility indexes SF-6D and EQ-5D when evaluating the effectiveness of interventions in older home care recipients.

The analyses presented in Paper V showed that there seems to be a high level of agreement between EQ-5D and SF-6D when evaluating interventions in home care recipients. There are also some differences. When selecting an HRQOL instrument to evaluate interventions it seems that the characteristics of both the studied population and the intervention can have an impact. When it comes to the characteristics of the sample, the older adults generally had a low level of self-perceived HRQOL compared to normative data on SF-6D and EQ-5D (414, 415). Previous research has shown that EQ-5D is more sensitive in patient groups with severe health conditions at baseline and is less sensitive in patient groups with milder health conditions at baseline, and the opposite applies to SF-6D (259). Because the sample mainly consisted of older adults with milder and chronic health conditions, the high sensitivity to changes in the EQ-5D shown in the present study was surprising. On the other hand, the greater responsiveness of EQ-5D could be explained by the characteristics of the intervention. EQ-5D seems to be more sensitive to changes in physical function compared to SF-6D. This could be due to the domains included in the instruments; for example, elements relating to physical health are more represented in EQ-5D compared to SF-6D. The latter instrument has a stronger focus on mental health (248). Because the intervention focussed to a larger degree on improving physical function by performing an exercise programme, this might explain the larger sensitivity of EQ-5D. Therefore, if the intervention had included actions also targeting other dimensions, such as social functioning or vitality, SF-6D could possibly have been more responsive. However, Papers III and IV showed that the intervention had an effect on physical HRQOL, measured by SF-36, but there were no significant differences in terms of EQ-5D. SF-6D derives from the responses to 11 of the 36 SF-36 items through preference weighting (260), and the focus of the instrument might have changed slightly in this process, possibly explaining the deviation in results.

6.2.6 Implementing research on falls prevention in clinical practice

Even though the focus of the PhD project was to evaluate the effectiveness of an evidence-based falls prevention programme conducted in primary care, further implementation of the programme in this setting is a longer-term objective. In this section, the focus is on the implementation of falls prevention research to clinical practice. Even though the literature on falls prevention is comprehensive, implementation to health policy and clinical practice has been challenging (266, 416). Research conducted in real-life settings is thus of great importance. The PhD project had a pragmatic design, aiming at maximising the applicability of the research results to usual care settings (330). All assessments and the intervention were conducted in a home care setting by clinical physiotherapists as part of their everyday work. Moreover, every effort was made to avoid selection bias in order to make the sample representative of the older adults to whom the intervention will be applied (265). The sample recruited is from a vulnerable population of older home care recipients and fallers requiring an individualised approach, which previous research has shown that physiotherapists prefer (417). Individualisation and adaptions of the intervention, such as providing extra visits following a hospital stay or contacting the nurse due to the risk of malnutrition, were necessary to ensure the ethical treatment of this group of frail older adults. These procedures also reflect what would be common in clinical practice. Moreover, the intervention performed had a low frequency of visits and was inexpensive compared to many other interventions commonly conducted in primary care. This means it is more likely to be implemented in different clinical settings.

Due to the low degree of implementation of falls prevention into clinical practice, the rate of falls has not been reduced in the population of older adults (266). There are a number of challenges to implementation of falls research into clinical practice, including economic considerations, access to the intervention, time and knowledge (418, 419). These challenges relate to the older adults, their families, the health care professionals and the health care systems (419). In a primary care setting, applying the evidence according to the resources available and the experience of the health professionals, is thus of importance (420). To improve the transferability of the OEP to the primary care setting in the six municipalities included for this PhD project, several meetings were held before start-up in which time, economic resources and knowledge on falls prevention were discussed with the clinicians and their managers. Additionally, interviews with the physiotherapists were conducted in the course of the project as a process evaluation to acquire more knowledge on their experiences of using OEP in clinical practice and to include them in the process. Moreover, to improve programme design it is important to incorporate the views of the older adults (421). Therefore, older adults were interviewed both before and during the project period to obtain their preferences and experiences to further improve the study design and future implementation of the programme.

The dissemination of both the results and experience gained in this research project has been an important strategy to improve further implementation of the results to clinical practice. As part of the preparations and as a follow-up to the research study, training on falls prevention in general and specifically on the OEP was provided to the health care professionals participating and to other clinicians. This type of active training of health care professionals has been shown to improve implementation (422). Additionally, disseminating the results to health managers and policy makers is important to be able to influence decision making at the policy level (423). Participating in resource groups to develop national guidelines and publishing in popular science journals have therefore been carried out as part of this PhD project. Finally, disseminating the project design and research results to other researchers in the field, both nationally and internationally, has been of importance to improve the internal and external validity of the study.

7 Conclusions

The final chapter in this thesis consists of the conclusions (7.1), the implications for clinical practice and suggestions for future research (7.2).

7.1 Conclusions

The overall aim of this PhD project was to develop new knowledge on falls prevention for older adults receiving home care as a strategy to enable them to remain at home with good HRQOL and physical function. Within this overall aim were several sub-aims. The first sub-aim was to describe the level of HRQOL, physical function and falls self-efficacy and the relationships between these factors in the population of home care recipients. The second sub-aim was to evaluate the short- and longer-term effects of a falls prevention programme based on the OEP on HRQOL, physical function and falls self-efficacy in this population. The third sub-aim was to examine the agreement between EQ-5D and SF-6D when evaluating interventions for older home care recipients.

The conclusions in the five papers included for this thesis can be summarised as follows:

- Older adults receiving home care and who have experienced falls comprise a growing and diverse group. Clinical research including this group is limited. More knowledge on health status, the effectiveness of falls prevention interventions and measuring HRQOL in this group of vulnerable older adults is needed.
- Older home care recipients who have experienced falls have a low level of HRQOL, poor physical function and poor falls self-efficacy compared to normative samples of older adults.
- A higher level of HRQOL was associated with better physical function and better falls self-efficacy. This association was independent of physical measures, number of falls, cognition and key background characteristics, such as age, sex and education.
- A falls prevention programme based on the OEP can improve physical HRQOL and balance in older adults receiving home care in the short term. Those who managed to complete the programme as prescribed had even greater improvements in physical HRQOL, balance and strength. For those who did not manage to complete the programme, a negative impact on mental HRQOL was observed.

- A falls prevention programme based on the OEP can improve physical HRQOL in older home care recipients in the longer term. The intervention increased the probability of maintaining exercise following the intervention period and reduced the probability of experiencing falls. Exercise carried out post-intervention mediated the effect of the intervention on physical HRQOL.
- Older adults with a higher level of HRQOL and/or better physical function achieved a relatively higher score on EQ-5D, and those with a lower level of HRQOL and/or poorer physical function achieved a relatively higher score on SF-6D. EQ-5D was more responsive to changes in physical function compared to SF-6D. Selecting an HRQOL instrument to evaluate an intervention might therefore depend on the characteristics of the intervention and of the studied population.

7.2 Implications for clinical practice and suggestions for future research

This PhD project showed that the sample of home care recipients had poor HRQOL, physical function and falls self-efficacy compared to the general population of community-dwelling older adults, even though the majority only received a limited amount of services, such as safety alarm services or practical assistance. Therefore, assessing this group more thoroughly when they first apply for home care service is essential. Interventions to prevent further decline can then be started before older adults eventually experience a fall.

Ensuring HRQOL for frail older adults and at the same time keeping the economic costs reasonable is a challenge for health care services in the municipalities. Developing effective interventions which can be individualised based on the heterogeneity and fluctuating health of this group of home care recipients is important. The present study demonstrated that a low-cost exercise programme focusing on self-training and conducted in a home care setting can improve physical HRQOL and balance in the short term. Perhaps even more importantly, the programme contributed to sustained physical HRQOL, a positive change in exercise behaviour and a reduction in the risk of falling in the longer term. The OEP performed at home can possibly work as an introductory programme, to get frailer older adults started with falls prevention exercises. Once mastering this programme, they can be included in falls prevention group sessions or other activities in their local environment.

Conducting economic evaluations of interventions for older adults in primary care is increasingly important to guide policy makers and health managers when prioritising and making decisions on service development. Knowledge on useful tools to calculate the costs and benefits of interventions is therefore essential. The present study showed that both EQ-5D and SF-6D can be utilised for economic evaluations; however, it depends on the characteristics of the population and of the intervention. SF-6D seems more applicable when assessing older adults with chronic and complex conditions, while EQ-5D seems more applicable when assessing older adults with acute and physical conditions. When conducting an intervention focusing on improving physical function, EQ-5D seems to be more responsive.

Frailer older adults and home care recipients represent an understudied group, and more research focusing on this group is necessary. The present study only assessed longer-term effects at 6 months; therefore, future studies should have longer follow-ups. Additionally, there was a lack of effect on falls self-efficacy in this study that might have limited the effect on mental HRQOL. Future research could include cognitive therapy in falls prevention interventions to be able to affect falls self-efficacy and possibly mental HRQOL. Age-specific HRQOL instruments could also have been included to evaluate the effect of the intervention on other age-related aspects of HRQOL. Finally, the population of home care recipients is heterogenous, and various sub-groups could benefit differently from the falls prevention intervention. Future studies could increase the sample size substantially and narrow the inclusion criteria to allow for systematic sub-group analyses.

8 References

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9 Appendix: Published papers

Paper I

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; 17(1):559, DOI: https://dx.doi.org/10.1186/s12913-017-2516-5.

Paper II

Bjerk M, Brovold T, Skelton DA, Bergland A. Associations between health-related quality of life, physical function and fear of falling in older fallers receiving home care. BMC Geriatrics. 2018; 18(1):253, DOI: https://dx.doi.org/10.1186/s12877-018-0945-6.

Paper III

Bjerk M, Brovold T, Skelton DA, Liu-Ambrose T, Bergland A. Effects of a falls prevention exercise programme on health-related quality of life in older home care recipients: a randomised controlled trial. Age and Ageing. 2019; 48(2):213-219, DOI: https://dx.doi.org/10.1093/ageing/afy192.

Paper IV

Bjerk M, Brovold T, Davis JC, Skelton DA, Bergland A. Health-related quality of life in home care recipients after a falls prevention intervention: a 6-month follow-up. European Journal of Public Health, Volume 30, Issue 1, February 2020, Pages 64–69, DOI: https://dx.doi.org/10.1093/eurpub/ckz106.

Paper V

Bjerk M, Brovold T, Davis JC, Bergland A. Evaluating a falls prevention intervention in older home care recipients: a comparison of SF-6D and EQ-5D. Quality of Life Research. 2019; 28(12):3187-3195, DOI: https://dx.doi.org/10.1007/s11136-019-02258-x.

Bjerk et al. BMC Health Services Research (2017) 17:559
DOI 10.1186/s12913-017-2516-5

BMC Health Services Research

STUDY PROTOCOL
Open Access

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

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Abstract

Background: Falls and fall-related injuries in older adults are associated with great burdens, both for the individuals, the health care system and the society. Previous research has shown evidence for the efficiency of exercise as falls prevention. An understudied group are older adults receiving home help services, and the effect of a falls prevention programme on health-related quality of life is unclear. The primary aim of this randomised controlled trial is to examine the effect of a falls prevention programme on quality of life, physical function and falls efficacy in older adults receiving home help services. A secondary aim is to explore the mediating factors between falls prevention and health-related quality of life.

Methods: The study is a single-blinded randomised controlled trial. Participants are older adults, aged 67 or older, receiving home help services, who are able to walk with or without walking aids, who have experienced at least one fall during the last 12 months and who have a Mini Mental State Examination of 23 or above. The intervention group receives a programme, based on the Otago Exercise Programme, lasting 12 weeks including home visits and motivational telephone calls. The control group receives usual care. The primary outcome is health-related quality of life (SF-36). Secondary outcomes are leg strength, balance, walking speed, walking habits, activities of daily living, nutritional status and falls efficacy. All measurements are performed at baseline, following intervention at 3 months and at 6 months' follow-up. Sample size, based on the primary outcome, is set to 150 participants randomised into the two arms, including an estimated 15–20% drop out. Participants are recruited from six municipalities in Norway.

Discussion: This trial will generate new knowledge on the effects of an exercise falls prevention programme among older fallers receiving home help services. This knowledge will be useful for clinicians, for health managers in the primary health care service and for policy makers.

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

Keywords: Falls prevention, Home help services, Elderly, Quality of life, Older adults, Exercise, Balance, Preventative care

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Background

Older adults and health-related quality of life

Health-related quality of life (HRQOL) is of great interest, both with respect to individuals themselves as well as a primary concern of public health administrations and professionals. The remarkable increase in life expectancy in the twentieth century implies a need to focus on factors capable of promoting a high level of HRQOL into old age. In fact, older adults seem to prefer a high HRQOL more than longevity, and researchers have concluded that the key challenge is to preserve a high level of HRQOL rather than increase length of life [1, 2]. HRQOL is a subjective, multidimensional concept shaped by, but not entirely dependent upon, the effects of disease and treatment [3]. The WHO Quality of life (QOL) group defines QOL as “individuals` perception of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns” [4]. Public health policies in many European countries are therefore primarily concerned with keeping older people living independently in the community with a good quality of life [5–7]. The raise in number of older adults implies more people with chronic diseases and a greater challenge for the health care system in finding effective and feasible interventions to reach this goal [5–8].

Aiming to enable older people to live at home as long as possible, the municipalities in Norway are responsible for providing services in the form of home help for older people [9]. Home help includes services that assist instrumental activities of daily living (iADL), such as vacuum cleaning, and personal activities of daily living (pADL), such as getting dressed, safety alarm services to provide assistance if they fall, and social support. The most important predictor of home care use seems to be dependency in IADL and ADL and cognitive impairment [10]. Home help receivers constitute a transitional group between independent community living older people, and people living in residential care facilities/nursing homes [11]. The combination of the increase of older people and the use of the so-called LEON (“lowest most efficient level of care”) principle [6], makes this a steadily growing group in society, and can be seen as an especially vulnerable group among the older population. Moreover, as economic resources are scarce, there seems to be more focus on post-acute care instead of health promotion and prevention to maintain older adults at home [12]. To date there is no evidence-based practice standard for falls-prevention in Norwegian home care services.

Older adults and falls

Falls and fall-related injuries are common in older adults and are associated with substantial economic costs that are borne by individuals, the community, and the medical system as a whole [13, 14]. Up to 40% of all nursing home admissions have been found to relate to falls and instability [15]. Important risk factors for falling in the group of older adults are impaired balance and gait, polypharmacy and a history of falls [16]. Poor nutritional status has also been associated with an increased risk of falling, [17] and malnutrition or being in risk of malnutrition is prevalent in half of the older adults receiving home care services [18]. Common consequences of a fall are fear of falling, activity restrictions, loss of mobility and loss of independence [19]. Falling, or being at risk of falling also has a negative influence on QOL [20]. Hence, it can be argued that HRQOL is an important outcome in the assessment of falls-prevention programmes [21].

