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PERSPECTIVES IN REHABILITATION

Process evaluation of a complex intervention evaluating the effectiveness of home-based rehabilitation in the chronic phase of traumatic brain injury

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ABSTRACT

Purpose: To perform a process evaluation of a randomized controlled trial (RCT) evaluating a manualized intervention aiming to ameliorate long-term symptoms of traumatic brain injury (TBI) by assessing implementation fidelity, delivery context and acceptability of the intervention.

Methods: Data from 60 participants were collected during recruitment, intervention delivery and outcome data collection in the RCT. Enrollment records, logs and checklists documented the delivery of the intervention (implementation fidelity) and the collaboration with family members and outside collaborators (delivery context). Attendance-rate, self-reported acceptability and willingness to participate in future studies were used to assess the acceptability of the intervention.

Results: The main elements and dose of the intervention were delivered as intended with an excellent adherence to the manual items. Family members co-participated in the intervention for 39 (65%) of the participants. Outside collaborators were contacted for 32 (53%) of the participants. Acceptability scores were high for participants, family members and therapists.

Conclusions: The intervention was successfully delivered with high acceptability. This process evaluation informs researchers, clinicians and stakeholders about important factors influencing the outcomes of the intervention that should be considered in clinical implementation of rehabilitation interventions.

Trial Registration: Pre-registered 4th of June 2018 at clinicaltrials.gov (NCT03545594).

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Process evaluation; traumatic brain injury; goal-oriented rehabilitation; community-based rehabilitation

Introduction

Rehabilitation interventions are typically considered complex interventions, as they usually have several interacting intervention components, and these components interact with the study context during intervention delivery [1, 2]. Although randomized controlled trials (RCTs) have been considered the gold standard for evaluating the effects of interventions, it has been argued that strict RCT designs tend to not capture complex causal relationships, i.e., that the joint influence of aspects of the participants, implementers and the context might be ignored [1]. Furthermore, it's important to evaluate whether an intervention has been delivered as intended [1, 3]. According to the British Medical Research Council (MRC) guidance on process evaluations of complex trials, investigation of fidelity is necessary to allow conclusions about intervention effectiveness [1, 2, 4]. Implementation fidelity refers to the degree to which the intervention is consistently delivered according to protocol [2, 3], while the term process evaluation encompasses a broader evaluation of trial delivery [3–6]. To conduct the current process evaluation, we were inspired by the MRC framework [3, 6]. This framework identifies key functions of process evaluation and relations among them, and the following was used in this study [3]: Implementation (what was delivered and how), context (how external factors influenced the intervention) and acceptability of the intervention (whether participants, family members and therapists were satisfied with the intervention).

Our research group has conducted an RCT in South-Eastern Norway which evaluated an intervention aiming to ameliorate long-term consequences of traumatic brain injury (TBI). The protocol has been published as recommended [7], and a feasibility trial was conducted before the RCT [8]. The intervention was a home-based, goal-oriented, and individualized rehabilitation program that aimed to improve health-related quality of life, participation, TBI-related difficulties, and physical and mental health. The intervention was manualized and designed to ameliorate the specific difficulties most important to each individual to address unmet needs as reported in the chronic phase of TBI [7, 9, 10]. The patient's self-nominated TBI-related problems were the main targets of the intervention (see Figure 1). The study was adapted from a study by Winter and colleagues [11] which was conducted on veterans with TBI in the United States (US). The goal-setting procedures have been evaluated previously [12], as has the effect of the intervention [13]. The effect evaluation showed that the

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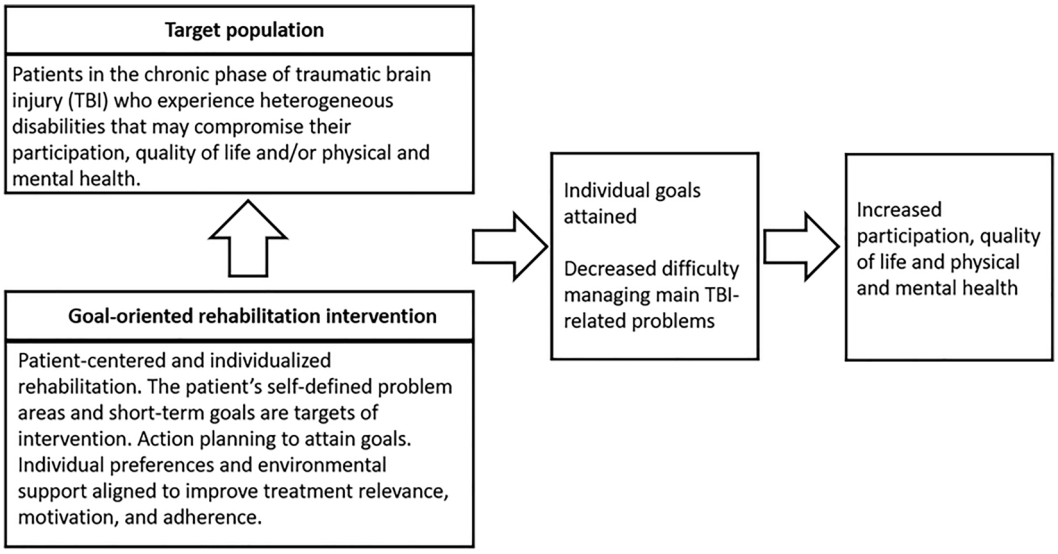

