Reablement in home-dwelling older adults

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Thesis for the degree of philosophiae doctor (PhD) at the University of Bergen

2017

Date of defence: 02.06.2017

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Year:2017TitleReablement in home-dwelling older adults

Author: Hanne Tuntland

Print: AIT Bjerch AS / University of Bergen

Scientific environment

The Faculty of Medicine and Dentistry, University of Bergen, Norway, granted me admission to doctoral education in 2013. The doctoral project was conducted in the period from August 2013 to February 2017. During that time, I have been a member of the scientific community in the Physiotherapy Research Group, Department of Global Public Health and Primary Care, Faculty Medicine and Dentistry, University of Bergen.

The PhD project derives from two different research projects: 1) research on reablement in the municipality of Voss in Western Norway funded by the Regional Research Funds Western Norway, and 2) a multicenter investigation of reablement in Norway funded by the Norwegian Directorate of Health. My employer, Western Norway University of Applied Sciences, also granted me time for research and development during the nearly 4-year doctoral period, and as such contributed significantly to the funding of my doctoral degree. Additionally, sponsorship was obtained from the Norwegian Occupational Therapy Association.

My daily PhD studies and research have taken place in the facilities and scientific environment of Western Norway University of Applied Sciences, Department of Occupational Therapy, Physiotherapy and Radiography, where I have also performed my 25% position work duty. As a PhD candidate, I have been connected to the Center for Care Research Western Norway, (which is located at the campus of Western Norway University of Applied Sciences in Bergen), and been a member of their Rehabilitation and Health Promotion Research Group.



Western Norway University of Applied Sciences



Acknowledgements

There are so many people, who in one-way or another, have contributed to making this work possible, and I would like to express my gratitude to all of them.

Above all, I would like to convey my sincere thanks to the nearly 800 older adults who have participated in the studies and to the countless number of healthcare providers who have contributed in data collection all over the country. Without their participation and efforts, there would have been no PhD project. Thereafter, I want to express my deepest gratitude to my supervisors:

Mona Kristin Aaslund has been my main supervisor. She works as an Associate Professor at the University of Bergen, Department of Global Public Health and Primary Care, as well as a neurological specialist in physiotherapy at Haukeland University Hospital. Doctor Aaslund's attributes have included her good spirits and positive attitude. She has always been encouraging towards me and my work. I appreciate that she prioritised having thorough discussions with me concerning various aspects of the included studies in this thesis. She taught me a lot about academic writing and research craftsmanship. Her professional insight in rehabilitation and mobility has also been of great value. Mona Kristin Aaslund has supervised the three studies and the synopsis.

Ingvild Kjeken has been my main co-supervisor. She works as a Professor at Oslo and Akershus University College of Applied Sciences, Department of Occupational Therapy, Prosthetics and Orthotics. In addition, she works as a Senior Researcher at Diakonhjemmet Hospital, National Advisory Unit on Rehabilitation in Rheumatology. She is an occupational therapist with special competence in rheumatology. Our scientific cooperation goes back to 2006. I consider Professor Kjeken to be my mentor, the one who introduced me to research. Moreover, she helped to design this PhD project and made me realise that a doctoral degree was achievable. She generously shared her comprehensive knowledge with me during our numerous phone calls and contributed to my doctoral education far more than could be expected from a co-supervisor. Sharing her insights into rehabilitation, the Canadian Occupational Performance Measure, psychometric properties, statistics, scientific methods and academic writing, has been of immense value. Ingvild Kjeken has supervised all four papers.

The second co-supervisor has been Eva Langeland. She works as an Associate Professor at the Western Norway University of Applied Sciences, Department of Nursing. She is a nurse with a specialisation in mental health. In conjunction with the Center for Care Research Western Norway, Doctor Langeland has been the project leader of the multicenter study on reablement, as well as the research leader of the Rehabilitation and Health Promotion Research Group. In this respect, the two of us have collaborated closely and well for several years. I thank Eva Langeland for her positive leadership and comprehensive contributions to our mutual publications, and for engagement in and facilitation of my doctoral studies. Eva Langeland has supervised the psychometric study and the prediction study.

Professor Birgitte Espehaug, Western Norway University of Applied Sciences, has been the statistical advisor in all the papers. I thank her for the patient and gentle guidance she gave me. She has taught me a lot concerning statistical analysis and use of SPSS. I am also indebted to Doctor Bjarte Folkestad for statistical support and valuable help with technical issues as a co-author in the prediction study.

Associate Professor Oddvar Førland, Center for Care Research Western Norway, has been a close collaborator in the two projects from which this thesis was derived and a co-author on three of the papers. I thank him for engagement, analytical perspectives and contributions.

Professor Frode Fadnes Jacobsen, Research Director of the Center for Care Research Western Norway, has been the project leader of the research project in Voss. He was able to find the requisite resources for this PhD project within the funds granted, which made it possible for me to commit myself to this work. I am very grateful for his timely support and prioritisation. I also want to thank the General Manager of the Center for Care Research Western Norway, Hilde Haaland-Kramer, for her involvement in my work.

Likewise, I want to thank the Norwegian Occupational Therapy Association for support, and in particular the President Nils Erik Ness. Our mutual interest in implementation and research on reablement in Norway, has led to a fruitful collaboration, which I hope will continue.

I would like to offer a special thanks to Olbjørg Skutle, Per Waardal, and Solrun Hauglum, all of whom contributed to the realisation of implementation and research on reablement in the Voss municipality in Western Norway. This was where it all started in 2011.

Moreover, I want to thank my friend for many years and PhD fellow, Hilde Smith Strøm, for mutual support, encouragement and exchange of acquired knowledge, during the period of our doctoral studies.

I would also like to thank Gunhild Austrheim, University Librarian at Western Norway University of Applied Sciences for valuable help with literature searches and reference manager software issues.

My colleagues at the Bachelor Programme in Occupational Therapy at the Western Norway University of Applied Sciences deserve thanks for their support and interest in my work. I also would like to thank the Director of the Department of Occupational Therapy, Physiotherapy and Radiography at Western Norway University of Applied Sciences, Bjørg Hafslund, for facilitation of my doctorial work.

Finally, I am very grateful to friends and family, and in particular to my beloved teenagers Adrian and Andrea, who profoundly add joy and meaning to my life.

Abstract

Background: Reablement is an alternative approach to home-based services for older adults at risk of functional decline. It is time-limited and aims to promote independence by offering a multidisciplinary, individualised and goal-directed intervention. The Canadian Occupational Performance Measure (COPM) is an instrument designed to help participants identify, prioritise and evaluate occupational performance (COPM-P) and satisfaction with performance (COPM-S) of important occupations. The COPM is the main instrument for goal determination and evaluation in Norwegian reablement.

Objectives: To investigate psychometric properties of the COPM used on an interprofessional basis, to explore potential factors predicting outcomes following reablement, and to evaluate the effectiveness of reablement in home-dwelling older adults.

Methods: The PhD project is based on two cohort studies (the psychometric study and the prediction study) and one randomised controlled trial (the effectiveness study).

Results: The results show that the COPM has adequate content validity, construct validity and feasibility in a population of home-dwelling older adults, and a moderate responsiveness to change. The minimal important changes are 3.0 and 3.2 points for COPM-P and COPM-S, respectively. High baseline scores of COPM-P and COPM-S, female gender, having fracture as the major health condition and high motivation for rehabilitation predict better outcomes. Home-dwelling older adults benefit from reablement by improving their self-perceived performance and satisfaction with performance in prioritised daily occupations.

Conclusion: This PhD project demonstrates that the psychometric properties of the COPM are adequate in an older, heterogeneous and home-dwelling population. The results support the use of COPM in clinical practice and research in this population. Furthermore, the results show that diagnosis, gender, motivation and functional level are significant predictors of outcomes of reablement. Lastly, this thesis confirms that reablement is an effective intervention when it comes to improving performance and satisfaction in everyday life.

List of publications

This thesis is based on the following four papers:

Paper 1:

Tuntland H, Aaslund MK, Langeland E, Espehaug B, Kjeken I. Psychometric properties of the Canadian Occupational Performance Measure in home-dwelling older adults. J Multidiscip Healthc 2016, 9: 411-434.

Paper 2:

Tuntland H, Kjeken I, Langeland, E, Folkestad B, Espehaug B, Førland O, Aaslund MK. Predictors of outcomes following reablement in community-dwelling older adults. Clin Interv Aging 2017, 12: 55-63.

Paper 3a:

Tuntland H, Espehaug B, Forland O, Hole AD, Kjerstad E, Kjeken I. Reablement in community-dwelling adults: study protocol for a randomised controlled trial. BMC Geriatr 2014, 14 (149): 1-9.

Paper 3b:

Tuntland H, Aaslund MK, Espehaug B, Førland O, Kjeken I. Reablement in community-dwelling older adults: a randomised controlled trial. BMC Geriatr 2015, 15 (145): 1-11.

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Abbreviations

ADL	Activities of Daily Living
САОТ	The Canadian Occupational Therapy Association
ССТ	Clinical Controlled Trial
СМОР-Е	The Canadian Model of Occupational Performance and Engagement
COSMIN	COnsensus-based Standards for the selection of health Measurement INstruments.
COPM	Canadian Occupational Performance Measure
COPM-P	COPM, measuring occupational performance
COPM-S	COPM, measuring satisfaction with performance
EQ-5D-5L	European Quality of Life Scale, five dimensions, five levels
IADL	Instrumental Activities of Daily Living
ICF	International Classification of Functioning, Disability and Health
MHC-SF	Mental Health Continuum - Short Form
MIC	Minimal Important Change
PADL	Personal Activities of Daily Living
PWS	Preferred Walking Speed
RCT	Randomised Controlled Trial
SD	Standard Deviation
SOC-13	Sense of Coherence questionnaire, 13 items
SPPB	Short Physical Performance Battery
TUG	Timed Up and Go
VAS	Visual Analogue Scale
WHO	World Health Organization

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1. Introduction

1.1 Ageing

1.1.1 The ageing population

Research on the self-care abilities of older persons is of future importance due to the steep increase of older people in the population. People are living longer than ever before and this can be seen as one of the world's most important success stories. Population ageing is a global phenomenon. Virtually all countries in the world are experiencing an increase in the absolute number and proportion of older persons in their population [1]. Between 2015 and 2030, the number of people aged 60 years or older is expected to increase by 56 percent. Furthermore, the number of people age 80 years or over is growing even faster. Projections indicate that the 'oldest-old' population will triple from 2015 to 2050, from 125 million to 434 million [2]. Population ageing is, however, the greatest cause of the rise in the prevalence of chronic conditions, such as dementia, stroke, chronic obstructive pulmonary disease, and diabetes, all of which are strongly associated with age [3].

Population ageing is currently predominantly portrayed as a problem, where many people are questioning whether health services, welfare provision and economic growth are sustainable [4]. A shrinking work force adds to these concerns about sustainability [5]. Naturally, there is reason for concern. Nonetheless, the demographic shift exposes both opportunities and challenges. Most people wish to live a long and healthy life, and the possibility of longevity is within reach of the majority. The World Health Organization's (WHO) World report on ageing and health concludes that: "it is good to get old and societies are better off for having these older people" [6, page 27]. Besides, older persons can be valuable economic, social, cultural and familial resources [5]. Despite evidence that older persons contribute to society in many ways, they are often depicted as frail, burdensome and care dependent [6].

1.1.2 Healthy ageing

The main factors in establishing the relationship between population ageing and health cost spending, are the health and functional status of older people [4]. This is a reason why healthy ageing is a desirable process from the society's perspective. Healthy ageing is defined as "the process of developing and maintaining the functional ability that enables well-being in older age" [6, page 28]. Hence, promoting functional ability is a core concept in healthy ageing. According to the WHO's framework for action on ageing and health from 2015, *functional ability* comprises the health-related attributes that enables people to do and be what they want. It is based on *intrinsic capacity* (the combination of all physical and mental capacities a person can draw on) and relevant environmental components that mitigate deficits [6]. Healthy ageing focusing on promoting functional ability. This can be achieved in two ways: by supporting the promotion and maintenance of intrinsic capacity and by removing or reducing environmental barriers [6]. The very purpose of rehabilitation interventions is to reduce the gap between the individual's intrinsic capacity and the environmental barriers, thus improving the person's functional ability [7, 8]. By doing so, it can be stated that rehabilitation such as reablement, promotes healthy ageing.

1.1.3 Ageing in place

During the last three decades, the concept of *ageing in place* has become an essential concept for policy-makers and researchers in their collective efforts to create communities that enable people to remain in their homes and neighbourhoods as long as possible [9]. Ageing in place means remaining living in the community with some level of independence, rather than in residential care [10]. However, the primary purpose of ageing in place is to enable older people to maintain independence, autonomy and connection to friends and family. Ageing in place is generally viewed as better for older persons [6]. Besides, having people remain in their homes also avoids the costly option of institutional care [11]. It is therefore often preferred by policy makers, healthcare providers and by many older people themselves [10]. Still, older people are as likely as people in general to be involved in an ongoing assessment of the

suitability of the house they are living in. Hence, a distinction between 'ageing in place' and 'staying put' needs to be made [12]. The term 'staying put' in this respect means that older persons live in their homes against their will.

1.1.4 Perspectives on health policy for older persons

The diversity in functional capacity of older persons is vast. The multitude of health and functional states experienced by older people, leads to multiple demands regarding health services [1]. The diverse needs of older people are best viewed as a continuum of functioning that ranges from good health and independent living to significant functional decline and need for substantial care and nursing home placement. Delivering differentiated and person-centred health services is one way of dealing with this diversity. Providing person-centred health services that meet individual preferences and needs is a shift from the way the health services that have been administered traditionally [6].

There is also a shift from viewing older people as passive care recipients towards seeing them as active participants who have resources of their own which they can contribute. Today, older persons want to have an active role in their own care and to make their own decisions. A focus on how older people's own resources can be used and fostered within the health services, helps to create innovative and empowering strategies for care [1]. Globally, in recent decades, we have seen a transformation in ageing policy from a paradigm that sees ageing as a dependent phase of life to one that embraces the idea of active ageing and improved self-management [13]. Hence, offering reablement reflects a wider change to health policy in high income countries that promotes more individually tailored services that permit greater choice and control for consumers [14].

1.2 Rehabilitation

1.2.1 Rehabilitation in general

In 2011, the WHO defined *rehabilitation* as "a set of measures that assists individuals who experience, or are likely to experience disability, to achieve and maintain optimal

functioning in interaction with their environments" [15, page 96]. This definition emphasises that the broad aim of rehabilitation is to assist a person with disability in achieving a life of optimal functioning in interaction with the environment. The assumption is that it is possible to increase or at least maintain the functional ability of an individual with functional limitations. The official Norwegian definition of rehabilitation from 1999 is "time-limited, planned processes with clearly defined objectives and means, in which several actors cooperate in providing necessary assistance to patients and users in their efforts to achieve optimal functional level, coping skills, independence, and social participation" [16, page 10]. This definition is more specific, focusing on planning, goal definition, time constraints, multidisciplinarity and multiple outcomes of rehabilitation amongst which is social participation. Both definitions stress optimal functioning and rehabilitation as an individual process, in which the role of the helpers is to assist. None of the definitions, however, highlight the individual's central role in defining their own goals or a more holistic understanding of disability that includes socio-psychological and physical environmental dimensions.

Rehabilitation theory reflects dominant cultural values that are rarely challenged or made explicit [17]. Today, rehabilitation among older persons draws on a perception of old age as a period of continued engagement and possibilities for change, whereas it was earlier depicted as a period of disengagement and inactivity [18]. Current multidisciplinary rehabilitation complies with new ideas within health policy that emphasise empowerment, coordination and individualisation [19]. However, the medical model, where disability has been seen as an individual deficit amendable to expert solutions, has traditionally underpinned the rehabilitation professions [17]. The medical model has dominated the rehabilitation professions to such a degree that it is viewed "as the right way of thinking about disability" [17, page 59]. In such biomedical thinking, a disability is viewed as an individual deficit that is addressed through individual interventions [20]. However, during recent decades there has been a shift away from the medical model, towards a thinking that encompasses societal, socio-psychological and physical environmental dimensions and focuses on health in

everyday life rather on disease [21]. There is also a shift towards enhanced focus on empowerment, by means of reallocating power from the professionals to the participants [22]. An increased weight is being placed on the participants' resources and preferences in their own life. In light of these trends within current rehabilitation practice, the question the practitioners ask, put in simple terms, has changed from "What is the matter with you?" to "What matters to you?" Reablement reflects this shift of focus. However, the rather outdated official definitions of rehabilitation presented previously lack these considerations.

The rehabilitation framework and process

The International Classification of Functioning, Disability and Health (ICF) was developed by the WHO and is a holistic, biopsychosocial model and a framework for rehabilitation that complies with the new thinking described above [15]. The ICF model can be seen as a synthesis that implies a coherent understanding based on various viewpoints from biological, individually oriented, and societal perspectives [23]. The conceptual model contributes to a shared understanding of core concepts and is widely used as a framework to organise information and structure multidisciplinary communication.

Moreover, rehabilitation may be considered as a problem-solving process in five steps which involves [15]:

- 1. Identification of a person's problems, needs and resources
- 2. Connecting the problems to relevant factors of the person and the environment
- 3. Defining rehabilitation goals
- 4. Planning, implementing and coordinating the measures
- 5. Evaluating the effects

In this section only Phase 3 in the rehabilitation process, goal setting, will be elaborated. This is because goal setting is viewed as an essential component of rehabilitation and a core skill of rehabilitation practitioners [24]. It is quintessential to establishing which goals are important to each participant, because goals are only effective if they are considered desirable by the individual [25]. Goals should be specific, ambitious, relevant and time-limited, with incremental steps that lead to

gradual attainment [26]. Whenever a participant's problems are sufficiently complex, then a formal goal-setting process may be needed to derive a set of goals that [25]:

- motivate the participant,
- ensure that individual healthcare team members work towards the same goals,
- ensure that important actions are not overlooked, and
- allow monitoring of change to avoid ineffective efforts.

Rehabilitation implies active engagement in occupations that are supposed to improve function [27]. The participant needs to be actively engaged in rehabilitation, not a passive recipient of therapy [28]. Many rehabilitation interventions require considerable engagement and motivation if they are to have maximum effect [27]. In order to underscore the active role of the person in question, the term *participant* is used in this thesis, instead of the terms *subject, user, recipient, client* or *patient*.

1.2.2 Rehabilitation and research in primary care

Various types of rehabilitation

Although beyond the scope of this thesis, it is important to acknowledge that rehabilitation in hospitals and institutions still plays a vital role. Reablement must be seen as a supplement to the existing rehabilitation services, not as a replacement. Reablement is considered to be a generic form of rehabilitation. Diagnosis-specific, specialised rehabilitation provided by highly qualified therapists, however, is still required [8].

Since the international literature uses various terms for rehabilitation provided by local authorities, a clarification is needed. *Community-based rehabilitation* (CBR) is a locally-based rehabilitation, which attempts to reach out to everybody with a disability, and in particular in rural areas in low-income countries [29]. The concepts of *rehabilitation in the community* or *home-based rehabilitation* are also used to differentiate from rehabilitation services delivered in institutions. In this thesis *home-based rehabilitation* is considered to be an umbrella term for rehabilitation services provided in peoples' homes or communities, whereas *reablement* is one type of home-based rehabilitation and *community-based rehabilitation* is another type.

Rehabilitation in primary care in Norway

In Norway, municipal authorities are responsible for the home-based services. The municipalities have freedom to determine the design and to some degree the extent of their health services themselves, although offering rehabilitation services is required. The conventional home-based services are predominantly public and include a variety of services, such as home nursing (personal assistance with medication, hygiene, dressing etc.), home help (practical assistance in cleaning, laundry, preparing meals, running errands etc.), security alarms and meals on wheels. Finally, home-based services include home-based rehabilitation services, such as physiotherapy and occupational therapy, which provide services like training and adaptation in activities of daily living (ADL), assistive technology, and exercises to improve physical fitness.

Research in primary care in Norway

A great proportion of Norwegian health research is conducted in specialised healthcare services and financed through the health trusts [30]. Research is one of four statuary tasks within Norwegian specialised healthcare services. In contrast, research is not required by Norwegian authorities in primary care. The municipalities only have a responsibility to partake in research [31]. As a result, little research has been conducted in primary care compared to specialised healthcare services [30], and this applies also for rehabilitation research. The financing of research in primary care is a challenge, as is also the organisation of participation and collaboration [31].

1.3 Reablement

1.3.1 The background

In order to meet the challenges in healthcare, the Norwegian Government has introduced several reforms and white papers. The drivers behind *the Coordination reform* were that the patient's needs for coordinated services were not being addressed sufficiently, there was too little emphasis on health promotion, and the demographic shift and change in disease patterns were raising sustainability concerns [32]. With the Coordination reform the Government introduced a new role for the municipalities with

respect to primary care with a focus on coordinated integrated pathways, prevention, early intervention, rehabilitation, more services closer to where the citizens live and a larger proportion of the services provided in the municipalities [32]. This was followed by the white paper *Future care* from 2013, where the Government aimed to contribute to a change in primary care with a stronger emphasis on rehabilitation and health promotion [33]. Hence, the Government aspired to stimulate municipalities to develop various models for early intervention and reablement. This intention was continued in 2014 in the white paper The primary health and care services of tomorrow [34] and in the document Care Plan 2020 [35]. The Government realised that older adults with complex health conditions and functional decline were a large and growing group with rehabilitation needs, and that the citizens did not receive the rehabilitation they needed [34]. The need for rehabilitation was often neglected. "When users are asked what is important to them, they often respond that they want to master daily tasks" [34, page 39]. In 2014, the Government stated that the interventions delivered must reflect this, [34]. Training in daily tasks was regarded as a critical component of the rehabilitation services and necessary to enable people to master their own lives. According to the Government, experience showed that early assessment of rehabilitation needs and appropriate intensive training, increase coping skills and reduce care needs. As a consequence, the Government intended to contribute to the development and dissemination of reablement in Norwegian municipalities [35].

1.3.2 Reablement wordwide

Internationally, reablement links with key strategic and international documents. Within the EU, reablement is highlighted under the EC Commission Social Investment Initiative and thus is recommended to all member states [36]. In an attempt to answer the 'billion dollar question' concerning how to address the new challenges in healthcare provision, among them the ageing population, Allen and Glasby have suggested 10 'high-impact' changes [37]. Reablement is one of these proposed changes. Several countries worldwide have followed the recommendation and implemented reablement. While countries like UK, USA, Ireland, Australia, New Zealand, Canada, The Netherlands, Finland, Denmark, Sweden and Norway have publications about

reablement, interest in the implementation of reablement has recently been detected in Italy, Island and Taiwan (personal knowledge). Whereas the rehabilitation form is termed *reablement* in the UK, the intervention is also known as *restorative care* in countries like US, Australia and New Zealand. In Norway, however, the intervention is termed *hverdagsrehabilitering*, the direct translation into English being *everyday rehabilitation*, emphasising that everyday life and everyday issues are the focuses of the intervention. However, since everyday rehabilitation is not established as a term in English literature, the term *reablement* is used in this thesis.

1.3.3 The reablement intervention

Definition

Førland and Skumsnes have outlined a definition of reablement that complies with the definition of reablement used in this thesis. The English version of the definition is as follows [38, page 11, translated by Hanne Tuntland]:

"Reablement is a time-limited, intensive and goal-oriented rehabilitation in the home and the local community of older persons who have experienced functional decline, where therapists, nurses and other employees in the home-based services in the municipality collaborate and assist the person in daily practice and adaptation of everyday occupations which matter to the individual".

In other words, reablement is a goal-directed, individualised, multidisciplinary and time-limited home-based form of rehabilitation for older adults living in their own homes. However, in reablement, the goal is not primarily to avoid or postpone institutional care, but to enable older adults to participate in meaningful activities in their homes and communities. Cochrane and colleagues have identified five criteria for an intervention to be called reablement [39]:

- Participants must have an identified need for formal care and support, or be at risk of functional decline
- The intervention must be time-limited and intensive (multiple home visits)
- The intervention must be delivered in the home setting (or in the local community)
- The intervention must focus on maximising independence

• The intervention must be person-centred and goal-directed

Theoretical assumptions

Ideally, the theoretical underpinnings of a treatment should be postulated a priori, however most rehabilitation treatments are not based on specific theories, but rather on tradition and administrative convenience [27]. This is also the case with regard to reablement, where a lack of theory has been acknowledged [40]. However, some relevant theoretical underpinnings are presented here.

The theory of optimising capacity is a newly developed concept within reablement that claims to explain how various strategies are used to optimise the function of the older adults making them able to age in place [40]. Optimising capacity implies making the best out of each person's resources, despite functional limitations. The identified strategies: appreciating a push, physical strengthening, adapting the environment, and building confidence, explains how the older adults become able to live in their own homes. Appreciating a push means accepting the motivational work of the healthcare providers and accepting the reablement service. Physical strengthening means training in physical fitness and everyday life occupations in order to increase physical capacities. Adapting the environment focuses on modifying the home and outdoor environments in order to optimise function. Building confidence is a process that runs parallel with the others. It is based on rehearsal of occupations and exercises, increased knowledge and support from others [40]. Together these strategies lead to optimal functioning according to the theory, making the older persons able to manage as well as possible in their own homes. The theory was developed using a grounded theory approach based on input from participants and caregivers, not on input from healthcare providers, and as such not covering the whole picture. One element lacking in this theory is the strategy of task analysis and simplifying the occupation in order to make the older person able to manage it, elements of the intervention that are reported elsewhere [41-43].

The philosophy of *person-centred* care is a central concept in reablement according to the criteria for reablement presented previously [44] and also highlighted in several

publications [40, 45-47]. Thus, an exploration of its conceptual meanings might be useful. Person-centredness in rehabilitation has multiple meanings, with its roots in different academic ideologies somewhat unrelated to rehabilitation. Four principal meanings of the concept have been identified with regard to rehabilitation [48, page 1556-1558]: 1) Addressing the person's specific and holistic properties. In this sense person-centredness means to tailor interventions for specific individual needs versus 'one size fits all' programs: 2) Addressing the person's difficulties in everyday life. This sense of person-centredness focuses on daily living occupations and real-life difficulties, reflecting the person's needs: 3) Addressing the person as an expert: participation and empowerment. This meaning of person-centredness emphasises that disabled persons should be active participants in the rehabilitation process: 4) Showing respect for the person behind the impairment or the disease. The fourth meaning is that disabled persons should be treated with respect and dignity, whatever their impairment or disability may be. The fourth meaning is rather general, but the three previous meanings do apply particularly well to reablement. Above all, the person-centred approach is highlighted in reablement with the question: "What are important occupations in your life now?", inviting the participant to formulate their own goals [45].

Key elements of the intervention

There exists hardly any coherent and consensual understanding of what reablement entails. There is a widespread variation in organisation and content of reablement [49]. All the same, reablement consists of both general and individual features. The general elements are the common components of the intervention all people undertaking reablement receive, for instance multidimensional assessment, skills training in daily occupations, work simplification, assistive technology, environmental adjustments, and strength, balance and endurance exercises. The individual elements are tailored to meet the unique goals of every participant [50]. Due to individualisation of the intervention components to meet each participant's goals, the mix of intervention components varies substantially. In reablement the participants identify their challenges in daily life and play an important role in the definition of their goals. Thereafter, the goals direct the individual tailoring of the intervention. Thus, the defined goals set by the person are the focus of that person's rehabilitation. When using a designated tool for identifying goals, the goals tend to be specific and individualised, compared to traditional domiciliary care where the goals are more generic and often focused on the services' core tasks [51]. Having goals that are perceived as valuable and meaningful by the person, enables motivation that might be a key to the success of reablement [47].

Reablement is a multidisciplinary intervention [52]. However, the composition of the multi-professional healthcare teams varies a lot due to national and local variations in the organisation of healthcare and social care services and supply of health professionals. Often the intervention is developed by a multi-professional team together with the participant, while the delivery of the intervention might be conducted by non-professionals under supervision of allied health workers [52]. Whatever the team composition: a key element for reablement is that the health professionals need to be reorganised from individual care providers into an integrated, coordinated multi-professional team pursuing shared goals [53].

Reablement focuses on changing "the philosophy from one where delivery of care may create dependency, to provision of care, which maximises independence, self-esteem and health-related quality of life, and reduces care needed" [51, page 654]. It deals with helping the participants to do the tasks themselves, rather than the traditional domiciliary care approach of performing domestic tasks on behalf of people and as such creating dependence [39]. Thus, reablement requires an attitudinal change in all care-staff from helping the participant in performing daily occupations (hands-on), to stimulating them do to the occupations themselves, adopting an attitude that promotes self-management (hands-off) [52, 54].

Reablement involves repetitive training and multiple home visits during the rehabilitation period. The quantity of an intervention can be examined by dose (i.e. number of sessions), intensity (i.e. frequency of sessions) and duration of each session

[55]. Some publications emphasise that reablement is an intensive intervention, without specifying the intensity [54, 56, 57]. Hence, it is not known what the typical intensity is. In usual domiciliary care, there is an assumption that the service will continue indefinitely. In contrast, reablement is time-limited and aims to diminish or terminate the need for home-based services [44]. The intervention period is usually of 4-10 weeks' duration.

The arena where reablement takes place is usually the participant's home or local community, hence the term *home-based rehabilitation*. However, reablement has also been reported to take place in rehabilitation institutions [58, 59], nursing homes [60], residential care [61] and intermediate care services [54]. However, such arenas for rehabilitation do not comply with the definition of reablement used in this thesis.

Reablement was designated originally as an intervention for older people. It is predominantly still older people who are the target group [44, 54]. All the same, reablement can be relevant at all ages, not only in late stages of life. However, the target group is predominantly home-dwelling older adults. This group is characterised by being a heterogeneous population with a wide range of diagnoses and functional limitations. Comorbidity is very often the case [53, 62].

The content of the reablement intervention described in the paragraphs above, may qualify reablement to be seen as a complex intervention. A complex intervention is an intervention with a number of interacting components, various behaviours required by those providing or receiving the intervention, number of groups targeted by the intervention, number and variability of outcomes, and degree of flexibility or tailoring of the intervention [63]. Complex interventions are often defined as a black box. We do not know, when the intervention works, why it works, which makes it difficult to replicate [55]. This applies to reablement too [64].

1.3.4 Scandinavian reablement

The description of reablement presented previously is based on publications from USA, United Kingdom, Australia, New Zealand, Canada and Ireland. A similar intervention has been implemented in Sweden, Denmark and Norway. However, there is no single established model for reablement services [54], neither internationally nor within Scandinavia. There are variations between countries and within countries in both cases [65].

During the development of reablement in the lead countries of United Kingdom, USA and Australia from around the year 2000 and onwards, the publications cite each other across countries. Thus, it is evident that the evolution of reablement in the different countries was mutually inspired and stimulated. A similar development has occurred within the three Scandinavian countries. Notably, there are no references to the international reablement literature found in Scandinavia before 2014 [8, 66]. Although influenced by the same cost pressures of a rapidly ageing population, it appears that the evolution of international and Scandinavian reablement has followed two parallel, but separate paths.

