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Evaluation of an intervention programme addressing ability to perform activities of daily living among persons with chronic conditions: study protocol for a feasibility trial (ABLE)

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ABSTRACT

Introduction The number of persons living with a chronic condition is increasing worldwide. Conditions are considered chronic when lasting 1 year or more and requiring ongoing medical attention and/or limiting activities of daily living (ADL). Besides medical treatment, physical exercise to improve body functions is recommended and prescribed. However, improvements in body functions do not necessarily improve ability to perform ADL. Thus, it is necessary to develop interventions aiming directly at enhancing ADL ability. As a part of the research programme 'A Better Everyday Life', the first version of the ABLE intervention programme was developed.

Methods and analysis This feasibility study examine the perceived value and acceptability of the ABLE programme by evaluating the fidelity, reach, dose and potential outcomes using a pretest and post-test design involving 30 persons living with chronic conditions. Qualitative interviews among occupational therapists delivering and participants receiving the ABLE programme will be conducted to explore aspects affecting the intervention.

Ethics and dissemination The results will form the base for refinement of the ABLE programme and planning of a large-scale randomised controlled trial investigating the effect of the programme on self-reported and observed ADL ability. Dissemination will include peer-reviewed publications and presentations at national and international conferences.

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Strengths and limitations of this study

- The study is the first to evaluate feasibility and potential outcome of a generic occupational therapy intervention programme aiming to enhancing activities of daily living (ADLs) ability.
- Potential outcomes related to enhanced ADL ability are evaluated based on both self-reported and observed ADL ability.
- A combination of qualitative and quantitative data involving both persons with chronic conditions and occupational therapists are systematically collected during and after the intervention period.
- The study design is a single group study; thus, no control group is involved.
- The study is not powered to determine the effectiveness of the intervention in terms of self-reported and observed ADL ability.

INTRODUCTION

Background and rationale

The number of persons living with chronic conditions is increasing worldwide causing both human suffering and socioeconomic challenges.[1] Chronic conditions are defined as 'conditions that last 1 year or more and require ongoing medical attention and/or limit activities of daily living' (ADL).[2] In accordance with this definition, existing research has revealed that persons with chronic conditions experience decreased ability to perform both personal ADL (PADL) and instrumental ADL (IADL) tasks.[3–6] PADL involves basic self-care tasks necessary to perform for all people independent of gender, age, culture and interests. It includes, for example, eating, toileting, grooming and dressing. IADL involves more complex household chores, necessary for independent living including shopping, cooking, cleaning and doing laundry. Which IADL tasks a person needs to perform can depend on his or her roles, age, family structure, culture, housing conditions and personal interests.[7]

Persons living with a chronic condition and who experience limitations related to performance of ADL tasks are offered various interventions. Besides medical treatment to prevent or treat symptoms, persons with

chronic diseases are often recommended physical exercise in order to improve physical and/or mental body functions. Often such interventions are expected to indirectly improve ADL ability by enhancing physical and mental body functioning. However, existing research[8–13] indicates that improvements in body functions do not necessarily translate into improved ADL ability, suggesting that use of interventions aiming directly at enhancing ADL task performance is needed.

Research investigating the outcomes of rehabilitation services designed directly to enhance ADL task performance is sparse and insufficient.[14–16] In a scoping review on occupational therapy interventions for various chronic conditions, Hand *et al*[15] conclude that similar interventions addressing ADL may be applicable across a range of diagnoses. However, the review identified studies mainly evaluating intervention programmes designed for specific diagnostic groups, suggesting the need for a generic programme directly aiming at enhancing ADL ability in persons with chronic conditions. To address this need, as part of the research programme 'A Better Everyday Life', the first version of the intervention programme 'ABLE' was developed.

