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Evaluation of an intervention addressing a Reablement program 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 program, 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 program regarding fidelity, reach and dose, and potential outcomes by using a pre-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 participants 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 program and for the subsequent planning of a full-scale randomized, controlled trial investigating the effect of the program 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: ClinicalTrials.gov NCT03505619

Strengths and limitations of the study

- The present study will evaluate the feasibility and potential outcomes of a theory based reablement intervention program 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 interventional, non-randomized with an intervention and control group and has a pre-post-test study design.
- Smart products, introduced to the home care staff in a process of co-creation, will be used to support the reablement intervention.
- A combination of qualitative and quantitative data involving both older persons, their significant others, and home care staff are systematically collected before, during and after the intervention period and will reflect the *e.g.* older participants self-efficacy, health, and well-being.
- The main outcome reflects the older person's self-assessed performance and satisfaction of chosen, important activities in everyday life, measured with the Canadian Occupational Performance Measure (COPM).

INTRODUCTION

Background and rationale

Aging societies worldwide are growing, creating a strong need for identifying 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.

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 persons (5) 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 traditional ways of working within home care services for older people in their home. Authors identify different aspects of reablement such as being person-centered (6), goal-directed (6-8), time-limited (6-12 weeks) (6, 8-10), intensive (7-10), multidisciplinary (7, 9-13) and as a multi-component 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 to 12 weeks). Reablement consists of a person-centered 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-centered 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 re-instating 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 programs.

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, geographic 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 program 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 stages 1.) development, 2.) feasibility/piloting, 3.) evaluation, and 4.) implementation.
In the present study, 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 program. The project planners draw upon 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 program in this study. Smart products in reablement programs have been suggested but have not as yet, been integrated into services (19) making this study unique.

The second phase is related to evaluating the feasibility of the program 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 randomized controlled trial (RCT) (20). In the present study, the feasibility of the first version of ASSIST 1.0 program will, therefore, be evaluated in terms of perceived value and acceptability of the intervention considering fidelity, reach and dose; and potential outcomes. Since ASSIST 1.0 is a new approach to providing home care, the chosen comparator in this intervention study will be home care services practiced as usual.

The reablement program 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 present a feasibility study in order to gather information on ASSIST 1.0., a theory based reablement intervention program, which includes coaching of home care staff and digitally based smart products, compared with ordinary home care services, in a Swedish context.

In response to the above-named challenges, this feasibility study intends to answer the following research questions:

1. Is ASSIST 1.0 design feasible regarding a.) The intervention components, b.) Mechanisms of change, c.) Perceived value, benefits and unintended consequences of the intervention, d.) Feasibility and acceptability of intervention in practice and e.) Fidelity, reach and the dose of intervention?
2. Can ASSIST1.0 performed by home care staff and facilitated by occupational therapists together with smart products support older adults' performance and satisfaction with the performance of activities in everyday life?
3. Is there a difference in the older adults' levels of performance and satisfaction with doing activities in everyday life when the home care staff received education and coaching by facilitators, compared to the older adults that did not receive the support of home care staff that had been educated but did not receive coaching?
4. Does the professional reasoning change over time among the staff involved in implementing the above-described reablement program?

METHODS AND ANALYSIS

Trial design

This feasibility study will be conducted using a non-randomised, comparative trial with a pre-post-test, two group design with 15 older persons in each arm, *i.e.* 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, including qualitative interviews (15), 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 program. The present protocol follows the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) 2013 statement (21, 22), which defines standard protocol items for clinical trials.

Study setting

The study will be conducted in cooperation with home care providers located in two designated geographical areas of Stockholm (one for the intervention, and a separate area for the control group) and will include; home care staff, older persons, and their designated significant others. All home care staff (n = 218) permanently employed by the same employer in both of the designated areas (intervention and control areas) have received a basic education organized as half-day seminars (approximately 3 hours on 3 separate occasions) regarding reablement, during the fall of 2017. The objective of 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. Home care staff included in the intervention arm will, through workshops and coaching sessions led by the researchers, offer the reablement program 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).

Participants: Eligibility criteria

Older persons potentially eligible for the reablement study will be identified by a representative for the home care staff and notify the researchers with relevant information regarding the older person. The older person will be included if they fulfil the following inclusion criteria a) ≥65 years or older and live at home, b) home care has been granted and the user is deemed not to need home rehabilitation performed by rehabilitation professionals, c) two or more identified challenges in everyday activities that can benefit from reablement, d) 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 help services for more than three years.

When the older person in either the intervention or control group agrees to be involved in the study, they will be asked if they could consider involving a significant other.

