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Effectiveness of the Perceive, Recall, Plan and Perform intervention for persons with brain injury in community-based rehabilitation: protocol for a single-case experimental design with multiple baselines

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ABSTRACT

Introduction There is a need for standardised interventions in community-based rehabilitation to improve everyday performance for older adults with cognitive challenges due to acquired brain injury (ABI). The Perceive, Recall, Plan and Perform System (PRPP) of intervention has a growing research base. The intervention is suitable for any client with decreased performance in everyday tasks due to ineffective cognitive strategy application to enhance mastery in performance of needed or desired activities. There is no current evidence on the effectiveness of the PRPP intervention for this population.

Purpose To describe a protocol for a clinical trial that investigates the effectiveness of the PRPP intervention in the context of community-based rehabilitation for persons (65+ years) with difficulties in task performance due to cognitive challenges after ABI.

Methods and analysis A non-concurrent multiple baseline design across participants with systematic replications (n=6) will be used. Nine sessions of PRPP intervention will be applied by trained occupational therapists in two community-based rehabilitation units. The participants will complete five repeated measurements of everyday tasks as target behaviours. PRPP Assessment stages 1 and 2 serve as outcome measures at baseline, in the intervention period, in the postintervention period and in the follow-up phase. Mastery percentage of the tasks and the participants' application of cognitive strategies at baseline acts as a control and will be compared with the following phases within the participant. Delayed intervention phases act as a control between participants. Goal Attainment Scaling and the Barthel Index will serve as generalisation measures. Data will be analysed using systematic visual inspection of graphical data, descriptions of clinical significance and descriptive statistical analysis.

Ethics and dissemination This trial, including the data management plan, is approved by The Norwegian Regional Ethics Committee (215391). Results will be published in congresses and scientific journals.

Trial registration number NCT05148247.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Outcomes will be evaluated directly on clients' desired everyday activities and close to ordinary rehabilitation practice.
⇒ Multiple baseline designs provide rich data of an individual's responses to an intervention.
⇒ The study uses a second sample of three participants to contribute to external validity.
⇒ Visual analyses are criticised for being subjective; therefore, visual aids and quantifications are applied.
⇒ The practice settings combined with ethical concerns for persons with newly acquired brain injury can influence methodological recommendations.

INTRODUCTION

The incidence of people with acquired brain injury (ABI) is expected to increase in Europe due to an ageing population even though there have been major improvements in prevention and acute treatment.[1 2] Cognition is reportedly affected in almost 50% of clients after stroke and traumatic brain injury, and this leads to implications for the clients' and their relatives' everyday lives and participation in society.[3–5] Adults over 65 years of age are underrepresented in ABI research often due to strict inclusion criteria.[6] Nevertheless, there is evidence that older adults with ABI benefit from rehabilitation, with the majority achieving functional improvements and living in their own homes.[7] It is essential that these clients are both empowered and able to reach their maximum level of independence for a sustainable health service system.[3]

The Norwegian welfare model is based on public funding and equal services, regardless of the financial situation of the individual. Health services are organised in national or

regional hospitals or community healthcare services in the municipalities.[8] Community health services have an increasingly important role in delivering rehabilitation services near or in the clients' own home environment both for sustainability reasons and the quality of life of the individual.[9]

Self-reported unmet needs after stroke are associated with cognitive challenges.[10] Research shows that Norwegian ABI survivors report that rehabilitation services typically focus on physical impairment and environmental adaptation, even when cognitive challenges are the dominant factor in experienced difficulties in occupational performance.[11 12]

Recent systematic reviews, however, provide evidence of how cognitive rehabilitation interventions can be effective to individuals, even years after the initial injury.[13] Nonetheless, the researchers debate the manner in which interventions used in cognitive rehabilitation often are decontextualised from the real world. They point out that evaluation of rehabilitation effectiveness typically occurs at the impairment level, with limited evidence on how these changes translate into meaningful improvements in clients' everyday lives.[13]

Occupational therapists (OT) are concerned with clients' occupational performances in everyday life, and persons with cognitive challenges after ABI are a large client group for community-based OTs in Norway.[14] Nevertheless, Norwegian community-based OTs call for a focus on and development of interventions to meet the needs of this client group.[15 16] International studies describe that community-based OTs apply interventions like task training in everyday activities, compensatory strategies, metacognitive strategy training, adaptations to the environment and paper-and-pencil/computer exercises in the rehabilitation of clients with cognitive challenges after ABI.[17–20] Only a few of these OTs report they use standardised interventions. Consequently, studies concerned with cognitive rehabilitation should evaluate standardised interventions for persons with cognitive challenges conducted directly on clients' occupational performances in everyday life.

