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Feasibility of The Perceive, Recall, Plan and Perform System of intervention study for persons with brain injury in community-based rehabilitation: A pilot for a multiple-baseline design study

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Complete List of Authors:	Lindstad, Marte; Norwegian University of Science and Technology, Department of Health Science Gjøvik Obstfelder, Aud; Norwegian University of Science and Technology, Department of Health Science Gjøvik Sveen, Unni; Oslo Metropolitan University, Department of Occupational Therapy, Prosthetics and Orthotics; Oslo University Hospital, Department of Physical Medicine and Rehabilitation Stigen, Linda; Norwegian University of Science and Technology, Department of Health Science Gjøvik
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Feasibility of the perceive, recall, plan and perform system of intervention study for persons with brain injury in community-based rehabilitation: A pilot for a multiple-baseline design study

Lindstad, M.Ø.[1], Obstfelder, A.[1], Sveen, U.[3, 4], Stigen, L.[1]

[1)] Department of Health Science Gjøvik, Norwegian University of Science and Technology, Gjøvik, Norway
[2)] Department of Occupational Therapy, Prosthetics and Orthotics, Oslo Metropolitan University, Oslo, Norway
[3)] Department of Physical Medicine and Rehabilitation, Oslo University Hospital, Oslo, Norway

Corresponding author: Marte Ørud Lindstad, NTNU Gjøvik, Pb 191, 2802, Gjøvik, Norway.
Tel: +47 99 592 692 marte.lindstad@ntnu.no

ABSTRACT

Objectives: This paper describes a pilot study investigating the feasibility of the PRPP intervention for persons with cognitive impairments after brain injury in the context of community-based rehabilitation for elderly individuals.

Design: The feasibility, acceptability and practicability of the research procedures were evaluated by exploring the effectiveness of the PRPP intervention. In the PRPP intervention, the OT supports the client in applying cognitive strategies in everyday activities to enhance task mastery. Three elderly participants (63+ years of age) in a community rehabilitation setting were included in a nonconcurrent multiple baseline design. The participants completed 5 repeated measurements of everyday tasks as a dependent variable. PRPP assessment stages 1 and 2 served as the primary and secondary outcome measures, respectively. The mastery percentage of the tasks and the participants' application of cognitive strategies in the baseline phase acted as a control and was therefore compared with the other phases within the participant. The Goal Attainment Scale and Barthel Index served as generalization measures. The uncertainties of the procedures were also investigated with a procedural checklist and qualitative statements.

Results: The procedures were acceptable for the OT and the participants and were feasible as long as the steps in the research procedure were clearly understood. The target behaviour should be changed to the use of one task with five measurement points instead of measuring five tasks. This can enable the application of recommended analysis methods.

Conclusion: The outcomes of this study led to a change in the target behaviour and clarification of the research procedure for the planned PRPP intervention study.

Trial registration: ClinicalTrials.gov Identifier: NCT05148247
Key words: The PRPP system, cognitive rehabilitation, activities of daily living, cognitive strategy use, occupational therapy
Word count: 4000

ARTICLE SUMMARY

Strengths and limitations of the study

- The research procedure's closeness to real-world practice is a strength.
- The pilot indicates that the PRPP intervention is effective.
- Information on the steps of the research procedure must be more precisely communicated to the OTs providing the intervention.
- To enable the application of established analysis methods, we need to change the target behaviour for further data collection.

INTRODUCTION

Persons with acquired brain injury (ABI) report a need for rehabilitation to manage everyday activities due to cognitive challenges [1 2]. Even though most ABIs occur in elderly individuals (65+ years of age), research often focuses on younger individuals[3 4]. With an ageing population, often with comorbidities, it is crucial that ABI survivors receive rehabilitation and reach their maximum level of independence[5]. In Norway, clients with ABI receive rehabilitation in regional specialized units and/or community-based programmes in the municipalities in health centres or in the clients' homes[6].

The Norwegian welfare system is based on public funding and is built on principles of equal essential health services for the entire population. One of the mandates of municipal health services is to ensure that the population receives needed rehabilitation services [6]. Occupational therapy has been an obligatory profession in community health services since 2020[7] and generally concerns people's everyday lives. Occupational therapy is a central rehabilitation profession for reaching the political goal of ageing in one's own home and local community as long as possible, both for sustainability reasons and for individual quality of life[8]. Community occupational therapists (OTs) in small and medium municipalities in Norway identify themselves as generalists, working with clients with a wide range of conditions and in various contexts, whereas there are opportunities to be more specialized in larger municipalities [9].

Norwegian community OTs call for a focus on and development of assessment and interventions to meet clients' cognitive challenges [10 11]. Community OTs in Norway working with clients with cognitive impairments report persons with ABI to be a large client group [12]. The same sample of OTs frequently use interventions related to environmental

modifications and assistive technology, with training of everyday activities reported as the third most provided intervention. This is comparable to case for Norwegian ABI survivors, who report that they are given services to adapt the environment to cope with physical issues and to rehabilitate physical impairments, even if they experience problems in activities due to cognitive challenges [1 2].

International studies describe a more nuanced picture of community OT interventions in rehabilitation for this client group. The most frequent interventions were task training, the use of external compensatory strategies, various types of cognitive strategy training, adaptation of the environment and exercises with paper and pencil/computer; however, only a few used standardized interventions [13-16]. Therefore, we should seek evidence for standardized interventions appropriate for use in community rehabilitation to meet the needs of heterogeneous clients with cognitive challenges after ABI.

The perceive, recall, plan and perform system (PRPP) is a standardized system of assessment and intervention with a focus on clients' everyday occupational performance[17]. The PRPP was developed by OTs to help clients apply cognitive strategies to enhance task mastery and focuses on both task training and cognitive strategy training within natural everyday tasks and contexts[18]. The uniqueness of the PRPP system is its focus on occupational performance both as an assessment and intervention, and it is designed for everyone experiencing information processing deficits, regardless of age, context and diagnosis[18]. The effectiveness of the PRPP intervention has been evaluated for younger persons with traumatic brain injury but has not yet been evaluated through systematic research for elderly individuals with ABI in community rehabilitation.

Systematic research investigating the effectiveness of interventions often excludes elderly individuals with comorbidities[3 4], and there is not a strong research tradition in Norwegian community health services[19]. Therefore, we designed a pilot study to evaluate the feasibility of the PRPP intervention for elderly clients in an ordinary practice setting.

Aim and objectives

The main purpose of this pilot study was to evaluate the feasibility, acceptability, and practicability of all research procedures for a planned PRPP intervention study to identify procedural, clinical and methodological uncertainties. We did this by exploring the

effectiveness of the PRPP intervention in a community rehabilitation context with persons observed having difficulties in everyday task performance due to cognitive challenges following ABI.

METHOD

To explore the planned PRPP intervention study design, we used a nonconcurrent multiple-baseline design (n=3) with three lengths of the baseline phases and at least five data points within each phase. This design allows the collection of empirical data systematically close to ordinary practice, along with experimental control of the variables [20]. For expanded details of the planned intervention study, we refer to the protocol[21]. This pilot study used mixed methods to collect data about feasibility.

The Medical Research Council guidance for developing and evaluating complex interventions [22] has guided the planning of the pilot and the planned intervention study together with The Risk of Bias in N-of-1 Trials (RoBiNT)[23]. To progress to the PRPP intervention study, our criteria for this feasible study procedure are as follows: 1) the OTs and participants find the procedure acceptable, and the fidelity checklist is met by at least 80%; 2) the measures are sensitive enough to show immediate changes in task mastery and cognitive strategy use; and 3) the research design and data analysis methods are feasible for showing visually, statistically, and clinically significant effects of the PRPP intervention.

Patient and public involvement

Planning of the pilot study took place in close dialogue between the four participating community OTs that collected data and the first author, both to use a realistic practice setting and to make the research procedures possible in a clinical setting. The first author had a dialogue with an organization for stroke survivors [24] to consider the relevance of the study.

Research setting

The pilot was conducted within community-based rehabilitation services in one medium municipality (15 000 inhabitants) and one large municipality (55 000 inhabitants) in South-East Norway. The OTs that collected the data and provided the PRPP intervention were not part of the research group. They worked at health centres that included short stay units,

rehabilitation units, and residential units for older adults with various diagnoses, conditions, and service needs. The OTs were trained and certified in the PRPP system of assessment and intervention.

Participants

The first three clients (table 1) admitted to the health centres with a new ABI were informed about and asked to participate in the trial by their OT. The exclusion criteria were previous diagnosis of dementia, congenital brain damage or developmentally disability. The participants also needed a minimum level of physical resources to manage everyday tasks, the ability to hear and/or understand simple instructions and to show mastery below 85% in PRPP assessment stage 1. The OT collected oral or written consent and allocated the participants (n=3) to a predefined baseline phase. The first participant included was allocated to a baseline phase of three days, the second participant five days and the third seven days. The random aspect of the allocation of the participants is that neither the researcher nor the OTs had influence which clients were admitted to the health centres.

	Anne	Carl	Birger
Sex, age	Female, 71	Male, 63	Male, 85
Marital status, living conditions	Lives with husband in own house	Lives with partner in own terraced house	Lives with wife in own flat
Activity level prior to ABI	Retired teacher, active lifestyle, routinely works out, assisting at previous workplace	Retired professional driver, handy man, always on his feet helping with practical reparations	Retired, mostly quiet indoor activities, listening (!) to TV, walks independently with walker in the flat but need help transferring to the toilet at night, and wife expressed she feels insecure leaving him alone for fear of falls.
Home health care prior to ABI	No	No	Yes, once a day for providing medical cream, eating and morning routines
Reported cognitive challenges prior to ABI	No	No	No
ABI diagnosis	Cerebral infarct left side, basal ganglia	Traumatic brain injury, with subarachnoid haemorrhage bilaterally and frontal contusion injury.	Cerebral haemorrhage right side, subcortical.
Neurological challenges reported in patient record	Severe aphasia, attention, visual and arousal deficits, half side paresis right side, dysphagia with tube feeding	Post-traumatic amnesia for 2 months; half side paresis left side; uncritical behaviour; difficulties with planning, structure, and attention; easily tired	Balance and mobility problems, orientation only to one side, uncritical in planning performance
Recruitment	12 days since ABI	93 days since ABI	18 days since ABI
Comorbidities	Fibromyalgia, hypertension, angina, lymphoedema and backpain	Diabetes mellitus 2, Chronic obstructive pulmonary disease grade 1, backpain, cataract, hypertension, chronic pancreatitis. After the TBI, he had high scores on a depression scale.	Blind in one eye, strongly reduced sight in other eye with tunnel vision, moderate hearing loss, age-decreased balance (uses a rollator)

Table 1: *Overview of the participants' demographic and health characteristics at inclusion*

Intervention to be studied

The aim of the PRPP intervention is to enhance mastery in the performance of the clients' needed or desired everyday tasks[18]. The PRPP system was developed based on the basic principles of the information processing approach[25] and evident theories of neural plasticity[26], systematic instructions[27], errorless learning[28] and task-oriented training[29].

The OTs followed the PRPP intervention manual[18]; however, the intervention delivery was highly individualized. This means that the PRPP assessment identified errors in the participants' cognitive strategy application behaviours that most impacted the mastery of tasks that were relevant or important to the client. On that basis, the OTs developed a plan for the use of systematic instructions of cognitive strategy training in extended traditional task training[30].

The intervention phase started directly after the baseline phase (see table 3). The PRPP intervention plan included a goal for the task, where the task was supposed to be performed, adaptations of the environment, timing and prompts from the OT from least to most. The OT gave clear information to the participants about the goal of the task, and then, systematic instructions were given by graded verbal, visual or physical prompts and cues directly during the participants' task performance. The OT taught the participants to apply strategies in relation to 'stop/attend, sense, think, do'. 'Stop/attend' helped the participants focus on the task, and 'sense' was prompted to assist the participants perceive the sensory information required to perform the task. 'Think' encouraged the participants to recall steps or develop a plan of action, and the application of 'do' supported the participants in implementing the plan. The participants initially observed and modelled the OTs until they learned and internalized the strategies in their task performance.

During all phases, the participants received other treatment 'as usual' from the interdisciplinary team. Other treatment and the degree to which the interdisciplinary team or relatives were supervised by the OT to provide prompts and cues varied and was described by the OT as a step in the research procedures.

Target behaviour: measures and data collection

As a primary outcome and functional measure, the criterion-referenced PRPP assessment stage 1[31] was used. Five needed or desired everyday tasks in the context for the participants were chosen by the OT in cooperation with each participant. The tasks were divided into a series of significant steps. Performance was measured in percentage mastery (0-100%) of the steps, and errors of omission, accuracy, repetition, and timing were recorded. A score above 85-90% indicates independence in the target task but with minor inefficient cognitive strategy application[32].

The PRPP assessment stage 2[31] was used as a second outcome measure. The effectiveness of 34 observable cognitive strategy application behaviours (outer ring fig. 1) in task performance was evaluated on a three-point criterion-referenced scale: (3) effective, (2) questionable or (1) not effective. The 12 subquadrants (middle ring fig. 1) and the information processing of Perceive, Recall, Plan and Perform are illustrated in the central quadrants in the theoretical model (fig. 1). Each subquadrant was then assigned a percentage score. The PRPP assessment stages 1 and 2 were used to collect data from all five tasks in all four phases.

(FIG 1 ABOUT HERE)

Fig 1. The Perceive, Recall, Plan and Perform System of Task Analysis [17].

As a generalized measure, the participants were evaluated with the Goal Assessment Scale (GAS) [33] and the Barthel Index [34 35]. A GAS score of -2 is the baseline value, 0 is expected goal attainment, better outcomes are indicated by scores of +1 and +2, whereas worse outcomes are indicated by scores of -1 and -2. The Barthel Index uses a score of 0, 1 or 2 points, with a maximum score of 20 indicating independence in personal daily activities and the lowest score of 0 indicating total dependency [34]. The GAS and the Barthel Index were used to collect data at baseline, postintervention, and follow-up phases.

Demographic data to describe the participants and their contexts and qualitative statements from the client or relatives, journals or the interdisciplinary team contributed to evaluating clinical significance.

Procedural fidelity

Data concerning feasibility were gathered with a checklist of the steps in the procedure. An agreement of at least 80% indicates high fidelity[20]. Treatment adherence was secured by the fact that the OT provided the intervention together with the participant according to the research procedure.

Data concerning the acceptability and practicability of the procedure were collected in regular dialogue meetings with the OTs and the first and last author. The OTs were free to give overall feedback, but the dialogue was focused on the steps in the procedure compared to their regular practice and to the PRPP manual. Because of the long distances, Teams were chosen as a digital meeting platform to communicate with all the OTs at the same time. During the various research phases, the OTs noted qualitative observations and statements from the individual participants, relatives, and team members in the procedural document. The content of these qualitative data was related to task performance, improvements or acceptability of the intervention or research procedure.

Blind rating and interrater reliability

To address the interrater reliability[23], an external, independent and blinded PRPP-trained OT assessed 20% of the PRPP stage 1 and 2 measurements from each phase by video recordings from the assessment situations. When video recording was not possible, a second PRPP-trained OT at the unit assessed 20% of the measurement, but it was not possible to blind the phases for this assessor.

Ethics

The PRPP intervention study was approved by the Norwegian Regional Ethics Committee (project number 215391). It was desirable to keep the research procedures close to real-world practice. This minimized ethical challenges but could also threaten the research validity that we needed to address in this pilot. The participants had to wait for the PRPP intervention to start for up to seven days, but they received all other treatment as usual. Because there are only a few community OTs delivering PRPP intervention, that was considered acceptable.

Data Analysis

We explored the feasibility of the outcome measures by analysing the data patterns of all five tasks in a visual graph for each participant. With guidance from Lane and Gast [36], each graph was visually inspected. The purpose was to determine whether the outcomes and graphs were appropriate to show immediate improvement in the target behaviours when the intervention was introduced and whether this improvement was maintained to the postintervention phase. Furthermore, if the mastery of task performance and cognitive strategy application was maintained when tasks were performed in another context and was generalized to other tasks in the follow-up phase. Decisions regarding whether improvements were seen in the graphs were indexed as yes, no, or unsure [20].

Clinical significance was explored by noticing whether the participants' percentage mastery in the everyday tasks was above 85-90%, the goal attainment scores for each task, and qualitative statements from the participants, relatives, or team members. It was important to consider whether independence in certain tasks also led to fewer service needs or other impacts. The independence in the target tasks was linked to the progress in the overall independence of self-care and mobility skills from the Barthel Index score.

The formula 'number of agreements' shared in ('number of agreements') + (number of disagreements') x 100 [20] (p. 200) analysed the feasibility of the procedural checklist together with the OTs' expressed experience of managing the procedure in a busy clinical setting.

RESULTS

Participants

From the two municipalities, two participants were recruited within two months after inclusion start-up (spring 2021), and the third participant was recruited one week after completing data collection for the first participant (table 2). They were allocated in staggered baseline phases (table 3).

	Rehabilitation process after ABI until inclusion	Assistance and challenges at baseline	Tasks chosen. End goal: Mastery above 85%	Cognitive strategy focus	Barthel Index total score	Other treatment
Anne	Admitted to short stay unit, rehabilitation potential questioned after 12 days of minimal recovery, received rehabilitation services in the short stay unit	She needed help with everything and could barely sit up straight in a wheelchair and had a short attention span. Could answer simple questions.	OT chose tasks after clinical reasoning and agreement from Anne and her husband, due to aphasia: 1) sitting in wheelchair in front of wash tub and mirror to wash face, 2) wash rest of upper body, 3) put on deodorant, 4) brushing teeth, 5) brushing hair	Recalled and knew the goal before each task and then prompted attend, notice, search, locate, recall steps and continue'	B=baseline P=postinter-vention F=follow-up B: 1 P: 5 F: Lost data	Physiotherapy, speech therapist, nursing
Carl	Transferred to community rehabilitation unit after three months of specialized rehabilitation, good physical outcomes, no cognitive screening possible at specialized rehabilitation due to cooperation, recovery curve stagnated	He needed close assistance for all morning and meal routines, including guidance of the well arm/hand. He walked 5-10 metres with a walker and close assistance due to uncritical behaviour. Did not manage to drive the wheelchair.	Clearly expressed desired tasks: 1) take a shower, 2) dry after shower, 3) put on t-shirt, 4) stand up from wheelchair, 5) put on trousers, 6) put on shoes	Worked mostly in the planning-quadrant with focus identify obstacles by prompting 'stop, analyse, choose and do'. Additionally, 'recall steps, use body, analyse, choose, continue, persist'	B: 9 P: 15 F: 17	Physiotherapy, speech therapist, nursing
Birger	Admitted to short stay unit for the first 14 days and then transferred to the rehabilitation unit. Minimal spontaneous recovery, staff members questioned rehabilitation potential and expressed he would still need help at home.	He needed close assistance for safe mobility with a walker, always walked towards the left direction, bumped into objects, and had a fall caused by uncritical behaviour during transfer to a chair. Received help for most of his morning routines.	Proper discussion about desired tasks: 1) transfer to toilet, 2) transfer to chair, 3) orientation when coming into a room, 4) put on t-shirt and 5) put on shoes	Modified environment with contrasts and put stuff in same place. Then, prompting 'stop, notice, monitor, continue'	B: 10 P: 16 F: 15	Physiotherapy, nursing

Table 2: Description of the participants' data at baseline

Tier 1/Anne	Baseline 3 days	Intervention: 9 sessions PRPP, 45-60 min each, 3 sessions a week for 3 weeks	Post-intervention measurement, incomplete and after 14-day delay due to hospital admission	Lost to follow-up measurement.
Tier 2/Carl	Baseline 5 days	Intervention: 30 sessions PRPP, 45-60 min each, 3 sessions a week for 9 weeks and then two weeks with a total of 3 sessions before postintervention 2	Post-intervention measurement after 10 and 13 weeks	Follow-up measurement; 4 weeks after discharge
Tier 3/Birger	Baseline 8 days	Intervention: 7 sessions PRPP, 45-60 min each, 3 sessions a week for 3 weeks	Post-intervention measurement the last two days of admission	Follow-up measurement; 4 weeks after discharge

Table 3: Timeline and intervention sessions completed

Effectiveness of intervention on task mastery and cognitive strategy application

The graphs demonstrate an immediate effect from the baseline to the intervention phase within the individual and between the participants' staggered baselines (fig.2). Further improvements are shown in the graphs throughout the phases for the primary (fig. 2) and secondary outcomes (fig. 3). The mean and median scores for task mastery for all tasks collapsed can be calculated and/or presented with visible changes in the graphs. However, as described in the guidelines of visual analysis of single-case experimental designs by Lane and Gast [36], the calculation of the stability of the baseline data, overlap and consistency of the data pattern across similar phases, and trend lines within each phase cannot be used for five separate tasks.

