



Received: 06 January 2019  
Accepted: 09 April 2019  
First Published: 30 April 2019

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## PHYSIOLOGY & REHABILITATION | RESEARCH ARTICLE

# The family as a resource for improving patient and family functioning after traumatic brain injury: A descriptive nonrandomized feasibility study of a family-centered intervention

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**Abstract:** The aim of this study was to address feasibility aspects of a multidisciplinary, family-centered rehabilitation intervention for persons with traumatic brain injury and their family. The study was done in preparation of a full-scale RCT and conducted as a collaboration between specialist and municipal health-care service, with two municipal health professionals included as collaborating partners. By applying the intervention on six persons, two families, we evaluated the attendance rate, the appropriateness of the intervention's topics, the collaboration with the municipal health professionals, and the data collection method. Predefined success-criteria were used to evaluate feasibility. The family intervention and study procedures were evaluated as feasible. Some challenges arose and were discussed prior to commencing the full-scale trial. They concerned the logistics regarding the delivery of the intervention and making appropriate adjustments to meet the families' unique needs and facilitate participation. A pragmatic approach was considered necessary in the full-scale RCT.

### ABOUT THE AUTHOR

All authors do their research in the field of rehabilitation after traumatic brain injury. This study is linked to the research group "Rehabilitation after trauma" at Oslo University Hospital in Oslo, Norway. The research group is multidisciplinary and aims to generate knowledge of the mechanisms and consequences of traumas, especially traumatic brain injury, as well as trends and challenges in treatment and rehabilitation. The aim of this study was to address feasibility aspects of conducting a family intervention for families facing traumatic brain injury, and was part of the preparation of a full-scale randomized controlled trial. The results add important knowledge for others planning family intervention research, which can apply to other patient groups as well. The research is done as a collaboration between the Department of Physical Medicine and Rehabilitation at Oslo University Hospital, municipal health care, and the TBI research group at the BioCruces Health Research Institute, Bilbao, Spain.

### PUBLIC INTEREST STATEMENT

From a family system perspective, sustaining a traumatic brain injury has an impact on all members of the family and the family as a whole. As the family members constitute the most important support for those injured, it is important that health and rehabilitation professionals know how to meet the family's needs. As the rehabilitation following a traumatic brain injury often is oriented toward the injured person, more research investigating the effectiveness of family interventions improving functioning and well-being of all family members is needed. In this study, we evaluated the feasibility of an eight-session family intervention as part of planning a larger full-scale trial. The results showed that the family intervention was feasible. However, some challenges arose. They concerned the logistics regarding the delivery of the intervention and making appropriate adjustments to meet the participants' unique needs. Evaluating feasibility is an important step in determining whether an intervention is suited to be tested for effectiveness.

**Subjects: Health Psychology; Family Therapy; Rehabilitation Medicine; Primary Health Care & Family Practice; Allied Health**

**Keywords: traumatic brain injury; adults; feasibility; family intervention; health related quality of life; caregiver burden**

## 1. Introduction

Traumatic brain injury (TBI), defined as an alteration in brain function or other evidence of brain pathology caused by an external force, is a leading cause of chronic disability worldwide (Menon, Schwab, Wright, & Maas, 2010). The disabilities following TBI tend to be multidimensional and include physical, cognitive, behavioral, and emotional problems, which can persist for years after the onset of injury (Forslund et al., 2017). Research studies have consistently demonstrated a poorer quality of life in individuals with TBI compared with healthy controls in both the short term (Arango-Lasprilla, Krch, Drew, De Los Reyes Aragon, & Stevens, 2012) and the long term (Soberg et al., 2013).

As rehabilitation services become less available in the chronic phase of recovery, the family often becomes the primary support system for those injured (Oddy & Herbert, 2003). Family members and caregivers have reported increased levels of anxiety and depression (Ennis, Rosenbloom, Canzian, & Topolovec-Vranic, 2013; Ponsford, Olver, Ponsford, & Nelms, 2003) and caregiver burden is frequently reported in the TBI literature (Baker, Barker, Sampson, & Martin, 2017). High levels of caregiver burden persist years after the injury (Bayen et al., 2016; Doser & Norup, 2016) and correlate negatively with life satisfaction in caregivers after severe TBI (Manskow et al., 2017). Moreover, the patients' and family members' functioning is interlinked. The behavioral changes often seen in persons with TBI seem to predict unhealthy family functioning and distress in relatives (Anderson, Simpson, & Morey, 2013; Schonberger, Ponsford, Olver, & Ponsford, 2010), and the injured person's neuropsychological status has shown to be reciprocally connected to the caregiver burden (Lehan, Arango-Lasprilla, de Los Reyes, & Quijano, 2012).

