

BMJ Open Evaluation of an intervention addressing a reablement programme for older, community-dwelling persons in Sweden (ASSIST 1.0): a protocol for a feasibility study

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ABSTRACT

Introduction Older persons with functional limitations often need assistance from home care staff to thrive and continue to live in their home environments. Reablement, a proactive, preventative approach administered by home care staff, stimulating active engagement of the older person, is often recommended. Even though reablement has a potential to become a new rehabilitation model and has been implemented in different countries in various degrees, there is a lack of knowledge regarding the process of establishing reablement, the theoretical underpinnings and the conditionality and outcomes in different contexts. This knowledge is needed before full-scale recommendations can be made for implementation in specific contexts.

Aim This study protocol aims to present a feasibility study of the intervention, ASSIST 1.0, a theory-based reablement programme, which includes coaching of home care staff and digitally based smart products, in a Swedish context.

Methods and analysis This feasibility study will evaluate the perceived value and acceptability of ASSIST 1.0 intervention programme regarding fidelity, reach and dose, and potential outcomes by using a pretest and post-test design involving an intervention group and a control group (n=30) of older persons living at home, needing home care services. Qualitative interviews with home care staff delivering ASSIST and the older adults receiving the intervention as well as their significant others will be conducted to explore aspects affecting the intervention.

Ethics and dissemination This study has been approved by the regional ethics board. The results of the feasibility study will form the base for refinement of the ASSIST programme and for the subsequent planning of a full-scale randomised controlled trial investigating the effect of the programme on a larger scale. Dissemination will include peer-reviewed publications and presentations at national and international conferences as well as information to involved stakeholders.

Trial registration number NCT03505619

INTRODUCTION

Background and rationale

Ageing societies worldwide are growing, creating a strong need for identifying

Strengths and limitations of this study

- ▶ A major strength of this study lies in the use of a theory-based reablement intervention programme, which involves coaching of home care staff so that the staff can provide innovative services to support older, home-dwelling persons' active participation in everyday life.
- ▶ The study is unique, including smart products for the home care staff to support the reablement philosophy and intervention.
- ▶ An additional strength lies in the combination of qualitative and quantitative data involving both older persons, their significant others, and home care staff, contributing different perspectives and thereby enriching the results.
- ▶ A potential limitation of this study protocol is the relatively small proposed sample size and the lack of randomisation of the intervention and control groups.
- ▶ An additional strength of this study is the strong adherence to a person-centred philosophy as well as using an outcome measure reflecting the older person's self-assessed performance and satisfaction of chosen, important activities in everyday life, the Canadian Occupational Performance Measure (COPM).

sustainable solutions for older people to be able to continue to live and thrive in their home environments. In order to continue to live at home, many older adults with functional limitations receive assistance from home care staff. However, the assistance must be appropriate; helping the older person with daily activities that they cannot do but at the same time stimulating the older person to do what they find meaningful and want to do and thereby increasing the older persons own activity. Since older persons describe health as doing things in their everyday life that 'keep them moving and are

meaningful',^{1 2} miss-directed assistance has the potential to be detrimental and inadvertently contribute to the pacification of the older person. This could negatively affect the older persons' health and well-being and ultimately impact their ability to continue to live in their home. In Sweden, the standard home care services are covered by the Social Services Act, a legislation that covers all forms of elderly care, mainly home care and nursing homes. This law ensures a general right to assistance if the needs cannot be met in any other way and that services should be provided in a way that ensures a 'reasonable standard of living'.

To support older people to continue to live at home, the European Commission, in the 'Social Investment Initiative' (2013) recommends member states to implement reablement services.³ Reablement services, also referred to as restorative care, are described as a home-based intervention to support older persons to manage their everyday lives in order for them to live as independently as possible.⁴ Reablement services are preventative and proactive with the active engagement of the older persons⁵ where home care staff 'do with' the older persons rather than 'do for' or 'do to' them.⁴ In this way, reablement represents a fundamental break with standard home care services for older people in Sweden, the context in which this study will be performed. Authors identify different aspects of reablement such as being person-centred,⁶ goal-directed,⁶⁻⁸ time-limited (6–12 weeks),^{6 8-10} intensive,⁷⁻¹⁰ multidisciplinary^{7 9-13} and as a multicomponent type of rehabilitation.^{8 11} Despite this, there are claims that reablement is an ill-defined intervention for an ill-defined problem.⁵