As performance of an ADL task unfolds as a transaction between a person and an environment as the person performs a task,[17] interventions addressing ADL task performance problems can be considered complex interventions, that is, interventions with several interacting components.[18] Hence, the research programme 'A Better Everyday Life' and the intervention programme 'ABLE' is designed in accordance with the Medical Research Council (MRC) guidance on how to develop and evaluate complex interventions.[18] 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. According to the guidance, the first step of developing an intervention involves identifying existing evidence. According to Straus *et al*,[19] the evidence-based practice triad comprises: (A) best theoretical and scientific evidence, (B) clinical expertise and (C) values and circumstances of the people with chronic conditions. Thus, at this first stage of the development of the 'ABLE' programme, existing theoretical and scientific evidence was identified based on a literature search and review. The literature review revealed that principles of energy conservation often were applied by occupational therapists working with persons living with chronic conditions.[20–25] Furthermore, two descriptive studies were conducted to inform the programme. The first study investigated self-reported quality of ADL tasks performance among men and women living with various chronic conditions.[26] The second study identified ideas on how to enhance ADL ability according to persons with chronic conditions and occupational therapists.[27]

The second phase of intervention development is related to evaluating the feasibility of the programme and piloting the applied methods.[18] Thus, evaluation of feasibility is considered a prerequisite for evaluating effectiveness of an intervention in a full-scale randomised controlled trial (RCT). In the present study, the feasibility of the first version of the 'ABLE' programme (ABLE 1.0) will therefore be evaluated in terms of: perceived value and acceptability of intervention; fidelity, reach and dose; and potential outcomes.

Objectives

The overall aim of this study will be to investigate the feasibility of the evidence-based occupational therapy programme, 'ABLE', aiming at enhancing ADL ability in persons with chronic conditions. More specifically, study objectives have been developed based on the framework by O'Cathain[28] addressing seven aspects of feasibility (table 1).

METHODS AND ANALYSIS

Trial design

This feasibility study will be conducted using a pretest and post-test design without a control group evaluating aspects of intervention feasibility and potential outcomes. Furthermore, the study protocol will include a nested qualitative interview study involving persons living with chronic conditions, who have received the 'ABLE' intervention and the occupational therapists who have delivered the intervention programme. The aim of the qualitative interviews is to explore aspects of (A) perceived values, benefits, harms or unintended consequences of the intervention, (B) acceptability of intervention and (C) fidelity, reach and dose of the intervention. The framework of O'Cathain *et al*[28] will be used to guide the evaluation of the feasibility of the intervention by addressing seven subcategories (table 1). The protocol follows the Standard Protocol Items: Recommendations for Intervention Trials 2013 statement,[29 30] which defines standard protocol items for clinical trials.

Study setting

The ABLE programme will be conducted in a Danish municipality by occupational therapists employed by the municipality, delivering the interventions in the participants' own homes.

Participants: eligibility criteria

Persons living with chronic somatic conditions (eg, rheumatological, neurological or medical diseases) will be included if they fulfil the following inclusion criteria: (A) age ≥18 years, (B) diagnosed (by a physician) with one or more chronic condition(s), (C) have participated in one or more of the standard diagnosis-specific short term rehabilitation programmes at the municipality, (D) living at home, (E) experiencing PADL and/or IADL tasks performance problems and (F) motivated for participating in the 'ABLE 1.0' programme. Participants with known substance abuse, mental illness, other more acute illnesses affecting ADL task performance and/or

Table 1 Overview of the specific objectives and related data collection methods based on the framework suggested by O'Cathain *et al*[28]