Figure 1. Assumed *causal* mechanisms of the intervention.

intervention group reported significantly fewer TBI- and anxiety-related symptoms, as well as higher health-related quality of life at 1-year follow-up compared to the control group. However, there is also a need to evaluate implementation fidelity of this intervention to enhance confidence in the outcomes of the RCT [14].

In the updated version of the framework for complex interventions [4, 5], it has been highlighted that factors related to the trial context and mechanisms of impact should be investigated as part of the process evaluation. Evaluating the context of delivery is particularly important in this trial, as it sought to bring rehabilitation closer to the participants' everyday lives and to provide rehabilitation in the chronic phase in collaboration with municipal services and family members. In the study by Winter and colleagues [11], all participants had a participating family member. However, results from our feasibility trial suggested that family member participation should be made optional as there were several participants in need of rehabilitation who had no available family members, and we amended the inclusion criteria accordingly [8]. Hence, it is important to evaluate to what degree the intervention was suitable for delivery to individuals both with and without participating family members. Further, co-operation with municipal services was thought to be important to facilitate long-term care for the participants, which was described in the protocol paper [7]. During the intervention, any person or service involved in the participant's daily life (e.g., municipal, or specialized health care workers, employers and the labor and welfare administration, i.e., "outside collaborators") could be invited as collaborators if available and deemed appropriate by participants and therapists. It was therefore relevant to evaluate to what degree such collaboration was established. Lastly, goal-oriented rehabilitation is thought to increase the patient-centeredness and satisfaction [15]. This intervention aimed at increasing relevance, motivation, adherence and satisfaction by highlighting individual preferences and collaborative goal-setting. Participant responses to the intervention, i.e., the intervention acceptability was thus important to establish, not the least because acceptability data might inform further refinement of the intervention [4].

The overall aim of this study was to conduct a process evaluation of the complex goal-oriented intervention, operationalized in the following specific aims:

1. Evaluate to what extent the intervention was delivered according to the study protocol and intervention manual (implementation fidelity).
2. Evaluate to what extent therapists collaborated with family members and outside collaborators during the intervention.
3. Evaluate whether the intervention was acceptable as evaluated by participants, family members and therapists.

Materials and methods

Study design

This process evaluation was conducted in the context of the RCT, see the study protocol and the effect evaluation for details [7, 13]. Longitudinal quantitative process evaluation data were collected during recruitment, intervention delivery and outcome assessments.

Participants

Participants were individuals included in the intervention arm of the RCT ($n = 60$). They were recruited from study registers and hospital records which cover all TBI patients admitted to Oslo University Hospital (OUH) the past 10 years. The recruitment started in June 2018 and was finalized in December 2020. The eligibility criteria for the RCT were 18–72 years of age, TBI diagnosis with CT/MRI-verified intracranial abnormalities, at least 2 years post-injury, living at home with ongoing TBI-related cognitive, emotional and/or physical problems and/or reduced physical and mental health, and/or difficulties with participation in activities with family, friends, and in the community. Participants had to be able to participate in the goal-setting process, be sufficiently fluent in Norwegian and capable of providing informed consent. If recruited during the Covid-19 pandemic, they had to have sufficient technical skill to use a computer to receive videoconferences. Family members or friends were included if the participant had a close relationship with the person concerned and wanted the person to be involved in the study. Individuals

Table 1. Demographic and injury-related characteristics of participants, $n = 60$.