After several decades of research on interventions to reduce falls and fall risk factors, there is now strong evidence for the effectiveness and cost-efficiency of exercise in reducing the number of falls [14, 22–25]. An important, but yet understudied group when it comes to the effect of falls prevention programmes are older adults receiving home help services, and especially those who recently have experienced a fall [11]. Previous research has shown that falls and fear of falling are common in this population and are correlated with the amount of home care needed [11, 26]. Vikman et al. [11] concluded that future studies should have a focus on the effects of falls prevention programmes in the group of those receiving home help services. Recently it has been shown that home help receivers fell more frequently than the independent home-dwelling older population [27]. Low functional level and high home care recipient health problems were independently associated with risk of falling [27]. Fear of falling is also reported more frequently in the group of older adults receiving home help services compared to those who do not receive home care [28]. This suggests that the higher level of fear of falling could be due to a higher level of frailty in this group. Finally, it has been shown that elderly home help receivers in Sweden have a lower QOL compared to those without help and that QOL was negatively correlated with the amount of help needed [29].

Interventions to improve quality of life

Although exercise-based falls prevention programmes have shown a clear effect on falls incidence and fall risk factors in the general older population, the evidence is still inconsistent about the effects on HRQOL and in particular related to the population of home help receivers [11, 21]. A systematic review by Vaapio et al. [21] considered the specific effect of falls prevention programmes on QOL. The review looked at 12 RCTs including older adults, but none of the studies were aimed at home help receivers. Six of these studies showed a positive effect on QOL. The interventions in these studies ranged from exercise (two studies), information based (one study), to comprehensive geriatric assessment (one study). The review concluded that there is a lack of evidence about the potential benefits of falls prevention programmes on QOL in older people and that more research is needed.

To the authors' knowledge, only two RCTs have been examining exercise interventions aimed specifically at the population of older home help receivers [30, 31]. The first study tested a home-exercise programme and found positive results on maximum walking speed, but unfortunately the assessors were not blinded to the intervention [31]. The other study explored the effects and costs of a multifactorial, interdisciplinary team approach to falls prevention in 109 older home help receivers with a risk for falls [30]. Exercise was part of the programme, but the amount and mode of exercise varied according to individual needs. At 6 months, no difference in the mean number of falls between groups were found. Subgroup analyses showed that the intervention effectively reduced falls in men (75–84 years old) with a fear of falling or negative fall history, but it is unclear whether the study had sufficiently power for subgroup analyses [30]. Nevertheless, the secondary outcome of QOL significantly improved in the intervention group.

The effect of exercise interventions on HRQOL in the general older adult population have had mixed results, reporting both statistically significant positive effects as well as no significant changes [32–35]. A meta-analysis found no difference between aerobic and strength training, suggesting that the different exercise modes yielded the same effect on self-reported physical function domains of HRQOL [34]. Acree et al. [3] concluded that healthy older adults who regularly participated in physical activity of at least moderate intensity for more than 1 h per week had higher HRQOL measures in both physical and mental domains than those who were less physically active. Although many intervention trials have found a positive association between exercise and HRQOL, the available data from other intervention trials conducted among older adults is inconsistent. Additionally, information of the most effective mode of exercise that may influence HRQOL is lacking [32–35]. Self-efficacy is a possible psychological mediating factor and physical function is a possible physiological mediating factor. Previous research has shown that self-efficacy beliefs can be related to well-being following exercise interventions [36, 37] and that self-efficacy can explain adherence to exercise programs [38–41]. A central concept of the self-efficacy theory is so-called performance accomplishment, i.e. mastery experiences related to certain activities [42], and this points towards testing the mediating effect also of physical function.

The primary aim of this study is to explore the effects of a falls prevention programme, lasting 12 weeks, on HRQOL in older adults receiving home help services. Effects on the secondary outcomes, physical function and falls efficacy, will also be explored. A secondary aim of this study is to explore the mediating factors between falls prevention and HRQOL.

Methods

Study design

The study is a single-blinded, pragmatic RCT comparing one intervention group with a control group. The intervention group will receive an adapted version of the Otago Exercise Programme (OEP) over 12 weeks, while the control group receives usual care. Measurements are performed at baseline, at 3 months and at 6 months. The intervention and assessments will be conducted in the participants' homes. Assessors will be blinded to group participation.

Study setting and recruitment

Six municipalities in the Oslo region have agreed to take part in the research project. Participants are recruited through consultants in the municipalities coordinating and providing home help services. The researcher visits the municipalities on a regular basis to conduct the recruitment. Additionally, health workers in the municipalities are informed about the criteria to participate and will alert about eligible participants. Eligible participants will be contacted by the researcher by telephone and asked to consent to being sent information about the study. After a week, they will be contacted again to see if they consent orally to participate. Before baseline testing, the participants must provide a written informed consent. Figure 1 presents the planned flow of participants in the study.

Inclusion and exclusion criteria

Inclusion criteria are: Individuals who 1) are 67 or older, 2) receive home help services 3) have experienced at least one fall during the last 12 months, 4) are able to walk with or without a walking aid and 5) understand Norwegian. Exclusion criteria are: 1) medical contraindications to exercise, 2) life expectancy below 1 year, 3) a score below 23 on the Mini Mental State Examination (MMSE) and 4) currently participating in other falls prevention programmes or trials.

Randomisation

The participants are randomly assigned at a 1:1 ratio to the intervention group and the control group. A computer-generated, permuted block randomisation scheme is used to allocate the participants. Following randomisation, the participants receive information by

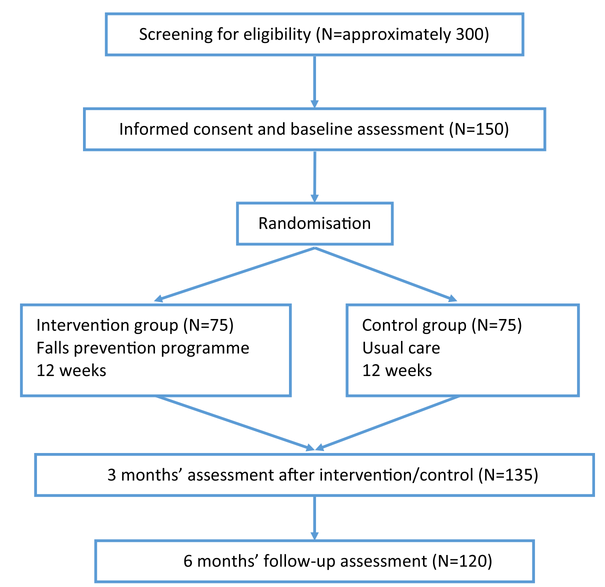

Fig. 1 Planned flow of participants in the study

telephone on which group they are allocated to. See flow chart in Fig. 1.

In order to optimize the rigor of the RCT and to minimize bias, a number of methodological factors have been incorporated into the design of the study. The study participants will be randomly allocated to the groups via concealed allocation, as inadequately concealed allocation has been associated with bias in RCTs [43]. Due to the nature of the intervention, it is not possible to blind the participants or the treating therapists to the allocated groups. However, all assessors are blinded to the allocated groups. In further attempts to reduce bias, data will be analysed on an intention-to-treat basis. This preserves the randomisation process and imitate the real-life situation where the possibility exists that not all participants receive the prescribed treatment.

Study intervention

The intervention performed is based on the OEP, including home visits and motivational phone calls [44]. Balance exercises comprise tasks in standing, walking backwards, stair-walking and rising from a chair. Strengthening exercises uses ankle weight cuffs to strengthen hip extension and abduction, knee flexion and extension and ankle plantar and dorsiflexion. The programme also includes warm-up exercises as movement of neck and shoulders. The OEP has been described in more detail previously [44]. This programme has been shown to be effective in reducing number of falls and number of injuries resulting from falls in addition to improving strength and balance, and maintaining falls efficacy in home-dwelling older adults [45].

In previous studies the OEP has been performed over a period of 1 year [45]. A meta-analysis by Sherrington et al. [46], looking at the effect of falls prevention programmes, recommend a dose of at least 3 hours of exercise weekly for 6 months. This weekly dose is attempted, but the duration of 3 months is shorter than in previous studies. Nevertheless, as in the original OEP, the same number of home visits and telephone calls will be made, and the participants will be encouraged to do a sufficient amount of exercise between home visits. The rational for the change in duration and frequency is both theoretical and pragmatic. Participants included for this study are frail older adults who have a fall history and who receive home help services. Previous research has shown that home help receivers fall more frequently and have a higher level of fear of falling [27, 47]. Poor health, fear of falling, depression and lack of strength are barriers for older adults in order to adhere to exercise programmes [48]. The participants in this study are thus likely to have a lower level of observance compared to more independent elderly and a duration of 1 year might be too long. Additionally, previous research has shown that falls prevention programmes which were considered too demanding by the participants even had a negative impact on QOL [49]. On the other hand, only receiving a few visits might not provide sufficient support which in turn could limit adherence. The pragmatic rationale relates to the organizational structure of physiotherapy services in the primary health care. For this group of older adults an intervention of 3 months is within the time frame of what the physiotherapists normally can provide. Finally, previous research has shown that also falls prevention programmes with a shorter duration than 6 months have had a positive effect on QOL [21].

The physiotherapists visit the participants at home five times during the intervention (week 1, 2, 4, 8 and 10) for instruction and for guiding the appropriate level and progression of each exercise. This includes one additional visit compared to the first 12 weeks of the original OEP intervention [44]. Each visit will take about 1 hour. The first visit may take longer is initial information is given and a relationship is established. At this visit advice related to safety when performing exercises is provided to the participants, both orally and written. In between supervised sessions, participants will be encouraged to continue exercising on their own three times weekly for 30 min. Equipment for exercising (ankle cuff weights of 1, 1,5, 2 and 2,5 kg) is provided for each participant. The weeks between home visits, the physiotherapists call the participants to motivate them to continue exercising and to answer possible questions. As a part of the programme, the participants are also encouraged to perform at least two or more weekly walks of ≥30 min. The participants are provided with a written exercise booklet including illustrations. Following the intervention period, the participants to keep the exercise equipment and booklets, in order to continue exercising.

The participants in the control group will receive usual care from the primary health care service. Following reassessment, the participants will have opportunity to participate in other falls prevention programmes, for example, already existing balance exercise group classes.

Education of intervention deliverers

Workshops and meetings will be held to inform the physiotherapists participating in the project. Before starting recruitment, one full day workshop on falls prevention and OEP is held for all therapists. Following start-up of recruitment and until the end of the project one workshop will be held approximately every forth months. These last half a day and include one lecture on a topic concerning older people and time for discussion on the development of the project. Additional to the workshops, the researcher will have monthly meetings with the physiotherapists in the different municipalities. In order to make sure that the intervention is performed as intended, a fidelity checklist based on the OEP-manual has been developed. The physiotherapists use the checklist when conducting the home visits and phone calls.

Outcome measures

Following recruitment participants are assessed before they are randomised. Assessors are blinded to the participants´ group assignment. The time window between baseline assessment and start of intervention is aimed to be within 2 weeks, and the same time window for assessments due at three and 6 months. Measurements and their order are selected to avoid physical and mental fatigue of the participants. Outcome measures that are employed have established reliability and validity, as recommended by the CONSORT group [50]. In addition to improving measurement quality and outcomes, it enables direct comparisons with other studies that investigate HRQOL and can possibly contribute to meta-analyses.

At baseline the Mini Mental Statement Examination (MMSE), a measurement of "Global cognitive function", is performed and is used as exclusion criteria. The maximum score is 30. A score below 23 indicates cognitive impairment and these participants are excluded [51]. Sociodemographic characteristics, like age and education, are also assessed at baseline. Primary and secondary outcome measures will be performed at baseline, at 3 months and at 6 months' follow-up.

Primary outcome variable

HRQOL is the primary outcome measured by the Short Form 36 Health Survey (SF-36) [52]. This is a generic and validated questionnaire which, translated into Norwegian, is conducted as an interview [53]. The 36 items in SF-36 are grouped into eight health status scales: physical functioning, role limitations due to physical problems and due to emotional problems, bodily pain, general health perception, vitality, social functioning and mental health [52].

Secondary outcome variables

In addition to the SF36, the EQ-5D (1990 EuroQOL EQ-5D) is reported. The EQ-5D is a generic and validated questionnaire [54–57]. It describes five dimensions of HRQOL (mobility, self-care, usual activities, pain/discomfort, anxiety/depression), each of which can take one of five responses at five levels of severity (no problems/slight problems/moderate problems/severe problems/severe problems/extreme problems).

Physical function includes measures of balance, gait speed, muscle strength as well as activities of daily living. The Bergs Balance Scale is a 14-item scale, which is applied to assess static and dynamic balance in older adults [58]. Gait speed is assessed by measuring usual walking speed over four meters [59] and muscle strength is measured by the 30 s sit to stand test [60]. Instrumental ADL is recorded using the Norwegian Version of the Lawton IADL scale, which is a valid and reliable measure of a person's self-reported ability to perform complex activities of daily living [61].

Physical activity is measured using the "Walking habits questionnaire", a valid questionnaire for walking habits and physical activity for frailer older people [62]. This questionnaire assesses general behaviour of walking, regarding how often and for how long. The following questions are asked: "Do you take a daily walk?" (yes/no) or "If you do not take a daily walk how many times per week do you take a walk?" (never/almost never/1–2 days/3–4 days/ almost daily) and "How long does you walk generally last? (0–15 min/15–30 min/30–60 min/ 1 h–2 h/>2 h)". Walking time in minutes per week is calculated by taking the lowest level of days multiplied by lowest level of minutes for each response alternative [62].

Nutritional status is measured using the Mini Nutritional Assessment (MNA- elderly, Société des Produits Nestlé, S.A., Vevey, Switzerland) form. The first screening part of six questions is used which includes measurement of weight and height for calculation of BMI [63–65].

Falls efficacy is assessed using the Falls Efficacy Scale International (FES-I). This scale has shown good reliability and validity assessing concerns about falling in older adults, and is recommended for clinical trials and practise [66, 67]. It is a self-reported questionnaire, containing 16 items on different activities of daily living. Level of concern is measured on a four-point scale ranging from 1, which is not at all concerned, to 4 which is very concerned [68].

Adherence to the programme is documented through an activity diary completed by the participants and a form checked by the physiotherapists during home visits and calls. Additionally, the participants have a falls calendar where they report adverse events. Adverse events are registered in the following four categories: falls, cardiovascular events, musculoskeletal injuries and health care utilization and will be documented as "due to the intervention" or "not due to the intervention" [69].

Sample size estimation

The sample size is estimated from the primary outcome, HRQOL (SF-36). A treatment difference of 10 points between the two groups in one of the domains in SF-36 is regarded to be of statistical and clinical significance. The associated standard deviation is assumed to be around 20 points. This implies a moderate effect size [70], which can be expected as previous OEP studies have shown substantial effects on physical outcomes [45]. Moreover, a similar Norwegian study, which included older adults performing exercise following discharge from hospital, estimated the required sample size identically [71]. Given a power of 80% and level $\alpha = 0.05$, we aim at including 150 participants, allowing for a 15–20% dropout, to detect a difference of 10 points between groups (see Fig. 1).

Statistical procedures

Statistical analysis is performed using SPSS or a similar statistical package. Descriptive data are reported for variables of interest. The data will be analysed following the intention to treat principle [72]. Prospective differences in primary and secondary outcomes and baseline characteristics between the intervention group and the control group will be assessed by t-tests for continuous and normal distributed variables and with non-parametric tests for categorical variables. Multiple linear regression modelling are used to control for confounding of between-group differences [73]. Hypotheses about mediating factors are tested through correlations, multiple regressions and bootstrapping methods exploring the correlations and explained variance of the chosen mediating factors and the changes in QOL [74]. Bootstrapping is a non-parametric method and is considered favourable with dichotomous variables (group 1 and 2) and small samples ($n < 250$) [74].