Subcategories	Intervention development	Intervention components	Mechanisms of action	Perceived value, benefits, harms or unintended consequences of the intervention	Acceptability of intervention in principle	Feasibility and acceptability of intervention in practice	Fidelity, reach and dose of intervention
Specific objective	Determine adjustments made to make the intervention programme more acceptable and/or relevant in the specific context.	Identify specific components implemented, including required time, equipment and material. Determine adjustments made to make the specific component more acceptable and/or relevant in the specific context.	Determine the extent to which intervention components contribute to goal achievement. Determine the proportion of participants obtaining clinically relevant improvements in self-reported and/or observed ADL ability.	Determine the most beneficial intervention components. Identify unintended positive/negative side effects. Determine the extent to which the components are perceived meaningful.	Evaluate the overall perception of the content and delivery of the programme. Determine to which extent the programme has potential to be implemented in usual practice.	Determine the retention rate and if the programme seems to be feasible across for example, gender and diagnostic groups. Describe challenges, satisfaction and confidence in relation to delivering the intervention. Identify institutional/organisational facilitators and barriers during delivery.	Determine adherence to intervention procedures and manual. Determine the number of sessions for each participant and duration of each session. Determine if each participant had a sufficient dose.
Data collection method	Registration forms will be filled out by the occupational therapists after each session in the programme.	Registration forms will be filled out by the occupational therapists after each session in the programme.	Registration forms will be filled out by occupational therapists and participants after each session in the programme. Goal setting preassessment and postassessment of ADL ability.	Qualitative interviews with occupational therapists and participants after completing the data collection for both participant groups. Registration forms will be filled out by occupational therapists and participants after each session in the programme.	Qualitative interviews with occupational therapists and participants after completing the data collection for both participant groups.	Questionnaire on the participants' demographic data. Registration forms will be filled out by the occupational therapists after each session in the programme.	Registration forms will be filled out by the occupational therapists after each session in the programme.

Continued

Table 1 Continued

Subcategories	Intervention development	Intervention components	Mechanisms of action	Perceived value, benefits, harms or unintended consequences of the intervention	Acceptability of intervention in principle	Feasibility and acceptability of intervention in practice	Fidelity, reach and dose of intervention
Data	Registrations of deviations from the intervention manual.	Registrations of applied components, time use and needed equipment. Registrations of deviations from the intervention manual.	GAS. ADL-I. AMPS.	Transcribed interview data. Registrations on unintended positive/negative side effects and perceived degree of meaningfulness.	Transcribed interview data.	Demographic data. Registrations on retention, challenges, satisfaction, confidence and institutional/organisational facilitators and barriers.	Registrations of number of sessions for each participant, time use and deviations from the intervention manual.

ADL, activities of daily living; ADL-I, ADL-Interview, version 2.0; AMPS, Assessment of Motor and Process Skills; GAS, Goal Attainment Scaling.

language barriers causing difficulties participating in the programme will be excluded from the study.

If a participant experiences health-related problems during the programme and/or at the postintervention re-evaluation, the occupational therapist will encourage the participant to contact his or her physician for an appointment. Participants may discontinue the study at any time. Reason for discontinuation will be recorded. Criteria for subject discontinuation include any health condition that, in the opinion of the researcher, potentially jeopardises the safety of the participant, if he/she continues participation.

The occupational therapy intervention programme 'ABLE 1.0'

Development of the intervention programme

As previously described, the 'ABLE 1.0' programme was developed based on a review of theory and scientific evidence as well as two studies gathering information about clinical experience and needs and expectations of persons living with chronic conditions. As previous studies have supported the use of the Occupational Therapy Intervention Process Model (OTIPM) as the basis for designing interventions within occupational therapy,[31–33] the programme is based on the present version of this theoretical model of the therapy process.[17] The model includes: (A) evaluation of the participant's self-reported and observed ADL ability, (B) individual goal setting, (C) implementation of interventions focused and/or based on performance of purposeful and meaningful everyday life tasks and (D) re-evaluation.