Characteristics		mean(SD)/ median(range)/n(%)
Age in years, mean (SD)		42.7 (13.9)
Gender, male, n (%)		44 (73%)
Education years, median (range)		12 (10–20)
Marital status, n (%)	Single, widowed or divorced	28 (47%)
	Married/domestic partner	32 (53%)
Injury severity (GCS), median (range)		8 (3–15)
	Mild complicated	16 (27%)
	Moderate	10 (17%)
	Severe	30 (50%)
	NA	4 (6%)
Time since injury*, y, median (range)		4 (2–23)
Work status, n (%)	Works full-time	17 (28%)
	Works part-time	13 (22%)
	Disability/sick leave/ retired	30 (50%)
Concurrent rehabilitation, n (%)	No	33 (55%)
	Yes	27 (45%)
	Physiotherapist	10 (37%)
	Psychologist	4 (15%)
	Nurse	3 (11%)
	Other professions	4 (15%)
	Multi professional	6 (22%)

*$n = 59$. GCS = Glasgow Coma Scale, NA = not available, SD = standard deviation.

with severe progressive neurologic or psychiatric disorders, active substance use disorder or violent tendencies were not eligible. Demographic and injury-related characteristics of the intervention group participants are presented in Table 1.

Intervention

The intervention consisted of eight sessions. Originally, six sessions were delivered in-home and two by phone. Participants could also receive sessions at the outpatient clinic of OUH if preferable. Due to the Covid-19 pandemic, videoconferences or phone calls replaced many home visits for participants recruited during periods of social distancing.

Goal-oriented rehabilitation has been proposed to theoretically involve a motivational phase and an action phase (action planning, feedback and evaluation of barriers [16]. In accordance with this framework, the intervention had three core components: 1) identification of main problem areas related to the TBI as experienced by participants and family members, 2) setting goals with a SMART goal approach [17, 18] along with Goal Attainment Scaling (GAS) [19], and 3) development of an action plan of strategies to help reach goals, based on suggestions by participants, family members and therapists. Therapists suggested strategies according to evidence-based rehabilitation for the problem area in question, and participants and family members suggested strategies based on previous experiences.

All therapists involved in intervention delivery were rehabilitation professionals with knowledge regarding evidence-based brain injury rehabilitation targeting various functional domains such as memory, anger management, or stress management. Evidence-based practice was ensured through literature reviews and by establishing shared folders with access for all therapists ("tool-box"). Two junior therapists (author MVF and IMHB; medical doctor and psychologist) and two senior therapists (authors IK and SLH; physiotherapist and neuropsychologist) were responsible for intervention delivery. Further, two senior researchers with vast clinical experience were closely involved in supervision meetings and fidelity assessments (authors CR and ML). Various strategies and measures were used to optimize fidelity to the intervention. A comprehensive intervention manual was developed. Team meetings were conducted weekly - biweekly and training of therapists delivering the intervention was done to ensure manual adherence across therapists. The four therapists were thoroughly trained during the feasibility part of this study, by close supervision and frequent meetings with senior researchers as well as pairings of junior therapists and senior therapists. For details on this training, please see Borgen et al. [8]. In addition, to help monitor and maintain treatment fidelity, several logs and checklists were developed. Therapists themselves filled out logs including manual checklists and logs on intervention dosage. Additionally, senior researchers participated in at least 10% of in-person or video sessions to provide an objective evaluation of therapists' fidelity to the manual (see Table 2).

The intervention was manualized, but session content was tailored to the individual. However, the number of sessions (eight), session length (60–150 min) and total intervention duration (four months) was fixed. Likewise, co-operation with outside collaborators was tailored to what was suitable for each participant, with the manual recommending establishing collaboration if feasible. The intervention manual included three psychoeducational topics which were presented to all participants: cognitive impairment after TBI, stress management and cognitive communication difficulties. For details, see the study protocol [7].

Data collection and data source

Process evaluation data were collected from the start of the trial in June 2018 until December 2021. Table 2 outlines the data sources for aims 1–3.

Acceptability scale

Acceptability was measured with an adapted version of the questionnaire applied by Winter et al. [11], which in their study was scored by therapists only. In the current study, the scale was translated, and adapted to the study content. Two therapist versions were applied, each containing 17 items. One version asked the therapist to rate the degree of acceptability in delivering the intervention to the participant, and the other asked about delivery to family members. The questionnaire included items related to both how the therapist experienced that the participants received intervention content (e.g., the extent to which they seemed to accept the treatment, experience benefit from the intervention, as well as their degree of active involvement), and how easy intervention delivery seemed to the therapist. Further, we established separate patient and family member versions. The patient and family member scale contained 10 items related to intervention acceptability, i.e., the extent to which they experienced being able to receive the treatment, felt it was useful, as well as their perceived involvement. When the participants filled out the acceptability scale, therapists specified that these responses would not be subject to discussion and the acceptability ratings were performed at the very end of the last intervention session to limit the therapist bias as much as possible. All acceptability scales were scored on a five-point Likert scale with higher scores

Table 2. Process evaluation components *from the MRC framework and corresponding* and data sources.