The intervention program "ASSIST 1.0" a program for reablement in a Swedish context

The foundations of the reablement program presented here rest on theoretical models such as The Canadian Model of Occupational Performance and Engagement regarding a person-centered approach (23, 24) and the "Do, Live, Well" framework describing the positive connections between engaging in meaningful everyday activities and health and well-being (25). Furthermore, both the workshops and coaching sessions will integrate principles based on the older person's and the care staffs' unique lived experiences (26). 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 program

ASSIST 1.0. is an eight to twelve-week intervention program and uses a person-centered approach. This program 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 (27).

By using the Canadian Occupational Performance Measure (COPM), occupational therapists (*i.e.* the researchers) will support the older person to identify issues in activities in everyday life (28). 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 strategies to fulfill the goals will be discussed both with 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.

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 app will also request documentation; for example, if the activity was attended to and the possible results.

After the goalsetting process, occupational therapists (*i.e.* the researchers) will provide both workshops and coaching sessions for the home care staff responsible for the reablement program 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 to 10 home care staff, one hour every other week), and will continue for a minimum of 10 weeks or until all of the older persons have completed the entire program. During the workshop sessions, the home care staff together with the researchers 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 sessions will be on a smaller scale, including 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 researcher will, when needed, be present in the participants' environment (home or other relevant places, *i.e.* 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 participant. The researcher 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. Both the workshops and coaching occasions will integrate principles based on a person-centered approach (23), initiate from the older person's unique lived experiences, and his/her wishes and needs (26). 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 program. 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 (29). Likewise, Lauvås and Handal (2015) argue that a great deal of what takes place in the field of practice is tacit, and therefore needs to be reflected upon (30) 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. Based on this knowledge, the authors hypothesize that receiving education regarding reablement is not sufficient for home care staff to accomplish a change in praxis without the central aspect of reflection upon 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 (31).

The researchers will use both the workshops and coaching sessions to emphasize adherence to the reablement ideals. They will also use field-notes to record procedural processes and issues as well as any reasons for non-adherence to the program (regarding both the older participants and the home care staff) as well as non-retention issues in both of these groups.

The control group: standard home care

The home care staff in the control group (CG) have received the basic education only and will provide home care services as usual to older adults participating in the control group. Home care staff in the CG will identify potential older persons to participate in the control group according to the same procedure and criteria as the intervention group.

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
The perceived degree of e.g. older adults' involvement, meaningfulness, and confidence in relation to intervention delivery will be based on the older adults' ratings on a VAS-scale from one to five.

Outcome data

The primary outcome measure will be the Swedish version of the Canadian Occupational Performance Measure (COPM) (28). 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 semi-structured 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 (28). 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, 28, 32).

Secondary outcomes

The secondary outcome measures used with the older participants include; Barthel/Katz ADL index which measures dependence/ independence of assistance in ADL (33, 34), and Frenchay Activity Index (FAI) which measures participation of performing social activities and everyday activities in the areas of domestic chores, leisure/work, and outdoor activities (35). The Swedish version of the General Self-Efficacy Scale (GSE) which measures ones perceived belief in one's ability in different situations (36), EQ5-D which measures self-reported health (37), Hospital Anxiety and Depression Scale (HAD) which measures anxiety and depression (38), Mental Health Continuum-short form, Swedish version (MHC-SF) which measures emotional well-being, social well-being and psychological well-being (39), Reintegration to Normal Living (RNL) measuring community integration (40) and Sense of Coherence (short form) which measures one's sense of health (salutogenesis) (41, 42) will be used.
All data will be analyzed according to the norms of the measure.

Significant Others

The following standardized outcome measures will be used with the participants significant others: Life Satisfaction Questionnaire (LiSat -11) which measures life satisfaction globally and in ten areas (43), Caregiver Burden Scale which measures caregivers perception of burden in caring (44), Sense of Coherence – short form which measures one's sense of health (salutogenesis)(41, 42), Mental Health Continuum –short form (MHC-SF) which measures emotional well-being, social well-being and psychological well-being (39) and Hospital Anxiety and Depression Scale (HAD) which measures anxiety and depression (38).

Qualitative Studies – Participants and the Significant others

Qualitative interviews will be performed with approximately 20 older participants and their significant others. They will be chosen through purposeful sampling, chosen from the total sample. Interviews will also be performed with approximately 15 home care staff. These interviews will be performed before and after the intervention is completed and will be analyzed with appropriate qualitative analysis. The aim of the semi-structured qualitative interviews is to explore aspects of a) perceived value, benefits, harms or unintended consequences of the intervention, b) acceptability of the intervention and c) fidelity, reach and dose of intervention (45) according to the older persons, significant others and the home care staff respectively.

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.

Before and after the intervention is ended the following questionnaires will be administered: Creative Climate Questionnaire (CCQ) which measures perceptions of organizational climate (46), strain in Dementia Care Scale (SDCS) which measures occupational strain in dementia

care (47), QPS Nordic which measures psychological and social factors in the workplace (48) and Health Complaints which measures staff satisfaction with work (49).