Moreover, the 'ABLE 1.0' programme is developed based on a scoping review by Hand *et al*[15] suggesting the following elements to be included in the interventions for persons with chronic diseases: (A) individualised programme (ie, individualised goal setting and problem solving), (B) family or peer support, (C) strategies to facilitate coping with ADL task performance and (D) promoting continued use of strategies. Furthermore, the interventions sessions are based on principles related to energy conservation.[20] In previous studies, such principles have been implemented among various diagnostic groups, including persons with heart failure,[21] chronic obstructive pulmonary disease (COPD),[22] multiple sclerosis[23 24] and persons with fatigue.[25]

Two studies have been conducted to further inform the intervention programme. That is, one study investigating the self-reported ADL ability in men and woman living with various chronic conditions (schizophrenia, COPD, cancer and rheumatological diseases).[26] The results of this study indicated which ADL tasks that persons living with chronic conditions perceive problems performing and also what kind of problems (ie, decreased safety, increased use of time and effort and need for assistance). The results revealed that persons living with chronic conditions predominantly perceive problems related to increased use of time and increased physical effort during ADL task performance. Thus, the findings led to designing intervention components based on energy

conservation principles (eg, dividing the specific task into minor parts) to decrease time use and physical effort.

The second study aimed at identifying ideas on how to enhance ADL ability according to persons with chronic conditions and occupational therapists.[27] The ideas identified in the study were organised in themes related to applying new strategies and adaptation in everyday life, personal factors of the persons living with chronic conditions, social environment, including the support from others and relevant services and opportunities in general. Hence, these findings were used to develop and integrate intervention components based on the clinical expertise of the occupational therapists as well as the needs and expectations of persons living with chronic conditions. For example, the theme Adaptation resulted in designing components related to applying adaptive equipment or modifying the physical environment (eg, rearrangements in the kitchen).

A joint display[34] was created to condense and translate the most central parts of the above-mentioned information into specific intervention components. Furthermore, during the development process, 'The Logic Model Development Guide' by W.K. Kellogg Foundation[35] was used as frame of reference to develop both a basic logic model and a theory-of-change logic model. Furthermore, two half-day workshops were conducted with 6 months in between, where authors of this paper were present to discuss and revise preliminary versions of the intervention programme.

Duration and specific content of the intervention programme

The 'ABLE 1.0.' is an 8-week intervention programme consisting of five to eight sessions: *session 1*: first meeting and occupational therapy evaluation (mandatory) involving a standardised ADL interview (ADL-Interview (ADL-I))[36 37] and ADL observation (Assessment of Motor and Process Skills (AMPS))[38 39]; *session 2*: goal setting using Goal Attainment Scaling (GAS)[40 41] and clarification of reasons for ADL task performance problems (mandatory); *sessions 3–7*: interventions aiming at enhancing ADL ability are enacted based on information from the first two sessions (the number of intervention sessions can vary, but a minimum of two sessions is mandatory) and *session 8*: re-evaluation (mandatory) including evaluation of goal attainment based on GAS.

Overall, an adaptational approach is being applied, and the interventions are focused and/or based on performance of purposeful and meaningful ADL tasks.[17] More specifically, the intervention sessions are founded on 'the compensatory model' of the OTIPM and organised using the person–environment–occupation model.[42] Thus, creating a 'tool box' including optional intervention components (for use in sessions 3–7) aiming at changing the *person* (eg, changing habits related to task performance), the *environment* (eg, changing physical and/or social environment) and/or the *occupation* (here ADL task) (ie, using task analysis to adjust the challenge of the task to the ability of the person by, e.g., dividing the task into minor parts in order to simplify the task). A total of nine optional intervention components were developed.

Central to the interventions is that these will be individually tailored (based on baseline evaluations) and implemented in natural/ecologic contexts, that is, where the participants typically perform ADL tasks (eg, home or local area) and with the tools and materials they usually use.[17] The intervention sessions are based on face-to-face and/or telephone contact between the occupational therapist and the participant. Based on an agreement between the occupational therapist and the participant, the participants can be asked to do 'homework' between two intervention sessions (eg, trying out a new way of performing an ADL task).

Training of the intervention providers

The intervention will be provided by two occupational therapists employed at the municipality, with at least 2 years' experience working with ADL problems among persons with chronic conditions, calibrated AMPS raters[38] and willing to participate in training sessions, supervision and meetings.