Discussion

The main purpose of the study is to evaluate the impact of OEP on HRQOL in older adults receiving home help services. We anticipate that the intervention described in this protocol will have a positive impact on the HRQOL. The tailored intervention will have a potential to promote evidence-based decision-making and empower older people receiving home help services to remain to a greater extent in charge of their own lives. We rely on a systematic approach, which corresponds with the guidance on developing and evaluating RCTs [75]. Only a few studies have included HRQOL when measuring the effect of a falls prevention programme, and most of these studies include it as a secondary outcome [21, 76]. Outcomes examining HRQOL are selected based on literature identifying a standard set of measurements in falls prevention programmes [77, 78]. SF-36 is chosen due to its good validity, reliability and responsiveness when assessing older adults [79]. This outcome is detailed and broad, but it might be putting a burden on the participants due to its length and sensitive questions. Nevertheless, estimating HRQOL is important to determine whether the effect of a falls prevention programme is significant enough to achieve clinical relevant changes and thus to justify the implementation.

Several studies have looked at the effect of exercise on HRQOL, but to the authors' knowledge, none of them have specifically focused on older adults who receive home help services and who have a fall history. Studying the relationship between exercise and HRQOL is interesting due to the potential influence of exercise on both health and wellness through improvement of HRQOL [3, 80]. However, results from previous clinical exercise trials have reported mixed effects on HRQOL following exercise [32–35, 81]. Although many studies have found a positive association between exercise and HRQOL, available data from other trials is inconsistent and lacks information on the most effective mode of exercise that may influence HRQOL [32, 33, 71, 81]. This study can provide insight into the effect of falls preventative exercise and its applicability to home-dwelling older fallers with dependency of help from the primary health care service.

There are two ways an intervention mechanism can influence HRQOL, it can be a mediator or a moderator [82]. A mediating factor is defined as an intervening causal factor that may provide information concerning why the intervention increases HRQOL. Moderator mechanisms help us to understand for whom an intervention works [38] and can be classified as either characteristic of the person/group i.e. baseline characteristics or characteristics of the exercise protocol [38, 83]. Mediating mechanisms between HRQOL and falls-prevention programs may be both physiological, such as increased balance and strength, and psychological, such as self-efficacy [38]. A recent study provide evidence that fear is related to falls and concluded that falls self-efficacy plays a mediation role on the relationship between fear of falls and falls [84]. They recommend that any falls prevention should consider psychological covariates of falls, especially subjects' self-efficacy to reduce falls, alongside other risk factors and covariates of falls. More theoretically driven research on these mechanisms behind treatment effects have been recommended [85–87].

It is widely accepted that falls and subsequent injuries are likely to result in a substantial reduction in quality of life for the persons affected as well a substantial economic burden to the healthcare system [88]. This provision of OEP in this setting could potentially be a beneficial and cost-effective intervention for this group of frail older adults, just as it is for community-dwelling older adults. Several studies have performed analysis on cost-effectiveness of exercise programmes which have shown that it can reduce healthcare costs [14, 89]. Due to its large sample size and theoretically based intervention the present study has the potential to generate new knowledge that may improve the design of future activity programmes for older fallers receiving home help services. Since both outcome measures as well as the intervention are carried out in a clinical setting, relevance and application of study findings to clinicians is enhanced. Results from this study will be primarily of interest to, and could be used by, health care managers and clinicians. Particularly, the results will be useful in decision making to set priorities relating to prevention measures in the community, to appropriately allocate resources and to assess costs and benefits of a falls prevention programme. Finally, the results can be useful for policy makers, in order to put preventative healthcare for this group of frail older adults on the agenda.

To conclude, older people receiving home help services represent a growing and diverse group as part of the population of community-dwelling older adults. The appropriate assessment of HRQOL, the mechanisms behind the relationship between fall prevention and HRQOL, the most effective mode of exercise, as well as the clinical relevance of the results, are challenging issues which are important to address.

Abbreviations

ADL: Activities of Daily Living; BMI: Body Mass Index; EQ-5D: European Quality of Life - 5 Dimensions; HRQOL: Health-related Quality of Life; iADL: Instrumental Activities of Daily Living; LEON: Lowest most efficient level of care; MMSE: Mini Mental State Examination; MNA: Mini Nutritional Assessment; OEP: Otago Exercise Programme; pADL: Personal Activities of Daily Living; QOL: Quality of Life; RCT: Randomised Controlled Trial; SF-36: Short Form 36 Health Survey; WHO: World Health Organization

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Availability of data and materials

The datasets generated and/or analysed during the proposed study are only available to the participating researchers due to data protection laws. Subsets or aggregation of these data will not include information that could compromise research participants' privacy. Consent can be made available from the corresponding author on reasonable request.

Authors' contributions

MB and AB were involved in choosing falls prevention programme as well as outcome measures. AB was responsible for the internal grant application for this trial. MB and AB contributed to the design of the study. MB administrates the data collection and coordination of conducting the fall prevention programme. MB and AB wrote the first draft of the manuscript. TB and DAS critically revised and approved the final version of this manuscript.

Ethics approval and consent to participate

The project proposal has been approved by The Regional Committee for Medical Research Ethics in South Norway (Ref. 2014/2051). Informed consent is obtained from all participants included in the analyses, and the project is conducted according to the WMA Declaration of Helsinki.

Consent for publication

Not applicable

Competing interests

DAS is a Director of Later Life Training Ltd., a UK based non-profit organisation providing training to therapists in the effective delivery of the OEP to older adults.

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RESEARCH ARTICLE Open Access

Associations between health-related quality of life, physical function and fear of falling in older fallers receiving home care

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Abstract

Background: Falls and injuries in older adults have significant consequences and costs, both personal and to society. Although having a high incidence of falls, high prevalence of fear of falling and a lower quality of life, older adults receiving home care are underrepresented in research on older fallers. The objective of this study is to determine the associations between health-related quality of life (HRQOL), fear of falling and physical function in older fallers receiving home care.

Methods: This study employed cross-sectional data from baseline measurements of a randomised controlled trial. 155 participants, aged 67+, with at least one fall in the previous year, from six Norwegian municipalities were included. Data on HRQOL (SF-36), physical function and fear of falling (FES-I) were collected in addition to demographical and other relevant background information. A multivariate regression model was applied.

Results: A higher score on FES-I, denoting increased fear of falling, was significantly associated with a lower score on almost all subscales of SF-36, denoting reduced HRQOL. Higher age was significantly associated with higher scores on physical function, general health, mental health and the mental component summary. This analysis adjusted for sex, education, living alone, being at risk of or malnourished, physical function like balance and walking speed, cognition and number of falls.

Conclusion: Fear of falling is important for HRQOL in older fallers receiving home care. This association is independent of physical measures. Better physical function is significantly associated with higher physical HRQOL. Future research should address interventions that reduce fear of falling and increase HRQOL in this vulnerable population.

Trial registration: ClinicalTrials.gov. NCT02374307. First registration, 16 February 2015. First enrolment of participants, February 2016.

Keywords: Health-related quality of life, Falls, Falls-efficacy, Fear of falling, Home care

Background

The increasing number of older adults living longer poses new challenges to health, long-term care and the welfare system [1]. The rising costs of falls and associated injuries are of global concern [2], estimated at 1.5% of health care costs in European countries, both directly from the fall-related injuries and indirectly through loss of mobility, confidence and functional independence [3]. Costs for long-term care are expected to increase substantially in the future. These expenses can be greatly reduced if the older adults are in good health and are able to remain at home [1]. Home care services are important in maintaining independence, contributing to functional health status and improving the quality of life (QOL) among older adults [4].

Home care is here defined as services provided by health professionals to people in their own homes and can cover a wide range of activities, from care related to individual needs to preventative assessments and actions [4]. The population of home care recipients constitutes a

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transitional group between independent community living older people, and people living in residential care facilities, and their health-related quality of life (HRQOL) and other health outcomes might be different from those [5]. Even though home care could be an important contributor meeting the challenges of an increasing older population, surprisingly few clinical studies have been carried out including this group of older fallers [6, 7]. Falls and disability are strong predictors of institutionalisation. By targeting home care recipients who have experienced falls, the frequency of nursing home admissions could be reduced [8].

In Norway, the municipalities are responsible for providing home care for older adults, and recent governmental guidelines have put more focus on these services to enable older adults to remain at home as long as possible [9]. Home care comprises services like home nursing, practical assistance with daily activities and safety alarm. Home nursing and assistance with personal care are free of charge, while practical assistance and safety alarm services have deductibles. In 2016, 12% of the Norwegian population in the age group 67–79 years received home care services. In the age group 80–90 years, the share was 50%, and 90% for those 90 years or older [10]. Across Europe, health services at home are becoming increasingly important [1]. WHO guidelines point out a change in focus of clinical care for older adults globally, where community and home-based care are emphasised [11].

The literature on falls in the general population of older adults is extensive. Home care receivers and other groups of frailer older adults are still underrepresented in this literature [12]. Older adults receiving home care services have a high incidence of falls, with 10% experiencing multiple falls during the previous 90 days [13]. The level of services provided correlates with the incidence of falls [14]. This group of older adults also report a high prevalence of fear of falling and activity restrictions associated with this fear [15]. In the general population of older adults, fear of falling and its consequences have been identified as important factors influencing HRQOL [16–18]. This relationship has not been established in the population of older home care receivers. It can be expected that receiving care and support could have an impact on the level of fear of falling and on HRQOL. Thus, this group of frailer older adults might be different than the general group of older adults when looking at the relationship between HRQOL and fear of falling.

The general population of fallers scores significantly lower on HRQOL, in particular on the physical component [19]. HRQOL has been shown to be associated with measures of mobility, balance and pain [20]. In the population of older adults receiving home care, studies looking specifically at HRQOL and further associations to physical function is lacking. However, studies exploring a broader concept, QOL, show that it is lower in this population compared to older adults in the same age group [21]. Among home care recipients, higher QOL has been associated with higher age, not living alone, a lower number of complaints like pain or impaired mobility, and managing to be alone at home [22]. Despite finding an association between mobility and QOL, HRQOL was not explored and different factors of physical activity as balance, walking speed or muscle strength were not included.

The complexity of the health challenges in the group of older fallers receiving home care makes it challenging for those delivering primary health care, both to ensure HRQOL for the client and at the same time keeping the costs reasonable [23]. There is a knowledge gap in clinical research on HRQOL and falls including older adults receiving home care [5, 24]. In recent guidelines, both locally in Norway, but also internationally, policy makers are increasingly focusing on the challenges of organising effective and high-quality health care services to meet the needs of the population of older home care recipients [9, 11]. In order to develop services and interventions, thorough information on the health status of this population is needed. The objective of this study is therefore to determine relationships between HRQOL and fear of falling as well as physical function in older fallers receiving home care services.

Method

Study design

The analysis employs cross-sectional data from baseline measurements of a randomised controlled trial conducted in 2016–17 [24]. The trial was registered at ClinicalTrials.gov in February 2015, NCT02374307. First enrolment of participants was in February 2016. The STROBE guidelines are followed to report on the design, analysis and presentation of data [25].

Setting and participants

Participants were recruited in six municipalities in Norway. Recruitment was based on registration lists of older adults receiving home care from primary health care services. The recruitment plan is described elsewhere [24]. The flow of participants at enrolment in the project is illustrated in Fig. 1. Eight hundred sixty five adults receiving home care were initially assessed for eligibility, 320 received an invitation letter and 167 were baseline tested. Data from 155 participants were included in the final sample analysed in this study.

The study was approved by the Regional Committee for Medical Research Ethics in South Norway (Ref. 2014/2051). Participants provided written, informed, consent.

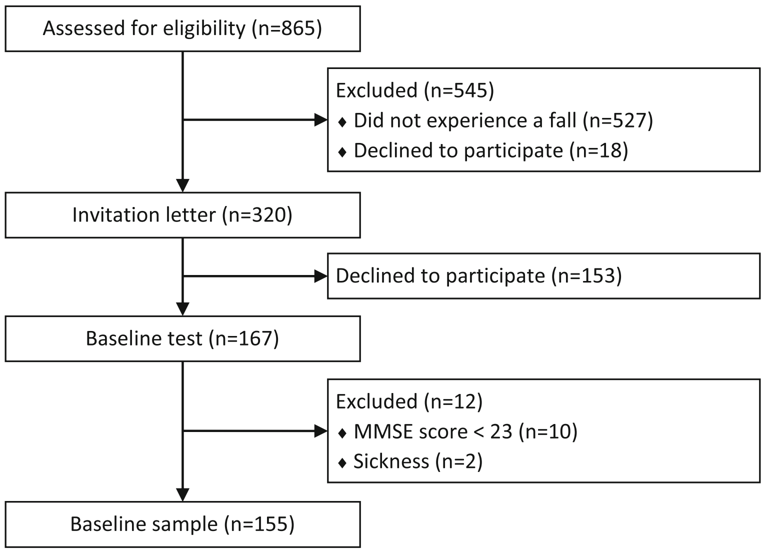

Fig. 1 Flow of participants

Inclusion criteria
Age 67+, receiving home care from the primary health care services, having experienced at least one fall in the last 12 months, able to walk with or without a walking aid and understand Norwegian.

Exclusion criteria
Medical contraindications to exercise, life expectancy less than 1 year, a score below 23 on the Mini Mental State Examination (MMSE) and participating in other falls prevention programmes.

Outcome measures
The outcome measures for this study were selected based on both theoretical and practical reasons [26, 27]. All assessments employed have established reliability and validity, as recommended by the CONSORT guidelines [28]. In addition to improving measurement quality and outcomes, it enables direct comparisons with other studies investigating HRQOL and can possibly contribute to future meta-analyses. The measurements were conducted by physiotherapists in the participants' home in one session, so considerations had to be made both concerning equipment and fatigue of the participants.

Health-related quality of life was assessed using the Short Form 36 Health Survey, version 2 (SF-36). This questionnaire is generic, validated and translated into Norwegian [29]. The 36 items in SF-36 are grouped into eight subscales: physical functioning (PF), role limitations due to physical problems (RP) and due to emotional problems (RE), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF) and mental health (MH). Based on the scores of these eight scales, a physical component summary (PCS) and a mental component summary (MCS) is calculated. The sum scores range from 0 to 100 (worst-best).

Fear of falling was measured using the Norwegian version of the Falls Efficacy Scale International (FES-I) [30]. In FES-I fear of falling is operationalised as the level of concern about falling when carrying out a range of 16 different physical activities [31]. It has a four-point scale ranging from 1 (not concerned) to 4 (very concerned). A sum score between 16 and 64 is achievable, where 16–19 indicates low concern, 20–27 moderate concern and 28–64 high concern [31].

Physical function was assessed by measurements on balance, gait speed, muscle strength and instrumental activities of daily living (IADL).

The Berg Balance Scale (BBS) assesses balance. The Norwegian version has been shown to have an excellent inter-rater reliability and high internal consistency in the geriatric population [32]. BBS measures performance on a 5-level scale from 0 (cannot perform) to 4 (normal performance) on 14 different tasks. The sum score of the 14 items ranges from 0 to 56, where a score below 45 indicates that the individual has a higher risk of falling.

Gait speed was assessed based on the time required to walk 4 meters, using any usual walking aid, and expressed in meters per second [33].

