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Study protocol for a randomised controlled trial (ABLE)

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ABSTRACT

Introduction The need to develop and evaluate interventions, addressing problems performing activities of daily living (ADL) among persons with chronic conditions, is evident. Guided by the British Medical Research Council's guidance on how to develop and evaluate complex interventions, the occupational therapy programme (A Better everyday LifE (ABLE)) was developed and feasibility tested. The aim of this protocol is to report the planned design and methods for evaluating effectiveness, process and cost-effectiveness of the programme.

Methods and analysis The evaluation is designed as a randomised controlled trial with blinded assessors and investigators. Eighty participants with chronic conditions and ADL problems are randomly allocated to ABLE or usual occupational therapy. Data for effectiveness and cost-effectiveness evaluations are collected at baseline (week 0), post intervention (week 10) and follow-up (week 26). Coprimary outcomes are self-reported ADL ability (ADL-Interview (ADL-I) performance) and observed ADL motor ability (Assessment of Motor and Process Skills (AMPS)). Secondary outcomes are perceived satisfaction with ADL ability (ADL-I satisfaction); and observed ADL process ability (AMPS). Explorative outcomes are occupational balance (Occupational Balance Questionnaire); perceived change (Client-Weighted Problems Questionnaire) and general health (first question of the MOS 36-item Short Form Survey Instrument). The process evaluation is based on quantitative data from registration forms and qualitative interview data, collected during and after the intervention period. A realist evaluation approach is applied. A programme theory expresses how context (C) and mechanisms (M) in the programme may lead to certain outcomes (O), in so-called CMO configurations. Outcomes in the cost-effectiveness evaluation are quality-adjusted life years (EuroQool 5-dimension) and changes in ADL ability (AMPS, ADL-I). Costs are estimated from microcosting and national registers.

Ethics and dissemination Danish Data Protection Service Agency approval: Journal-nr.: P-2020-203. The Ethical Committee confirmed no approval needed: Journal-nr.: 19 045 758. Dissemination for study participants, in peer-reviewed journals and conferences.

Strengths and limitations of this study

- The occupational therapy intervention programme (ABLE2.0) is developed based on research evidence, client perspectives and clinical experience, resulting in a programme applicable across gender, age and chronic conditions, aiming at enhancing the ability to perform activities of daily living among persons living with chronic conditions.
- This protocol, informed by two previous studies, covers the evaluation of ABLE V.2.0 in terms of effectiveness, process and cost-effectiveness, using a randomised controlled trial design.
- Conducting this trial, comprising three evaluations alongside each other, in a community-based rehabilitation setting involving clinicians in assessment and intervention represents challenges on blinding, adherence, inclusion procedures and outcomes assessment.
- Conducting this trial in a clinical setting, including clients, already referred to rehabilitation and offering an intervention programme delivered by occupational therapists employed in the municipality, increase the external validity of the study findings.
- The study is part of the research programme 'ABLE', systematically following the British Medical Research Council's guidance on how to develop and evaluate complex interventions, supporting the choice of appropriate methods.

Trial registration number NCT04295837

INTRODUCTION

Existing research have documented the need to develop, evaluate and implement evidence-based occupational therapy interventions, directly focusing on enhancing ability to perform activities of daily living (ADL) tasks among persons living with chronic conditions.[1–4] Consequently, the research programme 'A Better everyday LifE

' was established to develop and evaluate such an intervention programme.

Recent statistics from the WHO estimate that 71% of all deaths worldwide is caused by chronic conditions,[5] with the four most common being cardiovascular diseases, cancer, chronic respiratory diseases and diabetes. Further, a recent study revealed that more than 65% of the Danish population, aged 16 or above, live with one or more chronic conditions.[6] However, the probability of dying from one of these diseases between the ages of 30 and 70 decreased globally by 18% between 2000 and 2016,[5] leaving an increasing number of persons living with such diseases. This entails an increasing financial burden for community-based rehabilitation services[7–9] and potentially decreased quality of life for the persons concerned.

Chronic conditions have been defined as 'conditions that last a year or more and require ongoing medical attention and/or limit ADL'.[10] Performing ADL tasks is a widespread problem among persons living with chronic conditions.[11–18] ADL involve tasks that most people need to perform in their everyday lives, including personal and instrumental ADL tasks.[19] Personal ADL involve basic self-care tasks necessary to perform for all people across gender, age, culture and interests, for example, eating, toileting, grooming and dressing. Instrumental ADL tasks involve more complex household chores, necessary for independent living, including shopping, cooking, cleaning and doing laundry.[20] Persons living with chronic conditions report increased physical effort, increased use of time, safety risks and need for assistance when performing both personal and instrumental ADL tasks, reflecting decreased quality of performance.[11 13 14] Decreased quality in performance of ADL tasks may cause reduced energy and time for participation and engagement in other types of wanted and/or needed activities including work, leisure and social life[21]; resulting in occupational imbalance, that is, an experience of not having the right amount of and variation in daily activities.[22] Adressing such ADL task performance problems, among persons with various diseases, is a core area for occupational therapy.

Research suggests that occupational therapy interventions in general may improve ADL ability among older persons with chronic conditions.[1 2 4 23] Further, research provides evidence to support a structured and individualised problem-solving process applied as a part of the occupational therapy process.[1 2] Occupational therapy interventions have been designed for specific diagnostic groups, for example, persons with Parkinson's disease or dementia.[18 24] Still, research investigating the effectiveness and functioning of occupational therapy interventions for persons with various chronic conditions, detailed description of the intervention, and determination of the contribution of occupational therapy in multidisciplinary rehabilitation services is needed.[2 4 18 23 25]

Based on a scoping review on occupational therapy for chronic conditions, Hand *et al*[2] suggested that similar interventions addressing ADL may be applicable across a range of diagnoses. To investigate this further, our research group examined self-reported quality of ADL tasks performance among n=593 persons living with chronic conditions, and found similar types of ADL task performance problems across chronic conditions.[26 27] Accordingly, the first version of an occupational therapy intervention programme (termed ABLE V.1.0) was developed, addressing decreased ADL ability across chronic conditions causing disability. To our knowledge, ABLE V.1.0 is the first intervention programme addressing ADL task performance problems, for use across gender, age and chronic conditions. The idea of using a programme applicable across gender, age and chronic conditions is in accordance with Wade's[28] bio-psycho-social approach within rehabilitation, suggesting to focus on limitations in relation to activities rather than diagnosis during the process of rehabilitation.

The development and evaluation of the ABLE intervention programme is guided by the British Medical Research Council's (MRC) guidance on how to develop and evaluate complex interventions.[29] The guidance prescribes four stages: development, feasibility/piloting, evaluation and implementation.[29] The first phase of the research programme was conducted during 2015–2018 focusing on the development and feasibility of ABLE V.1.0[21 27 30]. This resulted in an 8-week occupational therapy programme, applicable across gender, age and chronic conditions, and addressing ADL task performance problems among persons living with chronic conditions at home. It consists of five to eight individualised sessions, based on an adaptational approach. The programme flexibly allows an individualised approach by employing a combination of intervention components adapted to the single client, the types of ADL task performance problems and the local settings. The programme is designed as a home-based service to be implemented as part of community-based rehabilitation.