To ensure uniformity and standardisation of the programme, a comprehensive manual describing the procedures, content of each session as well as the optional intervention components (the tool box) has been developed. Moreover, since training and ongoing supervision and communication is crucial when conducting intervention studies,[31 43] the therapists involved in the intervention will participate in a 2.5-day training workshop before starting to deliver the intervention programme. The training workshop will contain introduction to the OTIPM, the intervention manual, cases with role play, video demonstrations (1 day), ADL-I training (half day) as well as overall introduction to research in general and specifically to data collection in the present study (1 day). During the intervention period, the occupational therapists will participate in meetings to receive supervision aiming at clarifying issues related to the programme, including application of the manual in clinical practice. The collaborative learning process will be facilitated by the interactions sharing experiences and reflections.[43] The second author will be responsible for both the intervention-training sessions before the intervention period and for supervision during the intervention period. The last author will be responsible for teaching the ADL-I.

Outcomes

Feasibility data

A combination of qualitative and quantitative data will be collected among the occupational therapists and the participants using registration forms, as well as semistructured qualitative interviews (table 1). The aim of the 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[28] according

to occupational therapists and participants, respectively (table 1).

Outcomes data

As previous studies have revealed limited relationship between self-reported and observed ADL ability in persons with chronic conditions,[5 6] the coprimary outcomes will be self-reported, and observed ADL ability measured at baseline and post intervention. Self-reported ADL ability is measured using the ADL-I[36 37] and the observed ADL ability is measured using the AMPS.[38 39] As previously mentioned, aside from being coprimary outcomes, baseline ADL-I and AMPS data will also form the basis for goal setting and intervention planning in the intervention process. Therefore, the baseline evaluations will be conducted by the occupational therapists, whereas trained and calibrated occupational therapy students not involved in the intervention will conduct postintervention re-evaluations. Secondary outcome will be goal attainment evaluated by the GAS.[40 41]

Participant timeline

Participant enrolment will be initiated 1 September 2017 and the last qualitative interview is scheduled to be before 14 February 2018. During the period, two groups of participants (n=15) each will be enrolled in the 8-week intervention programme. At the time of submission of this study protocol, recruitment to the trial is ongoing.

For each participant, demographic data and baseline assessment (ie, ADL-I, AMPS and GAS) will be conducted during the first week after enrolment and postintervention re-evaluation (ADL-I and AMPS) within the last week of the intervention programme (figure 1). GAS re-evaluation will be conducted during the eighth session (or the last session) in the intervention programme. Moreover, registration forms addressing varies aspects of feasibility (table 1) will be filled out by occupational therapists and participants after each session in the programme.

Sample size

As this study is a feasibility study, a sample size calculation is not required.[44 45] However, the sample needs to be representative of the target population and to be large enough to provide information related to the feasibility and the potential outcome of the programme.[45] Results from a recent study,[44] using audit of sample sizes for pilot and feasibility studies conducted in the UK revealed sample sizes for feasibility studies from 10 to 300 participants. Hence, the results provide no clear guidelines on sample size estimations for future studies. In the present study, occupational therapists apply a new occupational therapy programme. As it may take some time for the occupational therapist to get experienced in applying the programme, several participants are needed. Consequently, the sample size is estimated to a total of 30 participants.

Recruitment and informed consent

Personnel at the municipality will be responsible for recruiting persons with chronic conditions from a list of persons who have terminated participation in group-based diagnosis-specific rehabilitation programmes consisting of psychoeducation and physical exercises for persons with various chronic conditions (eg, diabetes, osteoporosis and COPD). A structured checklist will be used to ensure that potential participants fulfil the inclusion criteria, including ensuring that he or she is motivated, and to guarantee that sufficient information is provided. Persons fulfilling the inclusion criteria will receive written and oral information about the study. Included participants will receive a letter with general information, such as rights to withdrawal and confidentially, and a letter about the first session (including the date and time). The occupational therapists, delivering the intervention programme, obtain written informed consent from the participant before initiating the first session of the 'ABLE' programme (figure 1).