(FIG 2 ABOUT HERE)

Fig. 2: Percent task mastery. The blue vertical line through all three graphs illustrates the staggered baseline phases. The horizontal red lines illustrate the mean value.

(FIG 3 ABOUT HERE)

Fig. 3 Cognitive strategy application across all five target tasks.

Clinical significance

Anne showed improvements during the three weeks and managed morning routines related to her face, teeth, and hair independently at postintervention. Although she improved, she still needed assistance to complete her entire morning routine. At the same time, her improvements led to transfer to specialized rehabilitation, while she was considered for palliative care instead of rehabilitation at inclusion. Carl exhibited clinically significant improvements and needed less personal assistance with independent mobility. At follow-up, Birger received some assistance for his morning routines and eating due to visual impairments present before the ABI. His wife reported that he used the toilet independently at night and expressed that she was more confident leaving him at home alone, as he walked safely with a rollator and transferred with caution. That improvement was beyond his level prior to the ABI. For both Anne and Birger, the nursing staff expressed surprise regarding their recovery and achievements.

The GAS showed improvements in line with improvements in the percent task mastery as expected because it was the exact same task as the target behaviour. The Barthel Index showed overall improvements and was in line with the task mastery where the tasks observed were the same.

Procedural fidelity, acceptance, and practicability

The procedural checklist could be followed as long as no unforeseen incidents occurred. Birger had an 8-day baseline instead of a 7-day due to OTs' work schedule. Two misunderstandings of the checklist resulted in 1) missing interrater observations in the baseline and intervention phases for Birger and Carl, but with video recording and blinded assessments in the postintervention and follow-up phases, and 2) Carl attended as many as 27 PRPP sessions before postintervention outcomes were measured. This means that it was not the practice setting or acceptability that hindered the procedure but rather issues with unclear communication from the researcher to the participating OTs. The checklist was followed by the OT in 83% and 86% of the steps for Birger and Carl, respectively, including misunderstandings. For Anne, the procedural checklist was followed by 86% for the three phases completed.

The OTs confirmed general acceptability for the procedures on behalf of themselves, the participants, and the practice setting, even if they reported a greater workload. At the same time, the OTs reported that the research procedures helped them practice the intervention more systematically with benefits for the clients. There were unexpected circumstances, such as participants being transferred to other health facilities and OTs being on sick leave. To cope with these circumstances, the OTs were forced to have a flexible attitude, but it also resulted in lost follow-up data for Anne.

DISCUSSION

This study examined the feasibility of a planned intervention study by exploring the effectiveness of the PRPP intervention in people experiencing problems with everyday task mastery due to ABI with cognitive problems. Our data suggest that the PRPP intervention used with elderly clients was largely feasible in terms of the procedural checklist, acceptability and practicability for clients and therapists, sensitive outcome measures and benefits of the intervention. We suggest some changes in the research procedure that can minimize the risk of bias. First, we need to clarify information around some steps in the procedure with the conducting OTs. Second, we need to adjust the use of target behaviour and, in the same context, the graphs and the associated analysis methods. This will be discussed below.

Strengths and limitations of the study

The strength of this study is the close relationship to ordinary practice and measuring the outcome of the cognitive challenges directly via everyday tasks performance. The included participants were considered to have low rehabilitation potential due to the severity of their cognitive challenges, comorbidities, and extant home health services. Studies show that adults 65+ years of age with ABI receive less intensive rehabilitation than younger adults and are often excluded from research due to age or comorbidities [3]. When research participants do not reflect diverse real-world conditions, this could fail to translate research into practice [5]. Cicerone, et al. [37] call for outcome measures that address cognition when performing everyday activities. The PRPP stages 1 and 2 are sensitive to changes in everyday activity performance and were acceptable for the participants and the community OTs. This shows that it is possible to include older participants with comorbidities in research and

assess cognition in everyday tasks. One of the advantages of the PRPP intervention is its usefulness for any difficulties with information processing across practice settings, diagnoses and ages[18].

There are limitations that should be considered when interpreting the data and planning for a full trial. The procedural checklist is acceptable to follow if the key functions in the procedure are clearly understood and no unforeseen events occur. Unclearly communicated procedures resulted in missing data for interrater reliability for Birger and Carl for some of the phases. Measuring interrater reliability reminds us of its role in minimizing reactivity and observational bias and plays a role in internal validity[38]. As long as the postintervention and follow-up phases include a blinded interrater assessor and show increasing improvements, we can assume that the measures in the intervention phase do not err in the direction of false positives.

Unclear communicated procedures also led to the postintervention measurement for Carl being collected first after 27 interventions. Incomplete implementation of the research plan is a threat to validity [39]. For Carl's prolonged intervention phase, the limitation did not affect the immediate change in task performance and cognitive strategy application between baseline and the intervention phase as shown in the visual graph. The results in the postintervention and the follow-up phases have a clear bias compared to those of other participants in the sample, but in a practice setting, the improvements will be valuable. Nevertheless, the procedural checklist was at least 80% followed, which indicates high fidelity for all the participants [20].

A second limitation is the choice of using five tasks. Although the immediate visual effects across the five tasks are clear, the choice minimized the opportunity to apply the most recognized analysis methods. Analysis of stability, overlap and consistency, and trend lines in the various phases from the widely used systematic inspection analysis from Lane and Gast [36] or statistical analysis methods are therefore not applicable. Even if all tasks are a part of, e.g., morning routines, they demand different cognitive strategy applications and functions. Ideally, the target behaviour should be the exact same task measured five times[20]. The decision to choose to measure five tasks instead of measuring the same task five times was an attempt to gently collect data for the participant and remain close to ordinary practice. It is possible that OTs can strive to use at least three, but optimally five[40],

measurement points in each phase for the same task without much extra effort or burden on the participants. This can be held close to a real-world context, when the chosen task can be performed naturally more than once during the day, such as using a cell phone or transferring safely to a chair. Nevertheless, it is important that the participant is guided to choose a task that is needed or desired.

The procedures secured the systematic delivery of the PRPP intervention, and as trained PRPP therapists, the OTs have a manual to follow. Our judgement is that comparing or pre-deciding a treatment adherence checklist as recommended in RoBiNT [23] is contraindicated because of the contextualized nature of the intervention. The intervention plan is based on the assessment, and the plan is a dynamic process in which the initiative of the OT fades when the client internalizes the strategies.

CONCLUSION

This pilot shows that the planned procedures for the PRPP intervention study are acceptable and practically feasible for community OTs and elderly participants with decreased mastery of everyday tasks due to cognitive challenges after ABI. This pilot study also reveals important issues requiring modification of the research procedure for future studies. It is important to communicate the research procedure steps clearly to the data-collecting OTs to minimize the risk of bias. One substantial change was made to enable the application of established systematic visual inspection and statistical analysis methods: attempting to include at least three and preferably five measurement points in each phase of the same task. The outcome measures are both manageable and sensitive to changes, and the effectiveness of the PRPP intervention looks promising for continuing data collection with the suggested modification.

Contributorship statement: MØL, AO, 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. Dr. [redacted] contributed to methodological discussions. We thank the collaborating municipalities, the OTs collecting the data, and the participants.

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Ethics statement: Patient consent for publication. Not required.

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FIGURES

Figure 1: The Perceive, Recall, Plan and Perform System of Task Analysis, the four quadrants Perceive, Recall, Plan and Perform, the 12 sub quadrants, and the outer circle with observable descriptors[17].

Figure 2: Percent task mastery.

Figure 3: Cognitive strategy application across all five target tasks.

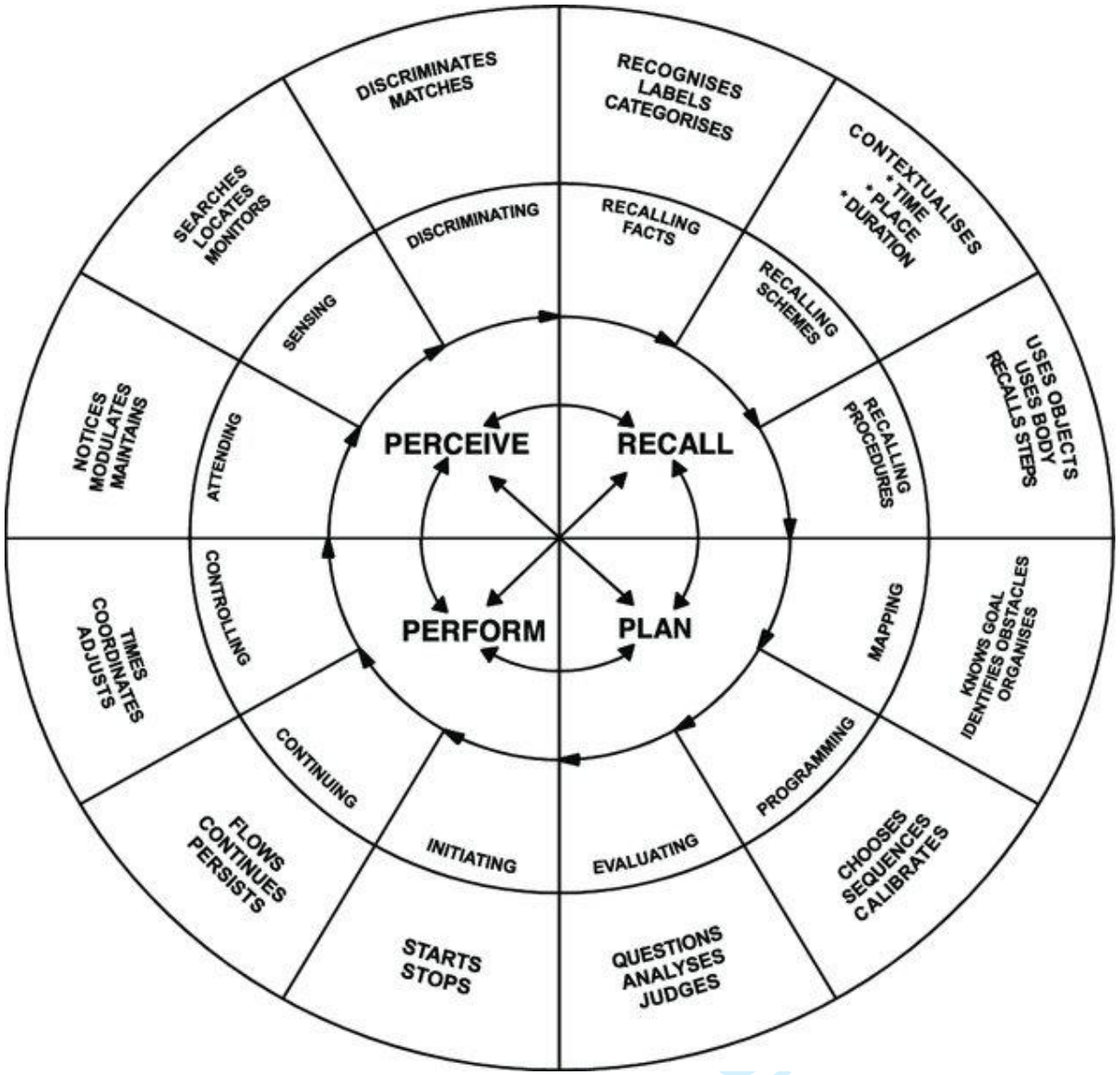


Figure 1.
Chapparo C, Ranka JL. The Perceive: Recall: Plan: Perform (PRPP) System of task analysis. 2013. Available from: <http://www.occupationalperformance.com/category/assessments/prpp/> (accessed 26.05.2020).

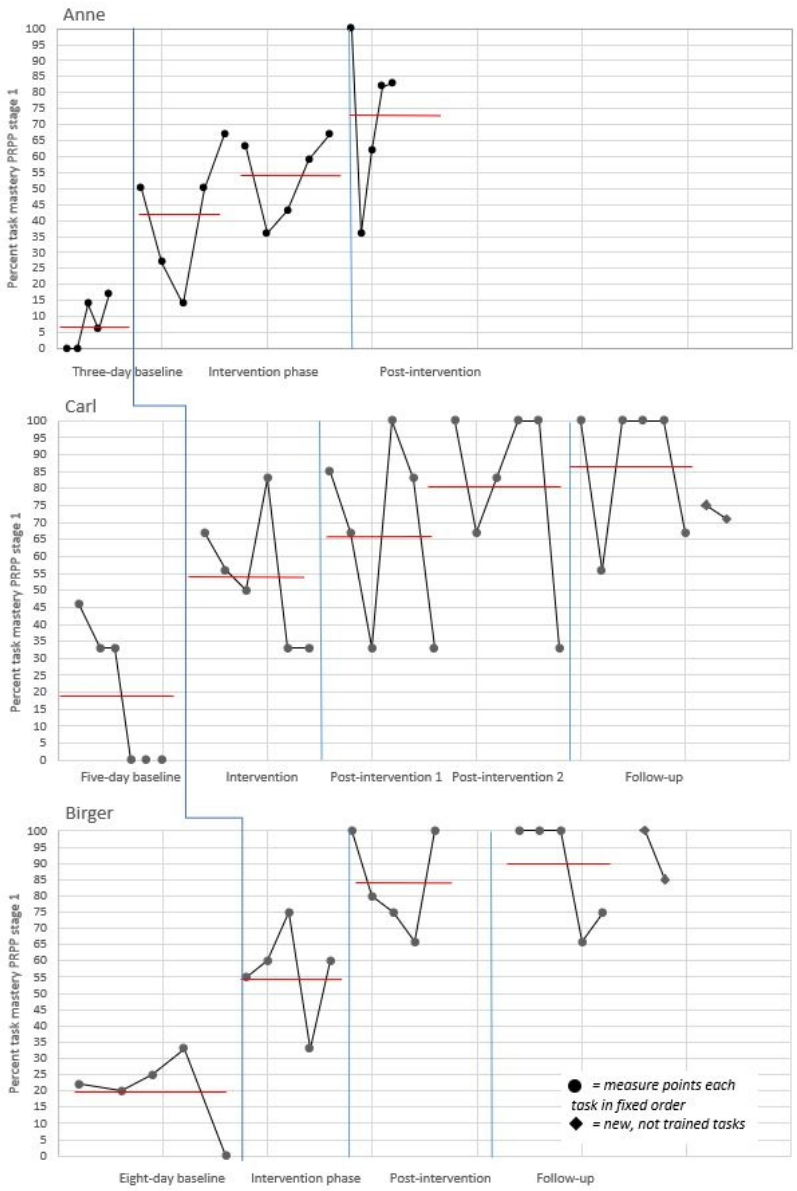
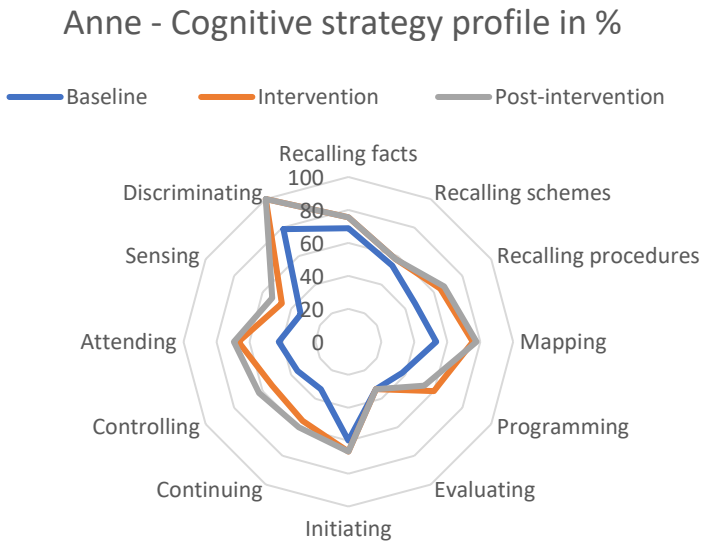
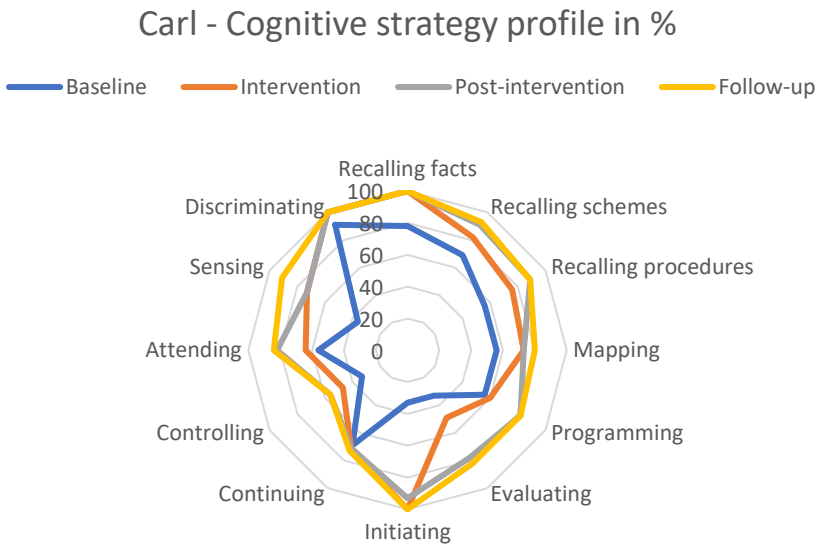
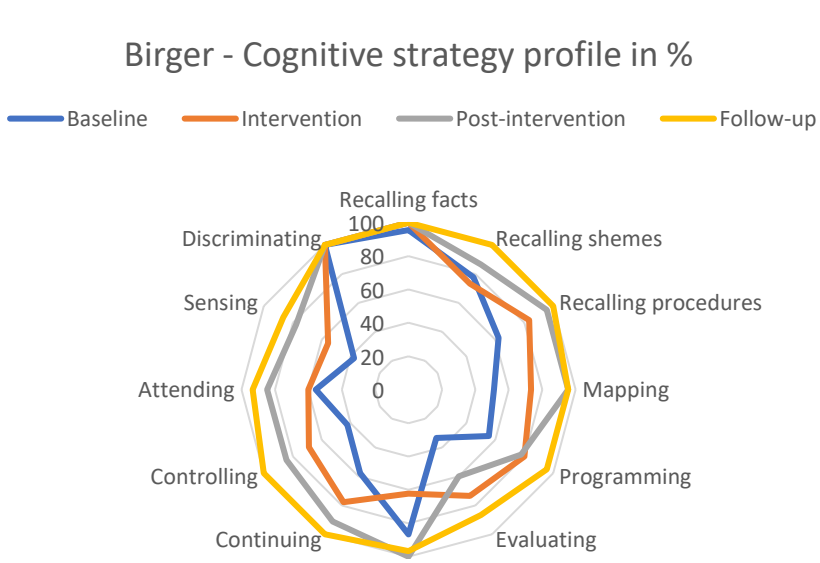


Fig. 2: Percent task mastery. The blue vertical line through all three graphs illustrates the staggered baseline phases. The horizontal red lines illustrate the mean value.