Process evaluation component	Description	Data source(s)	Description of data source(s)
Aim 1: Implementation	**What was delivered and how?**		
Fidelity	Whether intervention was delivered as planned	Manual delivery Checklist	Delivery of session components in accordance with the manual. A total score between 0 (low manual fidelity) and 45 (high manual fidelity) for all sessions was calculated. Filled out by therapists during sessions.
		Fidelity log	Delivery of main intervention components in accordance with the manual as evaluated by a senior researcher. Senior researchers participated in 10% of in-person or video sessions. A percentage of items reported as fulfilled calculated for each session (0-100, worst-best). Score >80% a priori defined as satisfactory. See online Appendix 1.
Dose	Amount of intervention delivered	Session log	Number of sessions attended, length of sessions and delivery mode. Filled out by therapist after sessions.
Reach	To what extent the target population received the intervention	Screening and recruitment data	Data providing the numbers of individuals contacted, number who declined, were excluded and included in the trial.
Adaptations	Alterations made to achieve a better contextual fit	Manual description	Description of how the manual was adapted, description of the application of video sessions (Covid-19 adaptation)
Aim 2: Context	**How external factors influenced the intervention**		
Family members	Whether family members were involved	Session log	Whether session was attended by family member. Filled out by therapists after sessions.
Outside collaborators	Whether outside collaborators were involved	Session log	Whether session was attended by outside collaborator. Filled out by therapist after sessions
		Telephone log	Any telephone contacts between sessions with participant, family member or outside collaborator. Filled out by therapist during intervention period.
		Additional support log	Additional support, i.e., any therapist-participant or therapist-family member interaction outside the eight intervention sessions, or therapist-outside collaborator contact that was not completed by phone or within intervention sessions. Filled out by the therapist during intervention period.
Aim 3: Acceptability	**Acceptability of the intervention**		
	Whether the participants, family members and therapists were satisfied with the intervention	Attendance	Number of sessions attended by each participant.
		Acceptability scale	Total acceptability reported on an acceptability scale filled out by participants, family members and therapists. See main text and online Appendix 2.
		Agreement to participate in a future study	Whether the participant would like to be contacted in the future to participate in a similar study (yes/no). Participants and family members were asked this at 1-year follow-up by a blinded assessor. Answering yes was considered as an indication of acceptability.

Table 3. Intervention dose results.

Variable	Description	Manual description	Median (range)
Duration			
Duration of full intervention	Time between first and last session	120 days	121 (91–153) days
Session length			
• Duration in-person	Length of home and hospital sessions	120–150 min*	120 (50–195) minutes
• Duration phone	Length of phone sessions	60–90 min*	60 (20–165) minutes
• Duration video	Length of video sessions	60–150 min**	90 (30–180) minutes
Frequency	Number of sessions completed	8 sessions	8 (2–8) sessions

*suggested length of sessions in the manual. **video sessions were not *a priori* part of manual, but sessions were expected to be similar as other sessions.

indicating a more positive response (ranging from 0: not at all, to 4: extremely). The sum-score ranged from 0 to 68 on the therapist versions and 0–40 on the participant and family member versions. The items in all questionnaire versions are presented in online Appendix 2 (supplementary material).

Statistical analyses

Post hoc statistical regression analyses were conducted to evaluate indicators of prolonged session length, see detailed procedures described in online Appendix 3. The association of family member collaboration on participant acceptability was analyzed using Mann Whitney U-tests.

Results

Implementation fidelity (aim 1)

Fidelity

The median score on the manual delivery checklist filled out by therapists at each session was 45 (range: 39–45). Senior researchers filled out the fidelity log in 39 of 360 in-person or video sessions, i.e., 10.8% of sessions. The fidelity log had a median score of 100% (range: 87.5%–100%). All manual checklists and fidelity logs showed >85% manual delivery, which was considered excellent adherence, indicating that the main elements of the intervention were delivered as intended.

Dose

Results regarding intervention dose are displayed in Table 3. A total of 471 sessions were delivered. The total duration of the intervention period and the length of intervention sessions were according to the manual. The manual suggested that in-home visits should be between 120 and 150 min (including informal conversation, building rapport and breaks but excluding documentation). However, experience from the feasibility trial [8] suggested that sessions >120 min might be tiresome for participants. Despite this, as many as 104 (22%) of sessions lasted

more than 120 min. Initial sessions typically lasted longer than sessions towards the end of the intervention. Further, 14 (3%) of sessions lasted more than 150 min. To investigate what factors may be related to total intervention length, *post hoc* multiple regression analyses were conducted. The analyses showed that lower employment levels, more severe injuries, poorer self-reported executive function and more anxiety, and the number of in-person sessions were related to longer session duration. The linear regression model had a R^2 of .257, F (5, 48) = 3.319, p=.012. Detailed results of the univariate regression analyses are presented in online Appendix 3.