The implementation of reablement in Scandinavia started in the municipality of Östersund in 1999 and spread from there to other municipalities in Sweden. Even so, its development in Sweden has been slower and taken a different form from that in the other Scandinavian countries. The development in Östersund, however, inspired Denmark to get started in 2007 [67]. The implementation of reablement in the municipality of Fredericia is well known because of its broad documentation [68-70]. Nowadays, all Danish municipalities have started offering reablement services [71]. As of 2015, Danish municipalities shall by law offer reablement when a citizen applies for home help [72]. Even older persons who already have home help, will be assessed regularly whether or not the compensating help can be terminated or diminished with rehabilitation [73]. Denmark, with its municipality Fredericia as a role model, inspired Norway to get started. Since the first municipalities began implementing reablement in 2012, there has also been a rapid development in Norway [8]. Uniquely for Norway, the implementation of reablement started as a grass-roots movement among devoted healthcare professionals and a few health profession associations, and then spread to administrators and policy-makers, all claiming that reablement was a better quality

intervention for those involved. To date, 178 of 428 Norwegian municipalities (42%) are offering reablement services and the growth continues (personal knowledge).

1.3.5 Previous research

Existing evidence of reablement that is relevant to this thesis is presented in the following sections. Although evidence from research regarding home-based rehabilitation in general might be relevant, the focus here is restricted to reablement research on effectiveness and prediction. Concerning research on reablement, the following four outcomes of relevance to this thesis are explored:

- Independence in activities of daily living
- Physical functioning
- Health-related quality of life
- Factors that determine occupational performance and satisfaction

In the subsequent sections, the existing literature is presented in order to investigate what is known in relation to these outcomes. The literature search complies with Cochrane and colleagues' five criteria for an intervention to be called reablement as described in section 1.3.3 [39]. In addition, the literature search had the following inclusion criteria in compliance with criteria defined by Tessier and colleagues [52]: the participants had to be >65 years on average, the intervention had to be delivered by paid professional (and non-professional) workers as part of home-care services, and the service had to be multidisciplinary in nature, defined in this thesis as provided by at least three professions.

Literature searches have been conducted in Medline, Embase, Amed and Google Scholar. First, literature searches were conducted when planning the studies and writing the PhD protocol. This was performed in 2012 and 2013. Next, literature searches were performed consecutively up to January 2017, when writing the individual papers and the current thesis. Thus, the synopsis includes newer publications than do the included papers.

It may be questioned whether the instruments compared in fact capture the same constructs. In any case, in the Cochrane review on reablement, a metaanalysis was performed between ADL outcomes and COPM outcomes, terming the new outcome 'functional status' [44]. This demonstrates that the constructs are also regarded to be comparable by other authors.

Independence in activities of daily living

As can be seen in Table 1, three systematic reviews and one single study which address this issue were included in the overview. Four single studies and one systematic review were excluded, owing to not being a multidisciplinary intervention with at least three professions [66, 74, 75] and not having professional healthcare workers in the team [64, 65].

The results of the included reviews and studies are inconsistent in terms of whether reablement results in improved independence in ADL or not. Two reviews found some improvement in favour of reablement [44, 76], whereas one review was inconclusive [52]. Notably, the Cochrane review on reablement has included two randomised controlled trials (RCTs), among them the current effectiveness study [44]. There is only a single study that found significant results of improved ADLs in favour of reablement, but this study cannot be given as much weight as the others due to its inferior design (a clinical controlled trial) [77]. Hence, there are still not many studies conducted which address this issue. The exclusion of one review and four studies due to shortcomings in the skill mix in the reablement teams, indicates that there is a lack of agreement concerning skills and competence needed in such teams. In Legg's systematic review for instance, studies were excluded if the intervention was delivered by professional staff [64]. Not surprisingly, this review found no studies to include.

Table 1: Systematic reviews and studies which examined the effects of reablement on

Study, sample and variable tested	Design	Instrument used	Conclusion
Cochrane 2016 [44], two studies included, N=249, measuring functional status (PADL, IADL and COPM-P)	Cochrane systematic review	-Modified Barthel Index -Lawton and Brody Scale -COPM	Reablement may be more effective than usual care in improving function in ADL at 9 to 12 months
Tessier 2016 [52], 10 included studies, of which four dealt with PADL and IADL, N= 2437	Systematic review	-ADL subscale of interRAI-HC- Home Care- Modified Barthel Index -Lawton and Brody Scale	Contradicting results on whether reablement leads to better improvement in ADL than usual care.
Whitehead 2015 [76], 13 included studies of which five dealt with PADL, N= 3533	Systematic review	-Modified Barthel Index -Self-care ADL score	There is limited evidence that reablement can reduce participants' dependency with self-care activities, the content of evaluated interventions varies greatly
Langeland 2016 [77], N= 833, 78 years, COPM-P and COPM-S	Multi- center CCT	-COPM	Significant differences between groups in favour of reablement on the three follow ups for COPM-P. Significant differences between groups in favour of reablement at 10-week and 6-month follow ups, but not at 12-month follow up for COPM-S

occupational performance (or activities of daily living).

Notes: ADL = Activities of Daily Living; CCT = Clinical Controlled Trial; COPM-P = COPM, measuring occupational performance; COPM-S = COPM measuring satisfaction with performance; IADL = Instrumental Activities of Daily Living; PADL = Personal Activities of Daily Living.

Physical functioning

Six single studies that address this issue were included in the overview (Table 2). However, six studies were excluded, owing to not being a multidisciplinary intervention with at least three professions [74, 78, 79], not having professional health workers in the team [65, 75], or not meeting the criteria for being a reablement intervention [80].

Although there is some inconsistency concerning whether reablement results in improved physical function, the majority of the studies favours reablement. The physical components examined in the trials are predominantly ambulation, balance, and rising from a chair. The function of the upper-extremities is not tested. The two studies by Lewin and colleagues [41, 81], which both use the Timed up and Go (TUG)

test, are conflicting. However, the studies by Langeland [77] and Parsons [46], which both use the Short Physical Performance Battery (SPPB), are more consistent in favour of reablement. Nonetheless, firm conclusions whether reablement improves physical function, can hardly be drawn.

Study, country, sample and variable tested	Design	Instrument used	Conclusion
Burton 2013 [81], Australia, N=80, 79 years, physical function	RCT	Various physical activity tests	A lifestyle exercise program was slightly more effective than the structured exercise program being used as part of reablement at the 8-week follow up
Levin 2013 [41], Australia, N=750, 82 years, physical function	RCT	TUG	No significant differences between the groups at any of the follow ups
Parsons 2012a [46], New Zealand, N=205, 79 years, physical function	RCT	SPPB	Significant differences in favour of reablement for 4-meter walking and total score at follow up, but not for chair stand and balance
Levin 2010 [42], Australia, N=200, 80 years, physical function	RCT	TUG	Significant differences between groups in physical function in favour of reablement at 3-month and 12-month follow up
Langeland 2016 [77], Norway, N= 833, 78 years, physical function	Multi- centre CCT	SPPB	Significant differences in favour of reablement for balance, four-meter walking, chair stand and total score at 10-week and 6-month follow up, but only for chair stand and total score at 12- month follow up
Tinetti 2002 [62], USA, N=1382, 79 years, mobility	Controlled before and after study, matched pairs	No validated instrument used, only questions raised	Significant differences between groups in mobility in favour of reablement at follow up

Table 2: Studies that examined the effects of reablement on physical functioning.

Notes: ADL= Activities of Daily Living; CCT = Clinical Controlled Trial; RCT = Randomised Controlled Trial; SPPB = Short Physical Performance Battery; TUG = Timed Up and Go.

Health-related quality of life

Only one review and four single studies were detected that address this topic (Table 3), of which one study was excluded owing to results reported only for informal caregivers, not participants [59]. Although there is a tendency in favour of reablement, there is inconsistency whether reablement leads to better results. Consequently, firm conclusions whether reablement improves health-related quality of life, cannot be drawn.

Table 3: Sy	stematic	reviews	and	studies	that	examined	the	effects	of	reablement	on
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1	2		
Study, country, sample and variable tested	Design	Instrument used	Conclusion
Cochrane 2016 [44], Ireland, two studies included, N=249, quality of life	Cochrane systematic review	-AAQ -COOP-Wonka	The findings are uncertain as to whether reablement affects quality of life
Parsons 2012b [82], New Zealand, N=205, 79 years	Cluster RCT	SF-36	Significant improvement in health-related quality of life in favour of reablement for SF-36 overall, SF-36 physical and SF-36 mental at follow up
Glendinning 2010 [83], United Kingdom, N=1015, 80 years	ССТ	-Self-perceived health (five point scale) -Perceived quality of life (seven point scale) -EQ-5D-3L	No significant differences between the groups at 12- month follow up on self-perceived health, but significant difference in favour of reablement in perceived quality of life. All five dimensions of EQ- 5D (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and health today were significant in favour of reablement at 12- month follow up
Langeland 2016 [77], Norway, N= 833, 78 years	Multi- center CCT	EQ-5D-5L	Significant improvement in favour of reablement for the dimensions mobility, self-care and health today at 10-week follow up, for mobility, self-care and usual activities at 6-month follow up, and for self- care at 12-month follow up

health-related quality of life.

Notes: AAQ= Assessment of Quality of Life Scale; CCT = Clinical Controlled Trial; EQ-5D-3L = European Quality of Life Scale, five dimensions, three levels; EQ-5D-5L = European Quality of Life Scale, five dimensions, five levels; RCT = Randomised Controlled Trial; SF-36 = Short Form-36 questionnaire measuring health-related quality of life.

Factors that determine occupational performance and satisfaction

This issue may comprise which components of the intervention are most beneficial and who receives the greatest benefit. No studies examine this issue directly. One study was excluded owing to not having a multidisciplinary intervention involving three professions [66]. Hence only one study can shed some light on this. This study has examined whether some characteristics of the municipality are predictors of reablement. In the multicenter clinical controlled trial by Langeland and colleagues neither the municipal organisational model, nor the municipal differences in duration of the reablement period or the intensity of service provided, were able to predict better COPM outcomes [77].

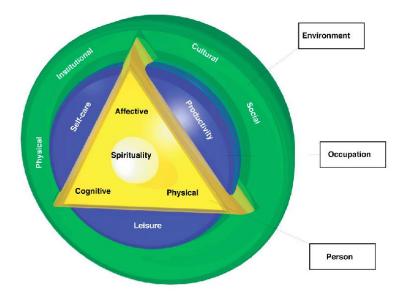
Nonetheless, in 2009, Ryburn and colleagues stated that "questions remain about which components are most beneficial, which clients are likely to receive the greatest benefit, and the appropriate intensity and duration of such interventions" [57, page 1]. There is still limited knowledge concerning how the intervention should be configured, the optimal timing and intensity [50, 76]. Even today, there is scarce evidence on which elements are vital in determining the effectiveness and how the effectiveness may vary depending on the characteristics of the participants [44, 65]. Consequently, there is a lack of knowledge concerning predictors of better outcomes in reablement.

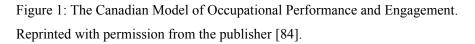
1.4 The Canadian Occupational Performance Measure (COPM)

1.4.1 The Canadian Model of Occupational Performance and Engagement (CMOP-E)

The Canadian Occupational Performance Measure (COPM) is conceptually based on the Canadian Model of Occupational Performance and Engagement (CMOP-E). The model was developed by the Canadian Association of Occupational Therapists (CAOT). The CMOP-E was originally published in 1991 and has been updated several times since then. In the 2007 revision, the concept of engagement (E) was added to the model. The CMOP-E is a graphic presentation of the Canadian perspective of occupational performance. Within occupational therapy, the model is regarded as one of the major models of occupation in the past 25 years [84].

The CMOP-E provides a three-dimensional illustration of the dynamic relationship between person, occupation and environment (see Figure 1). The *person*, depicted as a triangle in the middle of the model, comprises three performance components: affective, cognitive and physical, with spirituality at the core. The person is surrounded by the *environment* to imply that each person lives within their unique context, being cultural, institutional, physical and social, which enables occupational possibilities. *Occupation* is illustrated as the link that connects person and environment, signifying that persons act on the environment by means of occupation. Occupation is classified in three categories; self-care, productivity and leisure [84]. The amendment of *engagement* in the latest revision, signifies that occupational therapy focuses on both performance and engagement in activities. Occupational performance is understood both as the individuals' ability to perform occupations, and their satisfaction with that performance [85].





In summary, the COPM-E model emphasises the occupational perspective of occupational therapy, namely that human occupation occurs in a context as a result of the dynamic interaction between person, occupation and environment. In reablement, the participants with functional decline purports to improve their performance in occupations in an interaction with their environment. The CMOP-E provides a theoretical model that explains these relationships.

The term 'occupation'

Occupation is a central concept within both CMOP-E and COPM. It refers not only to work, but to all kinds of human doing. Occupational therapy literature differentiates between *occupation* and *activity*. Occupation is a broader and more superior concept

where value and meaning are emphasised, whereas activity is merely performing a set of tasks [84]. A well-known definition of occupation within the occupational therapy literature is the following:

"Occupation refers to groups of activities and tasks of everyday life, named, organised and given value and meaning by individuals and culture. Occupation is everything people do to occupy themselves, including looking after themselves (self-care), enjoying life (leisure) and contributing to the social and economic fabric of their communities (productivity)" [CAOT 1997, page 34, cited in 84].

Occupational performance is "the actual execution of carrying out an occupation" [84, page 26]. The definition of occupation above complies with the term used in both CMOP-E and COPM. Therefore, the term *occupation* is preferably used in this dissertation, although in some words and phrases the terms *activity* or *task* are so embedded that using them is unavoidable.

1.4.2 The COPM instrument

The COPM is an evidence-based instrument designed to encompass a person's selfperceived performance in everyday living over time. Initially published in 1991 [86], the instrument is currently used in over 40 countries and translated into more than 35 languages [87]. The COPM was designed as a person-centred tool to enable individuals to identify and prioritise everyday issues that limit or influence their performance in daily life. Conceptually grounded in the CMOP-E, the COPM focuses on occupational performance and satisfaction with performance in self-care, leisure and productivity. For the sake of brevity and variation, the two outcomes of occupational performance and satisfaction with performance, are shortened to COPM-P and COPM-S respectively. The COPM provides a structure for formulating rehabilitation goals identified by the participant in collaboration with the professional.

The COPM was originally developed to be used by occupational therapists in assessment of occupational performance for a wide range of health conditions at any developmental stage [86]. The instrument was developed to identify and prioritise

patient-specific problems in functioning and evaluate changes in these problems. Hence, the advantages of the COPM are that it is patient-specific, individualised, generic, for all age groups, and may be used both in defining goals, planning the intervention and evaluating changes in occupational performance over time. The COPM has been revised several times. The fifth, and so far the newest, revision from 2015 is as in earlier revisions, translated into Norwegian [85]. The Norwegian version is tested for psychometric properties in people with rheumatic diseases with good results [88].

The three categories that signify occupation, comprise three occupational categories each. *Self-care* consists of the occupations of personal care, functional mobility and community management: *productivity* comprises the three occupations of paid/unpaid work, household arrangement and play/school, whereas the category *leisure* consists of the occupations of quiet recreation, active recreation and socialisation.

1.4.3 COPM used in reablement

The COPM is widely used in reablement in Scandinavia, and in particular in Norway, despite a lack of evidence of the psychometric properties in a home-dwelling older population. An educated guess is that >80% of Norwegian municipalities, that have implemented reablement, use COPM as their main instrument for goal determination and evaluation. Even if the instrument was developed for use by occupational therapists, it is, in the context of reablement, used on a multidisciplinary basis. This distinguishes the COPM used in reablement compared to use in other kinds of rehabilitation practices. Kjeken has outlined the reasons for the popularity of the COPM within Norwegian reablement [89]. In Norway reablement starts with the question: "What are important occupations in your life now? Reablement is characterised by a goal-oriented focus on everyday occupations that matter to the individual. COPM encompasses this fundamental feature of reablement [89]. Hence, the use of COPM as a central instrument in reablement, reinforces the pivotal place empowerment and person-centredness have within reablement. Furthermore, the primary goal of reablement is not to improve physical function, nor health-related quality of life per se, but to improve functioning in everyday occupations perceived as important by the person in question [38]. Since improved functional ability is the main purpose of reablement, the COPM instrument is particularly well suited.

1.4.4 Psychometric and measurement aspects of the COPM

Instruments that measure problems experienced in occupations may be either performance tests with fixed items, or subjective assessment tools. The COPM provides patient-specific information that could not have been obtained with standardised measures with predefined items [90]. Notably, being a patient-specific instrument the COPM captures a wide variety of occupations. As a result, the 'noise' related to fixed items in standardised instruments experienced as irrelevant by participants is reduced [91].

The COPM interview and scoring process combines qualitative and quantitative methodologies respectively. Hence, the assessment also needs to be evaluated according to qualitative aspects of validity and reliability. *Validity* as a psychometric property is the degree to which an instrument truly measures the construct it intends to measure [92]. Whereas validity in a qualitative interview "pertains to the trustworthiness and the quality of the interviewing, which should include a careful questioning to the meaning of what is said and a continual check of the information obtained as a validation in situ" [93, page 284]. According to Kjeken, there should be a logical link between the conceptual basis of the instrument, the scope of the interview should be performed in an open and inclusive atmosphere. During the interview, there should be a continuous checking of the interview depends to a large degree on the competence of the interviewer [94].

Reliability is defined as the extent to which scores for participants who have not changed are the same for repeated measurement under several conditions [92]. Various types of reliability use different sets of items for the same patient-reported outcomes (internal consistency) over time (test-retest reliability) by different persons on the same

occasions (inter-rater reliability) or by the same person on different occasions (intrarater reliability) [95]. Inter-rater reliability is perceived to be irrelevant with regard to COPM, since it is always the participant who performs the scoring. Moreover, in a patient-specific instrument such as the COPM, where the scores are based on a qualitative and semi-structured interview, the intra-rater reliability will vary [85]. In addition, the information gained during the interview will differ, depending on the skills and knowledge of the interviewer, variability in the participant's condition and the environmental influence in which the interview is performed. Thus, the reliability of the interview is also to a large degree dependent on the competence of the interviewer [94].

1.4.5 Previous psychometric testing of the COPM

Several overviews and reviews of the psychometric properties and feasibility of the COPM have been published [85, 91, 94, 96, 97]. However, none of the reviews are restricted to a population of older persons. Hence, the following overview is limited to research testing psychometric properties of single studies targeting a population with a mean age of more than 60 years (Table 4). The literature search was not restricted to a home-dwelling setting, nor to studies published before the autumn of 2013 when the work with this PhD project began. Data bases searched have been Medline, Embase, Amed and Google Scholar. The literature search was performed consecutively up to January 2017.

Table 4 shows previous testing of reliability, validity, interpretability, responsiveness and feasibility of the COPM in this age group. According to the COSMIN guidelines, *interpretability* is the degree to which one can assign qualitative meaning to an instrument's quantitative scores or change in scores [92]. Furthermore, *responsiveness* is defined as the ability of the instrument to detect change over time in the construct measured [92]. Even if *feasibility* is not a psychometric property on its own, it is included in the table due to relevance and completeness. Feasibility in this respect refers to the problems with rating and scoring, time spent on completion of the COPM data and patient burden.

Ten studies were detected covering various aspects of psychometric properties of COPM when used in an older population. Most of the studies were conducted in a hospital setting on a diagnosis-specific target group.

Two studies have examined the *reliability* of COPM confirming the test-retest reliability of COPM. Furthermore, six studies have examined the various forms of *validity* of the COPM. The conclusion is that content validity, criterion validity, convergent validity and discriminant validity are confirmed for their respective diagnosis-specific target groups. However, there are no studies examining validity in a heterogeneous, community-dwelling, older population.

Notably, no studies have examined the *interpretability* of COPM. It was initially with the introduction of the COSMIN guidelines in 2010 that interpretability was established as a psychometric property on its own. The majority of the included studies were published before 2010. However, several of the studies used the established cut-off of two points from the COPM manual [85] between pre-assessment and post-assessment as their reference to measure improvement [98, 99].

Two studies have investigated *responsiveness* and concluded that the COPM is a highly responsive instrument. The study of Wressle and colleagues [99] has a target group that is very similar to the target group of this PhD project, making these results highly relevant, although not directly comparable owing to a different methodology. The results show that 73% of the participants had a change score of >2.0 points, which is interpreted as representing high responsiveness to change.

Table 4: Single studies testin	g the psychometric	properties of the COPM used in	a population of >60 years.

Population Reliability	Setting and country	Conclusions
Cup 2003 [100]. Participants with stroke (N=26), mean age 68 years	Rehabilitation during hospital stay and followed up at home, in the Netherlands	Test-retest reliability: Good reliability for COPM-P and COPM-S scores (r=0.89, 088)
Sewell 2001 [101]. Participants with chronic obstructive pulmonary disease (N=15, mean age 67.1 years	Outpatient-based rehabilitation programme in England	Test-retest reliability: Good reliability for COPM-P and COPM-S scores based on ICC (r=0.92, 090)
Validity		
Chan 1997 [102]. Participants with orthopaedic diseases and stroke (N=39), mean age 64.5 years	Rehabilitation in hospital in Canada	Content validity: Results suggest that the content reflects experts' views on participants' occupational performance issues. Criterion validity: Was confirmed between COPM and FIM, and between COPM and SPSQ. Convergent validity and discriminant validity: Was confirmed between COPM and FIM, but not between COPM and SPSQ, and COPM and KBADL
Cup 2003 [100]. Participants with stroke (N=26), mean age 68 years Edwards 2007 [103]. Participants with his feature (N=50), mean age 80.8	Rehabilitation during hospital stay and followed up at home in the Netherlands Rehabilitation in hospital in	Discriminant validity: The results confirm this type of validity as the COPM was able to better identify other occupations than the comparison instrument. Convergent validity: The results suggest that
hip fracture (N=50), mean age 80.8 years	Canada	COPM is a valid instrument, since the compared instruments correlate with COPM
Kjeken 2004 [88]. Participants with hand osteoarthritis (N=79), mean age 63.2 years	Occupational therapy intervention in a hospital in Norway	Content validity and criterion validity: The results confirm the validity of the Norwegian version of COPM
Mc Nulty 2008 [104]. Participants with depression (N=10), mean age 75.0, were matched with participants without depression $(N=10)$ mean age 75.0 user	Community-living persons in USA	Persons with depression identified more occupations than persons without depression. The authors imply that this indicates validity
depression (N=10) mean age 75.9 year. Stuber 2010 [105]. Participants with orthopaedic, cardiovascular, respiratory and other diagnoses (N=30), mean age 74 years	Rehabilitation in hospital in USA	Convergent validity: The results indicate that COPM is a valid instrument, since the compared instruments correlate significantly with COPM
Responsiveness Kjeken 2004 [88]. Participants with	Occupational therapy	The results indicate that the Norwegian
Wressle 1999 [99]. Participants with hand osteoarthritis (N=79), mean age 63.2 years Wressle 1999 [99]. Participants with neurologic, orthopaedic and other diagnoses (N=108), median age 78 vears	intervention in a hospital in Norway Institution-based and home- based rehabilitation in Sweden	version of COPM is highly responsive to change The results indicate that the Swedish version of COPM is highly responsive to change
Interpretability		
No studies identified		
Feasibility	0 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	
Enemark Larsen 2012 [98]. Participants with various diagnoses, (N=185), median age 82 years	Community-based geriatric rehabilitation in Denmark	The COPM is useful as an admission and outcomes measurement of older adults living at home
Kjeken 2004 [88]. Participants with hand osteoarthritis (N=79), mean age 63.2 years Stuber 2010 [105]. Participants with orthopaedic, cardiovascular, respiratory and other diagnoses (N=30), mean age 74 years	Occupational therapy intervention in hospital in Norway Rehabilitation in hospital in USA	Median time spent was 30 minutes. The questions were easy to understand, but 37% of the participants had scoring problems Mean time spent on assessment was 18.8 minutes

Notes: COPM-P = COPM, measuring occupational performance; COPM-S = COPM measuring satisfaction with performance; FIM = Functional Independence Scale; ICC = Intraclass correlation coefficient; KBADL: Klein-Bell ADL Scale; SPSQ = Satisfaction with Performance Scale Questionnaire.

Three studies were found concerning *feasibility*, which indicates that the COPM is a manageable instrument. In particular, the study by Enemark Larsen and Carlsson is relevant in this respect [98]. This is also the only study where the COPM is used on an interdisciplinary basis by occupational therapists and physiotherapists. No significant differences were found in the occupations the two professions identified in the assessments nor in the results obtained. However, 8.1% of the participants were not able to identify occupations with which they struggled. As a result, the authors state that aspects of education and administration must be considered before the instrument can be successfully implemented on a multidisciplinary basis [98].

In summary, no systematic reviews have examined the psychometric properties of the COPM when used in a heterogeneous older population. The populations tested in the studies included in Table 4 were predominantly older people in their sixties and early seventies. Only a few studies were detected examining people of advanced ages. Only one study explored the COPM used on an inter-professional basis.

1.5 Summary of introduction

In this chapter, relevant knowledge on ageing, rehabilitation, reablement and COPM have been presented. Although hardly any formal theory on reablement existed a priori, some conceptual underpinnings have been identified, such as the framework for action on ageing and health, and the biopsychosocial model of ICF, which both provide a holistic perspective on disability relevant to rehabilitation [6, 23]. The theory of optimising capacity provides a post hoc explanation on how various strategies are used to optimise the function of the older adults making them able to age in place [40]. Reablement is conceptually embedded in a person-centred perspective. An individually tailored intervention which focuses on daily living occupations and real-life difficulties, highlighting the person's needs and active participation, are essential elements of that perspective [48]. In reablement, the participant with functional decline aims to enhance performance in occupations in interaction with the environment. The CMOP-E model is a holistic model which explains that human occupation occurs in a

context as a result of the dynamic relationship between these factors (person, occupation and environment) [84].

The evidence found when exploring the literature on reablement is sparse and conflicting. Being a relatively new intervention, with research not emerging beyond a few countries, reablement is still rather unchartered territory that calls for more research [44, 54]. In Norway, reablement has been implemented in nearly half of all municipalities without much evidence of effectiveness and understanding of the factors that predict better outcomes. Therefore, there is an urgent need for more research regarding effectiveness and what constitutes best practice. The effectiveness study and the prediction study in this thesis were an attempt to fill this knowledge gap. Likewise, based on the current literature, it is reasonable to conclude that there is a lack of research when it comes to examining psychometric properties of the COPM in a heterogeneous. older community-dwelling population when used on а multidisciplinary basis. Therefore, in the psychometric study we wanted to test the psychometric properties of the COPM used in this target group by various professions.

2. Aims of the study

The overall aim of this PhD project was to investigate the psychometric properties of the COPM used on an inter-professional basis for home-dwelling older adults, the predictors of reablement, and the effectiveness of reablement.

The specific objectives were as follows:

Paper 1: The objective was to investigate the content validity, construct validity, responsiveness, interpretability, and feasibility of the COPM when used by different health professions in delivering reablement for home-dwelling older adults.

Paper 2: The objective was to determine potential factors that predict occupational performance and satisfaction with that performance at the 10-week follow up.

Paper 3a: The objective was to present the study protocol for the randomised controlled trial (Paper 3b) and the cost-effectiveness study following the randomised controlled trial.

Paper 3b: The objective was to investigate whether reablement is more effective with regard to self-perceived occupational performance and satisfaction with that performance, physical functioning and health-related quality of life, compared to usual care.

3. Materials and methods

3.1.1 Setting, study designs and participants

Although this thesis contains four papers, it comprises only three empirical studies, since Paper 3a is a study protocol. The three studies derive from two projects. The first project is a large multicenter study on reablement in Norway, of which the psychometric study and the prediction study are a small part. The second project deals with research on reablement in the municipality of Voss in Western Norway (the effectiveness study). Table 5 provides an overview of three studies. In short, the nearly 800 participants included in this PhD project are home-dwelling people of approximately 79 years of age, predominantly female and living alone, with functional decline and several health conditions.

The psychometric study and the prediction study

The samples in these studies derived from a nationwide, multicenter clinical controlled trial commissioned by the Norwegian Directorate of Health, as described elsewhere [77, 106]. The whole sample consisted of 833 participants living in 43 municipalities in Norway. The first 225 participants aged 65 years and older enrolled into the intervention group in the multicenter study and who had data collected at baseline and at 10-week follow up, were included in the psychometric study. People who had dropped out and people not being data registered at 10-week follow up by the time data analysis started, were not included. In the prediction study, we included all persons in the intervention group. As a result, this sample consisted of 712 participants. The participants lived in 32 and 34 of the 43 possible municipalities in the psychometric study and prediction study respectively, and 16 out of 19 counties stretching out from the south to the north of Norway were represented. The multicenter study (comprising the two studies) is registered in ClinicalTrials.gov with identifier NCT02273934.

The effectiveness study

This study was conducted in Voss, a rural municipality in Western Norway with approximately 14,500 inhabitants. The effectiveness study is registered in ClinicalTrials.gov with identifier NCT02043262.

The effectiveness study was a part of a larger research study on reablement in Voss, which has resulted in additional publications [107-110].

	The psychometric study,	The prediction study,	The effectiveness study,
	Paper 1	Paper 2	Paper 3a and 3b
Design	Prospective cohort study, 10 weeks follow up	Prospective cohort study, 10 weeks follow up	RCT with two arms, 9 months follow up
Participants	Home-dwelling older adults; N=225; mean age (SD) 80.8 (6.70); female gender 162 (72%); living alone 171 (76%); health conditions 3.82 (2.02), 1- 10	Home-dwelling older adults who have received reablement; N=712; mean age (SD) 78.18 (11.16); female gender 487 (69%); living alone 501 (71%); health conditions 3.27 (2.02), 1-11	Home-dwelling older adults; $N=61$; mean age (SD) 78.98 (10.09); female gender 42 (68%); living alone 47 (77%); health conditions 3.00 (1.38), 1-8
Baseline COPM scores	СОРМ-Р: 3.52 (1.70)	СОРМ-Р: 3.39 (1.57)	COPM-P: 2.70 (1.47)
	COPM-S: 3.38 (1.70)	COPM-S: 3.27 (1.78)	COPM-S: 2.92 (1.79)
Instruments used	COPM, SPPB, EQ-5D, SOC-13, MHC-SF	COPM, SPPB, EQ-5D	COPM, TUG, Jamar dynamometer, COOP/Wonka
Analyses	Qualitative interpretation, descriptive statistics, correlation tests, independent samples t- tests, chi-square tests, exact tests, one-way analysis of variance (F- tests)	Univariate and multiple linear regression	Independent samples t- tests, chi-square tests, exact tests for baseline differences, mixed effects models for treatment effects

Table 5: Overview of the PhD project studies organised by design, selected participant characteristics, functional level, instruments used and analyses.

Notes: COPM = Canadian Occupational Performance Measure; COPM-P = COPM, measuring occupational performance; COPM-S = COPM, measuring satisfaction with performance; EQ-5D-5L = European Quality of Life Scale, five dimensions, five levels; MHC-SF = Mental Health Continuum - Short Form, measuring positive mental health; RCT= Randomised Controlled Trial; SD= Standard Deviation; SOC-13 = Sense of Coherence questionnaire, 13 items; SPPB = Short Physical Performance Battery; TUG = Timed Up and Go. The study protocol (Paper 3a) is included in the thesis to provide completeness and convenience for readers. Paper 3a and Paper 3b should be seen as a whole covering the effectiveness study. Paper 3a contains more specific information about the reablement intervention, procedures and outcome measures than Paper 3b. The study protocol presents two studies: an RCT and a cost-effectiveness study alongside the RCT. The cost-effectiveness study is not included in this thesis, but the results are available elsewhere [108]. Since the effectiveness study in Voss was started two years prior to the psychometric study and the prediction study, Papers 3a and 3b were published first.