The Perceive, Recall, Plan and Perform system (PRPP) of assessment and intervention is a standardised system that was developed for OTs to determine the impact of cognitive challenges with a focus on clients' everyday occupational performances.[21] The PRPP system investigates how effective the client applies cognitive strategies to enhance task mastery, rather than the neuropsychological changes after the brain injury often expressed as specific cognitive impairments. Cognitive strategies are internally generated thinking processes a person uses to plan what they will do and to adapt to external demands during task performance.[22] Effective cognitive strategy application is strongly related to functional performance and independence in ABI clients.[23] Principles from information process theory and established theories of neural plasticity, systematic instructions, errorless learning and task oriented training forms the basis of the development of the PRPP intervention.[24] The intervention both focuses on task training and cognitive strategy training within natural everyday tasks and contexts.

The PRPP system is designed for use with persons with decreased performance in everyday tasks due to cognitive challenges, regardless of age and diagnosis, and it functions to both evaluate occupational performance and train independent mastery in everyday situations.[24] The intervention has a growing research base and usage.[25] The efficacy of the PRPP approach has been observed in younger persons with traumatic brain injury,[26] children with learning disabilities[27] and in combination with sensory activity schedules for children with autism and learning disabilities.[28] The approach is used for older persons with ABI in community-based rehabilitation but is so far not evaluated systematically through research. Therefore, we will investigate the effectiveness of the PRPP system of intervention as used in community-based rehabilitation to meet the needs of older adults with cognitive challenges after ABI to improve independence in everyday life.

Aim

The purpose of this paper is to describe the protocol for a trial to investigate the effectiveness of the PRPP intervention for older adults experiencing difficulties with task performance due to cognitive challenges after brain injury.

Research questions

1. How effective is the PRPP intervention in increasing mastery of task performance over a limited period of community-based rehabilitation for persons with cognitive challenges following ABI?
2. How effective is the PRPP intervention in increasing cognitive strategy application in task performance over a limited period of community-based rehabilitation for persons with cognitive challenges following ABI?
3. To what extent is task mastery maintained for participants with ABI who have received cognitive strategy training in the context of a community-based rehabilitation unit 4 weeks after discharge to home?
4. To what extent is the cognitive strategy application maintained and generalised in everyday tasks and contexts 4 weeks after discharge to home?

Rationale for trial design

Single-case experimental designs (SCEDs) are experimental designs aiming to evaluate the effect of an intervention in trials with a small number of participants.[29] In SCED, the experimental control comes from repeated measures within the individual participant, rather than the number of participants. The trial will apply a non-concurrent multiple baseline design (MBD) across participants that is particularly suited for evaluation of non-reversable rehabilitation effects.[29] At least five data collection points within each phase and a minimum of

three participants is recommended to meet design quality standards.[30]

The MBD design is chosen for both pragmatic and ethical reasons when considering the context in which the trial takes place. First, there are few PRPP-trained OTs working in community-based rehabilitation in Norway; thus, they cannot provide the PRPP intervention for enough participants for a randomised controlled trial. Second, an MBD can systematically collect empirical data, even from a heterogeneous rehabilitation setting, along with experimental control of the variables within a single participant.[31]

METHODS AND ANALYSIS

Designing the trial

The efficacy of nine sessions of the PRPP intervention will be evaluated using a non-concurrent MBD across participants (n=at least 6). Repeated measurements of the participants will be completed during a baseline phase, an intervention period, a postintervention phase and a follow-up phase. This paper is guided by the SPENT 2019 checklist for protocols for n-of-1 trial,[32] together with Risk of Bias in N-of-1 Trials to minimise risk of biases.[30] Important considerations for developing clinical trials are also found in the Medical Research Council guidance for developing and evaluating complex interventions.[33] The Single-Case Reporting Guideline In BEhavioral Interventions will be used to guide reporting of the results.[34]

Patient and public involvement

The Norwegian Association for Stroke Survivors[35] was contacted on behalf of stroke survivors and their relatives to receive input on the trials' relevance. Municipalities with PRPP-trained OTs were contacted, and two formal agreements were signed with their leaders. Planning of the study took place in dialogue with the participating OTs.