The feasibility study showed that ABLE V.1.0 was feasible in terms of content and delivery with minor adjustments to the intervention manual and recruitment procedures.[30] Accordingly, the intervention manual was revised, resulting in ABLE V.2.0. Following the feasibility study, a randomised controlled pilot study was conducted in the same context as the potential full-scale trial. The pilot study assessed feasibility in terms of trial procedures, adherence, appropriateness of additional outcome measurements and accessability to information on what was delivered in the control group (usual occupational therapy).[31] The results suggested few adjustments on outcome measurements, inclusion criteria and extraction of information on usual occupational therapy.[31] Moreover, information gathered in the pilot study suggested that ABLE V.2.0 differs from usual occupational therapy by building on a systematic, profession-specific, client-centred, problem-solving approach, including assessments, goalsetting and specified intervention components.[31] Therefore, ABLE V.2.0 is considered superior to usual occupational therapy. Proceeding to full-scale trial was recommended.[31]

This trial is designed to evaluate the ABLE V.2.0 in terms of effectiveness, process and cost-effectiveness, according to the MRC guidance recommendations.[29] Assessing effectiveness is considered important due to prevention of selection bias.[29] A process evaluation within the trial is valuable to investigate how the intervention programme is delivered, how it functions, and to inform interpretation of the outcomes.[29 32] Evaluation of cost-effectiveness makes it possible to compare cost of intervention versus its advantages.[29 32]

Aims and hypotheses

The aims of the ABLE V.2.0 randomised controlled trial are to:

1. Determine the effectiveness of ABLE V.2.0, compared with usual occupational therapy, in persons experiencing decreased ADL ability following chronic conditions. It is hypothesised that participants receiving ABLE V.2.0 will achieve:
   a. A significantly higher increase in self-reported ADL task performance and/or a significantly higher increase in observed ADL motor ability (coprimary outcomes).
   b. A significantly higher increase in self-reported satisfaction with ADL task performance and/or a significantly higher increase in observed ADL process ability (secondary outcomes).
2. Explore outcomes related to occupational balance, perceived problems and general health.
3. Evaluate the processes of ABLE V.2.0, including:
   a. Delivery of ABLE V.2.0 in terms of fidelity, dose, adaptations and reach.
   b. Interactions between context, mechanisms and outcomes, and determine under what circumstances, for whom, why and how ABLE V.2.0 enhances the ADL ability in persons living with chronic conditions.
4. Investigate the cost-effectiveness of ABLE V.2.0 compared with usual occupational therapy from a societal perspective.

METHODS AND ANALYSES

Design

For the purpose of effectiveness and cost-effectiveness evaluation, this is a single-centre, randomised controlled, outcome-assessor and investigator-blinded superiority trial, with two parallel groups, designed to compare ABLE V.2.0 with usual occupational therapy in two phases. Reporting of the protocol follows the Standard Protocol Items: Recommendations for Interventional Trials statement[33] and the Template for Intervention Description and Replication (TiDieR checklist).[34]

The first phase includes the main trial with a baseline and a 10-week follow-up, corresponding to the planned duration of ABLE V.2.0. Primary endpoint of change is at the end of intervention 10 weeks from baseline, since this is the time when the largest improvement is expected. The second phase includes the secondary endpoint being 26 weeks from baseline. Participants are randomised equally (1:1) to receive either ABLE V.2.0 or usual occupational therapy (see below for details). The design is illustrated graphically in figure 1.

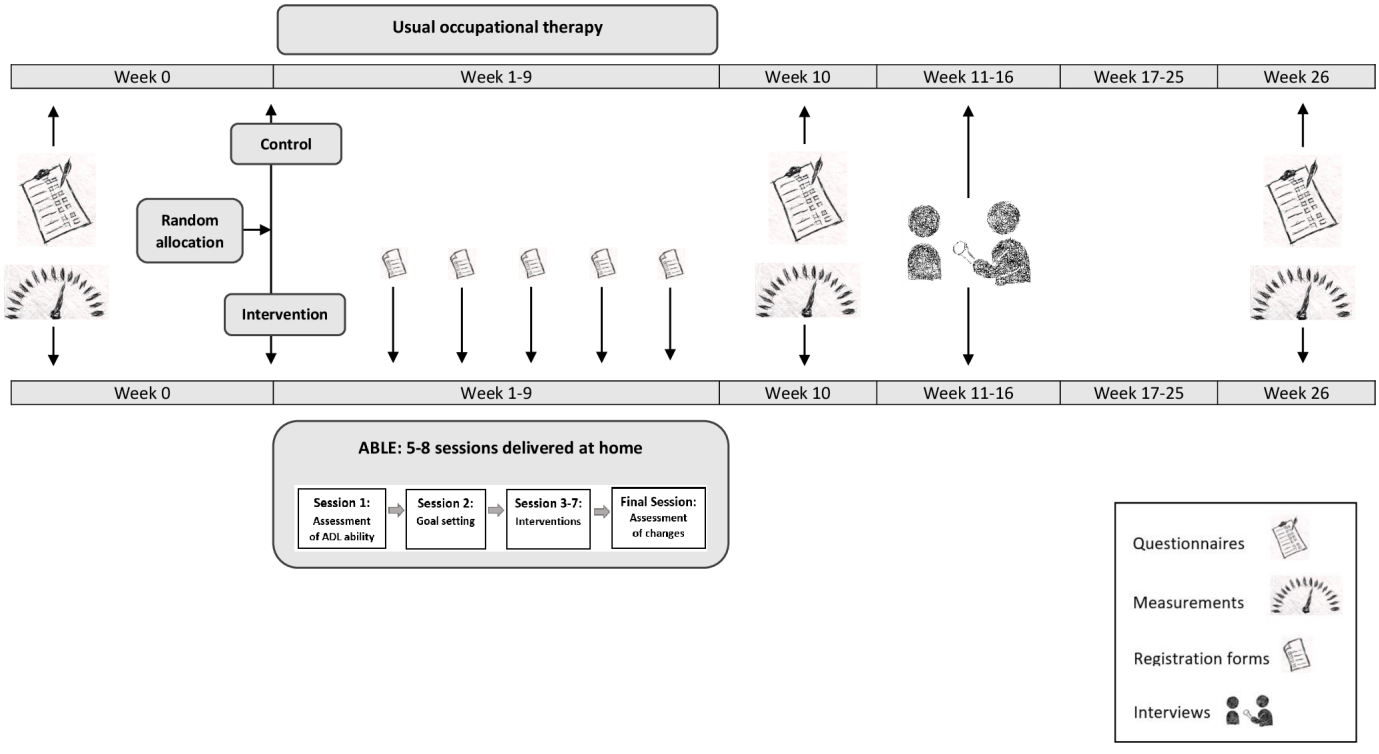

Figure 1 Graphical illustration of the A Better everyday LifE (ABLE) 2.0 trial.

Alongside, investigating the effectiveness and cost-effectiveness of ABLE V.2.0, data are collected to conduct a process evaluation in the ABLE group. A theory-driven approach, based on realist evaluation,[35 36] is applied during data collection and analyses.[37] Quantitative and qualitative data are collected among participants receiving ABLE V.2.0 and the ABLE occupational therapists (ABLE OTs) during and after the intervention period. To ensure equal attention to participants in the two groups and avoid influencing 26-week follow-up measurements in this parallel design, individual participant interviews between week 10 and 26 are conducted in both the ABLE and the control group. Results from interviews with participants in the control group will be reported elsewhere.

Setting

The study is conducted in the same setting as the pilot study,[31] a Danish municipality counting almost 90 000 inhabitants. About 50 000 live in the main town, and the rest lives in villages or in the countryside. Rehabilitation services in the municipality are organised in four demographically comparable geographic areas (North, East, South and West). Participants are recruited from all four areas. Delivery of intervention sessions and data collection take place in the homes of the participants.

Participants

Eligibility criteria

Participants living with one or more medically diagnosed chronic conditions must: be aged≥18 years, live in own home, experience ADL task performance problems, be motivated and ready for making changes in performance of ADL tasks, be motivated and ready to participate in an occupational therapy intervention, communicate independently and relevantly and be able to understand and relevantly answer a questionnaire. Exclusion criteria are: personal ADL problems with acute, unmet need for help, known substance abuse, mental illness and/or other acute illness (<three months) effecting ADL task performance, communication barriers (eg, severe cognitive deficits; barriers that prevent receiving information on study), receiving other occupational therapy services addressing decreased ADL ability during the intervention period (weeks 0–9).

OTs delivering ABLE V.2.0 (n=3) are recruited among OTs in the municipality, provided they have ≥2 years of experience working with the study target group, are calibrated Assessment of Motor and Process Skills (AMPS) raters, and that they also delivered ABLE V.2.0 in the pilot study.[31]

Recruitment

Persons referred to, or already receiving rehabilitation services, are assessed for eligibility. One OT from each geographic area assesses participants for eligibility. The recruitment process is structured by guidelines, including a checklist on eligibility criteria (online supplemental appendix A). In a phone conversation, the OT provides the client with initial information on the trial and asks for permission to forward contact information to the primary investigator. Within 3 weekdays, the primary investigator calls to provide potential participants with additional trial information and finalise screening of eligibility for inclusion, including confirmation of their motivation and readiness to make changes, and participate in occupational therapy delivered at home. If a person meets the eligibility criteria, preliminary oral consent to participate is obtained.