In studies evaluating the needs of families facing TBI, family members report to have unmet needs, especially within the area of emotional support (Kreutzer et al., 2018; Norup et al., 2015). Despite this, the family members and the family as a whole seldom seem to be the target for rehabilitation efforts (Qadeer et al., 2017), and health professionals often lack knowledge about how they could intervene to improve both patients' and family members' well-being (Lefebvre, Pelchat, & Levert, 2007). Moreover, caregiver and dyad intervention studies often are limited due to the low sample size and poor fidelity (Kreitzer et al., 2018).

A two-armed randomized controlled trial (RCT) titled "The family as a resource for improving patient and family functioning after traumatic brain injury: a randomized controlled trial of a family-centered intervention" will be conducted at Oslo University Hospital. The main aim of this trial is to determine the effectiveness of a multidisciplinary, family-centered intervention for TBI patients and their family members in improving family functioning and dynamics, including health-related quality of life (HRQL) and self-efficacy, and to reduce the family members' perceived caregiver burden over time.

Evaluating feasibility of interventions prior to larger-scale RCTs is in accordance with the complex intervention framework presented by the Medical Research Council (MRC) (Craig et al., 2008). Eldridge et al. (2016) proposed a conceptual framework defining feasibility as an overarching concept in which pilot and feasibility studies are included (Eldridge et al., 2016). In such studies, any part of the planned research can be performed to evaluate the feasibility of the process, resources, management, and science (Morris & Rosenbloom, 2017).

In the current study, we conducted the intervention arm of the planned RCT to evaluate feasibility aspects of a family intervention, the "Traumatic Brain Injury (TBI)/Spinal Cord Injury

(SCI) Family Intervention". This is an eight-session intervention building on cognitive behavioral therapy and a family system perspective (Stevens, Lehan, Duran, Plaza, & Arango-Lasprilla, 2016). A previously published pilot study of this intervention on four Latin-American families facing SCI, compared with a control group, showed promising results, with improvements in psychosocial function (Stevens et al., 2016). However, these results are preliminary, and further investigation of its effectiveness is warranted. In this study, we were especially interested in the following aspects of feasibility:

- (1) The families' willingness and ability to attend the sessions of the intervention.
- (2) The appropriateness of the intervention's topics, including the need for cultural adjustments.
- (3) The leadership structure of the sessions in the intervention and the collaborating mode with the municipal health professionals.
- (4) The appropriateness of the data collection method, including the participants' understanding of and response to the selected outcome measures.

## 2. Methods

This nonrandomized feasibility study of the intervention arm of a planned full-scale RCT was conducted in the south-eastern region of Norway. The full-scale RCT is registered at ClinicalTrials.gov with the identifier NCT03000400, and the Medical Ethics Committee in Norway has approved the study (#2016/1215).

### 2.1. Setting and procedures

The current study was done in a municipal health-care service in Southeastern Norway in collaboration with health professionals working in this health service. The first author (MSR), with nearly 10 years of clinical experience as a physiotherapist, had the primary responsibility as the group facilitator in the family intervention. A nurse and an occupational therapist working in a municipal health-care service were group facilitators together with the author MSR. Both municipal health professionals had more than 15 years of clinical experience. All facilitators received a 2-day in-person training for the intervention from one of the developers of the intervention (co-author JCA-L), followed by two workshops conducted by the principal investigator (HLS).

Three individuals attending a community-based rehabilitation service for persons with an acquired brain injury in the collaborating municipality at the time of the study were invited to participate by receiving oral and written information about the study. The persons with TBI nominated their respective family members for participation in the intervention, and eight persons were ultimately invited to participate. Six persons agreed to participate, whereas a married couple, declined to participate due to a lack of time to attend the eight sessions of the intervention for the spouse. Informed written consent was obtained for all participants.