Qualitative data will be collected to identify how professional reasoning develops over time among the home care staff involved in implementing the reablement program ASSIST 1.0. The home care staff involved in the project will be selected based on purposeful sampling (50). Data will be generated through focus-group methodology (51). Participants will be invited to tell significant stories from their professional practice during two focus groups meetings before and after the intervention. Data will be analyzed with interpretative narrative methodology following guidelines in Josephsson & Alsaker (2015) (52).

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 31st January 2020. During this period, 15 older adults will be enrolled in the intervention program. 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 post-intervention re-evaluation within one week after finalizing the program.

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 (53, 54). 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 program (54). If the program is feasible and reveals positive outcomes, the intention is to evaluate the outcomes of the program in a future large-scale randomized controlled trial (RCT). Initially, such a study will include a pilot period. If no adjustments of the ASSIST program are required, the data from the pilot period might be included in the large-scale RCT (internal pilot) (55). 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 should (53) be presented for Phase III – the RCT design in this project (Figure 1.).

All statistics and tests will be reported in accordance with the CONSORT 2010 Statement (56) in conjunction with the CONSORT 2010 Extensions for randomized trials of nonpharmacological treatment (57, 58).

Recruitment and informed consent

The home care staff will identify a potential study participant and inform the potential older person verbally of 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 intervention group as well as the control group.

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

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.

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 researchers preferably in the participant's home, after permission from the participant. Whenever possible, a member from the home care staff will be present. Designated trained research assistants, 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 follow-up assessments.

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 questionnaires are downloaded on to a secure electronic database allowing the participants' responses to be downloaded digitally on the data collectors' devices (tablets or laptop computers). All authorized users will receive training prior to the start of data collection to define standardized coding practices and ensure data accuracy. All data will be without personal identification but a code number will be connected with the responses. A code key of participant's names and personal identification numbers will be kept in a locked room at the sponsoring university and only three researchers (Bergström, Borell, & Guidetti) will have access. All of the collected data stored in the results database is temporary and will be exported to the sponsoring university's database and then erased from the trials results database. In order to identify data, one must have access to all three data areas (results database, university database and the code key), assuring the security of the information. The database allows the authorized researchers and research assistants to both enter and to store data, facilitating effective and secure data management.

All interviews will be digitally recorded and transcribed verbatim. All identifying factors will be eradicated (i.e. 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, and the home care staff.

The number of older persons being recruited will be presented in a flowchart; 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 program 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 will be registered by the home care staff and presented. The home care staff will rate the delivery of the intervention on a VAS-scale.

Feasibility of the intervention: qualitative interviews

The interviews with the older adults, significant others and the home care staff will be transcribed verbatim. A method of constant comparison (45, 59) will be used to analyze the semi-structured interviews describing a) perceived value, benefits, harms or unintended consequences of the intervention, b) acceptability of intervention in practice and c) fidelity, reach and the dose of intervention.

Evaluation of outcomes

The participants' change in perceived performance and satisfaction of their stated valued activities will be presented based on the COPM, the primary outcome measure. The clinically meaningful changes in the primary and secondary outcomes will also be presented.

A feasibility study such as this warrants the collection and assessment of any and all adverse events or other unintended effects. However, due to the person-centered nature of the intervention, the authors do not expect any adverse events related to the intervention. There is no data monitoring committee appointed for the present study due to the short duration and the known minimal risks, but may be considered prior to testing the intervention in a full-scale RCT. Pre-specified interim analyses may be useful, however, for adapting *i.e*. the intervention or the number of outcomes.

Analysis of effect

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 health care services (home care services, rehabilitation, and institutional) will be recorded for both the intervention and control groups 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) (60).

Discussion

The present study will contribute knowledge about the feasibility of the ASSIST 1.0 intervention program, a theory based reablement program 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 program, 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 program is in line with the MRC guidelines on how to develop and evaluate complex interventions (20). Accordingly, this first version of the program 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.

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 program. 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.

ETHICS AND DISSEMINATION

This study has been approved by the regional ethics board 2017/1439-31/1 and 2017/2172-32

Each participant will sign a consent form of voluntary participation, which emphasizes the rights to withdraw from the study. A copy of the form is provided to the participants. Each participant (older adults, significant others, 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. 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.

AUTHORS' CONTRIBUTIONS

SG and AB conceived the original idea and outline of the study. SG and AB contributed to designing the study. SG was responsible for developing the intervention in collaboration with AB and LB. SG and AB will further be responsible for collaboration with the municipality, and for training and supervising the home care staff. SG and AB wrote the study protocol. All authors 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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COMPETING INTERESTS

The authors declare that they have no competing interests.

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Figure legends-

Figure 1. Overall plan for the ASSIST 1.0 project

Figure 2. Participant timeline and data collection

Figure 1. Overall plan for the ASSIST 1.0 project.