Consent

Following recruitment, a letter is sent to the participants containing written information, consent form and baseline questionnaires. At the baseline home visits, the participants are asked if they understand the written information, and if they have any related questions. Finally, they are asked to sign and hand over the consent form.

Allocation

Randomisation and stratification

Participants are allocated in a 1:1 ratio to either ABLE V.2.0 or usual occupational therapy, taking into account their baseline level of observed ADL ability measured with the AMPS.[38 39] Independence cut-offs, indicating need of moderate to maximal assistance to live in the community, are applied: motor ADL ability (≤1.0 vs >1.0) and process ADL ability (≤0.7 vs >0.7),[38 39] that is, four mutually independent randomised sequences. Following baseline assessment, the primary investigator forward ID and baseline AMPS measures for each participant, to the principal investigator, who (blinded to coding of group allocation) allocates each participant to either '0' or '1' based on a randomisation list (ie, sequence generation). The randomisation list is generated by an independent statistician before inclusion of participants based on permuted random blocks of variable size (2–6 in each block).

The group allocation is concealed, as the primary investigator enrolling participants is not able to foresee group assignment, due to central randomisation. Following randomisation, information on allocation is returned to the primary investigator, who will then inform the ABLE or usual occupational therapy OT to initiate and complete the intervention.

Blinding

The nature of the trial precludes blinding of the therapists delivering the interventions. Outcomes assessors are not informed about the content of interventions delivered in the two groups and are blinded to the participants' group allocation. We aim not to break this assessor blinding at 10-week and 26-week assessments. With the intent to blind the participants, they are only informed that they will receive one of two occupational therapy programmes, containing similar elements. Hence, should they refer to these when talking to outcome assessors, it is not likely to affect blinding. Still, participants are reminded not to disclose information about their intervention to the

outcomes assessor, and assessors are prompted not to discuss the intervention with participants. Finally, to blind the investigators on the participants' group allocations, groups are recoded by an independent statistician before data analyses.

Interventions

The manualised ABLE V.2.0 is a systematic, client-centred, 8-week intervention programme, applicable across gender, age and chronic conditions, delivered by an OT in the client's home as part of community-based rehabilitation. The overall structure of ABLE V.2.0 is informed by the Occupational Therapy Intervention Process Model,[40] prescribing a problem-solving process. The problem-solving process serves as a structure for ABLE V.2.0, including to evaluate ADL ability based on both self-report and observation; and to involve the client in setting goals, clarifying reasons for the identified ADL task performance problems, and in finding solutions[40] . ABLE V.2.0 consists of a maximum of eight sessions including ADL assessment, using the ADL-Interview (ADL-I)[41] and AMPS[38 39] (session 1); goal setting, using Goal Attainment Scaling (GAS),[42 43] and clarification of reasons for ADL task performance problems (session 2); intervention sessions focused on adaptation by employing a combination of intervention components to improve ADL task performance (sessions 3–7); and re-evaluation of overall ADL ability (final session). The nine intervention components[30] are organised according to the Person–Environment–Occupation model.[44] Detailed description on the intervention programme, including a brief case example, is provided elsewhere.[31]

Clients in the control group receive usual occupational therapy services. These services are framed similarly in the four geographical areas, while content and dose vary based on the individual client's condition and needs. See 'Procedures—effectiveness evaluation' for information on how data on usual occupational therapy is collected.

Training of OTs delivering ABLE V.2.0

The ABLE OTs are trained in delivering ABLE V.2.0 by attending a three-and-a-half-day course, conducted by the researchers who developed the programme. The course consists of introduction to ABLE V.2.0 and the underlying theories and models, practising the use of ADL-I, AMPS and GAS, and training delivery of ABLE sessions. To further support delivery of the programme, feedback activities are offered in addition to the course throughout the intervention period, and a folder, containing the material needed for each session in ABLE V.2.0, is provided for each client.

Contamination

To minimise contamination between ABLE OTs and usual occupational therapy OTs, ABLE OTs are recruited from West and East areas, while usual occupational therapy OTs are recruited from South and North areas of the municipality. This is in line with the recruitement procedure in the pilot study.[31] In the study period, both the ABLE OTs and the usual occupational therapy OTs deliver interventions in all four geographical areas, to make randomisation at an individual level possible. The ABLE OTs rarely have contact with the usual occupational therapy OTs, and they are informed not to share information of any kind on ABLE V.2.0 with their colleagues.

		Allocation	Post group allocation		
	Screening	Baseline	Interventions	Primary endpoint	Secondary endpoint
TIMEPOINT week	-3 to -1	0	1-9	10	26
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
ABLE			⟷		
UOT			⟷		
ASSESSMENTS:					
ADL-I		X		X	X
AMPS		X		X	X
OBQ11		X		X	X
CWP-Q		X		X	X
SF1 of SF-36		X		X	X
EQ-5D		X		X	X
Dutch cost diary		X		X	X

Figure 2 Schedule of enrolment, interventions, and outcome assessments. ABLE, A Better everyday LifE (experimental group); ADL-I, activities of daily living-Interview; AMPS, Assessment of Motor and Process Skills; CWP-Q, Client-Weighted Problems Questionnaire; EQ5D, EuroQool 5-dimension; OBQ11, Occupational Balance Questionnaire; SF1 of SF36, First question of the MOS 36-item Short Form Survey Instrument; UOT, usual occupational therapy (control group).

Demographic data

At baseline, demographic data are collected including age, gender, types of chronic conditions, job situation, civic status, level of education and whether they live alone or with others.

Outcomes

Effectiveness evaluation

The assessment schedule is presented in figure 2. The applied instruments are briefly described below. Complete descriptions are provided in online supplemental appendix B.

Primary outcomes

Coprimary outcomes are assessed at week 10 as change from baseline in participants' self-reported ADL ability, measured using the ADL-I[41] and observed ADL motor ability measured using AMPS.[38 39] This combination is chosen, as previous studies have shown limited relationship between measures of self-reported and observed ADL ability.[13 14]

The ADL-I (performance and satisfaction)

ADL-I is a standardised evaluation tool, used by OTs, to describe and measure the self-reported ADL ability,[41 45] in terms of physical effort and/or fatigue, efficiency, safety and independence (ADL-I performance), that is, quality of ADL task performance. In the ADL-I, the clients report their perceived ADL ability for each of 47 ADL items using seven response categories ranging from 'I perform the task independently without use of extra time or effort and without risk' to 'the task is performed by others for me—I cannot participate actively'.[41 45] Moreover, ADL-I is used to measure the client's perceived satisfaction with the quality of performance for each of the 47 ADL tasks, using a 4-point ordinal satisfaction scale ranging from 'very satisfied' to 'very dissatisfied' (ADL-I satisfaction).[41]

To measure changes in self-reported quality of ADL task performance and satisfaction, the 47 ordinal quality of performance and satisfaction scores are transformed into overall linear (interval scale) measures of self-reported quality of ADL task performance and satisfaction, adjusted for the difficulty of the ADL tasks, based on Rasch measurement methods.[41] The measures are expressed in logits (log-odds probability units).[14 41]

Previous studies indicate that ADL-I can be used to generate valid and reliable linear measures of self-reported quality of ADL task performance among persons living with chronic conditions,[11 13 41] and furthermore, that the instrument is sensitive to change in older persons receiving a home-based reablement programme.[30 46] According to the ADL-I manual,[45] a difference of ≥0.64 logits indicates a clinically relevant difference in self-reported ADL task performance.