	Study period							
	Enrolment	Group 1 (n=15)			Group 2 (n=15)			After last participant's last visit
Time point		Week 1-2	Week 3-8	Week 8	Week 1-2	Week 3-8	Week 8	
Enrolment								
Eligibility screen	■							
Oral and written information	■							
Informed consent		■			■			
Intervention								
ABLE 8 week program		■	■		■	■		
Evaluations								
Demographic data		■			■			
Baseline ADL-I, AMPS,GAS		■			■			
Post intervention GAS – last session				■			■	
Post intervention ADL-I, AMPS,				■			■	
Registration forms		■	■	■	■	■	■	
Individual interviews (participants)								■
Individual interviews (occupational therapists)								■

Figure 1 Participant timeline and data collection. ABLE, The occupational therapy intervention program; ADL-I, Activities of Daily Living Interview, version 2.0; AMPS, Assessment of Motor and Process Skills; GAS, Goal Attainment Scaling.

Data collection

In the present study, data gathered will comprise participant demographic data, and feasibility data including registration forms, outcomes and qualitative interviews (figure 1).

Demographic data

Demographic data characterising the participants living with chronic conditions will be collected as part of the occupational therapy evaluation by the occupational therapists at the first session of the ABLE programme (baseline): age, gender, diagnosis, years living with a chronic condition and self-reported general health.

General health

General health is assessed using the first question (SF1) of the Short Form 36 (SF36).[46] The SF1 is a single question often used as an indicator of general health and well-being based on self-report. Thus, the following question will be asked: '*In general, would you say your health is: Excellent, Very good, Good, Fair or Poor?*' Previous studies indicate that the question is applicable in persons with chronic conditions.[46]

Data on the two occupational therapists delivering the ABLE intervention (age, gender, years since graduation as occupational therapist and years working with persons with chronic conditions) will be collected at the first training session. Furthermore, the number of participants treated by each of the therapists will be collected.

Registration forms

After each session, occupational therapists and participants will independently fill out registration forms. The registration forms are developed to capture aspects related to (A) intervention development, (B) intervention components, (C) mechanisms of change, (D) perceived value, benefits, harms or unintended consequences of the intervention, (E) acceptability of intervention in principle, (F) feasibility and acceptability of intervention in practice and (G) fidelity, reach and dose of intervention[28] (table 1). The participants will hand in their registration forms to the occupational therapists in closed envelopes after each session.

Outcomes

The occupational therapists delivering the intervention programme will perform baseline ADL-I and AMPS evaluations during the first week of the intervention programme, that is, at the first session (figure 1). Postintervention ADL-I and AMPS re-evaluations will be conducted in week 8, that is, during the last week of the intervention programme. These re-evaluations will be conducted by five pregraduate occupational therapy students calibrated as AMPS raters[38] and willing to participate in training session related to the ADL-I. The students have no personal or professional relation to the municipality, the occupational therapists involved in the interventions or the participants receiving the interventions. The occupational therapy students will undergo three training sessions involving overall introduction to data collection in the present study (2–3 hours) as well as specific training related to performing ADL interviews (3 hours). The second and last author will be responsible for these training sessions.

The *ADL-I, version 2.0*[36] is a standardised evaluation tool used by occupational therapists to describe and measure the self-reported quality of ADL task performance in 47 ADL items in terms of physical effort and/or fatigue, efficiency, safety and independence. The following seven response categories are used: (A) I perform the task independently without use of extra time or effort and without risk; (B) I perform the task independently, but I use helping aids; (C) I perform the task independently, but it takes me extra time; (D) I perform the task independently, but I use extra effort/get tired; (E) I perform the task independently, but there is a risk that I might injure myself; (F) I need assistance from someone but do participate; and (G) the task is performed by others for me – I cannot participate actively.

