

It's a family experience – improving patient and family functioning after traumatic brain injury

A randomized controlled trial of a family-centered intervention

Mari Storli Rasmussen

Department of Physical Medicine & Rehabilitation

Oslo University Hospital



Institute of Health and Society

Faculty of Medicine

University of Oslo

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Thesis summary

Background: Traumatic brain injury (TBI) constitutes a challenge for the entire family. An increased focus on family functioning and response after TBI has produced an international consensus that family should be an integral part of the rehabilitation process. However, evidence-based knowledge regarding the effectiveness of family-centered interventions in the TBI rehabilitation field is limited, and additional controlled studies within the context of family systems are needed. This thesis describes a research project of a TBI family intervention carried out at Dept. Physical Medicine and Rehabilitation at Oslo University Hospital (OUH) and conducted in collaboration with the Norwegian municipal health care service.

Aims: This thesis aims to (1) assess the feasibility of a theory-based, manualized family intervention in a Norwegian context and study procedures in preparation of a randomized controlled trial (paper I), (2) to describe aspects of mental health and family functioning, and factors associated with mental health in adults with mild to severe TBI and their family members (paper II), and (3) to assess the effectiveness of the theory-based family intervention in improving individual and family functioning among adults with mild to severe TBI and their family members (paper III).

Patients and methods: The feasibility study (paper I) included two individuals with TBI and their families, in total six participants, recruited from a community-based rehabilitation service. Feasibility was evaluated based on pre-defined success criteria, namely the families' willingness and ability to attend the family intervention, the need for cultural adjustment to the Norwegian version of the family intervention, the mode of collaboration with the municipal health professionals, and the data collection methods. The cross-sectional study (paper II) and the randomized controlled trial (RCT) (paper III) included 61 patients (54% women) with mild to severe TBI and 63 family members (52% women) recruited from a TBI outpatient clinic at Oslo University Hospital (OUH). The families were randomly assigned to the intervention group (n = 30 families) and the control group (n = 31 families). Outcomes were assessed with patient-reported outcome measures (PROMs) at the start of treatment and at 2-month and 8-month follow-up appointments. Primary PROMs were mental health-related quality of life (HRQL) and caregiver burden. Secondary PROMs were family functioning,

communication, and satisfaction, and TBI-specific HRQL. Several additional PROMs – self-efficacy, resilience, general health, and symptoms of depression and anxiety – were applied.

RCT study arms: The patients in both the intervention group and the control group received follow-ups at the specialized TBI outpatient clinic at OUH. In addition, the families in the intervention group were supplied with a manualized, eight-session family intervention, delivered to each family separately. In the control group, the family members were invited to attend a single 2.5 h caregiver group session.

Results: Paper I: The attendance rate for the intervention sessions (98%) and the home task compliance rate (100%) were high. Overall, the families described the intervention topics as relevant and recognizable. Both families and the collaborating municipal clinicians experienced some logistical challenges related to session scheduling. The leadership structure of the sessions and mode of collaboration with municipal health professionals functioned well, and the PROMs were answered within the given timeframe of 70 min with < 10% missing data variables. Paper II: The data collected at the first assessment point in the randomized controlled trial, a median 49 weeks post-injury, showed that 82% of patients had sustained a mild TBI. Most family members (92%) were patients' partners or spouses. The patients reported significantly worse mental HRQL, general health, depression, resilience, and self-efficacy than the family members. Fifty-seven percent of the family members reported mild to moderate symptoms of depression. Both the patients and the family members reported healthy family functioning, high levels of family communication, and moderate family satisfaction. Gender, symptoms of depression and anxiety, and resilience were significantly associated with the mental HRQL in patients and family members, and explained 56% of the variance in mental HRQL. Paper III: No significant between-group differences in mental HRQL, TBI specific HRQL, caregiver burden, or family functioning, communication, and satisfaction were evident at any assessment point in the RCT. Significant within-group improvements in mental HRQL, caregiver burden, and family functioning, communication, and satisfaction were observed in the intervention group from start of treatment to the 2-months follow-up (i.e. intervention period), whereas the patients in the control group showed significant improvements in TBI-specific HRQL during the same period.

Conclusion: Paper I: With minor adjustments and a pragmatic approach, the Norwegian version the eight-session family intervention and the study procedures of the planned RCT

were feasible. Papers II and III: The patients bore the main disease burden at start of treatment in the RCT, but the family members reported some depressive symptoms. The overall family functioning was healthy. Being female, having symptoms of depression and anxiety, and having lower levels of resilience were significantly associated with reduced mental HRQL in patients and family members. There was no extra benefit in receiving an eight-session family intervention in addition to outpatient follow-ups for the patients, although it may have accelerated the recovery process during the intervention period.

Sammendrag

Bakgrunn: En traumatisk hodeskade er en utfordring for hele familien. Det er bred enighet om at familien bør integreres i rehabiliteringen etter slike skader. Likevel er kunnskapsgrunnlaget for effekten av familietiltak etter traumatisk hodeskade begrenset, og det er behov for flere kontrollerte studier på feltet. Denne avhandlingen beskriver et forskningsprosjekt av et familietiltak for personer med traumatisk hodeskade og deres familiemedlemmer. Prosjektet ble gjennomført ved avdeling for Fysikalsk medisin og rehabilitering ved Oslo Universitetssykehus (OUS) i samarbeid med kommunehelsetjenesten.