For the purpose of this project, the authors define reablement as:

A specialty service delivered by home care staff on a regular basis but time limited (8–12 weeks). Reablement consists of a person-centred approach aimed to facilitate the recipient's own active involvement and performance of valued activities in everyday life, including participating in society. Reablement should start with a person-centred assessment, where the reablement recipient is enabled to identify issues and state goals that can be either directed towards maintaining a daily activity or for achieving new or reinstating previous valued activities in everyday life. Reablement services will be initiated by rehabilitation professionals (occupational and physical therapists) and consists of the rehabilitation professionals' support of home care staff. This support includes facilitating continuous reflection and critical thinking regarding the foundations of the approach as well as direct hands-on' support together with the recipient. Reablement is evaluated by the reablement recipient together with the rehabilitation professionals and the home care staff.

Older persons that perceive themselves as having no issues in doing valued activities in everyday life are exempted from reablement programme.

Even though reablement is implemented in different countries in various degrees, there is a dearth of knowledge

about the process of establishing reablement.¹³ Reablement could be considered a complex intervention and is context dependent and therefore important to study within the conditions of a certain context with consideration for existing services, geographical and demographic conditions.¹³ Furthermore, there is a lack of systematic research regarding the conditionality and outcomes in different contexts as well as inconsistent results from existing studies.⁴ Even though reablement may seem to be 'the right thing to do', a greater understanding of this service is essential before full-scale recommendations can be made for implementation in specific contexts.^{4 14}

This study, including the intervention programme ASSIST 1.0, is designed in accordance with the Medical Research Council (MRC) guidelines on how to develop and evaluate complex interventions.¹⁵ The MRC guidance prescribes the process of developing and evaluating complex interventions based on four main phases: (1) development, (2) feasibility/piloting, (3) evaluation and (4) implementation. This present study protocol involves phases 1 and 2.

The first phase regarding development will include a process of co-creation with important stakeholders. This includes the involvement of researchers with a technical background together with home care staff, older persons and their significant others, to develop digitally based products in order to integrate them with the ASSIST reablement programme. The project planners draw on experiences within the research group dealing with information and communication technology (ICT) solutions in interdisciplinary rehabilitation interventions.¹⁶⁻¹⁸ The smart products (digitally based) will be used to facilitate and manage the reablement programme in this study. Smart products in reablement programme have been suggested but have not as yet, been integrated into services¹⁹ making this study unique.

The second phase is related to evaluating the feasibility of the programme and piloting the applied methods. Evaluation of feasibility is considered a prerequisite for evaluating the effectiveness of an intervention in order to perform a full-scale randomised controlled trial (RCT).¹⁵ In the present study, the feasibility of the first version of ASSIST 1.0 programme will be evaluated in terms of perceived value and acceptability of the intervention considering fidelity, reach and dose; and the potential outcome measures used. Since ASSIST 1.0 is a new approach to providing home care, the chosen comparator in this intervention study will be home care services practised as usual.

The reablement programme presented in the present study is not intended to replace rehabilitation performed by rehabilitation professionals and should be seen as a complement to hospital rehabilitation.

Objectives

The main purpose of this study is to contribute new knowledge to support older persons' active participation in everyday life by enabling innovative and unique

services carried out by home care staff in older persons' home settings.

More specifically, this study protocol aims to gather information on ASSIST 1.0, a theory-based reablement intervention programme, which includes coaching of home care staff and digitally based smart products, compared with ordinary home care services, in a Swedish context. In this feasibility study, we will identify and address problems which might underline the acceptability and delivery of the ASSIST intervention. Specifically, this study examines the following research questions:

1. Is the ASSIST 1.0 feasible regarding (a) the content of the intervention and the delivery, (b) study design and the involved processes and (c) the used outcomes and measures?
2. Can Assist 1.0 support older adults' performance of, and satisfaction with activities in everyday life?
3. How do the older adults' participating in ASSIST 1.0 experience their performance and satisfaction with doing activities in everyday life in relation to the older adults having home care services as usual?
4. What are the perceived value, benefits, harms or unintended consequences of the intervention and the acceptability of intervention among the home care staff involved in implementing ASSIST 1.0?

METHODS AND ANALYSIS

Trial design

This feasibility study will be conducted using a non-randomised, comparative trial with a pretest and post-test, two group design with 15 older persons in each arm, that is, an intervention group (IG) and a control group (CG).