The participant can mark more than one response category if several apply to his or her performance of the specific ADL task (eg, mark both categories C and D if they spend extra time and get tired). To create an overall measure of self-reported quality of ADL task performance, the mark given in the lowest response category on each task is rated using a four-point ordinal *quality of performance* scale: 4='competent' (categories A/B), 3='extra time/effort' (categories C/D), 2='safety risk/need help' (categories E/F) and 1='unable' (category G). Furthermore, the participant is to rate his or her perceived satisfaction with the quality of each ADL task performance using a four-point ordinal *satisfaction* scale: 4='very satisfied', 3='satisfied', 2='dissatisfied' and 1='very dissatisfied'.[37]

The baseline ordinal *quality of performance* and *satisfaction* scores will form the basis for identification of ADL task performance problems to be prioritised at goal setting.[37] To measure change in self-reported quality of ADL task performance, the 47 ordinal *quality of performance* scores are transformed into one overall linear (interval scale) measure of self-reported quality of ADL task performance, adjusted for the difficulty of the ADL tasks, based on Rasch measurement methods.[36] The measures are expressed in logits (log-odds probability units).[6 36] Previous studies indicate that the ADL-I can be used to generate valid and reliable linear measures of self-reported quality of ADL task performance among persons with chronic conditions.[3 5 36]

The *AMPS*[38 39] is a standardised observation-based evaluation tool used by occupational therapists to measure a person's observed quality of ADL task performance in terms of physical effort and/or fatigue, efficiency, safety and independence. The person being evaluated chooses and performs at least two of the standardised ADL tasks that the person finds relevant and of appropriate challenge. During an AMPS evaluation, two domains of occupational performance are evaluated: motor skills (16

items) and process skills (20 items). After the observation, the quality of each skill is evaluated on a four-point ordinal scale according to the scoring criteria in the AMPS manual.[39]

The available AMPS software,[47] based on Many-Faceted Rasch statistics, makes it possible to convert the ordinal raw scores into overall linear ADL motor and ADL process ability measures adjusted for task challenge, skill item difficulty and rater severity. The measures are expressed in logits (log-odds probability units).[38] Several studies support that the AMPS ability measures are reliable and valid among persons with chronic conditions.[5 6 48–50]

GAS[40 41] is a tool for defining and monitoring a person's individual goals. The person is actively involved in defining goals and describing the levels of goal attainment. When a goal is being defined, measurable and observable indicators, that is, indicators that can be used to evaluate the progress towards the goal (eg, independence, duration and frequency), are applied. The level of goal attainment is described using a scale from −2 to +2. The actual level of performance is described at level −1, and the expected level is described at level 0. Level +1 and level +2 are descriptions of what the person will be able to, if he or she achieves more than expected. Level −2 describes the level, where the person achieves less than expected.

A feasibility study[51] concluded that GAS was applicable among older adults with multiple chronic conditions living at home.

Semistructured qualitative interviews

Semistructured qualitative interviews will be conducted by an occupational therapist not involved in developing and delivering the intervention programme. Participants and occupational therapists will be invited to participate in individual interviews.

Data analyses

Feasibility of the intervention: registrations forms

Descriptive statistical analyses will be conducted based on data recordings from the occupational therapists and participants (table 1).

The number of persons being recruited will be presented in a flow chart; the retention rate and the adherence to intervention manual will be presented based on frequencies and percentages. Based on registrations of time use at each session of the programme for each participant, the mean number of minutes used for each session will be presented. The number of participants seen by each occupational therapist 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 occupational therapist and presented. The perceived degree of, for example, participant involvement, meaningfulness and confidence in relation to intervention delivery will be presented based on the occupational therapists' ratings on visual analogue scale (VAS) from 1 to 5.