3.1.2 Procedures

Eligibility criteria

The inclusion and exclusion criteria were approximately the same in the three studies. People were eligible if they were home-dwelling, over 18 years of age (except for the psychometric study, where only persons aged 65 years and older were included), understood Norwegian and had experienced functional decline. People were excluded if they were in need of institution-based rehabilitation or nursing home placement, or if they were terminally ill or cognitively reduced.

The reablement intervention

A total of 35 different municipalities have participated in the three studies on which this PhD project is based. Naturally, the interventions delivered have not been identical. They vary in skill mix in the multidisciplinary team, dose, intensity and duration of rehabilitation and intervention components delivered. However, all municipalities comply with the criteria for reablement defined by Cochrane and colleagues presented in section 1.3.3 [39].

The reablement interventions delivered in the three studies consisted of both general and individual features. A rehabilitation period of 4-12 weeks was among the general features. The intervention period lasted on average 5.7 weeks in the psychometric study and the prediction study, and 10 weeks in the effectiveness study. All 35 municipalities have used the COPM as their primary tool for goal determination and evaluation. As part of the baseline assessments, the professionals used the COPM interview to pin-

point problems in occupations perceived as important by the participant. Subsequently, they used this information to develop the rehabilitation plan. The COPM assessment and rehabilitation plan were conducted by the occupational therapist, physiotherapist, or nurse in the psychometric study and prediction study, and by individuals from the first two of these professions in the effectiveness study. All three professionals supervised the other healthcare providers (auxiliary nurses and assistants), in how to stimulate and assist the participant in the daily training, which on average was involved by 4-5 professionals, one-on-one. The emphasis was on stimulating the participants to do the daily occupations themselves, rather than letting others do it for them. The most important individual feature was that the intervention was exclusively tailored to each participant's unique, prioritised occupations. As a result, the way in which the intervention components were mixed varied substantially. Despite this, the intervention components used were more or less the same. They were predominantly practice in daily occupations relevant inside the home, in daily occupations relevant outside the home, in task-oriented exercise programs, and in adaptations to the environment included assistive technology [77].

The control intervention

Usual care was chosen as the comparator in the effectiveness study, as this is the conventional treatment offered to homebound persons in most municipalities in Norway. For the majority of the participants, usual care meant receiving the compensating help they applied for, in terms of personal or practical assistance, safety alarm, meals on wheels, or assistive technology. However, a few participants received rehabilitation efforts provided by a physiotherapist and/or an occupational therapist.

3.1.3 Methods

The psychometric study

We followed the COSMIN guidelines and recommendations for evaluating methodological quality [95, 111]. The COSMIN guidelines are based on international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes [92]. The psychometric properties examined

were content validity, construct validity, responsiveness, interpretability and feasibility.

Content validity was defined as the degree to which the content of an instrument is an adequate reflection of the construct measured [111]. The constructs in question were occupational performance and satisfaction with performance. Content validity was explored by answering four relevant questions [95, 111]: 1) Do all occupational categories in the COPM refer to relevant aspects of the construct? 2) Are all occupational categories relevant for the study population, for example with regard to gender and age? 3) Are all occupational categories relevant for the purpose of the instrument? and 4) Do all occupational categories together comprehensively reflect the construct?

Construct validity was defined as the degree to which the scores were consistent with hypotheses stating that the instrument in question validly measures the construct to be measured [111]. We developed hypotheses comprising all comparative instruments and both the COPM-P and COPM-S outcomes.

Responsiveness was defined as the ability of the instrument to detect change over time in the construct measured [92]. We based evaluation of responsiveness on testing a priori hypotheses concerning mean differences of change scores for COPM-P and COPM-S compared with various global rating scale responses. Evaluation of responsiveness was also based on testing predefined hypotheses for levels of correlation for change values, that is differences between the 10-week follow up and the baseline scores between the COPM-P scores and some of the scores from the comparative instruments.

Interpretability is the degree to which one can assign qualitative meaning to an instrument's quantitative scores or change in scores [92]. The important aspect was to determine the size of the *minimal important change* (MIC), which is defined as the smallest change in score which individual participants perceive as important [95]. An anchor-based approach to determine the MIC was used. The five-point global rating

scale was chosen as a gold standard to obtain the participants` impression of change in coping with their daily occupations at 10-week follow up.

Feasibility in our study referred to whether participants were able to answer the questions in the instrument and it was evaluated by exploring response rate, time spent on completion of the COPM data collection, and required clinical expertise. We recorded the response rate and calculated median time spent on the COPM assessment at baseline and follow up. In addition, we recorded the various health professionals' experience and competence conducting the COPM assessment.

The prediction study

As the psychometric study, the effectiveness study and recent research had shown that occupational performance (COPM-P) and satisfaction with that performance (COPM-S) are relevant outcomes in reablement [77, 108], the scores at the 10-week follow up of these outcomes were chosen as dependent variables in the prediction study.

The effectiveness study

When planning the intervention, the work was guided by good clinical research practice (GCP) recommendations inspired from the WHO [112].

We performed a parallel-group randomised controlled superiority trial in which all participants were assessed at baseline, and after 3 and 9 months. The study complies with the CONSORT statement for transparent reporting [113]. The randomisation with allocation ratio of 1:1 using computer-generated an а permuted block randomisation sequence, with randomly selected block sizes of lengths 2 and 4, was performed by a biostatistician not involved in the assignment of participants to groups. We concealed the allocation sequence in sequentially numbered, opaque, sealed envelopes. The allocation list was kept in a safe deposit box in a central office in the municipality. Neither health-care providers enrolling participants nor research assistants had influence on group allocation. The research assistants performed the baseline assessments in the participant's home before randomisation. We advised the participants not to uncover their group allocation to the research assistants during follow up assessments. We recorded the success of the research assistants' blinding. Researchers conducting data entry and data analysis were blinded to group allocation.

3.1.4 Data collection

We used the same questionnaire in the psychometric study and prediction study, which consisted of sociodemographic and health condition questions, questions concerning use of the COPM, municipality-specific questions, in addition to the instruments used. However, the data that were actually used in each study vary. In both studies, we used data from baseline and at the 10-week follow up.

In the effectiveness study, we collected socio-demographic characteristics and data on health conditions. In addition, we used four instruments and these data were collected at baseline and again at the 3-month and 9-month follow up. Moreover, co-interventions were registered for hospital admissions, institution-based rehabilitation, day centre placement, and outpatient treatment at both follow ups. Work hours allocated to home-based services and data on distribution of health-care professionals were collected daily during the first 3 months.

All the instruments used are presented below. Table 5 (section 3.1.1) provides an overview of the instruments used in each study.

Canadian Occupational Performance Measure (COPM)

The COPM instrument has a dual purpose: it is both an instrument for goal determination and an instrument for evaluation of occupational performance and satisfaction with performance. The instrument and the manual were bought through the Norwegian distributor and could therefore be used in this research. In section 1.4, the COPM and its psychometric properties are outlined thoroughly (see Table 4).

Short Physical Performance Battery (SPPB)

In the psychometric study and in the prediction study, we measured physical functioning by using SPPB. The SPPB is a test for mobility and aims at identifying people at risk of functional decline and is recommended as a screening test in primary care [114, 115]. The test is not copyrighted and free to use. The test includes a balance

test, a four-meter walking test, and a chair stand test. In each test item, the time used is registered in seconds and converted into points (0-4), giving a total score between zero and 12 points. An improvement of one point in the total score, is regarded as a clinically important improvement. Based on the four-meter walking test, the preferred walking speed (PWS) was calculated in the prediction study. A systematic review, using studies where community-dwelling older adults were included, concluded that the SPPB has good validity, reliability and responsiveness [116].

European Quality of Life Scale (EQ-5D-5L)

In the psychometric study and in the prediction study, we also used EQ-5D-5L, which measures health-related quality of life [117, 118]. Permission to use this instrument was granted from Euroqol. The instrument consists of two parts, a questionnaire and a visual analogue scale (VAS). The questionnaire has five domains, (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), with five levels (no problems to extreme problems). The responses are scored on a five-point ordinal scale from 1 to 5, where a score of 1 is best. Hence, a decrease in score represents an improvement. The health today VAS score gives an indication of how the participants assess their own health on a 0 to 100 scale, with 100 being excellent health. A structured review of the psychometric properties of the EQ-5D concluded that there is good evidence for reliability, validity and responsiveness among older adults [119].

The Sense of Coherence Questionnaire (SOC-13)

We measured coping by using the SOC-13 in the psychometric study, which is an instrument developed by Antonovsky and available in his 1987 book [120]. The self-reported questionnaire contains 13 items related to comprehensibility (five items), manageability (four items), and meaning (four items). The range of the scale is from 1 to 7, where 7 is best. The scores range from 13 to 91 points, where higher scores indicate a strong sense of coherence. In a systematic review of 127 studies with samples of various diagnoses and age groups, the SOC scale was found to be a reliable, valid and cross-culturally applicable instrument measuring how people manage stress and stay well [121].

Mental Health Continuum - Short Form (MHC-SF)

The MHC-SF measures self-perceived positive mental health and was used in the psychometric study. The scale is not copyrighted and is free to use. The instrument measures three dimensions of the positive mental health concept: emotional well-being, psychological well-being and social well-being [122]. Each of the 14 items is scored by rating the frequency of various feelings during the past month on a six-point scale from never (0) to every day (5). The scores range from 0-70 points, where higher scores imply higher levels of positive mental health. In a study with a large sample of people aged 18-87 years, validity and reliability have been shown to be good [123].

Timed Up and Go (TUG)

We measured functional mobility using the TUG test in the effectiveness study, which is an observer-based instrument originally developed as a short test of basic mobility skills in frail community-dwelling older people [124]. The test is free to use. The task is to rise from a chair, walk three meters, turn around, walk back and sit down again. Normative values for community-dwelling older adults with 1.8 medical diagnoses aged 70-79 years is 9 seconds for both men and women [125]. The cut-off value for independent transfer in community-dwelling older adults with a variety of medical conditions is <20 seconds. Test-retest reliability [125, 126] and intra-rater reliability [124] in community-dwelling elderly people was found to be excellent and moderate, respectively. Criterion validity and construct validity have also been found to be excellent and moderate, respectively, in a community-dwelling older population [124, 126]. The responsiveness, however, was found to be inconclusive based on studies included in two systematic reviews [127, 128].

Jamar Dynamometer

In the effectiveness study, we also measured grip strength in kilograms with the hydraulic instrument Jamar Dynamometer, according to a standard protocol [129]. The test is not copyrighted and is available at no cost. Normative grip strength in a healthy community-dwelling population aged 70-79 years, is 42.4 kilos and 23.7 kilos for men and women respectively, for the right hand, and 40.5 kilos and 22.0 kilos, respectively, for the left hand [130]. The instrument has been tested for criterion validity in a normal

population and test-retest reliability in community-dwelling older adults [131, 132], respectively, with excellent results. The minimal detectable change was found to be 5.2 kilos for the right hand and 5.1 kilos for the left hand in an older population of both genders undertaking cardiac rehabilitation [133].

COOP-Wonka

Health-related quality of life was measured by the COOP-Wonka in the effectiveness study, which is a generic, self-reported outcome measure [134]. The instrument is freely available. We used the revised version, which consists of six questions with associated drawings, where each question represents a separate domain [135]. The responses are scored on a five-point ordinal scale ranging from 1 to 5, where 1 is best. Thus, a decrease in score represents an improvement. The instrument was in a structured review found to have weak evidence of reliability, adequate evidence of validity, and good evidence of responsiveness in an elderly population [119].

3.1.5 Data analysis

A variety of statistical analyses were performed in the studies, all using IBM SPSS Statistics version 22 or 23 (IBM corporation, Amonk, NY, USA). In addition, in the effectiveness study, R was used (The R Foundation) [136]. A two-tailed level of statistical significance of 5% was applied in the analyses and 95% confidence interval (CI) was reported. Descriptive statistics for continuous variables were presented as mean (or median) values with standard deviations (or interquartile range). For categorical variables, frequency counts and proportions were calculated.

The psychometric study

The psychometric properties examined were content validity, construct validity, responsiveness, interpretability and feasibility, as presented in section 3.1.3.

Regarding content validity, the participant's answers to the four questions raised were addressed differently. The first question dealt with whether all occupational categories in the COPM referred to relevant aspects of the construct. The occupational categories were categorised and summarised in total and for each gender. The second question was whether all occupational categories were relevant for the study population, for example, with regard to gender and age. The prioritised occupations were analysed quantitatively by means of proportions. The third question concerned whether all occupational categories were relevant for the purpose of the instrument. This question was addressed quantitatively by means of assessing the participant's response rate. The fourth question dealt with whether all occupational categories together comprehensively reflected the construct. This question was analysed qualitatively by categorising occupations or items that were not covered in the COPM interview into the nine occupational categories of COPM and quantitatively by summarising the occupations/items.

With regard to construct validity and responsiveness, a priori formulated hypotheses were tested. This is a recognised method of confirming construct validity and responsiveness [95]. Depending on the distribution of the scores, we used the Spearman's rho correlation or the Pearson's correlation coefficient (r) to investigate associations. A high correlation was defined as $r \ge 0.60$, a moderate correlation as r > 0.30 to r < 0.60, and a low correlation as $r \le 0.30$ [137]. Hypotheses of statistically significant mean differences in COPM change scores evaluating participants with various global rating scale responses ('no change' versus 'a little improved'; 'a little improved' versus 'much improved') were examined with independent samples t-tests. Adequate construct validity and responsiveness were considered established if >75% of the hypotheses were confirmed [138].

In order to calculate interpretability, statistically significant mean differences in COPM change scores between the five different categories in the global rating scale 1) 'much improved', 2) 'a little improved', 3) 'no change', 4) 'a little deteriorated', 5) 'much deteriorated') were determined by independent samples t-tests. We considered the change score in the category 'a little improved' to reflect the MIC.

With regard to feasibility, differences in self-perceived experience and competence between health professionals (nurses, occupational therapists, physiotherapists) conducting the COPM interviews were tested statistically with chi-square tests for categorical variables and one-way analysis of variance (F-tests) for continuous variables.

The prediction study

Analyses of potential predictors of occupational performance and satisfaction with that performance were conducted by means of multivariate (multiple) linear regression. At least 20 participants are recommended for each factor studied in a simultaneous regression [139]. In the current study, a maximum of 11 potential predictors were included in the regression analyses. With a sample of 585 participants at follow up, we had enough statistical power to assess this number of independent variables.

Linear regression analyses were conducted to examine associations between COPM-P and COPM-S measured at 10 weeks, and a selected set of baseline variables. Firstly, we performed univariate analyses to screen for predictor variables for COPM-P and COPM-S. The choice of independent variables used in the univariate analyses was based on a review of the literature and clinical judgement. Secondly, variables that were statistically significant at a P<0.2 level were included in multivariate regression models with additional adjustment for baseline levels of COPM-P and COPM-S, respectively. Estimated regression coefficients from the univariate and multivariate regression analyses were reported with 95% confidence intervals and P-values. As goodness-of-fit indicators of the regression models, the R2-squared (coefficient of determination) and the Root Mean Square Error (RMSE) were reported.

We performed regression diagnostics to examine any violation of the assumptions of normality, linearity, multicollinearity and homoscedasticity. Secondary analyses were conducted with interaction terms included in the regression models to assess whether an association between fracture and the COPM was dependent on gender.

The effectiveness study

We calculated the sample size based on the results from an earlier study performed on older adults, in which the standard deviation for the primary outcome was 1.4 for the COPM-P and 1.6 for the COPM-S [140]. Based on a presumed standard deviation of 2.5 and a within-subject correlation coefficient of 0.7, we estimated that 42 participants

were needed to identify a change of two points as statistically significant (with a twosided 5% level and a power of 80%). As a high dropout rate of up to 40% could be expected owing to the potential frailty of the participants, we determined to include 60 participants (30 people in each group).

All participants were analysed according to the intention-to-treat principle. Baseline differences between the two groups were analysed by using independent samples t-tests for means, chi-square test for proportions and exact test when assumptions of the latter were not met. Treatment effects (mean differences between the groups at 3 months and 9 months, and for the overall effect for the total trial period) were estimated with mixed-effects models with adjustment for baseline measurements [141]. We inserted group and time by group (interaction term) as fixed factors, time as a repeated factor and participant as a random factor. Models were fitted with random intercepts and with random intercepts in combination with random slopes for time. We conducted likelihood-ratio tests to investigate whether a random slope improved model fit. If not, the simpler model was chosen. Effect sizes defined as standardised mean differences (Cohen's d) were calculated at each time point. A simple adjustment for potential baseline group differences was performed by subtracting baseline effect sizes from effect sizes at follow up.

3.1.6 Ethical considerations

The research was carried out in accordance with the Declaration of Helsinki [142]. Personal confidentiality was assured and a declaration of voluntary participation with information about the study purposes and consequences, emphasising the right to withdraw from the study, was obtained. All participants signed the declaration confirming their consent. All data related to this PhD project were anonymised and data files were stored on the research server at Western Norway University of Applied Sciences.

All assessments took place in the participants` homes, which could be experienced as an intrusion of their privacy. However, the assessors were experienced workers in home-based services with knowledge in how to conduct themselves respectfully during home visits. Furthermore, the studies did not introduce any harmful or painful procedures to the participants, and no adverse effects were reported owing to participation in these studies.

The psychometric study and the prediction study

All participants in the multicentre trial received information about the study and gave written consent. The Regional Committee for Medical and Health Research Ethics for Western Norway (REK West, 2014/57-1) approved the study.

The questionnaire, including the five instruments was comprehensive and timeconsuming as each baseline data collection session was estimated to last 1.2-1.8 hours. Hence, it was a risk that the assessments would be exhausting for the older participants. In addition, some questions might be provocative, raise strong or negative feelings or be difficult to score, for instance with regard to the SOC-13 or the MHC-SF instruments. For this reason, the data collectors were urged to be sensitive to the participant's condition and feelings during the assessment session, and postpone the completion of the remaining instruments to the forthcoming days, or skip completion of the SOC-13 and MHC-SF assessments, if necessary.

The effectiveness study

The Regional Committees for Medical and Health Research Ethics in Norway (REK West, 2012/295) granted ethics approval for the study.

We followed the uncertainty principle when planning this study, meaning that trials should only be initiated in situations where we do not know which treatment is better [55]. We regarded the randomisation procedure as ethically acceptable, as none of the participants received an intervention under the standard they would otherwise have received if not participating in the trial. Further, we offered the control group reablement after finishing the 9-month follow up. As a result, we prevented delivering a potential inferior rehabilitation intervention to the control group.

4. Summary of results

The psychometric study

In this study, we investigated validity, responsiveness, interpretability and feasibility of the COPM when used by various health professionals in home-dwelling older adults receiving reablement. The study included 225 participants with a mean age of nearly 81 years. The COPM was found to have adequate content validity, construct validity and feasibility in this population of older adults, and a moderate responsiveness to change. Functional mobility was found to be the most frequent prioritised occupational category of all. Regarding interpretability, the minimal important change was 3.0 and 3.2 points for the COPM-P and the COPM-S, respectively. With respect to feasibility, the older adults reported that COPM was a useful and manageable instrument. The healthcare providers, that is the majority of the occupational therapists, physiotherapists and nurses involved, reported that they had the required expertise to conduct the COPM assessments.

The results support the use of the COPM in inter-professional clinical practice and research in a home-dwelling, heterogeneous population of older adults. Based on the findings, three points is recommended as a cut-off to differentiate between individual older adults who have a minimal important change in the COPM-P and the COPM-S, and those who have not.

The prediction study

In this study, we examined factors that predict self-perceived occupational performance and satisfaction with performance at 10 weeks follow up. The study comprised 712 participants with a mean age of 78 years. The functional characteristics measured by the PWS test, but also by the COPM and EQ VAS scores, indicate that the participants in general had moderate to severe disability. The results demonstrate that a higher baseline COPM score, female sex, having fracture as the major health condition and high motivation for rehabilitation significantly predict both better occupational performance and higher satisfaction with that performance 10 weeks after starting reablement. Inversely, there are two common predictors of poorer COPM-P and COPM-S outcomes, which are having neurological disease other than stroke and dizziness/balance problems as the major health condition. In addition, having pain/discomfort or anxiety/depression predict significantly poorer COPM outcomes. Finally, having pain/discomfort predicts poorer COPM-P outcomes. The two regression models explain 38.3% and 38.8% of the total variance of the dependent variables of occupational performance and satisfaction with that performance respectively. In summary, diagnosis, gender, motivation and functional level matter in reablement.

The effectiveness study

The aim of this study was to evaluate whether reablement is more effective than usual care with regard to self-perceived occupational performance and satisfaction with that performance, physical functioning, and health-related quality of life. The sample consisted of 61 participants with a mean age of nearly 79 years. The control group received care as usual. The participants were assessed at baseline, and again at the 3month and 9-month follow ups. The results showed that home-dwelling older adults with functional decline benefit from reablement by means of improving their performance and satisfaction with that performance in everyday living. Moreover, these effects were persistent on a long-term basis. There were no significant differences in the amount of home-based service work hours allocated to each of the groups. Participants in the reablement group received on average 2.1 service work hours per week. In more detail, there were significant improvements in mean scores in favour of reablement in the COPM-P at 3 months with a score of 1.5 points (P=0.02), at 9 months 1.4 points (P=0.03) and overall treatment 1.5 points (P=0.01); and for the COPM-S at 9 months 1.4 points (P=0.03) and overall treatment 1.2 points (P=0.04). No significant group differences were found concerning the COPM-S at 3-month follow up, or at any time point for physical capacity or health-related quality of life.

To conclude, in this study, a 10-week reablement program was found to be a superior intervention to usual care in terms of improving occupational performance and satisfaction with that performance on a long-term basis in community-dwelling older adults. However, the other outcomes showed no significant group differences.

5. Discussion

The discussion part of this synopsis is organised into two subchapters: the methodological considerations and the discussion of findings. The methodological considerations concern strengths and limitations regarding samples, designs and methods, but also some general considerations related to methodological issues. In the discussion of findings, issues related to the findings will be discussed, but the focus will also be on highlighting broader viewpoints derived from the three studies not highlighted in the articles.

5.1 Methodological considerations

5.1.1 Validity considerations

Study design

All studies in this thesis have a prospective design. This means that general and data collection procedures were established prior to the studies being commenced, which ensures relevance of the data. An advantage of this design is that the independent variable (the intervention) precedes the dependent variable (the changes in outcome) and as such reduces the risk of temporal ambiguity [139]. The psychometric and prediction studies are both prospective longitudinal cohort studies. A benefit of a longitudinal study compared to a cross-sectional study is that the change in an outcome can be studied over time and analysed with respect to the explanatory variables [143]. A challenge in cohort studies is to decide on the time intervals between the data collection points, as this will vary depending on the objective of the study. In both studies, we chose a rather short time frame of 10 weeks, owing to the research objective of studying change based on the intervention period. As a consequence, the results do not apply to the long-term impacts of reablement.

The effectiveness study is an RCT. This implies a parallel group design in order to compare the results of a specific intervention with the conventional procedure used for the control group. RCTs are prospective and experimental, meaning that the independent variable is under the controlled manipulation of the researcher and the

dependent variables are collected under controlled conditions [144]. The RCT design is considered to be the gold standard for yielding valid evidence about causes and effects. However, an RCT design may not often be suitable due to ethical and practical constraints with regard to which variables can be manipulated [139]. Fortunately, in this PhD project, we were able to overcome such constraints.

Study sample

Bias can occur when the sample is not representative of the studied population [145]. Hence, there is a need to describe the samples used in this thesis. The participants in the psychometric study and the prediction study were subsamples from the nationwide multicenter study. Moreover, the psychometric study was a subsample of the prediction study. However, in the effectiveness study, an entirely different sample was used. Nevertheless, there are many common features in the three samples regarding participants' characteristics as can be seen in Table 5 (section 3.1.1). The study samples in the psychometric and prediction studies derive from municipalities scattered all over Norway, assumedly representing the study population, which is the general population of home-dwelling older adults with functional decline.

As indicated by the title of this thesis, the target group was home-dwelling older adults. Despite that, due to ethical considerations and expected recruitment problems, we decided to include persons below the age of 65 years in the prediction study and in the effectiveness study. As anticipated the study population turned out to be of advanced age. Hence, the sample is only representative of an older population. However, with the main proportion of the sample being older did not seem to alter the results in the prediction study. Still, only including persons over the age of 65 years would in many respects have been advantageous, since the target group of this PhD project was home-dwelling older adults.

Internal validity

Internal validity is the extent to which the results of a study demonstrate that a causal relationship exists between the independent and dependent variables [139]. Within experimental research, this means that the intervention caused the observed changes in

the dependent variable. In non-experimental research, like the current prediction study, internal validity means whether the independent variable is a plausible explanation of group difference on the dependent variable [144]. The internal validity in the psychometric study and the prediction study rely on, amongst other issues, the validity of the instruments used, which are presented in section 3.1.4. The psychometric properties of the instruments used in this PhD project, are on the whole considered to be adequate. Due to the sampling method of recruiting consecutive participants, excluding the whole control group in the prediction study and excluding people not reporting at follow up in the psychometric study, there might be a risk of selection bias in both studies in this respect, for instance that the frailer participants were excluded. However, since an analysis comparing participants who completed and participants who dropped out in the multicenter study, showed no significant differences in baseline COPM scores [77], we do not consider selection bias to be a problem. Besides, owing to the short time frame of 10 weeks, retention rate was moderate and therefore did not represent selection bias. *Maturation*, that is changes within a participant caused by the passage of time, is a threat to internal validity [144]. Having a fracture was the most common reason for needing reablement in the samples in the three studies. As such, it cannot be ruled out that having a fracture represents maturation, as the fracture heals during the first weeks and months after the injury.

In addition, the internal validity of the prediction study relies on the correctness of the underlying assumption that occupational performance and satisfaction with that performance are relevant outcomes of reablement. In the psychometric study, it was found that the COPM is a valid and responsive instrument capable of capturing potential effects. The effectiveness study and additional studies have found that occupational performance and satisfaction with that performance are outcomes that are affected positively by the reablement intervention [77, 108]. Hence, there is reason to assume that internal validity is acceptable in this respect.

In experimental research such as the effectiveness study, the important question with regard to internal validity is whether the treatment caused the observed changes in the dependent variable. The RCT design, with random assignment to experimental or

control group, is considered by many to be the best design to control threats to internal validity in the form of bias [144]. Various types of bias are addressed in the following. Selection bias refers to systematic differences between baseline characteristics of the groups being compared [146]. In the effectiveness study, the procedures of sequence generation and allocation concealment are assumed to be performed adequately with low risk of bias. The randomisation was successful, as there were no significant differences between the groups at baseline. Systematic differences between groups in the treatment provided or in exposure to factors other than the intervention of interest, are termed *performance bias* [146]. In the effectiveness study, we could not blind the healthcare providers delivering the interventions. As such, there was a high risk of performance bias. Attrition bias is systematic differences between groups in withdrawal from a study [146]. Attrition was low for both groups. Hence, the risk of attrition bias is perceived to be low. Detection bias deals with systematic differences between groups in how outcomes are determined [146]. We did blind the researchers, and tried to blind the assessors, but the participants could not be blinded. Therefore, despite our efforts there is a moderate risk of detection bias. Furthermore, *reporting* bias is systematic differences between reported and unreported findings [146]. The results were reported to be consistent with the protocol and there was no selective reporting. Hence, there is a low risk of reporting bias. Finally, there were risks of other biases present. This was due to risk of contamination in the usual care group, lack of monitoring of therapist and participant adherence to the intervention protocol, and unequal co-interventions between the groups.

Regarding the effectiveness study, a Cochrane systematic review on reablement has already assessed the risk of bias in that study [44]. In such Cochrane assessments, risk of bias is either regarded as high or low, and no middle position exists. The Cochrane review stated that there was a high risk of performance bias, detection bias and other bias, but low risk of selection bias, attrition bias and reporting bias in the effectiveness study [44]. However, Cochrane systematic reviews have strict criteria for assessing internal validity, having the quadruple blinded RCT in medication research as the gold standard. As reablement research is conducted in a real-life setting and the intervention

is complex, it may be hard to acquire optimal conditions in every respect and blinding of participants and healthcare providers is impossible. In any case, the challenges and shortcomings in the effectiveness study of ensuring validity in a real-life context and when having a complex intervention, is discussed in more detail in section 5.1.2 in light of the framework for the design and the evaluation of complex interventions to improve health [63].

Reliability is defined as the extent to which scores for participants who have not changed are the same for repeated measurement under several conditions [92]. If data are not collected in a reliable way, validity cannot be obtained, hence reliability is a prerequisite to validity. The COPM is a patient-specific instrument where the scores are based on a qualitative, semi-structured interview. Hence, the inter-rater and intrarater reliability will vary [85]. This is because the information gained during the interview will differ, depending on the competence of the interviewer, fluctuations in the participant's condition and influence from the context in which the interview is performed [94]. The reliability of the instruments used to measure secondary outcomes, however, is perceived to be good, as pointed out in section 3.1.4. In the psychometric study and the prediction study many professionals performed the data collection. Joint courses in the use of the instruments for all data collectors, and close follow up of, and feedback to, data collectors when receiving their first data, were measures taken to ensure intra-rater reliability. Despite that, in a study with 34 different study sites, adequate intra-rater reliability may to some degree be compromised. As a result, the consistency of the data collected may be reduced. In the effectiveness study, however, only a few persons performed the data collection and all of them were trained by the first author to ensure that the procedures were conducted according to the protocol. Hence, in this study, intra-rater reliability is perceived to be good.

External validity

External validity refers to the generalisability of the results from the study sample to the target population [147]. Overall, the generalisability of the results is considered to be good. The study population is heterogeneous comprising a multitude of various health conditions, which means that the results may be generalised beyond the scope

of a specific diagnosis. The samples in the psychometric study and the prediction study are representing 32 and 34 municipalities respectively. The included municipalities were both urban and rural, and approximately 15% of the Norwegian population was living in them. Hence, the results are indeed generalisable to home-dwelling older adults with functional decline in Norway. Presumably, the results are also generalisable to the target population in other high-income countries. This is supported by the Cochrane review on reablement, which claims that the characteristics of the participants in the included studies were broadly similar to the participants in the excluded studies, thereby suggesting that they were generally representative of older people requiring home-based services across various countries [44].

In the nationwide study, a multilevel regression analysis was performed to examine whether various municipal organisational models of reablement and municipal differences in intensity or duration of the reablement intervention, made an impact on the results at an individual level [77]. The results showed that none of these factors made an impact. The reason is presumably that the various organisational models were locally adjusted to meet the specific needs of each municipality. Anyway, this contributes to the external validity of the results across municipal organisational model and modes of service delivery in Norway. However, there may be limits in the extent to which the results may be generalised to other countries with different levels of integration between healthcare and social care systems. Home-based services can be provided in a number of different ways, for instance by public or private sector, which add to the complexity when evaluating these services [44, 76].

Time can be a threat to external validity when the results of a study are applicable to limited time frames [144]. This is not considered to be a problem yet, but may be so in the future as the target group, and the intervention itself, change.

Statistical methods

Statistical validity depends upon using the right measures and statistical tests [145]. The following paragraphs present considerations made in order to ensure statistical validity in the three studies.