Assessment of eligibility was based on the following inclusion criteria: Patients that had been diagnosed with a TBI that (a) were between 16 and 65 years of age, (b) lived at home, and (c) received or had received rehabilitation from the municipal health-care service. Individuals nominated by the patients were eligible if they were (a) related to the patient with TBI by blood or marriage, (b) lived in the same household and/or were regarded as significant others, and (c) were between 16 and 65 years of age. Exclusion criteria for all participants were (a) inability to speak/read Norwegian, (b) learning difficulties, (c) ICD-10 diagnosis of severe psychiatric or degenerative neurological illness, (d) ongoing substance abuse, and (e) families in which other family members required extensive/professional care.

Even though the feasibility of the intervention was the scope of this article, a comment regarding sample size in the current study, is considered pertinent. In pilot studies a sample size of 0.03-times the planned sample size of the future study is recommended (Stallard, 2012). With respect to the intervention arm of the full-scale RCT, the six included participants

in the current study corresponded to 6% of the calculated sample size. We also took into account a shortage of the research timeline and scarce human and financial resources as recommended by (Feeley et al., 2009). Therefore, we considered six persons from two families to be sufficient for this feasibility study because making statistical inferences was not an aim.

## 2.2. The Traumatic Brain Injury/Spinal Cord Injury Family Intervention

The multicomponent, individually delivered family intervention is developed by co-author JCA-L and colleagues and aims to improve individual and family functioning (Stevens et al., 2016). By giving the family members knowledge about specific topics and training in practical strategies, it is expected that they can increase their understanding of each other's experiences and be able to manage family problems in a more functional way (Stevens et al., 2016). The intervention manual has been published as supplementary material to the previously published pilot study on the intervention (Stevens et al., 2016).

The intervention consists of eight 90-min sessions, preferably one session per week, with each session focusing on a specific topic, see Table 1 (Stevens et al., 2016). The sessions have a fixed structure containing both theoretical and practical components. Additionally, families are given between-session tasks. The intervention is described in a manual that provides text that can be used to explain the topics and handouts and work tasks assigned to the participants. Although the intervention is manualized, each family should be given the opportunity to share and discuss the challenges that are relevant to their situation so that the intervention is individually adjusted to meet each family's needs. Different health professionals and rehabilitation workers with clinical experience and training in the intervention can lead the sessions as group facilitators (Stevens et al., 2016).

The intervention was translated into Norwegian by a professional translator and was carefully reviewed by authors MSR and HLS. Minor adjustments of the sentence structure, changes in some of the myths and misconceptions about TBI covered in session 2, and updates of some of the references used in the handouts were made prior to conducting the current study. The adjustments were done in collaboration with a Danish research group, translating the intervention within a similar cultural context present in the Scandinavian countries.

**Table 1.** Overview and description of the sessions in the intervention (Stevens et al., 2016)

No	Topic	Description
1	Introduction	Overview of expectations, structure of the sessions, and purpose of the intervention. Completion of baseline questionnaires.
2	Making meaning of TBI/SCI	Normalize and validate the family members' experiences with TBI and overcome misconceptions about TBI.
3	Shifting focus	Shifting focus from negative to positive aspects of the situation and recognizing the relationships among thoughts, mood, and behaviour.
4	Managing emotions	Identify "warning-signs" indicating an escalation of emotions and strategies for managing emotions.
5	Communicating effectively	Recognizing warning signs for communication and providing techniques for communicating effectively.
6	Finding solutions	Moving from a problem-oriented perspective to a solution-oriented perspective, formulating goals, and tracking the progression toward achieving those goals.
7	Boundary making	Externalizations of problems, education of healthy vs. unhealthy family dynamics, and the importance of self-care.
8	Farewell	Summary of skills learned and how changes can be lasting and consistent, provision of feedback on the intervention, and completion of post-intervention questionnaires.

### 2.3. Objectives and success criteria

The results of this study are based on quantitative measures, such as attendance rate and between-session task compliance, by the qualitative feedback given by the participants, and the health professionals' discussion and notes as group facilitators regarding obstacles, difficulties, and benefits experienced during the delivery of the intervention. Prior to the study we defined some success criteria of the feasibility aspects, see Table 2. The three health professionals used 30 min after each session to discuss their experiences and to write down the feedback given by the participants during the sessions.