To which extent the participants perceived that they were informed, involved and on their way towards goal attainment will be presented based on the participants' ratings on VAS from 1 to 5. Furthermore, the perceived meaningfulness and satisfaction will be rated and potential positive and/or negative side effects will be registered and presented.

Feasibility of the intervention: qualitative interviews

Interviews will be transcribed verbatim. A method of constant comparison[28 52] will be used to analyse the semi-structure interviews describing: (A) perceived value, benefits, harms or unintended consequences of the intervention, (B) acceptability of intervention in practice and (C) fidelity, reach and dose of intervention (table 1).

Evaluation of outcomes

The proportion of participants with a change in ADL ability measures (AMPS and ADL-I) will be identified. Thus, in accordance with the AMPS manual, the proportion of participants with no change (<0.3 logits), a clinically relevant increase (≥0.3 logits) or decrease (≥−0.3 logits) in AMPS ADL motor and/or ADL process ability measure will be identified.[38] A criterion of 0.5 SD has previously been applied for evaluation of clinically relevant differences in measures based on self-report in persons with chronic pain.[53] As chronic pain often derives from a chronic condition, the criterion of 0.5 SD is also applied in the present study. Thus, the proportion of participants with no change (change in logits equal to <0.5 SD as measured at baseline), a decrease or an increase in logits equal to ≥0.5 SD on the ADL-I ability measures will also be identified.

Patient and public involvement

In preparation for this study, focus groups involving persons living with a chronic condition and occupational therapists working in clinical practice with this target group were conducted.

The purpose was to identify, organise and prioritise ideas on how to enhance ADL ability when living with a chronic condition. Thus, the content of the intervention evaluated in this study was influenced by patients' priorities, experience and preferences.

DISCUSSION

The present study will contribute with knowledge about the feasibility of the 'ABLE' intervention programme, a new occupational therapy intervention programme aiming directly at enhancing ADL ability among persons living with chronic conditions using an adaptational approach. It is expected that the study will provide information on aspects related to perceived value, acceptability, fidelity, reach, dose and potential outcome to be used to further develop and refine the programme. If the study results suggest that the programme is feasible and reveals indications for positive

outcomes, the intention is to evaluate the outcomes of the programme in a future large-scale RCT.

The process of developing the 'ABLE' intervention programme is in accordance with the MRC guidance on how to develop and evaluate complex interventions.[18] Consequently, the first version of the programme is being developed based on a comprehensive process including several steps, that is, searching for and reviewing existing evidence, gathering evidence based on the experiences of occupational therapists and persons living with chronic conditions, basing the programme on occupational therapy theory and models, developing logic models and conduction workshops with experts.

In conclusion, based on a need of an intervention programme aiming directly at enhancing ADL ability in persons living with chronic conditions, this feasibility study will be conducted. The results will be applied to refine a large RCT study aiming at investigating the outcomes of the 'ABLE' intervention programme.

ETHICS AND DISSEMINATION

The study will be conducted in accordance with Danish law and the Helsinki declaration. The local research ethics committee decided that according to Danish law, the study does not need approval. The participants are insured by the Danish Patient Insurance Association. Each participant will sign a consent form of voluntary participation, which emphasise the rights to withdraw from the study. A copy of the form is provided to the participants. The second author will be responsible for saving the consent forms in the participant's study file. Each participant 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 occupational therapists 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, healthcare professionals and the public in general, through various national and international events.

Contributors EEW and KTN conceived the original idea and outline of the study, and LK and SG contributed to designing the study. KTN was responsible for developing the intervention in collaboration with MSP, CvB, LK, SG and EEW. KTN will further be responsible for collaboration with the municipality and for training and supervising the occupational therapists and occupational therapy students. KTN and EEW wrote the study protocol, and SG has been responsible for turning the study protocol into a manuscript. All authors discussed and commented on draft versions and approved the final version.

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Competing interests None declared.

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Ethics approval Approval from the Danish Data Protection Agency has been obtained (journal no. FOU-PHD-2017–001).

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