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 the designated areas 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 Home care staff, educators from the organization. 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			
Activities: Workshops lead by the researchers including group discussions regarding: - the lived experiences of aging - a person-centred approach - activities and health		Home care staff in groups of approximately 6-10	Every other week for a minimum of 10 weeks
Two different interventions directed to the persons in need of home-care and their significant others			
Intervention group (IG) versus Control Group (CG) *ASSIST versus ordinary home help services*	Researchers provide specific support and coaching to the home care staff in the IG concerning smart products and specific participants	3 groups of 6-10 home care staff conducting ASSIST including Group workshops + coaching occasions with the older person Intervention group (IG)	30 home care staff conducting ordinary home help service Control group (CG)
	Older persons (according to inclusion criteria) in need of home-care services	n=15 older persons (IG) will received ASSIST (duration: approx. 6-12 weeks)	n=15 older person (CG) receiving ordinary home help services
	Older persons significant others	n=15 significant others from IG	n= 15 significant others from CG
Assessments			
Focus groups interviews / individual interviews before and after education sessions and implementation		Home care staff	5 / 10 5 / 10
Data collection according to work environment, stress, implementation process for all 218 home care staff in the area		Home care staff	IG n=30 home-care providers/ CG n=188 a total of 218
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 = 15 CG = 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. Numbers dependent on the older participants.
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 2. Participant timeline and data collection

Time point	Study period							
	Enrolment	Intervention Group (n=15)			Control Group 2 (n=15)			After last participant's last visit
		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								
Focus-group interviews (home care staff)								
Individual interviews (older adults, significant others)								

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

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1 & 2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 2
	2b	All items from the World Health Organization Trial Registration Data Set	All items checked and met, however trial registered with ClinicalTrials.gov and not WHO
Protocol version	3	Date and version identifier	Page 1
Funding	4	Sources and types of financial, material, and other support	Page 14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 1 & 14
	5b	Name and contact information for the trial sponsor	Page 1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Page 14

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Not applicable
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 2-4
	6b	Explanation for choice of comparators	Page 5
Objectives	7	Specific objectives or hypotheses	Page 4 & 5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 5 & 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 6-8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Page 8
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Page 8
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Page 6

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 6-9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1, Timeline
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Not applicable
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Not applicable
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Not applicable
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Not applicable
Methods: Data collection, management, and analysis			

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Fig 1,Timeline & Pages 6-11
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Page 7
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 11 & 12
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 8,10-11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Not applicable
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Not applicable
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Page 12
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Page 12
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Not applicable
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 12
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Page 12
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 10
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Not applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 11 & 12
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 14
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Not applicable
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	Not applicable
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 13
	31b	Authorship eligibility guidelines and any intended use of professional writers	Page 14
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Not applicable
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	(in Swedish, available on request)

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	Not applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

BMJ Open

Evaluation of an intervention addressing a Reablement program for older, community-dwelling persons in Sweden (ASSIST 1.0) - A protocol for a feasibility study.

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BMJ Open version

Evaluation of an intervention addressing a Reablement program 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 program, 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 program regarding fidelity, reach and dose, and potential outcomes by using a pre-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 program and for the subsequent planning of a full-scale randomized, controlled trial investigating the effect of the program 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: Clinical Trials. gov NCT03505619

Strengths and limitations of the study

- A major strength of this study lies in the use of a theory based reablement intervention program 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 randomization 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).

INTRODUCTION

Background and rationale

Aging societies worldwide are growing, creating a strong need for identifying 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 persons (5) 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 multi-component 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 to 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 re-instating 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 programs.

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, geographic 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 program 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 stages 1.) development, 2.) feasibility/piloting, 3.) evaluation, and 4.) implementation.
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 program. The project planners draw upon 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 program in this study. Smart products in reablement programs have been suggested but have not as yet, been integrated into services (19) making this study unique.

The second phase is related to evaluating the feasibility of the program 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 randomized controlled trial (RCT) (20). In the present study, the feasibility of the first version of ASSIST 1.0 program 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 practiced as usual.

The reablement program 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 program, 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 phase, we therefore would like to identify and address problems which might undermine the acceptability and delivery of the intervention or the transference of the ASSIST intervention.

In response to the above-named challenges, this feasibility study intends to answer the following research questions:

1. Is ASSIST 1.0 design feasible regarding a.) The interventions components, b.) Mechanisms of action, c.) Fidelity, reach and the dose of intervention and, d.) The acceptability of intervention in practice?
2. Can ASSIST1.0 performed by home care staff and facilitated by occupational therapists together with smart products support older adults' performance and satisfaction with the performance of activities in everyday life?
3. How do the older adults' experience their performance and satisfaction with doing activities in everyday life when the home care staff received education and coaching by facilitators, in relation to the older adults that did not receive the support of home care staff that had been educated but did not receive coaching?
4. What are the home care staffs' perceived value, benefits, harms or unintended consequences of the intervention and the acceptability of intervention in principle among the staff involved in implementing the above-described reablement program?