Muscle strength was measured by using the functional proxy measure of 30 seconds sit-to-stand (STS) test, where the number of rises from a chair within 30 seconds is recorded [34].

IADL was measured using the Norwegian version of the Lawton IADL scale [35]. It assesses a person's self-reported ability to perform complex activities of daily living. There are eight areas of function that are assessed, and the summary scores ranges from 0 (low function) to 8 (high function).

Demographic and background variables were age, sex, living alone, education (primary and lower secondary school/upper secondary school/university 1–4 years/university more than 4 years), medical history including medications, nutritional status measured by Mini Nutritional Assessment (MNA) [36], walking aid use, type of home care (home help/home nursing/safety alarm service) and history of falls.

Data analysis

Statistical analyses were conducted using STATA/SE 14. Descriptive characteristics of the study population are reported. Percentages are used to describe categorical data, and mean and standard deviation (SD) are calculated for continuous data. Skewness was examined by comparing mean and median values. Differences between males and females were inspected by t-tests and χ^2 tests. Coefficients with *p*- values ≤0.05 were considered statistically significant.

Pearson correlations coefficients display the association between the subscales of SF-36 and measures of physical function and fear of falling. The strength of correlations was interpreted according to Cohen, where 0.10 to 0.29 is weak, 0.3 to 0.49 is moderate and 0.5 to 1.0 is strong [37].

Explanatory variables for the multivariate regression of the scales of SF-36 were chosen from the available set of variables displayed in Table 1. The regressions adjust for the background variables age, sex, education, living alone, risk of or being malnourished, falls ≥3 during the previous 12 months and the number of different medications. The minimum values from the inclusion criteria were subtracted from age (67) and MMSE (23) to increase interpretability of the coefficients. A dummy variable was created for more than two falls in the last 12 months. Most participants had one or two falls, while some had a large number of falls. Additionally, the regression included as independent variables 4-m walk test (4MWT), BBS, IADL, FES-I and MMSE. STS was highly correlated (> 0.6) with both BBS and 4MWT and this variable was therefore excluded from the regressions. The impact of the variables health care services and walking aid were negligible, and those were also excluded. Four records containing missing observation of medications and 4MWT had to be dropped.

Floor- and ceiling effects were considered when more than 20% of the participants achieved the lowest or highest possible score. For RE, 48.4% reached the top score of 100. In this case, a logistic regression was fitted.

Results

Participants

Table 1 presents the characteristics of the total sample and separately for females and males. The study included 123 females and 32 males. The only statistical significant difference between sexes was found on the number of falls and if a safety alarm service was provided. Men had a significant higher rate of falls, 4.9, compared to women, 2.1 ($p < 0.001$). Women received a safety alarm more often, 79.7%, than men, 59.4% ($p = 0.017$). Mean (SD) age is 82.7 (6.7). HRQOL, measured by SF-36, shows a better summary score on the mental components (49.4, SD 10.3) than on the physical components (38.3, SD 9.0).

Correlation coefficients

In Table 2, the correlation coefficients between subscales of SF-36 and different measures of physical function and fear of falling are presented. All measures of physical function are highly correlated with the subscale PF ($p < 0.01$). FES-I is moderately negatively correlated with all subscales of SF-36, except from BP and SF, where there is a weaker negative correlation.

Multivariate regressions

Table 3 presents results of multivariate regressions of scales of SF-36 on background variables and measures of physical function and fear of falling. Having a lower score on FES-I is significantly associated with achieving a higher score on all subscales of SF-36 except from BP and SF. Scoring 10 points lower on FES-I, is expected to increase the scores of SF-36 between 0.9 (RE) to 7.3 (RP). The subscale PF is significantly associated with higher scores on the physical measures 4MWT ($p \leq 0.05$), BBS ($p \leq 0.001$) and IADL ($p \leq 0.01$). Higher age is significantly associated with better scores on MCS ($p \leq 0.05$), PF ($p \leq 0.05$), GH ($p \leq 0.01$) and MH ($p \leq 0.01$). Taking fewer medications is significantly associated with a higher score on PCS ($p \leq 0.001$) and GH ($p \leq 0.001$). Finally, a higher MMSE score is significantly associated with a higher score on MH ($p \leq 0.05$).

Discussion

The objective of this study was to determine the relationship between HRQOL, fear of falling and physical function in older fallers receiving home care. The results show that a higher level of HRQOL, measured by SF-36, is substantially associated with lower fear of falling, measured by FES-I. The associations are independent of physical measures like BBS and 4MWT, number of falls, cognition and key background characteristics. All associations are statistically significant in almost all scales of SF-36, except BP and SF. On physical function, the results show that a higher score on the subscale PF is significantly associated with better gait speed (4MWT), improved balance (BBS) and better ability in IADL.

The present study extends the results of two previous studies on the association between HRQOL and fear of falling. In a Canadian study of older community-dwelling women, quality-adjusted life years were calculated from the EQ-5D scale and compared to falls-related self-efficacy

Table 1 Characteristics of the study population. Means, standard deviations (SD) and percentages

	Total (*N* = 155)	Female (*N* = 123)	Male (*N* = 32)
Characteristics			
Age, mean (SD)	82.7 (6.7)	83.0 (6.7)	81.3 (6.7)
Living alone, %	84.5	87.0	75.0
Higher education (> 12 years), %	36.1	35.0	40.6
No. of medications weekly, mean (SD)	5.3 (3.4)	5.1 (3.4)	6.0 (3.6)
Primary health care services			
Practical assistance, %	69.7	68.3	75.0
Nursing, %	30.3	27.6	40.6
Safety alarm service, %	75.5	79.7	59.4
Walking aid %	73.5	74.0	71.9
Falls the last 12 months			
No., mean (SD)	2.7 (3.7)	2.1 (2.5)	4.9 (6.0)
Location:			
Indoor, %	47.4	49.6	38.7
Outdoor, %	18.8	19.5	16.1
Both, %	33.8	30.9	45.2
Injuries from falls:			
Minor injuries %	45.5	45.5	45.2
Serious injuries, hospitalisation %	35.1	37.4	25.8
Mini-Mental State Examination			
MMSE, mean (SD)	27.4 (2.2)	27.5 (2.2)	27.2 (2.2)
Falls Efficacy			
FES-I, mean (SD)	30.7 (9.8)	31.0 (9.9)	29.4 (9.5)
Physical function			
IADL, Lawton and Brody. > 6, %	56.1	56.1	56.3
Sit to stand, mean (SD)	5.1 (4.1)	5.1 (4.2)	4.8 (3.7)
4-m walk test m/s, mean (SD)	0.62 (0.21)	0.62 (0.22)	0.61 (0.18)
Berg Balance Scale, mean (SD)	39.1 (11.3)	39.6 (11.4)	37.2 (10.8)
Mini Nutritional Assessment			
Risk of or malnourished %	24.4	27.6	12.5
Health-related quality of life			
SF-36 scores, mean (SD)			
Physical component summary	38.3 (9.0)	38.0 (9.2)	39.4 (8.4)
Mental component summary	49.4 (10.3)	49.0 (10.6)	50.9 (9.1)
Physical function	44.6 (23.1)	44.5 (23.0)	45.2 (23.8)
Role physical	51.7 (29.7)	50.9 (30.1)	54.9 (28.3)
Body pain	53.8 (32.2)	51.8 (32.4)	61.4 (30.7)
General health	57.6 (23.3)	57.6 (23.5)	57.6 (22.7)
Vitality	38.3 (21.5)	36.7 (28.8)	44.2 (19.1)
Social function	66.9 (31.2)	66.1 (31.3)	69.9 (30.8)
Role emotional	75.8 (28.5)	75.6 (28.1)	76.6 (30.6)
Mental health	72.1 (17.4)	71.1 (17.8)	75.6 (15.6)

Table 2 Correlation between HRQOL (SF-36) and different measures on physical function and falls efficacy

SF-36 subscales	Sit to stand	4 Meter Walk Test	Berg Balance Scale	Instrumental ADL	Falls Efficacy Scale - I
Physical Function	0.515***	0.537***	0.585***	0.439***	−0.425***
Role Physical	0.352***	0.275***	0.287***	0.250**	−0.388***
Bodily Pain	0.113	0.146	−0.013	− 0.036	− 0.221**
General Health	0.270***	0.168*	0.175*	0.120	− 0.367***
Vitality	0.193*	0.175*	0.116	0.110	−0.327***
Social Function	0.267***	0.123	0.216**	0.210**	−0.262***
Role Emotional	0.289***	0.120	0.201*	0.134	−0.355***
Mental Health	0.225**	0.100	0.082	0.056	−0.362***

* $p < 0.05$ **$p < 0.01$ ***$p < 0.001$

[17]. This study accounted for similar control variables and found comparable results on their measure of HRQOL. However, the women included did not necessarily experience a fall and it was uncertain whether the results could be generalised to older adults with a lower level of function. Another study from Taiwan reported on the association between HRQOL, measured by summary scores of SF-36, and fear of falling [16]. This larger survey included both fallers and non-fallers and adjusted for some background characteristics. Fear of falling was measured simply by asking a yes/no question. Unlike the study by Davis et al. [17] and this present study, the association was not independent of physical or cognitive function. Here, the results show that fear of falling, measured by a validated and reliable instrument, is independently associated with almost all scales of SF-36 and thus confirms that it is an important predictor of HRQOL in this group of older fallers with poor function.

All measures of physical function and IADL were significantly associated with the physical subscale of HRQOL. A higher PF was significantly associated with higher scores on the physical measures 4MWT, BBS and IADL. Similar results have been shown in previous studies where lower HRQOL was associated with difficulties with basic and instrumental activities of daily living [38, 39], low maximal gait speed [40] and reduced physical fitness [41]. The present study did not show any significant associations on other subscales, but the sample size could have been too low to detect other associations.

Research on older adults often excludes those who are frailer [7]. In previous studies, participants were younger

Table 3 Regression of SF-36 on measures on demographics, physical measures, cognition and falls efficacy

	Physical Comp. Summary	Mental Comp. Summary	Physical Function	Role Physical	Bodily Pain	General Health	Vitality	Social Function	Role Emotional	Mental Health
Age (years ≥67)	0.19	0.31*	0.49*	0.58	0.80	0.74**	0.04	0.70	0.02	0.64**
	(0.10)	(0.13)	(0.23)	(0.37)	(0.42)	(0.28)	(0.28)	(0.42)	(0.03)	(0.22)
Falls ≥3 last 12 months	2.48	−4.23*	4.57	1.43	3.90	1.06	−4.37	−9.02	−0.27	−4.64
	(1.56)	(1.99)	(3.51)	(5.49)	(6.36)	(4.17)	(4.22)	(6.28)	(0.46)	(3.27)
No. medications weekly	−0.72***	0.16	−0.74	−1.02	−1.10	−2.65***	− 0.58	0.43	0.06	−0.33
	(0.19)	(0.24)	(0.42)	(0.66)	(0.77)	(0.50)	(0.51)	(0.76)	(0.06)	(0.39)
4 Meter Walk Test, m/s	8.28*	− 1.03	21.12*	15.30	23.88	−0.24	16.53	−1.26	0.12	4.37
	(3.84)	(4.88)	(8.61)	(13.47)	(15.62)	(10.24)	(10.35)	(15.43)	(1.18)	(8.03)
Berg Balance Scale	0.14	0.00	0.80***	0.31	−0.12	0.18	−0.23	0.33	0.03	−0.00
	(0.08)	(0.10)	(0.18)	(0.27)	(0.32)	(0.21)	(0.21)	(0.31)	(0.02)	(0.16)
Instrumental Activities of Daily Living	0.50	−0.11	3.16**	2.01	−1.48	−0.96	0.16	2.36	0.02	− 0.85
	(0.51)	(0.65)	(1.15)	(1.80)	(2.08)	(1.37)	(1.38)	(2.06)	(0.15)	(1.07)
Falls Efficacy Scale – International	−0.18*	−0.30**	−0.37*	− 0.73**	−0.55	− 0.55**	−0.63**	− 0.46	−0.09 ***	− 0.52***
	(0.07)	(0.09)	(0.16)	(0.25)	(0.29)	(0.19)	(0.19)	(0.29)	(0.02)	(0.15)
Mini-Mental State Examination (score ≥ 23)	−0.26	0.45	−0.11	− 0.38	−1.42	0.70	0.78	0.44	−0.03	1.25*
	(0.29)	(0.37)	(0.66)	(1.03)	(1.19)	(0.78)	(0.79)	(1.18)	(0.09)	(0.61)
R^2 adj.	0.32	0.15	0.47	0.21	0.08	0.27	0.10	0.07		0.20

Additionally adjusted for sex, education, living alone, risk of or being malnourished. Ordinary least squares (OLS) regressions, except on role emotional, where a logistic regression is fitted. Unstandardised regression coefficients, standard error (SE) in parentheses. Model fit reported by R^2-adjusted. $N = 151$. * $p < 0.05$ **$p < 0.01$ ***$p < 0.00$

than here, where the mean age is 82.7. Research on older fallers has been carried out, but those who receive home care are underrepresented. Risk factors and incidence of falls in this population have received most attention [13, 14]. Associations between HRQOL and potentially influential factors have not been analysed in this group. QOL among older adults receiving home care has been explored in Sweden [21]. In this study, the extent of help with IADL influenced QOL negatively, while it was positively influenced by the density of the social network. Measures of physical and cognitive function were not included in the Swedish study which was based on a postal questionnaire.

Compared to normative values from a Norwegian sample of adults, aged 70 to 80 years, the sample in the present study has lower values in all subscales of SF-36 [42]. This might be due to better function of older people in the general population, not necessarily requiring home care. Similar findings were demonstrated in a Swedish study, where elderly receiving home care had very low QOL compared to older adults in the same age group [21].

Interestingly, higher age was associated with better scores within the scales MCS, PF, GH and MH. This might be due to what has been described in literature on HRQOL as response shift [43]. It refers to a change in the meaning of one's self-evaluation of HRQOL resulting from changes in internal standards, values and conceptualisation. The oldest of the participants might have lower expectations of their everyday life, what they can manage and their health status, while the younger participants might on average have higher expectations. An earlier Swedish study on QOL of older people living at home found comparable results. High QOL was related to higher age, lower number of complaints and managing to live alone at home [22].

This study has several limitations. First, the sample comprised participants recruited to a controlled trial to potentially perform a falls prevention programme. The participants might be fitter and more motivated for physical activity than the general population of older adults receiving home care. To improve generalisability, recruitment was outreaching, calling from lists of people receiving home care. Half of those who were eligible to participate and sent an invitation letter were also included in the study. This could make self-selection of more active participants less likely. Secondly, the sample was recruited from only six municipalities which are not necessarily representative for Norway in general. However, the six municipalities included both cities and rural areas. Thirdly, performing subgroup analyses on sex is difficult as a low percentage of the sample were males. The descriptive statistics show, however, that males and females in this sample are not significantly different, except for number of falls and if a safety alarm is provided. A further limitation is that the study is cross-sectional and definitive causal relations cannot be established. Finally, some of the measures like the number of falls are self-reported.