The study will evaluate the aspects of the intervention's feasibility and potential outcomes. Further, a process evaluation, recommended by the MRC guidelines, will be conducted, to explore the way in which the intervention under study is implemented and could provide valuable insight into how the intervention works and how it can be optimised. The process evaluation will assess the fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes.¹⁵ The process evaluation will include qualitative interviews studying the older adults and their significant others who have received the ASSIST 1.0 intervention as well as the home care staff who have delivered the intervention programme. The present protocol follows the Standard Protocol Items: Recommendations for Intervention Trials 2013 statement,^{20 21} which defines standard protocol items for clinical trials.

Study setting

In phase 1, home care staff (n=218) in a designated area within Stockholm county have received a basic education organised as half-day seminars (approximately 3 hours on three separate occasions) regarding reablement, during the fall of 2017. This basic education was to inform the home care staff regarding the basic principles of

reablement and give them an opportunity to reflect on their own ways of working. These data will be used for the development and modelling of the intervention. Phase 2, organised to pilot the feasibility of the ASSIST, will include home care staff located in two designated geographical areas of Stockholm (one for the intervention and a separate area for the CG) as well as older persons, and their designated significant others (see figure 1). A registered occupational therapist (OT) working as a research assistant will conduct the pre-evaluation and post-evaluation as well as conducting the workshops and coaching sessions for the home care staff. Home care staff included in the intervention arm will, through workshops and coaching sessions offer the reablement programme to promote and support older persons own activity so that the older person can achieve their goals of doing valued activities in everyday life.⁴

Recruitment and informed consent

The home care staff will identify potential study participants and inform them verbally regarding the study and ask permission to contact the researcher. The final decision regarding inclusion will be taken together with the researchers and according to the inclusion criteria. The potential participant will be informed both verbally and in writing and given a chance to ask questions before the researcher asks for written informed consent. If the potential older adult accepts, they will then be included in the study. This procedure will be adapted in the IG as well as the CG.

If the participant identifies a significant other they will receive verbal and written information describing what the study entails for their significant other (documentation of demographic data, as well as questionnaires). If the older adult agrees, the researchers will ask permission to contact this person. After contact, the significant other will then be informed by the researcher of the study and be asked for written permission to participate in the study.

If the potential older person declines to participate in the study, the older person will receive standard home care (home care as usual).

Participants: eligibility criteria

The older person will be included if they fulfil the following inclusion criteria (1) ≥ 65 years or older and live at home, (2) home care has been granted and the user is deemed not to need home rehabilitation performed by rehabilitation professionals, (3) two or more identified challenges in everyday activities that can benefit from reablement and (4) are able to understand and express themselves in Swedish. One or more of the following reasons will result in exclusion from the study: cognitive limitations that make reablement inappropriate, in need of care in an institutional dwelling or are terminally ill, or if the older adult has had home care services for more than 3 years. The OT will perform the initial assessment and judge the older person's cognitive level through the interview. If the older person cannot describe his or her

PHASE 1: Development & modelling year 2017-2018		
1) Identifying the evidence base, 2) Identifying the theory and 3) Modelling the processes		
Activities: Literature search, meetings with different stakeholders. All home care staff (n = 218) in a designated area have received a basic education organized as half day seminars (approximately 3 hours on 3 separate occasions) regarding reablement during the fall of 2017 Co-creation workshops with important stakeholders including the involvement of to develop digitally based products in order to integrate them with the reablement services.	Researcher, home care staff, administrative personnel Focus groups interviews (n=4) with home care staff after education sessions were conducted as a part of the development and modelling the intervention. Researchers with a technical background, home care staff, significant others, older adults	
PHASE 2 Feasibility/ -piloting The ASSIST 1.0 January 2019		
1) Testing the procedure, 2) Estimating the recruitment process and 3) determining sample size		
Two different interventions directed to the persons in need of home-care and their significant others <i>ASSIST versus ordinary home help services</i>		
Intervention group (IG) An occupational therapist (OT) (research assistance) will provide specific support to the home care staff (n=15) conducting ASSIST. Activities: Workshops every other week for a minimum of 10 weeks discussions regarding: - the lived experiences of aging - a person-centred approach - activities and health + coaching occasions with the older person n=15 older persons (IG) will received ASSIST (duration: 10 weeks) n=15 significant others from IG	Control group (CG) Home care staff (n=15) conducting ordinary home help service n=15 older person (CG) receiving ordinary home help services n= 15 significant others from CG	
Assessments		
Individual interviews before and after the study.	Home care staff	n=15 individual interviews
Data collection according to organizational climate, work environment, occupational strain, psychological and social factors in the workplace, satisfaction with work.	Home care staff	IG n=30 / CG n=30
Pre-post assessment sociodemographic, provision of informal care, clinical characteristics at baseline, and the outcome measures at all time points. In depth qualitative interviews.	Older persons	IG n= 15/ CG n = 15
Pre-post assessment sociodemographic, provision of informal care, clinical characteristics at baseline, and the outcome measures at all time points. In depth qualitative interviews.	Significant others	Minimum of 5 from each group (IG/CG). Numbers dependent on the older participants.
Data collection according to the process evaluation. Log book, qualitative interview.	OT	n=1
PHASE 3: Full-scale RCT- Evaluation		
1) Evaluation 2) Understanding the change process 3) assessing the cost-effectiveness.		
Extend the study settings to other parts of Sweden (representing urban and rural areas) with cohorts in a) Stockholm, b) Östersund and c) Umeå in order to fulfill a full-scale RCT		
PHASE 4: Implementation		