158x236mm (96 x 96 DPI)







CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	2,3
	2b	Specific objectives or research questions for pilot trial	3,4
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	3,4,6
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	4,5
	4b	Settings and locations where the data were collected	4
	4c	How participants were identified and consented	4,5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7,12
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	7-9, 12
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	4
Sample size	7a	Rationale for numbers in the pilot trial	3,4
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	4,5
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4,5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	9,10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	10-12
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the pilot trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	6,11
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	N/A
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	N/A
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	10-14
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	13,14
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	14-16
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	14-16
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	16
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	16
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	1
Protocol	24	Where the pilot trial protocol can be accessed, if available	4
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	ScolarOne
	26	Ethical approval or approval by research review committee, confirmed with reference number	9

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Feasibility of the Perceive, Recall, Plan and Perform System of intervention study for persons with brain injury in community-based rehabilitation: A pilot for a multiple-baseline design study

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Feasibility of the Perceive, Recall, Plan and Perform System of intervention study for persons with brain injury in community-based rehabilitation: A pilot for a multiple-baseline design study

Lindstad, M.Ø.[1], Obstfelder, A.[1], Sveen, U.[3, 4], Stigen, L.[1]

[1)] Department of Health Science Gjøvik, Norwegian University of Science and Technology, Gjøvik, Norway
[2)] Department of Occupational Therapy, Prosthetics and Orthotics, Oslo Metropolitan University, Oslo, Norway
[3)] Department of Physical Medicine and Rehabilitation, Oslo University Hospital, Oslo, Norway

Corresponding author: Marte Ørud Lindstad, NTNU Gjøvik, Pb 191, 2802, Gjøvik, Norway.
Tel: +47 99 592 692 marte.lindstad@ntnu.no

ABSTRACT

Objectives: This paper describes a pilot study investigating the feasibility of the Perceive, Recall, Plan and Perform (PRPP) System for persons with cognitive impairments after brain injury in the context of community-based rehabilitation for older individuals.
Design: The feasibility, acceptability and practicability of the research procedures were evaluated by exploring the effectiveness of the PRPP intervention with nonconcurrent multiple baseline designs.
Setting and Participants: Three participants (63+ years of age) from two health centres were included.
Intervention: In the PRPP intervention, the occupational therapist (OT) supports the participant in applying cognitive strategies in everyday activities to enhance task mastery, with nine sessions of 45-60 minutes over three weeks.
Primary and secondary outcome measures: The participants completed five repeated measurements of everyday tasks as a dependent variable. PRPP assessment stages 1 and 2 served as the primary and secondary outcome measures, respectively. The mastery percentage of the tasks and the participants' application of cognitive strategies in the baseline phase acted as a control and was therefore compared with the other phases within the participant. The Goal Attainment Scale and Barthel Index served as generalization measures. The uncertainties and acceptability of the procedures were also investigated with a procedural checklist and qualitative statements reported in the procedures or noted in dialogue meetings with the conducting OTs.
Results: The procedures were acceptable for the OT and the participants and were feasible if the steps in the research procedure were clearly understood. The target behaviour should be changed to the use of one task with five measurement points instead of measuring five tasks. This can enable the application of recommended analysis methods.
Conclusions: The outcomes of this study led to a change in the target behaviour and clarification of the research procedure for the planned PRPP intervention study.
Trial registration: ClinicalTrials.gov Identifier: NCT05148247

Key words: The PRPP system, cognitive rehabilitation, activities of daily living, cognitive strategy use, occupational therapy

Word count: 4197

ARTICLE SUMMARY

Strengths and limitations of the study

- The research procedure's closeness to real-world practice is a strength.
- The pilot indicates that the PRPP intervention is effective.
- Information on the steps of the research procedure must be more precisely communicated between the researchers and the OTs providing the intervention.
- To enable the application of established analysis methods, we need to change the target behaviour for further data collection.

INTRODUCTION

Persons with acquired brain injury (ABI) report a need for rehabilitation to manage everyday activities due to cognitive challenges [1,2]. Although most ABIs occur in older individuals (65+ years of age), research often focuses on younger individuals[3,4]. With an ageing population, often with comorbidities, it is crucial that ABI survivors receive rehabilitation and reach their maximum level of independence[5]. In Norway, clients with ABI receive rehabilitation in regional specialized units and/or community-based programmes in the municipalities in health centres or in the clients' homes[6].

The Norwegian welfare system is based on public funding and is built on principles of equal essential health services for the entire population. One of the mandates of municipal health services is to ensure that the population receives needed rehabilitation services [6]. Occupational therapy has been an obligatory profession in community health services since 2020[7] and generally concerns people's everyday lives. Occupational therapy is a central rehabilitation profession for reaching the political goal of ageing in one's own home and local community as long as possible, both for sustainability reasons and for individual quality of life[8]. Community occupational therapists (OTs) in small- and medium-sized municipalities in Norway identify themselves as generalists, working with clients with a wide range of conditions and in various contexts, whereas there are opportunities to be more specialized in larger municipalities [9].

Norwegian community OTs call for a focus on and development of assessment and interventions to meet clients' cognitive challenges [10,11]. Community OTs in Norway working with clients with cognitive impairments report persons with ABI to be a large client group [12]. The same sample of OTs frequently use interventions related to environmental modifications and assistive technology, with training of everyday activities reported as the third most provided intervention. This is comparable to the case for Norwegian ABI survivors, who report that they are given services to adapt the environment to cope with physical issues and to rehabilitate physical impairments, even if they experience problems in activities due to cognitive challenges [1,2].

International studies describe a more nuanced picture of community OT interventions in rehabilitation for this client group. The most frequent interventions were task training, the use of external compensatory strategies, various types of cognitive strategy training, adaptation of the environment and exercises with paper and pencil/computer; however, only a few used standardized interventions [13-16]. Therefore, we should seek evidence for standardized interventions appropriate for use in community rehabilitation to meet the needs of heterogeneous clients with cognitive challenges after ABI.

The Perceive, Recall, Plan and Perform System (PRPP) is a standardized system of assessment and intervention with a focus on clients' everyday occupational performance[17]. The PRPP was developed by OTs to help clients apply cognitive strategies to enhance task mastery and focuses on both task training and cognitive strategy training within natural everyday tasks and contexts[18]. The uniqueness of the PRPP system is its focus on occupational performance both as an assessment and intervention, and it is designed for everyone experiencing information processing deficits, regardless of age, context and diagnosis[17]. The effectiveness of the PRPP intervention has been evaluated for adults with acquired brain injury[19] but has not yet been evaluated through systematic research for older individuals with ABI in community rehabilitation.

Systematic research investigating the effectiveness of interventions often excludes older individuals with comorbidities[3,4], and there is not a strong research tradition in Norwegian community health services[20]. Therefore, we designed a pilot study to evaluate the feasibility of the PRPP intervention for older clients in an ordinary practice setting.

Aim and objectives

The main purpose of this pilot study was to evaluate the feasibility, acceptability, and practicability of all research procedures for a planned PRPP intervention study to identify procedural, clinical, and methodological uncertainties. We did this by exploring the effectiveness of the PRPP intervention in a community rehabilitation context with persons observed to have difficulties in everyday task performance due to cognitive challenges following ABI.

METHOD

To explore the planned PRPP intervention study design, we used a nonconcurrent multiple-baseline design (n=3) with three lengths of the baseline phases and at least five data points within each phase. This design allows the collection of empirical data systematically close to ordinary practice, along with experimental control of the variables [21]. For expanded details of the planned intervention study, we refer to the protocol[22]. This pilot study used various methods to collect information about feasibility.

The Medical Research Council guidance for developing and evaluating complex interventions [23] has guided the planning of the pilot and the planned intervention study together with The Risk of Bias in N-of-1 Trials (RoBiNT)[24]. To progress to the PRPP intervention study, our criteria for this feasibility study procedure are as follows: 1) the OTs and participants find the procedure acceptable regarding time consumed, comfort, respecting the rehabilitation goals and the context, and the fidelity checklist is met by at least 80%; 2) the measures are sensitive enough to show immediate changes in task mastery and cognitive strategy use; and 3) the research design and data analysis methods are feasible for showing visually, statistically, and clinically significant effects of the PRPP intervention.

Patient and public involvement

Planning of the pilot study took place in close dialogue between the participating community OTs that collected data and the first author to make the research procedures possible in a clinical setting. The first author had a dialogue with an organization for stroke

survivors [25] during which they confirmed the importance of focusing on cognitive rehabilitation and everyday tasks and had no further comments.

Research setting

The pilot was conducted within community-based rehabilitation services in one medium municipality (15 000 inhabitants) and one large municipality (55 000 inhabitants) in Southeast Norway. The OTs that collected the data (n=4) and provided the PRPP intervention were not part of the research group. They worked hectic and multifaceted days at health centres that included short-stay units, rehabilitation units, and residential units for older adults with very different diagnoses, conditions, and service needs. The OTs (n=4) were all female with a range of 9-16 years of clinical experience. They were trained and certified in the PRPP System 6 years ago at the time of inclusion and have in the years since regularly used the system in their clinic with various clients with information processing challenges.

Participants

The first three clients (table 1) admitted to the health centres with a new ABI were informed about and asked to participate in the trial by their OT. The exclusion criteria were previous diagnosis of dementia, congenital brain damage or developmental disability. The participants also needed a minimum level of physical resources to manage everyday tasks, the ability to hear and/or understand simple instructions and to show mastery below 85% in PRPP assessment stage 1. The OT collected oral or written consent and allocated the participants (n=3) to a predefined baseline phase. The first participant included was allocated to a baseline phase of three days, the second participant five days and the third seven days. Neither the researcher nor the OTs had influence on which clients were admitted to the health centres.

	Anne	Carl	Birger
Sex, age	Female, 71	Male, 63	Male, 86
Marital status, living conditions	Lives with husband in own house	Lives with partner in own terraced house	Lives with wife in own apartment
Activity level prior to ABI	Retired teacher, active lifestyle, exercises regularly, assisting at previous workplace	Retired professional driver, handy man, always on his feet helping with household repairs	Retired, mostly quiet indoor activities, listen* to TV. Walks independently with walker in the flat but needs help transferring to the toilet at night, and his wife expressed she feels insecure leaving him alone for fear of falls
Home health care prior to ABI	No	No	Yes, once a day for providing medical cream, eating and morning routines
Reported cognitive challenges prior to ABI	No	No	No
ABI diagnosis	Cerebral infarct left side, basal ganglia	Traumatic brain injury, with subarachnoid haemorrhage bilaterally and frontal contusion injury	Cerebral haemorrhage right side, subcortical.
Neurological challenges reported in patient record	Severe aphasia, attention, visual and arousal deficits, half side paresis right side, dysphagia with tube feeding	Post-traumatic amnesia for 2 months; half side paresis left side; poor tolerance and impulsive control; difficulties with planning, structure, and attention; easily tired	Balance and mobility problems, orientation only to one side, impaired judgement, and plan of action
Recruitment	12 days since ABI	93 days since ABI	18 days since ABI
Comorbidities	Fibromyalgia, hypertension, angina, lymphoedema and backpain	Diabetes mellitus 2, Chronic obstructive pulmonary disease grade 1, backpain, cataract, hypertension, chronic pancreatitis. After the TBI, he had high scores on a depression scale	Blind in one eye, strongly reduced sight in other eye with tunnel vision, moderate hearing loss, age-decreased balance (uses a rollator)

Table 1: *Overview of the participants' demographic and health characteristics at inclusion. *because of reduced vision*

Intervention to be studied

The aim of the PRPP intervention is to enhance mastery in the performance of the clients' needed or desired everyday tasks[17]. The PRPP intervention was developed based on the basic principles of the information processing approach[26] and evident theories of neural plasticity[27], systematic instructions[28], errorless learning[29] and task-oriented training[30].

The OTs followed the PRPP intervention manual[31]; however, the intervention delivery was highly individualized. This means that the PRPP assessment identified errors in the participants' cognitive strategy application behaviours that most impacted the mastery of tasks that were relevant or important to the client. On that basis, the OTs developed a plan for the use of systematic instructions of cognitive strategy training in extended traditional task training[32].

The intervention phase started directly after the baseline phase. The PRPP intervention plan included a goal for the task, where the task was supposed to be performed, adaptations of the environment, timing and prompts from the OT. The OT started by making the goal of the task clear, which was followed by providing systematic instructions through graded verbal, visual or physical prompts and cues directly during the participants' task performance. The OT taught the participants to apply strategies in relation to 'stop/attend, sense, think, do'. 'Stop/attend' helped the participants initially to focus on details of the task, and 'sense' was prompted to assist the participants in perceiving the sensory information from the objects and environment required to perform the task. In relation to the strategy 'think', the OT prompted the participants to recall steps, develop a plan of action or evaluate as needed to 'do' the performance as fluently as possible. The application of 'do' also supported the participants in implementing the plan. As each participant improved mastery and internalized the strategies in their task performance, the OT decreased the number and frequency of prompts.

During all phases, the participants received other treatment 'as usual' from the interdisciplinary team. Other treatments and the degree to which the interdisciplinary team (or relatives) was supervised by the OT to provide prompts and cues varied and was described by the OT as a step in the research procedures.

Target behaviour: measures and data collection

As a primary outcome and functional measure, the criterion-referenced PRPP assessment stage 1[33] was used. Five needed or desired everyday tasks in the context for the participants were chosen by the OT in cooperation with each participant; measuring them each at least once during each phase, provided five measurement points all together. The tasks were divided into a series of significant steps. Performance was measured in percentage mastery (0-100%) of the steps, and errors of omission, accuracy, repetition, and timing were recorded. A score above 85-90% indicates independence in the target task but with minor inefficient cognitive strategy application[34].

The PRPP assessment stage 2[33] was used as a second outcome measure. The effectiveness of 35 observable cognitive strategy application behaviours (outer ring fig. 1) in task performance was evaluated on a three-point criterion-referenced scale: (3) effective, (2) questionable or (1) not effective. The 12 subquadrants (middle ring fig. 1) and the information processing of Perceive, Recall, Plan and Perform are illustrated in the central quadrants in the theoretical model (fig. 1). Each subquadrant was then assigned a percentage score. PRPP assessment stages 1 and 2 were used to collect data from all five tasks in all four phases.

(FIG 1 ABOUT HERE)

Fig 1. Perceive, Recall, Plan and Perform System of Task Analysis[35].

As a generalisation measure, the participants were evaluated with the Goal Assessment Scale (GAS) [36] and the Barthel Index (BI) [37,38]. The 5 target behaviours were inserted into the GAS. Based on observations made by the OT, a score of -2 is the baseline value, 0 represent the expected short-term goal attainment, better outcomes are indicated by scores of +1 and +2, and outcomes below the expected short-term goal attainment are indicated by scores of -1. The BI includes ten tasks: eating, bathing/showering, personal hygiene, dressing, bowel and bladder control, toileting, transfer between bed and chair, mobility, and walking stairs. The index uses a score of 0, 1 or 2 points, with a maximum score of 20 indicating independence in the tasks and the lowest score of 0 indicating total dependency [37] based on

observations made by a member of the interdisciplinary team. The GAS and the BI were used to collect data at baseline, postintervention, and follow-up phases.

Demographic information used to describe the participants and their contexts and qualitative statements from the client or relatives, journals or the interdisciplinary team were noted by the OT in the procedure document and contributed to evaluating clinical significance. Clinical significance reflects the rehabilitation goals and the potential difference the treatment contributes to practical, social, or applied value in the everyday life of the participants [21].

Procedural fidelity

Data concerning feasibility were gathered with a checklist of the steps in the procedure completed by each OT and assessed by the first author. An agreement of at least 80% indicates high fidelity[21]. Treatment adherence was secured by the fact that the OT provided the intervention together with the participant according to the research procedure.

Information concerning the acceptability and practicability of the procedure was collected in regular dialogue meetings with the OTs and the first and last author. The OTs were free to give overall feedback, but the dialogue was focused on the steps in the procedure compared to their regular practice and to the PRPP manual. Because of the long distances, Microsoft Teams were chosen as a digital meeting platform to communicate with all the OTs at the same time. Notes were made by the first author during the meetings, with the possibility of email for clarification. During the various research phases, the OTs noted qualitative observations and statements from the individual participants, relatives, and team members in the procedural document. The content of these qualitative data was related to task performance, improvements or acceptability of the intervention or research procedure.

Blind rating and interrater reliability

To address the interrater reliability[24], an external, independent and blinded PRPP-trained OT assessed 20% of the PRPP stage 1 and 2 measurements from each phase by video recordings from the assessment situations. When video recording was not possible, a second PRPP-trained OT at the unit assessed 20% of the measurement, but it was not possible to blind

the phases for this assessor. An interrater agreement of at least 80% is considered acceptable[21].

Ethics

The PRPP intervention study was approved by the Norwegian Regional Ethics Committee (project number 215391). It was desirable to keep the research procedures close to real-world practice. This minimized ethical challenges but could also threaten the research validity that we needed to address in this pilot. The participants had to wait for the PRPP intervention to start for up to seven days, but they received all other treatment as usual. Because there are only a few community OTs delivering PRPP intervention, that was considered acceptable.

Data Analysis

We explored the feasibility of the outcome measures by analysing the data patterns of all five tasks in fixed order in a visual graph for each participant. With guidance from Lane and Gast [39], each graph was visually inspected. The purpose was to determine whether the outcomes and graphs were appropriate to show immediate improvement in the target behaviours when the intervention was introduced and whether this improvement was maintained to the postintervention phase. Furthermore, the mastery of task performance and cognitive strategy application was maintained when tasks were performed in another context and was generalized to other tasks in the follow-up phase. Decisions regarding whether improvements were seen in the graphs were indexed as yes, no, or unsure [21].