Setting

The study will be conducted within community-based rehabilitation services in two municipalities in South-East Norway with about 15 000 (municipality A) and 55 000 (municipality B) inhabitants, which in Norway represents one medium and one large sized municipality.[36] The rehabilitation services are offered at health centres that include residential units for older adults with various diagnoses, conditions and service needs. The services in municipality A are organised in a short stay unit with 24/7 nursing staff and a physician once a week or more if required. The clients can receive rehabilitation services from nurses, nursing assistants, physical and OTs in this unit. The services in municipality B consist of an assessment unit from which clients are then transferred to either short stay units or rehabilitation units in the health centre. The short stay units are similar to municipal A, and the rehabilitation unit has an interdisciplinary team consisting of nursing staff 24/7, physical and OTs, and a physician once a week or more if required. Speech therapy can be referred across units. The vast majority of the clients are over 65 years old, and a typical stay in both health centers is 2–4 weeks, with the possibility of supplementing with another 2–3 weeks or more in special circumstances, such as a drop in the client's health condition or the client's home not yet sufficiently adapted to their needs. The OTs providing the PRPP intervention are working in different units in these health centers and are trained in the PRPP assessment and intervention.

Participants, recruitment and inclusion criteria

Any client admitted to the health centre with an ABI that is referred to OT services will be considered for inclusion in the trial by their OT. In this way, we follow ordinary practice and do not exclude clients because of their age; however, since we started the dialogue with the OTs, all their clients were older adults (65+ years). Exclusion criteria will be already diagnosed dementia, congenital brain damage or developmental disability, language barriers or severe hearing loss so instructions cannot be understood, or severe arousal problems, and physical disabilities that hinder performance of most daily activities. If the participant shows mastery above 85% of PRPP assessment stage 1, they either need to be assessed in more cognitively challenging tasks based on the OTs clinical reasoning or will be excluded with 'effective cognitive strategy applications in occupational performance'. If the client meets the inclusion criteria, the OT provides information about the trial, asks the client to participate, and collects oral or written consent.

Intervention to be studied

The aim of the PRPP intervention is to enhance mastery in performance of needed or desired everyday tasks and extend traditional task training.[24] The specific cognitive strategy application behaviours identified through the PRPP assessment as having the most impact on mastery are addressed for individualised intervention planning (see figure 1).[37]

The OT follows the PRPP intervention manual[24] and gives systematic instructions to support the clients' cognitive capacity to think about 'doing' in different tasks in various contexts. Further, the OT uses graded verbal, visual or physical prompts and cues directly during task performances through teaching participants to apply a sequence of processing strategies to 'Stop/Attend, Sense, Think, Do'. 'Stop/attend' is to gain the required level of arousal/attention for the task, while 'Sense' is to perceive sensory information relevant to the task. 'Think' relates to engaging in recall or planning strategies to develop a plan of action. Lastly, 'Do' is then to implement the plan. Clients will learn to apply these strategies to their task performance by initially observing and modelling the OTs. The OT's role as a cognitive mediator fades as the person begins to internalise the strategies and apply them across a range of tasks and settings.[24]

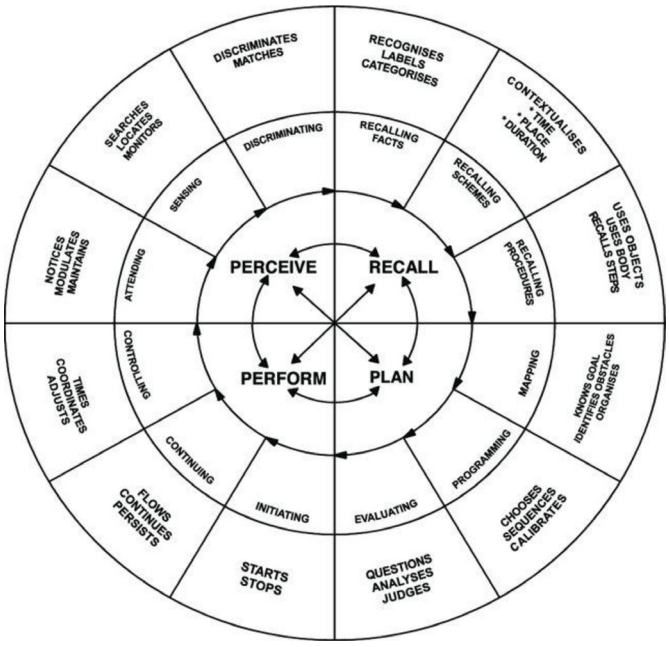

Figure 1 The Perceive, Recall, Plan and Perform System of Task Analysis, the 4 quadrants Perceive, Recall, Plan and Perform, the 12 subquadrants, and the outer circle with observable descriptors.[21]