Figure 1 Overall plan for the ASSIST 1.0 project. RCT, randomised controlled trial.

activities in everyday life and cannot identify an issue in performing these activities, as well as not be able to follow simple commands, the person will be disqualified. Thus, persons with milder forms of cognitive impairments will be included in the study.

When the older person in either the intervention or CG agrees to be involved in the study, they will be asked if they could consider involving a significant other. This, however, is not a criterion for participation in the study. A significant other is decided on by the older person and is defined as any person that does not have a professional relation with the older person, is deemed close to the older person and could possibly provide assistance, and

is either living with the older person or not. This could involve partners, friends or children.

The intervention program 'ASSIST 1.0' a programme for reablement in a Swedish context

The foundations of the reablement programme presented here rest on theoretical models such as The Canadian Model of Occupational Performance and Engagement regarding a person-centred approach^{22 23} and the 'Do, Live, Well' framework describing the positive connections between engaging in meaningful everyday activities and health and well-being.²⁴ Furthermore, both the workshops and coaching sessions will integrate principles

based on the older person's and the care staffs' unique lived experiences.²⁵ The ASSIST 1.0 intervention also includes smart products such as mobile phones and tablets to be used by the staff as reminders or encouragement regarding the older persons stated goals.

Duration and specific content of the intervention programme

ASSIST 1.0. is a 10-week intervention programme and uses a person-centred approach. This programme aims to empower the older person so they can do what they want and need to do, and in turn, increase their self-efficacy, perceived health and well-being.²⁶

By using the Canadian Occupational Performance Measure (COPM), the older person will identify issues in activities in everyday life.²⁷ Goals will be formulated based on the identified activities that the older person wants or needs to do in everyday life and will then be presented to the home care staff. The expectations are that the older person will experience improved satisfaction and performance of the stated activities at the end of the intervention. The OT will discuss the strategies to fulfil the goals with both the home care staff and the older adults since the objective for the home care staff is to support and enable the older person to reach their stated goals.

The coaching occasions will include practical advice and strategies for how the staff can best support the older person in achieving their goals. During the intervention period, a smart application in the home care staff mobile phone or tablet will display the set goals as well as send reminders and feedback regarding the older persons' activity goals. The ASSIST 1.0 application will also request documentation; for example, if the activity was attended to and the possible results. The purpose of this application is to enhance the communication and documentation regarding the older person's goals since home care staff at present do not use mobile phone devices in this way.

After the goal-setting process, the OT will provide both workshops and coaching sessions for the home care staff responsible for the reablement programme for the specific older person. Both the workshop sessions and coaching occasions will deal with the challenges met by the home care staff and the older person.

Workshops and coaching of the intervention providers

Thus, the ASSIST intervention encompasses two parts: the workshop sessions and the coaching occasions. The workshop sessions will be held at the regular home care staff meetings (with approximately 6–10 home care staff, 1 hour every other week), and will continue for a minimum of 10 weeks or until all of the older persons have completed the entire programme. During the workshop sessions, the home care staff together with the OT will discuss relevant issues regarding reablement, supporting the home care staffs' reflection process. Issues regarding the digital smart products developed as part of the ASSIST 1.0 will also be addressed.