Clinical significance was explored by noticing whether the participants' percentage mastery in the everyday tasks was above 85-90%, the goal attainment scores for each task, and qualitative statements from the participants, relatives, or team members. It was important to consider whether independence in certain tasks also led to fewer service needs or other impacts. The independence in the target tasks was linked to the progress in the overall independence of self-care and mobility skills from the BI score.

The formula 'number of agreements' x 100 shared in (number of agreements) + (number of disagreements) [21] (p. 200) analysed feasibility of the procedural checklist together with the OTs' expressed experience of managing the procedure in a busy clinical setting.

RESULTS

Participants

From the two municipalities, two participants were recruited within two months after inclusion start-up (spring 2021), and the third participant was recruited one week after completing data collection for the first participant (table 2). They were allocated in staggered baseline phases (table 3).

	Rehabilitation process after ABI until inclusion	Assistance and challenges at baseline	Tasks chosen. End goal: Mastery above 85%	Cognitive strategy focus	GAS score Task no.: B/P/F	Barthel Index total score	Other treatment
Anne	Admitted to short stay unit, rehabilitation potential questioned after 12 days of minimal recovery, received rehabilitation services in the short stay unit	She needed help with everything and could barely sit up straight in a wheelchair and had a short attention span. Could answer simple questions.	OT chose tasks after clinical reasoning and agreement from Anne and her husband, due to aphasia: 1) sitting in wheelchair in front of wash tub and mirror to wash face, 2) wash rest of upper body, 3) put on deodorant, 4) brushing teeth, 5) brushing hair	Recalled and knew the goal before each task and then prompted 'attend, notice, search, locate, recall steps and continue'	1: -2/-2/Lost data 2: -2/-1/Lost data 3: -2/-1/Lost data 4: -2/-1/Lost data 5: -2/-2/Lost data	B: 1/ P: 5/ F: Lost data	Physio-therapy, speech therapist, nursing
Carl	Transferred to community rehabilitation unit after three months of specialized rehabilitation, good physical outcomes, no cognitive screening possible at specialized rehabilitation due to cooperation, recovery curve stagnated	He needed close assistance for all morning and meal routines, including guidance of the well arm/hand. He walked 5-10 metres with a walker and close assistance due to uncritical behaviour. Did not manage to drive the wheelchair.	Clearly, expressed desired tasks: 1) take a shower, 2) dry after shower, 3) put on t-shirt, 4) stand up from wheelchair, 5) put on trousers, 6) put on shoes	Worked mostly in the planning-quadrant, with focus identify obstacles by prompting 'stop, analyse, choose and do'. Additionally, 'recall steps, use body, analyse, choose, continue, persist'	1: -2/-1/+1 2: -2/-1/+1 3: -2/-1/+1 4: -2/-1/+1 5: -2/-2/+1 6: -2/-2/0	B: 9 P: 15 F: 17	Physio-therapy, speech therapist, nursing
Birger	Admitted to short stay unit for the first 14 days and then transferred to the rehabilitation unit. Minimal spontaneous recovery, staff members questioned rehabilitation potential and expressed he would still need help at home.	He needed close assistance for safe mobility with a walker, always walked towards the left direction, bumped into objects, and had a fall caused by uncritical behaviour during transfer to a chair. Received help for most of his morning routines.	The OT had a thorough discussion with Birger about important tasks: 1) transfer to toilet, 2) transfer to chair, 3) orientation when coming into a room, 4) put on t-shirt and 5) put on shoes	Modified environment with contrasts and put stuff in same place. Then, prompting 'stop, notice, monitor, continue'	1: -2/+2/+2 2: -2/+2/+2 3: -2/-2/0 4: -2/-1/+1 5: -2/-2/+2	B: 10 P: 16 F: 15	Physio-therapy, nursing

Table 2: Description of the participants' data at baseline. B=baseline, P=postintervention F=follow-up

Tier 1/Anne	Baseline 3 days	Intervention: 9 sessions PRPP, 45-60 min each, 3 sessions a week for 3 weeks	Post-intervention measurement, incomplete and after 14-day delay due to hospital admission	Lost to follow-up measurement.
Tier 2/Carl	Baseline 5 days	Intervention: 30 sessions PRPP, 45-60 min each, 3 sessions a week for 9 weeks and then two weeks with a total of 3 sessions before postintervention 2	Post-intervention measurement after 10 and 13 weeks	Follow-up measurement; 4 weeks after discharge
Tier 3/Birger	Baseline 8 days	Intervention: 7 sessions PRPP, 45-60 min each, 3 sessions a week for 3 weeks	Post-intervention measurement the last two days of admission	Follow-up measurement; 4 weeks after discharge

Table 3: Timeline and completed intervention sessions

Effectiveness of intervention on task mastery and cognitive strategy application

The graphs demonstrate an immediate effect from the baseline to the intervention phase within the individual and between the participants' staggered baselines (fig. 2). Further improvements are shown in the graphs throughout the phases for the primary (fig. 2) and secondary outcomes (fig. 3). Figure 3 shows how the 12 subquadrants, which reflect effective cognitive strategy use, improve from the baseline (inner blue ring).

The mean and median scores for task mastery for the five tasks collapsed can be calculated and/or presented with visible changes in the graphs (fig. 2). However, the calculation of the stability of the baseline data, overlap and consistency of the data pattern across similar phases, and trend lines within each phase[39] cannot be used when there is only one measurement point for each of the five separate tasks, even though they constitute five measurement points all together.

(FIG 2 ABOUT HERE)

Fig. 2: Primary outcome: Percent task mastery of each of the five tasks presented in fixed order. The blue vertical line through all three graphs illustrates the staggered baseline phases. The horizontal red lines illustrate the mean value.

(FIG 3 ABOUT HERE)

Fig. 3: Secondary outcome: Cognitive strategy application across all five target tasks collapsed.

Clinical significance

Anne showed improvements during the three weeks and managed morning routines related to her face, teeth, and hair independently at postintervention. Although she improved, she still needed assistance to complete her entire morning routine. At the same time, her improvements led to her transfer to specialized rehabilitation, while she was considered for palliative care instead of rehabilitation at inclusion. Carl exhibited clinically significant improvements and needed less personal assistance with independent mobility. At follow-up, Birger received some assistance for his morning routines and eating due to visual impairments present before ABI. His wife reported that he used the toilet independently at night and expressed that she was more confident leaving him at home alone, as he walked safely with a walker and transferred with caution. That improvement was beyond his level prior to the ABI. For both Anne and Birger, the nursing staff expressed surprise regarding the participants' recovery and achievements.

The GAS showed improvements in line with the percent task mastery as expected because it was the exact same task as the target behaviour. The BI showed overall improvements and was in line with the task mastery where the tasks observed were the same. This may contribute to external validity but give otherwise small benefits to lighten the measure of generalisation.

Procedural fidelity, acceptance, and practicability

The procedural checklist could be followed as long as no unforeseen incidents occurred. Birger had an 8-day baseline instead of a 7-day baseline due to OTs' work schedule. Two misunderstandings of the checklist resulted in 1) interrater observations through video recording were only collected for the follow-up phase for Carl, and the postintervention and follow-up phases for Birger and 2) Carl attending as many as 27 PRPP sessions before postintervention outcomes were measured. To score a basis at discharge for the follow-up measurement, the OTs scored a second postintervention phase. This means that it was not the practice setting or acceptability that hindered the procedure but rather issues with unclear communication from the researcher to the participating OTs. The procedural checklist was followed by the OT in 91% and 89% of the steps for Birger and Carl, respectively, but follow-up errors after the misunderstandings with Carl's intervention

sessions were not taken into account. For Anne, the procedural checklist was followed by 84% for the three phases completed. For Anne interrater observations were collected in the baseline and intervention phases through direct observations. The interrater assessments were chosen by the OT based on when it was most practical to them.

The OTs confirmed the general acceptability for the procedures on behalf of themselves, the participants, and the practice setting, even if they reported a greater workload, such as the time needed to administer scores and documentation. At the same time, the OTs reported that the research procedures helped them practice the intervention more systematically with benefits for the clients. There were unexpected circumstances, such as participants being transferred to other health facilities and OTs being on sick leave. To cope with these circumstances, the OTs were forced to have a flexible attitude, but it also resulted in forgotten a PRPP stage 2 score at postintervention and lost follow-up data for Anne.

For all three participants all five tasks were worked on sequentially in each session. For all participants, the nursing staff followed a simplified intervention plan made with suggested strategies; however, this plan was followed to various degrees and not recorded in detail.

DISCUSSION

This study examined the feasibility of a planned intervention study by exploring the effectiveness of the PRPP intervention in people experiencing problems with everyday task mastery due to ABI with cognitive problems. Our data suggest that the PRPP intervention used with older clients was largely feasible in terms of the procedural checklist, acceptability and practicability for clients and therapists, sensitive outcome measures and benefits of the intervention. We suggest some changes in the research procedure that can minimize the risk of bias. First, we need to clarify information around some steps in the procedure with the conducting OTs. Second, we need to adjust the use of target behaviour and, in the same context, the graphs and the associated analysis methods. This will be discussed below.

Strengths and limitations of the study

The strength of this study is the close relationship to ordinary practice and measuring the outcome of cognitive challenges directly via everyday task performance. The included

participants were considered to have low rehabilitation potential due to the severity of their cognitive challenges, comorbidities, and extant home health services. Studies show that adults 65+ years of age with ABI receive less intensive rehabilitation than younger adults and are often excluded from research due to age or comorbidities [3]. When research participants do not reflect diverse real-world conditions, this could fail to translate research into practice [5]. Cicerone, et al. [40] call for outcome measures that address cognition when performing everyday activities. The PRPP stages 1 and 2 are sensitive to changes in everyday activity performance and were acceptable for the participants and the community OTs. This shows that it is possible to include older participants with comorbidities in research and assess cognition in everyday tasks. One of the advantages of the PRPP intervention is its usefulness for any difficulties with information processing across practice settings, diagnoses and ages[31].

There are limitations that should be considered when interpreting the data and planning for a full trial. The procedural checklist is acceptable to follow if the key functions in the procedure are clearly understood and no unforeseen events occur. Unclearly communicated procedures resulted in missing data for interrater reliability for Birger and Carl for some of the phases. Measuring interrater reliability reminds us of its role in minimizing reactivity and observational bias and plays a role in internal validity[41]. As long as the postintervention and follow-up phases include a blinded interrater assessor and show increasing improvements, we can assume that the measures in the intervention phase do not err in the direction of false positives.

Unclear communicated procedures also led to the postintervention measurement for Carl being collected first after 27 interventions. Incomplete implementation of the research plan is a threat to validity [42]. For Carl's prolonged intervention phase, the limitation did not affect the immediate change in task performance and cognitive strategy application between baseline and the intervention phase, as shown in the visual graph. The results in the postintervention and follow-up phases have a clear bias compared to those of other participants in the sample, but in a practice setting, the improvements will be valuable. Nevertheless, the procedural checklist was followed at least 80% of the time, which indicates high fidelity for all the participants [21].

A second limitation is the choice of using five tasks. Although the immediate visual effects across the five tasks are clear, the choice minimized the opportunity to apply the most recognized analysis methods. Analysis of stability, overlap and consistency, and trend lines in the various phases from the widely used systematic inspection analysis from Lane and Gast [39] or statistical analysis methods are therefore not applicable. Even if all tasks are a part of, e.g., morning routines, they demand different cognitive strategy applications and functions. Ideally, the target behaviour should be the exact same task measured five times[21]. The decision to choose to measure five tasks instead of measuring the same task five times was an attempt to gently collect data for the participant and remain close to ordinary practice. It is possible that OTs can strive to use at least three, but optimally five[43], measurement points in each phase for the same task without much extra effort or burden on the participants. This can be held close to a real-world context, when the chosen task can be performed naturally more than once during the day, such as using a cell phone or put on shoes. Nevertheless, it is important that the participant is guided to choose a task that is needed or desired.

The procedures secured the systematic delivery of the PRPP intervention. As trained PRPP therapists, the OTs have a manual to follow but must react with flexibility regarding what each situation requires. Our judgement is that comparing or predeciding a treatment adherence checklist as recommended in RoBiNT [24] is complicated because of the contextualized nature of the intervention. The intervention plan is based on the assessment, and the plan is a dynamic process in which the initiative of the OT fades when the client internalizes the strategies.

CONCLUSION

This pilot shows that the planned procedures for the PRPP intervention study are acceptable and practically feasible for community OTs and older clients with decreased mastery of everyday tasks due to cognitive challenges after ABI. This pilot study also reveals important issues requiring modification of the research procedure for future studies. It is important to communicate the research procedure steps clearly to the data-collecting OTs to minimize the risk of bias. One substantial change was made to enable the application of established systematic visual inspection and statistical analysis methods: attempting to include at least

three and preferably five measurement points in each phase of the same task. The outcome measures are both manageable and sensitive to changes, and the effectiveness of the PRPP intervention appears promising for continuing data collection with the suggested modification.

Contributorship statement: MØL, AO, 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. We thank the collaborating municipalities, the OTs collecting the data, and the participants.

Competing interests: There are no competing interests.

Funding: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Data sharing statement: The research data can be shared upon reasonable request, and the data shared in open publications are free to use; however, they should be used with caution and with qualitative information following the statistics in mind.

Ethics statement: Approved by the Norwegian Regional Ethics Committee, project number 215391. Patient consent for publication.

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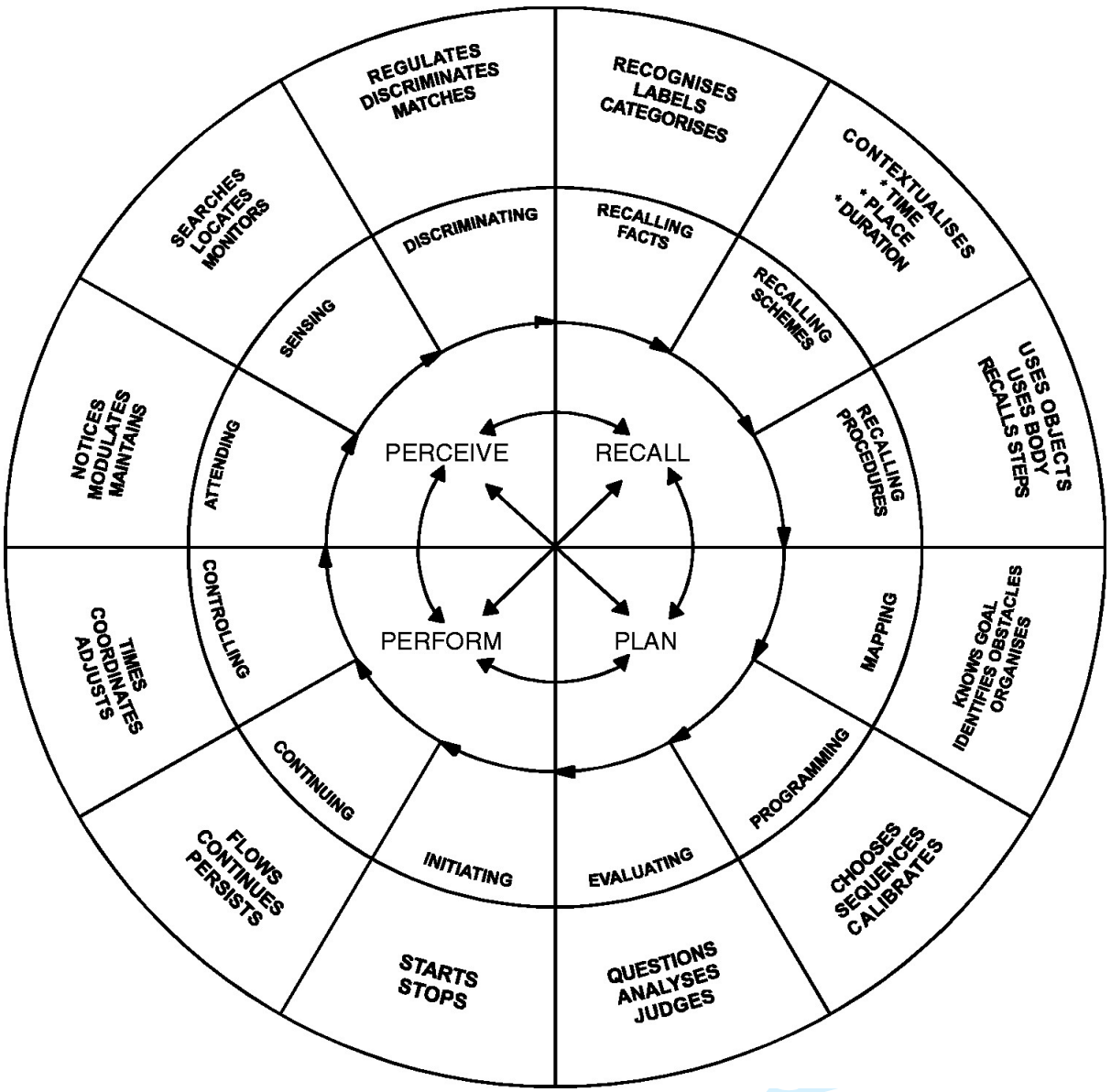
FIGURES

Figure 1: The Perceive, Recall, Plan and Perform System of Task Analysis, the four quadrants Perceive, Recall, Plan and Perform, the 12 sub quadrants, and the outer circle with observable descriptors[35].

Figure 2: Primary outcome: Percent task mastery of each of the five tasks presented in fixed order. The blue vertical line through all three graphs illustrates the staggered baseline phases. The horizontal red lines illustrate the mean value.

Fig. 3: Secondary outcome: Cognitive strategy application across all five target tasks collapsed.

Chapparo C and Ranka J (2014) The perceive, recall, plan & perform system assessment course manual (Available from authors: jranka@bigpond.net.au).