This study contributes new knowledge on the level of HRQOL, physical function and fear of falling in addition to the relationship between these factors in a group of older fallers receiving home care. This population is understudied and more information is needed to be able to improve care and other public services for this group. The results from this study can be of importance for clinicians and health managers for developing interventions and organising clinical services in primary health care. Since this group of older fallers is relatively large in Norway and other developed countries, the information can also be useful for policy makers to set priorities and allocate resources. Future research on interventions on how to modify HRQOL and fear of falling within this group is needed.

Conclusions

Higher HRQOL is substantially associated with a lower level of fear of falling in older fallers receiving home care. This association is independent of physical measures, number of falls, cognition and key background characteristics such as age, sex and education. Better physical function is significantly associated with higher physical HRQOL, independent of the same background characteristics and fear of falling.

Abbreviations

4MWT: 4 Meter Walk Test; BBS: Berg Balance Scale; BP: Bodily Pain; EQ-5D: EuroQol - five dimensions scale; FES-I: Falls Efficacy Scale - International; GH: General Health; HRQOL: Health-related Quality of Life; IADL: Instrumental Activities of Daily Living; MCS: Mental Component Summary; MH: Mental Health; MMSE: Mini Mental State Examination; PCS: Physical Component Summary; PF: Physical Function; QOL: Quality of Life; RE: Role Emotional; RP: Role Physical; SD: Standard Deviation; SF: Social Function; SF-36: Short From 36 Health Survey; STS: Sit to Stand; VT: Vitality

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Availability of data and materials

The raw data collected in this project is only available to the participating researchers due to risk to confidentiality of participants and data protection laws. An anonymised subset of the raw data, where direct and potentially indirect person identifiers are removed, is planned to be made available in a public data repository after the project is finished. An anonymised dataset analysed in this baseline study is available from the corresponding author on reasonable request.

Authors' contributions

MB and AB initiated the study, and all authors contributed to its design. MB managed the data collection, performed the data analysis and wrote the first draft of the manuscript. MB, TB, DS and AB are collectively responsible for interpreting the results, reviewed critically subsequent drafts of the manuscript and approved its final version.

Ethics approval and consent to participate

The project proposal has been approved by The Regional Committee for Medical Research Ethics in South East Norway (Ref. 2014/2051). Informed consent was obtained from all participants included in the analyses, and the project is conducted according to the WMA Declaration of Helsinki.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

Publisher's Note

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

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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 self-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 by the Short-Form 36 Health Survey (SF-36). Secondary outcomes were Berg Balance Scale (BBS), 30-s sit to stand (STS), 4-m 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.
Trial registration: ClinicalTrials.gov. NCT02374307. First registration, 16 February 2015.

Keywords

health-related quality of life, falls prevention, exercise interventions, home care, balance, older people

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 self-efficacy can be improved by falls prevention interventions

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 self-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 (IADL) 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 self-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 12 months, able to walk with or without a walking aid and understand Norwegian.

Exclusion criteria: medical contraindications to exercise, life expectancy below 1 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 min and walk up to 30 min 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 3 months. Trained research assistants, blinded to the participants' group allocation, performed the assessments.

At baseline global cognitive function was assessed by 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 to 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-s sit to stand test (STS) [19], gait speed by 4-m 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 $a = 0.05$ 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 analyses were 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.

Research ethics

The project proposal has been approved by The Regional Committee for Medical Research Ethics in South East Norway (Ref. 2014/2051). Informed consent was obtained from all participants included in the analyses, and the project is conducted according to the WMA Declaration of Helsinki.

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. Seventy-seven 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 75.8. Secondary outcomes showed a mean STS value of 5.1, a mean 4MWT of 0.62 m/s and a mean BBS score of 39.1. The participants had a mean FES-I score of 30.7.

ITT analysis

Table 2 presents the ITT analysis. After 3 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 on 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

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	32.5	37.7
Mini-Mental State Examination			
MMSE, mean (SD)	27.4 (2.2)	27.4 (2.2)	27.4 (2.2)
Falls self-efficacy			
Falls Efficacy Scale Internationa, 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
30-s Sit to stand, mean (SD)	5.1 (4.1)	5.5 (3.8)	4.7 (4.4)
4-m walk test m/s, 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; IADL, Instrumental Activities of Daily Living; SF-36, 36-Item Short-Form Survey

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).

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 matched 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 =

Table 2. ITT 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 difference (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 difference (SE)			
Falls Efficacy Scale International	−0.9 (1.5)	−2.3 (1.2)	0.6 (1.7)
30-s sit to stand	0.8 (0.7)	0.8* (0.4)	0.4 (0.6)
4-m walk test m/s	−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)

*$P < 0.05$, **$P < 0.01$, ***$P < 0.001$

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 difference (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 difference (SE)			
Falls Efficacy Scale International	4.5 (2.6)	−0.5 (1.8)	−1.1 (1.7)
30-s sit to stand	−0.8 (0.9)	0.9 (0.6)	1.4* (0.6)
4-m walk test m/s	−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)

*$P < 0.05$, **$P < 0.01$, ***$P < 0.001$

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 ($P < 0.001$).

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 3 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 self-efficacy was not impacted by the programme. This is 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 self-efficacy. From previous studies, falls self-efficacy has shown to be an important predictor of HRQOL [30]. The lack of effect on falls self-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 self-efficacy.

Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

Declaration of Conflicts of Interest: D.A.S. is the Director of Later Life Training Ltd., a UK-based non-profit organisation providing training to therapists in the effective delivery of the OEP to older adults.

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Health-related quality of life in home care recipients after a falls prevention intervention: a 6-month follow-up

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Background: Falls in older adults are an increasingly important public health concern due to the expanding older population and contribute considerably to the global burden of disease. Home care recipients have a high incidence of falls and a low level of health-related quality of life (HRQOL). In this understudied group of older adults, exercise interventions could prevent falls, promote HRQOL and enable healthy ageing in the longer term. **Methods:** The study is a single-blinded parallel-group randomized controlled trial, lasting 3 months with a follow-up at 6 months, conducted in primary care. The objective was to explore the effects of a falls prevention exercise programme post-intervention at a 6-month follow-up in home care recipients 67+ years with a history of falls. The Otago Exercise Programme lasting 3 months was performed. The primary outcome was HRQOL measured by the Short Form 36 Health Survey (SF-36). Linear mixed regression models and structural equation models were employed. **Results:** At 6-month follow-up, the intervention group scored significantly higher on SF-36's physical component summary compared with the controls; 3.0 points, 95% confidence interval (CI) = 0.4, 5.6. This effect was mediated by an increased probability of maintaining exercise in the post-intervention period; odds ratio = 2.3 (CI = 1.1, 5.1). Exercising was associated with a 7.1-point increase in physical component summary (CI = 3.2, 10.9). **Conclusion:** A falls prevention exercise programme can improve physical HRQOL in home care recipients post-intervention. The exercise programme also led to longer-term changes in exercise behaviour mediating this effect.

Introduction

Falls in older adults are an increasingly important public health concern due to the severe consequences and the rise in number of older adults, contributing considerably to the global burden of disease.[1] Globally, about 30% of home-dwelling older adults above 65 years and 50% above 80 years experience at least one fall yearly.[2] Falls are one of the main causes of longstanding pain, functional impairment and disability in the population of older adults, which can reduce health-related quality of life (HRQOL).[3,4] Developing and maintaining functional abilities enabling well-being in older adults, defining healthy ageing, has received increased attention in international public health policy.[1]

Falls and injuries from falls are often a starting point for older adults consuming substantial health services like home care.[5,6] Home care refers to care given by professional health workers at home, covering a range of activities from short-term rehabilitation to long-term assistance with daily activities, which are important to enable older adults to remain at home.[6] In Norway, about 12% of the population 67–79 years, 50% of 80–90 years and 90% of those 90 years and older receive home care.[7] Characteristics of home care recipients are high incidence of falls, low level of falls self-efficacy, poor physical function (PF), medical instability and low level of HRQOL.[8,9] Effective interventions for older adults in primary care are emphasized in public health policy.[10] Nevertheless, there is limited research including frailer older adults like home care recipients.[11] By targeting frailer older adults who have experienced falls, HRQOL could be improved, institutionalization could be postponed or prevented, and economic costs could be reduced in the long term.[6,12]

Previous research has demonstrated that exercise is effective preventing falls.[2,13] The Otago Exercise Programme (OEP) is one approach of delivery of falls prevention that has shown to reduce the number of falls and injuries from falls, improve strength and balance and maintain falls self-efficacy in home-dwelling older adults.[14] Falls prevention exercise interventions may affect HRQOL positively through different mechanisms, for instance, by reducing falls injuries, and including this outcome is of importance.[15] Measuring HRQOL specifically is vital since functional improvements might not necessarily have a direct positive effect on perceived HRQOL.[16] A recent study on the same sample showed that a falls prevention exercise programme based on OEP can improve short-term HRQOL.[17] The effect on HRQOL in the longer term is still unclear.[15,18]

The health and social needs of the ageing population are typically complex and persisting, and health services should focus on maintenance of functional ability and physical activity, promoting quality of life in older adults and enabling them to remain at home.[10] Improving quality of life through exercise is likely to enhance the chance of continued participation in activity and increased future physical function.[19] Unfortunately, there is limited research on how exercise programmes can improve HRQOL.[20] Exploring mediators can help understand why and how an intervention works. Previous research has shown that exercise can be positive for physical performance in older adults in the long run, but the impact on other outcomes is unclear.[21,22] We conducted a follow-up study 3 months after the intervention ended, to explore the prolonged effect of a falls prevention exercise programme as a strategy to promote HRQOL in home care recipients. We also explored the relative importance of maintaining exercise to improve HRQOL in the longer term.

Methods

Study design

This study was a single-blinded, parallel-group, randomized controlled trial with two arms. Group allocation was on a 1:1 ratio. The study was a follow-up based on measurements 3 months after either completing a falls prevention intervention or receiving usual care lasting 3 months. In this follow-up period, only usual care was provided. At intervention end, participants in both groups were encouraged to exercise until follow-up at 6 months. If requested, the participants received information on activities in their municipality. A study protocol provides more details on the design of the trial.[11] Further information on the study results at intervention end are available elsewhere.[17]

Reporting follows the CONSORT 2010 Statement.[23] The study was approved by the Regional Committee for Medical Research Ethics in South Norway (Ref. 2014/2051) and is registered in Clinical Trials (NCT02374307, first registration, 16 February 2015).

Setting and participants

The study was conducted in primary health care in six municipalities in Norway. Local clinical physiotherapists performed the intervention in the participants' homes. Participants were recruited from lists of people receiving professional home care. All participants provided written informed consent before baseline testing. Recruitment started in February 2016 and the last follow-up was conducted in September 2017. A flow diagram is provided as Supplementary material.

Inclusion criteria were: 67+ years (retirement age), receiving home care, having experienced at least one fall during the last 12 months, able to walk with or without a walking aid and understand Norwegian. Exclusion criteria were: medical contraindications to exercise, life expectancy below 1 year (physician assessment), a score below 23 on the Mini-Mental State Examination indicating cognitive impairment,[24] and currently participating in other falls prevention programmes or trials.

Intervention

The intervention group completed a falls prevention exercise programme based on the OEP.[14] This is a programme focussing on individually adjusted strengthening and balance exercises and information on falls risks, exercise safety and activities in daily life. The 12-week intervention consisted of five home-visits and seven motivational telephone calls. In addition, participants were encouraged to perform exercises on their own at least three times weekly and walk at least two times weekly. More details on the content are described in the OEP manual.[14]

Outcome measures

Trained assessors, who were blinded to group allocation, performed measurements in the participants' homes. Measurements were carried out at baseline, at intervention end at 3 months and at 6-month follow-up. Background information like sex, age, falls history, living alone, education, medical history, walking aid use and type of home care was collected at baseline.

Primary outcome measure

HRQOL was the primary outcome, measured by the Short Form 36 Health Survey (SF-36).[25] The two summary scores of SF-36, the physical component summary (PCS) and the mental component summary (MCS) are based on eight subscales: 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 to 100 (worst-best) in each scale.

Secondary outcome measures

Balance was measured by the Bergs Balance Scale (BBS), which is a 14-item scale assessing static and dynamic balance.[26] Usual walking speed was measured by timing usual walking with or without walking aid for 4-m walking test (4MWT).[27] Leg muscle strength was measured by the 30-s sit-to-stand test (STS), where the number of rises from a chair in 30 s is reported.[28] Falls self-efficacy was measured by the Falls Efficacy Scale-International (FES-I).[29] This scale derives from a self-report questionnaire, assessing concerns about falling in 16 different daily activities.

At 6-month follow-up, all participants were asked about their level of exercise since their assessment at intervention end. Possible answers were: performing individual exercises, group exercises, both individual and group exercises or none. The participants were also asked about the number of falls since intervention end.

Sample size

The sample size was estimated based on the primary outcome, HRQOL (SF-36). We needed a sample of 150 participants to detect a difference of 5 points with a standard deviation of 10 points on the SF-36 summary scales PCS and MCS. Power was set to $\beta = 0.8$ and the level significance to $\alpha = 0.05$. Included in the sample size, was an anticipated drop-out of 15–20% based on experiences from a study on a similar population.[30]

Randomization

For randomization, we applied a computer-generated permuted block scheme. Each block contained six subjects of the same municipality and sex. Research assistants who performed baseline testing enrolled the participants. The scheme allocated participants according to the sequence of enrolment. A double key number concealed the randomization sequence. M.B. administered the scheme.

Statistical procedures

We conducted the statistical analyses in STATA/SE14.1. Comparisons between the intervention group and the control group in differences in changes of scores from baseline to 6-month follow-up were made using linear mixed models. We performed intention-to-treat (ITT) analyses including all randomized participants. Missing values were handled using multiple imputation techniques.[31] When more than 20% of the participants reached the highest or lowest possible score ceiling- and floor-effects were considered.

Differences in exercise level between groups are described by percentages and an odds ratio (OR). Two-sample *t*-tests were used to explore differences in characteristics of those continuing exercise and those discontinuing exercise. We fitted regression models and structural equation models to explore the mediating factors of the intervention on the effect on PCS. The structural equation model included a direct path and an indirect path through a mediator from the intervention to PCS.