The correlation coefficient is a tool for quantitatively describing the magnitude and direction of a linear relationship between two variables [139]. Hence, we decided to use this measure to examine predefined hypotheses of construct validity, and to some degree responsiveness, in the psychometric study. We chose to confirm predefined hypotheses and to use an anchor-based approach to examine responsiveness and interpretability using the global rating scale as a criterion. However, in order to assess responsiveness, we could have chosen to plot the COPM change scores on a Receiver Operating Characteristic (ROC) curve against sensitivity and specificity for distinguishing between those who improved and those who did not improve, as argued by Polit and Beck [139]. We considered, however, that confirming hypotheses was the best method of establishing responsiveness, as recommended by the COSMIN guidelines when no gold standard exists [148]. The global rating scale is an assessment based on changes from the participant's perspective [95]. We used the global rating scale as an anchor, since we wanted the interpretability of the results to be based on input from the participants. However, use of hypotheses to test construct validity and responsiveness is not straightforward. Hypotheses are based on clinical knowledge and experience, combined with theoretical expectations of the instrument [149]. If the hypotheses are not confirmed, it may be due to the instrument not being valid or responsive, but it may also be caused by failed hypotheses that do not reflect reality. As such, there is a high degree of uncertainty connected to this methodology, which we in fact experienced and discussed in the psychometric study (Paper 1).

Since we wanted to predict outcomes of reablement, we chose to conduct regression analysis in the prediction study to investigate associations between the COPM-P and the COPM-S measured at 10 weeks, respectively, and a selected set of baseline variables. Multiple regression is designed to analyse complex relationships among many different variables [144]. Linear regression estimates the coefficient of the linear equation, comprising one or more independent variables that are perceived to best predict the dependent variable. We used simultaneous multiple linear regression, which enters all predictor variables into the regression equation at the same time. This strategy is most appropriate when there is no basis for considering any particular predictor as being causally prior to another [139]. We used mixed effects model analysis with three time points in the effectiveness study. which is a model with both fixed effects and random effects [141]. With the development of statistical methods such as mixed effects model analysis, it has been possible to analyse longitudinal relationships using all available longitudinal data without summarising the longitudinal data on each person into one value. In a longitudinal dataset, the observations collected on the same person are highly dependent on each other. Therefore, a cross-sectional linear regression analysis cannot be used [143]. A mixed effects model is developed to adjust for this dependency. Overlooking the dependency may lead to either ending up with false significant results, or missing true substantial effects [150]. Additional advantages of the mixed effects model are the versatility in the modelling of the time factor and that it allows varying measurements per individual. The analysis is also known as multi-level analysis, because of its potential for analysing several hierarchical levels [143]. A disadvantage with this type of analysis is that it is rather complicated and as a result, requires high statistical competence. Thus, in the effectiveness study, a statistician had the main responsibility for conducting these analyses.

5.1.2 General considerations

Reablement as a complex intervention

A limitation of this PhD project, is that we did not fully design the reablement intervention in accordance with recommendations from the Medical Research Council framework for design and evaluation of complex interventions to improve health [63]. Following the framework of complex interventions, the key elements of the process are development, feasibility/piloting, evaluation and implementation [151]. Since we did not explicitly follow the recommendations when planning the studies, it is a good opportunity now to do a post hoc analysis with reflections upon considerations and measures that might have been taken in each of these four phases. The critique from the Cochrane systematic review on reablement has added to the need and relevance of such self-reflections [44]. In these reflections, the effectiveness study in the municipality of Voss will be used as an example.

The first phase deals with the development of the intervention. It was not relevant to develop an entirely new intervention, since the intervention we wanted to examine was described in the literature prior to our studies. When planning the intervention, our work was guided by good clinical research practice (GCP) recommendations inspired from the WHO [112]. As presented in the introduction (Chapter 1), the philosophy of person-centred care is underpinning reablement [48]. The theory of optimising capacity was, however, developed after the studies were conducted and may only serve as a post hoc theoretical underpinning [40]. Our understanding of disability was based on holistic conceptual models [6, 23] and the understanding of the participant's interaction with occupation and the environment was based on the CMOP-E model [84]. We chose to use a variety of instruments to be able to identify unknown consequences, as recommended in the literature [63]. The intervention was adapted to the local setting, which is also pointed out by Craig and colleagues [63]. Since Voss is a vast municipality, the organisation of the intervention had to be embedded in three local home-based services districts each providing service to their citizens. However, due to having only a few physiotherapists and occupational therapists, these professionals were located centrally, collaborating with each home-based services district. Due to long travel distances for the therapists, fewer home visits per week were estimated. In other words, owing to context adaptation and person-centeredness, standardisation of the intervention was not emphasised. Lack of standardisation may be seen as a quality feature of the intervention, but it represents a challenge when conducting research. This is because variations in intervention delivery may make comparisons between municipalities or countries problematic.

The second phase deals with assessing feasibility and pilot testing. Evaluations often underestimate problems with acceptability, compliance, delivery of the intervention, recruitment, retention, and small effect sizes, which could be improved by assessing feasibility and piloting methods [151]. As recruiting participants was expected to take time, and we planned to conduct a small-scale study, we did not conduct a pilot study in advance. A sample of approximately 60 participants is generally considered enough to give meaningful results, but not so large that the study becomes large, long and costly [55], although this depends also on the responsiveness of the instrument used. Anyway,

for pragmatic reasons we did not pilot the intervention or conduct a feasibility study beforehand and could not have done otherwise with the resources available at the time. However, if we had conducted a feasibility study, we might have detected shortcomings with regard to the intervention delivery.

The evaluation phase comprises assessing both effectiveness and process. The assessment of effectiveness was conducted adequately using an RCT design. However, parts of the process assessment could have been performed more systematically. Process evaluations aim to capture whether the intervention was delivered as intended (fidelity) and the quantity of what was implemented [55]. We undertook actions to ensure treatment fidelity and we did register the quantity of the intervention delivered. However, we did not monitor these processes while the intervention was underway, which, according to the Cochrane review criteria contributes to higher risk of bias [44]. We did not systematically register treatment fidelity and compliance with the intervention and we did not conclude on the dose and intensity registration before the study was terminated. As a result, we have insufficient information about whether the intervention was delivered as intended and about participants' compliance with the intervention, which represent threats to internal validity. Moreover, we did not adjust the quantity of the intervention when the study was underway. Thus, it was a surprise at the end of the effectiveness study to find that, due to the long intervention period of 10 weeks, the duration of home visits per participant per week was only 2.1 hours. This was unfortunate, as high intensity is considered to be an element of the reablement intervention.

The final phase of the process deals with examining the translation of the intervention into practice, paying attention to the rate of the uptake, the stability of the intervention, the broadening of target groups and possible adverse effects [152]. This involves a long-term surveillance of the intervention delivery and adjustments made accordingly. One adjustment made in Voss after the study was terminated is that the intervention delivered today is more concentrated with higher dose and intensity and fewer weeks involved. Unfortunately, as the studies have been terminated, we do not have the opportunity or resources to conduct a long-term monitoring of the service delivery in Voss or in the other municipalities involved.

One of the major drivers behind the development of the Medical Research Council framework was the recognition that too many trials fail to deliver clear results. "Poor design choices, low levels of recruitment, significant attrition, lack of intervention fidelity and interventions unacceptable to those delivering or receiving the intervention can all ultimately lead to research projects that deliver inconclusive results" [55, page 123]. Although, our efforts when developing and evaluating the reablement intervention could have been more systematic and thorough, we did deliver conclusive results, and as such succeeded with our endeavor.

Implications of the sample size in the effectiveness study

Paper 3b was rated as the most influential article in BMC Geriatrics in 2015 with an Altmetric score in the top 5% of all research outputs, which is very gratifying. The reason for this popularity is presumably the uniqueness of the study being the only RCT on reablement outside Oceania and the significant results in favour of reablement. Besides, the timely publication met a strong demand in Europe for evidence on the reablement intervention, as reported elsewhere [50]. In addition, one important strength of the study is the RCT design in accordance with the CONSORT statement of transparent reporting. Moreover, we were able to find significant results in favour of reablement, despite several factors that contributed to underestimating the effect. The therapeutic effect of the COPM interview [153, 154], may have contributed to prompt the control group to improve their function, and as such reduce the group differences. In addition, the control group received significantly more co-interventions in the forms of out-patient physiotherapy, which contributes in the same direction. Hence, in spite of these circumstances that promote function in the control group, it was possible to detect significant results in favour of reablement.

As credited by the Cochrane review on reablement, we indeed "highlighted methodological concerns that are probably not uncommon in RCTs of this type" [44, page 20]. The rather small sample size of 61 participants, is one of the limitations of

this study, in addition to the risk of bias presented in section 5.1.1. The study was only statistically powered to find results for the primary outcomes. Thus, a Type II error, i.e. a false negative conclusion, might have occurred regarding the secondary outcomes. An effect size (ES) of ≤ 0.5 is generally considered to be a small effect, between 0.5-0.8 to be a moderate effect, and ≥ 0.8 to be a large effect [155]. Even if a larger sample size could have contributed to significant results, the effect sizes were small regarding mobility measured by the TUG (ES=0.1) and grip strength measured by Jamar dynamometer (ES=0.1-0.3). It is therefore questionable whether the participants would have experienced this as a clinically relevant improvement.

This leads us to examine the responsiveness of the instruments used to measure the secondary outcomes. The responsiveness of the TUG in an older population has been examined in two systematic reviews [127, 128]. Only a few studies included in the reviews gave information about responsiveness, thus the results could not be evaluated properly. As a consequence, the responsiveness of the TUG is inconclusive.

In the effectiveness study the effect sizes for grip strength were in general small (ES=0.1-0.3) and there were only improvements for the right hand in favour of reablement. However, no significant differences were found between the two arms of the study regarding grip strength. The minimal detectable change for this instrument is established to be 5.2 and 5.1 kilograms for the right and left hand respectively in an older population [133]. Although a responsive instrument, the improvement of a maximum 1 kilogram as reported in Table 3 in Paper 3b, is assumed to be far below the minimal detectable change, indicating clinically insignificant results. Hence, the results imply that reablement does not improve grip strength.

The results measured by the various items of COOP-Wonka, however, had effect sizes from 0.1-0.6. Most of them were in favour of reablement and some of them were not. The responsiveness of the instrument is found to be good in an older population [119]. Hence, in this case a larger sample might have contributed to a greater degree of certainty with regard to whether reablement improves health-related quality of life or not.

Interestingly, in the multicenter clinical controlled trial from which the psychometric study and prediction study were derived, the results for the secondary outcomes were contrary to the effectiveness study. In this study the sample consisted of 833 participants [77]. The SPPB was used to capture the outcomes of physical functioning and EQ-5D to capture the outcomes of health-related quality of life. Not only were significant results at follow ups in favour of reablement found for most of the items in these instruments, but the improvements were clinically important (based on established cut-offs for SPPB) and the effects sustained for a 6-month period and regarding a few items, a 12-month period. There may, however, be differences in the intervention delivery, for instance with regard to intensity, which may have contributed to the differences in results between the multicenter study and the effectiveness study. Moreover, the constructs measured with the instruments used in the two studies may to some degree differ. In addition, the significant results found for physical function and health-related quality of life, may be a result of improved statistical power and more responsive instruments in the multicenter study.

At the time the effectiveness study commenced, the municipality of Voss was a pioneer and one of the two first municipalities in Norway to implement reablement. In the years 2011-2012, it was hard to get a municipality to agree to implement and subsequently allow research on reablement. Several municipalities with a larger number of inhabitants declined to participate in this endeavour. A shortcoming of having only one study site and a densely inhabited municipality, however, was that we had to recruit participants to the intervention group and the control group from the same home-based districts, thus risking contamination to the control group since some of the same staff delivered the intervention to both groups. If starting the research today, several larger municipalities would have been preferred, where each municipality delivered either reablement or usual care. However, as reablement now is more established, it is difficult to recruit a control group, as indicated elsewhere [44].

The role of the researcher

There is an assumption within the quantitative paradigm that research is value-free. The controlled, objective nature of quantitative research is assumed to eliminate the influence of the researcher's opinions and societal norms [144]. In this thesis, however, there is a risk that my enthusiasm for reablement in general, may have influenced my judgement when writing this thesis. Even if I have been aware of this issue and tried to present reablement in a balanced and neutral manner, complete objectivity in research is hardly achievable. Postmodern philosophers have contested the belief that researchers can be objective and value-free, recognising instead that what we perceive is influenced by contemporary beliefs [17, 20]. Scientists cannot divorce themselves from the cultural, social and political context of their works [156].

The cronological sequence of the studies

In an ideal world, the psychometric study would have been conducted first of the three studies. Only when the psychometric properties of the COPM in a home-dwelling, heterogeneous population of older adults were established to be adequate, should the other studies using the COPM as the primary instrument have been performed. However, when starting our research in the municipality of Voss in 2011-2012, it was the effectiveness and the experience with reablement that were our objectives, not validity testing of instruments. Hence, it was for pragmatic reasons that we started with the effectiveness study first. Nonetheless, we thought at the time, and still do, that the COPM was the best instrument to capture the effects of reablement as pointed out in section 5.2.1. Besides, there was good evidence from testing the instrument on other populations. Furthermore, our clinical experience with, and theoretical knowledge of the instrument, indicated that it had adequate psychometric properties. In any case, the psychometric properties of the COPM in a home-dwelling older population were supported post hoc. The prediction study, however, was conducted in the right order following the psychometric study. For readability reasons, the studies are presented in the optimal order in this synopsis.

5.2 Discussion of findings

5.2.1 Discussions concerning the COPM instrument

Is a patient-specific instrument the best instrument to capture the outcomes of reablement?

When evaluating an intervention, it is important that there is a logical link between what the intervention purports to affect and the instrument that is used to evaluate the effect [157]. A match between the content of the intervention and the main outcome is required. There are several relevant outcomes of reablement, for instance physical function, mental health, health-related quality of life and costs. Still, since the intervention primarily deals with practice in and adaptation of daily occupations [44], it is reasonable that the outcomes of daily living are considered as the primary outcomes in reablement. Consequently, the main instrument in reablement should measure outcomes of daily living. Other considerations are that the instrument should include occupations/activities that are relevant to older adults and that the instrument should be responsive to the degree of change expected from the intervention.

There are two main categories of instruments that measure daily occupations. The first category is standardised ADL instruments, like ADL taxonomy, Functional Independence Measure (FIM) and Barthel Index [158-160]. Such ADL instruments have fixed items that measure ability to perform various ADLs. The second category is a patient-specific goal determination instrument like the COPM. Other examples of such instruments are Towards Achieving Realistic Goals in Elders Tool (TARGET) and the Patient-Specific Functional Scale (PSFS) [51, 161]. An advantage with a patient-specific instrument, as opposed to a standardised instrument with fixed items, is that the occupations are experienced to be relevant by the participants, since they are able to choose occupations they find important. Another advantage experienced with the use of the COPM, is that the COPM interview itself has a therapeutic side effect motivating the participants to work towards achieving their goals [153, 154]. Therefore, there is little doubt that a person-centred instrument with a beneficial side effect, which encapsulates goal determination, provides the basis for planning of the intervention, and which can also be used in evaluation, is the best choice as a primary

instrument in reablement. Nevertheless, there are advantages with using ADL instruments, for instance that the scoring provides a broader picture of the level of functional decline of the individual. Another feature of an ADL instrument is that it captures performance in a range of ADLs. Based on our reablement research, a relevant hypothesis is that there is a beneficial spill-over effect from a prioritised occupation to a non-prioritised occupation. This would explain why the participants also increase their performance and independence in occupations that have not been the focus of their rehabilitation and as such decrease the demand for home-based services [108]. However, so far, there is no data collected to support or refute such a hypothesis. If we used an ADL instrument in addition to the COPM, it would have been possible to capture such a spill-over effect. In research, and in clinical practice, the total amount of instruments used should be assessed carefully, in order not to tire the participants. However, if the total amount of instruments is reasonable, a combination of a patientspecific instrument and an ADL instrument would be preferred to capture the functional outcomes of reablement. If planning the effectiveness study today, an ADL instrument would have been preferable to the Jamar dynamometer.

Is it necessary to have two outcomes in the COPM instrument?

Table 5 (section 3.1.1) presents the baseline COPM-P and COPM-S scores in the three studies. As can be seen the scores of performance and satisfaction with that performance are very similar within each sample. This tendency is exactly the same for follow up scores as can be seen in Table 3 in the effectiveness study (Paper 3b). Moreover, Table 2 and Table 3 in the prediction study (Paper 2) show that the outcomes of the COMP-P and COPM-S predict nearly the same factors and the two models explain very similar amounts of variance. Hence, in general, the results of this PhD project show that the COPM-P and COPM-S initial scores, reassessment scores and change scores respectively, are highly correlated. Many studies examining various target groups report similar correlations or matching results between the two outcomes [77, 98, 99, 108, 153, 162-167]. The correlation between mean the COPM-P and COPM-S reassessment scores is found to be as high as 0.92 (P<0.001) [166], indeed representing a problem with multicollinearity. In the prediction study we raised the question of whether it is really necessary to have both dimensions in the same

instrument and suggested to omit satisfaction with performance. Surprisingly, only one study has been found where the authors raise the same question [166]. Since this is a sparsely discussed issue within the occupational therapy literature, there is a need for deeper exploration of the presumed differences between the outcomes. It has not been possible to get access to the three earliest versions of the COPM manual, but the first publications where the funders describe the rationale for developing the instrument are examined [86, 162, 168]. It is claimed that satisfaction with performance is an important outcome, but the rationale for having both outcomes is not explicitly outlined. It is stated that the instrument takes into account the participant's roles and role expectations [86]. Moreover, the COPM is based on the model of occupational performance and a client-centred approach [162]. This complies with the theory base of occupational therapy indicating that occupational performance is intrinsically satisfying and inherently related to life satisfaction [163]. It is also claimed that the difference between the two outcomes is that performance is an objective dimension, whereas satisfaction with that performance is a subjective dimension [163]. The last statement needs to be modified right away, as the COPM-P is a self-perceived and subjective outcome, not an objective measure of functional independence [96]. However, the COPM-P is the outcome of the two that is closest to measuring functional independence. What distinguishes the two outcomes most is probably that the COPM-P depends more on the physical ability of the participant and thus is more stable over time [164], whereas COPM-S to a larger degree is influenced by the daily functioning of the participant and as a result is more changeable [90]. Hence, the variability is often greater in the COPM-S scores than in the COPM-P scores.

There are several disadvantages associated with having the two dimensions in the same instrument. Problems with discriminating between the COPM-P and the COPM-S have been reported among participants [97, 98, 166]. Furthermore, satisfaction may be difficult to score and therefore reflect the score of performance [91]. Rating both dimensions is more time-consuming for participants. Both in clinical practice and in research having the two dimensions requires more resources allocated.

The fundamental question is whether the two constructs allegedly measured are different enough to justify having both dimensions in the same instrument. Based on the significant high correlation between performance and satisfaction with performance found in many studies [99, 162, 163, 166], and the sparse amount of extra information gained by having two similar outcomes [77, 88, 98, 108, 153, 165, 167], the research conducted needs to be systematically reviewed in order to answer this question. Subsequently, the instrument may need to be revised, possibly omitting the COPM-S outcome. Meanwhile, practitioners and researchers may choose to use only the COPM-P outcome. Unfortunately, it was not known that the constructs between the two outcomes were so alike when conducting the psychometric study, otherwise this issue might have been pursued when testing construct validity.

5.2.2 What factors predict reablement?

In the prediction study, we were only able to explain 38% of the variance concerning which factors predict better performance and satisfaction with performance in reablement. This is an opportunity to briefly reflect on what kind of factors the 62% of the variance that are not explained may be. There may be an infinite number of potential causes of any observed effect, hence testable theories are used to narrow down the number and types of variables that are hypothesised to exert the effects [27]. Clinical judgement and experience with how the intervention works, may also be employed. In this case, the CMOP-E model, presented previously in section 1.4.1, will be used as a framework for the post hoc analysis. This is a holistic model that describes the dynamic relationship between person, occupation and environment [84].

The *person*, depicted in the middle of the model, comprises three performance components: affective, cognitive and physical, with spirituality at the core. All the factors we found that did predict better outcomes, were linked to the person, namely functional level, motivation, diagnoses and gender. We did explore other relevant factors related to the person that we suspected might be predictors, such as age, comorbidity, educational level, living status, health status and preferred walking speed, but these factors did not predict better outcomes.

The person is in the model surrounded by the *environment* to imply that each person lives within their unique context, being cultural, institutional, physical and social, which enables occupational possibilities [84]. We examined three different organisational models for delivering reablement, representing the institutional environment. The degree to which the staff had internalised the ideology or culture of promoting self-management, is a possible predictor we did not explore. Moreover, there is reason to believe that the quality of the participant's relationship with the healthcare professionals has an impact, and also the degree to which the professionals or the relatives are able to encourage and stimulate the participant in their daily routine. We did not examine whether reducing physical barriers in the home and local community of the participant, or provision of assistive technology, might be predictors. As a result, there are several environmental factors that might predict better outcomes in reablement that we did not examine.

Occupation is illustrated in the model as the link that connects person and environment, signifying that persons act on the environment by means of occupation [84]. Occupation is classified in three categories; self-care, productivity and leisure, which are divided into nine subcategories in the COPM instrument. It is possible that some prioritised occupations representing certain subcategories of occupation, for instance mobility or personal care, are predictors of better outcomes. In addition, simplification of the occupational performance is a component of the intervention that may have an impact. Furthermore, there are other features of the intervention delivery, for instance duration and intensity that might predict better outcomes.

In summary, the CMOP-E model is used as a framework for identifying potential factors that may predict better outcomes in reablement. Our research has found that factors related to the person are predictors of better outcomes in reablement. There are however, several factors related to the environment and occupation (and intervention) that also might be predictors of reablement, which for various reasons we did not explore. These factors might be investigated in future research.

5.2.3 Should reablement be rolled out all over Norway?

In addition to the studies included in this PhD project, several other Norwegian studies have been published recently which contribute to the evidence base of reablement in Norway [45, 77, 107-110, 169]. Besides, more studies will be published in the near future [170]. Based on the studies published so far, reablement is found to be favourable when it comes to effect on occupational performance and satisfaction with that performance in the current effectiveness study and in Langeland and colleagues` large clinical controlled trial [77]. This was also found for physical function and healthrelated quality of life in the latter study, although several of the effects gained did not last beyond 6 months. In the current prediction study, diagnosis, gender motivation and functional level were found to be predictors of better outcomes in reablement. Concerning cost-effectiveness, reablement is found to be effective when it comes to improving occupational performance, satisfaction with that performance and qualityadjusted life years (OALYs) respectively, at an equal or reduced cost as standard treatment [77, 108]. With an investment of 65000 NOK per person, health-related quality of life measured by QALYs has been found to be substantially improved, thus providing a cost-effective service [77]. Moreover, the experiences from participants and relatives are positive towards reablement [45, 109, 110]. The staff finds the integrated multidisciplinary work stimulating [77, 109, 169, 171] and the reablement service a better framework for working in [109]. Hence, based on the growing evidence base from Norwegian research in favour of reablement, one might question if now is the time to roll reablement out all over the country.

In order to answer that question, the international research literature needs to be assessed. As previously described, international comparisons between reablement services are complex, due to national differences in service provision [44]. Hence, to generalise evidence across countries is not straightforward. Nevertheless, four systematic reviews on reablement have been conducted [44, 52, 64, 76]. The reviews have various research questions, inclusion criteria and selected outcomes. However, their overall conclusion is that there is still very limited and low quality evidence in favour of reablement. Therefore, the present international evidence base on reablement

does not justify a full-scale implementation of reablement in Norway. There are various reasons why the results from the systematic reviews do not concur with the results from the Norwegian studies. One reason is that several of the Norwegian studies are qualitative that investigate experiences, not effects. The Cochrane review on reablement can be used as an example to illustrate another reason. The review downgraded the quality of evidence in the meta-analyses due to high risk of bias in various aspects, such as having fewer than 400 participants [44]. Hence, there are strict criteria for assessing the quality of evidence in systematic reviews.

An important aspect to take into consideration when evaluating the Norwegian research is that most of the publications so far derive from the same two research projects: the studies from Voss and the nationwide multicenter study. This means that the same two samples have repeatedly been used in the publications. Hence, one might question the independence of data involved in the studies attached to this thesis and the other Norwegian publications [77, 107-110, 170]. As a result, evidence from independent research groups using other samples is warranted before final conclusions can be drawn concerning the evidence of Norwegian reablement.

There are, however, other aspects that one also should take into consideration. The reason for why nearly half of all Norwegian municipalities have implemented reablement, despite sparse evidence initially, is presumably that reablement entails several aspects that meet the current challenges in home-based services. Healthcare providers and policy-makers all over the country have wanted to implement reablement. They have not been willing to wait for the research evidence, as also stated elsewhere [50]. Before reablement was implemented, participants with functional decline had less chance of being offered rehabilitation in their own home and local community [38]. Moreover, policy-makers know that sustainable interventions are needed in the future facing the ageing population, and reablement appears to many to be a more sustainable intervention [50]. Health services that are cost-effective by promoting care independence, are the kind of services budget holders yearn for [50]. Furthermore, reablement reflects the shift from bio-medical thinking towards enhanced person-centredness, empowerment and emphasis on the participant's own resources

and preferences. In short, the advantages of reablement seem manifold and appear to many to be "simply the right thing to do" [50, page 4].

Implementation of reablement, though, comes with a cost. Although it is a costeffective service once it is running, there are investments needed when implementing the new service. Furthermore, we still do not know whether a consequence of implementing reablement is lower quality of other home-based services for various target groups [38, 77]. So far, very few negative experiences, disadvantages or adverse effects of reablement have been reported in Norway. In Denmark however, a country with a longer history of reablement, and where assessment of rehabilitation needs when applying for home help is compulsory, several negative experiences with reablement have been reported [73, 172]. The publications found that some participants were missing the daily contact with the staff which promoted safety, once the rehabilitation was terminated. Fear of loneliness as a result of improved care independence, has also been reported [73]. Less motivated participants are perceived as less attractive to work with by the professionals [73]. Some service-users experience a lack of respect for their assessment of the service needed, when being observed and assessed by professionals before compensating services are granted [172]. These are all concerns that are worth noticing.

In this section, the existing evidence base on reablement nationally and internationally is briefly presented. The results from this thesis contribute to strengthening that evidence base. As described previously, there are also other relevant aspects to consider when implementing reablement including its advantages and disadvantages. This reflects a broader debate about what constitutes valid evidence and how much evidence is needed before we make changes to our services [50]. It can be argued that *knowledgebased practice*, recognising that the practice wisdom of health practitioners and the lived experience of participants, can be just as valid a way of knowing the world as formal research [173]. However, from merely a scientific point of view, it can be claimed that the formal research is yet too limited and the quality of evidence too low, to justify rolling reablement out all over Norway.

The nationwide multicenter study involving 43 municipalities, from which the psychometric study and the prediction study were derived, is quite unique in a Norwegian context. Without the help from Norwegian authorities, it would not have been possible to recruit many municipalities into a research project. The Norwegian Directorate of Health required that all municipalities that were granted stimulation funds to start implementing reablement, had to be part of the research project [77]. Hence, this is a good, but unfortunately a rare, example of how the Government may stimulate research in primary care. The multitude of research sites and healthcare providers involved contributed to the rarity of this research. It is, however, a confirmation that such research is achievable, despite obstacles with infra structure, lack of culture for innovation and lack of research competence in the municipalities, as reported elsewhere [30, 31].

The modest amount of research in primary care compared to specialised healthcare services is acknowledged by Norwegian authorities [35]. Norway has had too low ambitions for research within primary care [30]. The research has had a national focus, few international publications, low prestige, little volume, and little collaboration within higher academic institutions and competence centres [30]. Despite the fact that tasks and responsibility have been transferred from specialised healthcare services to primary care as a result of the coordination reform, a corresponding transfer of research funding has not occurred. The Government states that it will facilitate research efforts that are guided towards prioritised needs [34]. Research in primary care in general, and rehabilitation research in particular, should to a higher degree be a prioritised area for Norwegian research funding. To have research programs for primary care directed by the Norwegian Research Council would be a step in the right direction. Having research as one of the health trust's statutory tasks, has been an important driver for augmented research in that sector. Correspondingly, the municipalities' role in research should in a future with larger municipalities be changed from a responsibly to partake, to a responsibility to ensure that research takes place [30].

6. General conclusions

6.1 Conclusions and implications

The results in this PhD project show that the psychometric properties of the COPM are satisfactory in a heterogeneous, home-dwelling, older population. The minimal important change is 3.0 and 3.2 points for the COPM-P and COPM-S, respectively. An implication is that at least 3 points is recommended as a cut-off in clinical practice and research in order to distinguish between older adults who report a clinical important change and those who do not. When it comes to feasibility, the healthcare providers involved, predominantly the occupational therapists, physiotherapists and nurses, reported that they had the required expertise to conduct the COPM assessments. Hence, an implication of these results is that the COPM may be used by various health professionals. The COPM is found to be a useful and manageable instrument by older adults.

The results demonstrate that a high baseline COPM score, female sex, having fracture as the major health condition, and high motivation for rehabilitation significantly predict both better occupational performance and higher satisfaction with performance 10 weeks after starting reablement. Conversely, having neurological disease other than stroke, dizziness/balance problems as the major health condition, having pain/discomfort or anxiety/depression predict poorer COPM outcomes. Hence, the results show that functional level, diagnosis, gender and motivation are significant predictors of outcomes of reablement. A clinical implication of this finding is that the intervention needs to be tailored according to the diagnosis. Finally, as including the outcome of COPM-S in the COPM instrument may not contribute with extra information, use of only the COPM-P outcome might be considered in clinical practice.

Based on the results in the current PhD project, a 10-week reablement program is found to be a superior intervention compared to usual care in terms of improving selfperceived performance and satisfaction with that performance in everyday living on a long-term basis in community-dwelling older adults. No significant group differences were found at any time point for physical capacity or health-related quality of life. For municipalities, the clinical implication of this finding might be to start offering reablement instead of conventional treatment. However, more high quality evidence is needed before such a general recommendation can be given.

In summary, this thesis has contributed to increase the insight into the psychometric properties of the COPM used on an inter-professional basis for home-dwelling older adults, the predictors of reablement, and the effectiveness of reablement.

6.2 Future perspectives

National and international research on reablement is still in its early stages and needs to be reinforced in the future. In general, the evidence base on reablement is limited and the quality of evidence is low [44, 52, 76].

On an international level, there is a need for research to establish to which degree comparisons across countries are valid, in particular regarding various service provisions, instruments to measure relevant outcomes and the home-dwelling older population itself.

There is a need for theory development with regard to reablement [40]. More theories based on empirical data that are applicable for practice, should be developed.

Regarding the psychometric properties of the COPM in a home-dwelling older population, more research is needed on reliability and responsiveness. In addition, a systematic review is needed to explore the two constructs of the COPM-P and the COPM-S in order to document a need for a revision of the instrument if the constructs are found to be very alike.

With regard to prediction of reablement, there is a need to identify additional factors that predict better outcomes in reablement. Furthermore, there is a need for subgroup analyses in order to determine which neurological diagnoses other than stroke profit from reablement and which do not. More research is also needed to identify the critical components or processes that are most effective in promoting care independence [44].

It can be derived from the effectiveness study that the whole intervention 'package' works, but there is still only limited knowledge concerning why, when, which components and for whom the intervention works. As a result, one cannot fully optimise the intervention. Hence, there is a need to reveal and understand more of the intervention black box of reablement.