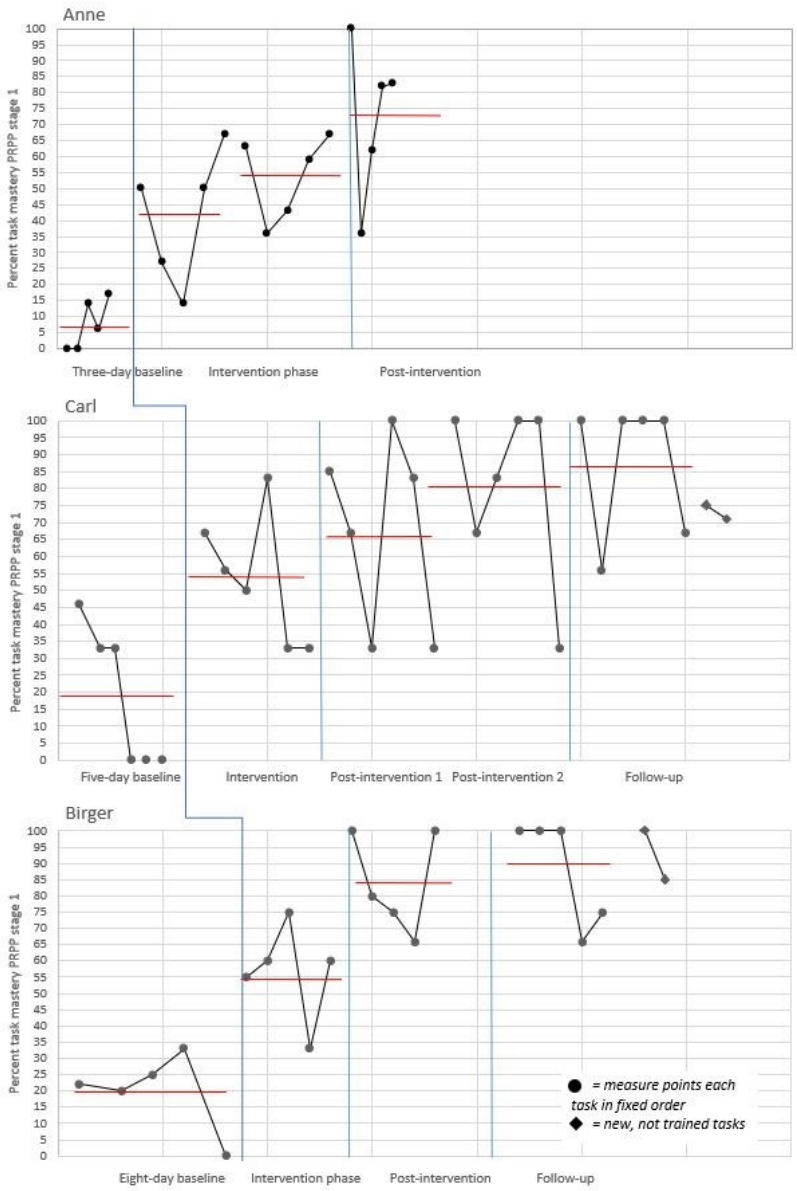


Fig. 2: Primary outcome: Percent task mastery of each of the five tasks presented in fixed order. The blue vertical line through all three graphs illustrates the staggered baseline phases. The horizontal red lines illustrate the mean value.

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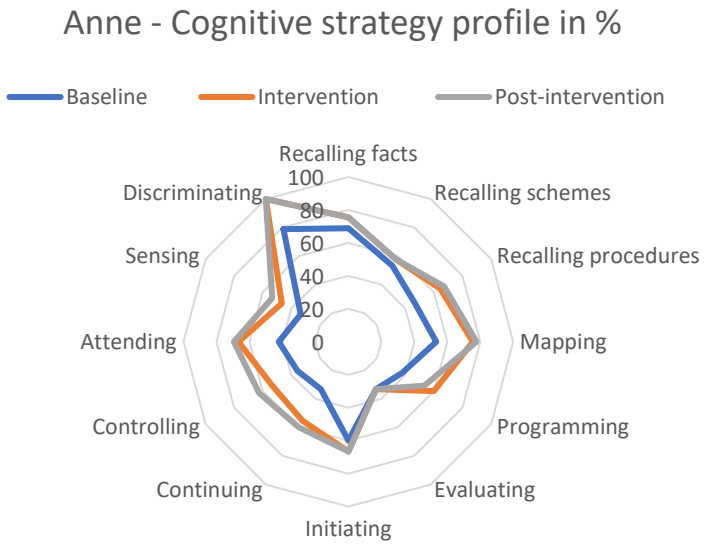

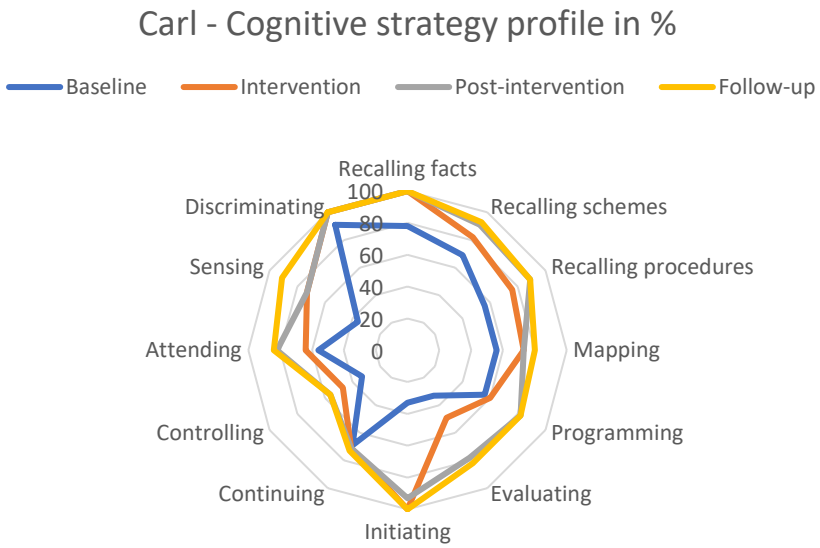

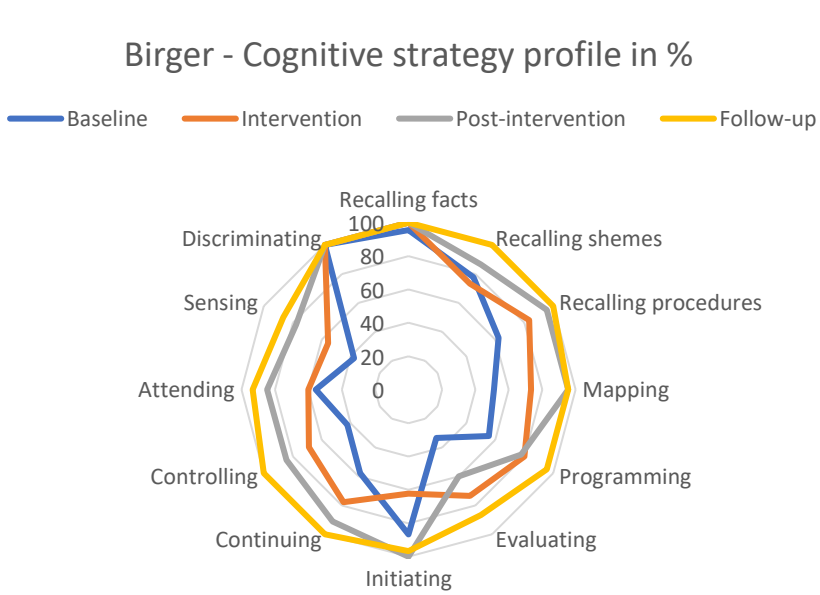

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	2,3
	2b	Specific objectives or research questions for pilot trial	3,4
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	3,4,6
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	4,5
	4b	Settings and locations where the data were collected	4,5
	4c	How participants were identified and consented	4,5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7,12,13 + protocol
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8,9,13
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	4
Sample size	7a	Rationale for numbers in the pilot trial	4
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	11-13
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	11
	14b	Why the pilot trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	6,12
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	N/A
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	N/A
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	14,15
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	14,15
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	15-17
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	15-17
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	15-17
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	15-17
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	1
Protocol	24	Where the pilot trial protocol can be accessed, if available	4
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	ScolarOne
	26	Ethical approval or approval by research review committee, confirmed with reference number	10

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*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Feasibility of the Perceive, Recall, Plan and Perform System of intervention for persons with brain injury in community-based rehabilitation: A pilot for a multiple-baseline design study

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Feasibility of the Perceive, Recall, Plan and Perform System of intervention for persons with brain injury in community-based rehabilitation: A pilot for a multiple-baseline design study

Lindstad, M.Ø.[1], Obstfelder, A.[1], Sveen, U.[2,3], Stigen, L.[1]

[1)] Department of Health Science Gjøvik, Norwegian University of Science and Technology, Gjøvik, Norway

[2)] Department of Occupational Therapy, Prosthetics and Orthotics, Oslo Metropolitan University, Oslo, Norway

[3)] Department of Physical Medicine and Rehabilitation, Oslo University Hospital, Oslo, Norway

Corresponding author: Marte Ørud Lindstad, NTNU Gjøvik, Pb 191, 2802, Gjøvik, Norway.
Tel: +47 99 592 692 marte.lindstad@ntnu.no

ABSTRACT

Objectives: This paper describes a pilot study investigating the feasibility of the Perceive, Recall, Plan and Perform (PRPP) System for persons with cognitive impairments after acquired brain injury in the context of community-based rehabilitation for older individuals.
Design: The feasibility, acceptability and practicability of the research procedures were evaluated by exploring the effectiveness of the PRPP intervention with nonconcurrent multiple baseline designs.
Setting and participants: Three participants (63+ years of age) from two health centres were included.
Intervention: In the PRPP intervention, the occupational therapist (OT) supports the participant in applying cognitive strategies in everyday activities to enhance task mastery, with nine sessions of 45-60 minutes over three weeks.
Primary and secondary outcome measures: The participants completed measurements of five everyday tasks in each phase as dependent variables. PRPP assessment stages 1 and 2 served as the primary and secondary outcome measures, respectively. The percentage of mastery of the tasks and the participants' application of cognitive strategies at baseline acted as a control and was therefore compared with the other phases within the participant. The Goal Attainment Scale and Barthel Index served as generalization measures. The uncertainties and acceptability of the procedures were also investigated with a procedural checklist and qualitative statements reported in the procedures or noted in dialogue meetings with the conducting OTs.
Results: The procedures were acceptable for the OT and the participants and were feasible if the steps in the research procedure were clearly understood. The target behaviour should be changed to the use of one task with five measurement points instead of measuring five tasks. This can enable the application of recommended analysis methods.
Conclusions: The outcomes of this study led to a change in the target behaviour and clarification of the research procedure for the planned PRPP intervention study.
Trial registration: ClinicalTrials.gov Identifier: NCT05148247

Key words: PRPP System, cognitive rehabilitation, activities of daily living, cognitive strategy use, occupational therapy, acquired brain injury.

Word count: 4166

ARTICLE SUMMARY

Strengths and limitations of this study

- The research procedure's closeness to real-world practice is a strength.
- The pilot indicates that the PRPP intervention can contribute to meaningful improvements in task performance.
- Information on the steps of the research procedure must be more precisely communicated between the researchers and the OTs providing the intervention.
- To enable the application of established analysis methods, we need to change the target behaviour for further data collection.

INTRODUCTION

Persons with acquired brain injury (ABI) report a need for rehabilitation to manage everyday activities due to cognitive challenges[1,2]. Although most ABIs occur in older individuals (65+ years of age), research often focuses on younger individuals[3,4]. With an ageing population, often with comorbidities, it is crucial that ABI survivors receive rehabilitation and reach their maximum level of independence[5]. In Norway, clients with ABI receive rehabilitation in regional specialized units and/or community-based programmes in the municipalities in health centres or in the clients' homes[6].

The Norwegian welfare system is based on public funding and is built on principles of equal essential health services for the entire population. One of the mandates of municipal health services is to ensure that the population receives needed rehabilitation services[6]. Occupational therapy has been an obligatory profession in community health services since 2020[7] and generally concerns people's everyday lives. Occupational therapy is a central rehabilitation profession for reaching the political goal of ageing in one's own home and local community as long as possible, both for sustainability reasons and for individual quality of life[8]. Community occupational therapists (OTs) in small- and medium-sized municipalities in Norway identify themselves as generalists, working with clients with a wide range of conditions and in various contexts, whereas there are opportunities to be more specialized in larger municipalities[9].

Norwegian community OTs call for a focus on and development of assessment and interventions to meet clients' cognitive challenges[10,11]. Community OTs in Norway working with clients with cognitive impairments report persons with ABI to be a large client group[12]. The same sample of OTs frequently use interventions related to environmental modifications and assistive technology, with training of everyday activities reported as the third most provided intervention. This is comparable to the case for Norwegian ABI survivors, who report that they are given services to adapt the environment to cope with physical issues and to rehabilitate physical impairments, even if they experience problems in activities due to cognitive challenges[1,2].

International studies describe a more nuanced picture of community OT interventions in rehabilitation for this client group. The most frequent interventions were task training, the use of external compensatory strategies, various types of cognitive strategy training, adaptation of the environment and exercises with paper and pencil/computer; however, only a few used standardized interventions[13-16]. Therefore, we should seek evidence for standardized interventions appropriate for use in community rehabilitation to meet the needs of heterogeneous clients with cognitive challenges after ABI.

The Perceive, Recall, Plan and Perform System (PRPP) is a standardized system of assessment and intervention with a focus on clients' everyday occupational performance[17]. The PRPP was developed by OTs to help clients apply cognitive strategies to enhance task mastery and focuses on both task training and cognitive strategy training within natural everyday tasks and contexts[18]. The uniqueness of the PRPP system is its focus on occupational performance both as an assessment and intervention, and it is designed for everyone experiencing information processing deficits, regardless of age, context and diagnosis[17]. The effectiveness of the PRPP intervention has been evaluated for adults with acquired brain injury[19] but has not yet been evaluated through systematic research for older individuals with ABI in community rehabilitation.

Systematic research investigating the effectiveness of interventions often excludes older individuals with comorbidities[3,4], and there is not a strong research tradition in Norwegian community health services[20]. Therefore, we designed a pilot study to evaluate the feasibility of the PRPP intervention for older clients in an ordinary practice setting.

Aim and objectives

The main purpose of this pilot study was to evaluate the feasibility, acceptability, and practicability of all research procedures for a planned PRPP intervention study to identify procedural, clinical, and methodological uncertainties. We did this by exploring the effectiveness of the PRPP intervention in a community rehabilitation context with persons observed to have difficulties in everyday task performance due to cognitive challenges following ABI.

METHOD

To explore the planned PRPP intervention study design, we used a nonconcurrent multiple-baseline design (n=3) with three lengths of the baseline phases and at least five data points within each phase. This design allows the collection of empirical data systematically close to ordinary practice, along with experimental control of the variables[21]. For expanded details of the planned intervention study, we refer to the protocol[22]. This pilot study used various methods to collect information about feasibility.

The Medical Research Council guidance for developing and evaluating complex interventions[23] has guided the planning of the pilot and the planned intervention study together with The Risk of Bias in N-of-1 Trials (RoBiNT)[24]. To progress to the PRPP intervention study, our criteria for this feasibility study procedure are as follows: 1) the OTs and participants find the procedure acceptable regarding time consumed, comfort, respecting the rehabilitation goals and the context, and the fidelity checklist is met by at least 80%; 2) the measures are sensitive enough to show immediate changes in task mastery and cognitive strategy use; and 3) the research design and data analysis methods are feasible for showing visually, statistically, and clinically significant effects of the PRPP intervention.

Patient and public involvement

Planning of the pilot study took place in close dialogue between the participating community OTs that collected data and the first author to make the research procedures possible in a clinical setting. The first author had a dialogue with an organization for stroke

survivors[25] during which they confirmed the importance of focusing on cognitive rehabilitation and everyday tasks and had no further comments.

Research setting

The pilot was conducted within community-based rehabilitation services in one medium municipality (15 000 inhabitants) and one large municipality (55 000 inhabitants) in Southeast Norway. The OTs that collected the data (n=4) and provided the PRPP intervention were not part of the research group. They worked hectic and multifaceted days at health centres that included short-stay units, rehabilitation units, and residential units for older adults with very different diagnoses, conditions, and service needs. The OTs (n=4) were all female with a range of 9-16 years of clinical experience. They were trained and certified in the PRPP System 6 years ago at the time of inclusion and have in the years since regularly used the system in their clinic with various clients with information processing challenges.

Participants

The first three clients (table 1) admitted to the health centres with a new ABI were informed about and asked to participate in the trial by their OT (Supplementary Material - Patient Consent). The exclusion criteria were previous diagnosis of dementia, congenital brain damage or developmental disability. The participants also needed a minimum level of physical resources to manage everyday tasks, the ability to hear and/or understand simple instructions and to show mastery below 85% in PRPP assessment stage 1. The OT collected oral or written consent and allocated the participants (n=3) to a predefined baseline phase. The first participant included was allocated to a baseline phase of three days, the second participant five days and the third seven days. Neither the researcher nor the OTs had influence on which clients were admitted to the health centres.

Please note, pseudonyms have been used to refer to the participants throughout.

	Anne	Carl	Birger
Sex, age	Female, 71	Male, 63	Male, 86
Marital status, living conditions	Lives with husband in own house	Lives with partner in own terraced house	Lives with wife in own apartment
Activity level prior to ABI	Retired teacher, active lifestyle, exercises regularly, assisting at previous workplace	Retired professional driver, handy man, always on his feet helping with household repairs	Retired, mostly quiet indoor activities, listen* to TV. Walks independently with walker in the flat but needs help up transferring to the toilet at night, and his wife expressed she feels insecure leaving him alone for fear of falls
Home health care prior to ABI	No	No	Yes, once a day for providing medical cream, eating and morning routines
Reported cognitive challenges prior to ABI	No	No	No
ABI diagnosis	Cerebral infarct left side, basal ganglia	Traumatic brain injury, with subarachnoid haemorrhage bilaterally and frontal contusion injury	Cerebral haemorrhage right side, subcortical
Neurological challenges reported in patient record	Severe aphasia, attention, visual and arousal deficits, half side paresis right side, dysphagia with tube feeding	Post-traumatic amnesia for 2 months; half side paresis left side; poor tolerance and impulsive control; difficulties with planning, structure, and attention; easily tired	Balance and mobility problems, orientation only to one side, impaired judgement, and plan of action
Recruitment	12 days since ABI	93 days since ABI	18 days since ABI
Comorbidities	Fibromyalgia, hypertension, angina, lymphoedema and backpain	Diabetes mellitus 2, chronic obstructive pulmonary disease grade 1, backpain, cataract, hypertension, chronic pancreatitis. After the TBI, he had high scores on a depression scale	Blind in one eye, strongly reduced sight in other eye with tunnel vision, moderate hearing loss, age-decreased balance (uses a rollator)

Table 1: *Overview of the participants' demographic and health characteristics at inclusion. *because of reduced vision*

Intervention to be studied

The aim of the PRPP intervention is to enhance mastery in the performance of the clients' needed or desired everyday tasks[17]. The PRPP intervention was developed based on the basic principles of the information processing approach[26] and evident theories of neural plasticity[27], systematic instructions[28], errorless learning[29] and task-oriented training[30].

The OTs followed the PRPP intervention manual[31]; however, the intervention delivery was highly individualized. This means that the PRPP assessment identified errors in the participants' cognitive strategy application behaviours that most impacted the mastery of tasks that were relevant or important to the client. On that basis, the OTs developed a plan for the use of systematic instructions of cognitive strategy training in extended traditional task training[32].

The intervention phase started directly after the baseline phase. The PRPP intervention plan included a goal for the task, where the task was supposed to be performed, adaptations of the environment, timing and prompts from the OT. The OT started by making the goal of the task clear, which was followed by providing systematic instructions through graded verbal, visual or physical prompts and cues directly during the participants' task performance. The OT taught the participants to apply strategies in relation to 'stop/attend, sense, think, do'. 'Stop/attend' helped the participants initially to focus on details of the task, and 'sense' was prompted to assist the participants in perceiving the sensory information from the objects and environment required to perform the task. In relation to the strategy 'think', the OT prompted the participants to recall steps, develop a plan of action or evaluate as needed to 'do' the performance as fluently as possible. The application of 'do' also supported the participants in implementing the plan. As each participant improved mastery and internalized the strategies in their task performance, the OT decreased the number and frequency of prompts.