Results

Participants

Table 1 shows the baseline characteristics of the 155 participants (77 intervention, 78 control group). Mean age was 82.7 years and 79.3% were females. They were all appointed different home care services and the majority received practical assistance or safety alarm service. Mean number of falls were 2.7 in the last 12 months and 80.6% had minor or major injuries due to falls. More details on the characteristics of the sample are presented elsewhere.[8,17]

Intervention effect

The ITT analysis, summarized in table 2, was based on 3 × 155 observations. The cumulative missing was 9.8%, including all analyzed variables and observation points. Linear mixed models on scores from SF-36 at 6 months show that PCS was significantly

Table 1 Baseline characteristics

	Total (*N* = 155)	Intervention (*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
Falls the last 12 months			
No., mean (SD)	2.7 (3.7)	2.5 (3.3)	2.9 (4.0)
Injuries from falls:			
No injuries %	19.5	22.1	16.9
Minor injuries %	45.5	45.5	45.5
Serious injuries, hospitalization %	35.1	32.5	37.7
SF-36 summary scores, mean (SD)			
Physical components (PCS)	38.3 (9.0)	38.2 (9.0)	38.4 (9.1)
Mental components (MCS)	49.4 (10.3)	50.4 (9.9)	48.4 (10.6)
SF-36 subscores, mean (SD)			
Physical functioning (PF)	44.6 (23.1)	44.6 (21.9)	44.7 (24.4)
Role participation (RP)	51.7 (29.7)	53.2 (30.1)	50.2 (29.4)
Bodily pain (BP)	53.8 (32.2)	53.8 (28.9)	53.8 (35.2)
General health (GH)	57.6 (23.3)	58.8 (22.7)	56.5 (23.9)
Vitality (VT)	38.3 (21.5)	39.0 (21.7)	37.5 (21.3)
Social functioning (SF)	66.9 (31.2)	67.7 (29.1)	66.0 (33.2)
Role emotional (RE)	75.8 (28.5)	78.0 (27.7)	73.6 (29.3)
Mental health (MH)	72.1 (17.4)	74.0 (16.8)	70.1 (17.8)
Physical measures			
Berg balance scale (BBS), mean (SD)	39.1 (11.3)	39.1 (11.1)	39.1 (11.6)
30-s sit-to-stand (STS), mean (SD)	5.1 (4.1)	5.5 (3.8)	4.7 (4.4)
4-m walking test (4MWT) m/s, mean (SD)	0.6 (0.2)	0.6 (0.2)	0.6 (0.2)
Falls efficacy scale-international (FES-I), mean (SD)	30.7 (9.8)	30.2 (10.1)	31.1 (9.6)

Note: Descriptive statistics of the sample at baseline. SD, standard deviation; *n*, number of individuals; SF-36, 36-Item Short Form Survey.

Table 2 Intention-to-treat analysis

	Intervention group		Control group		Differences between groups	
	Mean 6-month follow-up (SE)	Change 0–6 months (SE)	Mean 6-month follow-up (SE)	Change 0–6 months (SE)	Change 0–6 months (SE)	95% CI change 0–6 months
SF-36 summary scores						
Physical components (PCS)	41.3 (1.1)	3.0 (0.9)	38.4 (1.3)	0.1 (0.9)	3.0 (1.3)	0.4, 5.6
Mental components (MCS)	52.0 (1.1)	1.7 (1.1)	53.1 (1.3)	4.7 (1.3)	−3.1 (1.7)	−6.4, 0.3
SF-36 subscores						
Physical functioning (PF)	48.6 (3.0)	4.0 (2.3)	45.2 (3.2)	0.5 (2.3)	3.6 (3.3)	−2.9, 0.0
Role participation (RP)	70.7 (3.2)	17.5 (3.9)	63.8 (3.7)	13.6 (3.7)	3.9 (5.4)	−6.8, 4.5
Bodily pain (BP)	56.9 (3.3)	3.2 (3.3)	52.4 (3.9)	−1.4 (3.2)	4.6 (4.5)	−4.3, 3.5
General health (GH)	60.6 (2.6)	1.8 (2.2)	57.3 (3.2)	0.8 (2.4)	0.9 (3.2)	−5.4, 7.3
Vitality (VT)	41.0 (2.4)	2.0 (2.4)	37.8 (3.1)	0.3 (2.3)	1.7 (3.3)	−4.7, 8.2
Social functioning (SF)	83.3 (2.9)	15.6 (3.4)	75.9 (3.7)	9.8 (3.5)	5.7 (5.0)	−4.0, 5.5
Role emotional (RE)	84.7 (3.1)	6.7 (3.7)	88.3 (2.7)	14.7 (3.3)	−8.0 (5.1)	−18.0, 1.9
Mental health (MH)	72.8 (2.1)	−1.2 (1.7)	75.7 (2.2)	5.5 (2.0)	−6.8 (2.6)	−11.9,−1.7
Physical measures						
Berg balance scale (BBS)	44.0 (1.4)	4.9 (0.9)	42.6 (1.5)	3.5 (0.9)	1.4 (1.3)	−1.2, 3.9
30-s sit-to-stand (STS)	6.7 (0.6)	1.2 (0.4)	5.7 (0.6)	1.1 (0.4)	0.2 (0.6)	−1.0, 1.3
4-m walking test (4MWT) m/s	0.7 (0.0)	0.1 (0.0)	0.7 (0.0)	0.1 (0.0)	0.0 (0.0)	−0.0, 0.1
Falls efficacy scale-international (FES-I)	28.5 (1.1)	−1.7 (1.2)	29.8 (1.3)	−1.3 (1.2)	−0.4 (1.6)	−3.6, 2.8

Notes: Means at 6-month follow-up, changes from baseline to follow-up within groups and differences between groups estimated using linear mixed regression models with multiple imputation. SEs are given in parentheses, 95% CI.

higher in the intervention group compared with the control group, by 3 points (CI = 0.4, 5.6). The subscale MH was substantially lower in the intervention group compared with the control group by −6.8 points (CI = −11.9, −1.7). There were significantly less participants in the intervention group experiencing falls since the previous assessment compared with the controls; OR = 0.4 (CI = 0.2, 0.9). No other harms or unintended effects were reported in the follow-up period.

Considering within group changes, both groups improved significantly in some subscales from baseline to 6-month follow-up. On

Table 3 Effect of exercising post-intervention

	Exercising	Not exercising	Differences between groups	
	Mean 6-month follow-up (SE)	Mean 6-month follow-up (SE)	Difference 6-month follow-up (SE)	95% CI difference
SF-36 summary scores				
Physical components (PCS)	42.4 (1.0)	35.4 (1.8)	7.1 (1.9)	3.2, 10.9
Mental components (MCS)	52.4 (0.9)	52.8 (1.8)	−0.3 (1.9)	−4.0, 3.3
SF-36 subscores				
Physical functioning (PF)	53.7 (2.5)	36.3 (4.4)	17.4 (5.0)	7.6, 27.2
Role participation (RP)	71.1 (2.8)	59.4 (5.4)	11.7 (5.6)	0.6, 22.8
Bodily pain (BP)	58.9 (3.0)	46.8 (5.0)	12.1 (5.7)	0.7, 23.5
General health (GH)	62.4 (2.2)	52.9 (4.7)	9.6 (4.7)	0.4, 18.8
Vitality (VT)	42.8 (2.1)	35.1 (4.4)	7.7 (4.4)	−0.9, 16.3
Social functioning (SF)	83.6 (2.4)	73.6 (5.3)	10.0 (5.1)	−0.1, 20.1
Role emotional (RE)	85.9 (2.5)	87.3 (4.0)	−1.4 (4.7)	−10.7, 8.0
Mental health (MH)	74.9 (1.7)	73.1 (3.3)	1.8 (3.5)	−5.1, 8.7
Physical measures				
Berg balance scale (BBS)	46.4 (1.0)	41.3 (2.8)	5.1 (2.3)	0.5, 9.7
30-s sit-to-stand (STS)	7.5 (0.5)	4.7 (0.9)	2.9 (0.9)	1.0, 4.7
4-m walking test (4MWT) m/s	0.7 (0.0)	0.7 (0.0)	0.0 (0.0)	−0.0, 0.1
Falls efficacy scale-international (FES-I)	28.3 (0.9)	29.8 (1.8)	−1.5 (1.9)	−5.2, 2.2

Notes: Differences in scores of SF-36 and physical measures by exercising/not exercising irrespective of group allocation. Complete case analysis. SEs are given in parentheses, 95% CI.

RP, the intervention group increased their score by 17.5 points (CI = 9.8, 25.1) and the control group by 13.6 points (CI = 6.3, 20.9). On SF, the intervention group improved by 15.6 points (CI = 9.9, 22.2) and the control group by 9.8 points (CI = 2.9, 16.8). On secondary outcomes, both groups improved significantly on BBS by 4.9 points (CI = 3.1, 6.9) in the intervention group and 3.5 (CI = 1.7, 5.3) in the control group. Both groups also achieved a better result on STS, by 1.2 raises (CI = 0.4, 2.0) in the intervention group and 1.1 (CI = 0.3, 1.9) in the control group.

A potential ceiling effect occurred on SF and RE at 6-month follow-up and these results must therefore be interpreted with caution.

Exercise in the follow-up period

In the intervention group, 80.3% exercised post-intervention, compared with 63.6% in the control group. In the intervention group, most did individual exercise (64.8%), while few exercised in a group (4.2%) and some did both (11.3%). In the control group, most participants also reported individual exercise (39.7%), but more exercised in groups (17.5%) and some did both (6.4%). The OR of continuing with exercise in the intervention group post-intervention was OR = 2.3 (CI = 1.1, 5.1).

The differences in mean scores of SF-36, BBS, STS, 4MWT and FES-I, between those continuing activity and those discontinuing activity, are presented in table 3. Those who performed exercise post-intervention, irrespective of group allocation, had significantly higher scores on PCS by 7.1 points (CI = 3.2, 10.9), PF by 17.4 points (CI = 7.6, 27.2), RP by 11.7 points (CI = 0.6, 22.8), BP by 12.1 points (CI = 0.7, 23.5) and GH by 9.6 points (CI = 0.4, 18.8). On the physical measures, the participants who stayed active had significantly higher scores on BBS by 5.1 points (CI = 0.5, 9.7) and STS by 2.9 raises (CI = 1.0, 4.7) at 6-month follow-up.

Mediating factors of the intervention

The structural equation model, illustrated in figure 1, shows how exercise post-intervention was mediating the effect of the falls prevention exercise intervention on PCS at 6-month follow-up. Estimating the direct and indirect effect on PCS, gave the same OR as in the logit-model (2.3, CI = 1.1, 5.1). Exercising post-intervention was a mediating factor, increasing PCS with 7 points (CI = 3.1, 10.8) on average. The direct effect of the intervention on PCS

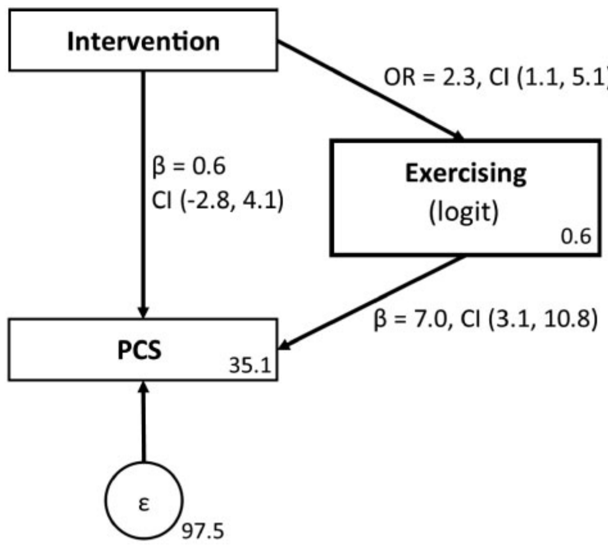

Figure 1 Structural equation model on the mediating factor of exercising post-intervention on PCS at 6-month follow-up. A latent error component (ε) is included on PCS. Regression coefficients (β), OR and 95% CIs

vanished when exercising post-intervention was accounted for (β = 0.6, CI = −2.8, 4.1).

Discussion

This study shows that a falls prevention exercise programme had a significant effect on physical HRQOL in older home care recipients, 3 months post-intervention. The self-training in the follow-up period mediated the effect of the programme on physical HRQOL. Compared with the result immediately at intervention end, the effect on HRQOL declined slightly in the post-intervention period.[17]

This study contributes to previous research evaluating OEP for community-dwelling older adults by including home care recipients and having HRQOL as primary outcome. Related studies evaluating OEP have focussed primarily on different physical outcomes and falls.[2,22] This study also shows a significantly reduced incidence of falls post-intervention in participants who had performed the programme. Longer-term effects on physical HRQOL have been reported after 6 months, but limited to comparisons between individual exercise and group exercise.[22] Here, the control group received only usual care as would be standard in clinical practice. Moreover, a negative effect on the subscale MH was shown in the intervention group at follow-up. A similar effect appeared at intervention end and can be explained by those who could not complete the programme due to sudden incidences who also scored lower on MH.[17] They might have had higher expectations of positive health outcomes which were not fulfilled.

Relative improvements in HRQOL, physical function and falls self-efficacy in the intervention group were limited in this study. Although the 3-point improvement in PCS in the intervention group is small, it has been acknowledged as a minimal clinical important difference.[32] Both groups improved significantly in several subdomains of SF-36, on BBS and on STS. A large percentage in the control group did also exercise in the post-intervention period which might have contributed to the smaller differences. The home-visits for assessment delivered by health professionals might have influenced exercise behaviour positively in the control group diluting the intervention effect.[33] Nevertheless, the participants were frail, medically unstable and had mobility-restrictions, and the focus should rather be on preventing decline and maintaining function than showing large improvements.[34] Finally, exercise could have broader benefits (e.g. social function) beyond health alone, not necessarily detected by HRQOL instruments.[1]

Achieving longer-term effects on HRQOL of a home-based exercise intervention can be challenging, in particular in frail older adults.[15] However, for this group, exercising at home might be the only feasible option. Providing physical activity interventions at home can address the transportation barrier and make it easier to integrate into daily life improving adherence.[1] This study demonstrated that a large number of the participants completing the OEP continued exercising. This mediated the intervention effect on physical HRQOL and is in line with previous results suggesting that staying physically active can improve physical HRQOL in the long term.[35] Hence, health promotion programmes that facilitate or encourage increased physical activity in frailer older adults are of importance.[36]

Establishing long-term exercise behaviour in frail older adults is essential for maintaining the effects of an exercise intervention and preventing or postponing decline of functional performance and quality of life.[37] Previous research has shown that the best adherers are those who have better self-rated health, physical abilities and cognitive abilities.[38] This was also confirmed here. Participants who stayed active had better physical HRQOL, strength and balance compared with non-active. On the other hand, low adherence has been shown to be primarily due to change in health status.[39] Eighteen participants in the intervention group experienced sudden health incidences in the course of the programme and could not adhere fully to the OEP, for instance performing less exercise for a period of time. Nevertheless, even though many of the participants experienced different incidences, the drop-out rate was low. The flexible structure of the programme, with limited home-visits and the additional telephone calls focussing on self-management, could explain the good adherence. Previous research has shown that low cost self-management programmes can improve health status in older adults with chronic conditions.[40]

The pragmatic design of this study has both strength and limitations. The intervention was conducted in the participants' homes by local physiotherapists as part of their daily work. This design makes it easily replicable to clinical practice. Based on age and sex, the sample was representative of the population of older home care recipients, increasing the generalizability of the results.[7] Measurement tools had been chosen both considering time and equipment. Several of the measurements were self-reported, which might have increased the likelihood of recall and response bias. The level of exercise between intervention end and follow-up could have been described in more detail to be explored further. Finally, the follow-up at 6 months might be too short to show sustained differences in HRQOL in the longer term.

In conclusion, a falls prevention exercise programme can improve physical HRQOL in the longer term. The intervention increased the probability of maintaining exercise after the intervention ended and reduced the probability of experiencing falls. Exercise carried out post-intervention mediated the effect of the falls prevention programme on physical HRQOL. Staying active was associated with better physical HRQOL, balance, and leg strength at 6-month follow-up. Clinical practice should emphasize self-management exercise programmes for home care recipients to prevent falls and promote their HRQOL in the long term. Interventions to maintain frail older adults' functional ability and well-being are important to enable healthy ageing at home, which is an essential aim of public health policy around Europe.

Supplementary data

Supplementary data are available at *EURPUB* online.

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Conflicts of interest: D.A.S. is a director of Later Life Training Ltd., a UK-based non-profit organization providing training to therapists in the effective delivery of the OEP to older adults. M.B., T.B., J.C.D. and A.B. report no potential conflict of interest.