Regarding mode of delivery, 51.8% of sessions were conducted as home visits, 27.6% of sessions were delivered by phone, 17.4% were video sessions and 3.1% were delivered at the hospital outpatient clinic. In-person meetings lasted the longest, phone sessions were shortest, and video sessions were shorter than in-person meetings.

Reach

This trial intended to include patients treated by the South-Eastern Norway Health Authority, which covers approximately 3 million people and thus, more than half of the Norwegian population [20]. Patients admitted to OUH for acute TBI treatment, and who were living in the Eastern part of South-Eastern Norway where recruited, while patients from the southern area were not assessed for eligibility due to travelling distance. The principal investigator identified potentially eligible participants by screening previous study registers and hospital records, which covers all patients admitted to OUH, from 2010 and onwards. Subsequently, 555 adult subjects with TBI and positive CT/MRI findings were contacted by phone and 120 were randomized according to study protocol. The recruitment process is depicted in the study flowchart (Figure 2).

Altogether, 140 of the contacted subjects (25%) reported no need, 153 (28%) declined, did not show up for assessment, or withdrew, 106 (19%) could not be reached, and 36 (6.5%) were excluded. The enrollment period lasted for 2 ½ years from June 2018 until December 2020. Enrollment was stopped for three months (March-May 2020) due to the Covid-19 pandemic and was delayed for shorter periods until December 2020 due to pandemic-related restrictions.

Adaptations

The intervention manual was translated and adapted to a Norwegian context by the research team. An evaluation of the planned manual adaptations from the US and veteran context has been reported previously during the feasibility stage of the trial (8). Due to the Covid-19 pandemic, societal restrictions

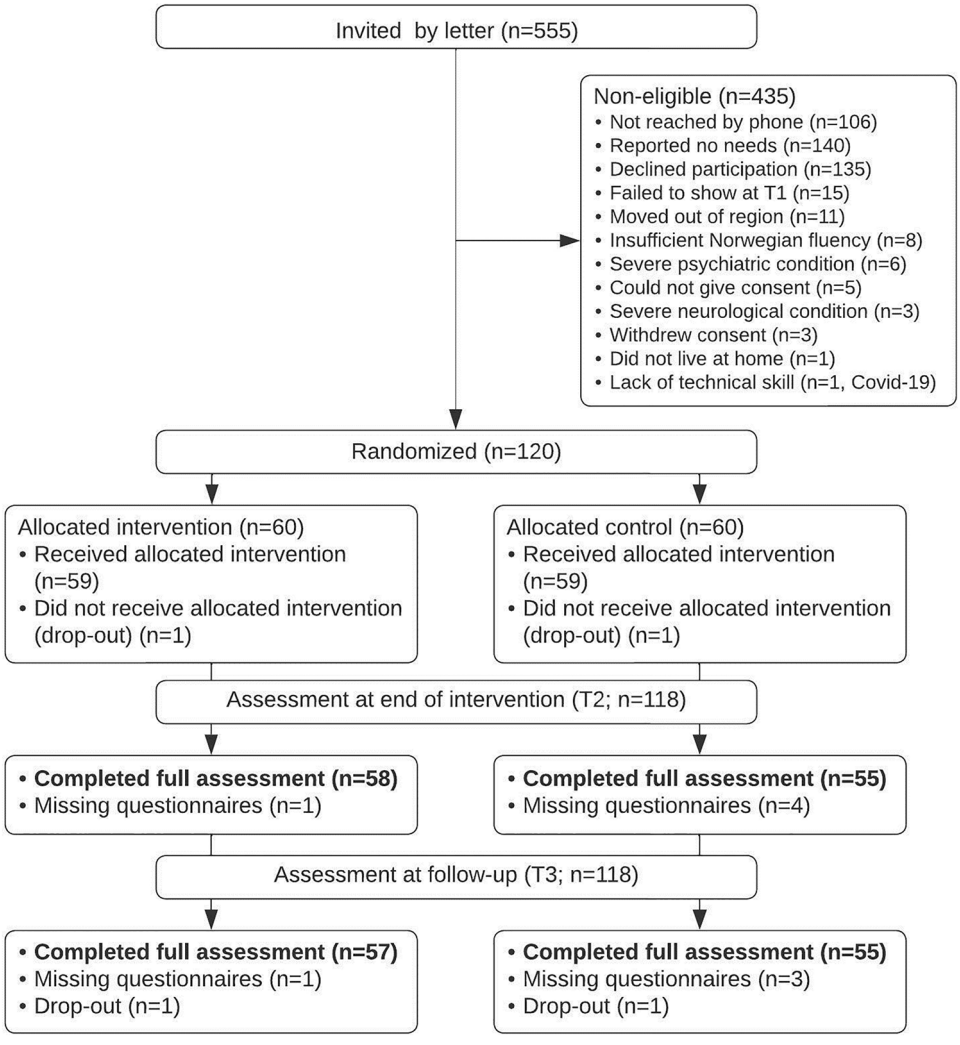

Figure 2. Study flowchart.