During all phases, the participants received other treatment 'as usual' from the interdisciplinary team. Other treatments and the degree to which the interdisciplinary team (or relatives) was supervised by the OT to provide prompts and cues varied and was described by the OT as a step in the research procedures.

Target behaviour: measures and data collection

The target behaviour consists of mastery across different daily tasks and capacity for the use of cognitive strategies in occupational performance. As a primary outcome and functional measure, the criterion-referenced PRPP assessment stage 1[33] was used. Five needed or desired everyday tasks in the context for the participants were chosen by the OT in cooperation with each participant; measuring them each at least once during each phase provided five measurement points all together. The tasks were divided into a series of significant steps. Performance was measured in percentage mastery (0-100%) of the steps, and errors of omission, accuracy, repetition, and timing were recorded. A score above 85% indicates independence in the target task, but with minor inefficiency in cognitive strategy application[34].

The PRPP assessment stage 2[33] was used as a second outcome measure. The effectiveness of 35 observable cognitive strategy application behaviours (outer ring fig. 1) in task performance was evaluated on a three-point criterion-referenced scale: (3) effective, (2) questionable or (1) not effective. The 12 subquadrants (middle ring fig. 1) and the information processing of Perceive, Recall, Plan and Perform are illustrated in the central quadrants in the theoretical model (fig. 1). Each subquadrant was then assigned a percentage score. PRPP assessment stages 1 and 2 were scored in the same observation and were used to collect data from all five tasks in all four phases.

(FIG 1 ABOUT HERE)

Fig 1. Perceive, Recall, Plan and Perform System of Task Analysis[35].

As a generalisation measure, the participants were evaluated with the Goal Assessment Scale (GAS)[36] and the Barthel Index (BI)[37,38]. The 5 target behaviours were inserted into the GAS. Based on observations made by the OT, a score of -2 is the baseline value, 0 represents the expected short-term goal attainment, better outcomes are indicated by scores of +1 and +2, and outcomes below the expected short-term goal attainment are indicated by scores of -1. The BI includes ten tasks: eating, bathing/showering, personal hygiene, dressing, bowel and bladder control, toileting, transfer between bed and chair, mobility, and walking stairs. The index uses a score of 0, 1 or 2 points, with a maximum score of 20 indicating

independence in the tasks and the lowest score of 0 indicating total dependency[37] based on observations made by a member of the interdisciplinary team. The GAS and the BI were used to collect data at baseline, postintervention, and follow-up phases (reported in table 2).

Demographic information used to describe the participants and their contexts and qualitative statements from the client or relatives, journals or the interdisciplinary team were noted by the OT in the procedure document and contributed to evaluating clinically meaningful changes. Clinically meaningful changes reflect the rehabilitation goals and the potential difference the treatment contributes to practical, social, or applied value in the everyday life of the participants[21].

Procedural fidelity

Data concerning feasibility were gathered by the first author, who counted the procedure steps completed by each OT and compared them with the procedure checklist. An agreement of at least 80% indicates high fidelity[21]. Treatment adherence was secured by the fact that the OT provided the intervention together with the participant according to the research procedure.

Information concerning the acceptability and practicability of the procedure was collected in regular dialogue meetings with the OTs and the first and last author. The OTs were free to give overall feedback, but the dialogue was focused on the steps in the procedure compared to their regular practice and to the PRPP manual. Because of the long distances, Microsoft Teams were chosen as a digital meeting platform to communicate with all the OTs at the same time. Notes were made by the first author during the meetings, with the possibility of email for clarification. During the various research phases, the OTs noted qualitative observations and statements from the individual participants, relatives, and team members in the procedural document. The content of these qualitative data was related to task performance, improvements or acceptability of the intervention or research procedure.

Blind rating and inter-rater agreement

To monitor observer drift[24], an external, independent and blinded PRPP-trained OT assessed 20% of the PRPP stage 1 measurements from each phase by video recordings from the assessment situations. When video recording was not possible, a second PRPP-trained OT at the unit assessed 20% of the measurement, but it was not possible to blind the phases for this assessor. An inter-rater agreement of at least 80% is considered acceptable[21].

Ethics

The PRPP intervention study was approved by the Norwegian Regional Ethics Committee (project number 215391). It was desirable to keep the research procedures close to real-world practice. This minimized ethical challenges but could also threaten the research validity that we needed to address in this pilot. The participants had to wait for the PRPP intervention to start for up to seven days, but they received all other treatment as usual. Because there are only a few community OTs delivering PRPP intervention, that was considered acceptable.

Data Analysis

We explored the feasibility of the outcome measures by analysing the data patterns of all five tasks in fixed order in a visual graph for each participant. With guidance from Lane and Gast [39], each graph was visually inspected. The purpose was to determine whether the outcomes and graphs were appropriate to show immediate improvement in the target behaviours when the intervention was introduced and whether this improvement was maintained to the postintervention phase. Furthermore, the mastery of task performance and cognitive strategy application was maintained when tasks were performed in another context and was generalized to other tasks in the follow-up phase. Decisions regarding whether improvements were seen in the graphs were indexed as yes, no, or unsure[21].

Clinically meaningful changes were explored by noting whether the participants' percentage mastery in the everyday tasks was above 85%, the goal attainment scores for each task, and qualitative statements from the participants, relatives, or team members. It was important to consider whether independence in certain tasks also led to fewer service needs or other

impacts. The independence in the target tasks was linked to the progress in the overall independence of self-care and mobility skills from the BI score.

The formula 'number of agreements' x 100 shared in (number of agreements) + (number of disagreements)[21] (p. 200) was used to calculate the inter-rater agreement and the feasibility of the procedural checklist, together with the OTs' expressed experience of managing the procedure in a busy clinical setting.

RESULTS

Participants

From the two municipalities, two participants were recruited within two months after inclusion start-up (spring 2021), and the third participant was recruited one week after completing data collection for the first participant (table 2). They were allocated in staggered baseline phases (table 3).

	Rehabilitation process after ABI until inclusion	Assistance and challenges at baseline	Tasks chosen. End goal: Mastery above 85%	Cognitive strategy focus	GAS score	Barthel Index total score	Other treatment
Anne	Admitted to short stay unit, rehabilitation potential questioned after 12 days of minimal recovery, received rehabilitation services in the short stay unit	She needed help with everything and could barely sit up straight in a wheelchair and had a short attention span. Could answer simple questions.	OT chose tasks after clinical reasoning and agreement from Anne and her husband, due to aphasia: sitting in wheelchair in front of wash tub and mirror to 1) wash face, 2) wash rest of upper body, 3) put on deodorant, 4) brushing teeth, 5) brushing hair	Recalled and knew the goal before each task and then prompted 'attend, notice, search, locate, recall steps and continue'	Task no.: B/P/F 1: -2/-2/Lost data 2: -2/-1/Lost data 3: -2/-1/Lost data 4: -2/-1/Lost data 5: -2/-2/Lost data	B: 1/ P: 5/ F: Lost data	Physio-therapy, speech therapist, nursing
Carl	Transferred to community rehabilitation unit after three months of specialized rehabilitation, good physical outcomes, no cognitive screening possible at specialized rehabilitation due to cooperation, recovery curve stagnated	He needed close assistance for all morning and meal routines, including guidance of the well arm/hand. He walked 5-10 metres with a walker and close assistance due to uncritical behaviour. Did not manage to drive the wheelchair.	Clearly, expressed desired tasks: 1) take a shower, 2) dry after shower, 3) put on t-shirt, 4) stand up from wheelchair, 5) put on trousers, 6) put on shoes	Worked mostly in the planning-quadrant, with focus identify obstacles by prompting 'stop, analyse, choose and do'. Additionally, 'recall steps, use body, analyse, choose, continue, persist'	1: -2/-1/+1 2: -2/-1/+1 3: -2/-1/+1 4: -2/-1/+1 5: -2/-2/+1 6: -2/-2/0	B: 9 P: 15 F: 17	Physio-therapy, speech therapist, nursing
Birger	Admitted to short stay unit for the first 14 days and then transferred to the rehabilitation unit. Minimal spontaneous recovery, staff members questioned rehabilitation potential and expressed he would still need help at home.	He needed close assistance for safe mobility with a walker, always walked towards the left direction, bumped into objects, and had a fall caused by uncritical behaviour during transfer to a chair. Received help for most of his morning routines.	The OT had a thorough discussion with Birger about important tasks: 1) transfer to toilet, 2) transfer to chair, 3) orientation when coming into a room, 4) put on t-shirt and 5) put on shoes	Modified environment with contrasts and put stuff in same place. Then, prompting 'stop, notice, monitor, continue'	1: -2/-2/+2 2: -2/-2/+2 3: -2/-2/0 4: -2/-1/+1 5: -2/-2/+2	B: 10 P: 16 F: 15	Physio-therapy, nursing

Table 2: Description of the participants' data at baseline. B=baseline, P=postintervention F=follow-up. The numbers for the GAS score are the same as the task numbers.

Tier 1/Anne	Baseline 3 days	Intervention: 9 sessions PRPP, 45-60 min each, 3 sessions a week for 3 weeks	Post-intervention measurement, incomplete and after 14-day delay due to hospital admission	Lost to follow-up measurement.
Tier 2/Carl	Baseline 5 days	Intervention: 30 sessions PRPP, 45-60 min each, 3 sessions a week for 9 weeks and then two weeks with a total of 3 sessions before postintervention 2	Post-intervention measurement after 10 and 13 weeks	Follow-up measurement; 4 weeks after discharge
Tier 3/Birger	Baseline 8 days	Intervention: 7 sessions PRPP, 45-60 min each, 3 sessions a week for 3 weeks	Post-intervention measurement the last two days of admission	Follow-up measurement; 4 weeks after discharge

Table 3: Timeline and completed intervention sessions.

Effectiveness of intervention on task mastery and cognitive strategy application

The graphs demonstrate an immediate effect from the baseline to the intervention phase within the individual and between the participants' staggered baselines (fig. 2). Further improvements are shown in the graphs throughout the phases for the primary (fig. 2) and secondary outcomes (fig. 3). Figure 3 shows how the 12 subquadrants, which reflect effective cognitive strategy use, improve from the baseline (inner blue ring).

The mean achievement and change in task mastery for the five tasks collapsed can be calculated and/or presented with visible changes in the graphs (fig. 2). However, the calculation of the stability of the baseline data, overlap and consistency of the data pattern across similar phases, and trend lines within each phase[39] cannot be used when there is only one measurement point for each of the five separate tasks, even though they constitute five measurement points all together.

(FIG 2 ABOUT HERE)

Fig. 2: Primary outcome: Percent task mastery of each of the five tasks presented as dots of different shapes in a fixed order. The blue vertical line through all three graphs illustrates the staggered baseline phases. The horizontal red lines illustrate the mean value, and the reference line is 85%, indicating independence. The numbers on the x-axis indicate sessions.

(FIG 3 ABOUT HERE)

Fig. 3: Secondary outcome: Cognitive strategy application measured as the mean scores for the five target tasks.

Meaningful clinical changes

Anne showed improvements during the three weeks and managed morning routines related to her face, teeth, and hair independently at postintervention. Although she improved, she still needed assistance to complete her entire morning routine. At the same time, her improvements led to her transfer to specialized rehabilitation, while she was considered for palliative care instead of rehabilitation at inclusion. Carl exhibited clinically meaningful improvements and needed less personal assistance for safe independent mobility. At follow-up, Birger received some assistance for his morning routines and eating due to visual impairments present before ABI. His wife reported that he uses the toilet independently at night and expressed that she was more confident leaving him at home alone, as he walked safely with a walker and transferred with caution. That improvement was beyond his level prior to the ABI. For both Anne and Birger, the nursing staff expressed surprise regarding the participants' recovery and achievements.

The GAS showed improvements in line with the percent task mastery, which was expected because the tasks were exactly the same as the target behaviours (see table 2). The BI showed overall improvements and was in line with the task mastery where the tasks observed were the same. This may contribute to external validity but give otherwise small benefits to lighten the measure of generalisation.

Procedural fidelity, inter-rater agreement, acceptance, and practicability

The procedural checklist could be followed as long as no unforeseen incidents occurred (see supplementary material for checklist). Birger had an 8-day baseline instead of a 7-day baseline due to OTs' work schedule. Two misunderstandings of the checklist resulted in 1) inter-rater observations through video recording were only collected for the postintervention and follow-up phases for Birger, and 2) Carl attending as many as 27 PRPP sessions before postintervention outcomes were measured. To score a basis at discharge for the follow-up measurement, the OTs scored a second postintervention phase. This means that it was not the practice setting or acceptability that hindered the procedure but rather

issues with unclear communication from the researcher to the participating OTs. The procedural checklist was followed by the OT in 91% and 89% of the steps for Birger and Carl, respectively, but follow-up errors after the misunderstandings with Carl's intervention sessions were not taken into account. For Anne, the procedural checklist was followed by 84% for the three phases completed.

For Anne, the observations to be assessed for inter-rater agreement in PRPP stage 1 were collected for two tasks at baseline (agreement range 83-94%) and 5 tasks in the intervention phases (range 55-100%) by direct observations. Carl's observations for inter-rater comparison were collected by video-recording and blinded assessment for two tasks in the follow-up phase, and 100% agreement was noted. Birger's data were collected for one task in the post-intervention phase and two tasks in the follow-up, all through video recording and blinded assessment; the rate of agreement was 100%. Observations for inter-rater comparisons were lost for some of the phases due to a transfer to specialized rehabilitation (Anne), refusal of planned video recording (Carl), and misunderstanding of the procedure (Birger). The tasks evaluated for inter-rater agreement were chosen by the OT based on feasibility.

The OTs confirmed the general acceptability for the procedures on behalf of themselves, the participants, and the practice setting, even if they reported a greater workload, such as the time needed to administer scores and documentation. At the same time, the OTs reported that the research procedures helped them practice the intervention more systematically with benefits for the clients. There were unexpected circumstances, such as participants being transferred to other health facilities and OTs being on sick leave. To cope with these circumstances, the OTs were forced to have a flexible attitude, but it also resulted in a lost PRPP stage 2 score at post-intervention and lost follow-up data for Anne.

For all three participants, all five tasks were worked on sequentially in each session. For all participants, the nursing staff followed a simplified intervention plan made with suggested strategies; however, this plan was followed to various degrees and not recorded in detail.

DISCUSSION

This study examined the feasibility of a planned intervention study by exploring the

effectiveness of the PRPP intervention in people experiencing problems with everyday task mastery due to ABI with cognitive problems. Our data suggest that the PRPP intervention used with older clients was largely feasible in terms of the procedural checklist, acceptability and practicability for clients and therapists, sensitive outcome measures and benefits of the intervention. We suggest important changes in the research procedure that can minimize the risk of bias. First, we need to clarify information around some steps in the procedure with the conducting OTs. Second, we need to adjust the use of target behaviours to meet design criteria and, and in the same context, adjust the selection of graphs and associated analysis methods. This will be discussed below.

Strengths and limitations of this study

The strength of this study is the close relationship to ordinary practice and measuring the outcome of cognitive challenges directly via everyday task performance. The included participants were considered to have low rehabilitation potential due to the severity of their cognitive challenges, comorbidities, and extant home health services. Studies show that adults 65+ years of age with ABI receive less intensive rehabilitation than younger adults and are often excluded from research due to age or comorbidities [3]. When research participants do not reflect diverse real-world conditions, this could fail to translate research into practice [5]. Cicerone, et al. [40] call for outcome measures that address cognition when performing everyday activities. The PRPP stages 1 and 2 are sensitive to changes in everyday activity performance and were acceptable for the participants and the community OTs. This shows that it is possible to include older participants with comorbidities in research and assess cognition in everyday tasks. One of the advantages of the PRPP intervention is its usefulness for any difficulties with information processing across practice settings, diagnoses and ages[31].

There are limitations that should be considered when interpreting the data and planning for a full trial. The procedural checklist is acceptable to follow if the key functions in the procedure are clearly understood and no unforeseen events occur. Unclearly communicated procedures resulted in missing data for inter-rater agreement for Birger and Carl for some of the phases. Measuring inter-rater agreement reminds us of its role in minimizing reactivity and observational bias and plays a role in internal validity[41]. As long as the postintervention

and follow-up phases include a blinded inter-rater assessor and show increasing improvements, we can assume that the measures in the intervention phase do not err in the direction of false positives.

Unclear communicated procedures also led to the postintervention measurement for Carl being collected first after 27 interventions. Incomplete implementation of the research plan is a threat to validity [42]. For Carl's prolonged intervention phase, the limitation did not affect the immediate change in task performance and cognitive strategy application between baseline and the intervention phase, as shown in the visual graph. The results in the postintervention and follow-up phases have a clear bias compared to those of other participants in the sample, but in a practice setting, the improvements will be valuable. Nevertheless, the procedural checklist was followed at least 80% of the time, which indicates high fidelity for all the participants [21].

A second limitation is the choice of using five tasks. Although the immediate visual effects across the five tasks are clear, the choice minimized the opportunity to apply the most recognized analysis methods. Analysis of stability, overlap and consistency, and trend lines in the various phases from the widely used systematic inspection analysis from Lane and Gast [39] or statistical analysis methods are therefore not applicable. Even if all tasks are a part of, e.g., morning routines, they demand different cognitive strategy applications and functions. The decision to measuring five tasks once each instead of the same task five times was to make data collection unobtrusive for the participant and keep the procedures close to ordinary practice, but this decision led to important bias in the analysis process. It is possible that OTs can strive to use at least three, but optimally five[43], measurement points in each phase for the same task without much extra effort or burden on the participants. This can be held close to a real-world context, when the chosen task can be performed naturally more than once during the day, such as using a cell phone or put on shoes. Nevertheless, it is important that the participant is guided to choose a task that is needed or desired.

The procedures secured the systematic delivery of the PRPP intervention. As trained PRPP therapists, the OTs have a manual to follow but must react with flexibility regarding what each situation requires. Our judgement is that comparing or predeciding a treatment adherence checklist as recommended in RoBiNT [24] is complicated because of the

contextualized nature of the intervention. The intervention plan is based on the assessment, and the plan is a dynamic process in which the initiative of the OT fades when the client internalizes the strategies.

CONCLUSION

This pilot shows that the planned procedures for the PRPP intervention study are acceptable and practically feasible for community OTs and older clients with decreased mastery of everyday tasks due to cognitive challenges after ABI. This pilot study also reveals important issues requiring modification of the research procedure for future studies. It is important to communicate the research procedure steps clearly to the data-collecting OTs to minimize the risk of bias. One substantial change was made to enable the application of established systematic visual inspection and statistical analysis methods: attempting to include at least three and preferably five measurement points in each phase of the same task. The outcome measures are both manageable and sensitive to changes, and the effectiveness of the PRPP intervention appears promising for continuing data collection with the suggested modification.

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Data sharing statement: The research data can be shared upon reasonable request, and the data shared in open publications are free to use; however, they should be used with caution and with qualitative information following the statistics in mind.

Ethics statement: Approved by the Norwegian Regional Ethics Committee, project number 215391. Patient consent for publication.

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FIGURES

Figure 1: The Perceive, Recall, Plan and Perform System of Task Analysis, the four quadrants Perceive, Recall, Plan and Perform, the 12 sub quadrants, and the outer circle with observable descriptors[35].