### 2.4. Data collection and outcome measures

Independent variables were collected through a short questionnaire developed by the authors MSR and HLS. From all participants, we collected sex, age, marital status (partner, married/cohabitant, single), education (elementary school, high school/vocational school, and college/university), current employment status (employed vs. unemployed), and type of work. From the patients, we collected: Number of persons living in the household, employment status pre- and post-injury, time since the injury (months/years), and the current amount of rehabilitation services received (hours per week). Additionally, from the medical records we collected injury-related data, including the date of injury, injury mechanism (traffic accident, fall, violence, other), and Glasgow Coma Scale Score (GCS) upon admission to the emergency room/trauma center, with 3–8 indicating severe TBI, 9–12 indicating moderate TBI, and 13–15 indicating mild TBI (Prasad, 1996). From the family members, we collected the type of kinship to the injured individual and whether they lived in the same household as the person with TBI.

The outcome measures were assessed through self-report questionnaires, which the participants completed during the first introductory session and in the last session of the intervention. In the full-scale RCT, the participants will also complete the questionnaires at the 6-month follow-up. As this is a complex intervention, the use of a single outcome measure is insufficient to capture the effects of the intervention on TBIs and the family system (Mayo & Scott, 2011). Health-related quality of life (HRQL) and caregiver burden were the primary outcomes. HRQL was measured by the Medical Outcomes 36-items Short Form Health Survey (SF-36), which assesses eight dimensions of functioning: physical functioning (PT), role-physical function (RP), bodily pain (BD), general health (GH), vitality (VT), social functioning (SF), role-emotional function (RE), and mental health (MH) (Ware & Gandek, 1994). In the current study, we used the SF-36 version 1 and report the mental scales median scores: VT, SF, RE and ME, whereas the SF-36 version 2 will be used in the full-scale RCT which give the

**Table 2. Study objectives and success criteria**

Objectives	Success criteria
The participants' willingness and ability to attend the sessions	The participants attend all sessions and complete the given between-session tasks.
The appropriateness of the topics covered in the intervention, including the need for cultural adjustments	Participants and health professionals experience the topics and strategies in the intervention as relevant and recognizable.
The leadership structure of the sessions and collaboration form with the municipal health professionals	(a) The municipal health professionals have the opportunity to attend all sessions and have sufficient training in the intervention. (b) The participants are satisfied with the leadership structure and collaboration form through all sessions
The appropriateness of data collection method, including the participants' understanding of and response to the selected outcome measures	The participants answer the self-reported questionnaires within a given timeframe (70 minutes) with less than 10 % missing variables.

possibility to calculate the Mental Component Summary which is not available for version 1. The SF-36 has been shown to be a valid and reliable measurement for use in TBI populations (Findler, Cantor, Haddad, Gordon, & Ashman, 2001). Caregiver burden was assessed using the Caregiver Burden Scale (Elmståhl, Malmberg, & Annerstedt, 1996), which captures five dimensions of caregivers' subjective burden: general strain, isolation, disappointment, emotional involvement, and environment (Elmståhl et al., 1996). The CBS has previously been used for Norwegian caregivers after TBI (Manskow et al., 2015), and the questionnaire has shown good validity and internal consistency when tested in studies involving stroke and dementia (Elmståhl et al., 1996).

The secondary outcome measures included the Quality of Life after Brain Injury (QOLIBRI) (von Steinbuchel et al., 2010) and The Family Adaptability and Cohesion Evaluation Scale, fourth edition (FACES IV) (Olson, 2011). QOLIBRI has been used in Norwegian TBI populations and has shown good psychometric properties (Soberg, Roe, Brunborg, von Steinbuchel, & Andelic, 2017). The FACES IV assesses the participants' perceptions of family cohesion and flexibility. Additionally, how the participants perceive their family communication and how satisfied they are with the family dynamic are assessed by the Family Communication Scale (FCS) and the Family Satisfaction Scale (FSS), which are embedded in FACES IV (Olson, 2011). For additional measurements, see Table 3.

(Andenaes, Bentsen, Hvinden, Fagermoen, & Lerdal, 2014; Friborg, Hjemdal, Rosenvinge, & Martinussen, 2003; Huckans et al., 2010; Kroenke, Spitzer, & Williams, 2001; Spitzer, Kroenke, Williams, & Löwe, 2006)

### 3. Results

#### 3.1. Patient and family information

Patient and family characteristics are presented in Table 4.

#### 3.2. Feasibility of the study

The evaluation of the predetermined success criteria in the current study was based on the participants' feedback of the acceptability of the intervention and the health professionals' discussion and notes of obstacles, difficulties, and benefits experienced in the sessions.