The coaching occasions will include both the home care staff together with the older person and will be based primarily on the needs and wishes of the older participant. There will be the possibility to support problem solving, enabling the older person to become engaged in the daily activities he/she needs and wants to do in their daily life. The OT will, when needed, be present in the older persons' environment (home or other relevant places, ie, nearby store) together with the home care provider to give 'hands-on' advice and/or training regarding how the home care provider can best continue supporting the older person. The OT will be able to inform and demonstrate how to best advance the level of assistance concerning the amount, duration and frequency with the goal that the older person becomes more confident in performing their daily activities. Approximately three coaching sessions per included older adult will be scheduled and will be done on an as - needed basis determined from the information provided by the staff in the workshops alternatively after approximately a week after starting, and with then with about 2–3 weeks interval thereafter. Both the workshops and coaching occasions will integrate principles based on a person-centred approach,²² initiate from the older person's unique lived experiences, and his/her wishes and needs.²⁵ Whenever relevant, significant others will be involved in the coaching sessions.

Since reablement presents a new and different approach to home care staff, a process of change in the knowledge and practice of home care is anticipated. Narratives can be a useful source to access the home care staffs' professional reasoning and the present project will strive to discern any changes in the staffs' professional reasoning during the course of the programme. The theoretical model supporting both the workshops and the coaching used in the present study is based on situated learning, where knowledge is seen as integral to doing and where knowledge and practice are inseparable.²⁸ Likewise, Lauvås and Handal argue that a great deal of what takes place in the field of practice is tacit, and therefore, needs to be reflected on²⁹ in order for practice to become an object to change. Lauvås and Handal describe a praxis triangle for the three phases of a reflection process that ties together actions/experiences, theoretical base, and values and argue that active, professional coaching is essential for becoming aware of one's actions. This will be achieved by asking the workshop participants to talk about what they do in their daily work with the older persons and any issues in the provision of reablement services, encouraging the other group members to provide support and solve reablement issues together. The OT will guide these discussions, ensuring that the reablement philosophy will be upheld. Based on this knowledge, the authors hypothesise that receiving education regarding reablement is not sufficient for home care staff to accomplish a change in praxis without the central aspect of reflection on practice. Additionally, the workshops and coaching sessions will be based on co-design principles, including a focus

on home care staffs' previous experiences and their active participation in learning.³⁰

The CG: standard home care

The home care staff in the CG will provide home care services as usual to older adults participating in the CG. Home care staff in the CG will identify potential older persons to participate in the CG according to the same procedure and criteria as the IG.

Outcomes

Feasibility data

A combination of qualitative and quantitative data will be collected among the older adults and their significant others as well as the home care staff and the OT providing the support (see figure 1). The aim of the interviews is to explore aspects of perceived value, benefits, harms or unintended consequences of the intervention, acceptability of the intervention and fidelity, reach and dose of the intervention according to the participants.

The perceived degree of, for example, older adults' involvement, meaningfulness and confidence in relation to the intervention delivery will also be based on the older adults' ratings on a Visual Analogue Scale (VAS) from 1 to 5. The OT will write a log book including field notes and reflections after the workshops and coaching sessions in order to follow the process of implementation. To evaluate adherence to the intervention both the OT and the home care staff will register their follow-up meetings with the older adults, and all other services related to the intervention.

Outcome data

The primary outcome measure will be the Swedish version of the COPM.²⁷ The COPM measures the self-assessed performance and satisfaction of valued activities in everyday life within the areas of self-care, productivity and leisure. For the initial evaluation, the COPM starts with a semistructured interview during which the older person identifies activities in everyday life that they consider to be important, but difficult to do. Each activity is documented and the older person rates the importance of each activity on a 10-point scale. The older person is asked to choose up to five relevant activities and to rate their performance and satisfaction with the performance of each activity on separate scales, where a higher score reflects greater importance, better performance and greater satisfaction. For the re-evaluation at the end of the intervention period, the participant is again asked to rate their performance and satisfaction with each activity. A difference of two or more points between the two evaluations indicates a clinically relevant change.²⁷ The COPM is a valid and reliable measure, has been translated into the language of the participants and previously used in this type of study.^{8 27 31}