Concerning the effectiveness of reablement, a marked lack of RCTs is reported, reflecting the challenges inherent in conducting research on healthcare in a real world community setting [44]. Replication of the results in other independent studies, is also needed. Moreover, RCTs with a sample of at least 400 participants are preferred to be able to establish high quality evidence. In addition, there is a demand for research that examines the long-term effects of reablement [50]. A follow up period of 2 years is recommended. A lesson learned from the effectiveness study has been the need to fully design a research study according to the Medical Research Council framework for complex interventions, in particular with regard to process evaluation, in order to avoid the pitfalls revealed.

In general, there is a great demand to strengthen research within primary care. Augmenting research on reablement will contribute to this. However, there is little doubt that the prioritation of research in primary care, is too low from Norwegian authorities.

Source of data

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Papers 1-3

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ORIGINAL RESEARCH

Psychometric properties of the Canadian Occupational Performance Measure in home-dwelling older adults

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Background: The Canadian Occupational Performance Measure (COPM) is an occupational therapy instrument designed to help participants identify, prioritize, and evaluate performance of important occupations.

Objective: To investigate the validity, responsiveness, interpretability, and feasibility of the COPM when used by various health professions in home-dwelling older adults receiving reablement. Reablement is a new form of multidisciplinary home-based rehabilitation for older adults experiencing functional decline.

Participants and methods: The sample of 225 participants, mean age 80.8 years, who were in need of rehabilitation for various health conditions were included in the study. Data collection was conducted at baseline and at 10 weeks follow-up. The COSMIN guidelines and recommendations for evaluating methodological quality were followed.

Results: Content validity, construct validity, and feasibility were found to be adequate. Responsiveness, however, was moderate. Functional mobility was the most frequently prioritized occupational category of all. Regarding interpretability, the minimal important change was 3.0 points and 3.2 points for performance and satisfaction, respectively. The older adults reported that COPM was a useful and manageable instrument. The majority of the occupational therapists, physiotherapists, and nurses reported that they had the required expertise to conduct the COPM assessments.

Conclusion: The results support the multidisciplinary use of the COPM in clinical practice and research in a home-dwelling, heterogeneous population of older adults. Based on the findings, 3 points are recommended as a cutoff point to distinguish between older adults who have a minimal important change in COPM performance and COPM satisfaction and those who have not. **Keywords:** rehabilitation, reablement, health services for the aged, COPM, validity, multidisciplinarity

Introduction

The Canadian Occupational Performance Measure (COPM) is an instrument designed to help participants identify, prioritize, and evaluate occupational performance (COPM-P) and satisfaction with performance (COPM-S) of important occupations they encounter in their daily lives.¹ The term occupation refers not only to work but also to all kinds of human doing, be it self-care, productivity, or leisure.² The COPM is an occupational therapy tool, which is now being used on a multidisciplinary basis. In Norway, the COPM is widely used in reablement as a tool for goal determination and evaluation.³ Also in other countries, COPM is used in reablement. Reablement is a relatively new form of home-based rehabilitation for people experiencing functional decline. The

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intervention, which is time limited, person-centered, and goal directed, is delivered by a multidisciplinary team.⁴⁻⁶ In Norway, where rehabilitation is a statutory service in primary care, there has been a rapid implementation of reablement during the last 4 years.⁷ The key question underpinning the emphasis on person-centered practice in reablement is "What are important activities for you now?".⁸ The COPM is used to enhance congruence between participants' needs and priorities, professionals' clinical judgment, intervention priorities, and evaluation of outcomes and is assumed to have the capability to capture the possible effects of reablement.⁹

The psychometric properties of the COPM have been widely tested. In a literature review including 19 methodological studies conducted on various target groups, the authors conclude that the COPM is a valid, reliable (test-retest), responsive, and feasible instrument.¹⁰ Validity, test-retest reliability, and responsiveness of the COPM have been tested in older adults with various diagnoses, such as stroke,¹¹ depression,¹² hip fracture,¹³ and hand osteoarthritis.14 However, only two studies were conducted in a heterogeneous elderly population investigating validity and responsiveness, respectively.15,16 Hence, more research on content validity, construct validity, and responsiveness is needed on the oldest of old people. The Norwegian version of the COPM was tested for validity, responsiveness, testretest reliability, and feasibility in people with rheumatic diseases and had good results.14,17

Regarding interpretability, that is the degree to which one can assign qualitative meaning to an instrument's quantitative scores or change in scores,¹⁸ it is stated in the COPM manual that a change of 2 points implies an important change.¹ However, evidence to support this statement is not confirmed. We find it not plausible that the minimal important change (MIC) is constant, irrespective of diagnoses, severity of disability, age, and the COPM-P versus COPM-S dimensions. Nonetheless, one study has found the optimal cutoff to be 1.37 points and 1.90 points for occupational performance and satisfaction with occupational performance, respectively, but this study was conducted among adults.¹⁹ As a result, the MIC for the COPM has not yet been evaluated with scientific methods in a population of old people.

Some studies suggest that the COPM assessment may be performed by health professionals other than occupational therapists,^{20,21} but none of the authors have explored the various professions' self-perceived competence in conducting COPM assessments. For this reason, investigation of competence required to conduct COPM assessments, which is considered to be a part of feasibility, is warranted. Hence, the objective of this study was to investigate the content validity, construct validity, responsiveness, interpretability, and feasibility of the COPM when used by different health professionals in delivering reablement for homedwelling older adults.

Participants and methods Participants

The sample in the current study was derived from a nationwide, multicenter, clinical controlled trial evaluating the effects of reablement.22 The nationwide sample consisted of 833 participants living in 43 different municipalities. The enrollment period lasted from the beginning of April 2014 until the end of June 2015. People applying for, or referred to, public home-based services were potential participants for the study based on their self-reported activity limitations. Some of the participants had been hospitalized due to an acute illness, while others were recruited after having gradually developed functional decline not needing hospitalization or institution-based treatment. People were eligible if they were home dwelling, >18 years of age, understood spoken and written Norwegian, and experienced functional decline. The participants were excluded if they were in need of institution-based rehabilitation or nursing home placement or if they were terminally ill or cognitively diminished. The intervention group participated in reablement that lasted for a maximum of 10 weeks. The control group received care as usual.

The first 225 participants, aged 65 years and older, enrolled into the intervention group in the large multicenter study whose data have been collected at baseline and after 10 weeks were included in the current study. Hence, people who had dropped out and people whose data was not registered at 10 weeks follow-up by the time data analysis started were not included.

All participants received information about the study and gave written consent prior to study enrollment. The trial was approved by the Regional Committee for Medical and Health Research Ethics for Western Norway (REK West, 2014/57-1).

Training of data collectors

As reablement was implemented in 43 different municipalities in the nationwide study, it was essential to train data collectors to ensure high-quality data and complete data sets. A 2-day course was conducted. The first day covered the use of the COPM, containing lectures, demonstrations, and practical exercises. One representative from each of the municipalities attended the course and was responsible for the internal training in how to conduct the COPM interview. Each municipality had appointed a contact person to be in charge of communication with the researchers. On the second day, the contact persons were trained in the general procedures of the research project and data collection procedures for the other outcome measures used. Each municipality also received a trial manual that contained information on all the procedures and the data collection instruments. In addition, the researchers had close contact with all municipalities in the course of the data collection and implementation period in order to ensure adherence to the protocol and minimize occurrence of missing data.

Data collection

We collected demographic characteristic of the sample, including information on health conditions. The participants scored degree of motivation for rehabilitation on a scale from 1 to 10, where 10 was the best. We used five different outcome measures, all of which were collected at baseline and at treatment conclusion after 10 weeks. The instrument under investigation in the current study was the COPM measuring occupational performance and satisfaction with performance. The other instruments used in the multicentre study were used as comparative instruments in the current study. They comprised physical functioning (measured by the Short Physical Performance Battery [SPPB]), healthrelated quality of life (measured by the European Quality of Life Scale [EQ-5D]), coping (measured by the Sense of Coherence questionnaire [SOC-13]), and positive mental health (measured by the Mental Health Continuum - Short Form [MHC-SF]). Data were collected by the clinicians in the reablement teams who also delivered the interventions. The clinicians were blinded for the assessment when reassessing the COPM.

The COPM is a patient-specific measure, which means that it is focusing on issues that matter to each participant.²³ The instrument measures a person's self-perceived occupational performance within three occupational performance areas. Occupational performance is perceived as the result of interaction and interdependence between the person(s), the environment, and the occupation(s).¹ We used the Norwegian translation of the fourth edition of the instrument.²⁴ During a semistructured interview, the participants described which occupations they considered were important but difficult to perform. The importance of each occupation was thereafter rated on a 1–10-point scale (10= very important). Next, the participants prioritized a maximum of five of the most important occupations and rated performance and satisfaction with performance for each of these occupations on a scale from 1 to 10 (a higher score reflected better performance or higher satisfaction). Sum scores for the COPM-P or COPM-S, respectively, were calculated by adding the performance or satisfaction scores and thereafter dividing by the number of prioritized occupations.

After the COPM interview was finished, the participants were asked to rate to what degree they felt that the COPM was useful in determining goals for rehabilitation (scale 1–10, 10= very useful), and they answered open questions regarding the scoring process, their experiences, and possible difficulties in completing the interview and scoring. Furthermore, the health care providers conducting the COPM interviews were asked to what degree they considered that the results from the assessment were useful as a basis for planning and evaluating the intervention and to rate the difficulty they experienced assisting the participant during the interview (scale 1–10, 10= very useful or very simple). Their education and need for further education in the COPM were also recorded.

The SPPB is a screening test for mobility and aims at identifying people at risk of functional decline.²⁵ The test includes a balance test, a gait test, and a chair stand test. The gait test involves 4 m of walking in preferred walking speed. Good validity, reliability, and responsiveness have been reported in a systematic review using studies where community-dwelling older adults were investigated.²⁶

EQ-5D measures health-related quality of life. The instrument consists of two parts, a questionnaire and a visual analog scale (VAS). The questionnaire has five domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) with five levels (no problems to extreme problems). The VAS gives an indication of how the participants assess their own health on a 0–100 scale, with 100 being excellent health. A structured review of the psychometric properties of the EQ-5D concluded that there is good evidence for reliability, validity, and responsiveness among older adults.²⁷

Coping was measured by the SOC-13, which was developed by Antonovsky.²⁸ The self-reported questionnaire comprised 13 items. A systematic review of 127 studies with samples of various diagnosis and age groups concluded that the SOC scale is a reliable, valid, and cross-culturally applicable instrument measuring how people manage stress and stay well.²⁹

Positive mental health was measured by the MHC-SF. This instrument measures three dimensions of the positive mental health concept.³⁰ Each of the 14 items is scored by rating the frequency of various feelings during the past month on a 6-point scale from never (0) to every day (5). Higher scores imply higher levels of positive mental health. Validity and reliability have been shown to be good in a study with a large sample of people aged 18–87 years.³¹

A 5-point global rating scale question was used to capture the participants' impression of change at 10 weeks follow-up. The question was: "To what degree have you experienced a change in management in daily activities since the start of reablement 10 weeks ago"? The five responses were: 1) "much improved"; 2) "a little improved"; 3) "no change"; 4) "a little deteriorated"; and 5) "much deteriorated".

The municipalities selected which professionals should administer which instruments. Usually, one participant was evaluated by one or two professionals who administered all the instruments.

Data analysis

The COSMIN guidelines and recommendations for evaluating methodological quality were followed.^{32,33} The acronym COSMIN stands for COnsensus-based Standards for the selection of health Measurement INstruments. The COSMIN guidelines are based on international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes.¹⁸

Content validity

According to the COSMIN terminology, content validity is defined as the degree to which the content of an instrument is an adequate reflection of the construct measured.³³ The constructs in question in the COPM are occupational performance and satisfaction with performance. Content validity was explored by answering four relevant questions:^{32,33} 1) Do all occupational categories in the COPM refer to relevant aspects of the construct? 2) Are all occupational categories relevant for the study population, for example with regard to sex and age? 3) Are all occupational categories relevant for the purpose of the instrument? and 4) Do all occupational categories together comprehensively reflect the construct?

The first question was addressed by examining whether the identified occupations in fact were occupational categories covering relevant aspects of the construct. The second question was addressed by exploring the prioritized occupations listed by the participants. Issues of interest concerning the study population were distribution of prioritized occupations according to sex and whether the occupations were relevant for older adults. The third question was answered by examining whether occupations were described within all relevant occupational categories and whether the participants were able to score the identified occupations for performance and satisfaction with performance on a 10-point scale at baseline and follow-up. The fourth question was addressed by asking each participant after the COPM interview and scoring was completed whether he or she had other important occupations not covered in the COPM interview. The participants' narrative answers were written down, grouped, and categorized.

Content validity was regarded as confirmed if >80% of the participants' answers confirmed questions 1, 3, and 4. Since some of the occupational categories are age specific, it cannot be expected that all occupations will be equally relevant for old persons as for young ones (question 2). The principal investigator performed the analysis of the participants' answers.

Construct validity

Construct validity was defined as the degree to which the COPM scores were consistent with hypotheses stating that the instrument in question validly measures the construct to be measured.33 We developed hypotheses covering all comparative instruments and both the two outcomes COPM-P and COPM-S. Hence, construct validity was based on a priori hypotheses for levels of correlation between baseline COPM-P and COPM-S sum scores and sum scores for mobility (SPPB), scores for the gait test (part of the SPPB), single-item scores on usual activities (EQ-5D), VAS scores of health-related quality of life, and sum scores for coping (SOC-13) and mental health (MHC-SF). When the instruments were measuring different constructs, low correlations were expected. Even when the constructs were similar, only low (to moderate) correlations were expected since the COPM is a patient-specific and not a fixed-item instrument, whereas the other instruments are performance tests or questionnaires with standardized items. We expected the COPM to correlate higher with the EQ-5D VAS score, and in particular with EQ-5D usual activities and the SPPB gait test, based on an assumption that these items corresponded most with the construct of occupational performance (Table 1).

Responsiveness

Responsiveness was defined as the ability of the COPM instrument to detect change over time in the construct measured.¹⁸ Evaluation of responsiveness was based on testing a priori hypotheses regarding mean differences of change scores for COPM-P and COPM-S compared with various global rating scale responses (Table 2). Our hypotheses postulated large differences in mean COPM change scores

Instrument	Dimension	COPM dimension	Hypotheses ^a	Results	Confirmed hypotheses (yes/no)
SPPB	Sum score physical function	Performance	Low	0.22*	Yes
SPPB	Single-item score, gait test	Performance	Low/moderate	0.13	Yes
EQ-5D	Single-item score, usual activities	Performance	Low/moderate	-0.36*	Yes
EQ-5D	VAS score health today	Performance	Low/moderate	0.23*	Yes
SOC-13	Sum score coping	Performance	Low	0.02	Yes
SOC-13	Sum score coping	Satisfaction	Low	0.04	Yes
MHC-SF	Sum score mental health	Performance	Low	0.03	Yes
MHC-SF	Sum score mental health	Satisfaction	Low	-0.02	Yes

Table I Construct validity hypotheses and results

Notes: *Expected level of Spearman's correlations. *Correlation is significant at 0.01 level (two-tailed).

Abbreviations: COPM, Canadian Occupational Performance Measure; SPPB, Short Physical Performance Battery; EQ-5D, European Quality of Life Scale; VAS, visual analog scale; SOC-13, Sense of Coherence questionnaire; MHC-SF, Mental Health Continuum – Short Form.

Instrument	Hypotheses	Result	Confirmed hypotheses (yes/no)
Global rating scale	Significant mean difference ^a in COPM-P change score for "no change" versus "a little improved"	-1.45*	Yes
Global rating scale	Significant difference ^a in mean COPM-S change score for "no change" versus "a little improved"	-1.12	No
Global rating scale	Significant difference ^a in mean COPM-P change score for "a little improved" versus "much improved"	-1.53**	Yes
Global rating scale	Significant difference ^a in mean COPM-S change score for "a little improved" versus "much improved"	-1.61**	Yes
SPPB (sum score)	Low correlation ^b between SPPB change scores and COPM-P change scores	0.40**	No
EQ-5D (single-item score)	Low correlation ^b between EQ-5D self-care change scores and COPM-P change scores	-0.33**	No
SOC-13 (sum score)	Low correlation ^b between SOC-13 change scores and COPM-P change scores	0.11	Yes
MHC-SF (sum score)	Low correlation ^b between MHC-SF change scores and COPM-P change scores	0.17	Yes

Table 2 Responsiveness hypotheses and results

Notes: Independent samples t-test. ^aPearson's correlation coefficient. ^aStatistically significant at 0.05 level (two-tailed). ^{aes}Statistically significant at 0.01 level (two-tailed). Abbreviations: COPM, Canadian Occupational Performance Measure; COPM-P, COPM measuring occupational performance; COPM-S, COPM measuring satisfaction with performance; SPPB, Short Physical Performance Battery; EQ-SD, European Quality of Life Scale; SOC-13, Sense of Coherence questionnaire; MHC-SF, Mental Health Continuum – Short Form.

between groups defined by responses on the global rating scale ("no change" versus "a little improved"; "a little improved" versus "much improved"). In line with the COS-MIN guidelines, evaluation of responsiveness was also based on testing predefined hypotheses for levels of correlation for change values (differences between 10 weeks follow-up and baseline scores between the COPM-P scores and scores for physical function [SPPB], single-item scores on self-care [EQ-5D], coping [SOC-13], and mental health [MHC-SF]).

As the intervention focused on occupational performance, we expected moderate-to-large changes in COPM-P, whereas we expected no or small changes in mobility measured with the SPPB, mental health measured with the MHC-SF, or coping measured with SOC-13. Thus, we hypothesized low correlations between COPM-P change scores and the change scores of these comparative instruments. Furthermore, even if self-care (measured by the EQ-5D) and COPM-P cover the same construct (occupational performance), we did not expect that the single EQ-5D item would capture change in self-care following reablement, as the self-care item implies only personal hygiene and dressing, while the COPM construct implies all kinds of daily activities. We therefore hypothesized low correlation here as well.

Interpretability

According to the COSMIN terminology, interpretability is the degree to which one can assign qualitative meaning to an instrument's quantitative scores or change in scores.¹⁸ In the current study, the important aspect was to determine the size of the MIC, which is defined as the smallest change in score which individual participants perceive as important.³² We used an anchor-based approach to determine the MIC. The 5-point global rating scale was used as a gold standard to capture the participants' impression of change in coping with their daily activities at 10 weeks follow-up. The global rating scale is suitable provided the change question refers to the same construct as the instrument under study.³² Owing to few participants, the responses in the categories "a little deteriorated" and "much deteriorated" are not reported.

Feasibility

Even if feasibility is not a psychometric property, it is described in the COSMIN recommendations as a relevant issue to consider when assessing outcome measures.³² Feasibility in this type of study refers to whether participants are able to answer the questions in the instrument and may be evaluated by exploring response rate, time spent on completion of the COPM data collection, patient burden, and required clinical expertise. We recorded the response rate and calculated median time spent on the COPM interview at baseline and follow-up. The participant's narrative answers were written down. Thereafter, the principal investigator grouped and categorized the data.

Five different health professionals were involved in the COPM assessments (nurses, occupational therapists, physiotherapists, auxiliary nurses, and social educators). However, since some interviews were performed by two or three different professionals together, these assessments were excluded from the analysis (n=39) in order to be able to compare the professionals separately. Moreover, since there was only one social educator and five auxiliary nurses, their assessments were excluded when performing significance tests.

Statistical analysis

Demographic characteristics of the participants and the COPM baseline scores were described by frequencies and mean/median scores.

Construct validity and responsiveness

Correlation tests of hypotheses are an established method of confirming construct validity and responsiveness.³² Depending on the distribution of the scores, Spearman's rho correlation or Pearson's *r* was used for testing hypotheses. A high correlation was defined as $r \ge 0.60$, moderate correlation as r > 0.30 and r < 0.60, and a low correlation as $r \le 0.30$.³⁴ Hypotheses of mean differences in COPM change scores comparing participants with various global rating scale responses ("no change" versus "a little improved", "a little improved" versus "much improved") were tested with independent samples *t*-tests. In accordance with Terwee et al, ³⁵ adequate construct validity and responsiveness were established when >75% of the hypotheses were confirmed.

Differences in mean change scores of COPM-P and COPM-S between the five different categories in the global rating scale were determined by independent samples *t*-tests. The change score in the category "a little improved" was considered to reflect the MIC.

Feasibility

Differences in self-perceived experience and competence between health professionals (nurses, occupational therapists, physiotherapists) conducting the COPM interviews were examined statistically with chi-square tests for categorical variables and one-way analysis of variance (F-tests) for continuous variables.

For the statistical analysis, IBM SPSS Statistics Version 22 (IBM Corporation, Armonk, NY, USA) was used. All *P*-values <0.05 were considered to be statistically significant.

Results

Participants

The 225 participants were primarily female (72%), the mean age was 80.8 years, and 76% lived alone. They had a variety of reasons for needing rehabilitation, most frequently fractures and balance problems, and they had a median of three additional health conditions. The participants included in this study lived in 32 of the 43 possible municipalities, representing 16 out of 19 counties stretching out from the south to the north of Norway. A total of 13.6% of the sample in the multicenter study dropped out at 10 weeks follow-up. However, an analysis comparing the participants who completed the study and the participants who dropped out showed no significant differences in baseline COPM-P and COPM-S scores (P=0.87 and P=0.83, respectively). Table 3 presents the baseline demographic characteristics.

Health care providers

A total of 78 health care providers conducted the assessments of the 225 participants. There were 12 nurses, 33 occupational therapists, 27 physiotherapists, five auxiliary nurses, and one social educator.

Content validity

The first question to be answered dealt with whether all occupational categories in the COPM refer to relevant aspects of the construct. Figure 1 shows the distribution of prioritized occupations in total and for each sex. The participants described a total of 1,371 occupations and prioritized 757 of these. The occupational performance areas

Table 3 Baseline characteristics

Baseline characteristics (N=225)	
Age, mean years (SD), range	80.8 (6.7), 65–95
Female, n (%)	162 (72.0)
Living alone, n (%)	171 (76.0)
Higher education \geq university/university college, n (%)	48 (21.3)
Retired, n (%), n=221	219 (97.3)
Motivation for rehabilitation, scale $1-10$, 10 is best, mean (SD), n=223	8.17 (2.0)
Occupational performance (COPM-P) sum score, mean (SD), n=223	3.52 (1.7)
Occupational satisfaction (COPM-S) sum score, mean (SD), n=223 $$	3.38 (1.7)
Major health condition, n (%)	
Fracture	53 (23.6)
Dizziness/balance problem	40 (17.8
Pain	24 (10.7)
Stroke	18 (8.0)
Cardiovascular disease	15 (6.7)
Problem/disease in back, hip, knee, or ankle	14 (6.2)
Rheumatoid arthritis/arthrosis	(4.9)
Respiratory disease	10 (4.4)
Unspecified functional decline	7 (3.1)
Vision problem/eye disease	4 (1.8)
Cancer	4 (1.8)
Mental illness	4 (1.8)
Other health condition	21 (9.3)
Number of additional health conditions, median (SD), IQR	3 (3.0), 0–9

Note: n is specified in the table only when the amount of participants was <225. Abbreviations: COPM, Canadian Occupational Performance Measure; COPM-P, COPM measuring occupational performance; COPM-S, COPM measuring satisfaction with performance; IQR, interquartile range; SD, standard deviation.

with >70 responses are specified in order to illustrate the most frequently prioritized occupations (Figure 1). Fifty-four statements (7%) could not be categorized into any of the occupational categories of the COPM. Forty-nine of these statements were body function items according to the International Classification of Functioning, Disability and Health terminology,³⁶ such as balance, strength, endurance, memory, and pain, while the remaining five occupations were to prevent falls, to have regular meals, to have extra energy, to have motivation for outdoor walks, and to remove plaster. To conclude, only 7% of the items/occupations did not refer to the construct.

The second question to be answered was whether all occupational categories were relevant for the study population, for example with regard to sex and age. Of the 757 prioritized occupations, 67% were in the self-care domain, 20% were in the leisure domain, and 13% were in the productivity domain. The most dominating occupational category was functional mobility (40%; Figure 1). As could be expected in a retired population, paid/unpaid work (0.3%) and play/school (0%) were prioritized by only a few participants. Relative to their proportion, household management, socialization, and quiet recreation appear to be more frequently prioritized occupations for females than for males in this population of older adults. To summarize, the frequency of prioritized occupations varied among the nine occupational categories and there were also sex-specific and age-specific variations.

The third question concerned whether all occupational categories were relevant for the purpose of the instrument. Almost all participants (>99%) were able to define occupations, thereby confirming that the instrument served the purpose of goal determination in reablement of elderly people. Likewise, almost all participants (>99%) were able to rate performance and satisfaction with performance at baseline and follow-up, which demonstrates that the instrument's purpose of evaluation was also satisfactory (the number of missing scores was 2 and 0 for COPM-P and 1 and 2 for COPM-S at baseline and 10 weeks follow-up, respectively).

Finally, the fourth question was whether all occupational categories together comprehensively reflect the construct. Following the COPM interview, 27 participants (12%) reported a total of 29 important occupations and items not covered in the interview (20 occupations reported by females and nine occupations by males). Almost all of these could, however, be categorized into the following occupational categories or items: active recreation (n=10), quiet recreation (n=6), socialization (n=4), functional mobility (n=2), community management (n=2), personal care (n=1), household management (n=1), body function (sleep and hearing; n=2), and unclassifiable (to be independent; n=1). This categorization was performed retrospectively based on the clinical judgment of the principal investigator. The results demonstrate that occupations not identified during the COPM interview also reflected the construct.

Construct validity

As shown in Table 1, all the hypotheses were confirmed, demonstrating that the construct validity of the COPM is adequate. The findings show that, in general, there is a low correlation between the COPM and the other instruments. We found a moderate correlation between COPM-P and EQ-5D usual activities, indicating that these two indices partly measure the same construct.

Responsiveness

The mean difference between COPM change scores among those answering "no change" versus "a little improved" and

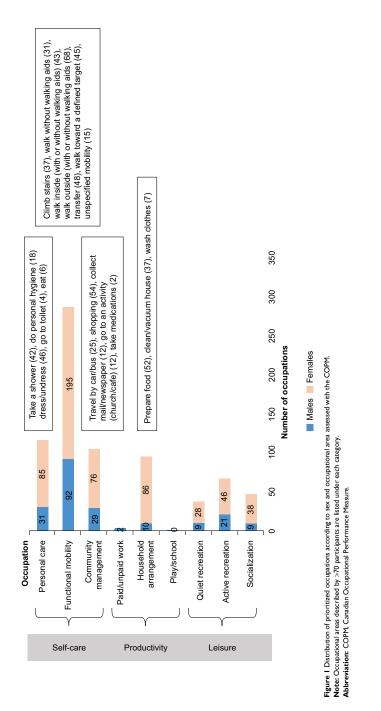


Table 4 The mean change scores (SD) for occupational performance and satisfaction with performance scored on a numerical rating scale (range 1-10), according to participants' answers in the global rating scale of perceived change

Global perceived change	Number of participants	Mean change score (SD)		
COPM-P				
Much improved	97	4.6 (2.1)		
A little improved	74	3.0* (2.0)		
No change	28	1.6 (2.2)		
COPM-S				
Much improved	96	4.8 (2.1)		
A little improved	73	3.2* (2.1)		
No change	28	2.2 (2.2)		

Notes: Independent samples t-tests performed. *The MIC.

Abbreviations: COPM, Canadian Occupational Performance Measure; COPM-P, COPM measuring occupational performance; COPM-S, COPM measuring satisfaction with performance; MIC, minimal important change; SD, standard deviation.

"a little improved" versus "much improved" was statistically significant for three of the four tested hypotheses. The correlations between difference in COPM-P change scores and the comparative instruments' change scores were low to moderate. As such only two of the four correlation hypotheses were confirmed. Table 2 shows that 62.5% (five of eight) of the hypotheses were confirmed, indicating that the responsiveness of the COPM in this population is moderate.

Interpretability

As shown in Table 4, the MIC (mean change score in participants who reported "a little improved" after 10 weeks) is 3.0 points and 3.2 points for COPM-P and COPM-S, respectively.

Feasibility

The COPM response rate was 99.5% and 100% for COPM-P and 99.5% and 99.1% for COPM-S at baseline and followup, respectively. The median time values (range) for the COPM at baseline and follow-up interview were 33 minutes (10–100 minutes) and 9 minutes (2–68 minutes), respectively.

The participants' mean (SD) rating of the degree to which they felt that the instrument was useful for goal determination was 7.8 (2.0). When examining the participants' narrative answers (n=225), the majority (82%) of the participants stated that they experienced the interview and scoring as useful. In particular, they experienced that the COPM interview contributed to information about "what is important to me". Furthermore, they felt that the COPM interview led to a greater awareness about their daily lives and to a feeling of being seen and listened to. They also described that the interview enhanced their motivation to focus on improving occupational performance, and that information brought forward during the interview and scoring process was useful as a basis for developing rehabilitation goals. However, ~10% of the participants also described difficulties with answering questions and scoring or regarded the instrument as less useful in the goal-setting process. A deeper exploration of the perceived difficulties revealed that these participants mainly experienced difficulties related to scoring; however, these difficulties were less at follow-up. In addition, some participants regarded defining a score as very abstract or theoretical and explained that they were not accustomed to thinking in this way. Finally, some participants (8%) did not give any explanation for their responses.

Concerning the question of addressing participants' experiences related to describing occupations and defining occupational goals, the majority of the participants (89%) regarded these as positive. They answered that it was "okay", referring to the interview situation, and "easy" referring to the process of goal determination. However, almost 9% of the participants also described negative experiences, most frequently related to difficulties with identifying occupations and defining goals. A minority of them said that they felt the interview itself was tiring and time consuming. Finally, some participants (2%) did not give any explanation for their negative experiences.

The health care providers' mean (SD) score of the degree to which they considered that the results from the assessment were useful as a basis for planning and evaluating on the intervention was 8.2 (1.7; Table 5). Moreover, they described that they experienced a few difficulties, 7.5 (2.0), when assisting the participant during the baseline COPM interview. Most of the health care providers had taken courses (61.8%) and/or other education in the use of the COPM (66.2%). However, 29.0% of them felt a need for additional COPM education, thereby indicating that they regarded their expertise as insufficient.

The occupational therapists, physiotherapists, and nurses believed that the COPM was useful, that they had few difficulties conducting the COPM interview, and that they had sufficient formal competence in the COPM assessment but needed to some degree additional education (Table 5). However, the one profession that was without a bachelor-level qualification deviated the most from this pattern, namely, the auxiliary nurses. These professionals considered the COPM least suitable for planning and evaluation, demonstrated less competence, and wanted more education in the COPM assessment.