METHODS AND ANALYSIS

Trial design

This feasibility study will be conducted using a non-randomised, comparative trial with a pre-post-test, two group design with 15 older persons in each arm, *i.e.* 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 program. The present protocol follows the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) 2013 statement (21, 22), which defines standard protocol items for clinical trials.

Study setting

In *phase1,* home care staff (n = 218) in a designated area within Stockholm county, have received a basic education organized as half-day seminars (approximately 3 hours on 3 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. This data will be used for the development and modelling of the intervention. *Phase 2,* organized 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 control group) 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- 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 program 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 cons

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 intervention group as well as the control group.

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 a) ≥65 years or older and live at home, b) home care has been granted and the user is deemed not to need home rehabilitation performed by rehabilitation professionals, c) two or more identified challenges in everyday activities that can benefit from reablement, d) 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 three 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 hers 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 control group 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 program for reablement in a Swedish context

The foundations of the reablement program presented here rest on theoretical models such as The Canadian Model of Occupational Performance and Engagement regarding a person-centred approach (23, 24) and the "Do, Live, Well" framework describing the positive connections between engaging in meaningful everyday activities and health and well-being (25). Furthermore, both the workshops and coaching sessions will integrate principles based on the older person's and the care staffs' unique lived experiences (26). 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 program

ASSIST 1.0. is a ten-week intervention program and uses a person-centred approach. This program 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 (27).

By using the Canadian Occupational Performance Measure (COPM), the older person will identify issues in activities in everyday life (28). 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.

New advice for how the staff could best support the older person in goal achieving and developed from the coaching sessions will be included. 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 goalsetting process, the OT will provide both workshops and coaching sessions for the home care staff responsible for the reablement program 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 to 10 home care staff, one hour every other week), and will continue for a minimum of 10 weeks or until all of the older persons have completed the entire program. 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 sessions 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, *i.e.* 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 week intervals thereafter. Both the workshops and coaching occasions will integrate principles based on a person-centred approach (23), initiate from the older person's unique lived experiences, and his/her wishes and needs (26). 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 program. 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 (29). Likewise, Lauvås and Handal (2015) argue that a great deal of what takes place in the field of practice is tacit, and therefore needs to be reflected upon (30) 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 hypothesize that receiving education regarding reablement is not sufficient for home care staff to accomplish a change in praxis without the central aspect of reflection upon 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 (31).

The control group: standard home care

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

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 Figure1). 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 e.g. older adults' involvement, meaningfulness, and confidence in relation to intervention delivery will also be based on the older adults' ratings on a VAS-scale from one to five. 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 Canadian Occupational Performance Measure (COPM) (28). 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 semi-structured 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 (28). 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, 28, 32).

Secondary outcomes

The secondary outcome measures used with the older participants include; Barthel/Katz ADL index which measures dependence/ independence of assistance in ADL (33, 34), and Frenchay Activity Index (FAI) which measures participation of performing social activities and everyday activities in the areas of domestic chores, leisure/work, and outdoor activities (35). The Swedish version of the General Self-Efficacy Scale (GSE) which measures ones perceived belief in one's ability in different situations (36), EQ5-D which measures self-reported health (37), Hospital Anxiety and Depression Scale (HAD) which measures anxiety and depression (38), Mental Health Continuum-short form, Swedish version (MHC-SF) which measures emotional well-being, social well-being and psychological well-being (39), Reintegration to Normal Living (RNL) measuring community integration (40) and Sense of Coherence (short form) which measures one's sense of health (salutogenesis) (41, 42) 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 standardized outcome measures will be used with the participants significant others: Life Satisfaction Questionnaire (LiSat -11) which measures life satisfaction globally and in ten areas (43), Caregiver Burden Scale which measures caregivers perception of burden in caring (44), Sense of Coherence – short form which measures one's sense of health (salutogenesis)(41, 42), Mental Health Continuum –short form (MHC-SF) which measures emotional well-being, social well-being and psychological well-being (39) and Hospital Anxiety and Depression Scale (HAD) which measures anxiety and depression (38).

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) which measures perceptions of organizational climate (45), strain in Dementia Care Scale (SDCS) which measures occupational strain in dementia care (46), QPS Nordic which measures psychological and social factors in the workplace (47) and Health Complaints which measures staff satisfaction with work (48). 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, 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 semi-structured qualitative interviews are to explore aspects of a) perceived value, benefits, harms or unintended consequences of the

intervention, b) acceptability of the intervention and c) fidelity, reach and dose of the intervention (49) according to the older persons, significant others and the home care staff respectively that have participated in ASSIST. The semi-structured 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, 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 decribe 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 program 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 (50). The home care staff involved in the project will be selected based on purposeful sampling (51).