Secondary outcomes

The secondary outcome measures used with the older participants include: Barthel/Katz Extended Activities

of Daily Living (ADL) index that measures dependence/independence of assistance in ADL,^{32 33} and Frenchay Activity Index (FAI) that measures participation of performing social activities and everyday activities in the areas of domestic chores, leisure/work and outdoor activities.³⁴ The Swedish version of the General Self-Efficacy Scale (GSE) that measures one's perceived belief in one's ability in different situations,³⁵ EQ5-D (a widely used standardized instrument developed by the EuroQol Group) that measures self-reported health-related quality of life,³⁶ Hospital Anxiety and Depression Scale (HAD) that measures anxiety and depression,³⁷ Mental Health Continuum-Short Form, Swedish version (MHC-SF) that measures emotional well-being, social well-being and psychological well-being,³⁸ Reintegration to Normal Living (RNL) measuring community integration³⁹ and Sense of Coherence (short form) that measures one's sense of health (salutogenesis)^{40 41} will be used. Also the number of falls will be self-assessed before and after the study by the older adults.

Significant others

The following standardised outcome measures will be used with the participants significant others: Life Satisfaction Questionnaire (Li-Sat 11) which measures life satisfaction globally and in ten areas,⁴² Caregiver Burden Scale which measures caregivers perception of burden in caring,⁴³ Sense of Coherence—short form that measures one's sense of health (salutogenesis),^{40 41} MHC-SF that measures emotional well-being, social well-being and psychological well-being³⁸ and HAD that measures anxiety and depression.³⁷

Home care staff

To be able to describe the working situation for the home care staff (n=30 from each group), the following questionnaires will be administered before and after the study is ended: Creative Climate Questionnaire (CCQ) that measures perceptions of organisational climate,⁴⁴ strain in Dementia Care Scale (SDCS) that measures occupational strain in dementia care,⁴⁵ The General Nordic questionnaire for psychological and social factors (QPS Nordic) that measures psychological and social factors in the workplace⁴⁶ and Health Complaints that measures staff satisfaction with work.⁴⁷ The hypothesis is that with support from the OT there will be a perceived positive change for the home care staffs' working situation.

Qualitative studies: older adults and the significant others

Qualitative interviews will be performed by the researchers (SG and AB) after informed consent of the older persons (n=15 from each group) and their significant others (minimum of 5 from each group (IG/CG) dependent on the older participants). The significant others will be chosen through purposeful sampling from the total sample. These interviews will be performed before and after the intervention is completed and will be analysed with appropriate qualitative analysis. The aim of the semistructured

qualitative interviews is to explore aspects of (1) perceived value, benefits, harms or unintended consequences of the intervention, (2) acceptability of the intervention and (3) fidelity, reach and dose of the intervention⁴⁸ according to the older persons, significant others and the home care staff respectively that have participated in ASSIST. The semistructured interviews with the participants from the CG aim to describe the content and the experiences of the ordinary home help services.

Qualitative studies: home care staff

Data on age, gender, education and the number of years working in home care will be collected from all staff participating in the project. Furthermore, the number of older adults met by each of the home care staff will be collected.

Qualitative data will be collected by the researchers (SG and AB) from the home care staff before and after their participation in the study (in total n=15). The participants involved in the IG will be asked to describe the perceived value, benefits, harms or unintended consequences of the intervention and the acceptability of the intervention in principle among the staff involved in implementing the reablement programme ASSIST 1.0. Also, the interviews will include reflections about the staffs’ professional reasoning in relation to reablement in order to explore if they develop over time during participation in the implementation of the intervention. The participants in the CG will be invited to tell significant stories from their professional practice.⁴⁹ The home care staff involved in the project will be selected based on purposeful sampling.⁵⁰

Please refer to [figure 1](#) for a schematic description of the study.

Participant timeline

Participant enrolment will be initiated in January 2019 and the last qualitative interview is scheduled to be before 31 January 2020. During this period, 15 older adults will be enrolled in the intervention programme. At the time of submission of this study protocol, the planning phase of the trial is ongoing.

For each participant, demographic data and baseline assessments will be conducted during the first week after enrolment and postintervention re-evaluation within 1 week after finalising the programme.

Please see the timeline, [figure 2](#).

Sample size and power considerations

As this study is a feasibility study, a sample size calculation is not required.^{51 52} However, the sample should be representative of the target population and be large enough to provide information related to the feasibility and the potential outcome of the programme.⁵² If the programme is feasible and reveals positive outcomes, the intention is to evaluate the outcomes of the programme in a future large-scale RCT. Initially, such a study will include a pilot period. If no adjustments of the ASSIST programme are required, the data from the pilot period might be included in the large-scale RCT (internal pilot).⁵³ Furthermore, the results of the feasibility study and the pilot period will be the basis for a power calculation for the future large-scale study and thereafter, a sample size justification should⁵¹ be presented for phase III—the RCT design in this project ([figure 1](#)).