(lockdowns) also disrupted delivery of intended home sessions and led to unexpected Covid-related adaptations. This included practical changes related to infection prevention, affecting the conduct of baseline assessments and home visits (Covid-screening, physical distance, wearing masks and disinfection procedures), and home sessions being converted to video or phone sessions (see Methods section).

Context (aim 2)

Family member participation

As many as 60% of sessions were conducted between the participant and the therapist only. In total, 39 (65%) of the participants had family members who participated in one or more sessions. Of these, 27 (69.2%) were spouses/domestic partners, seven (17.9%) were parents and five (12.8%) were other family members. The median number of sessions completed for family members was 4 (IQR: 3–6) and for participants with a participating family member, a total of 57% of sessions included the family member.

Collaboration during intervention

Overall, the therapists initiated and established collaboration between therapists, participants and outside collaborators for 32 (53%) participants. The collaboration consisted either of outside collaborators participating in intervention sessions, phone calls made by therapist outside intervention sessions to the collaborators, or additional support (any therapist-participant or therapist-family member interaction that was given outside the eight intervention sessions, or therapist-outside collaborator contact that was not completed by phone or within intervention sessions).

Only six participants had personnel from municipal services actively participating in one or more intervention sessions. Four of these were professional assistants, one was a general practitioner and one a speech therapist.

For 23 (38%) participants, therapists were in contact with collaborators through phone calls (see Table 4), with a total of 59 phone calls being made. Eight phone calls were made to specialized health care services, 20 to municipal health care services, 17 were work-related, and 11 phone calls were made to family members.

As many as 26 (43%) participants received additional support. Of the additional support, more than half of the therapist-participant interactions were related to psychiatric symptom management. Therapist-outside collaborator additional support consisted of meetings, outpatient appointments, referrals, and written reports (see Table 4 for details).

Acceptability (aim 3) Total participant attendance was 98%. Only one participant dropped out after attending two sessions. Three participants completed seven out of eight possible sessions, while the remaining 56 (93%) participated in all eight sessions.

Acceptability scores for both participants and family members were high. The median total score for participants ($n = 59$) and family members ($n = 36$), was 35 (IQR 32–37) and 34.5 (IQR 31–36), respectively. There was no significant group difference in acceptability ($p = 0.16$) for participants with and without attending family members. Therapist acceptability scores were also high. The median total score for therapist rating of participants was 59 (IQR 53–64), and the median score for the therapist rating of family members was 58 (IQR 54–62). There was no significant difference ($p = 0.23$) between therapist reported acceptability for participants with or without attending family members. For detailed acceptability scale results, see online Appendix 2.

Further, at the 1-year follow-up, 55 of 57 participants (96%) and 34 of 34 family members (100%) answered that they would like to participate in a similar future study.

Table 4. Total frequency of collaborations outside intervention sessions.

Description of collaboration	Phone calls, total frequency*	Additional support, total frequency*
Health care services, specialized	**14%**	**18%**
Social worker at hospital	3	3
Specialized psychiatric services	2	1
Physical medicine outpatient clinic	0	1
Hospital, psychoeducational sleep program	0	1
Hospital, not specified	1	0
Habilitation services	1	0
Rehabilitation coordination unit	1	0
Health care services, municipal	**34%**	**21%**
Physiotherapist	7	0
Speech therapist	1	2
Municipal/residential team	3	3
General practitioner	3	0
Psychiatric team/psychiatric nurse	5	0
Rehabilitation team	1	1
General practitioner, rehabilitation, and psychiatric team	0	1
Work	**34%**	**21%**
Employer	3	4
Norwegian Labor and Welfare administration ("NAV")	7	3
Apprenticeship coordinator	4	0
Participant; preparing meetings/applications to "NAV"	3	0
Other work (human resources, recruitment agency)	3	0
Family	**19%**	**9%**
Family member(s)	11	3
Participant	**0%**	**30%**
Phone calls (mental health support during lockdowns)	0	3
Outpatient consultation (evaluation of psychiatric status)	0	2
Extended phone call to assess suicidal ideation	0	1
Weekly reminders (part of strategies to reach goal)	0	2
Other	0	2
Total frequency	**59**	**33**
Total number of participants receiving support	23	24

*Total frequency, not per participant. Percentages refer to what amount of phone calls or additional support was related to each category of collaborators. Additional support was defined as any therapist-participant or therapist-family member interaction that was given outside the eight intervention sessions, or therapist-outside collaborator contact that was not completed by phone or within intervention sessions.