Table 5 Various health care professionals' self-perceived experience and competence when conducting the COPM baseline interview

Chamatanistica	Tatal	Numero	Ormational	Dhusiathauraista	Duralius	A	Casial
Characteristics	Total	Nurses	Occupational	Physiotherapists (n=27)	r-value	-	Social
	(n=78)	(n=12)	therapists (n=33)	(n=27)		nurses (n=5)	educator (n=1)
Number of COPM interviews per	3.3 (3.4)	1.1 (0.3)	4.1 (4.0)	2.7 (2.5)	0.001	1.89 (0.9)	I.0 (NA)
professional, mean (SD), n=186							
Degree of COPM goals considered	8.2 (1.7)	7.9 (1.2)	8.4 (1.4)	8.2 (1.5)	0.3	4.4 (3.5)	9.0 (NA)
useful for planning and evaluation by							
health care provider, baseline, scale							
1-10, 10 is the best, mean (SD), n=180 ^a							
Degree of perceived difficulty assisting	7.5 (2.0)	7.3 (2.2)	7.7 (1.8)	7.3 (2.4)	0.4	6.8 (1.9)	6.0 (NA)
the participant during the baseline							
COPM interview, scale 1-10, 10 is the							
most simple, mean (SD), n=180ª							
COPM assessor has taken COPM	105 (61.8)	10 (58.8)	71 (72.4)	23 (47.9)	0.01	0	1 (100)
course, n (%) "yes", n=170ª	. ,	. ,	. ,	. ,			. ,
Number of course days in COPM,	2.0 (0.9)	1.3 (0.4)	2.2 (0.9)	1.6 (1.0)	0.003	0	1.0 (NA)
mean (SD), n=176ª	. ,	. ,	. ,				. ,
Other/additional COPM education	96 (66.2)	11 (100)	47 (58)	30 (66.7)	0.02	8 (100)	0
taken, n (%) "yes", n=145ª	. ,	. ,					
Self-perceived need for additional	51 (29.0)	8 (44.4)	22 (21.6)	14 (29.2)	0.1	7 (87.5)	1 (100)
COPM education, n (%) "yes", n=177ª	. ,	. ,					

Note: *Each health care provider has performed several COPM assessments.

Abbreviations: COPM, Canadian Occupational Performance Measure; NA, not applicable; SD, standard deviation.

Discussion

This study supports the use of the COPM in an elderly home-dwelling population and its application as an outcome measure within reablement. The study focused on the validity, responsiveness, interpretability, and feasibility of COPM in a heterogeneous population of 225 home-dwelling older adults. In general, the results show adequate content and construct validity and suggest moderate responsiveness to change. Functional mobility was the most frequently prioritized occupational category of all. The MIC was found to be 3.0 points and 3.2 points for COPM-P and COPM-S, respectively. The majority of the occupational therapists, physiotherapists, and nurses reported that they had the required expertise to conduct the COPM assessments. Having a bachelor-level qualification as a health care provider seems to be an advantage when conducting the COPM assessments.

Content validity

The sex pattern related to prioritized occupations and the low proportion of participants reporting problems related to paid/unpaid work and play/school were in line with what would be expected in this population of old and retired participants, thereby confirming content validity. Furthermore, the finding that functional mobility was the most frequently prioritized occupation by the participants is in accordance with the results from other studies on older adults.^{9,13,16,20,37} This suggests that mobility is a key priority among older

important to address in interventions aimed at enhancing occupational performance and satisfaction with performance in this age group.
 Responsiveness

adults as a basis for management of self-care, productivity, and leisure occupations and underlines that mobility is

In this study, <75% of the responsiveness hypotheses were confirmed. However, according to de Vet et al,³² responsiveness can be considered to be high when <25% of the hypotheses are rejected, moderate if 25%–50% of the hypotheses are rejected, and poor when >50% of the hypotheses are rejected. In our study, three out of eight (37.5%) of the responsiveness hypotheses were rejected, suggesting moderate responsiveness. These results are in contrast to the other responsiveness study on a heterogeneous old population, where high responsiveness was indicated.¹⁶ However, in this study, high responsiveness was not determined by testing hypotheses, but simply by stating that 73% of the participants reported a change score of ≥2 points. Thus, the methodology used in the two studies differs.

Owing to a few participants in the present study in the groups reporting "no change" in performing their daily activities at 10 weeks follow-up, the power to detect statistically significant mean differences between these participants and those who reported "a little improved" may, however, be questioned. Furthermore, as correlations usually are lower when assessing change scores than single scores, low correlations were expected. In hindsight, we acknowledge that we underestimated EQ-5D's responsiveness and therefore should have hypothesized a higher correlation between change scores in COPM-P and EQ-5D self-care since they both measure the construct of occupation. In addition, we did not expect the SPPB sum change score to correlate moderately with the COPM-P change score, given the SPPB sum score includes not only gait but also balance and chair stand. However, this might be explained by the fact that the majority of the prioritized occupations were functional mobility.

As discussed in other studies adhering to the COSMIN recommendations, it is difficult to develop hypotheses concerning correlations between change scores measured with different instruments, since such hypotheses are mostly based on clinical experience.^{38,39} It is even more difficult when a patient-specific instrument is involved, as instruments such as the COPM may capture a wide variety of occupations, which thereafter are compared to instruments with a more limited number of fixed occupational domains.²¹ Thus, it is hard to predict which occupations will be chosen and prioritized by the older adults during the COPM interview. This illustrates that there is a random factor involved, which under other circumstances, might have resulted in 75% of the hypotheses being confirmed.

Interpretability

The MIC was calculated to be 3.0 points and 3.2 points for COPM-P and COPM-S, respectively, which is above the suggested MIC of 2 points in the COPM manual.¹ In general, the MIC probably varies among diagnoses and age groups and therefore needs to be determined according to specific patient groups. The clinical implication of the results is that larger improvements in performance and satisfaction than previously recommended are needed if older individuals receiving reablement perceive an improvement as important. Another implication is that at least 3 points should be considered as a cutoff point in order to distinguish between older adults who report a clinically important change and those who do not.

Feasibility

The median time for the baseline COPM interview of 33 minutes was in accordance with the time frame of 30–40 minutes in studies on adults and early older adults.^{14,40} The relatively moderate time use was therefore less than expected in this elderly and frail population, based on a general perception that older adults need more time to complete a task. Furthermore, the majority of the participants felt that the instrument was useful and reported that their experiences with the instrument were positive. Moreover, almost all the participants were able to complete the COPM interview. Consequently, the COPM is a useful and manageable instrument in a population of older adults.

Some participants experienced problems related to the scoring system. Difficulties with numeric scoring procedures in the COPM are also common for younger adults.^{17,19,40,41} As such, it might not be a generational issue, but a general difficulty for participants of all ages. Hence, in line with Kjeken et al,¹⁷ the results of this study do not support the hypotheses that scoring problems increase with older age. However, in general, clinicians might need to develop strategies for overcoming the problems with the scoring procedures.

The occupational therapists felt most competent performing the COPM assessments. This is no surprise as occupation is the core domain of concern in occupational therapy practice and education.² The reasons why the auxiliary nurses to a lesser degree thought that the COPM goals were suitable for planning and evaluation were presumably caused by a lack of comprehensive understanding of the instrument's purpose, nature, or conceptual basis. Consequently, having a bachelorlevel qualification in health care seems to be an advantage when conducting COPM assessments. These results should, however, be interpreted with caution, since the number of participants in some of the groups was small.

At any rate, the clinical implications of these results might be to underpin the COPM training when used in a multidisciplinary context, as argued by Enemark and Carlsson.²⁰

Strengths and limitations

A strength of this study is that there were few missing data. Another strength is the diagnostic and geographical heterogeneity among the participants, which implies that the results may be generalizable within this age group. However, in this study, we have examined a generic population of older adults and a generic intervention to establish the psychometric properties of the COPM. Hence, the results we found may not be generalizable to specific diagnostic groups and specific interventions, even in an elderly population. This refers in particular to the responsiveness and the MIC.

A limitation of this study is that significance testing of experience and competence among all health professionals could not be performed, due to a small number of auxiliary nurses and social educators. In addition, although a dropout analysis was performed at 10 weeks follow-up, selection bias cannot be ruled out. Furthermore, test-retest reliability of the COPM is not established in this population and should be investigated in future studies. Likewise, responsiveness should also be retested.

Conclusion

The results support the multidisciplinary use of the COPM in clinical practice and research in a home-dwelling, heterogeneous population of older adults. The COPM has adequate content validity, construct validity, and feasibility in this population of older adults and a moderate responsiveness to change. The MIC was established to be 3.0 points and 3.2 points for COPM-P and COPM-S, respectively. The COPM is found to be a useful and manageable instrument in a population of older adults. Test–retest reliability assessments and further responsiveness assessments are needed to supplement the results of this validation study.

Acknowledgments

We want to thank all the participants and the health care providers who participated in this trial. We also want to thank Bjarte Folkestad, Centre for Care Research Western Norway, for help with the data analysis setup. Finally, we want to thank the Norwegian Directorate of Health who commissioned the study.

Disclosure

The authors report no conflicts of interest in this work.

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Clinical Interventions in Aging

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ORIGINAL RESEARCH

Predictors of outcomes following reablement in community-dwelling older adults

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Background: Reablement is a rehabilitation intervention for community-dwelling older adults, which has recently been implemented in several countries. Its purpose is to improve functional ability in daily occupations (everyday activities) perceived as important by the older person. Performance and satisfaction with performance in everyday life are the major outcomes of reablement. However, the evidence base concerning which factors predict better outcomes and who receives the greatest benefit in reablement is lacking.

Objective: The objective of this study was to determine the potential factors that predict occupational performance and satisfaction with that performance at 10 weeks follow-up.

Methods: The sample in this study was derived from a nationwide clinical controlled trial evaluating the effects of reablement in Norway and consisted of 712 participants living in 34 municipalities. Multiple linear regression was used to investigate possible predictors of occupational performance (COPM-P) and satisfaction with that performance (COPM-S) at 10 weeks follow-up based on the Canadian Occupational Performance Measure (COPM).

Results: The results indicate that the factors that significantly predicted better COPM-P and COPM-S outcomes at 10 weeks follow-up were higher baseline scores of COPM-P and COPM-S respectively, female sex, having a fracture as the major health condition and high motivation for rehabilitation. Conversely, the factors that significantly predicted poorer COPM-P and COPM-S outcomes were having a neurological disease other than stroke, having dizziness/ balance problems as the major health condition and having pain/discomfort. In addition, having anxiety/depression was a predictor of poorer COPM-P outcomes. The two regression models explained 38.3% and 38.8% of the total variance of the dependent variables of occupational performance and satisfaction with that performance, respectively.

Conclusion: The results indicate that diagnosis, functional level, sex and motivation are significant predictors of outcomes following reablement.

Keywords: home-based rehabilitation, Canadian Occupational Performance Measure, aged, sex, frailty

Introduction

Reablement – or restorative care, as it is called in some countries – involves focused, time-limited interventions delivered in people's homes or outdoors in the community. It has been seen as a solution to a number of long-standing challenges in health care, including the cost pressures associated with a rapidly aging population, and is therefore being implemented in a growing number of countries.¹ There is limited evidence, although not conclusive, that reablement leads to improved function in daily occupations, physical function and health-related quality of life for home-dwelling older adults²⁻⁵ and to reduced costs and decreased demand for public health care services.⁴⁻⁶

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Reablement focuses on supporting people to relearn skills and regain confidence in daily occupations. The rehabilitation model is goal-orientated, holistic and person-centered, designed to achieve goals that matter to each individual.^{1,5} The approach is multidisciplinary in nature and aims to help home-dwelling older people live independently and in fulfilling lives following functional decline, while simultaneously reducing the need for continuing support and long-term services.² Reablement is an inclusive approach and seeks to work with all people who could benefit from this kind of support, irrespective of their age and diagnosis.¹

In Norway, rehabilitation is a statutory service in primary care. Reablement is one form of rehabilitation that has rapidly spread across the country during the last 4.5 years. To date, more than one-third of Norwegian municipalities have implemented reablement,⁷ and the majority are using the Canadian Occupational Performance Measure (COPM) as the main instrument for goal determination and evaluation.

Despite an emerging evidence base on reablement internationally, very little is known about how the intervention is configured, the optimal timing and intensity and who receives the greatest benefit.^{1,3,8} Moreover, there is limited evidence on which elements are critical in determining its effectiveness and how the effectiveness may depend upon the characteristics of the participants.^{5,9} Consequently, there is a lack of knowledge concerning predictors of changed outcomes following reablement.

Hence, the objective of this study was to determine the potential factors that predict occupational performance and satisfaction with that performance at 10 weeks follow-up.

Methods

Design and participants

This is a prospective cohort study with a sample derived from a nationwide, clinical controlled trial aimed at evaluating the effects of reablement.^{4,10} The Norwegian Directorate of Health, which commissioned the study, granted municipalities financial support if attending the research project. Since the Norwegian Directorate of Health wanted adequate geographic representation and variability with regard to the amount of participants, measures were taken to ensure that municipalities from all parts of Norway and of various sizes were included. The whole sample consisted of 833 participants, of whom 712 people were in the intervention group receiving reablement and 121 people were in the control group receiving standard health care services. Data were collected at baseline, at 10 weeks follow-up and again after 6 and 12 months. A central allocation office in each municipality recruited consecutive participants to the study. The inclusion period lasted from April 1, 2014, until June 20, 2015, while the data collection ended on December 31, 2015. People were eligible if they were home-dwelling, >18 years of age, understood Norwegian and had experienced a functional decline. Participants were excluded if they were in need of institution-based rehabilitation or nursing home placement or if they were terminally ill or cognitively reduced (subjectively assessed by health care providers based on observation and communication). More details concerning the design of the study are available in the published protocol.¹⁰ An analysis comparing the participants who completed with the participants who dropped out in the clinical controlled trial showed no significant differences in baseline COPM-P and COPM-S scores (P=0.87 and P=0.83, respectively).⁴

In this study, we included only the intervention group, as we wanted to examine the predictors of outcomes following reablement. Since having a large sample was important, we chose not to use data from the 6-month or 12-month data collection, as there would have been a high number of noncompleters and more people who dropped out. Besides, we wanted the results to be based on changes in outcomes after the intensive rehabilitation phase, not based on the subsequent follow-up periods. Consequently, our sample consisted of 712 participants living in 34 municipalities.

All participants received information about the study and gave written consent. The Regional Committee for Medical and Health Research Ethics for Western Norway approved the trial (REK West, 2014/57-1). The trial was registered at ClinicalTrials.gov on October 24, 2014, identifier: NCT02273934.

Intervention fidelity

As reablement was implemented in multiple municipalities, it was essential to train data collectors to ensure adherence to the protocol in all teams. A 1-day course was held on the use of the primary instrument, the COPM, where all municipalities sent one representative. We arranged another 1-day course for the contact persons in all municipalities focusing on the other instruments used and on the procedures of the research project with information on the required key elements of the reablement intervention. Hence, all data collectors were trained the same way. The contact person from each municipality also received a training manual with all the necessary information. The contact persons were given the responsibility of providing the requisite training to their respective team members. In addition, the project leader had close contact with all municipalities in the course of the data collection and implementation period in order to ensure intervention fidelity and follow-up of missing data. The reablement intervention consists of individual and general features as described elsewhere.¹⁰

Data collection – dependent variables

Occupational performance (COPM-P) and satisfaction with that performance (COPM-S), measured by the COPM, are typically used as primary outcomes in reablement research.4,6,11 Therefore, the COPM scores at 10 weeks follow-up were used as dependent variables in this study. The COPM instrument measures a person's self-perception of COPM-P and COPM-S outcomes in three areas: selfcare, productivity and leisure.12 During a semi-structured interview, participants described which occupations they experienced as important, but found difficult to perform. The term "occupation" is, in short, everything people do to occupy themselves, including looking after themselves, enjoying life, and contributing socially and economically to their communities.13 The importance of each occupation is rated on a 1-10 point scale (10= very important). Next, the participant is asked to prioritize a maximum of five of the most important occupations and thereafter rate performance and satisfaction with performance for each of these occupations on a scale from 1 to 10 (higher score reflects better performance and higher satisfaction). Sum scores for the COPM-P and COPM-S, respectively, are calculated by adding the performance or satisfaction scores and thereafter dividing by the number of prioritized occupations. The COPM is found to have adequate psychometric properties in a home-dwelling older population.14

Data collection – predictor variables

We collected socio-demographic data from the participants. Age, sex, living status, educational level, motivation for rehabilitation and number of additional health conditions were used as independent variables, as well as ten categories of major health conditions. We used three different instruments to gather individual functional data at baseline. In addition, a questionnaire was sent to the contact person in each municipality, with questions about municipalityspecific details.

The first instrument used was the COPM, which measures occupational performance and satisfaction with that performance, an instrument that was described earlier. Baseline scores of COPM-P and COPM-S were used as independent variables. These outcomes were regarded as a measure of functional level. The second instrument used was the Short Physical Performance Battery (SPPB), which is a physical test for balance, walking and muscle strength in the lower extremities.¹⁵ Based on the 4 m static start walking test included in the SPPB, preferred walking speed (PWS) was calculated and used as an independent variable. A walking speed >1.0 m/s is perceived as normal, a speed between 0.6 and 1.0 m/s is perceived as initial disability and a walking speed <0.6 m/s is perceived as reflecting frailty.¹⁶ Good validity, reliability and responsiveness of the SPPB were shown in a systematic review involving studies where community-dwelling older adults were investigated.¹⁷

The third instrument used was the European Quality of Life Five Dimension Five Level Scale (EQ-5D-5L) that measures health-related quality of life.¹⁸ The instrument consists of a questionnaire and a visual analog scale (VAS). The questionnaire has five domains (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) with five levels (1= no problems, 5= extreme problems). The health status today VAS score gives an indication of how the participants assess their own health on a 0–100 scale, with 100 being excellent health. The domains of pain/discomfort, anxiety/ depression and health status today were used as independent variables. A structured review of the psychometric properties of the EQ-5D-5L concluded that there is good evidence for reliability, validity and responsiveness among older adults.¹⁹

Finally, one question about the organizational team model from the municipal questionnaire was used. The organizational model within the home-based services comprises three different categories. The first and most common team model is a home-care services integrated model, where the nurses, auxiliary nurses and assistants work closely together with the occupational therapist and physiotherapist (the home-based rehabilitation services). In the second model, the rehabilitation services in collaboration with the home-care services. The third model is a specialist team model, comprising a multidisciplinary team that works only with reablement tasks and covers a larger district. Except for the three organizational models, all independent variables are presented in Table 1.

Data analysis

Continuous variables were described by means and standard deviations (SD), whereas categorical variables were described by frequencies and percentages.

Linear regression analyses were performed to investigate associations between COPM-P and COPM-S measured at

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Table I Participant characteristics at baseline

Variables	Total (N=712)
Age, mean (SD), min-max, years	78.2 (11.2), 19–95
Sex, females, frequency (%)	487 (68.7)
Living alone, frequency yes (%)	501 (70.6)
Higher education, frequency yes (%)	140 (16.7)
Major health condition, frequency (%)	
Fractures	147 (20.7)
Dizziness/balance problems	113 (15.9)
Orthopedic disease	73 (10.3)
Pain	70 (9.8)
Stroke	67 (9.4)
Arthritis	47 (6.6)
Heart disease	37 (5.2)
Pulmonary disease	29 (4.1)
Neurological disease other than stroke	24 (3.4)
Other health condition	100 (14.0)
Number of additional health conditions,	2.28 (2.02), 0-10
mean (SD), min-max	
Motivation for rehabilitation, scale 1–10,	8.2 (2.0), 1-10
10 is best, mean (SD), min–max	
Occupational performance, COPM-P, scale	3.4 (1.6), 1.0-8.5
I-10, 10 is best, mean (SD), min-max	
Occupational satisfaction, COPM-S, scale	3.4 (1.8), 1.0-8.6
I-10, 10 is best, mean (SD), min-max	
PWS test, m/s, mean (SD), min-max	0.5 (0.2), 0.1-1.9
Health status today, EQ VAS, scale 0–100,	48.6 (19.3), 0-100
100 is best, mean (SD), min–max	
Anxiety/depression, EQ-5D-5L, scale 1–5,	1.9 (0.9), 1-5
I is best, mean (SD), min-max	
Pain/discomfort, EQ-5D-5L, scale 1–5, 1 is	2.7 (1.0), 1–5
best, mean (SD), min–max	

Abbreviations: COPM, Canadian Occupational Performance Measure; COPM-P, COPM measuring occupational performance; COPM-S, COPM measuring satisfaction with performance; EQ-5D-SL, European Quality of Life Five Dimension Five Level Scale; min, minimum; max, maximum; SD, standard deviation; VAS, visual analog scale.

10 weeks and a selected set of baseline variables. Univariate analyses were first performed to screen for predictor variables for COPM-P and COPM-S. The choice of independent variables used in the univariate analyses was based on the review of literature and clinical judgment. In the next step, variables that were statistically significant at a P<0.2 level in the univariate analyses were included in multivariate regression models with additional adjustment for baseline levels of COPM-P and COPM-S, respectively.

Estimated regression coefficients from the univariate and multivariate regression analyses were reported with 95% confidence intervals and *P*-values. The R^2 (coefficient of determination) and the root mean square error (RMSE) were reported as goodness-of-fit indicators of the regression models.

Regression diagnostics were performed to investigate any violation of the assumptions of normality, linearity, multicollinearity and homoscedasticity.

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Secondary analyses were performed with interaction terms included in the regression models to assess whether an association between fracture and COPM was dependent on sex.

P-values <0.05 were considered statistically significant. Statistical analyses were performed with IBM SPSS Statistics version 23 (IBM Corporation, Armonk, NY, USA).

Results

The main baseline socio-demographic and functional characteristics are presented in Table 1. The participants were mostly female, had no higher education and were living alone. The mean age was 78 years. Fractures and dizziness/balance problems were the most frequent reasons for needing rehabilitation. The functional characteristics measured not only by PWS but also by COPM and EQ-5D VAS scores demonstrated that the participants had moderate to severe disability. Approximately 15% of the Norwegian population was living in the municipalities included in this study. The municipalities geographically stretched from the south to the north of Norway. The dropout rates for COPM-P and COPM-S were 17.1% and 17.4%, respectively, at 10 weeks follow-up.

The results from the univariate regression analyses of the associations between baseline variables and the COPM-P score at 10 weeks follow-up are presented in Table 2. All independent variables with P < 0.2 are presented in Table 2. Factors with higher *P*-values were PWS, number of additional health conditions and home-care services integrated model versus specialist team model.

Table 2 also displays the results of the multivariate regression analysis for COPM-P (Model 1). Higher baseline scores for COPM-P were associated with better COPM-P scores (b=0.20, P=0.001). Moreover, having a fracture as the major health condition predicted better outcomes (b=0.73, P=0.001). In addition, female sex and high motivation were significant predictors of higher COPM-P scores after 10 weeks. The home-care services integrated model versus the rehabilitation services integrated model did not reach statistical significance (P=0.054).

Having a neurological disease other than stroke and having dizziness/balance problems as the major health condition significantly predicted poorer COPM-P outcomes. This was also observed for having pain/discomfort and having anxiety/ depression. The model explained 38.3% of the total variance of the dependent variable COPM-P. The RMSE was equal to 1.93.

The results from the univariate regression analyses of the associations between baseline variables and the COPM-S score at 10 weeks follow-up are presented in Table 3. All

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Variables	Univariate regression (N=590)			Multivariate regression (N=590)			
	Ь	95% CI	P-value	Ь	95% CI	P-value	
Age	0.01	-0.09, 0.03	0.12	0.01	-0.02, 0.17	0.94	
Sex (female)	0.53	0.17, 0.89	0.004	0.49	0.13, 0.85	0.008	
Fracture (as major health condition)	1.10	0.70, 1.50	< 0.001	0.73	0.31, 1.15	0.001	
Dizziness/balance problems (as major health condition)	-0.58	-1.04, - 0.11	0.02	-0.79	-1.26, -0.32	0.001	
Neurological disease (as major health condition)	-1.17	-2.13, -0.22	0.02	-1.29	-2.31, -0.28	0.01	
Motivation for rehabilitation, scale 1–10, 10 is best	0.16	0.07, 0.24	< 0.001	0.13	0.05, 0.22	0.003	
Occupational performance, COPM-P, scale 1–10, 10 is best	0.18	0.07, 0.29	0.001	0.20	0.08, 0.31	0.001	
Occupational satisfaction, COPM-S, scale 1–10, 10 is best	0.17	0.07, 0.26	0.001	-	-	-	
Pain/discomfort, EQ-5D-5L, scale 1–5, 1 is best	-0.25	-0.41, -0.08	0.003	-0.19	-0.37, -0.02	0.03	
Anxiety/depression, EQ-5D-5L, scale 1–5, 1 is best	-0.25	-0.43, 0.06	0.009	-0.19	-0.38, -0.00	0.05	
Health status today, EQ VAS, scale 0–100, 100 is best	0.02	0.01, 0.03	< 0.001	0.01	-0.00, 0.15	0.28	
Home-care services integrated model versus rehabilitation services integrated model ^a	-0.34	-0.74, -0.05	0.09	-0.37	-0.75, 0.01	0.05	

Table 2 Factors at baseline associated with COPM-P outcomes at 10 weeks follow-u	ID	(Model	LI))
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Notes: b denotes unstandardized coefficients. "Favors home-care services integrated model.

Abbreviations: CI, confidence interval; COPM, Canadian Occupational Performance Measure; COPM-P, COPM measuring occupational performance; COPM-S, COPM measuring satisfaction with performance; EQ-5D-5L, European Quality of Life Five Dimension Five Level Scale; VAS, visual analog scale.

independent variables with P < 0.2 are displayed in Table 3. Factors with higher *P*-values were PWS, home-care services integrated team model versus specialist team model and home-care services integrated team model versus rehabilitation services integrated model.

Table 3 also shows the results of the multivariate regression analysis for COPM-S (Model 2). Higher baseline scores for COPM-S were associated with better COPM-S scores at 10 weeks follow-up (b=0.23, $P \le 0.001$). Furthermore, being female predicted better outcomes (b=0.63, P=0.002). In addition, having a fracture as the major health condition and high motivation were significant predictors of higher COPM-S scores after 10 weeks.

Having dizziness/balance problems as the major health condition and having a neurological disease other than stroke were significant predictors of poorer COPM-S outcomes. In addition, having pain/discomfort significantly predicted poorer outcomes. The model explained 38.8% of the total variance of the dependent variable COPM-S. The RMSE was equal to 2.07.

Analyses showed no violation of the assumptions of normality, linearity, multicollinearity and homoscedasticity in any of the models, although there was a high correlation between baseline scores of COPM-P and COPM-S (r=0.75, P=0.01). These factors were therefore not entered into the same regression models.

Variable	Univari	ate regression (I	N=588)	Multivariate regression (N=588)		
	Ь	95% CI	P-value	Ь	95% CI	P-value
Age	0.02	0.00, 0.04	0.02	0.01	-0.01, 0.02	0.55
Sex (female)	0.64	0.25, 1.02	0.001	0.63	0.24, 1.01	0.002
Fracture as major health condition	1.01	0.59, 1.44	<0.001	0.58	0.13, 1.02	0.01
Dizziness/balance problems as major health condition	-0.62	-1.11, -0.12	0.02	-0.85	-1.35, -0.35	0.001
Neurological disease as major health condition	-1.65	-2.66, -0.64	0.001	-1.75	-2.82, -0.67	0.02
Number of additional health conditions	-0.09	-0.18, -0.00	0.04	-0.02	-0.11, 0.07	0.68
Motivation for rehabilitation, scale 1–10, 10 is best	0.11	0.02, 0.20	0.02	0.11	0.01, 0.20	0.03
Occupational performance, COPM-P, scale 1–10, 10 is best	0.14	0.03, 0.26	0.02	-	-	-
Occupational satisfaction, COPM-S, scale 1–10, 10 is best	0.24	0.14, 0.35	<0.001	0.23	0.12, 0.34	< 0.00 I
Pain/discomfort, EQ-5D-5L, scale 1–5, 1 is best	-0.30	-0.47, -0.13	0.001	-0.24	-0.42, -0.06	0.01
Anxiety/depression, EQ-5D-5L, scale 1–5, 1 is best	-0.27	-0.46, -0.07	0.007	-0.17	-0.38, 0.03	0.09
Health status today, EQ VAS, scale 0–100, 100 is best	0.02	0.01, 0.03	<0.001	0.00	-0.01, 0.01	0.51

Table 3 Factors at baseline associated with better COPM-S outcomes at 10 weeks follow-up (Model 2)

Note: b denotes unstandardized coefficients.

Abbreviations: CI, confidence interval; COPM, Canadian Occupational Performance Measure; COPM-P, COPM measuring occupational performance; COPM-S, COPM measuring satisfaction with performance; EQ-5D-5L, European Quality of Life Five Dimension Five Level Scale; VAS, visual analog scale.

Secondary analyses showed that sex was not a statistically significant moderator of the association between COPM-P (P=0.93) and COPM-S (P=0.36) outcomes, respectively, and having a fracture.

Discussion

To the best of our knowledge, this is the first study identifying predictors of outcomes following reablement. The results demonstrate that a high baseline COPM score, female sex, having a fracture as the major health condition and high motivation for rehabilitation significantly predict both better occupational performance and higher satisfaction with performance 10 weeks after starting reablement. Conversely, the predictors of poorer performance and satisfaction with performance after 10 weeks are having a neurological disease other than stroke, having dizziness/balance problems as the major health condition and having high levels of pain/discomfort. In addition, having anxiety/depression is a predictor of poorer occupational performance.

Having dizziness/balance problems as the major health condition was a significant predictor for poorer performance and lower satisfaction with performance after 10 weeks. An explanation for this finding may be that dizziness and balance problems lead to fear of falling and limited activity.²⁰ Many older people live alone and feel more secure when professionals are present in their homes and guide them when performing daily occupations.²¹ Older people with dizziness and balance problems may not dare to practice on their own in daily occupations involving mobility, and, therefore, they show less progress.

A neurological disease other than stroke was also a predictor of poorer COPM outcomes. One reason for this may be that many neurological diseases are chronic and also progressive in nature with fewer prospects of improvement. This category is a collective term, and the results do not reveal to which neurological diagnoses the predictor of poorer outcomes apply. Hence, we have no knowledge of which neurological diagnoses are advantageous or disadvantageous in this respect. Future research should conduct subgroup analysis in order to determine this.

Moreover, having anxiety/depression and pain/discomfort are predictors of poorer outcomes. Chronic pain affects people's well-being and the ability to maintain an independent and active life. Mood and anxiety disorders have been found to be associated with chronic pain.²² Hence, the explanation for why these health conditions predict poorer outcomes may be that the health conditions by their nature are conditions that represent increased immobility and passivity, which implies that progress in reablement is dependent on active engagement and intensive practice.

Having a fracture diagnosis, on the other hand, is a strong predictor of better functional outcomes. Another study of people with a hip fracture supports this finding.²³ This is despite the fact that fracture is also a collective term encompassing various types of fractures with different prospects of recovery. An explanation for this finding may be that a fracture is an acute traumatic event, and improvement is expected as the fracture heals during the first weeks and months after the injury.

In summary, an important finding in this study is that diagnosis matters in reablement. In this study, several diagnoses or health conditions were found to be predictors of better or poorer outcomes. Hence, the results show that the outcomes of reablement are not irrespective of diagnosis as previously assumed.1 Due to the general features of the intervention, reablement may in some respects be considered as "one size fits all" intervention. Anyway, a "one size fits all" intervention is unlikely to suit most participants.24 However, as this is not a controlled study, there is, based on our research, insufficient evidence to support a shift of target group, for instance omitting certain diagnoses. We do not know if the participants' function would have deteriorated more without the reablement intervention. However, individual adjustments according to diagnosis may be needed in order to optimize the intervention.

Higher baseline scores were found to be associated with better COPM outcomes at 10 weeks follow-up. We find it reasonable that the participants, who scored highest initially, did the same at follow-up. Likewise, the ones who scored lowest initially also scored lowest at follow-up. Hence, the results are a reflection of the participants' development during the rehabilitation phase. Since we did not examine the change scores from baseline to follow-up, the results do not reveal which of the two groups improved the most. Therefore, the results only imply that there is an association between the pre-assessment and post-assessment functional level with regard to COPM outcomes.