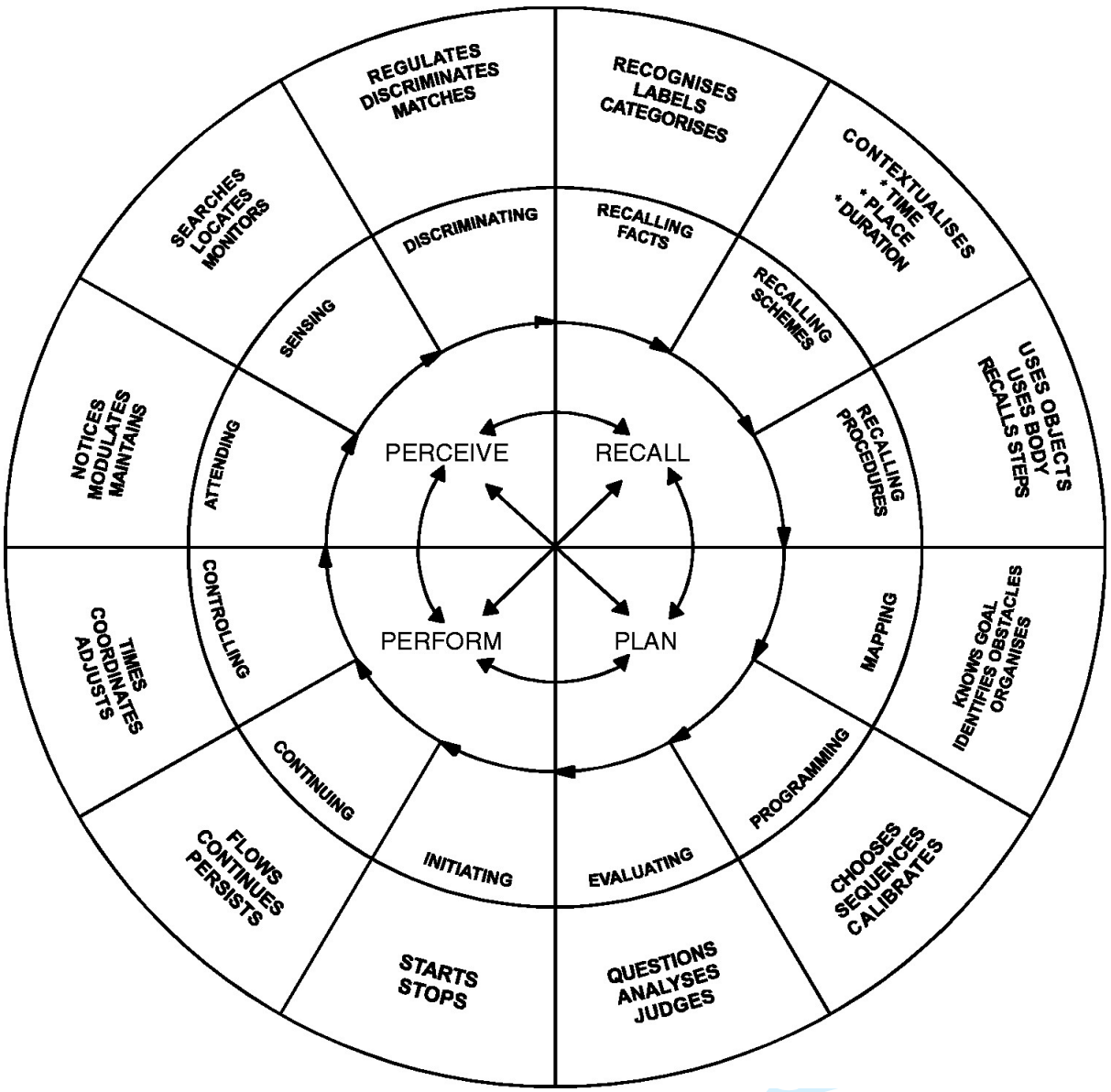
Fig. 2: Primary outcome: Percent task mastery of each of the five tasks presented as dots of different shapes in a fixed order. The blue vertical line through all three graphs illustrates the staggered baseline phases. The horizontal red lines illustrate the mean value, and the reference line is 85%, indicating independence. The numbers on the x-axis indicate sessions.

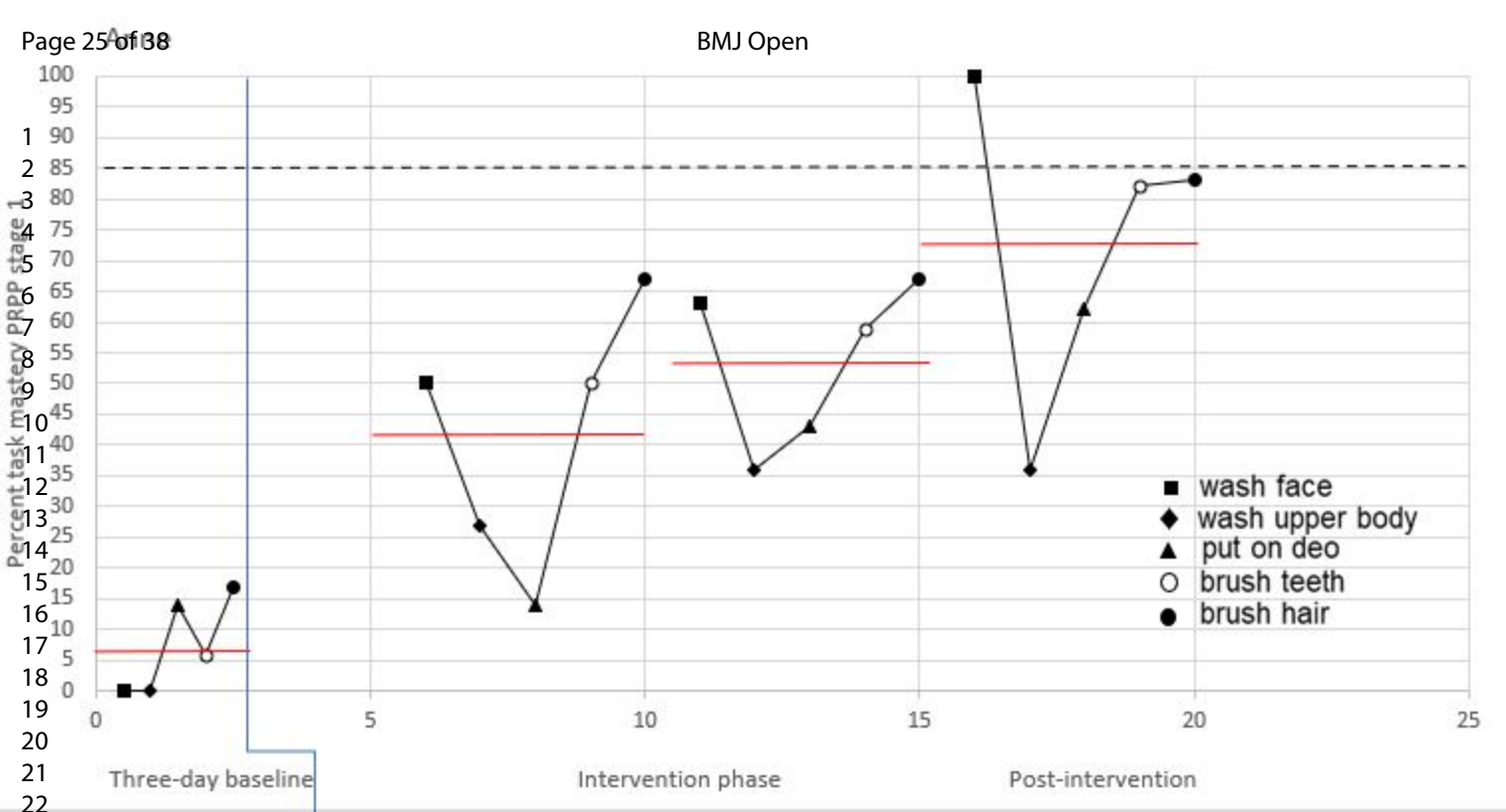
Fig. 3: Secondary outcome: Cognitive strategy application measured as the mean scores for the five target tasks.

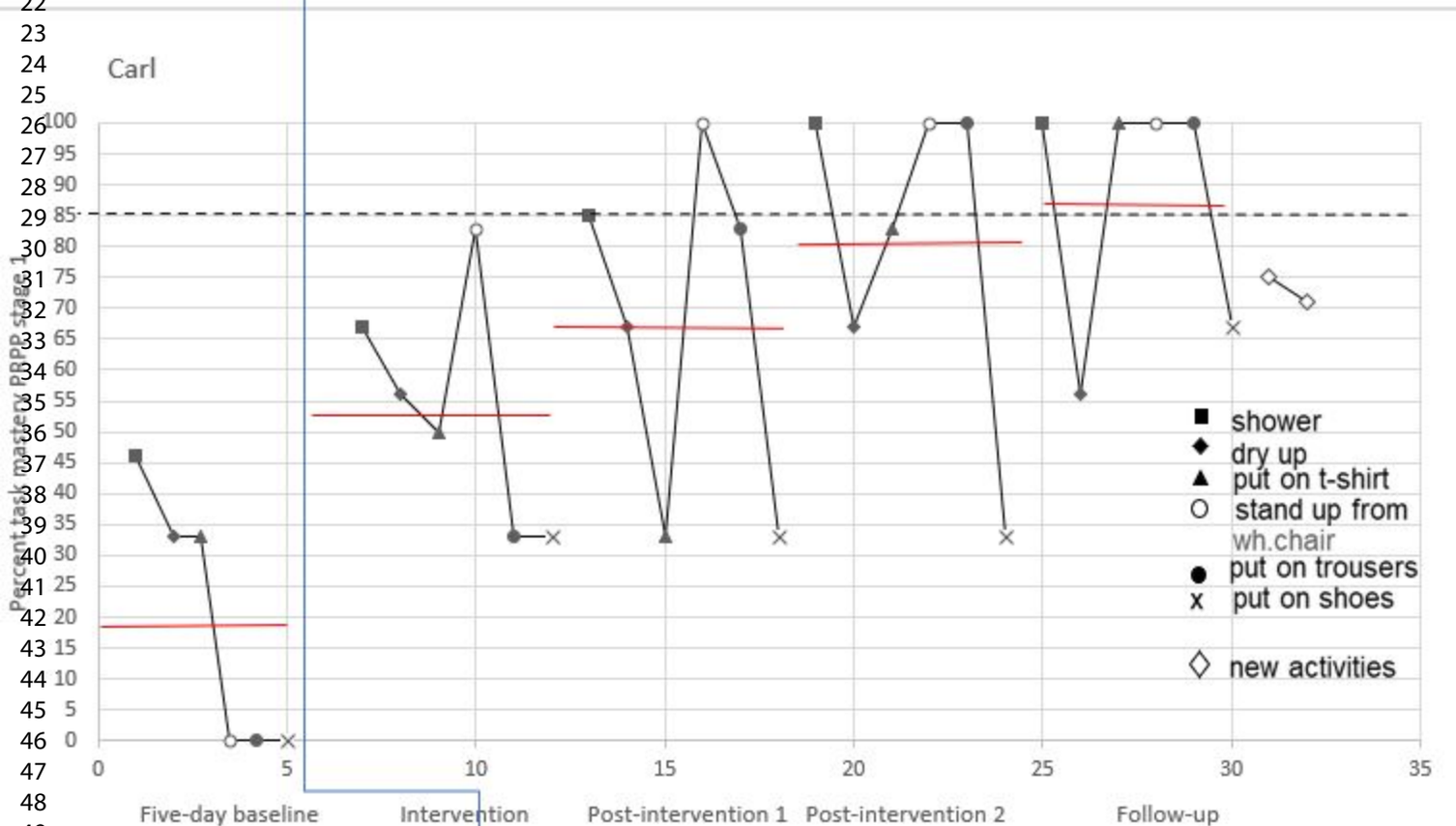
SUPPLEMENTARY MATERIAL

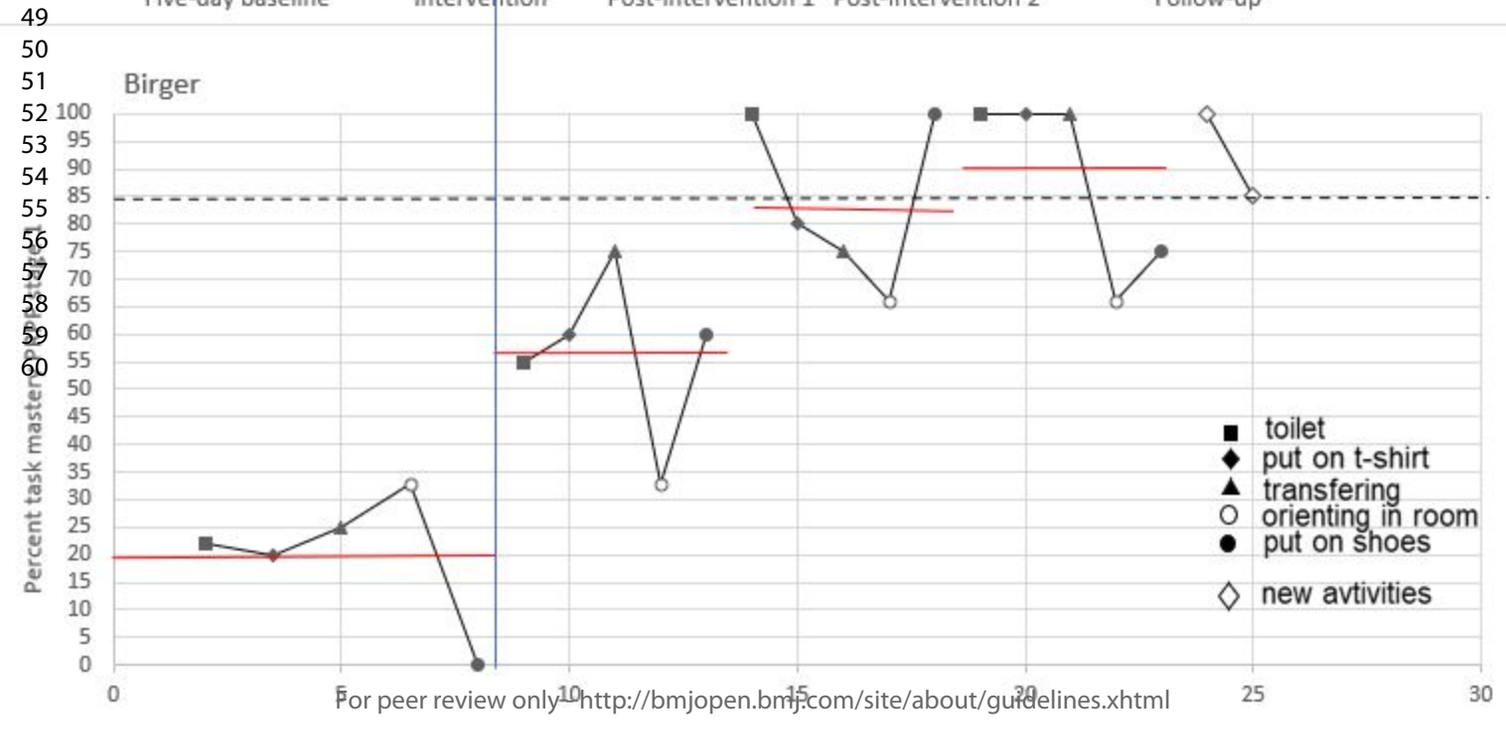
Procedural checklist

Chapparo C and Ranka J (2014) The perceive, recall, plan & perform system assessment course manual (Available from authors: jranka@bigpond.net.au).




Percent task mastery PRPP stage 1
wash face
wash upper body
put on deo
brush teeth
brush hair
Three-day baseline
Intervention phase
Post-intervention


Carl
Percent task mastery PRPP stage 1
shower
dry up
put on t-shirt
stand up from wh.chair
put on trousers
put on shoes
new activities
Five-day baseline
Intervention
Post-intervention 1
Post-intervention 2
Follow-up


Birger
Percent task mastery PRPP stage 1
toilet
put on t-shirt
transfering
orienting in room
put on shoes
new avtivities
8-day baseline
Intervention phase
Post-intervention
Follow-up

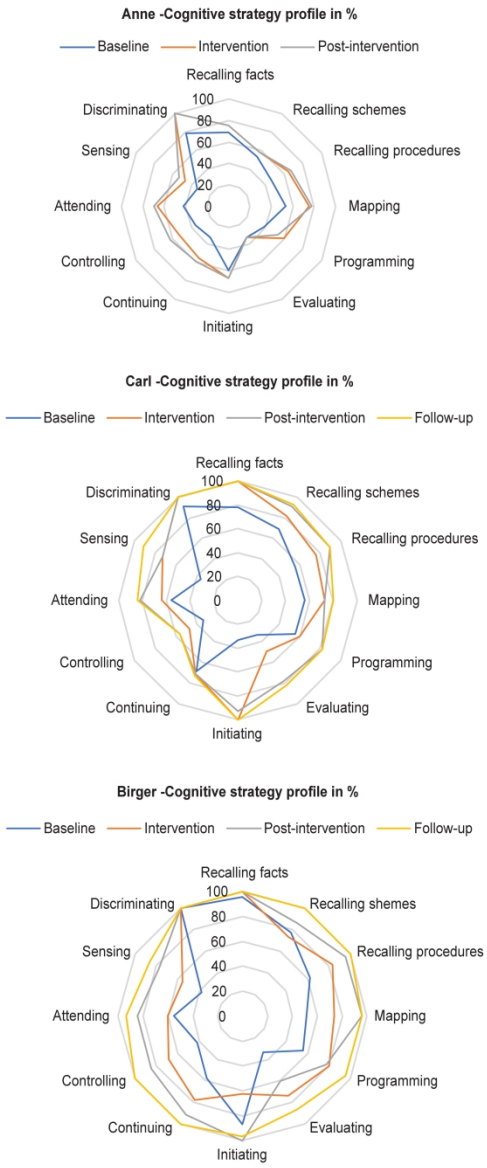


Fig. 3: Secondary outcome: Cognitive strategy application measured as the mean scores for the five target tasks.

82x197mm (600 x 600 DPI)

Participant: Pilot Anne

Procedural fidelity checklist: A step-by-step checklist is made for the therapists to follow, and they tick off when completed. High fidelity is suggested by at least 80% agreement to the procedural checklist (Tate & Perdices, 2019).