**Table 3. Outcome measures**

Outcome measure	Scale range	Patient	Family member
<b>Primary</b>			
SF36 Mental Health Scales	0–100 (worst–best)	X	X
Caregiver burden scale	22–88 (best–worst)		X
<b>Secondary</b>			
QOLIBRI	0–100 (worst–best)	X	
FACES IV ratio score	0–10 (worst–best)	X	X
Family communication scale	10–50 (worst–best)	X	X
Family satisfaction scale	10–50 (worst–best)	X	X
<b>Additional measures</b>			
Generalized Self-Efficacy Scale (GSE)	10–40 (worst–best)	X	X
TBI Self-Efficacy Scale (TBI SE)	0–66 (worst–best)	X	
Patient Health Questionnaire-9 (PHQ-9)	0–27 (best–worst)	X	X
Generalized Anxiety Disorder-7 (GAD-7)	0–21 (best–worst)	X	X
Resilience Scale for Adults (RSA)	33–165 (worst–best)	X	X

**Table 4. Patient and family characteristics**

	<b>Family A</b>	<b>Family B</b>
Patient (age)	Male with TBI (50)	Female with TBI (24)
Injury severity (GCS)	Severe (3)	Mild (15)
Time since injury	5 years	1 year
Main symptoms and concerns	Impaired memory, lack of taking initiative, problems with decision making	Fatigue, sensitivity to light and sound, and headache
Municipal rehabilitation service	None	2 hours per week
Employment status patient	Part time	Sick-leave
Education patient	University	High School
Family members (age)	Wife (50) Child (16)	Partner (46) Mother (56)
Living in the household (yes/no)	Wife (yes) Child (yes)	Partner (yes) Mother (no)
Education family members	Wife (University) Child (Elementary School)	Partner (University) Mother (University)
Employment status family members	Wife (full-time) Child (student)	Partner (full-time) Mother (disability pension)

Family members are described by their relation to the individual with TBI.

### 3.2.1. *The families' willingness and ability to attend the sessions*

The patients nominated two family members each for participation. Although there were other potential family members that could have participated, the families expressed that the reason for not including them was that they lived too far away, and that they were not actively involved in the patients' daily life. The health professionals experienced the participating family members to willingly share thoughts, experiences, and concerns. With an attendance rate of 98%, the families appeared motivated to attend all sessions of the intervention. One family member missed session number 4. All between-session tasks were completed. Some logistic challenges when scheduling the sessions evolved due to other responsibilities that the participants had, such as work and school obligations. The health professionals experienced that being flexible when scheduling the sessions was necessary to succeed with completion of the intervention within 8 to 10 weeks.

### 3.2.2. *The appropriateness of the intervention's topics, including the need for cultural adjustments*

Overall, the participants' perceived the topics and strategies as relevant and recognizable. This was also the health professionals' impression, as most of the participants showed a good understanding of the background knowledge. However, there were different opinions by the participants regarding the relevance of the myths and misconceptions about TBI, covered in session 2. The family who had lived with the consequences of a severe TBI for five years expressed that some of the myths and misconceptions were not relevant, whereas the other family pointed out that the myths and misconceptions were consistent with concerns they had at that point. Some participants perceived the language used in some of the examples as sharper in tone than what was considered normal for them, i.e. an example illustrating danger-signs in communication. Additionally, one of the injured participants found parts of the intervention difficult to understand due to impaired ability in abstract thinking and memorizing. This was also observed by the health professionals. The youngest participant, aged 16, stated he found the intervention to be more relevant to couples and less relevant for him at that point in life. This was also the health professionals' impression, as we experienced him to be less engaged in some of the sessions.

### 3.2.3. The leadership structure of the sessions and collaboration mode with the municipal health professionals

One family highlighted the importance of having the same group facilitators in all sessions to build a trusting relationship between the participants and facilitators and to make the sessions a safe place to openly express thoughts and concerns. The health professionals evaluated the leadership structure of the sessions as well as functioning. However, it was important to have clarified role expectation in advance of the intervention to improve the group dynamic and make sure we covered each session according to the manual and within the given time frame. The participation represented an extra workload for the municipal health professionals, as they also had ordinary work responsibilities to fulfill which made it more challenging for them to show flexibility regarding scheduling of the sessions.

### 3.2.4. The appropriateness of the data collection method, including the participants' understanding of and response to the selected outcome measures

The participants answered within the timeframe of 70 min, with less than 10% missing data variables. The participant with a mild TBI reported some brief symptoms of headache and fatigue immediately after answering the questionnaires, but recovered fast, and was otherwise satisfied with the process.