The Assessment of Motor and Process Skills (AMPS)

The AMPS[38 39] is a standardised observation-based evaluation tool used by OTs to measure a person's observed ADL ability in terms of physical effort and/or fatigue, efficiency, safety and independence, that is, quality of ADL task performance. The person evaluated chooses and performs two standardised ADL tasks of personal relevance and appropriate challenge. During an AMPS evaluation, two domains of performance are evaluated: ADL motor (16 items) and ADL process (20 items) skills. Following observation, the quality of each skill is evaluated on a 4-point ordinal scale according to scoring criteria in the AMPS manual.[39] Available AMPS software,[47] based on Many-Faceted Rasch statistics, makes it possible to convert ordinal raw scores into overall linear ADL motor and ADL process ability measures adjusted for task challenge, skill item difficulty and rater severity. Measures are expressed in logits (log-odds probability units).[38] Several studies support that AMPS ability measures are reliable and valid among persons with chronic conditions.[13 14 48–50] Furthermore, several studies reveal that the AMPS demonstrates sensitivity to change.[24 30 50 51] According to the AMPS manual,[38] a difference of ≥0.30 logits on the ADL motor and ADL process scales defines a clinically relevant difference in ADL ability.

Secondary outcomes

Secondary outcomes are assessed at weeks 10 and 26 as changes from baseline in the participant's perceived satisfaction with quality of ADL tasks performance (ADL-I satisfaction)[41]; and observed ADL process ability (AMPS).[38 39] Moreover, participants' self-reported quality of ADL task performance (ADL-I performance)[41 45] and observed ADL motor ability (AMPS) are secondary outcomes assessed at week 26.

Explorative outcomes

At baseline and at weeks 10 and 26, the participants' perceived occupational balance (Occupational Balance Questionnaire (OBQ11),[22] perceived problems (Client-Weighted Problems Questionnaire) and general health (SF36-SF1) are examined.

Occupational Balance Questionnaire

OBQ11 is a generic 11-item instrument assessing aspects necessary for the experience of and satisfaction with occupational balance, defined as 'the experience of having the right amount of occupations and the right variation between occupations in the occupational pattern'.[22] A four-category response scale ranging from 'completely disagree' to 'completely agree' is employed. Scores are summed into a total score ranging from 0 to 33, with 33 representing complete occupational balance. OBQ11 has been examined for internal construct validity in a general population using Rasch measurement theory,[22] but not yet in clinical samples.

Client-Weighted Problems Questionnaire

A 5-item questionnaire addressing participants' identified problems, need for help and hope for the future was constructed. Each item is rated on an 11-point ordinal scale ranging from 'not at all' to 'to a high extent'. The questionnaire was tested for appropriateness in the previous pilot study.[31]

General Health (SF36-SF1)

General health is assessed using the first question (SF1) of the MOS 36-item Short Form Survey Instrument (SF36)[52] as an indicator of general health and well-being based on self-report. Thus, the following question is asked: 'In general, would you say your health is excellent (=1), very good (=2), good (=3), fair (=4) or poor (=5)'. Previous studies indicate that this question is applicable in persons with chronic conditions.[52]

Process evaluation

The process evaluation addresses the delivery of ABLE V.2.0 in terms of fidelity, dose, adaptations and reach; and interactions between context, mechanisms and outcomes. Data consist of a combination of quantitative and qualitative data,[53] collected among participants receiving ABLE V.2.0 and ABLE OTs.

Investigation of delivery is a replication of what was done in the previous feasibility study,[30 54] that is, determine adjustments made; components implemented;

extent of contribution to goal attainment; perceived value, benefits, harms and unintended consequences; feasibility and acceptability in practice; and adherence to intervention procedures and manual. The framework by O'Cathain *et al*[55] is used.

A realist evaluation approach is applied to investigate under what circumstances, for whom, why and how ABLE V.2.0 enhances the ADL ability in persons living with chronic conditions. Accordingly, a programme theory has been developed, illustrating the causal assumptions between ABLE V.2.0 and the outcomes. The programme theory is expressed as so-called context+mechanisms=outcomes (CMO) configurations (CMOs), that is, how contexts (C), understood as 'material/social/organisational/economic/technical/individual characteristics'[36] and mechanisms (M), understood as 'the interaction between the resources in the intervention programme and the persons' reasoning'[35 36 56] may produce desired outcomes (O), understood as 'results of the interaction between a mechanism and its triggering context'.[36 57] In short, CMOs describe how particular aspects of the context shapes the mechanisms leading to certain outcomes (C+M=O).[35 36 57] The CMOs were informed by the results of the feasibility study.[30] Table 1 provides an overview of the CMOs to be tested.

Registration forms

Clients' registration forms inform on mechanisms of impact. OTs' registration forms also inform on mechanisms of impact as well as intervention delivery (ie, dose: the quantity delivered; fidelity: whether the intervention is delivered as intended and; adaptations: changes made during delivery)[32] ; experienced positive and/or negative side effect; organisational or practical barriers and/or facilitators to delivering the intervention components.[32] Table 2 provides an overview of the questions asked in the

Table 1 CMO configurations to be tested in process evaluation of ABLE V.2.0

CMO title	CMO related to ABLE V.2.0	Context	Mechanism	Outcome
CMO (a) Relationship and collaboration	Assumed to be active throughout the programme	ABLE is delivered by an OT feeling engaged and prepared to deliver session content to a client motivated for making changes …	… activates a therapeutic relationship and the client finding the programme meaningful and satisfactory …	… leading to: ► Client staying in the programme ► Increased ADL ability
CMO (b) Valid assessment	Assumed to be active during delivery of session 1	OT conducts valid occupation-focused and /or occupational-based assessments in the client's home, taking client's perspectives into account …	… activates client getting a deeper understanding of his/her problems related to ADL task performance and feeling informed and involved …	… leading to: ► Occupation-focused and/or occupation-based starting point ► Client finding participation in session 1 satisfactory ► Client finding the content of session 1 meaningful
CMO (c) Goal setting	Assumed to be active during delivery of session 2	OT and client together define occupation-focused goals and clarify causes for ADL problems …	… activates client feeling involved …	… leading to: ► Client finding participation in session 2 satisfactory ► Client finding the content of session 2 meaningful
CMO (d) Adaptive interventions	Assumed to be active during delivery of session 3–7	Adaptive intervention components delivered in the client's home (including optional homework), delivered by OT familiar with components and acting as facilitator of change …	… activates collaboration between client and OT on finding solutions and client being willing to try solutions during performance of ADL tasks …	… leading to: ► Commencing goal attainment ► Client finding participation in programme purposeful ► Client finding participation in session 3–7 satisfactory ► Client finding the content of session 3–7 meaningful
CMO (e) Reevaluation	Assumed to be active during delivery of the final session	Client gets feedback on goal attainment and obtained changes …	… activates client expecting to carry on using the new solutions …	… leading to: ► Goal attainment ► Measurable changes in perceived and observed ADL task performance ► Satisfaction with obtained ADL ability

ABLE, occupational therapy programme; ADL, activities of daily living; CMO, context+mechanisms=outcomes; OT, occupational therapist.

Table 2 Questions asked in registration forms

Aspect	Timepoint	Questions for clients To what extent …*	Questions for ABLE OTs To what extent …*
Mechanisms of impact	**All sessions**	Did you feel informed? Did you feel involved? Did you find the content meaningful? Did you feel satisfied with the content? Do you feel that participation in the programme has a purpose?	Was the session meaningful to you? Was the session in your opinion meaningful to the client? Was delivery of this session satisfactory to you? Was this session in your opinion satisfactory to the client?
	Session 1	Did the interview and observation of your performance provide you with new knowledge on problems related to your activities of daily living? Did the interview and practical testing contribute to clarification of focus for intervention? Did you and the OT establish a good basis for further cooperation?	Did you gain knowledge about problems related to the client's ADL tasks and skills? Did the session clarify focus for intervention? Did you and the client establish a good basis for further cooperation?
	Session 2	Did you like setting goals for the intervention? Was the conversation about reasons for your problems relevant?	Did the conversation about discrepancies work well? Did the conversation related to goal setting work well? Did the conversation about reasons for ADL task performance problems work well?
	Session 3–7	Did the session contribute to your goal attainment? Have you currently reached your goals?	Did the session contribute to client's goal attainment? Did the client and you have a beneficial collaboration when finding solutions? Was the client willing to practice the suggested solutions?
	Final session	Did the programme overall contribute to your goal attainment? Did the programme overall contribute to improved ability to perform activities of daily living? Will you carry on using the new solutions?	Did the intervention programme overall contribute to client's goal attainment? Did the intervention programme overall contribute to enhancing client's ADL ability? Do you believe the client will continue using the new solutions?
			Register:
Intervention delivery (dose, fidelity, adaptations)	**All sessions**		Minutes delivered What was delivered? Did you deliver according to manual?
Context	**All sessions**		Did you experience organisational barriers and/or facilitators?† Did you experience practical barriers and/or facilitators? † To what extent did you feel prepared to deliver the session/familiar with content?* To what extent did you feel engaged during the session?* To what extent did you Involve the client?*
Other	**All sessions**		Did you perceive positive/negative side effects?†