All statistics and tests will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement⁵⁴ in conjunction with the

Time point	Study period							After last participant's last visit
	Enrolment	Intervention Group (n=15)			Control Group 2 (n=15)			
		Week 1	Week 10	Week 11-12	Week 1	Week 10	Week 11-12	
Enrolment								
Eligibility screening								
Oral and written information								
Informed consent								
Intervention								
ASSIST 10-12 week program								
Evaluations								
Demographic data								
Baseline COPM								
Post intervention COPM								
Secondary outcomes								
Registration forms								
Individual interviews (home care staff)								
Individual interviews (older adults, significant others)								

ASSIST 1.0 = The reablement intervention program, COPM= Canadian Occupational Therapy Measure

Figure 2 Participant timeline and data collection.

CONSORT 2010 extensions for randomised trials of non-pharmacological treatment.^{55 56}

Data collection

All of the instruments measuring primary and secondary outcomes will be collected at baseline (before intervention) and at the end of the intervention (approximately 10 weeks after the baseline evaluations) for the IG and CG by the OT preferably in the participant's home, after permission from the participant. Whenever possible, a member from the home care staff will be present. A designated researcher, not involved with the workshops or coaching and with no professional relation to the municipality or to the home care staff or participants involved in the interventions, will conduct the qualitative interviews.

Demographic data will be collected at the onset for both the CG and IG including age, gender, previous home care services, living conditions, as well as a subjective medical/health descriptions (figure 2).

All authorised users will receive training prior to the start of data collection to define standardised coding practices and ensure data accuracy. All information will be collected on a secure electronic database and recorded without personal identification.

All interviews will be digitally recorded and transcribed verbatim. All identifying factors will be eradicated (ie, names) during transcription. Copies of the digital recordings will be destroyed after transcription is completed. Interview transcriptions will be stored in the universities database.

Data analyses

Feasibility of the intervention

Descriptive statistical analyses will be conducted on the data from the older adults, significant others, the home care staff and the participating OT.

The number of older persons being recruited will be presented in a flow chart; the retention rate and the adherence to intervention will be presented based on frequencies and percentages.

Based on registrations of time use at each session of the ASSIST programme for each older adult, the mean number of minutes used for each session will be presented. The number of older adults seen by each home care staff will be presented based on frequencies and percentages. Furthermore, conditions facilitating and/or hindering the delivery of the sessions and potential positive and/or negative side effects registered by the home care staff as well as their rating on a VAS of the delivery of the intervention will be reported.

From the OT logbooks, the feasibility of the estimated parameters; sample size, recruitment of participants, response rates, as well as the possibility and acceptability of OTs to carry out the intervention will be presented.

Evaluation of outcomes

Primary outcome measure

The participants' change in perceived performance and satisfaction of their stated valued activities will be presented

based on the COPM scores. The chosen activities will be presented separately for performance and satisfaction to create two summative scores. The summative scores will be divided by the number of rated activities to provide COPM scores for comparisons across time.

Secondary outcomes

All data regarding Barthel/Katz Extended ADL index, FAI, GSE, HAD, MHC-SF, RNL and Sense of Coherence from the older adults will be analysed and reported according to the norms of the measures.

Significant others and the home care staff

The data from the used outcome measures from the significant others and the working situation for the home care staff will be analysed according to the norms of the measures.

Analysis of cost-effectiveness

To assess the cost-effectiveness of ASSIST 1.0, we will need to estimate health outcomes and costs. The health outcomes will be measured using the EQ-5D and the costs will include healthcare sector costs. To estimate costs, we will include the cost of the intervention, which includes the hours, frequency and type of service as well as the time used for the workshops and coaching, for the older adults.

Furthermore, the use of other healthcare services (home care services, rehabilitation and institutional) will be recorded for both the IG and CGs over a period of 6 months. Standard methods for economic evaluation will be applied and the cost-effectiveness will be calculated as the incremental cost-effectiveness ratio, which is defined by the cost per incremental quality-adjusted life years (QALY).⁵⁷

Feasibility of the intervention: qualitative interviews

A method of constant comparison^{44 58} will be used to analyse the semistructured interviews from the older adults, the significant others and the home care staff describing (1) perceived value, benefits, harms or unintended consequences of the intervention, (2) acceptability of intervention in practice and (3) fidelity, reach and the dose of intervention.