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 31st January 2020. During this period, 15 older adults will be enrolled in the intervention program. 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 post-intervention re-evaluation within one week after finalizing the program.

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 (52, 53). 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 program (53). If the program is feasible and reveals positive outcomes, the intention is to evaluate the outcomes of the program in a future large-scale randomized controlled trial (RCT). Initially, such a study will include a pilot period. If no adjustments of the ASSIST program are

required, the data from the pilot period might be included in the large-scale RCT (internal pilot) (54). 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 should (52) be presented for Phase III – the RCT design in this project (Figure 1.).

All statistics and tests will be reported in accordance with the CONSORT 2010 Statement (55) in conjunction with the CONSORT 2010 Extensions for randomized trials of nonpharmacological treatment (56, 57).

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 trained research assistant, 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 authorized users will receive training prior to the start of data collection to define standardized 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 (i.e. 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 flowchart; 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 program 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-scale 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 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 health care services (home care services, rehabilitation, and institutional) will be recorded for both the intervention and control groups 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) (58).

Feasibility of the intervention: qualitative interviews

A method of constant comparison (45, 59) will be used to analyse the semi-structured interviews from the older adults, the significant others and the home care staff describing a) perceived value, benefits, harms or unintended consequences of the intervention, b) acceptability of intervention in practice and c) fidelity, reach and the dose of intervention.

Qualitative interviews with the control group

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 *phase1,* data from focus groups interviews with home care staff within Stockholm county council after their education sessions was 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 program with suggestions for ways to implement ASSIST will be presented for important actors, such as the organization 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 program, a theory based reablement program 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 program, 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 program is in line with the MRC guidelines on how to develop and evaluate complex interventions (20). Accordingly, this first version of the program 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 (i.e. doing own laundry) and does not receive support as to how to assist the older person to achieve the goal (i.e. 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 standardized 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 program. 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.

ETHICS AND DISSEMINATION

This study has been approved by the Regional Ethical Review Board in Stockholm, Sweden 2017/1439-31/1 and 2017/2172-32.

Each participant will sign a consent form of voluntary participation, which emphasizes the rights to withdraw from the study. A copy of the form is provided to the participants. Each participant (older adults, significant others, 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.

AUTHORS' CONTRIBUTIONS

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 (OT). 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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COMPETING INTERESTS

The authors declare that they have no competing interests.

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Figure legends-

Figure 1. Overall plan for the ASSIST 1.0 project

Figure 2. Participant timeline and data collection

Figure 1. Overall plan for the ASSIST 1.0 project.

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 *ASSIST versus ordinary home help services*		
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	***Control group (CG)*** Home care staff (n=15) conducting ordinary home help service	
n=15 older persons (IG) will received ASSIST (duration: 10 weeks)	n=15 older person (CG) receiving ordinary home help services	
n=15 significant others from IG	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		

210x297mm (300 x 300 DPI)

Figure 2. Participant timeline and data collection

Time point	Study period							
	Enrolment	Intervention Group (n=15)			Control Group 2 (n=15)			After last participant's last visit
		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

209x297mm (300 x 300 DPI)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1 & 2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 2
	2b	All items from the World Health Organization Trial Registration Data Set	All items checked and met, however trial registered with ClinicalTrials.gov and not WHO
Protocol version	3	Date and version identifier	Page 1
Funding	4	Sources and types of financial, material, and other support	Page 14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 1 & 14
	5b	Name and contact information for the trial sponsor	Page 1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Page 14

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Not applicable
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 2-4
	6b	Explanation for choice of comparators	Page 5
Objectives	7	Specific objectives or hypotheses	Page 4 & 5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 5 & 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 6-8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Page 8
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Page 8
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Page 6

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 6-9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1, Timeline
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Not applicable
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Not applicable
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Not applicable
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Not applicable
Methods: Data collection, management, and analysis			

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Fig 1,Timeline & Pages 6-11
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Page 7
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 11 & 12
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 8,10-11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Not applicable
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Not applicable
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Page 12
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Page 12
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Not applicable
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 12
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Page 12
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 10
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Not applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 11 & 12
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 14
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Not applicable
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	Not applicable
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 13
	31b	Authorship eligibility guidelines and any intended use of professional writers	Page 14
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Not applicable
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	(in Swedish, available on request)

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	Not applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

BMJ Open

Evaluation of an intervention addressing a Reablement program for older, community-dwelling persons in Sweden (ASSIST 1.0) - A protocol for a feasibility study.