A novel finding in this study is that female sex was a predictor of better COPM outcomes. Sex differences have been found in many health-related aspects, for instance in longevity in old age.²⁵ There are also sex differences in morbidity among older people.²⁶ Therefore, we had a hypothesis that female sex was a moderator of the association between COPM outcomes and having a fracture, but this hypothesis was not confirmed. Hence, we do not know why women benefit more from reablement than men do.

As could be expected, high motivation is found to be a predictor of better COPM outcomes. Motivation for rehabilitation may be present before the start of reablement or be developed during the COPM interview or in the rehabilitation phase. The importance of motivation in reablement is supported by a qualitative study, where the dynamic interactions between intrinsic and extrinsic motivational factors were found to be the main driving forces.21 Intrinsic motivation was based on the person's own willpower and responsibility, whereas extrinsic motivation was enhanced in cooperation with the reablement team. This dynamic interaction is also believed to occur during the COPM interview. The interview allows participants to identify problems in their self-care, productivity and leisure occupations and prioritize the most important of these. Hence, the participants' intrinsic motivation may be stimulated through increased awareness when defining their own goals, and their extrinsic motivation may be enhanced by the professional staff's support and engagement.21 It is also recognized that goals defined by the participants themselves motivate the most.²⁷ In the literature, clear personalized goals for the outcomes of reablement have been found to promote motivation.28 Moreover, it has been found that using a patient-specific instrument such as COPM enhances participation²⁹ and results,³⁰ while a staffdirected goal-setting and rehabilitation process reduces participant engagement.31

Even if the inclusion criterion regarding age was 18 years or older, the recruitment gave a sample of advanced age with a mean age of 78 years. Therefore, with the main proportion of the sample being old, it was not possible to provide results indicating a significant association between age and COPM outcomes. However, the results do imply that reablement can be offered to people of all ages, as stated also elsewhere.¹

The results indicated a tendency where a reablement team that derives from a municipal home-based service integrated team model in cooperation with rehabilitation services seems to provide better COPM-P outcomes, although these results were not statistically significant. This organizational model means that nurses, auxiliary nurses and assistants are the basis of the team in collaboration with rehabilitation services. Successful reablement requires an approach that stimulates the participants to do the occupations themselves.² Our results indicate that teams from the home-based services give better care-staff commitment for this approach and therefore a tendency for better outcomes after 10 weeks.

The total variance of the dependent variables explained by the two models was 38%–39% indicating that factors not explored in this study exist that can further explain COPM outcomes after reablement. The professionals' competence and the quality of their relationship with the participants may be factors that can have an impact. Future research may explore these possible explanations. We found that outcomes of COPM-P and COPM-S are predicted by nearly the same factors and the models have very similar explained variances, indicating that the two dependent variables are closely related. As a result, one may question if it is necessary to have these two dimensions in the same instrument. It may be sufficient to only measure the dimension of occupational performance (COPM-P), since the dimension satisfaction with performance (COPM-S) does not seem to contribute with additional information.

A major strength of this study is the large sample, which allowed multiple relevant variables to be tested. It has been suggested that for regression analysis, at least 20 participants are required for each factor studied.³² In this study, a maximum of 11 potential predictors were included in the regression analyses. With a sample of 588 participants at follow-up, we had enough power to assess this number of independent variables.

Another strength is the diagnostic and geographical heterogeneity among the participants, which implies that the results may be generalizable to the population of home-dwelling older adults with functional decline. There was also a great variety in health professionals providing the reablement intervention. Moreover, the study was conducted in a real-life context in multiple settings in primary care, which contributes to the representativeness of the results. However, a study consisting of 34 municipalities with multiple data collectors and health care providers presents a challenge to ensuring standardization of data collection procedures and the intervention delivered. Since measures were taken to ensure reliability in data collection and intervention fidelity, we found that the advantages surpassed the disadvantages in this respect.

A limitation in this study is that data from the control group were not included in the analyses. Hence, we cannot draw strong conclusions regarding the clinical implications of the results. However, we have pointed out some implications for future research.

Another limitation in this study is the moderate dropout at 10 weeks follow-up, which does represent a possibility of selection bias. We do not consider this as a general problem, since an analysis comparing the participants who completed and the participants who dropped out in the clinical controlled trial showed no significant differences in baseline COPM-P and COPM-S scores. However, we did not perform retention analyses in relation to diagnosis. Hence, we do not know whether there are systematic dropouts regarding specific diagnoses. In addition, the short time frame of 10 weeks is a limitation in this prediction study.

Conclusion

Reablement is not an intervention that is irrespective of diagnosis as previously assumed. As a result, individual adjustments according to diagnosis may be needed in order to optimize the intervention. The results indicate that diagnosis, functional level, sex and motivation at baseline are significant predictors of outcomes following reablement at 10 weeks follow-up.

Acknowledgments

We want to thank all the participants and the health care providers who participated in this trial. In addition, we want to thank the Norwegian Directorate of Health who commissioned the study.

Disclosure

The authors report no conflicts of interest in this work.

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STUDY PROTOCOL



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Reablement in community-dwelling adults: study protocol for a randomised controlled trial

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Abstract

Background: As a result of the ageing population, there is an urgent need for innovation in community health-care in order to achieve sustainability. Reablement is implemented in primary care in some Western countries to help meet these challenges. However, evidence to support the use of such home-based rehabilitation is limited. Reablement focuses on early, time-intensive, multidisciplinary, multi-component and individualised home-based rehabilitation for older adults with functional decline. The aim of this study is to investigate the effectiveness of reablement in home-dwelling adults compared with standard treatment in relation to daily activities, physical functioning, health-related quality of life, use of health-care services, and costs.

Methods/Design: The study will be a 1:1 parallel-group randomised controlled superiority trial conducted in a rural municipality in Norway. The experimental group will be offered reablement and the control group offered standard treatment. A computer-generated permuted block randomisation sequence, with randomly selected block sizes, will be used for allocation. Neither participants nor health-care providers will be blinded, however all research assistants and researchers will be blinded. The sample size will consist of 60 participants. People will be eligible if they are home-dwelling, over 18 years of age, understand Norwegian and have functional decline. The exclusion criteria will be people in need of institution-based rehabilitation or nursing home placement, and people who are terminally ill or cognitively reduced. The primary outcome will be self-perceived performance, and satisfaction with performance of daily activities, assessed with the Canadian Occupational Performance Measure. In addition, physical capacity, health-related quality of life, use of health-care services, and cost data will be collected at baseline, and after 3 and 9 months in both groups, and again after 15 months in the intervention group. Data will be analysed on an intention-to-treat basis using a linear mixed model for repeated measures.

Discussion: The findings will make an important contribution to evaluating cost-effective and evidence-based rehabilitation approaches for community-dwelling adults.

Trial registration: The trial was registered in ClinicalTrials.gov November 20, 2012, identifier: NCT02043262.

Keywords: Activities of daily living, Rehabilitation, Aged, Randomised controlled trial, Home-care services, Health care costs

Background

The increasing aged population, in conjunction with an expected shortage of health-care personnel in developed countries, present a huge challenge to the containment of future health-care costs [1]. Further, in times of budget cuts to front-line public services, policy makers are seeking new approaches to get more for less by

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investing the resources available in ways which have an optimal impact on outcomes [2]. As a result, in recent years, there has been an increasing interest in home-care reablement services (hereafter 'reablement') [3]. Reablement, termed 'restorative care' in US, Australia and New Zealand, is an approach to improve home-care services for older people needing care or experiencing functional decline. It is a goal-directed and intensive intervention, which takes place in the person's home and local surroundings with a focus on enhancing performance of everyday activities defined as important by the person.



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The intention is to increase independence in daily activities, and enable people to age in place, be active and participate socially and societally. The health-care providers are organised in an integrated, coordinated multidisciplinary team that works together with the person towards shared goals [4]. In Norway, a substantial proportion of municipalities are currently implementing reablement.

The effects of reablement have so far been evaluated in three randomised controlled trials (RCTs). Two of these were conducted in New Zealand, and the results showed improved social support and physical functioning [5] and improved quality of life [6]. In a third Australian RCT with 750 participants and a 2-year follow-up, reablement was compared with usual care [7]. Even if the results showed few differences between groups in individual outcomes over time, a significantly smaller proportion of the reablement group required assistance with personal care. In a later publication from the same trial, the results showed that participants in the reablement group required fewer home-care hours, were less likely to be approved for a higher level of aged care such as nursing homes, and were less likely to be in need of emergency department treatment than the conventional care group [8]. The results thereby indicate that reablement may reduce the need for ongoing home-care, as well as for other health care services.

Two studies have investigated cost-effectiveness of reablement. The results in a large British non-randomised study with 1015 participants showed no significant differences between the intervention and control groups with respect to cost savings [9]. However, the results in the aforementioned Australian RCT showed that aggregated health and home-care costs of reablement were lower than the costs of the conventional home-care [8].

In summary, the research on the effectiveness of reablement is scarce, the results are conflicting and more studies are needed.

Aims and research questions for the study

The main objective will be to evaluate health effects and cost-effectiveness of a reablement intervention compared with current standard treatment for home-dwelling adults experiencing functional decline.

More specifically, our study will answer the following research questions:

- Is reablement more effective with regard to performance and satisfaction with performance of daily activities, physical functioning, and health-related quality of life compared with standard treatment?
- Does the experimental intervention or the control intervention provide more cost-effective use of health-care resources?

Methods/Design

Study design and setting

This will be a parallel-group randomised controlled superiority trial in which all participants will be assessed at baseline, and after 3 and 9 months. Participants in the intervention group will also be re-assessed after 15 months. The study will be conducted in a primary care setting in a rural municipality in Norway with approximately 14,000 inhabitants. The intervention group will receive reablement and the control group will receive standard treatment and care. For ethical reasons, the control group will be offered reablement 9 months after baseline assessment. Thus, potential long-term effects data at 15 months after baseline will only be collected from the experimental group. The flow diagram of the study protocol is outlined in Figure 1. The protocol employs relevant standard protocol items for clinical trials according to the SPIRIT 2013 statement [10], and follows the CONSORT statement [11] for transparent reporting. The trial is registered in ClinicalTrials.gov, identifier NCT02043262.

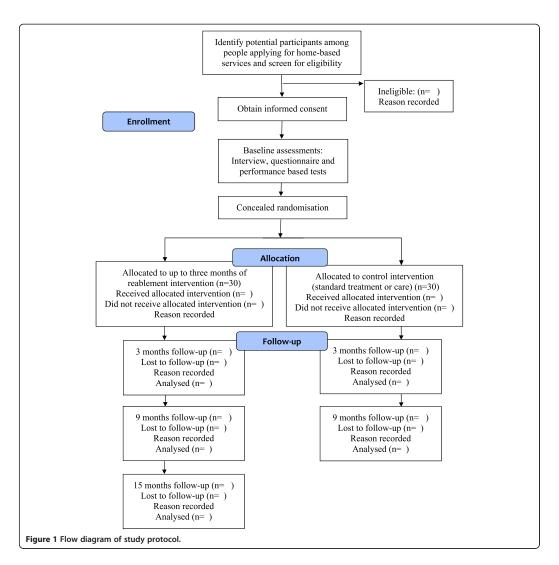
Participants and eligibility criteria

People applying for, or referred to, home-based services are potential participants in the study. Health-care providers in a central office responsible for the allocation of public health-services in the municipality will identify potential participants amongst the applicants, inform them about the new reablement service, and invite them to participate. Those who are interested will be screened for eligibility, and in order to enrol, participants will have to give their written informed consent. An additional strategy to achieve adequate participant enrolment to reach target sample size will be self-selection through advertisements.

We will include home-dwelling persons over the age of 18 years, who currently live in the municipality, are able to understand Norwegian, and have a functional decline in one or more daily activities. To enhance recruitment, the study will not be restricted to older adults even though we expect the majority of participants to be in that age group. We will exclude participants if they are in need of institution-based rehabilitation or a nursing home placement, are terminally ill, or are moderately or severely cognitively reduced (subjectively assessed by health-care providers based on observation and communication).

Randomization and allocation concealment

A bio-statistician (BE), not involved in the assignment of participants to groups, will perform the randomisation with an allocation ratio of 1:1 using a computer-generated permuted block randomisation sequence, with randomly selected block sizes. We will conceal the allocation sequence in sequentially numbered, opaque, sealed envelopes.



The allocation list will be stored in a safe deposit box in a central office in the municipality. After baseline assessments, but still in the home of the participant, the research assistant will randomly assign the participant to one of the two trial groups, by means of calling the central office. The health-care provider in this office will unlock the safe deposit box containing the allocation list and reveal information on the particular participant's group assignment. To prevent subversion of the allocation sequence, the name of the participant will be written on the envelope after disclosing group assignment in each case. Hence, neither health-care providers enrolling participants

nor research assistants will have influence on group assignment.

Blinding

Occupational therapists and physiotherapists in the municipality will conduct the baseline assessments in the participant's home prior to randomisation. The research assistants, who are also occupational therapists and physiotherapists, will be blinded to group allocation and perform all follow-up assessments. The research assistants will urge the participants not to reveal their group allocation during follow-up assessments, which will also take place in the participant's home. The success of research assistant blinding will be evaluated for both follow-ups. Due to the nature of the interventions, it will not be possible to blind participants and health-care providers. Researchers performing data entry and data analysis will, however, be blinded to group allocation.

Training of the intervention providers

Reablement will be implemented in the municipality after a period of administrative planning and competencebuilding. The competence-building will involve all the members of the multidisciplinary reablement team, such as nurses, auxiliary nurses, social educators, occupational therapists, physiotherapists, home-helpers and assistants. The health-care providers will be given lectures and seminars, and invited to attend external courses. Special attention will be given to the use of the Canadian Occupational Performance Measure (COPM) [12], a patient-specific measure which will be used to identify activity limitations and as a basis for formulating the goals that will be addressed in the reablement intervention. It will also be important to ensure that all members of the reablement team have internalised the required rehabilitation approach of encouraging the participant to selfmanagement.

Interventions

Reablement

The intervention will have a maximum duration of 3 months. As part of baseline assessments, the occupational therapist and physiotherapist will use the COPM interview to identify activity limitations perceived as important by the participant. This information will thereafter be used to develop a rehabilitation plan, and to ensure congruence between the participant's needs, therapy priorities, and interventions. After initiating the reablement intervention, the occupational therapist and Page 4 of 9

physiotherapist will supervise the home-care personnel, some of whom have no formal education, in how to encourage and assist the person in the daily training. The focus is on stimulating the participants to do the daily tasks themselves, rather than receiving help or letting others do the tasks for them. As reablement is tailored according to participants' goals, the components of the invention will vary. However, the intervention will consist of both general and individual features as described in Table 1.

The control intervention

Standard treatment/care is the conventional treatment homebound persons in most municipalities in Norway are offered, and this will be used as the comparator. For most participants, standard treatment will involve receiving the compensating help they apply for, in terms of personal or practical assistance, Meals on Wheels, safety alarm or assistive technology. However, for some participants, it may comprise rehabilitation by an occupational therapist and/or physiotherapist based on the participants' own efforts. Hence, the standard treatment will also be diverse. The standard treatment will not be timelimited, and may continue after 3 months if needed.

Outcomes

Data collection will involve the use of four different outcomes measures. In addition, cost outcomes in terms of consumption of different home-based services will be registered on a daily basis during the first 9 months after inclusion. This comprises registering minutes spent by different health professionals in the participant's home. The first author will train all research assistants in how to conduct the data collection in order to obtain protocol adherence. Table 2 provides an overview of the various outcomes that will be measured.

Table 1 Features of the reablement int	tervention
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General features	Individual features
 The rehabilitation period will be a maximum of 3 months. An occupational therapist or physiotherapist will conduct the COPM interview and develop the rehabilitation plan together with the participant based on the identified activity goals. Thereafter, an integrated multidisciplinary team with shared goals will guide the participant during the whole rehabilitation period. 	 Training in daily activities such as dressing, food preparation, vacuuming, bus transport, visiting friends at a club, or being able to knit. Adaptations such as advice on appropriate assistive technology or adapting the activity itself or the environment, in order to simplify activity performance.
 In addition to home-care personnel assisted training, a minimum of one hour physiotherapist and/or occupational therapist assisted training will be guaranteed each week. 	 Exercise programs such as indoor or outdoor walking with or without walking aids, climbing stairs, transferring, and performing exercises to improve strength, balance or fine motor skills. The exercises will be
 The treatment will involve repetitive training and multiple home-visits by health-care personnel, who will be present during daily training for the purposes of building confidence and relearning skills. 	incorporated into daily routines and the person will be given a manual explaining each of the exercises and encouraged to train on their own.
 All health-care personnel will stimulate the participant in self-management and self-training. 	

Table 2 Summary of measures to be collected

Outcome	Data collection instrument and scale	Time points
Primary outcome measures		
Activity performance	Canadian Occupational Performance Measure. Scale 1–10, 1 is low performance	t1, t2, t3
Satisfaction with activity performance	Canadian Occupational Performance Measure. Scale 1–10, 1 is low satisfaction	t1, t2, t3
Secondary outcome measures		
Lower extremity function and mobility	Timed Up and Go, measured in seconds, the second of two trials will be used	t1, t2, t3
Grip strength	Jamar dynamometer, measured in kilograms, the mean of two trials will be used	t1, t2, t3
Health-related quality of life	COOP/Wonka. Scale 1–5, 1 is low health-related quality of life	t1, t2, t3
Other measures		
Age	Years	t1
Gender	Female/Male	t1
Marital status	Married/Cohabiting/Single/Widowed/Separated or divorced	t1
Level of education	Primary school/High school/1–3 years university/> 4 years university	t1
History of paid work	Yes/No	t1
Profession	Type of work	t1
Current work status	Retired/Disability benefit/Working	t1, t2, t3
Motivation for rehabilitation	Numeric scale 1–10, 1 is lowest	t1
Main disease	Type of dominant disease	t1, t2, t3
Comorbidity	Presence of additional diseases	t1, t2, t3
Prescribed medication	Type and usage	t1, t2, t3
Un-prescribed medication	Type and usage	t1, t2, t3
Research assistant identification of participant's group assignment	Yes/No	t2, t3
Control of research assistant's identification of group assignment of participant	Intervention group/Control group	t2, t3
Health-care services and cost measures		
Warranted community-based	Type of assistance wanted	t1
assistance in time of inclusion	Home-helper/Nurse/Auxiliary nurse/Occupational therapist/Physiotherapist/ Nursing home placement long term/Nursing home placement short term/ Assisted living/Meals on Wheels/Safety alarm/Rehabilitation	
Inpatient and outpatient treatment	Frequency and type of co-interventions	t2, t3
since last assessment	Hospital admissions/Admissions to other institutions/Day centre placement/ Outpatient treatment	
Current home-based assistance offered	Presence and frequency of home-based assistance	t2, t3, t4
	Home-helper/Nurse/Auxiliary nurse/Occupational therapist/Physiotherapist/ Meals on Wheels/Reablement/No assistance	
Current community institution-based	Type of institution-based service offered	t4
service offered	Nursing home placement long-term/Nursing home placement short-term/ Day placement/Other institution placement/No institution placement	
Usage of home-based services	Daily time registration in minutes of working time used during home-visits	t5
	Home-helper/Nurse/Auxiliary nurse/Occupational therapist/Physiotherapist/ Social educator/Assistant/Speech therapist/Student	

t1 = baseline assessment, t2 = 3 months after baseline assessment, t3 = 9 months after baseline assessment, t4 = 15 months after baseline assessment, t5 = daily assessment during 9 months after baseline assessment.

Primary outcome

The primary outcome will be performance of activities of daily living and satisfaction with that performance, measured by the COPM [12]. During a semi-structured interview, the participant will be encouraged to identify problems with their self-care, productivity and leisure activities. The participant will thereafter rate importance of each identified activity on a 1 to 10-point scale, before the five most important activities are rated for performance and satisfaction with performance, again on 1 to 10-point scales (higher scores reflect higher importance, better performance or higher satisfaction). A change of two points is regarded as a clinically relevant improvement or deterioration [12].

A literature review based on 19 methodological studies [13], concludes that COPM is a valid, reliable, clinically useful and responsive outcome measure. The Norwegian version of COPM has been tested for validity and responsiveness [14] and reliability [15] in persons with rheumatic diseases with good results. Psychometric properties have also been found satisfactory in elderly persons with a variety of diagnoses [14,16,17].

Secondary outcomes

Functional mobility will be measured using the Timed Up and Go (TUG) Test, which was developed as a short test of basic mobility skills in frail community-dwelling elderly persons [18]. The participant will be encouraged to walk fast without compromising safety. The time taken to rise from a chair with arm rests, walk 3 m, cross a line on the floor, turn, walk back, and sit down again will be registered. Normative data for home-dwelling older adults exists [19]. Test-retest reliability [19] and intrarater reliability [18] in community-dwelling elderly people has been found to be excellent and moderate, respectively. Criterion validity [18] and construct validity [20] has also been found to be excellent and moderate, respectively, in a community-dwelling older population.

Grip strength will be measured with the hydraulic instrument, Jamar Dynamometer. The participant will sit in front of a table holding the dynamometer. With the elbow at 90 degrees flection, the participant will be asked to grip and squeeze the dynamometer as hard as possible. Both hands will be tested twice. The mean of the two assessments will be calculated. Normative values for average grip strength in an elderly population are available [21]. The instrument has been tested for criterion validity in a normal population [22] and test-retest reliability in community-dwelling older adults [23] with excellent results.

Health-related quality of life will be measured by the COOP/Wonka, which is a generic, self-reported outcome measure [24]. The chosen revised version [25] consists of six questions with associated drawings, where each question represents a separate domain. The responses are scored on a five-point ordinal scale ranging from 1 to 5 (1 = best, 5 = worst). In a structured review, COOP/Wonka was found to have weak evidence of reliability, adequate evidence of validity, and good evidence of responsiveness in an elderly population [26].

Sample size calculation

In an earlier study performed on older adults, the standard deviation for the primary outcome has been shown to be 1.4 for COPM performance and 1.6 for COPM satisfaction [27]. With a conservative estimate of the standard deviation of 2.5, sample size calculations showed that 21 participants need to be included in each group to detect a change of 2 points as statistically significant (with a two-sided 5% level and a power of 80%) [28]. We also assumed a within-subject correlation coefficient for the three follow-up measurements of 0.7. To take into account the possibility of a relatively high dropout rate (up to 40%) due to frail participants, 60 participants (30 people in each group) will be included.

Statistical analysis

A bio-statistician blinded to group allocation will monitor the data analysis. The intention-to-treat principle will be followed.

Descriptive statistics

Descriptive statistics of baseline characteristics, and of outcome measures at all time-points, will be presented for each group. Mean (standard deviation), median values (interquartile range), or number and percentages will be reported.

Analysis of effectiveness

Outcome measures will be compared between the treatment groups at the 3 and 9 month follow-ups using linear mixed-effects models with adjustment for baseline measurements [29]. The mixed-effects model approach (also called random coefficient model or multilevel model) will be used to account for correlated data introduced by the repeated measures study design, due to its versatility in the modelling of the time factor and in allowing varying numbers of measurements per individual. In the analyses, group and time by group interaction will be entered as fixed factors, time as a repeated factor and participant as a random factor. In the case of group imbalance in the distribution of gender or other baseline characteristics, these variables will be included in the model. Models will be fitted with random intercepts and also with random slopes. Robustness and underlying assumptions will be investigated. Estimated regression coefficients will be presented with 95% confidence intervals and p-values.

Health economic analysis

To assess potential welfare effects of the intervention, a cost-efficiency analysis (CEA) and a cost-utility analysis (CUA) will be conducted. Effect measures of the intervention are changes in COPM for the CUA and changes in e.g. grip strength for the CEA. Detailed registration of time spent at each home will enable us to establish the aggregate costs associated with provision of services for

individuals in both groups. The hourly wage including pay roll tax and other taxes for the different categories of staff members will be applied. Costs will vary according to the duration and/or type of competence that is offered to each participant. The detailed time registration will make it possible to differentiate between types of staff with respect to costs. An incremental cost efficiency ratio (ICER) will be calculated.

Potential long-term changes in the intervention group will be examined after 15 months. Employing the panel data structure, variations in cost per unit change in effect measures across individuals will be analysed, controlling for gender, age, and other variables. Both fixed effect and random effect models will be estimated.

Ethics and dissemination

The Regional Committees for Medical and Health Research Ethics (REK West, 2012/295) granted ethics approval for the study. The research will be carried out according to the Declaration of Helsinki. Personal confidentiality will be assured and a declaration of voluntary participation with information about the study purposes and consequences, emphasising the right to withdraw from the study, will be signed by each participant. The randomisation procedure is regarded as ethically acceptable, as none of the participants will receive an intervention that is below the standard she or he would otherwise have received if not participating in the trial. Besides, the control group will be offered reablement after completing 9 months follow-up. Thus, delivering an inferior rehabilitation intervention will be avoided.

We will communicate the results in peer-reviewed journals. In addition, results will be presented to healthcare professionals and the public through various regional and national events and websites.

Discussion

To our knowledge, this will be the first RCT examining the effect of reablement in a Scandinavian context. The protocol has been developed according to the SPIRIT 2013 statement [10], follows the CONSORT statement [11], and is registered in ClinicalTrials.gov, 2012/295. Reablement has evolved in countries like Sweden, Denmark and Norway in recent years and is increasingly being implemented in these countries. However, so far, only one Danish non-controlled study, evaluating if a home-based reablement program influenced the ability of older adults to perform activities of daily living, has been published in Scandinavia [30]. Current evidence from international reablement is also sparse and inconclusive [5-9] and evidence from high quality RCTs is lacking. This paper outlines the protocol for a study where the main aim is to assess the effects of reablement on a long-term basis. The trial uses a randomised controlled design, which is considered the gold standard for testing the effect of a specific intervention.

In this trial, a combination of a patient-specific measure (COPM), standardised generic measures (TUG, Jamar Dynamometer), and a questionnaire with standardised items (COOP/Wonka) will be used. The intention is that the combination of instruments will capture the multi-component nature of the experimental intervention and the effects it has on the ability to perform daily activities, functional capacity and health-related quality of life. This will also allow for comparison of populations and results across studies. In addition, the study will provide socio-demographic, health-care service consumption, and related cost data. Thus, despite the modest sample size, it will be a comprehensive study with the potential to capture a diversity of outcomes.

One limitation in the study will be the lack of blinding of participants and health-care providers. We will, however, record and evaluate the success rate of the assessor blinding strategy. Another possible limitation will be the risk of contamination from the intervention arm of the study to the control arm. Due to potential problems with recruitment in a rather sparsely inhabited municipality, the intervention will be implemented in all home-care districts in the municipality. Hence, it will not be possible to avoid the same health-care personnel providing both the experimental and control interventions, even though this will be to different participants. As a consequence, the differences between the groups may be diminished.

A third limitation may be the nature of the COPM interview, which, in a previous study, was found to have a therapeutic effect independent of further interventions [31]. In the COPM interview and scoring process, the participants in both groups will be encouraged to verbalise important activity limitations and participation restrictions. This may have an effect that results in perceptual and behavioural changes initiated by the participant, which again may blur the effects of the reablement intervention. On the other hand, reablement is a goaldirected and individualised intervention. The use of COPM will allow each participant to choose and rate the activity limitations that he/she considers important, thereby capturing aspects of everyday life that are of direct concern to the individual. As a consequence, the "noise" related to items in standardised instruments experienced as irrelevant by participants will be reduced, which in theory will have the potential to make the COPM more responsive to capturing the effects of reablement. In addition, the described activities will be used as a basis for discussing both long-term and shortterm goals for reablement, thus enhancing communication and an active role for the participant in the reablement process.

In conclusion, this study will contribute to the knowledge of the effect and cost-effectiveness of reablement in community-dwelling adults.

Abbreviations

CEA: Cost-efficiency analysis; CONSORT: Consolidated standards of reporting trials; COPM: Canadian occupational performance measure; CUA: Cost-utility analysis; ICER: Incremental cost efficiency ratio; RCT: Randomised controlled trial; SPIRT: Standard protocol items: recommendations for interventional trials; TUG: Timed up and go.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

HT initiated the study. HT and OF planned the study. HT and IK developed the research design, with help from ADH and EK concerning health-care service and cost outcomes. BE performed the randomisation and calculated the sample size. IK, BE, ADH and EK planned the data analysis. HT was responsible for the collaboration with the local project leader and for training and supervising the research assistants. HT wrote the first draft and was responsible for revisions. All authors discussed and commented on draft versions and approved the final version.

Acknowledgements

HT, BE, IK, ADH, EK and local research assistants are sponsored by Regional Research Funds Western Norway, grant number 229759. In addition, the Norwegian Association of Occupational Therapy also supports HT. We thank local project leader, Solrun Hauglum, for planning the implementation of reablement and we thank the research assistants for conducting the data collection. We also want to thank the board who planned the implementation of the intervention with representatives from the Voss municipality, Bergen University College, Centre for Care Research Western Norway, The Centre for Development of Institutional and Home Care Services in Hordaland, Voss Hospital (Helse Bergen) and The Norwegian Federation of Organisations of Disabled People (FFO). Finally, thanks to Professor Frode Fadnes Jacobsen for support during the research planning process.

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Received: 4 December 2014 Accepted: 15 December 2014 Published: 18 December 2014

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doi:10.1186/1471-2318-14-139

Cite this article as: Tuntland *et al*: **Reablement in community-dwelling** adults: study protocol for a randomised controlled trial. *BMC Geriatrics* 2014 14:139.

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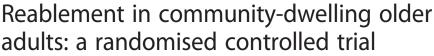
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RESEARCH ARTICLE



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Hanne Tuntland^{1,2*}, Mona Kristin Aaslund¹, Birgitte Espehaug³, Oddvar Førland^{2,4} and Ingvild Kjeken^{5,6}

Abstract

Background: There has been an increasing interest in reablement in Norway recently and many municipalities have implemented this form of rehabilitation despite a lack of robust evidence of its effectiveness. The aim of this study was to investigate the effectiveness of reablement in home-dwelling older adults compared with usual care in relation to daily activities, physical functioning, and health-related quality of life.

Methods: This is a parallel-group randomised controlled trial conducted in a rural municipality in Norway. Sixty-one home-dwelling older adults with functional decline were randomised to an intervention group (n = 31) or a control group (n = 30). The intervention group received ten weeks of multicomponent home-based rehabilitation. The Canadian Occupational Performance Measure (COPM) was used to measure self-perceived activity performance and satisfaction with performance. In addition, physical capacity and health-related quality of life were measured. The participants were assessed at baseline and a 3- and 9-month follow-ups.

Results: There were significant improvements in mean scores favouring reablement in COPM performance at 3 months with a score of 1.5 points (p = 0.02), at 9 months 1.4 points (p = 0.03) and overall treatment 1.5 points (p = 0.01), and for COPM satisfaction at 9 months 1.4 points (p = 0.03) and overall treatment 1.2 points (p = 0.04). No significant group differences were found concerning COPM satisfaction at 3 months, physical capacity or health-related quality of life.

Conclusion: A 10-week reablement program resulted in better activity performance and satisfaction with performance on a long-term basis, but not the other outcomes measured.

Trial registration: The trial was registered in ClinicalTrials.gov November 20, 2012, identifier NCT02043262.