Qualitative interviews with the CG

The same method will be used to analyse the interviews with the participants from the CG aiming to describe the content and the experiences of the ordinary home care services.

Patient and public involvement

In phase 1, data from focus groups interviews with home care staff within Stockholm county council after their education sessions were used as a part of the development and modelling of the intervention. The researchers also met several times with the home care staff, listening to the staffs' experiences from their everyday work and using this knowledge to design the project and formulate the research questions. Six older adults in the same county council participated in piloting the used outcome

measures and answered open ended questions about their home care services. In phase 2, home care staff located in two designated geographical areas of Stockholm will participate and pilot the ASSIST and will also include older persons and their designated significant others.

The results of this study will be presented to various stakeholders, regionally and nationally and others actors in, for example, private elderly care. The researchers will continuously present the results for these stakeholders and for various partners as providers in municipal health and medical care and home care. The results will also be presented to the public through press releases and articles in the daily press, as well as at conferences and fairs. A complete programme with suggestions for ways to implement ASSIST will be presented for important actors, such as the organisation representing Sweden's municipalities and county councils. The results will also be presented at international research conferences and in publications.

DISCUSSION

The present study will contribute knowledge about the feasibility of the ASSIST 1.0 intervention programme, a theory-based reablement programme in a Swedish context, aiming to empower the older person so they can do what they want and need to do in everyday life. The reablement programme, which includes coaching of home care staff and digitally based smart products, will strive to increase the older person's self-efficacy, perceived health and well-being. The process of developing the ASSIST intervention programme is in line with the MRC guidelines on how to develop and evaluate complex interventions.¹⁵ Accordingly, this first version of the programme was developed based on several steps, where the first step was to search for and review existing evidence regarding reablement services from evaluations in different countries.

The description of the ASSIST intervention is unique to this project and is not included in standard practices in Sweden. For example, standard practice does not involve any counselling or involvement by other professionals. Standard practice involves a referral or work order for home care staff to perform home care services, such as shopping, or cleaning or performing personal care services to the older person such as assistance in bathing or dressing. Home care staff is not routinely informed of the older persons' personal goals (ie, doing own laundry) and does not receive support as to how to assist the older person to achieve the goal (ie, encourage the older person to sit down, providing stand-by assistance while the older person retrieves the laundry from the machine, etc). Home care staff might not routinely ask the older person what they want to do themselves and does not use standardised measures to record this.

It is expected that this feasibility study will provide information on aspects related to perceived value and acceptability of the intervention; fidelity, reach and dose; and potential outcomes to be used to further develop and refine the programme. If the study results find that

ASSIST is feasible and positive outcomes are indicated, the intention is to evaluate the outcomes of the intervention in a future large-scale RCT.

Dissemination

Each participant will sign a consent form of voluntary participation, which emphasises the rights to withdraw from the study. A copy of the form is provided to the participants. Each participant (older adults, significant others and home care staff) will receive an ID number. The analysis and the results will, therefore, be performed and presented anonymously. It is the responsibility of the recruiting personnel to ensure that any potential participant has gained an understanding of the information given. Study participation is not expected to be associated with risks or complications but all risks due to incident will be reported by the OT and the home care staff to the researchers and if needed the participants could be withdrawn from the study.

The applied intervention will be delivered by educated and experienced researchers with relevant qualifications.

The findings will be reported to the funder and in papers published in peer-reviewed journals. In addition, the results will be presented to staff and decision-makers at the municipality involved in the study, health care professionals and the public in general, through various national and international events.

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Contributors SG and AB conceived the original idea and outline of the study. SG and AB contributed to designing the study. SG has been responsible for developing the intervention in collaboration with AB and LB. SM is responsible for the technical development and smart products used in the study in the intervention ASSIST. SG and AB will further be responsible for collaboration with the municipality, and for training and supervising the home care staff together with a research assistant. SG and AB wrote the study protocol. All authors (AB, SM, LB and SG) discussed and commented on draft versions and approved the final version. Authorship for future studies stemming from the main trial will be discussed between the present authors and consequent decisions will be based on the prospective author's contributions.

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