Key points

- Falls in older adults are an increasingly important public health concern due to demographic changes with a rising number of older adults and the severe consequences of falls.
- A falls prevention exercise intervention based on the Otago Exercise Programme can improve physical HRQOL post-intervention in older home care recipients.
- Performing the exercise programme led to prolonged positive changes in exercise behaviour and reduced the risk of falls.
- Sustained exercise performed post-intervention mediated the positive effect on physical HRQOL at 6-month follow-up.
- The results from this study can advise clinicians and public health policy when developing and implementing effective interventions for frailer older adults promoting and maintaining their functional ability and well-being, and further enabling healthy ageing at home.

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Evaluating a falls prevention intervention in older home care recipients: a comparison of SF-6D and EQ-5D

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Abstract

Purpose Health-related quality of life (HRQOL) is an important outcome in economic evaluations of health care interventions for older adults. The aim of this study was to compare two commonly used preference-based utility measures, SF-6D and EQ-5D, to provide knowledge on their applicability when evaluating falls prevention interventions in primary health care.

Methods The study is a secondary analysis of longitudinal data from a randomised controlled trial, which included 155 older home care recipients participating in a falls prevention intervention in Norway. HRQOL was measured by SF-6D and EQ-5D. Physical function was measured by Berg Balance Scale, 4-m walk test, 30-s sit-to-stand and Falls Efficacy Scale International. Assessments were performed at baseline, 3 months and 6 months. The agreement between SF-6D and EQ-5D was examined using Bland–Altman plots and Spearman correlations. Elasticities from regression analysis were employed to compare the instruments' responsiveness.

Results SF-6D and EQ-5D were strongly correlated (0.71), but there were differences in the instruments' agreement and domains of HRQOL covered. Participants with a higher mean HRQOL and/or better physical function scored generally higher on EQ-5D. Participants with a lower mean HRQOL and/or poorer physical function achieved a relatively higher score on SF-6D. EQ-5D was more responsive to changes in physical function compared to SF-6D.

Conclusions SF-6D and EQ-5D have both similarities and differences regarding sensitivity, domains covered and responsiveness to changes when evaluating a falls prevention intervention. Selecting the appropriate instrument depends on the characteristics of the participants and the intervention being evaluated.

Keywords Health-related quality of life · Home care · Falls prevention · Economic evaluation · SF-6D · SF-36 · EQ-5D

Introduction

Falls in older adults are a leading cause of disability, pain and reduced health-related quality of life (HRQOL), contributing considerably to the global burden of disease [1–3]. Due to the large consequences of falls, maintaining and improving HRQOL is one of the main goals of falls prevention [4]. Home care recipients have a high incidence of falls and low level of HRQOL compared to the general older population [5, 6]. Effective interventions to prevent falls and to improve HRQOL in older home care recipients are necessary to maintain functional abilities and well-being, contributing to healthy ageing [1, 3], as well as reducing costs [7–9].

HRQOL is an important outcome in evaluations assessing the effects of health care and policy interventions for older adults [10]. Given the rise in number of older adults and the associated increase in health care costs, evaluations are necessary to inform about the cost-effectiveness of interventions [4]. Preferences over health states in older adults can be measured by various instruments which in turn can influence the outcome of the evaluation [4, 10, 11].

The Short Form 36 Health Survey (SF-36) and the EuroQOL EQ-5D (EQ-5D) are two of the most widely used

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generic measures of HRQOL, which have shown to be valid and reliable when assessing older adults [12]. In the population of community-dwelling older adults, EQ-5D has been recommended due to its shortness and high response rate, while SF-36 has been recommended for more detailed and broad assessments [12, 13]. Scores from SF-36 have been translated into the preference-based utility index SF-6D, comparable to EQ-5D. Both EQ-5D and SF-6D can be employed to calculate quality adjusted life years (QALYs) in economic evaluations [11]. Comparing EQ-5D and SF-6D in older adults can provide knowledge on how the instruments respond to changes in the underlying health state in this frail group. [13]. This can assist clinicians and researchers when choosing an instrument, and policymakers interpreting recommendations.

Differences and similarities in EQ-5D and SF-6D have been studied previously in various populations. Although both instruments measure HRQOL, differences have been demonstrated, in particular in the lower end of the utility scale [14]. Across various patient groups, floor effects in SF-6D and ceiling effects in EQ-5D have been shown [11, 13, 15]. In the domains pain and mood/mental health, similar utilities have been found, while EQ-5D puts more weight on physical functioning and SF-6D on social functioning [14, 15]. In the general population, EQ-5D seems to be more responsive to chronic physical conditions [16]. This was also evident when comparing the responsiveness of EQ-5D and the age-specific index of capability for older adults (ICE-CAPO) detecting changes over a 12-month period in fallers with mobility impairments [4]. However, in older people with severe chronic obstructive pulmonary disease, SF-6D was more efficient in detecting differences among subgroups in disease severity, but this observation was made at one time-point and not longitudinally [17, 18].

In economic evaluations, EQ-5D has demonstrated larger health gains and lower cost-utility ratios compared to SF-6D [19, 20]. Due to large differences in the incremental cost-utility ratios, the comparability of results from these instruments has been disputed [20, 21]. In patient groups with mild health conditions, the probability of acceptance of the incremental cost-utility ratio was larger when using EQ-5D, while in patient groups with worse health conditions the probability of acceptance was larger when using SF-6D [21]. Hence, when selecting a HRQOL instrument for evaluative purposes, the characteristics of the participants and the content of the intervention is relevant to consider. The group of frail older home care recipients has not been focused on previously.

Health care interventions for older fallers receiving home care are important to maintain their physical function and quality of life and further enable them to remain at home. Evaluations are necessary to develop efficient and high-quality health care services for this group of frail older adults. By comparing SF-6D and EQ-5D, further knowledge on the instruments' impact and their effect on evaluations can be obtained. This can be important information for health care managers and policy makers conducting evaluations to prioritise between different health care interventions for this population. We therefore conducted a study to examine the agreement between EQ-5D and SF-6D using longitudinal data on older home care recipients. We also assessed differences and similarities in HRQOL domains covered by the instruments and the responsiveness to changes in physical function over time.

Methods

Design

The study is a secondary analysis of data from a randomised controlled trial (RCT). Longitudinal data from three time points, baseline, 3 months and 6 months, was employed. The randomised controlled trial has been described elsewhere [5, 22, 23]. Reporting follows the STROBE guidelines [24].

Participants and setting

This study was conducted in primary health care service in six municipalities in Norway. Participants were recruited from lists of people receiving home care by health professionals. All assessments were performed in the participants' homes by trained research assistants. Participants provided informed written consent before baseline testing.

Recruitment was conducted from February 2016 to February 2017 and follow-up assessments were carried out until September 2017. The sample size was determined based on power calculations for the RCT [23]. The inclusion criteria for the participants were that they received professional home care, either home nursing, practical assistance or safety alarm service. They were 67 years or older and had experienced at least one fall during the previous 12 months. They were able to walk with or without a walking aid and could understand Norwegian. Exclusion criteria were that they had any medical contraindications to exercise or a life expectancy below 1 year. They were also excluded if they had a score below 23 on the Mini Mental State Examination (MMSE), indicating cognitive decline, or if they already were participating in another falls prevention programme or trial.

Outcome measures

HRQOL was measured by two common self-report assessment tools, Short Form 36 Health Survey (SF-36) and EuroQOL EQ-5D (EQ-5D). SF-36 is a generic and validated questionnaire, which has been translated into Norwegian [25]. It consists of 36 questions on physical functioning, role limitations due to physical functions, role limitations due to emotional problems, bodily pain, general health perception, vitality, social functioning and mental health. Scores for the different items range from 1 to 6, where 1 is good and 6 is worse. Based on SF-36, SF-6D utility indexes can be calculated, with scores ranging from 0.29 to 1 [26]. SF-6D derives from the responses on 11 items of the SF-36 which are combined into six dimensions of health with four to six levels each [18]. The six dimensions are: physical functioning, role participation, social functioning, pain, mental health and vitality. EQ-5D is a generic and validated tool, but briefer, and comprises five domains: mobility, usual activities, pain/discomfort and emotions [27]. Scores for the different domains range from 1 to 5, where 1 is good and 5 is worse. The corresponding utilities in EQ-5D are ranging from − 0.59 to 1 [19]. The utility scores for SF-6D and EQ-5D were calculated. The published algorithm with parametric preference weights for United Kingdom was employed as there is no Norwegian value set [27, 28]. Measurements were taken as interviews to increase the response and completion rate [12].

Physical function consisted of measures of balance, usual walking speed and leg muscle strength. Static and dynamic balance was assessed by the Berg Balance Scale (BBS), a 14-item scale measuring performance on a scale from 0 (cannot perform) to 4 (normal performance) [29]. The sum score ranges from 0 to 56, and a score below 45 indicates a high risk of falling. Usual walking speed was based on the time that was required to walk 4 meters in their usual speed (4MWT) and was expressed in meters per second [30]. The participants could use a walking aid if needed. Leg muscle strength was assessed using the functional 30 s sit-to-stand test (STS), which reports the number of rises from a chair within 30 s [31].

Falls self-efficacy was assessed by the Falls Efficacy Scale International (FES-I) [32]. This questionnaire measures concern about falling in 16 different activities in older adults and has been recommended for clinical practice as well as research [33]. Each activity has a four-point scale from 1 (not concerned) to 4 (very concerned), and the sum score ranges from 16 to 64.

Background variables like sex, age, falls history and health care services were collected at baseline. Mini Mental State Examination (MMSE) was performed at baseline to exclude participants with cognitive decline [34].

Statistical analyses

The statistical analyses were conducted using STATA/SE 14. Descriptive statistics on the study population are reported. Mean and standard deviations (SD) were calculated for continuous data and percentages for categorical data. The distribution of SF-6D and EQ-5D scores over domains and levels is presented. Furthermore, for different baseline characteristics a threshold (median) value has been calculated and mean utility scores are reported for the groups below and above this threshold. Complete case analyses were conducted.

Bland–Altman plots illustrate the agreement between EQ-5D and SF-6D. Plots were drawn for absolute values and changes at different time points. In the Bland–Altman plots, a fitted regression line and boundaries of agreement were drawn. Outliers were investigated to check characteristics, but were not excluded as they did not substantially affect the results. To study the associations between the domains of SF-6D and EQ-5D, and physical measures, Spearman rank correlations were calculated as most of the data was ordinal. The strength of correlations was interpreted according to Cohen, where 0.10 to 0.29 is weak, 0.3 to 0.49 is moderate, and 0.5 to 1.0 is strong [35].

To examine the responsiveness of SF-6D and EQ-5D related to measures of physical outcomes, elasticities were calculated from a linear mixed regressions model with individual-specific effects [36]. An elasticity of an outcome variable y with respect to a predictor variable x is calculated such as it equals approximately the proportional change in y for a proportional change in x. The elasticities were calculated at the mean level of x and can conveniently be interpreted as the percentage change in y in response to a one percentage change in x at this level. This removes the unit of measurement and makes responses in different regression models more illustrative and directly comparable.

Results

Descriptive statistics

Eight-hundred and sixty-five older adults receiving home care from the primary health care services in Norway were contacted and checked for eligibility. One hundred and sixty-seven were assessed at baseline and 12 were excluded, ten due to a score lower than 23 on MMSE and two due to ill-health. One hundred and fifty-five participants agreed to participate, gave informed consent and were tested at baseline (T0). At intervention end at 3 months (T1), 138 completed the assessments. At follow-up at 6 months (T2), 136 participants completed the assessments. Missing data at the different time points were due to death, ill-health, declining to participate or other reasons. For EQ-5D complete data was obtained for 155 at T0, 135 at T1 and 135 at T2. For SF-6D complete data was obtained for 155 at T0, 136 at T1 and 133 at T2.

Table 1 shows baseline characteristics of the sample. The participants had a mean age of 82.7 (SD 6.7) and 73.3% were females. They all received home care services. Practical assistance (69.7%) and safety alarm service (75.5%) were most common. The mean number of falls in the previous 12 months was 2.7 (SD 3.7). 36.1% had higher education with more than 12 years of education and the mean score on MMSE was 27.4. The measures of physical function were generally low, with a mean of 39.1 points (SD 11.3) on BBS, a mean of 5.1 raises (SD 4.1) on STS, a mean of 0.6 m/s (SD 0.2) on 4MWT and a mean of 30.7 points (SD 9.8) on FES-I. The mean index score of SF-6D was 0.64 (SD 0.12) and the mean index score of EQ-5D was 0.62 (SD 0.23).

Tables 2 and 3 present the distribution of SF-6D and EQ-5D results at baseline. EQ-5D has a larger proportion of responses in the top category of each dimension compared to SF-6D. Very few responses are within level five of EQ-5D.

Table 1 Baseline characteristics of the sample $N = 155$

Characteristics	
Age, mean (SD)	82.7 (6.7)
Sex, males, %	20.7
Higher education (> 12 years), %	36.1
Falls in the last 12 months, mean (SD)	2.7 (3.7)
Mini Mental State Examination (MMSE), mean (SD)	27.4 (2.2)
Primary health care services	
Practical assistance, %	69.7
Nursing, %	30.3
Safety alarm service, %	75.5
EQ-5D, mean (SD)	
EQ-5D Index score	0.62 (0.23)
SF-6D, mean (SD)	
SF-6D Index score	0.64 (0.12)
Physical measures, mean (SD)	
Berg Balance Scale (BBS)	39.1 (11.3)
30 s sit-to-stand (STS)	5.1 (4.1)
4-m walk test m/s (4MWT)	0.6 (0.2)
Falls Efficacy Scale (FES-I)	30.7 (9.8)

SD Standard deviation

Table 3 Distribution of EQ-5D results at baseline (%) $N = 155$

Level	Mobility	Self-care	Usual activities	Pain/discomfort	Anxiety/depression
1	27.7	60.0	24.5	26.5	51.6
2	29.7	25.2	37.4	23.9	34.8
3	21.9	12.3	27.1	30.3	9.7
4	20.0	2.6	10.3	15.5	3.2
5	0.7	–	0.7	3.9	0.7

Both distributions of SF-6D and EQ-5D scores appear to be reasonable spread across the scales.

Table 4 presents a comparison of SF-6D and EQ-5D utility scores over selected groups of the sample. The table shows that there is a larger spread of values within EQ-5D utility scores compared to SF-6D between those with higher/lower age and better/worse physical function. The exception is on number of falls, where both instruments are more similar. Higher age and better scores on physical measures are associated with higher utility scores of both SF-6D and EQ-5D. Having lower scores on physical measures is associated with relatively higher scores on SF-6D compared to EQ-5D, and contrary.

More information on the flow of participants, on their characteristics at baseline, as well as the results of the RCT are presented elsewhere [5, 23].