Treatment as usual

During all phases, the participants will receive 'treatment as usual' from the interdisciplinary team, except for the PRPP intervention. Treatment as usual from the OT could involve providing assistive technology, housing and environmental adaptation and upper extremity training. Treatment as usual could also involve other rehabilitation services, such as physical therapy, and the clients are encouraged by the nursing staff to do daily activities. Treatment as usual is described by the treating OTs based on the patient record and dialogue with the interdisciplinary team and the influence considered by the researcher in dialogue with the OT.

Target behaviour: measures and data collection

Target behaviour is five everyday tasks that are valued by the participant and useful in their rehabilitation. The tasks could include different parts of morning routines, simple or complex meal planning or preparation, use of a cell phone, leisure activities or other household and community activities.

The primary outcome measure is the PRPP assessment stage 1.[38] The five everyday tasks will each be divided into a series of significant steps and measured in the percentage mastery (0%–100%) of the steps according to the PRPP assessment stage 1 as a functional measure. Performance on stage 1 is simultaneously scored by denoting errors of omission, accuracy, repetition and timing as a basis for intervention planning.

As a second outcome measure, the PRPP assessment stage 2[38] is used to measure the effectiveness of observable cognitive strategy application behaviours in everyday task performance. A total of 34 cognitive strategy behaviours, termed descriptors, can be seen in the outer ring of the PRPP-model in figure 1. The PRPP assessment stage 2 is criterion-referenced and evaluated on a three-point scale: (3) effective task performance, (2) questionable or (1) not effective.

Studies have established clinical utility, validity and reliability in brain injury populations for the PRPP assessment.[39–42] The tool can be used to establish measurable and client-centred goals for the intervention and enable a dynamic assessment.[23 39] Construct validity is demonstrated,[41] the assessment is sensitive to changes,[40] and a high test procedure reliability and a moderate inter-rater reliability was established when used to measure agreement between therapists.[42] Additional validity and reliability studies are conducted, but they are on other populations.[43–45]

Generalisation measures

Generalisation measures will be used to evaluate whether there are relevant changes beyond the primary and secondary outcomes and, thus, contribute to external validity.[30] The Goal Attainment Scale (GAS) and the Barthel Index will serve as generalisation measures for the target behaviours. The GAS[46] provides an individualised measure for a clinically meaningful level of performance for the five tasks. The GAS is a method of quantifying the extent to which the participants' individual goals are achieved during intervention. The score of −2 is the baseline value, 0 is goal attainment, better outcome scores are +1 and +2, and worse outcome scores are −1 and −2.

The Barthel Index is a functional evaluation of independence in daily activities.[47] The participants score 0, 1 or 2 points and a maximum score of 20 indicates independence in personal daily activities, and a score of 0 points indicates total dependency.[48]

Demographic data will be gathered and used to describe the sample, such as age, marital status, living conditions, education, work history, diagnoses and comorbidities, home healthcare services at the time of the ABI-incident and the time since the ABI, characteristics of the ABI, medication and information of other interventions will be documented.

Blind rating and inter-rater reliability

OTs who provide the interventions complete data collection for the PRPP assessment and provide the PRPP intervention as is usual in the rehabilitation process. An aspect of the SCED is to address the inter-rater reliability of the assessments, which is done for evaluating the effectiveness of the interventions. To address the inter-rater reliability,[30] 20% of the assessments with PRPP stages 1 and 2 from each phase are video recorded by the treating OT or a colleague and assessed randomly by an external and blinded PRPP-trained OT. If the participant opposes video recording, a second PRPP-trained OT at the unit assesses 20% of the measurement, but in the present units it is not possible to blind the phases for this assessor.