*A 5-point ordinal scale is applied: 1=to a very low degree; 2=to a low degree; 3=to some degree; 4=to a high degree; 5=to a very high degree.
†Response categories: yes or no.
ABLE, occupational therapy programme; ADL, activities of daily living; OT, occupational therapist.

registration forms. A flow chart will capture information on reach, including number of sessions received (ie, the participants' contact with the intervention).[32]

Goal Attainment Scale

GAS,[42 43] used for goal setting in session 2 and re-evaluation in the final session of ABLE V.2.0, informs about goal attainment. Since the collaboration on goal setting is an important part of ABLE V.2.0, GAS is chosen as a process outcome. The level of goal attainment is described using an ordinal scale from −2 to +2. The actual level of performance is described at level −1, and the expected level is described at level 0. Levels +1 and +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 study[58] concludes that GAS is applicable among older adults with multiple chronic conditions living at home.

Interviews

Individual interviews are conducted with the ABLE OTs, followed by invidual interviews with a sample of participants in the ABLE group and finally, a focus group interview with the ABLE OTs. This longitudinal structure, allowing insights from completed interviews to inform the interview guide for the subsequent ones, aims to

further develop and validate the programme theory as the investigators get more knowledge along the way.[59] Interview guides are developed and structured to capture in-depth information on the CMOs. The realistic evaluation approach[36 59] is reflected in interview guides as well as during interviews, to help identifying key contextual differences in outcome patterns[59] (see table 1).

In the ABLE OT interviews, the questions relate to their experiences of what (mechanisms), for who and under which circumstances (context) successes and failures (outcomes) occurred.[36] Concerning the participants in the ABLE group, the questions relate to their experiences of whether ABLE V.2.0 encouraged them to make changes in relation to ADL task performance (mechanisms).[36] The final focus group interview with the ABLE OTs provides a deeper insight into what was revealed on the CMOs in the individual interviews.[36 59]

The individual interviews with the ABLE OTs are conducted by two experienced investigators both knowledgeable about ABLE V.2.0 and the hypothesised CMOs, but otherwise not involved in the evaluation. The individual interviews with participants in the ABLE group are conducted by the primary and the principal investigator, whereas the focus group interview with the ABLE OTs is conducted by one of the interviewers from the first interviews and the primary investigator.

Economic evaluation

As recommended by the MRC guidance on how to develop and evaluate complex interventions,[29] a cost-effectiveness evaluation from a societal perspective is performed.

Cost-utility

EuroQool 5-dimension

The outcome in the cost-utility analysis is quality-adjusted life years (QALYs) assessed by the EuroQool 5-dimension (EQ-5D-5L) and valued by preference.[60] The EQ-5D-5L assesses five different health dimensions; mobility, self-care, usual activities, pain/discomfort and depression/anxiety on 5-point Likert scales.[61] Permission to use the outcome measure has been given by the EuroQol Research Foundation . Currently, there are no value sets available for the Danish Version of the EQ-5D-5L, and therefore the value sets for the UK is used.[62]

Cost-effectiveness

The outcome in the cost-effectiveness analysis is changes in ADL ability measured by the AMPS ADL motor scale[38 39] and the ADL-I performance scale.[41 45]

Costing

The costs of the intervention is estimated using micro-costing. Use of primary healthcare services (including costs to general practitioner, specialised doctor, physiotherapist, etc) is extracted and valued from the Danish National Health Service Register for Primary Care. Use of secondary healthcare services is extracted from the National Patient Registry. This register includes information on hospital departments, dates of admission and discharge, and diagnosis. The valuation is determined by reimbursement rates from the Diagnosis-related grouping and the outpatient-grouping system. A modified version of the Dutch cost diary is used in order to collect costs related to formal and informal care, delivery of food from the municipality and non-prescriptive medication.[63]

Procedures

Effectiveness evaluation

Outcome measures are collected approximately 1 week before session 1 (week 0, baseline), 10 weeks after baseline (week 10, primary endpoint) and 6 months after baseline (week 26, secondary endpoint). Baseline test takes place within 7 weekdays after inclusion. At each timepoint, assessors visit participants in their homes to collect data. Participants receive questionnaires 2–8 days before each visit. Filled-in questionnaires are handed in to the assessor at each visit. Assessors are OTs, who are trained and recalibrated (ie, their testing skills are approved for use in research) AMPS raters and certified to use ADL-I.

Data on usual occupational therapy are extrachted from client records according to a study specific schedule, tested in the pilot study,[31] including information on: dose, methods applied for evaluation of ADL ability, goal setting, content of treatment phase, referral services and programmatic and/or clinical changes during trial (eg, new clinical guidelines).[64] Data extraction is conducted retrospectively by the primary investigator assisted by a physiotherapist from the municipality, familiar with clinical practice and client records. As information on duration of visits in minutes is not extractable from client records, this information is collected in registrations forms filled in by the usual occupational therapy OTs. Description on usual occupational therapy will follow the TiDieR checklist.[34]

Process evaluation

Registration forms are filled in after each session by client and OT separately.

Qualitative interviews are employed after completion of the intervention period of the study (figure 1). The ABLE OTs are the first ones to be invited for individual interviews. Then the individual interviews with participants are carried out, followed by the focus group interview with the ABLE OTs. Knowing that the process of theory testing is unpredictable,[59] and considering the purpose of obtaining knowledge about variations in how ABLE V.2.0 works,[59 65] eight participant interviews will be conducted.[65] To focus on mechanisms and minimise recall bias, a sample with a variety in outcome reach (GAS) and process outcomes (see outcomes in table 1) among the last participants allocated to ABLE V.2.0 is composed. The following criteria for the sample are sought fulfilled: ≥three males; ≥four participants with baseline AMPS ADL motor ability <1.0 logits; variation in number of sessions received; and in age.

Economic evaluation

The EQ-5D-5L[60–62] and the modified version of the Dutch cost diary[63] used in the economic evaluation are collected in parallel to the effectiveness outcomes (figure 2). The register-based data used in the study are administrated by the Danish Health Data Authority and permission to extract pseudo anonymised data is requested through Scientific Services. The date of randomisation counts as the start of the time frame, ending at week 26 follow-up.

Retention

To promote participant retention and complete follow-up, an appointment for week 10 assessment is made at the baseline home visit. Furthermore, all participants are contacted by telephone, to schedule an appointment for week 26 follow-up.

Data analysis

Sample size for evaluation of effectiveness

Sample size is calculated based on prior studies.[30] The calculation was performed using nQuery Advisor.[66] The portal 'repeated measures for two means' was selected. The number of levels was set to be 3.

For the observation-based primary outcome, AMPS ADL motor ability, an average difference of 0.30 logits (ie, a clinically relevant difference[38]) between the ABLE group and the control group is expected; the SD is assumed to be 0.56.[30] When the sample size in each group is n=25, a two-sided test for the time averaged difference between two means in a repeated measure design with a significance level set to 5% ($p<0.05$) has a statistical power of 90%. Similarly, for the self-reported coprimary outcome, ADL-I ability, a clinically relevant difference of 0.64 logits[45] between the intervention and control group is expected; the SD is assumed to be 1.45.[30] With a sample size of n=34 in each group, a two-sided test for the time averaged difference between two means in a repeated measures design with a 0.05 significance level, has a statistical power of 90%. Account for dropout is taken by recruiting 40 participants in each group.