Discussion

This study describes a process evaluation of an individually tailored and goal-oriented intervention delivered to individuals living with TBI-related difficulties in the chronic phase. The main focus was on evaluation of implementation fidelity, investigation of the delivery context, particularly to what degree collaboration with

family members and community resources was accomplished, and lastly, we aimed to investigate intervention acceptability.

Implementation fidelity was excellent, with high adherence to the intervention manual. The high numbers of logs kept by the therapist for each session likely helped improve manual adherence. Further, the calibration and practice of manual delivery accomplished during feasibility testing, along with regular team meetings and senior fidelity evaluations likely also contributed to high fidelity. The importance of training therapist skills and knowledge before implementing interventions have been acknowledged in other process evaluations in the field of goal-oriented rehabilitation [16, 21, 22].

Regarding dose, the intervention was mainly delivered with the duration and frequency as planned. The Covid-19 adaption allowed us to evaluate delivery of the intervention using videoconferencing. Many studies have shown videoconferences to be an acceptable alternative to face-to-face meetings [23, 24], although more research is needed. This process evaluation also suggests that videoconferencing was an acceptable alternative, but that a few participants preferred in-person meetings. Thus, videoconferencing might be a clinical and cost-effective approach to rehabilitation in the chronic phase of TBI, although some might prefer more traditional modes of treatment and should be given this option. In hindsight, we see that an item regarding acceptability of videoconferencing should have been included in the acceptability scales.

The feasibility study suggested that sessions should not be longer than two hours, to avoid tiring the participants [8]. This seems especially important considering the number of participants reporting fatigue as a main problem area [25]. Nevertheless, as many as 22% of sessions lasted more than two hours. Exploratory analyses suggested that in addition to in-person delivery, having more severe injuries and lower rates of employment was related to longer intervention sessions, as was self-reported executive dysfunction and anxiety, with the latter being the most influential factor. This suggests that in clinical implementation, patients with severe injuries, anxiety and dysexecutive symptoms may need more time to participate in goal-based interventions. Importantly, the longer session times here refers to the length of time therapists must use in follow-up of these patients, i.e., including more breaks for fatigued patients or the need for repetition or more detailed written information provided for participants in cases of severe cognitive deficits.

The intervention reach was deemed acceptable; although we cannot rule out that some individuals from the target population were not reached in this trial as we could not legally record the characteristics for those who did not respond or who declined participation. Earlier findings in our health region indicates that about one third of patients with moderate to severe TBI are expected to experience unmet needs 5 years after injury [10]. Of those contacted in this study, 28% reported a positive interest in participating, which is close to the expected number of those with needs in the chronic phase. Of these 28%, we excluded 6% due to our eligibility criteria, giving a total reach of 22% of all those invited. The reach of the complete intervention, with 98% of participants receiving at least 7 sessions, indicates that the goal-setting format works well with this patient group and this is in accordance with the results from the study by Winter et al. [11].

As the intervention aimed at improving everyday life of participants, key aspects of the study involved collaborating with family members and local resources. Family members should be considered an asset in rehabilitation, and their involvement has been shown to improve outcomes [26, 27]. As noted, the feasibility study resulted in optional family member participation. This might be considered wise when considering that 1/3 of our sample could not otherwise have participated, as they did not have an available family member. We have previously shown that family member participation did not affect goal attainment [12], and this process evaluation confirms having participating family members or not did not affect the length of intervention or acceptability. In summary, a flexible approach to recruitment of family members seems advisable when considering clinical implementation.