Table 1 Study procedure

Tier 1	3 days baseline	9 sessions PRPP intervention 45–60 min each, at 3 sessions for 3 weeks	Postintervention measurement	4 weeks after discharge; follow-up measurement
Tier 2	5 days baseline	9 sessions PRPP intervention 45–60 min each, at 3 sessions for 3 weeks	Postintervention measurement	4 weeks after discharge; follow-up measurement
Tier 3	7 days baseline	9 sessions PRPP intervention 45–60 min each, at 3 sessions for 3 weeks	Postintervention measurement	4 weeks after discharge; follow-up measurement

PRPP, Perceive, Recall, Plan and Perform.

Procedure

The first participant included in each municipality will automatically be assigned by the OT to the first of 3 tiers and allocated to a baseline phase of 3 days (see table 1). For replication across participants and a delayed start of the intervention phase, the second participant included will be allocated to a baseline phase of 5 days and the third a baseline phase of 7 days.

The baseline phases

In interdisciplinary teams, it is natural that other members have adopted some of the prompting techniques used in PRPP Intervention. The OT, nursing staff and rehabilitation team members are directed explicitly not to give any PRPP strategy training in this phase. The OT scores PRPP assessment stage 1 and 2 at five points and GAS for each of the five tasks. The Barthel Index is scored by a member of the interdisciplinary team.

The intervention phases

The intervention phase starts immediately after the given baseline phase. A PRPP intervention plan is developed by the OT with information about tasks, environment, goals, location where tasks will be performed, timing and prompts from least to most. The OT will practice PRPP strategy training in the five selected tasks in its natural context in the units three times a week with each session at 45–60 min in duration. To what degree the interdisciplinary team or relatives give prompts and cues based on the PRPP intervention will vary and be described. The OTs measure the five tasks with PRPP assessment stage 1 and 2 at five points during the intervention phase.

The postintervention phases

After nine sessions, there will be five measurements of the same tasks without the PRPP intervention to assess if the client has internalised the strategies. The OT scores the GAS, and a member from the interdisciplinary team scores the Barthel Index.

The follow-up phases

The OT from the rehabilitation unit conducts a home visit to the participant 4 weeks after discharge. A new measurement with PRPP stages 1 and 2 of the 5 tasks will be completed by the OT in addition to two new tasks. This is to measure whether the observed effects from the intervention and postintervention phases persist and whether the cognitive strategy application is generalised to a variety of everyday tasks and contexts. The OT scores PRPP assessment stages 1 and 2, and GAS, and home care staff or a person from the rehabilitation team scores Barthel Index.

Data analysis plan

Visual analysis and descriptive statistics will be used to examine the effect of the intervention. Data patterns from the primary outcome measure from PRPP assessment stage 1 will be graphed for each participant in percentage mastery for each task. The secondary outcome measures from the participants' cognitive strategy application from PRPP assessment stage 2 for each participant for all tasks collapsed are inserted in the Cognitive Strategy Use Profile graph.[38] The expected data pattern is variability between the tasks, and an immediate improvement is expected when the intervention is introduced; further, it is expected that the strategies are internalised and therefore a persistent positive trend in the postintervention and follow-up phases will be shown. Both graphs will be analysed to determine if there is an immediate change in the target behaviour from the baseline to the intervention phase. Furthermore, if the expected trends drop, persist, or increase when measured without intervention in the postintervention. The follow-up measurements will be compared with the postintervention data for maintenance of task mastery and a presumable internalisation of the cognitive strategies. The cognitive strategy application will be analysed if they are applied in the two new and untrained activities compared with the five trained activities. Decisions are indexed as yes, no, or unsure, but they need further investigation.[31]

A four-step procedure will be used to systematically evaluate the graphs for the presence of a functional relationship within each participant[31] p. 157:

Step 1: Evaluates the stability of the baseline data.

Step 2: Within-phase data are assessed for consistency.

Step 3: Consists of making between-phase comparisons of adjacent phases.

Step 4: Consists of integrating all this information to determine if the intervention effect has been independently demonstrated at least three times.

Steps 1–3 will be examined for level, trend, variability, immediacy of the effect, overlap and consistency of the data pattern across similar phases. The detailed steps for systematic visual analysis from Lane and Gast[49] will be followed. Step 4 will be inspected for evidence after the

categorisation of strong (at least three demonstrations of effect and no demonstration of no effect), moderate (at least three demonstrations of effect, but with at least one demonstration of no effect) or no evidence (less than three demonstrations of the intervention effect) after Kratochwill *et al*.[50] The mean and median values are described for all tasks collapsed and changes described between the phases for both primary and secondary outcomes to compare to the examination of the visual inspections.