Data management

Details of data management procedures are described in the registration of the study (J.nr. P-2020-203), approved by the Knowledge Center for Data Registration, in the Capital Region of Denmark

Demographics

Baseline participant characteristics are presented descriptively. Nominal data are reported based on numbers and percentages. Ordinal data are presented in medians, ranges, quartiles, absolute numbers and frequencies. Continuous variables are reported in means (SD), if data are normally distributed. Continuous data with lack of normal distribution are presented based on median (range).

Analysis of effectiveness

Data are analysed using IBM SPSS Statistics, V.25.[67]

Statistical analyses

All confirmatory data analyses are carried out according to the prespecified analysis plan. The coprimary outcomes are analysed on an intention-to-treat (ITT) basis, with the last observation carried forward in case of missing data. The trial is designed as a superiority trial, that is, the group allocated to ABLE V.2.0 will improve ≥0.30 logits on the ADL motor scale, and/or ≥0.64 logits on the ADL-I performance scale, compared with the usual occupational therapy group. Following the ITT analysis, a per-protocol analysis is conducted, including participants with baseline and week 10 measures. Moreover, participants in the ABLE group should have received a minimum of three sessions, and participants in the usual occupational therapy group sufficient intervention (based on a professional estimate by usual occupational therapy OTs after the end of intervention period).

Primary (AMPS ADL motor and ADL-I performance) and secondary (AMPS ADL process and ADL-I satisfaction) outcomes are investigated using analyses of covariance with time by programme (ABLE V.2.0/usual occupational therapy) as repeated measures, reported at the primary and secondary endpoint and followed by post-hoc testing. The model includes ADL-I performance baseline measures as an additional covariate. Differences in means between groups are statistically significant at $p\leq0.05$ and are investigated for clinical relevance.

Responder analysis

Responders are defined as participants achieving a clinically relevant improvement in AMPS ADL motor ability (≥0.30 logits)[38] and ADL-I ability (≥0.64 logits)[45] measures. The proportions (number and percentages) of responders is calculated and compared by Pearson's χ^2 test, and mean changes in observed and self-reported ADL ability for responders are analysed and compared using paired samples and independent samples t-tests and reported in means and 95% CI.

Analysis of process

Analysis of data related to delivery of ABLE V.2.0 is conducted in line with what was done in the previous feasibility study.[30 54] Reach is analysed by investigating the flow chart and characterising who received the ABLE V.2.0 at the end of the study, providing a descriptive result on the persons who the intervention reached.

Analysis of data related to CMOs takes shape as an iterative process within and across data sources. That is, core and recurrent patterns of CMOs are identified to inform refinement or further development of the ABLE V.2.0 programme theory.[36 68] During the analysis a 'retroductive' approach is applied, referring to the use of a combination of inductive and deductive reasoning, and incorporation of the different data sources.[69] The process of retroduction leads to refinement of the programme theory.[69]

Quantitative data

Analyses of quantitative process data begin with descriptive statistics related to the dimensions investigated.[32] The mechanisms in ABLE V.2.0 are tested through intragroup comparison, by investigating if there is a relationship between the mechanisms (eg, the therapeutic relationship) and the process outcomes (eg, client staying in programme) on different contextual factors (eg, OTs feeling engaged and prepared to deliver session content). For this purpose, cross tabulations are applied.[70]

Following the descriptive statistics, it is decided whether regression analyses are possible, given the relatively small sample.[70] Still, it also depends on the strength of the mechanisms that is, regression analysis on CMOs with few, strong mechanisms may be relevant to explore the functioning of the programme.

Qualitative data

Interview data are transcribed verbatim and analysed in the following steps following Realist And Meta-narrative Evidence Syntheses: Evolving Standards(RAMESES) II reporting standards for realist evaluations[57] and inspired by Gilmore *et al*[71]: (1) recordings are listened through and transcripts read to gain overview of each interview; (2) transcripts are separately examined for CMO configurations, by colour coding: context in blue, mechanisms in yellow and outcomes in green; (3) a table is produced for each type of transcript (ie, ABLE OTs (individual), clients, ABLE OTs (focus group)), listing the identified CMOs and registering the exact source of findings.[57] Core citations are extracted to document the findings; (4) the most effective CMOs are identified, marked and extracted. A CMO is determined effective, if it: (a) is found in more than one data source; (b) is expressed which emphasis in one data source; and/or (c) causes particularly positive or negative changes. Each CMO is assessed on its impact on the programme theory (support/refute/refine initial programme theory) including suggestions for future actions, for example, how to improve the manual. A template (online supplemental appendix C) is used to depict the results of this step. Steps 1 and 2 are conducted independently by two investigators, whereas step 3 is conducted by the primary investigator. Step 4 is conducted by two investigators in collaboration and the results discussed in the overall research group.

Synthesis of analysis of quantitative and qualitative data

As a final step of the analysis of CMOs, the results of the analysis of the mechanisms (intragroup comparison) and the most effective CMOs, identifyed from qualitative data, are compared and synthesised. The synthesis will result in evidence to corroborate and/or refine the initial programme theory.[57 71]

Analysis of cost-effectiveness evaluation data

The cost-effectiveness evaluation is performed in accordance with the ITT principle. The incremental cost-effectiveness ratio (ICER) is calculated using the formula: ICER = (CA − CB)/(EA − EB), where C denotes costs and E denotes effects with A and B referring to comparators. Bias corrected and accelerated bootstrapping with 10 000 replications are performed in order to estimate 95% confidence intervals around cost differences and the uncertainty surrounding the ICERs.[72] Uncertainty is shown in cost-effectiveness plans. The cost-effectiveness acceptability curve is drawn in order to show the probability that the ABLE intervention is cost-effective at different thresholds for willingness to pay for a gain in QALY or a clinically relevant improvement in ADL ability (ADL-I performance and/or AMPS motor) as defined earlier.[73] Sensitivity analyses are performed to test the robustness of the study results.

Participants and public involvement

As reported in earlier papers concerning this research programme, persons from the target group were involved during development of the intervention.[21 30] Thus, their values and preferences are integrated in the programme. Furthermore, the results of the feasibility study,[30] including registration forms and qualitative interviews with participants, informed the revision of the ABLE manual and the design of this study.

Trial status

The protocol was prospectively registered at www.ClinicalTrials.gov on 12 December 2019.

Originally, this study was planned to be initiated on 1 January 2020 and to include an internal pilot. Due to the COVID-19 pandemic, the study was truncated on 11 March 2020, and as a consequence the internal pilot was turned into an external pilot. Based on the results of the external pilot, a few adjustments on outcome measurements, inclusion criteria and extraction of information on usual care were applied, before initiation of this full-scale trial. Recruitment was started on 20 July 2020, and the first participant was included on 1 August 2020. No amendments have been made to the protocol (V.1.6 on 15 July 2020) or the registration since recruitment of the first participant. Any future amendments will be communicated together with the results. When this manuscript was submitted for publication (25 March 2020), a total of 66 participants had been included in the trial. The last evaluation of the last participant is expected by October 2021.

ETHICS AND DISSEMINATION

The study is approved by the Danish Data Protection Service Agency: Journal-nr.: P-2020-203. The Ethical Committee confirmed that no approval is needed for this study: Journal-nr.: 19 045 758. Informed consent is obtained from each participant, emphasising the right to withdraw from the study. Participants are given an ID code, with which all data are pseudonymised and only accessed by authorised study personnel obliged to secrecy. After data collection is completed, personalised

information is deleted and all data completely anonymised. Analyses are performed on anonymised data. The results will be disseminated to participants, published in peer-reviewed journals and presented on national and international conferences.