Similarities and differences in SF-6D and EQ-5D

The index scores of SF-6D and EQ-5D are strongly correlated (0.71). This is also confirmed by the Bland–Altman plots in Figs. 1 and 2. Figure 1 shows the agreement of these two preference-based measures at the time points T0, T1 and T2. Many observations cluster around 0 difference between the instruments. Furthermore, the difference is proportional to the mean HRQOL scores, illustrated by the fitted regression line. A positive difference is associated with a higher mean score, and a negative difference is associated with a lower mean score. Participants with higher mean

Table 2 Distribution of SF-6D results at baseline (%) $N = 155$

Level	SF physical functioning (six levels)	SF role participation (four levels)	SF social functioning (five levels)	SF bodily pain (six levels)	SF mental health (five levels)	SF vitality (five levels)
1	–	18.7	37.4	24.5	36.1	1.9
2	7.7	32.9	19.4	16.1	30.3	7.7
3	27.7	5.2	16.1	13.6	19.4	15.5
4	26.5	43.2	21.9	14.2	11.6	33.6
5	32.9	–	5.2	20.7	2.6	41.3
6	5.2	–	–	11.0	–	–

Table 4 Comparison of SF6D and EQ 5D utility scores over selected groups of baseline characteristics

Characteristics	SF-6D	EQ-5D
Age. Median 83 years		
Age < 83 years	0.61	0.56
Age ≥ 83 years	0.66	0.67
Falls baseline		
Falls = 1	0.65	0.61
Falls ≥ 2	0.63	0.62
Berg Balance Scale. Median 41 points		
BBS < 41	0.62	0.55
BBS ≥ 41	0.65	0.68
30-s sit-to-stand. Median 6 raises		
STS < 6	0.60	0.53
STS ≥ 6	0.67	0.70
4-m walk test. Median 0.603 m/s		
4MWT < 0.603	0.62	0.55
4MWT ≥ 0.603	0.66	0.69
Falls Efficacy Scale. Median 29 points		
FES-I < 29	0.68	0.70
FES-I ≥ 29	0.59	0.54

HRQOL have higher scores on EQ-5D compared to SF-6D, and analogously participants with lower mean HRQOL have generally lower scores on EQ-5D compared to SF-6D. This relationship becomes more evident from TO to T2. Figure 2 illustrates the agreement on changes in HRQOL from T0 to T1, T1 to T2 and T0 to T2. A similar pattern can be observed as in Fig. 1. Participants with a positive change in mean HRQOL have a generally stronger positive change in EQ-5D than in SF-6D, while for the participants with negative changes in mean HRQOL, the negative change is generally stronger in EQ-5D than in SF-6D.

Associations between subdomains of SF-6D and EQ-5D and physical measures

Table 5 presents correlations between the different subdomains of SF-6D and EQ-5D and physical measures. First, three items from EQ-5D are strongly correlated with four items from SF-6D; EQ-5D Self-care and SF Physical Function (0.65), EQ-5D Pain/Discomfort and SF Bodily Pain (0.71) and EQ-5D Anxiety/Depression and SF Role Participation (0.61) and SF Mental Health (0.71). Weak to moderate correlations were shown between SF Social Functioning and SF Vitality and all domains of EQ-5D. Similarly, only weak to moderate correlations were shown between EQ-5D Mobility and all domains of SF-6D.

BBS is the only physical measure which is strongly correlated with one of the HRQOL domains, EQ-5D Mobility (0.54). On EQ-5D, moderate correlations were shown between all physical measures and Mobility, Self-care and Usual Activities. On SF-6D, moderate correlations were shown between BBS, STS and FES-I and Physical Functioning and Role Participation. In addition, BBS was moderately

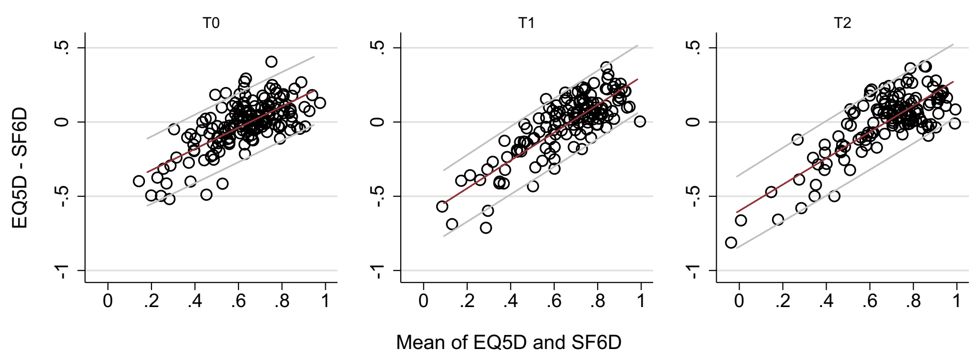

Fig. 1 Bland–Altman plot on the agreement of EQ-5D and SF-6D at time points T0, T1 and T2

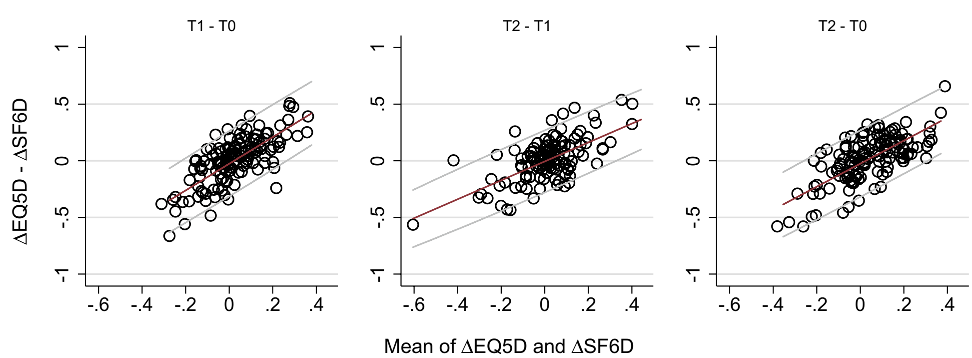

Fig. 2 Bland–Altman plot agreement on changes in EQ-5D and SF-6D from T0 to T1, T1 to T2 and T0 to T2

Table 5 Correlations between subdomains of SF-6D, subdomains of EQ-5D and physical outcomes

	SF physical functioning	SF role participation	SF social functioning	SF bodily pain	SF mental health	SF Vitality	Berg balance scale	30-s sit-to-stand	4-min walk test	Falls Efficacy Scale
EQ-5D mobility	0.38	0.35	0.25	0.25	0.14	0.21	−0.54	−0.40	−0.42	0.40
EQ-5D self-care	0.65	0.32	0.32	0.25	0.25	0.34	−0.36	−0.40	−0.27	0.40
EQ-5D usual activities	0.44	0.32	0.39	0.28	0.18	0.34	−0.38	−0.28	−0.36	0.37
EQ-5D pain/discomfort	0.23	0.27	0.39	0.71	0.28	0.25	−0.11	−0.17	−0.21	0.17
EQ-5D anxiety/depression	0.26	0.61	0.36	0.31	0.71	0.26	−0.10	−0.24	−0.18	0.34
Berg Balance Scale (BBS)	−0.36	−0.31	−0.20	−0.03	−0.07	−0.13				
30-s sit-to-stand (STS)	−0.34	−0.39	−0.24	−0.11	−0.21	−0.12				
4-min walk test (4MWT)	−0.28	−0.25	−0.15	−0.12	−0.06	−0.08				
Falls Efficacy Scale (FES-I)	0.35	0.35	0.27	0.27	0.30	0.25				

Table 6 Elasticities from linear mixed regressions with individual-specific effects

Physical measures	HRQOL	Elasticity	SE	*p* value
Berg Balance Scale	EQ-5D	0.54	0.11	0.000
	SF-6D	0.18	0.06	0.002
30-s sit-to-stand	EQ-5D	0.09	0.04	0.010
	SF-6D	0.02	0.02	0.194
4-min walk test	EQ-5D	0.20	0.08	0.013
	SF-6D	0.06	0.04	0.118
Falls Efficacy Scale International	EQ-5D	−0.24	0.07	0.001
	SF-6D	−0.13	0.03	0.000

SE standard error

correlated on SF-6D with Bodily Pain and FES-I with Mental Health.

Responsiveness assessed by elasticities

Table 6 presents elasticities from linear mixed regressions. Each regression includes as covariate a physical measure and individual-specific effects. Changes in physical outcomes have larger impacts on changes of HRQOL measured by EQ-5D compared to SF-6D. Elasticities can be interpreted for small changes in the dependent variable. For instance, a 10% increase in BBS score is expected to increase EQ-5D by 5.4% ($p < 0.001$) and SF-6D by 1.8% ($p < 0.001$). A 10% improvement of FES-I is expected to give an improvement of 2.4% ($p < 0.001$) on EQ-5D and 1.3% ($p < 0.001$) on SF-6D. On STS and 4MWT an increased score is expected only leading to significant changes ($p < 0.05$) of EQ-5D.

Discussion

This study compares two widely used metrics of HRQOL in this growing population of older fallers living at home. The results show that SF-6D and EQ-5D are strongly correlated in index scores and some subdomains. There are, however, some differences in the utilities' agreement and in their responsiveness to changes in physical function. EQ-5D gave generally higher scores than SF-6D at a higher mean HRQOL and/or when physical function was better. In contrary, SF-6D provided relatively higher scores than EQ-5D when mean HRQOL was lower and/or when physical function was poorer. EQ-5D showed to be more responsive to changes in physical function compared to SF-6D in older home care recipients who have experienced falls.

There seems to be a high level of agreement between SF-6D and EQ-5D, both in absolute values and in changes over time. There are also some differences. EQ-5D appears to be more sensitive to changes than SF-6D. Similar results have been presented previously. A study comparing the two instruments in mental health patients showed that EQ-5D resulted in larger health gains, in particular in the subgroup with higher severity of mental health problems [19]. Another study showed that, even though SF-6D had better distributional properties, it did not improve the sensitivity to change [15]. EQ-5D has fewer health states, but it seems not limiting its ability to measure utilities [13]. Hence, the range and variability of the two outcomes, where SF-6D has a smaller range and lower variability, could contribute to its lower sensitivity [11]. The sensitivity of EQ-5D is even more evident at T2 (6 months) than at T0 (baseline). This result could be due to the change in HRQOL over the 6 months' time period, possibly caused by the intervention.

Another reason for limitations in the agreement could be differences in domains of HRQOL covered by the instruments [15]. HRQOL is a complex concept and includes both physical, mental and social domains of health [37]. SF Physical Function was strongly correlated with EQ-5D Self-Care, and SF Role Participation was strongly correlated with EQ-5D Anxiety/Depression. SF Bodily Pain was strongly correlated with EQ-5D Pain/Discomfort and SF Mental Health with EQ-5D Anxiety/Depression. Interestingly, SF Social Functioning and SF Vitality were only weakly to moderately correlated with EQ-5D subscales. This could be due to the discrepancy in domains included. Other elements than physical health, as mental health, might be under-represented in EQ-5D compared to SF-6D [38]. A previous study showed that SF-6D was more efficient at detecting external indicators of health status, for instance longstanding illness or disability, compared to EQ-5D [14]. SF-6D can tap into broader aspects of HRQOL, as role participation and social functioning, which could be the reason why it is more sensitive in complex health conditions. Moreover, a higher number of response items on each of the domains can result in a larger descriptive system with possibly greater sensitivity to the external health indicators. Enhancing several dimensions of health can be important when evaluating interventions for older home care recipients. This should be considered when selecting HRQOL measurement tools for this population.

The instruments' responsiveness to changes seems to be influenced by the type of intervention being evaluated [15]. In the present study, a relatively higher responsiveness to changes in physical function was shown in the scores of EQ-5D compared to SF-6D. Positive changes in HRQOL were associated with improvement of balance, measured by Berg Balance Scale, and falls self-efficacy, measured by Falls Efficacy Scale International. Results were illustrated using elasticities, another representation of regression coefficients enabling direct comparison of the estimates. The findings emphasise the importance of picking an instrument that is more sensitive to the elements that the intervention is aiming to change. When evaluating a falls prevention exercise intervention, responsiveness to underlying physical changes could therefore be of importance. However, if the falls prevention intervention had included actions also targeting other dimensions, as social functioning or vitality, SF-6D could be more responsive. The HRQOL outcome selected will influence the economic evaluations conducted and further the decision-making in public health policy.

Another element to consider when selecting HRQOL instruments is the older adults' health status and level of function at baseline. EQ-5D is thought to be sensitive in patient groups with more severe health states at baseline and less sensitive in patient groups with milder health states at baseline, and the opposite applies to SF-6D [21]. In comparison with normative data on SF-6D and EQ-5D, the participants in the present study had a lower level of self-perceived HRQOL [39, 40]. The older home care recipients had a mean index score of 0.62 on EQ-5D. In a study including Danish population norms, the index score was 0.85 in males and 0.82 in females aged 70–79 [39]. In SF-6D, the mean index score in the present study was 0.64. Norms from a sample of the British population demonstrated a mean index score ranging from 0.77 in the age-group 70–74, to 0.69 in the age-group above 85 [40]. While the Danish and British population of older adults are similar to the Norwegian, there might be some differences in socioeconomic status influencing the general health status [41]. Nevertheless, the low level of HRQOL in this population of home care receivers and fallers emphasise the need for effective health services in the primary care to maintain or improve their HRQOL contributing to healthy ageing.

In addition to health policy, this study has implications for patient management in primary care. Measuring HRQOL in older adults is increasingly seen as important in evaluations and there is a lack of tools that can be applied in clinical practise [4, 42, 43]. In the present study, both measurements were conducted as interviews as recommended for this population, achieving high completion rates, but are at the same time more time-consuming and costly [12]. Previous research including older adults has suggested that EQ-5D might be sufficient when brevity is required and the health changes are expected to be substantial, while SF-36 is more beneficial when several details are required and the health changes expected are less substantial [12, 44]. Although general measures of HRQOL provide relevant information in the group of older adults, there might be some important age-specific factors that are missing, as for instance sensory abilities and autonomy [42]. Instruments designed specifically for older adults could therefore be an important addition in clinical practise.

This study has both strengths and limitations. Due to a thorough follow-up a low number of missing for both SF-6D and EQ-5D was achieved. The participants were recruited from six municipalities to a falls prevention exercise intervention, and the results might not representative for the general population of older home care recipients. A low percentage of males were included, but this is typical for the population of older home care recipients. The preference weights of SF-6D and EQ-5D have been developed specifically for the United Kingdom, but the Norwegian population could have different preferences. The two scales also differ in their range. To deal with this issue elasticities were calculated, where responsiveness is expressed as comparable changes in percentages. Few index scores are in the lowest end of the distribution, where EQ-5D has health states regarded worse than what SF-6D is able to generate. Finally, responsiveness was only explored related to important physical measures collected in the randomised controlled trial. Other outcomes might also be relevant for this population.

Conclusion

SF-6D and EQ-5D are strongly correlated, but there are some differences in their agreement, aspects of HRQOL covered and responsiveness to changes. Older adults with a generally higher level of HRQOL and/or better physical function achieved a relatively higher score on EQ-5D, and older adults with a generally lower level of HRQOL and/or poorer physical function achieved a relatively higher score on SF-6D. EQ-5D was more responsive to changes in physical function compared to SF-6D in older home care recipients who had experienced falls. This study shows that selecting a HRQOL instrument for evaluating an intervention may depend on the characteristics of the intervention and the studied population. The choice of instrument can affect the outcome of evaluations in the group of frail older adults and consequently health policy for this increasing population.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval The project proposal has been approved by The Regional Committee for Medical Research Ethics in South East Norway (Ref. 2014/2051).

Informed consent Written informed consent was obtained from all participants before baseline testing.

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