A visual comparison of pre- and post-median scores on the primary and secondary outcome measures showed primarily unchanged or slightly improved scores (see Table 5). The Social Functioning Scale of the SF-36 had increased by >10 points, which can be viewed as an important clinical change (Loge & Kaasa, 1998). The family members' scores on the CBS had decreased slightly after intervention and were in a range of a low level of burden (1.00–1.99) (Elmståhl et al., 1996). Of the secondary outcome measures, the median score for the two individuals with TBI on the QOLIBRI had increased by 6.4 points indicating a better quality of life post-intervention. All participants in the current study reported scores on the FACES IV above 1 both at baseline and after completing the family intervention indicating healthy family systems (Olson, 2011). Particularly, the median scores of the Family Communication Scale and the Family Satisfaction Scale had increased with 5.4 and 4.0 points, respectively.

**Table 5. Median scores and interquartile range (IQR) of the primary and secondary outcome measures at baseline (T1) and post-intervention (T2)**

Outcome measure	Median T1	IQR	Median T2	IQR
SF-36 Role Emotional	66.7	33.3 to 100	66.7	0 to 100
SF-36 Social Function	56.3	31.3 to 100	68.8	46.9 to 100
SF-36 Vitality	52.5	35.0 to 60.0	52.5	42.5 to 65.0
SF-36 Mental Health	66.0	44.0 to 84.0	68.0	58.0 to 79.0
Caregiver Burden Scale	45.0	37.5 to 47.3	38.5	31.0 to 46.3
FACES IV Ratio Score	3.0	2.3 to 3.2	3.2	2.3 to 3.9
Family Communication	39.5	37.8 to 43.0	44.9	41.3 to 47.3
Family Satisfaction	40.5	36.3 to 41.3	44.5	40.8 to 47.0
QOLIBRI	35.5		41.9	

Interquartile range is reported. The QOLIBRI (Quality of life after brain injury) was only answered by the patients (n = 2) and the IQR could not be estimated.



## 4. Discussion

In summary, this article provides a rationale for commencing a full-scale RCT aiming to evaluate the effectiveness of a family-centered intervention for families facing TBI. We aimed to evaluate aspects of feasibility related to benefits, obstacles, and challenges when conducting the intervention. Based on the participants' responses and health professionals' observations as group facilitators, the intervention was evaluated as feasible. However, some obstacles and challenges became evident and were discussed prior to commencing the full-scale RCT.

### 4.1. Interpretation of the results

#### 4.1.1. The families' willingness and ability to participate in the sessions

The participants were perceived as actively engaged in the sessions by the health professionals, and these observations are supported by the high attendance rate and the completion of all between-session tasks. However, eight 90-min sessions posed some logistic challenges for the families due to work and study obligations. Factors such as time demands may affect families' opportunity and willingness to participate in intervention studies (Wade & Kurowski, 2017). The health professionals tried to minimize the burden of participation for the families by showing flexibility when scheduling the sessions. We believe this flexibility will be crucial in succeeding with the recruitment of families in the full-scale RCT, and we also determined that delivery of the intervention in the families' homes, if desired, should be an option in the full-scale RCT to minimize the burden of participation for the families.

In the intervention manual, it is recommended that families receive the intervention from 6 months to 1 year after the patient's discharge from post-acute rehabilitation (Stevens et al., 2016). In the feasibility study, we included one family 1 year after injury and one family 5 years after injury. However, as the research supports the notion of early intervention after brain injuries (Ponsford, 2005; Ponsford et al., 2002), we have decided to include patients 6 to 18 months post-TBI in the full-scale RCT. By increasing the inclusion period from 12 to 18 months post-injury, the likelihood of succeeding with recruitment and reach the estimated sample size in the RCT will be enhanced. Inclusion often can be challenging in many clinical trials (McDonald et al., 2006; Nichol, Bailey, & Cooper, 2010), and the incidence of hospital-admitted patients with TBI is lower in Norway than in other countries (Andelic, Sigurdardottir, Brunborg, & Roe, 2008).