DISCUSSION

This study will contribute to establish evidence for an occupational therapy intervention programme aiming at enhancing ADL ability among persons with chronic conditions and add knowledge to the complexities in delivering such interventions. The study is conducted in a 'real-world context' and will generate new knowledge on the effectiveness of ABLE V.2.0 on ADL ability, how the programme functions and the cost-effectiveness of the programme. The evaluation will provide important knowledge in case of recommending implementation in municipal settings.[29]

The strengths of the planned study design include a strategy to reach a relatively high response rate. Hence, all assessor visits are agreed on in a telephone conversation and followed by a letter with information on the agreement. Further, to obtain a more complete data set, the assessors collect the questionnaires during participant visits. Recruitment procedures are developed to ensure recruitment of persons matching the aims of the intervention, that, a less biased sample.[74 75] However, considering the target group of the study, being mostly elderly and frail persons, withdrawel is expected. This, due to the burden of study-related activities or due to development in their condition. To accommodate this, and based on recommendation from the pilot study, the number of questionnaires is low.[31]

While the design of an effectiveness, process and cost-effectiveness study conducted alongside each other is considered a strength, it is also important to recognise inherent limitations. In the intervention group, activities related to the process evaluation are applied, including filling in registration forms after each session and interviews with eight participants post intervention. To balance the attention in the two groups, the same number of interviews is conducted with participants in the control group, as a separate process evaluation of the usual occupational therapy services. Still, to avoid affecting what is delivered in the control group, a replacement for the registration forms is not applied in the control group. In terms of the qualitative interviews conducted as part of the process evaluation, the primary investigator is involved as interviewer in the client interviews and the focus group, to exploit her insight in the ABLE programme theory. As the ABLE OTs cooperate with her during the intervention period, and the participants talk to her on the phone when recruited, their reporting may be affected.

The study is designed to intend blinding of participants, assessors and investigators. However, as the OTs delivering ABLE V.2.0 and usual occupational therapy are not blinded to allocation, the blinding of participants may be broken, even though they are instructed not to disclose the allocation. Contamination is minimised as the OTs delivering ABLE V.2.0 and usual occupational therapy are recruited from different geographical areas in the municipality. This is supported by delivering all interventions in the clients' homes.

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Recruitment guideline and checklist
ABLE 2.0 RCT

A Better everyday LifE

This guideline provides instructions on how to recruit participants for the ABLE 2.0 trial.

Step 1

This step is conducted by occupational therapists from the municipality (one from each geographical area).

Overview of procedure:

1. Identify potential participants
2. Provide initial information on the study to the client and have the client decide whether her/she would like to receive further information on the study
3. a: For clients who do not want further information; follow the usual procedure in the municipality
   b. For clients who would like further information; collect oral consent to handover contact information to primary investigator
4. Forward contact information to primary investigator through the electronic client record
5. Register the contact in the document 'Flow of contacts'

Description of procedure:

Ad 1.
Assess if persons referred to, or already receiving rehabilitation immediately meets the eligibility criteria, eventually in collaboration with the rehabilitation team). Use the checklist at the bottom of this document.

The assessment is based on knowledge of the client and on information from the client record. Specifically, it is important, at this step, to clarify if the client meets the following inclusion criteria: is aged ≥ 18 years, live in own home, live with one or more medically diagnosed chronic condition, perceives ADL task performance problems; and that the client does not meet the following exclusion criteria: perceives PADL problems with acute need for help (if the client does not already receive help from home carer); has a known substance abuse; has mental illness, and/or other acute illness effecting ADL task performance (within the last three months); has communication barriers (e.g. severe cognitive deficits; and barriers that prevents receiving information on study).

Ad 2.
Contact clients who immediately meets the eligibility criteria, either by telephone or face-to-face, as described here:

"Hello, my name is… and I am calling from X Municipality. I am calling you because we are currently looking for participants for a research study named "A better everyday LifE". You have been referred to / have applied for support at home, and we therefore think that participation might be relevant to you. May I tell you about the study?"

If the client accepts, carry on:

"The study is named 'A better everyday life' and the purpose of the study is to evaluate a newly developed program, aiming to improve the ability to perform everyday tasks for clients living with chronic conditions. If you are part of the study, you will receive either this new program or the program usually provided in X Municipality. In both cases, the program will be delivered by an occupational therapist in your home."

"If you choose to participate, you contribute to gaining more knowledge about how we best help persons in situations like yours."

"If you are interested in hearing more about the study, I will ask for your permission to handover your name and phone number to the primary investigator. She will then contact you within the next three weekdays, to provide more information, so that you can decide if you want to participate or not."

Remember to say, *"thank you for the conversation."*

Ad 3a.
If the client at this point is *not* interested in the study; continue to handle the case as usual.

Register date; client's gender, age and chronic conditions; and reason for not being interested in participating in the study, in the document 'Persons not included in the ABLE trial'.

Ad 3b.
If the client is interested in receiving further information on the study; collect consent to handover contact information to the primary investigator.

Document the consent in the client record.

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Recruitment guideline and checklist
ABLE 2.0 RCT

A Better everyday LifE

Ad 4.
Forward contact information to primary investigator through the electronic client record.

Ad 5.
Register the contact in the document 'Flow of contacts'.

Step 2

This step is conducted by the primary investigator.

Overview of procedure

1. Assess if the client meets the eligibility criteria
2. Provide detailed information on the study
3. Determine if the client is to be included
4. a: For clients who do not meet eligibility criteria and/or do not wish to participate; send the referral back to usual procedure in the municipality
   b. For clients who meet eligibility criteria and wish to participate; collect oral consent and continue inclusion procedure
5. Schedule date and time for baseline home visit
6. Register the contact in the document 'Flow of clients'

Description of procedure:

Ad 1.
Contact the client via telephone as described here:

"*Hello, my name is … and I am calling from a study named 'A Better everyday LifE'. Thank you for letting me call you to tell you more about the study. Do you have time to talk with me now?"*

If the client confirms …

"*I am calling because you have expressed that you experience some challenges when doing your everyday tasks. In this study we investigate a newly developed intervention program. The program aims to improve the performance of everyday tasks when living with chronic conditions. If you are part of the study, you will receive either this new intervention program, or the intervention program that is usually offered here in X Municipality. In the study we will compare these two different occupational therapy intervention programs, to gain more knowledge about what works best, when being in a situation like yours.*

In both cases, the intervention takes place in your home with an occupational therapist. Before I tell you more about the study, I suggest we talk about whether the study is suitable for you. Is that okay with you?"

If the client confirms …

"I have told you that the study concerns the problems you may experience, when doing your everyday tasks. Can you confirm that you experience such problems?"

If the client confirms …

"*Will you give me some examples?"*

Conduct a dialogue on the client's experience of ADL task performance problems (e.g. experience to use extra time and/or effort, to need help, or feel unsafe performing grooming, cooking, shopping, cleaning, etc.), to assess if participation in the study is relevant for the client.

To finally assess if the client meets the eligibility criteria, ask the following questions:

- *"How would you feel about making changes in performance of your everyday tasks? Would you like to make changes? (e.g. to be able to perform the tasks more independently, with less physical effort, or with less time use)"*
- *"Do you feel ready for making changes in performance of your everyday tasks?"*
- *"How would you feel about participating in an occupational therapy intervention at home?"*
- *"Do you feel ready for participating in occupational therapy/ cooperate with an occupational therapist at home?"*
- *"How do you feel about answering questionnaires?"*

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Recruitment guideline and checklist
ABLE 2.0 RCT

A Better everyday LifE

Ad 2.
If the client meets the eligibility criteria, detailed information on the study is provided:

"Based on what we just talk about, I can confirm that you are in the target group for the study. I will now tell you more about the study and what it will mean for you to participate. Afterwards you may decide whether you want to participate in the study.

A total of 80 persons from X Municipality will be involved in the study. All 80 persons will receive an intervention program, delivered by an occupational therapist from X Municipality. 40 persons will receive the newly developed intervention program, whereas the other 40 will receive what is usually delivered in such situations. Because this is a research study, I would prefer not to tell you details about the newly developed intervention program.

I can tell you that neither the length of the intervention program nor the number of visits is dependent on which intervention program you receive. Furthermore, all interventions are delivered in your home (or by telephone if relevant), and in all intervention programs you and the occupational therapist together decide what to focus on and how to collaborate.

It will be decided by drawing lots which intervention program each person will receive.

What do you think about that? Would you be interested in participating in such a study?"

If the client confirms …

"To be able to investigate the intervention program, we need to gather various information along the way. Therefore, if you chose to participate, an assessor will visit you three times during the study period. The first visit is before the intervention program is initiated, the second one will be 10 weeks later, and the last one another 4 months later. At these visits, information about you and your everyday life will be collected.

You will also receive a questionnaire before each visit from the assessor. It takes approximately 20 minutes to answer the questionnaire.