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BMJ Open version

Evaluation of an intervention addressing a Reablement program 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 program, 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 program regarding fidelity, reach and dose, and potential outcomes by using a pre-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 program and for the subsequent planning of a full-scale randomized, controlled trial investigating the effect of the program 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: Clinical Trials. gov NCT03505619

Strengths and limitations of the study

- A major strength of this study lies in the use of a theory based reablement intervention program 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 randomization 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).

INTRODUCTION

Background and rationale

Aging societies worldwide are growing, creating a strong need for identifying 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 persons (5) 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 multi-component 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 to 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 re-instating 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 programs.

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, geographic 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 program 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 phase one and two.

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 program. The project planners draw upon 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 program in this study. Smart products in reablement programs have been suggested but have not as yet, been integrated into services (19) making this study unique.

The second phase is related to evaluating the feasibility of the program 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 randomized controlled trial (RCT) (20). In the present study, the feasibility of the first version of ASSIST 1.0 program 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 practiced as usual.

The reablement program 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 program, 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 every-day 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 pre-post-test, two group design with 15 older persons in each arm, *i.e.* 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 program. The present protocol follows the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) 2013 statement (21, 22), which defines standard protocol items for clinical trials.

Study setting

In *phase1,* home care staff (n = 218) in a designated area within Stockholm county, have received a basic education organized as half-day seminars (approximately 3 hours on 3 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. This data will be used for the development and modelling of the intervention. *Phase 2,* organized 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 control group) 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- 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 program 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 intervention group as well as the control group.

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 a) ≥65 years or older and live at home, b) home care has been granted and the user is deemed not to need home rehabilitation performed by rehabilitation professionals, c) two or more identified challenges in everyday activities that can benefit from reablement, d) 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 three 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 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 control group 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 program for reablement in a Swedish context

The foundations of the reablement program presented here rest on theoretical models such as The Canadian Model of Occupational Performance and Engagement regarding a person-centred approach (23, 24) and the "Do, Live, Well" framework describing the positive connections between engaging in meaningful everyday activities and health and well-being (25). Furthermore, both the workshops and coaching sessions will integrate principles based on the older person's and the care staffs' unique lived experiences (26). 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 program

ASSIST 1.0. is a ten-week intervention program and uses a person-centred approach. This program 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 (27).

By using the Canadian Occupational Performance Measure (COPM), the older person will identify issues in activities in everyday life (28). 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 goalsetting process, the OT will provide both workshops and coaching sessions for the home care staff responsible for the reablement program 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 to 10 home care staff, one hour every other week), and will

continue for a minimum of 10 weeks or until all of the older persons have completed the entire program. 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, *i.e.* 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 week intervals thereafter. Both the workshops and coaching occasions will integrate principles based on a person-centred approach (23), initiate from the older person's unique lived experiences, and his/her wishes and needs (26). 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 program. 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 (29). Likewise, Lauvås and Handal (2015) argue that a great deal of what takes place in the field of practice is tacit, and therefore needs to be reflected upon (30) 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 hypothesize that receiving education regarding reablement is not sufficient for home care staff to accomplish a change in praxis without the central aspect of reflection upon 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 (31).

The control group: standard home care

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

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 Figure1). 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 e.g. older adults' involvement, meaningfulness, and confidence in relation to the intervention delivery will also be based on the older adults' ratings on a VAS-scale from one to five. 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 Canadian Occupational Performance Measure (COPM) (28). 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 semi-structured 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 (28). 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, 28, 32).

Secondary outcomes

The secondary outcome measures used with the older participants include; Barthel/Katz ADL index which measures dependence/ independence of assistance in ADL (33, 34), and Frenchay Activity Index (FAI) which measures participation of performing social activities and everyday activities in the areas of domestic chores, leisure/work, and outdoor activities

(35). The Swedish version of the General Self-Efficacy Scale (GSE) which measures ones perceived belief in one's ability in different situations (36), EQ5-D which measures self-reported health (37), Hospital Anxiety and Depression Scale (HAD) which measures anxiety and depression (38), Mental Health Continuum-short form, Swedish version (MHC-SF) which measures emotional well-being, social well-being and psychological well-being (39), Reintegration to Normal Living (RNL) measuring community integration (40) and Sense of Coherence (short form) which measures one's sense of health (salutogenesis) (41, 42) 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 standardized outcome measures will be used with the participants significant others: Life Satisfaction Questionnaire (LiSat -11) which measures life satisfaction globally and in ten areas (43), Caregiver Burden Scale which measures caregivers perception of burden in caring (44), Sense of Coherence – short form which measures one's sense of health (salutogenesis)(41, 42), Mental Health Continuum –short form (MHC-SF) which measures emotional well-being, social well-being and psychological well-being (39) and Hospital Anxiety and Depression Scale (HAD) which measures anxiety and depression (38).