Clinical significance can immediately be noticed from the participants' percentage mastery in the everyday tasks. In addition, this will be supported with improvements in the Barthel Index and GAS and qualitative statements from the participant, relatives and staff members. It is important to consider if the independence in certain tasks also leads to less service needs or other impacts compared with the different phases.

Replication and generalisation

To meet the SCED standard to show the experimental effect in MBD,[30] three direct replications across a sample of three participants are included. This experimental effect is then systematically replicated with another sample of three participants. The first pilot was included in April 2021, and we will continue to recruit participants throughout the end of 2022, even if the number exceeds two full samples of six participants altogether.

Procedural fidelity

A checklist for the entire protocol is made, where the treating OTs mark the steps as completed or not. This checklist is assessed by the first author, and high fidelity is suggested by at least 80% agreement with the procedure checklist.[31] The treatment sessions are highly individualised to the participant and the context and are not externally assessed for fidelity. The fact that the OTs need PRPP training and are assessed as competent supports the delivery of the interventions across the treating OTs. The number of invited participants and number and cause of excluded clients will be noted. Participants who provide incomplete data will be presented in a raw data record. A process evaluation of the trial is planned to be explored with qualitative data including interviews of OTs and participants about their experiences of the study and the intervention.

DISCUSSION

This paper describes a study protocol for the evaluation of the PRPP System of intervention for use in community-based rehabilitation with older persons that have difficulties with task performance due to cognitive challenges after ABI. The main goal of the PRPP is to enable clients to use cognitive strategies more effectively to increase mastery in everyday tasks. It is of great importance both to the individual and sustainability of community healthcare that the ageing population can reach their maximum independence level in their everyday life. Cognitive rehabilitation research is typically performed at an impairment level, with the expectation that the results will translate into increased performance in everyday tasks.[13] This trial will not measure cognitive challenges at an impairment level, but rather how effectively the participants apply cognitive strategies to perform real-world tasks. The PRPP System of assessment and intervention allows both evaluation and intervention directly in the participants' everyday task performance. To date, studies have not evaluated the PRPP System of intervention in this population of older adults, and the results of this trial can potentially contribute to an evidence-based practice for community-based OTs.

SCED is a method used to collect empirical data systematically and with experimental control and are suitable for a heterogenous ABI population in a neuropsychological rehabilitation setting.[31] The use of MBD across participants enables us to analyse changes within the individual rather than an average as is typical in group-level designs. Concurrent baseline phases are preferred, but in this chosen real-world setting, this is not possible.

The design is also compatible with the mission of occupational therapy, where the context should be natural and dynamic and the tasks should be meaningful for the individual.[51] In rehabilitation after ABI, we expect recovery; therefore, it is important to monitor if the immediate effect after the experimental PRPP intervention is present, and it is also important to monitor if the improvements continue after the OT fades their presence. We are aware that the everchanging practice setting combined with the participants' very different needs and expectations for rehabilitation can threaten methodological recommendations.

Ethics and disseminations

This trial, including the protocol and data management plan, is approved by The Norwegian Regional Ethics Committee (Project number 215391) and the trial will be conducted in line with the Declaration of Helsinki.[52] The PRPP intervention study is considered to have few risks and harms. In addition, we emphasise the ethical aspect that the present intervention procedure is close to the ordinary practice for this client group.

Each participant will have a dialogue about their own results (both positive and negative) with the OT as is usual in a rehabilitation process. The results of the study will be published in peer-reviewed scientific journals, preferably rehabilitation or occupational therapy journals, as well as communicated at relevant national and international congresses.

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Contributors MØL, AUO, US and LS all contributed to planning and designing the study, critically revised the manuscript and approved the final version. MØL and LS held contact with the conducting OTs. MØL wrote the first draft of the manuscript and is the submitting author.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s) in fully trial

Ethics approval For the fully trial, we have approval from the Norwegian Regional Ethics Committee, ID 215391, and participants will give informed consent to participate in the study before taking part. For this submitting protocol manuscript, there are no human participants involved.

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