Are you still interested?"

If the client confirms …

"Then I will tell you about the visits you will get from an assessor. The assessor will conduct two tests at each visit.

The first one is an interview about your everyday tasks. The second one is a practical examination, where you select two tasks that are typical for your everyday life, and which you are willing to perform while the assessor observes. It can be tasks where you experience spending extra time, extra energy or that you currently need help performing. It can be something like cooking, cleaning, shopping, or doing laundry - something you are used to do in your everyday life. You do not have to prepare anything in advance. We just ask that you set aside approximately 1½-2 hours for the visits.

Would this be okay with you?"

Before finalising the conversation, the primary investigator ensures that the client is informed about:

- The possibility of having time to think about deciding whether to participate in the study or not (remember to agree on when to call back – information can possibly be sent via e-mail)
- That participation is voluntary and that it is possible, at any time, to withdraw a given consent without losing current or future rights to treatment
- That anonymity is guaranteed, and that data is treated with confidentiality

Ad 3.
Determine if the client is to be included, i.e. meets the eligibility criteria and wishes to participate in the study.

Ad 4a.
If the client does not meet the eligibility criteria and/or does not wish to participate; send the referral back for usual procedure in the municipality. This is done in the electronic client record.

Register date; client's gender, age and chronic conditions; and reason for not being included in the study, in the document 'Persons not included in the ABLE trial'.

Ad 4b.
If the client meets the eligibility criteria and wishes to participate; collect oral consent.

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Recruitment guideline and checklist
ABLE 2.0 RCT

Document the consent in the client record.

Ad 5.
Schedule the first assessor home visit.

Provide the following information:

"The next thing that will happen is that you will receive a letter with:

- *Written information about the study, in line with what I have told you today*
- *A consent form for you to sign*
- *A questionnaire that I will ask you to fill out before the first visit from the assessor*

After the study is completed (in 2022) you will be invited to an information event where we will tell about the results of the research study."

Say thank you and end the conversation.

Ad 6.
Register the contact in the document 'Flow of contacts'.

Eligibility criteria - checklist		✔
Inclusion criteria	Aged ≥ 18 years	
	Live in own home	
	Live with one or more medically diagnosed chronic condition	
	Perceive ADL task performance problems (e.g. use of extra time and/or effort, need for help, or feeling unsafe performing grooming, cooking, shopping, cleaning, etc.)	
	Motivated and ready for making changes in performance of ADL tasks (e.g. to be able to perform ADL tasks more independently, with less physical effort, or with less time use)	
	Motivated and ready to participate in the ABLE 2.0 program	
	Communicate independently and relevantly	
	Able to understand and relevantly answer a questionnaire	
Exclusion criteria	PADL problems with acute need for help (if the client does not already receive help from home carer)	
	Known substance abuse	
	Mental illness, and/or other acute illness effecting ADL task performance (within the last three months)	
	Communication barriers (e.g. severe cognitive deficits; and barriers that prevents receiving information on study)	
	Receiving other OT services related to ADL ability during the intervention period	

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Outcome measurements

The ADL Interview (ADL-I) (Performance and Satisfaction)

ADL-I is a standardised evaluation tool, used by OTs, to describe and measure the self-reported quality of ADL task performance (1,2), in terms of physical effort and/or fatigue, efficiency, safety and independence. In the ADL-I, the clients report their perceived ADL ability for each of 47 ADL items using the following seven response categories: (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 person can mark more than one response category if several apply to their performance of the specific ADL task (e.g. mark both c and d if they spend extra time and get tired) (1,2).

To create an overall linear measure of self-reported quality of ADL task performance (reported in log-odds probability units; logits), based on Rasch measurement methods, the mark given in the lowest response category on each task is re-scored using an ordinal rating scale from 0 to 3: C*ompetent* (score =3) covering response categories (a) and (b), *Using extra time/effort* (score=2) covering response categories (c) and (d), *At risk/need help* (score =1) covering response categories (e) and (f) and *Unable* (score = 0) covering response category (g) (1).

Moreover, ADL-I can be used to measure the client's perceived satisfaction with the quality of performance for each of the 47 ADL tasks, using a four-point ordinal satisfaction scale: 4='very satisfied', 3='satisfied', 2='dissatisfied' and 1='very dissatisfied' (1). ADL-I satisfaction measures are also generated based on Rasch Measurement methods.

To measure change in self-reported quality of ADL task performance and satisfaction, the 47 ordinal quality of performance and satisfaction scores are transformed into overall linear (interval scale) measures of self-reported quality of ADL task performance and satisfaction, adjusted for the difficulty of the ADL tasks, based on Rasch measurement methods (1). The measures are expressed in logits (log-odds probability units) (1,3).

Previous studies indicate that ADL-I can be used to generate valid and reliable linear measures of self-reported quality of ADL task performance among persons living with chronic conditions (1,4,5), and furthermore, that the instrument is sensitive to change post-intervention in older persons receiving a home-based reablement program (6). According to the ADL-I manual (2), a difference of >0.64

logits (based on mean SD=1.28) indicates a clinically relevant difference in self-reported ADL task performance.

The Assessment of Motor and Process Skills (AMPS)

The AMPS (7,8) 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 (8). The available AMPS software (9), 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) (7). ADL ability measures below the 1.50 logit independence cut-off on the ADL motor scale and below the 1.00 logit independence cut-off on the ADL process scale indicate a likely need for assistance (7). Measures below the lower independence cut-offs of 1.00 and 0.70 logits for ADL motor and ADL process ability, respectively, mark a need for moderate/maximal assistance (10). Several studies support that the AMPS ability measures are reliable and valid among persons with chronic conditions (3,5,11–13). Furthermore, several studies reveal that the AMPS demonstrates sensitivity to change post-intervention (13–16). According to the AMPS manual (7) a difference of ≥ 0.30 logits on the ADL motor and/or ADL process scales defines a clinically relevant difference in ADL ability. AMPS can only be administered by calibrated assessors.

Occupational Balance Questionnaire

Occupational Balance Questionnaire (OBQ11) is a generic 11 item instrument measuring aspects necessary for the experience of occupational balance. OBQ11 measures a person's experiences of their amount and variation of occupations, regardless of which these are (17). OBQ11 captures the perceived occupational balance for each of 11 items, using a four-categorical response scale: 0=completely disagree, 1=tend to disagree, 2=tend to agree, and 3=completely agree. Scores are summed into a total score ranging from zero to 33, with 33 representing complete occupational balance. OBQ11 has been examined for internal construct validity in a general population using Rasch measurement theory (17), but yet not in clinical samples.

Client-Weighted-Problems Questionnaire (CWP-Q)

To complete the investigation on how, from the participant's point of view, engagement in ADL task performance contribute to well-being, and how the participant perceives changes, questions related to identified problems, need for help and hope for the future have been specifically constructed for this study:

Identified problems:

- *"To what extent is it a problem for you, that your chronic condition(s) affects your possibilities to perform and participate in everyday activities in and around your home? (e.g. shopping, cleaning, doing laundry, transport)?"*
- *"To what extent is it a problem for you, that your chronic condition(s) affects your possibilities to participate in social activities with friends and family?"*

Need for assistance:

- *"To what extent do you need help accepting your chronic condition(s)?"*
- *"To what extent do you need help to better take care of your everyday activities (e.g. perform them more securely, efficiently, with less effort or more independently?"*

Hope for the future:

- *"To what extent does your chronic condition(s) affect your hope for the future?"*

The perceived weight is scored on an 11-point ordinal scale ranging from '0' representing "*not at all*" to '10' representing "*to a high extent*".

General Health (SF36-SF1)

General health will be measured using the first question (SF1) of the MOS 36-item Short Form Survey Instrument (SF36) (18). The question is 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* (=1), *very good* (=2), *good* (=3), *fair* (=4) or *poor* (=5)". Previous studies indicate that the question is applicable in persons with chronic conditions (18).

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Template for analysis step 4	
CMO title	
CMO link to ABLE 2.0	
Context	
Mechanism	
Outcome	
Data sources	
Support/refute/refine	
Suggestions for future actions	
Researchers' comments	