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) which measures perceptions of organizational climate (45), strain in Dementia Care Scale (SDCS) which measures occupational strain in dementia care (46), QPS Nordic which measures psychological and social factors in the workplace (47) and Health Complaints which measures staff satisfaction with work (48). 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, 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 semi-structured qualitative interviews are to explore aspects of a) perceived value, benefits, harms or unintended consequences of the intervention, b) acceptability of the intervention and c) fidelity, reach and dose of the intervention (49) according to the older persons, significant others and the home care staff respectively that have participated in ASSIST. The semi-structured 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, 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 decribe 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 program 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 (50). The home care staff involved in the project will be selected based on purposeful sampling (51).

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 31st January 2020. During this period, 15 older adults will be enrolled in the intervention program. 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 post-intervention re-evaluation within one week after finalizing the program.

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 (52, 53). 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 program (53). If the program is feasible and reveals positive outcomes, the intention is to evaluate the outcomes of the program in a future large-scale randomized controlled trial (RCT). Initially, such a study will include a pilot period. If no adjustments of the ASSIST program are required, the data from the pilot period might be included in the large-scale RCT (internal pilot) (54). 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 should (52) be presented for Phase III – the RCT design in this project (Figure 1.).

All statistics and tests will be reported in accordance with the CONSORT 2010 Statement (55) in conjunction with the CONSORT 2010 Extensions for randomized trials of nonpharmacological treatment (56, 57).

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 authorized users will receive training prior to the start of data collection to define standardized 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 (i.e. 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 flowchart; 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 program 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-scale 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 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 health care services (home care services, rehabilitation, and institutional) will be recorded for both the intervention and control groups 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) (58).

Feasibility of the intervention: qualitative interviews

A method of constant comparison (45, 59) will be used to analyse the semi-structured interviews from the older adults, the significant others and the home care staff describing a) perceived value, benefits, harms or unintended consequences of the intervention, b) acceptability of intervention in practice and c) fidelity, reach and the dose of intervention.

Qualitative interviews with the control group

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 *phase1,* data from focus groups interviews with home care staff within Stockholm county council after their education sessions was 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 program with suggestions for ways to implement ASSIST will be presented for important actors, such as the organization 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 program, a theory based reablement program 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 program, 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 program is in line with the MRC guidelines on how to develop and evaluate complex interventions (20). Accordingly, this first version of the program 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 (i.e. doing own laundry) and does not receive support as to how to assist the older person to

achieve the goal (i.e. 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 standardized 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 program. 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.

ETHICS AND DISSEMINATION

This study has been approved by the Regional Ethical Review Board in Stockholm, Sweden 2017/1439-31/1 and 2017/2172-32.

Each participant will sign a consent form of voluntary participation, which emphasizes the rights to withdraw from the study. A copy of the form is provided to the participants. Each participant (older adults, significant others, 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.

AUTHORS' CONTRIBUTIONS

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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COMPETING INTERESTS

The authors declare that they have no competing interests.

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Figure legends-

Figure 1. Overall plan for the ASSIST 1.0 project

Figure 2. Participant timeline and data collection

Figure 1. Overall plan for the ASSIST 1.0 project.

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 *ASSIST versus ordinary home help services*		
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	***Control group (CG)*** Home care staff (n=15) conducting ordinary home help service	
n=15 older persons (IG) will received ASSIST (duration: 10 weeks)	n=15 older person (CG) receiving ordinary home help services	
n=15 significant others from IG	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		

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Figure 2. Participant timeline and data collection

Time point	Study period							
	Enrolment	Intervention Group (n=15)			Control Group 2 (n=15)			After last participant's last visit
		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

209x297mm (300 x 300 DPI)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1 & 2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 2
	2b	All items from the World Health Organization Trial Registration Data Set	All items checked and met, however trial registered with ClinicalTrials.gov and not WHO
Protocol version	3	Date and version identifier	Page 1
Funding	4	Sources and types of financial, material, and other support	Page 14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 1 & 14
	5b	Name and contact information for the trial sponsor	Page 1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Page 14

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Not applicable
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 2-4
	6b	Explanation for choice of comparators	Page 5
Objectives	7	Specific objectives or hypotheses	Page 4 & 5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 5 & 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 6-8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Page 8
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Page 8
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Page 6

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 6-9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1, Timeline
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Not applicable
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Not applicable
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Not applicable
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Not applicable
Methods: Data collection, management, and analysis			

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Fig 1,Timeline & Pages 6-11
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Page 7
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 11 & 12
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 8,10-11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Not applicable
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Not applicable
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Page 12
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Page 12
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 12
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Not applicable
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 12
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Page 12
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 10
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Not applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 11 & 12
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 14
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Not applicable
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	Not applicable
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 13
	31b	Authorship eligibility guidelines and any intended use of professional writers	Page 14
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Not applicable
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	(in Swedish, available on request)

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	Not applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.