For only half of the participants, therapists were in touch with outside collaborators and there might be several reasons for this. Norwegian rehabilitation services are mainly delivered by community resources in the chronic phase, and is based on available services in the municipalities [28], rather than necessarily what resources are needed to address the needs of individuals with complex challenges post-TBI. Indeed, only 45% of the participants received any concurrent rehabilitation services, which is low considering all participants reported ongoing TBI-related difficulties. In some cases, establishing contact with or helping participants applying for services within the time frame of the intervention was not feasible. Further, some participants received services not related to the problem areas or specific goals addressed during the intervention, and collaboration was therefore not considered relevant. In accordance with several studies [9, 10], we experienced that the unmet needs in our sample were often related to cognitive, emotional, and vocational functioning, while physiotherapy was the service most often delivered. For example, as many as 34% of phone calls and 21% of additional support was related to work and/or contact with the labor and welfare administration. This suggests that collaboration with employers and labor and welfare resources should be considered when implementing interventions for this patient group [29–31]. Our results display that outside collaboration was more feasible outside the intervention sessions (phone calls or additional support), which might be in part be due to the fixed duration of the intervention applied in this RCT. However, for the few participants who currently had assistants involved in their daily care (all severe TBIs), their co-participation in intervention sessions was feasible and deemed very valuable. Clinical implementation of this intervention might require more flexibility regarding duration and timing to ease involvement of relevant outside collaborators. Also, the fact that 30% of the additional support outside sessions was given directly to the participant might imply that for some, eight sessions were insufficient, which calls for a more flexible approach to treatment volume in a clinical setting.

The high acceptability as reported by both participants, family members and therapists is in line with a review article displaying high satisfaction among participants of goal-oriented rehabilitation [15]. Thus, the acceptability results did not suggest a need for intervention refinement as suggested by Skivington et al. [4]. However, there might have been a social desirability bias [32] in that the participants were grateful for follow-up and wanted to acknowledge the therapists. More indirect signs of high acceptability were the high attendance rates and the fact that 96% of participants said they would be happy to participate in a similar future study. Overall, results support that the intervention was highly acceptable.

Some limitations of this process evaluation should be acknowledged. Firstly, it was conducted by the therapists who delivered the intervention, which supported the interpretation of data, but may have biased the fidelity, dose, and acceptability outcomes. Further, qualitative interviews were not conducted, which might have helped shed light on some of the results and facilitated

in-depth insights, e.g., by informing on contextual factors that influenced implementation, fidelity, and acceptability and the perspectives of participants and collaborators. Unfortunately, resources to include this type of data was not available in the current project but we considered that our quantitative data had acceptable quality and provided satisfactory information to evaluate the aims of this process evaluation.

Implications

This process evaluation has several implications for the clinical implementation of individualized and community-based rehabilitation interventions. Firstly, it suggests that manualized interventions should be supported using checklists and close team collaboration to ensure manual adherence. Secondly, it displays that there might be individual factors that entails a need for a flexible delivery regarding the dose of the intervention. Thirdly, family members should be included if available. Lastly, collaboration between specialized and community resources might be highly beneficial but necessitates that time and resources for such collaboration is prioritized. Therapists should especially be aware of specific needs for collaboration related to cognitive, emotional, and vocational difficulties.

All in all, this intervention demonstrates how specialized rehabilitation resources could support individuals in the chronic phase and play an important role in establishing collaboration across health sectors and support local personnel who may lack the expertise or resources to address unmet needs after TBI. In Norway, reports by the government have suggested that there is a decrease in rehabilitation service delivery and difficulties with meeting policies regarding collaboration between the specialist and municipal health care services [33, 34]. This intervention thus meets a known demand in Norway, namely ambulatory specialized rehabilitation services to support municipal services. Although the intervention was developed to support individuals with long-lasting impairment post TBI, many of the domains targeted in this study [25] were problem areas that bear relevance to other neurological conditions. The study manual of this RCT should inspire future implementation of community-based, individualized and goal-oriented rehabilitation in the chronic phase of TBI, and potentially other neurological conditions.

Conclusions

The implementation fidelity in this study was considered excellent and it was found to be highly acceptable to participants, family members and therapists delivering the intervention. The collaboration with family members and outside collaborators achieved in this study was lower than anticipated. A more flexible delivery of the intervention in clinical practice might support higher rates of collaboration.

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Disclosure statement

The authors report there are no competing interests to declare.

Ethics approval and consent to participate

The study has been presented to the Norwegian Regional Committee for Medical and Health Research Ethics (REK number 2017/1081). The study is approved by the Data Protection Office at OUH (2017/10390). Signed written informed consent forms are collected from all participants and participating family members.

Implications for rehabilitation

- Rehabilitation in the chronic phase of traumatic brain injury (TBI) should be individualized and community-based and unmet needs related to cognitive, emotional and vocational difficulties should specifically be considered and addressed.
- Collaboration across health sectors is important for patients but necessitates prioritization of time and resources.
- Specialized rehabilitation resources could support individuals and local personnel who may lack the resources or expertise to address unmet needs after TBI.
- Family members should be included in rehabilitation interventions if possible.
- The dose of individualized and goal-oriented interventions should be flexibly delivered to accommodate individual needs.
- Manualized interventions should be supported by using checklists and close team collaboration to ensure manual adherence.

Data availability statement

Not applicable

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