Keywords: Rehabilitation, Activities of daily living, Older adults, COPM, Randomised controlled trial

Background

The growth in the ageing population, in combination with an expected shortage of health-care personnel in developed countries, present a huge challenge to the containment of future health-care costs [1]. A radical rethink of health-care services is required in order to address this challenge. As a consequence, there has been an increasing interest in home-care re-ablement services (hereafter 'reablement') in recent years [2, 3]. The term 'reablement' is used in the UK [4], Ireland [2], and Denmark [5], whereas this form of rehabilitation is

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known as 'restorative care' in the US [6], Australia [7], and New Zealand [8]. The two terms are however, regarded as synonyms [2, 9-11]. Reablement is a timely approach to improve home-care services for older people needing care or experiencing functional decline. The health-care providers are organised into an integrated, coordinated multidisciplinary team whose members work together with the person towards shared goals [12]. The intervention is targeted, multicomponent and intensive, and takes place in the person's home and local surroundings. The focus is on enhancing performance of daily activities defined as important by the person. The aim is to increase independence in daily activities, and enable people to age in place, be active and participate socially and in the society.



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The effects of reablement on Personal Activities of Daily Living (PADL) have been summarised in a systematic review [13], in which five trials were included. The authors concluded that there is some, but limited, evidence that reablement can reduce the home-care service users' dependency in PADL. Further, the effects of reablement have been evaluated in three randomised controlled trials (RCTs). In an Australian RCT with a 12-month follow-up, reablement was compared with usual care [11]. The trial reported outcomes such as PADL, Instrumental Activities of Daily Living (IADL), physical functioning, risk of falls and health-related guality of life. The results showed no differences between groups in individual outcomes over time, except for improvement in IADL at the 12-month follow-up for the reablement group. In addition, two RCTs were conducted in New Zealand. The first RCT investigated social support and physical functioning and found improved physical functioning in favour of reablement [8]. The second RCT investigated health-related quality of life and demonstrated significant differences in favour of reablement [14]. In summary, the research on the effectiveness of reablement is scarce and the results are inconsistent.

To the best of our knowledge, 28 % of Norwegian municipalities have implemented reablement during the last 3 years despite a lack of robust evidence of its effectiveness. In this first RCT on reablement conducted in Europe, our aim was to evaluate whether reablement is more effective with regard to self-perceived activity performance and satisfaction with performance, physical functioning, and health-related quality of life compared with usual care.

Methods

Study design and setting

We performed a parallel-group randomised controlled superiority trial in which all participants were assessed at baseline, and after 3 and 9 months. We conducted the study in a primary care setting in a rural municipality in Norway with approximately 14,000 inhabitants. The recruitment period lasted from May 2012 until February 2014. The intervention group was offered reablement and the control group was offered usual care. The study complies with the CONSORT statement [15] for transparent reporting (see Additional file 1) and is registered November 20, 2012 in ClinicalTrials.gov, identifier NCT02043262. The study protocol has been published previously [16].

Ethics approval for the study was granted by the Regional Committees for Medical and Health Research Ethics in Norway (REK West, 2012/295). All participants received information about the study and gave written consent. The research was carried out in accordance with the Declaration of Helsinki.

Participants

People applying for, or referred to, home-based services were potential participants for the study based on their self-reported activity limitations. Some of the participants had been hospitalised due to an acute illness, while others were recruited after having gradually developed functional decline not needing hospitalisation or institution-based treatment. We included home-dwelling persons over the age of 18 years, who lived in the municipality, were able to understand Norwegian, and had a functional decline in one or more daily activities. We excluded people if they were in need of institution-based rehabilitation or a nursing home placement, were terminally ill, or were moderately or severely cognitively reduced (subjectively assessed by health-care providers based on observation and communication.

Randomisation and blinding

The randomisation with an allocation ratio of 1:1 using a computer-generated permuted block randomisation sequence, with randomly selected block sizes of lengths 2 and 4, was performed by a biostatistician not involved in the assignment of participants to groups. We concealed the allocation sequence in sequentially numbered, opaque, sealed envelopes. The allocation list was stored in a safe deposit box in a central office in the municipality. Neither health-care providers enrolling participants nor research assistants had influence on group allocation. The research assistants conducted the baseline assessments in the participant's home prior to randomisation. The participants were urged not to reveal their group allocation to the research assistants during follow-up assessments. The success of the research assistants' blinding was recorded. Researchers conducting data entry and data analysis were blinded to group allocation.

Interventions

Reablement

The Canadian Model of Occupational Performance and Engagement (CMOP-E) [17] matches the client-centred reablement intervention and was used as a theoretical framework in the study. In CMOP-E, occupational performance is perceived as the result of interaction and interdependence between the person(s), the environment, and the occupation(s). Accordingly, the primary outcome was measured by the Canadian Occupational Therapy Performance (COPM), which was developed as part of the first version of the CMOP-E [17]. COPM is a client-centred tool to enable individuals to identify and prioritise everyday issues that restrict or impact their performance in everyday living. COPM focuses on enabling people to perform activities they experience as difficult, but important in their daily life. As a consequence, the therapeutic process is tailored according to the needs

and aims of the individual participant, resulting in differences in the number and type of elements in the intervention across participants, as described elsewhere [16]. However, the intervention consisted of both general and individual features. Among the general features was a maximum rehabilitation period of 3 months. Further, as part of baseline assessments, the occupational therapist and physical therapist used the COPM to identify activity limitations perceived as important by the participant. Thereafter, this information was used to develop a rehabilitation plan. The therapists supervised the homecare personnel, some of whom had no formal education (assistants), in how to encourage and assist the person in the daily training. The focus was on stimulating the participants to perform the daily activities themselves, rather than letting others do it for them. Among the individual features were training in daily activities, adaptations to the environment or the activity, and exercise programs.

All health-care personnel attained training before the intervention was implemented, in particular in the ideology of self-management. The therapists took courses and were instructed in how to conduct the assessments. The therapists had weekly informal lunch meetings with the home-care staff in order to ensure good communication and follow-up of individual participants. Simpler physical exercises or skills training the assistants could provide, were illustrated and described in a booklet in the participant's home and also demonstrated during the informal meetings. New staff members were given extra attention in order to ensure adherence to the treatment.

The control intervention

Usual care was chosen as the comparator, as this is the conventional treatment offered to homebound persons in most municipalities in Norway. For most participants, usual care meant receiving the compensating help they applied for, in terms of personal or practical assistance, safety alarm, meals on wheels, or assistive technology. However, for a few participants, it comprised rehabilitation assisted by an occupational therapist (n = 1) and/or physical therapist (n = 5) based on the participants' own efforts. Hence, the usual care was also diverse. Usual care was not time-limited, and persisted after the 3 months intervention period if needed.

Outcome measures

Socio-demographic characteristics were collected at baseline. We used four different outcome measures, which were collected at the three measurement time points. Cointerventions were registered for hospital admissions, institution-based rehabilitation, day centre placement, and outpatient treatment at both follow-ups. Work hours allocated to home-based services and distribution of healthcare professions were collected daily during the first 3 months. A detailed description of measurements and outcomes collected are published in the protocol [16].

Primary outcome

Self-perceived activity performance and satisfaction with that performance were measured by the COPM [17]. During a semi-structured interview, the participant was encouraged to identify problems with his/her self-care, productivity and leisure activities. The participant rated the importance of each identified activity (range 1 to 10, 10 = extremely important). Thereafter, the participant prioritised and rated the five most important activities in performance and satisfaction with performance again on 1 to 10-point scales (higher scores reflect better performance or higher satisfaction). For the reablement group, the rehabilitation goals were the prioritised activities, hereafter termed 'activity goals'. The activity goals identified by the control group were only used for evaluation purposes. We calculated two mean sum scores based on the performance and satisfaction scores of the activity goals in COPM, respectively. According to the COPM manual, a difference of 2 points in the mean sum score is regarded as either a clinically relevant improvement or deterioration [17].

Secondary outcomes

We measured functional mobility using the Timed Up and Go test, which is an observer-based instrument originally developed as a short test of basic mobility skills in frail community-dwelling elderly persons [18]. Normative values for community-dwelling older adults with 1.8 medical diagnoses aged 70–79 years is 9 s for both men and women [19]. The cut-off value for independent transfer in community-dwelling older adults with a variety of medical conditions is < 20 s [18].

We measured grip strength in kilograms with the hydraulic instrument, Jamar Dynamometer, according to a standard protocol [20]. Normative grip strength in a healthy community-dwelling population aged 70–79 years, is 42.4 k and 23.7 k for men and women respectively, for the right hand, and 40.5 k and 22.0 k, respectively, for the left hand [21].

Health-related quality of life was measured by the COOP/Wonka, which is a generic, self-reported outcome measure [22]. We chose the revised version [23], which consists of six questions with associated drawings, where each question represents a separate domain. The responses were scored on a five-point ordinal scale ranging from 1 to 5 (1 = best, 5 = worst).

Statistical analysis

The calculation of sample size was based on the results from an earlier study performed on older adults, in which the standard deviation for the primary outcome was 1.4 for COPM performance and 1.6 for COPM satisfaction [24]. With an assumed standard deviation of 2.5 and a within-subject correlation coefficient of 0.7, we estimated that 42 participants were needed to detect a change of 2 points as statistically significant (with a twosided 5 % level and a power of 80 %). As a high dropout rate of up to 40 % could be expected due to the potential frailty of the participants, we decided to include 60 participants (30 people in each group).

All participants were analysed according to initial group allocation (intention-to-treat). Differences at baseline between participants in the two groups were analysed by the independent samples t-test for means, the χ^2 test for proportions, and exact test when assumptions were not met. These tests were also applied in the cointervention analysis and in the analysis of usage of home-based services and distribution of health-care professions. Treatment effects (mean differences between the groups at 3 months and 9 months, and for the overall effect for the total trial period) were estimated with mixed-effects models [25], with adjustments for baseline measurements. Group and time by group interaction were entered as fixed factors, time as a repeated factor and participant as a random factor. Models were fitted with random intercepts and with random intercepts in combination with random slopes for time. Likelihood-ratio tests were performed to investigate whether a random slope improved model fit. If not, the simpler model was selected. Effect sizes defined as standardised mean differences (Cohen's d) were computed at each time point. A simple adjustment for potential baseline group differences was performed by subtracting baseline effect sizes from effect sizes at follow-up. The analyses were performed using IBM SPSS Statistics version 22 and R [26]. P-values < 0.05 were considered statistically significant.

Results

Participants

Sixty-one participants were randomised to reablement (n = 31) or to usual care (n = 30). Due to continuous monitoring of missing data during the trial period, there were few missing outcomes data. The dropout rate was 11 % and 16 % at the 3-month and 9-months follow-ups respectively, and was mainly due to deaths among participants. The flow diagram of the study is outlined in Fig. 1. No adverse events related to treatment occurred during the data collection period.

Participants were primarily older females (69 %), who lived alone (77 %) and without higher education (84 %). The baseline Timed Up and Go, Jamar dynamometer and the COOP/Wonka physical fitness scores, together with the high number of deaths, indicate a frail sample with lower physical function than normative scores for community-dwelling persons aged 70–79 years. The total number of prescribed medications was equally distributed between the two groups at all measurement time points and stable during the 9-month follow-up period, with 6 and 7 medications in the reablement group and control group, respectively. Table 1 presents the baseline demographic characteristics by study group. Overall, the baseline characteristics were well matched between the groups.

In baseline COPM interviews, the participants described 297 activity limitations of which 228 were prioritised. The distribution of activity goals among the nine activity categories are illustrated in Fig. 2. The most frequent activity goal was to improve mobility.

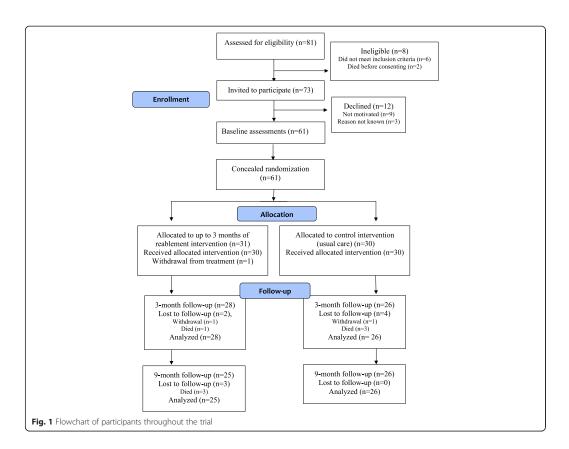
Intervention

Table 2 presents time registration data with a description of work hours allocated to home-based services and distribution of health-care professions during the first 3 months. For the reablement group the rehabilitation period lasted, on average, 10 weeks. There were no significant differences in the amount of home-based service work hours (*p*-values not shown). There were however significant differences in the distribution of health professionals (*p*-value <0.001). The higher emphasis on rehabilitation in the reablement group is reflected in the substantially higher number of home visits from therapists in this group, and also in the more diverse team composition in this group compared to the control group.

We found a significantly higher number of cointerventions at the 3-month follow-up in the control group; 12 outpatient treatments in the control group versus 3 outpatient treatments in the intervention group (p = 0.007), of which 10 of the outpatient treatments were physiotherapy (data not shown).

Primary outcomes

After 3 months, there was a significant mean difference in favour of the reablement group in the COPM performance score of 1.5 points (95 % CI: 0.3-2.8, p = 0.02) (Table 3). The difference was still significant at the 9-month follow-up with a mean difference of 1.4 points (95 % CI: 0.2-2.7, p = 0.03). Further, there was a significant overall treatment effect in the 9-month trial period of 1.5 points (95 % CI: 0.4-2.6, p = 0.01). While there were no significant differences between the groups in the COPM satisfaction scores after 3 months, the mean difference score at 9 months was 1.4 points (95 % CI: 0.4-2.7, p = 0.03), and the overall treatment score was 1.2 points (95 % CI: 0.1-2.3, p = 0.04) in favour of the reablement group. The effect sizes were moderate to large (range 0.7-0.9).



Secondary outcomes

There were no significant differences between the groups in any of the secondary outcomes after 3 or 9 months, nor in the overall mean difference scores. However, both groups improved in their mobility/balance and in most of the health-related quality of life domains, and these effects were sustained at the 9-month follow-up (Table 3). Grip strength did not improve in either of the groups.

Blinding of research assistants had a success rate of 63 % at the 3-month and 64 % at the 9-month follow-up.

Discussion

The main aim of this study was to evaluate whether reablement is more effective than usual care with regard to self-perceived activity performance and satisfaction with activity performance, physical functioning, and healthrelated quality of life. The results demonstrate that homedwelling older adults with functional decline benefit from reablement in terms of improving their self-perceived performance and satisfaction with performance in prioritised daily activities. Furthermore, these health effects were sustained on a long-term basis.

The COPM treatment effects for COPM performance of 1.4 -1.5 points are both below the cut-off value of 2 points (a 22 % change), being a clinically relevant change reported in the COPM manual [17]. However, evidence to support this cut-off value is lacking. The significant difference between groups of 1.4 points in the current study does, however, equal the optimum threshold for improvements for performance scores reported in a previous study of responsiveness of the COPM [27], and has also been used as an estimate of a clinically relevant difference in another trial [28]. Nonetheless, more studies are needed in order to establish the clinically relevant change of COPM.

As shown in Table 2, the weekly intensity of the reablement intervention was quite low. However, an important finding in this study was that despite the fact that no extra time resources were allocated to the reablement group, significant improvements were found in COPM performance and satisfaction with performance

Characteristics	Intervention ($n = 31$)	Control ($n = 30$)	<i>p</i> -value
Age, mean (SD), range	79.9 (10.4), 45	78.1 (9.8), 42	0.49
Female, no (%)	22 (71.0)	19 (63.3)	0.53
Married/cohabitating, no (%)	10 (32.3)	4 (13.3)	0.08
Education < university/university college, no (%)	27 (87.1)	24 (80.0)	0.51
Retired, no (%)	28 (90.3)	26 (86.7)	0.65
Motivation for rehabilitation, scale 1–10, 10 is best, mean (SD)	7.5 (2.3)	7.7 (2.1)	0.70
Total number of prescribed medications, mean (SD), range	6.1 (2.8), 13	6.7 (3.1), 11	0.46
Self-reported number of medical conditions, mean (SD), range	3.0 (1.7), 8	2.9 (1.1), 4	0.79
Category of main medical condition			0.42
Cardiovascular condition, no (%)	5 (16.1)	2 (6.7)	
Neurological condition included strokes, no (%)	8 (25.8)	8 (26.7)	
Orthopedic condition, no (%)	10 (32.3)	12 (40.0)	
Lung condition, no (%)	4 (12.9)	1 (3.3)	
Other/unspecified condition, no (%)	4 (12.9)	7 (23.3)	
Activity performance (COPM), sum score, scale 1–10, 10 is best, mean (SD)	2.6 (1.5)	2.8 (1.4)	0.70
Activity satisfaction (COPM), sum score, scale 1–10, 10 is best, mean (SD)	2.6 (1.6)	3.3 (1.9)	0.12
Mobility and balance (Timed Up and Go), seconds, mean (SD), $(n = 56)$	24.6 (11.9)	23.3 (17.3)	0.73
Grip strength (Jamar dynamometer), men right hand, kilograms, mean (SD), ($n = 19$)	24.4 (14.1)	28.8 (9.6)	0.43
Grip strength (Jamar dynamometer), men left hand, kilograms, mean (SD), ($n = 17$)	27.3 (13.4)	25.8 (9.0)	0.79
Grip strength (Jamar dynamometer), women, right hand, kilograms, mean (SD), ($n = 39$)	17.7 (5.7)	15.8 (6.6)	0.34
Grip strength (Jamar dynamometer), women, left hand, kilograms, mean (SD), ($n = 41$)	17.1 (6.7)	14.4 (6.1)	0.18
Physical fitness (COOP/Wonka), scale 1–5, 1 is best, mean (SD)	4.4 (0.6)	4.2 (0.7)	0.29
Feelings (COOP/Wonka), scale 1–5, 1 is best, mean (SD)	2.4 (1.5)	2.3 (0.9)	0.71
Daily activities (COOP/Wonka), scale 1–5, 1 is best, mean (SD)	3.5 (1.1)	3.2 (0.8)	0.16
Social activities (COOP/Wonka), scale 1–5, 1 is best, mean (SD)	2.4 (1.4)	2.9 (1.3)	0.13
Change in health (COOP/Wonka), scale 1–5, 1 is best, mean (SD)	2.4 (1.0)	2.1 (0.9)	0.34
Overall health (COOP/Wonka), scale 1–5, 1 is best, mean (SD)	3.0 (0.9)	2.9 (0.8)	0.46

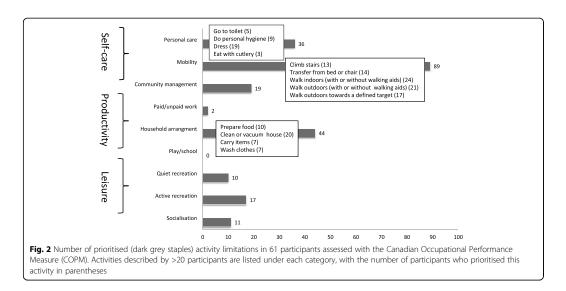
SD Standard deviation

N is only specified if less than 61 participants

Differences between groups were tested by using independent samples t-tests for means and χ^2 for proportions (exact test when assumptions were not met)

compared to the control group. This is contrary to the expectation that implementation of reablement requires more resources than usual care during the rehabilitation phase [29]. However, even though the total time resources were similar between groups, the reablement group had more therapy time and less nursing time compared to the usual care group.

Interestingly, the control group also reported increased levels of activity performance and satisfaction with performance. The same phenomenon has been reported in previous studies, where the authors suggest that the improvement may be caused by the therapeutic effect of the baseline COPM interview, which increases the control group's awareness of their activity limitations and prompts them to seek solutions themselves [28, 30]. Another explanation is the phenomenon of spontaneous recovery after an episode of functional decline. Many of the participants had fractures, where a spontaneous recovery after surgery is expected. Hence, a subgroup analysis of this group would have been interesting in order to explore this issue further. However, the sample was too small for such analysis. The improvements in the control group may also have been caused by contamination from the intervention arm of the study to the control arm. Due to problems with recruitment in a sparsely inhabited municipality, the intervention was implemented in all home-care districts in the municipality. Thus, it was not possible to avoid the situation where the same health-care personnel provided both the experimental and control interventions, however to different participants. Also, the significantly higher amount of co-interventions in terms of outpatient physiotherapy received by participants in the control group during the first 3 months might have had an impact.



Despite the significant improvements in activity performance and satisfaction with performance, there were no differences between the two groups in functional mobility, grip strength, or health-related quality of life over the trial period. This is in contrast to another trial with a similar intervention who found improvement in physical function after reablement [8]. However, our study was only statistically powered to find results for the primary outcome. As a result, the small sample size with the control group improving as well, does not rule out a Type 2 error. However, it is well established that there is a complex relationship between body functions and activity performance [31], in which physical performance such as muscle strength correlates only moderately with

Table 2 Usage of home-based services and distribution of health-care professions during the first three months

Home visits and time usage	Intervention ($n = 29$)	Control $(n = 23)$
Mean home visits pr. person (no, SD)	78 (65)	71 (82)
Mean home visits pr. person pr. week (no, SD) ^a	7 (5)	6 (7)
Mean hours home-based service pr. person (no, SD) ^b	24.7 (21.7)	20.1 (39.0)
Mean hours home-based service pr. person pr. week (no, SD) $^{\rm a\ b}$	2.1 (1.8)	1.7 (3.2)
Distribution of home visits among health-care professions	Intervention ($n = 29$)	Control $(n = 23)$
Nurse (%)	15.0	24.2
Auxiliary nurse (%)	35.0	43.2
Assistant (%)	22.7	24.0
Physical therapist (%)	9.9	2.6
Occupational therapist (%)	13.3	0.2
Social educator (%)	1.1	1.5
Speech therapist (%)	0.0	0.0
Student (%)	3.0	3.1
Unknown profession (%)	0.0	1.2
Mean number of professions involved pr. person ^c	5	3

^aBased on a 12-week data collection period

^cStudents are excluded from analysis

^bTravel time excluded

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	Reablement group Mean (95 % Cl)	Control group Mean (95 % Cl)	Adjusted effect size	Treatment effect, mean difference (95 % Cl)	<i>p</i> -value	Overall treatment effect ^d , mean difference (95 % Cl)	<i>p</i> -value
Activity performance $^{\rm e}$ (COPM) (1–10, 10 is best performance)						1.5 (0.4-2.6)	0.01
Baseline	2.6 (2.1-3.2)	2.8 (2.2-3.3)			,	ı	
3 months ^b	6.9 (6.1-7.8)	5.5 (4.7-6.3)	0.8	1.5 (0.3-2.8)	0.02		,
9 months ^c	6.3 (5.0-7.6)	4.8 (4.1-5.5)	0.7	1.4 (0.2-2.7)	0.03		
Activity satisfaction $^{\circ}$ (COPM) (1–10, 10 is best satisfaction)						1.2 (0.1-2.3)	0.04
Baseline	2.6 (2.0-3.2)	3.3 (2.6-4.0)					,
3 months ^b	6.7 (5.9-7.6)	6.0 (5.3-6.8)	0.7	1.0 (-0.3-2.2)	0.13		,
9 months ^c	6.5 (5.2-7.8)	5.2 (4.5-5.9)	0.9	1.4 (0.1-2.7)	0.03		,
Mobility and balance $^{\mathrm{f}}$ (Timed up and Go) (seconds)						-0.1 (-3.8-3.5)	0.96
Baseline	24.6 (20.1-29.2)	23.3 (16.4-30.1)					,
3 months ^b	19.6 (14.2-25.1)	17.9 (14.0-21.8)	0.1	-0.4 (-4.3-3.5)	0.82		,
9 months ^c	19.9 (14.7-25.0)	18.1 (13.4-22.8)	0.1	0.3 (-3.7-4.3)	0.88		
Grip strength ^e (Jamar dynamometer), iight hand (kilograms)						-0.4 (-2.4-1.5)	0.66
Baseline	19.6 (16.2-23.0)	20.6 (16.6-24.5)					,
3 months ^b	20.1 (17.3-22.9)	20.6 (16.4-24.7)	0.1	-0.3 (-2.5-2.0)	0.81		,
9 months ^c	18.6 (15.4-21.8)	19.5 (15.3-23.7)	0.1	-0.6 (-2.9-1.7)	0.59		
Grip strength $^{\mathrm{e}}$ (Jamar dynamometer), left hand (kilograms)						-1.1 (-3.5-1.3)	0.36
Baseline	19.8 (16.1-23.5)	18.0 (14.6-21.5)	,	1	,	ı	,
3 months ^b	20.8 (16.9-24.7)	20.0 (16.7-23.2)	-0.1	-0.1 (-3.1-2.8)	0.92		
9 months ^c	19.4 (15.9-23.0)	20.4 (15.1-25.6)	-0.3	-2.2 (-5.2-0.9)	0.16	ı	,
Physical fitness ^{fg} (COOP/Wonka) (1–5, 1 is best)						-0.2 (-0.6-0.2)	0.34
Baseline	4.4 (4.2-4.7)	4.2 (4.0-4.5)	,		,	ı	ı
3 months ^b	4.0 (3.6-4.3)	3.9 (3.5-4.3)	-0.2	0.0 (-0.4-0.5)	0.94	ı	ı
9 months ^c	3.8 (3.4-4.2)	4.1 (3.8-4.5)	-0.6	-0.4 (-0.9-0.1)	0.09	ı	
Feelings ^f (COOP/Wonka) (1–5, 1 is best)						0.0 (-0.5-0.5)	06:0
Baseline	2.4 (1.9-3.0)	2.3 (2.0-2.6)		ı		ı	
3 months ^b	2.3 (1.8-2.7)	2.2 (1.7-2.7)	0.0	0.0 (-0.5-0.6)	0.89	ı	,
9 months ^c	2.2 (1.7-2.6)	2.1 (1.7-2.5)	-0.1	0.0 (-0.6-0.6)	1.00	ı	
Daily activities ^f (COOP/Wonka) (1–5, 1 is best)						-0.4 (-0.8-0.1)	0.14
Baseline	3.5 (3.1-3.9)	3.2 (2.9-3.5)	ı	ı	,	I	ı
3 months ^b	2.7 (2.3-3.1)	2.9 (2.5-3.2)	-0.6	-0.4 (-0.9-0.2)	0.21		ı

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9 months ^c	2.5 (2.0-3.0)	2.8 (2.3-3.2)	-0.6	-0.4 (-0.3-0.5)	0.22		,
Social activities ⁶ (COOP/Wonka) (1–5, 1 is best)						0.3 (-0.3-0.8)	0.35
Baseline	2.4 (1.9-2.9)	2.9 (2.4-3.4)		ı		ı	
3 months ^b	2.3 (2.0-2.7)	2.2 (1.7-2.6)	9.0	0.4 (-0.2-1.0)	0.23		
9 months ^c	2.3 (1.7-2.8)	2.3 (1.9-2.7)	0.4	0.1 (-0.5-0.8)	0.65		
Change in health ^f (COOP/Wonka) (1–5, 1 is best)						0.0 (-0.3-0.3)	0.78
Baseline	2.4 (2.0-2.7)	2.1 (1.8-2.5)		ı		ı	
3 months ^b	2.8 (2.5-3.1)	2.6 (2.4-2.9)	0.0	0.1 (-0.2-0.5)	0.40		
9 months ^c	3.0 (2.9-3.2)	3.1 (2.9-3.4)	-0.4	-0.1 (-0.4-0.3)	0.66		
Overall health ^{f} (COOP/Wonka) (1–5, 1 is best)						-0.2 (-0.6-0.2)	0.31
Baseline	3.0 (2.7-3.4)	2.9 (2.6-3.2)					
3 months ^b	2.8 (2.5-3.0)	2.9 (2.5-3.2)	-0.3	-0.2 (-0.6-0.2)	0.36	ı	
9 months ^c	2.8 (2.4-3.1)	2.9 (2.6-3.3)	-0.4	-0.2 (-0.6-0.2)	0.40		
C/ Confidence interval							

³Adjusted for baseine values ¹Freatment effect is the estimated mean group difference at the 3-month follow-up ¹Treatment effect is the estimated mean group difference at the 3-month follow-up ² Oreall treatment effect is the estimated mean group difference for the whole trial period of 9 months ^e Dositive values favour the reablement group ^f Negative values favour the reablement group

activity performance [32]. Reablement is directed at achieving personal activity goals. Thus, an important intervention component is to perform the specified activities in the participant's home environment with healthcare professionals present. The positive effect on activity performance in the reablement group may therefore be caused by factors such as increased confidence in performing activities, and by optimising performance through adaptations of the activity and/or the environment.

The study was conducted in a real-life context in primary care. Even if the inclusion criteria permitted participation of persons over the age of 18 years, the sample turned out to be an aged, heterogeneous population with comorbidities and a wide range of functional decline. Hence, the results may not be generalisable to an adult population with other characteristics.

A strength of this study is that we used a patientspecific outcome measure to ensure congruence between participants' needs, therapy priorities, intervention and evaluation. Further, COPM allowed each participant to choose and rate the activity limitations he/she considered important. As a consequence, the 'noise' that frequently occurs in standardised instruments related to fixed items experienced as irrelevant by participants was reduced, thereby increasing the responsiveness for capturing the effects of reablement. Additional strengths are that researchers performing data entry and data analysis were blinded. Although outcomes were collected on a long-term basis, few outcomes data were missing and the dropout rate at the 9-month follow-up was low. Further, all outcomes in the study are reported according to the protocol.

Methodological limitations of this study are similar to those of many other rehabilitation trials in that participant and health-care provider blinding was impossible. The blinding of research assistants at follow-ups was not completely successful. Further, all co-interventions were not equally distributed between the groups. Treatment fidelity, i.e. if the treatment was delivered as intended [33], was not adequately monitored. Consequently, we do not know whether assistants delivered the intervention as intended. Moreover, the compliance to the interventions was not systematically recorded, and there was a possibility of contamination from one arm of the study to the other.

Conclusions

In this study, reablement was found to be a superior intervention to usual care in terms of improving selfperceived activity performance and satisfaction with performance on a long-term basis in community-dwelling older adults. However, the other outcomes measured showed no significant group differences. The intervention was given to a frail, elderly population, who still demonstrated a significant improvement despite no extra time resources being allocated.

Additional file

Additional file 1: Consort checklist. (DOC 218 kb)

Abbreviations

CONSORT: Consolidated standards of reporting trials; COPM: Canadian occupational performance measure; IADL: Instrumental activities of daily living; PADL: Personal activities of daily living; RCT: Randomised controlled trial.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

HT initiated the study. HT and OF planned the study. HT and IK developed the research design. BE performed the randomisation and calculated the sample size. HT was responsible for the collaboration with the local project leaders and for training and supervising the research assistants. HT monitored the data gathering and performed the preparations for the analyses. HT, BE, MKA and OF performed the data analysis, where BE had the main responsibility for the mixed models analysis. HT wrote the first draft and was responsible for revisions. All authors discussed and commented on draft versions and approved the final version.

Acknowledgments

We thank the local project leaders, Toril Hunnalvatn and Synnove Herre, for administering the data collection and we thank research assistants for conducting it.

Funding

HT, BE, and IK and local research assistants are sponsored by Regional Research Funds Western Norway, grant number 229759. In addition, the Norwegian Association of Occupational Therapists supported HT.

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Received: 13 May 2015 Accepted: 30 October 2015 Published online: 04 November 2015

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