There is no defined upper limit for how many family members that could participate in the intervention (Stevens et al., 2016). Both patients nominated two of their closest family members each. In Norway, the immediate families usually are small, and the average household in Oslo consists of 1.98 people ("Families and households," 2016). Additionally, Norway has a welfare system ensuring that all inhabitants have equal rights to health services. These factors might influence to what extent the family is involved in the rehabilitation process and the amount of informal care they provide for the injured family member, as opposed to other cultures and countries where the familial sense is stronger and formal health services are limited. As we could potentially have larger groups in the intervention, we determined that significant others, such as close friends, can be included in the full-scale RCT.

#### 4.1.2. The appropriateness of the topics covered in the intervention, including the need for cultural adjustments

The family intervention is culturally sensitive and need for adjustments should be considered before applying the intervention in other cultures (Stevens et al., 2016). The family intervention is developed by integrating elements and strategies from several evidence-based cognitive and psychological techniques. However, some of the examples used in the intervention were perceived as culturally different from what were considered normal in the families. For instance, the language used in some examples was sharper in tone than what was considered normal in the families. Despite this, the examples clearly function well to illustrate what they intended to and we decided to keep them as is with just minor changes in wording.

There were also different opinions between the families regarding the myths and misconceptions about TBI covered in session 2. This might relate to differences between Latin-America and Norway regarding the amount of available information about TBI and the consequences of such injury, but the observed differences between how they perceived the myths and misconceptions might also be explained by what stage in the recovery process the families were when the intervention was delivered. It is likely that families facing a severe TBI receive more health services and get more information compared to families who initially believed their family member had sustained a mild TBI with symptoms resolving in weeks. In the full-scale RCT, we will include patients with all severities of TBI, and consequently, we will need to adjust the myths and misconceptions according to severity and phase of recovery to make it relevant for each family.

The need for individual adjustment became evident in the current study, as one of the individuals with TBI found parts of the intervention somewhat difficult to understand. If the participants do not experience a sense of mastery, the intervention could potentially be a reminder for the family of the problems caused by TBI. Considering common cognitive problems often experienced by people with TBI, such as slowed information-processing and impaired memory and attention (Azouvi, Arnould, Dromer, & Vallat-Azouvi, 2017), it is important that the group facilitators have the knowledge and skills to recognize these problems when they occur and adapt the content to suit an individual's unique needs.

In the previously published pilot study of the intervention by Stevens et al. (2016), licensed psychologists were group facilitators, whereas the allied health professionals in the current study had more limited psychological expertise. However, as the intervention was developed as a multi-professional approach, it is important to evaluate the intervention when conducted by other than psychologists. This is also in accordance with a pragmatic approach in research, where interventions should be tested under circumstances closer to regular clinical practice and to ensure the external validity for which the intervention was intended (Zwarenstein & Treweek, 2009).

The youngest participant stated he found parts of the intervention less relevant for him and more suited for couples, which was in accordance with the health professionals' observations as we observed that he was less engaged in some of the sessions. In the intervention manual, it is recommended that family members are at least 18 years, and our experience supports this recommendation. However, due to the small sample size, one cannot make a conclusion based on this single experience. Nonetheless, we decided to follow the manual recommendation with an age limit of 18 years for family members in the full-scale RCT even if this might result in a loss of adult family members as children often move out to pursue further education or to submit to initial compulsory military services.

#### *4.1.3. The leadership structure of the sessions and collaboration mode with the municipal health professionals*

The municipal health-care service was motivated to be involved in the research; however, the health professionals did not receive any allowances for their ordinary work responsibilities and participation therefore represented an extra workload and some logistic challenges. This is in line with what other researchers have identified to be challenges for clinicians involved in research, as limited time and resources often restrict their possibility for participation (Di Bona et al., 2017; Wusthoff, Waal, & Grawe, 2012). Likely, the logistic challenges will increase when we include more families in the RCT study. It had already been determined that the municipal health professionals should be co group-facilitators for a total of 10 out of 33 families in the RCT intervention arm, which might be realistic based on our experience in the current study.

#### *4.1.4. The appropriateness of data collection method, including the participants' understanding of and response to the selected outcome measures*

The family-centered intervention aims to give the families new and extended knowledge about topics concerning interactions and relationships within the family after TBI, coping and self-efficacy, and practical skills to manage challenges and problems in more functional ways. Achieving this, the families can recognize and change inexpedient behaviors and patterns to

improve family function and dynamics. Behavioral changes are difficult to achieve for everyone and might even be more complicated for persons who have sustained a TBI. Hence, the 6-month follow-up in the full-scale RCT will provide important information about the effectiveness of the family-centered intervention.