(number of agreements) X 100
(number of agreements)+(number of disagreements)
Formula p.200 Tate&Perdices, 2019

Completed	Number	Item	Comment
Consent and enrolment			
X	1	Inform and ask to participate, oral or written consent	
X	2	Ask participant about video recording	
X	3	Inform team about not giving PRPP-like intervention	
X	4	Allocate participant to baseline phase 3, 5 or 7 days	
Comment:			
Baseline phase			
X	5	PRPP Assessment stage 1	
X	6	PRPP Assessment stage 1	
X	7	PRPP Assessment stage 1	
X	8	PRPP Assessment stage 1	
X	9	PRPP Assessment stage 1	
X	10	PRPP Assessment stage 1 video rec./another assessor	
X	11	PRPP Assessment stage 2	
X	12	PRPP Assessment stage 2	
X	13	PRPP Assessment stage 2	
X	14	PRPP Assessment stage 2	
X	15	PRPP Assessment stage 2	
X	16	PRPP Assessment stage 2 video rec./another assessor	
X	17	Barthel Index	
X	18	GAS	
Comment: No video recording because of intimate situations, but another assessor not blinded assessed at least 20%.			
Intervention phase			
X	19	Intervention plan written	
X	20	PRPP Intervention 45-60 min	
X	21	PRPP Intervention 45-60 min	
X	22	PRPP Intervention 45-60 min	
X	23	PRPP Intervention 45-60 min	
X	24	PRPP Intervention 45-60 min	
X	25	PRPP Intervention 45-60 min	
X	26	PRPP Intervention 45-60 min	
X	27	PRPP Intervention 45-60 min	
X	28	PRPP Intervention 45-60 min	
X	29	PRPP Assessment stage 1	
X	30	PRPP Assessment stage 1	
X	31	PRPP Assessment stage 1	
X	32	PRPP Assessment stage 1	
X	33	PRPP Assessment stage 1	
X	34	PRPP Assessment stage 1 video rec./another assessor	
X	35	PRPP Assessment stage 2	
X	36	PRPP Assessment stage 2	
X	37	PRPP Assessment stage 2	
X	38	PRPP Assessment stage 2	
X	39	PRPP Assessment stage 2	
X	40	PRPP Assessment stage 2 video rec./another assessor	
Comment: Had 10 sessions of PRPP intervention. No video recording because of intimate situations, but another assessor not blinded assessed at least 20%.			

Post-intervention phase			
(X)	41	PRPP Assessment stage 1	
(X)	42	PRPP Assessment stage 1	
(X)	43	PRPP Assessment stage 1	
(X)	44	PRPP Assessment stage 1	
(X)	45	PRPP Assessment stage 1	
	46	PRPP Assessment stage 1 video rec./another assessor	
	47	PRPP Assessment stage 2	
	48	PRPP Assessment stage 2	
	49	PRPP Assessment stage 2	
	50	PRPP Assessment stage 2	
	51	PRPP Assessment stage 2	
	52	PRPP Assessment stage 2 video rec./another assessor	
(X)	53	Barthel Index	*
X	54	GAS	
Comment: Post-intervention after 14 days delays due to hospital-stay with lung-emboli and poor general conditions. Participant had then had 14 days lying in bed. The week after starting up again, there were sick leave among the OTs resulting post-intervention PRPP stage 1 was assessed, but stage 2 data was forgotten. When OT came back from sick leave, the participant was transferred to specialist rehabilitation. *Barthel Index was then scored after participant left, after observations done before participant left.			
Follow-up phase			
	55	PRPP Assessment stage 1	
	56	PRPP Assessment stage 1	
	57	PRPP Assessment stage 1	
	58	PRPP Assessment stage 1	
	59	PRPP Assessment stage 1 (video/2.assessor?)	
	60	PRPP Assessment stage 1 video rec./another assessor	
	61	New task PRPP Assessment stage 1 (video/2.assessor?)	
	62	New task PRPP Assessment stage 1	
	63	PRPP Assessment stage 2	
	64	PRPP Assessment stage 2	
	65	PRPP Assessment stage 2	
	66	PRPP Assessment stage 2	
	67	PRPP Assessment stage 2 (video/2.assessor?)	
	68	PRPP Assessment stage 2 video rec./another assessor	
	69	New task PRPP Assessment stage 2 (video/2.assessor?)	
	70	New task PRPP Assessment stage 2	
	71	Barthel Index	
	72	GAS	
Comment: Lost to follow-up due to several infections and hospital transfers.			
Other			
X	73	Demographic data	
X	74	Note about PRPP-intervention given by others	
X	75	Document about treatment as usual	
X	76	Document - influence on data collection or results	

Step-by-step checklist: 76 items 80% of 76 items= 60,8. 18 not completed, 56 completed, disagreements: 20 Without the follow-up phase: : 37 of 44 agreement	56x100=5600/56+20 = 73,68% 37x100=3700/37+7 = 84,09	74% 84%

Participant: Pilot Birger

Procedural fidelity checklist: A step-by-step checklist is made for the therapists to follow, and they tick off when completed. High fidelity is suggested by at least 80% agreement to the procedural checklist (Tate & Perdices, 2019).

(number of agreements) X 100
(number of agreements)+(number of disagreements)
Formula p.200 Tate&Perdices, 2019

Completed	Number	Item	Comment
Consent and enrolment			
X	1	Inform and ask to participate, oral or written consent	
X	2	Ask participant about video recording	
X	3	Inform team about not giving PRPP-like intervention	
X	4	Allocate participant to baseline phase 3, 5 or 7 days	7 (8) days
Comment:			
Baseline phase			
X	5	PRPP Assessment stage 1	
X	6	PRPP Assessment stage 1	
X	7	PRPP Assessment stage 1	
X	8	PRPP Assessment stage 1	
X	9	PRPP Assessment stage 1	Another assessor
	10	PRPP Assessment stage 1 video rec./another assessor	
X	11	PRPP Assessment stage 2	
X	12	PRPP Assessment stage 2	
X	13	PRPP Assessment stage 2	
X	14	PRPP Assessment stage 2	
X	15	PRPP Assessment stage 2	Another assessor
	16	PRPP Assessment stage 2 video rec./another assessor	
X	17	Barthel Index	
X	18	GAS	
Comment: No video recording, but another assessor not blinded assessed at one task – but the conducting OT did not assess the same task.			
Intervention phase			
X	19	Intervention plan written	
X	20	PRPP Intervention 45-60 min	
X	21	PRPP Intervention 45-60 min	
X	22	PRPP Intervention 45-60 min	
X	23	PRPP Intervention 45-60 min	
X	24	PRPP Intervention 45-60 min	
X	25	PRPP Intervention 45-60 min	
X	26	PRPP Intervention 45-60 min	
	27	PRPP Intervention 45-60 min	*
	28	PRPP Intervention 45-60 min	*
X	29	PRPP Assessment stage 1	
X	30	PRPP Assessment stage 1	
X	31	PRPP Assessment stage 1	
X	32	PRPP Assessment stage 1	
	33	PRPP Assessment stage 1	Another assessor
X	34	PRPP Assessment stage 1 video rec./another assessor	
X	35	PRPP Assessment stage 2	
X	36	PRPP Assessment stage 2	
X	37	PRPP Assessment stage 2	
X	38	PRPP Assessment stage 2	
	39	PRPP Assessment stage 2	Another assessor
X	40	PRPP Assessment stage 2 video rec./another assessor	

Comment: *The last week of the stay he missed 2 sessions of intervention. Had 7 sessions and not 9 of PRPP intervention, due to sick-leave and vacation for OTs. No video recording, but another assessor not blinded assessed at one task – but the conducting OT did not assess the same task. Misunderstanding.			
Post-intervention phase			
X	41	PRPP Assessment stage 1	
X	42	PRPP Assessment stage 1	
X	43	PRPP Assessment stage 1	
X	44	PRPP Assessment stage 1	
X	45	PRPP Assessment stage 1	Video
X	46	PRPP Assessment stage 1 video rec./another assessor	Blinded–independ. OT
X	47	PRPP Assessment stage 2	
X	48	PRPP Assessment stage 2	
X	49	PRPP Assessment stage 2	
X	50	PRPP Assessment stage 2	
X	51	PRPP Assessment stage 2	Video
X	52	PRPP Assessment stage 2 video rec./another assessor	
X	53	Barthel Index	
X	54	GAS	
Comment: Video recording of putting on t-shirt			
Follow-up phase			
X	55	PRPP Assessment stage 1	video
X	56	PRPP Assessment stage 1	
X	57	PRPP Assessment stage 1	
X	58	PRPP Assessment stage 1	
X	59	PRPP Assessment stage 1	Video
X	60	PRPP Assessment stage 1 video rec./another assessor	Blinded–independ. OT
X	61	New task PRPP Assessment stage 1	
X	62	New task PRPP Assessment stage 1	
X	63	PRPP Assessment stage 2	video
X	64	PRPP Assessment stage 2	
X	65	PRPP Assessment stage 2	
X	66	PRPP Assessment stage 2	
X	67	PRPP Assessment stage 2	video
X	68	PRPP Assessment stage 2 video rec./another assessor	Blinded–independ. OT
X	69	New task PRPP Assessment stage 2	
X	70	New task PRPP Assessment stage 2	
X	71	Barthel Index	
X	72	GAS	
Comment: Video recording of putting on t-shirt and shoes			
Other			
X	73	Demographic data	
X	74	Note about PRPP-intervention given by others	
X	75	Document about treatment as usual	
X	76	Document - influence on data collection or results	

Step-by-step checklist: 76 items 80% of 76 items= 60,8. 69 agreements, 7 disagreements	69x100 = 6900 6900/76 = 90,78	Overall fidelity: 91%

Participant: Pilot Carl

Procedural fidelity checklist: A step-by-step checklist is made for the therapists to follow, and they tick off when completed. High fidelity is suggested by at least 80% agreement to the procedural checklist (Tate & Perdices, 2019).

(number of agreements) X 100
(number of agreements)+(number of disagreements)
Formula p.200 Tate&Perdices, 2019

Completed	Number	Item	Comment
Consent and enrolment			
X	1	Inform and ask to participate, oral or written consent	
X	2	Ask participant about video recording	
x	3	Inform team about not giving PRPP-like intervention	
x	4	Allocate participant to baseline phase 3, 5 or 7 days	5 days
Comment:			
Baseline phase			
X	5	PRPP Assessment stage 1	
X	6	PRPP Assessment stage 1	
X	7	PRPP Assessment stage 1	
X	8	PRPP Assessment stage 1	
X	9	PRPP Assessment stage 1	Another assessor
	10	PRPP Assessment stage 1 video rec./another assessor	
X	11	PRPP Assessment stage 2	
X	12	PRPP Assessment stage 2	
X	13	PRPP Assessment stage 2	
X	14	PRPP Assessment stage 2	
X	15	PRPP Assessment stage 2	
	16	PRPP Assessment stage 1 video rec./another assessor	
X	17	Barthel Index	
X	18	GAS	
Comment: Misunderstanding that another assessor alone should do the assessment. Also had 6 different activities because participant at one point rejected the planned task, but later was ok with it. Participants allow video recording at consent form but reject it in the situation.			
Intervention phase			
x	19	Intervention plan written	
X	20	PRPP Intervention 45-60 min	
X	21	PRPP Intervention 45-60 min	
X	22	PRPP Intervention 45-60 min	
X	23	PRPP Intervention 45-60 min	
X	24	PRPP Intervention 45-60 min	
X	25	PRPP Intervention 45-60 min	
X	26	PRPP Intervention 45-60 min	
X	27	PRPP Intervention 45-60 min	
X	28	PRPP Intervention 45-60 min	
X	29	PRPP Assessment stage 1	
X	30	PRPP Assessment stage 1	
X	31	PRPP Assessment stage 1	
X	32	PRPP Assessment stage 1	
X	33	PRPP Assessment stage 1	
	34	PRPP Assessment stage 1 video rec./another assessor	
X	35	PRPP Assessment stage 2	
X	36	PRPP Assessment stage 2	
X	37	PRPP Assessment stage 2	
X	38	PRPP Assessment stage 2	
X	39	PRPP Assessment stage 2	
	40	PRPP Assessment stage 1 video rec./another assessor	

Comment: Participant Carl had 30 interventions, 27 of them before the first post-intervention. Unclear how this disagreement should be noted in this checklist.			
Post-intervention phase			
X	41	PRPP Assessment stage 1	
X	42	PRPP Assessment stage 1	
X	43	PRPP Assessment stage 1	
X	44	PRPP Assessment stage 1	
X	45	PRPP Assessment stage 1	
	46	PRPP Assessment stage 1 video rec./another assessor	
X	47	PRPP Assessment stage 2	
X	48	PRPP Assessment stage 2	
X	49	PRPP Assessment stage 2	
X	50	PRPP Assessment stage 2	
X	51	PRPP Assessment stage 2	
	52	PRPP Assessment stage 1 video rec./another assessor	
X	53	Barthel Index	
X	54	GAS	
Comment: Participant Carl had two post-intervention-phases. This was because the OT had understood the post-intervention was the two last days of the stay, and not after 9 interventions. As this was cleared, they assessed as soon as possible and a 2-3 weeks later he was discharged and then they assessed post-intervention once more to get a correct baseline for the follow-up phase.			
Follow-up phase			
X	55	PRPP Assessment stage 1	
X	56	PRPP Assessment stage 1	
X	57	PRPP Assessment stage 1	
X	58	PRPP Assessment stage 1	
X	59	PRPP Assessment stage 1	
	60	PRPP Assessment stage 1 video rec./another assessor	
X	61	New task PRPP Assessment stage 1	Video
X	62	New task PRPP Assessment stage 1	Video
X	63	PRPP Assessment stage 2	
X	64	PRPP Assessment stage 2	
X	65	PRPP Assessment stage 2	
X	66	PRPP Assessment stage 2	
x	67	PRPP Assessment stage 2	
	68	PRPP Assessment stage 1 video rec./another assessor	
x	69	New task PRPP Assessment stage 2	video
X	70	New task PRPP Assessment stage 2	video
X	71	Barthel Index	
X	72	GAS	
Comment: Have video recording of putting of organizing breakfast and finding a glass of water and bring it to living room. That means we have possibility for at least 20% IRR in this phase, even not the planned task			
Other			
X	73	Demographic data	
X	74	Note about PRPP-intervention given by others	
X	75	Document about treatment as usual	
X	76	Document - influence on data collection or results	

Step-by-step checklist: 76 items 80% of 76 items= 60,8. 68 agreements, 8 disagreements	68x100=6800/76= 89,4%	89%* *way too many intervention sessions not showing in this checklist

NTNU
Norwegian University of Science and Technology

REQUEST TO PARTICIPATE IN THE RESEARCH PROJECT 'OCCUPATIONAL THERAPY FOR BRAIN INJURIES IN COMMUNITY-BASED HEALTH SERVICES'

This is a request for you to participate in a research project to evaluate the usefulness of PRPP (Perceive, Recall, Plan and Perform), which is a type of occupational therapy intervention. You are being asked based on your admission to health services in the municipality and because you have had a brain injury.

WHAT DOES THE PROJECT MEAN TO YOU PERSONALLY?

Ordinary practice:

- The occupational therapist observes you in everyday activities using the PRPP System
- You receive intervention from the method belonging to the PRPP System

Out of the ordinary practice as a result of the project:

- A second occupational therapist performs some of the observations. If this is not possible in the rehabilitation department, we will ask you if we can record a video so that Linda Stigen (the project manager) can make the observation. You can decline this.
- Observation of the activities will be repeated during the interventions, before discharge and 4 weeks after discharge from the rehabilitation unit. This is to evaluate changes in the measures that can be caused by the intervention.
- Two additional assessments will be scored, one that measures independence in daily activities and one that evaluates the goals set for the everyday activities observed. This will be the same as regular assessment and rehabilitation, while evaluation before discharge and after 4 weeks will be an extra follow-up, calculated to be 2x1 hours.

General information about you:

The occupational therapist informed the researchers of your age, telephone number, marital status, education, (previous) work, diagnoses and time since the injury, either from the patient record or by direct questions to you.

BENEFITS AND DISADVANTAGES

The advantage of participating will be that you are followed up in an extra systematic and structured way, that the initiated measures are carefully evaluated and with follow-up visits after 4 weeks. The disadvantage will be that one of the interventions from the occupational therapist can be initiated a few days later than usual and that the examinations will take some extra time beyond normal treatment time. All other follow-ups from the interdisciplinary team and the occupational therapist will be provided as usual.

VOLUNTARY PARTICIPATION AND THE OPPORTUNITY TO WITHDRAW CONSENT

Participation in the project is voluntary. You can withdraw your consent at any time and without giving any reason. This will not have consequences on your further rehabilitation.

If you withdraw from the project, you can demand that the collected information be deleted, unless the information has already been included in analyses or used in scientific publications.

WHAT HAPPENS TO THE INFORMATION ABOUT YOU?

The information registered about you will only be used as described and is planned to be used until 2029. Any extensions of the project and storage time can only take place after approval from REK and other relevant authorities. You have the right to access the information that is registered about you and the right to have any errors in the information corrected. You have the right to access the security procedures when processing the information.

All information will be handled without name and birth date or other directly recognizable information. A code links your name to the information about you. Only project manager Linda Stigen and Marte Ørud Lindstad have access to this code list.

The information about you will be kept for 5 years after the end of the project for control reasons.

FOLLOW-UP PROJECTS

It may be relevant to contact you later for an interview or if another occupational therapist/student asks for the opportunity to participate in the observations. This is completely voluntary and can be answered with yes or no if it becomes relevant.

For training purposes for occupational therapists/students, we would appreciate permission to record a video of patients with stroke or other types of brain injury when performing everyday activities. If you allow us to record a video, your face will be visible, but no name will be linked to the video. Of course, this is also completely voluntary, and you have the same opportunity to withdraw consent as described above.

APPROVAL

The Regional Committee for Medical and Health Research Ethics has evaluated the project and has given prior approval with reference number 215391.

According to the new Personal Data Act, the Department of Health Sciences Gjøvik and NTNU, under the Head of department Heidi Vifladt and the Project manager Linda Stigen, have an independent responsibility to ensure that the processing of your information has a legal basis. This project has a legal basis in the EU Privacy Regulation Article 6 (1a) and Article 9 (2a) and your consent.

You have the right to complain about the processing of your information to the Norwegian Data Protection Authority.

CONTACT INFORMATION

If you want to withdraw or have questions about the project, you can contact Marte Ørud Lindstad, 99 592 692, marte.lindstad@ntnu.no or Project Manager Linda Stigen, 932 23 019, linda.stingen@ntnu.no.

Data protection manager at NTNU: thomas.helgesen@ntnu.no

I AGREE TO PARTICIPATE IN THE PROJECT AND THAT MY PERSONAL DATA CAN BE USED AS DESCRIBED

Yes No

☐ ☐ I accept to be contacted for other projects.
I can still decline by a later direct request.

☐ ☐ I accept video recording of some daily activities for educational purposes.
I can still decline by a later direct request.

Place and date

The participants' signature

The participants' name in capitalized letter

I confirm I have given the following information:

Place and date

Signature

Role in the project

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	2,3
	2b	Specific objectives or research questions for pilot trial	3,4
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	3,4,6
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	18,19
Participants	4a	Eligibility criteria for participants	4,5
	4b	Settings and locations where the data were collected	4,5
	4c	How participants were identified and consented	4,5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7,12,13 + protocol
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8,9,13
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	18,19
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	4
Sample size	7a	Rationale for numbers in the pilot trial	4
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	11-13
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	11
	14b	Why the pilot trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	6,12
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	N/A
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	N/A
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	14,15
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	14,15
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	15-17
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	15-17
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	15-17
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	15-17
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	1
Protocol	24	Where the pilot trial protocol can be accessed, if available	4
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	ScolarOne
	26	Ethical approval or approval by research review committee, confirmed with reference number	10

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.