The participants managed to answer all questionnaires within the given timeframe. One participant reported a brief increase in symptoms of pain and fatigue immediately after completing the questionnaires. However, we evaluated the selected outcome measures as feasible as this participant otherwise expressed being very satisfied with the process. An option in the RCT would be to give patients extended time to answer the questionnaires if needed. Making statistical inferences regarding the effectiveness of the intervention was not the aim of this study, but a visual comparison of the baseline and post-intervention median scores on the primary and secondary outcome measures showed primarily unchanged or slightly improved scores. However, we cannot make any suggestions of trends regarding the effectiveness of the interventions based on these results.

**4.1.4.1. Strengths and limitations.** A strength of this study was that all aspects of the intervention arm were thoroughly tested, which resulted in some adjustments that will increase the validity of the full-scale RCT. However, a major limitation of this study was the small sample size, six persons in two families. This is a consequence of a shortage of research timeline and limited human resources. Thus, we obtained limited information regarding the larger target group's willingness to participate in the intervention and we could not determine recruitment rates based on the sample in the current study.

In addition, we did not evaluate the feasibility of delivering the intervention to individuals other than immediate family members, due to the fact that many Norwegian families are small, and the extended family is less involved in the rehabilitation process. On the other hand, the study might be of international interest because Norway is a welfare state with a long tradition of organizing and allocating resources to comprehensive rehabilitation of patients with long-term disabilities, including TBI. Furthermore, it can be considered a limitation that the a priori success criteria were not systematically assessed, as this would have given us more accurate data when evaluating the feasibility and potential changes in the study protocol.

## 4.2. Conclusion

The "Traumatic Brain Injury/Spinal Cord Injury Family Intervention" was feasible when evaluating the objectives and success criteria of this study based on a high attendance rate and between-session task compliance, and feedback and observations from the participants and the health professionals. A pragmatic approach was considered necessary in the full-scale RCT to minimize the burden of participation and succeeding with the recruitment of families. Further investigation of the effectiveness of the family-centered intervention and the results of the full-scale RCT will form a basis for evaluating the effectiveness and the possibility of implementing the intervention in routine clinical practice.

### Abbreviations

TBI	Traumatic Brain Injury	QOLIBRI	Quality of Life after Traumatic Brain Injury
RCT	Randomized Controlled Trial	FACES IV	Family Adaptability and Cohesion Scale
HRQL	Health-related Quality of Life	FCS	Family Communication Scale
GCS	Glasgow Coma Scale	FSS	Family Satisfaction Scale
SF-36	Short Form 36 Health Survey	GSE	Generalized Self-Efficacy Scale
CBS	Caregiver Burden Scale		

TBI SE	Traumatic Brain Injury Self-Efficacy Scale
RSA	Resilience Scale for Adults
SCI	Spinal Cord Injury
PHQ-9	Patient Health Questionnaire-9
GAD-7	Generalized Anxiety Disorder 7-item scale.

#### Acknowledgements

Not applicable.

#### Funding

This study and the future full-scale RCT have been made possible through grants from the Norwegian ExtraFoundation for Health and Rehabilitation [2016/FO77196]. The trial funders played no role in the study design, data collection, analysis or interpretation, manuscript writing, or decision to submit the article for publication.

#### Competing Interests

The authors declare that they have no competing interests.

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#### Availability of data and materials

All data upon which the conclusion of this paper relies upon are published in the article. The datasets generated from the self-reported questionnaires are not publicly available, due to privacy concerns and to ensure the anonymity of the participants. De-identified responses to the self-reported questionnaires are available from the corresponding author, upon reasonable request.

#### Ethics approval and consent to participate

Ethics approval of the full-scale RCT was granted by the Regional Committees for Medical and Health Research Ethics in southeast Norway (#2016/1215) and the Data Privacy Officer at Oslo University Hospital. Potential participants were provided with written information sheets

about the project. In the first session of the intervention, the rationale and purpose of the study were discussed with the participants, and they were given the opportunity to ask questions before signing the written consent form.

#### Citation information

Cite this article as: The family as a resource for improving patient and family functioning after traumatic brain injury: A descriptive nonrandomized feasibility study of a family-centered intervention, Mari S. Rasmussen, Nada Andelic, Tonje H. Nordenmark, Juan C. Arango-Lasprilla & Helene L. Soberg, *Cogent Medicine* (2019), 6: 1607433.

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