Formål: Formålet med avhandlingen var å (1) undersøke gjennomførbarheten av et teoretisk forankret, manualbasert familietiltak i en norsk kontekst og planlagte studieprosedyrer i forkant av en randomisert kontrollert studie (artikkel I), (2) beskrive aspekter ved mental helse og familiefunksjon, samt faktorer assosiert med mental helse hos personer med mild til alvorlig traumatisk hodeskade og deres familiemedlemmer (artikkel II), og (3) undersøke hvorvidt et manualbasert familietiltak ga bedre mental helserelatert livskvalitet, mindre pårørendebelastning, samt bedre familiefunksjon, kommunikasjon, og familietilfredshet sammenlignet med en gruppe som fikk ordinær behandling (artikkel III).

Pasienter og metode: I gjennomførbarhetsstudien (artikkel I) ble to personer med TBI og deres familier, totalt 6 deltakere, rekruttert fra kommunehelsetjenesten. Predefinerte kriterier ble brukt til å vurdere gjennomførbarhet med hensyn til familienes mulighet og villighet til å delta i familietiltaket, behovet for kulturelle endringer av den norske versjonen av familietiltaket, samarbeidsformen med involverte fagpersoner fra kommunen og datainnsamlingsmetoden. Tverrsnitts-studien (artikkel II) og den randomiserte kontrollerte studien (artikkel III) inkluderte 61 pasienter (54% kvinner) med mild til alvorlig TBI og 63 familiemedlemmer (52% kvinner) rekruttert fra en spesialisert poliklinikk ved OUS. Familiene ble randomisert til en intervensjonsgruppe (n=30 familier) og en kontrollgruppe (n=31 familier). Deltakerne svarte på pasientrapporterte utkommemål ved behandlingsstart, samt ved 2 og 8 måneders oppfølging. Primære utkommemål var mental helserelatert livskvalitet og pårørendebelastning. Sekundære utkommemål var familiefunksjon, kommunikasjon, og familietilfredshet, samt diagnose-spesifikk helserelatert livskvalitet. Andre utkommemål omfattet mestringstro, resiliens og symptomer på depresjon og angst.

Gruppene i den randomiserte kontrollerte studien: I både intervensjons- og kontrollgruppen fikk pasientene ordinær oppfølging ved poliklinikken for traumatiske hodeskader på OUS. Familiene i intervensjonsgruppen fikk i tillegg et familietiltak bestående av 8 sesjoner levert til hver enkelt familie. Familiemedlemmene i kontrollgruppen ble inviterte til å delta i en enkelt gruppesamling for pårørende på 2.5 timer ved OUS.

Resultater: Artikkel I: oppmøte i samlingene (98%) og gjennomføringen av hjemmeoppgavene (100%) var god. Deltakerne beskrev familietiltakets innhold som relevant og gjenkjennelig, og svarte på de selvrapporterte spørreskjemaene innen gitt tidsramme på 70 min og med < 10% manglende data. Både familiene og fagpersonene fra kommunen erfarte noen logistiske utfordringer med tanke på tidspunkt for samlingene. Samarbeidsformen med fagpersonene fra kommunene fungerte godt. Artikkel II: Data fra første måletidspunkt i den randomiserte kontrollerte studien, median 49 uker etter skaden, viste at 82% av pasientene hadde en mild traumatisk hodeskade. 92% av familiemedlemmene var pasientens ektefelle eller partner. Pasientene rapporterte statistisk signifikant dårligere mental helse relatert livskvalitet og generell helse, mer symptomer på depresjon, og lavere resiliens og mestringstro enn familiemedlemmene gjorde. 57% av familiemedlemmene rapporterte milde til moderate symptomer på depresjon. Både pasienter og familiemedlemmer rapporterte å ha balansert familiefunksjon, et høyt nivå av familiekommunikasjon, og moderat familietilfredshet. Kjønn, symptomer på depresjon og angst, samt resiliens var faktorer som assosierte signifikant med og forklarte 56% av variansen i mental helse relatert livskvalitet hos pasienter og familiemedlemmer. Artikkel III: Det var ingen statistisk signifikante forskjeller i mental helse relatert livskvalitet, diagnose-spesifikk helse relatert livskvalitet, pårørendebelastning, eller familiefunksjon, -kommunikasjon, eller -tilfredshet mellom deltakerne i intervensjonsgruppen og kontrollgruppen på noen måletidspunkt i den randomiserte kontrollerte studien. Innad i intervensjonsgruppen hadde deltakerne statistisk signifikant bedring i mental helse relatert livskvalitet, pårørendebelastning, og familiefunksjon, -kommunikasjon og -tilfredshet fra første til andre måletidspunkt (dvs. intervensjonsperioden). Pasientene i kontrollgruppen hadde en signifikant bedring i diagnose-spesifikk helse relatert livskvalitet i den samme perioden.

Konklusjon: Med mindre justeringer var familieintervensjonen og studieprosedyrene i intervensjonsarmen i randomiserte kontrollerte studien gjennomførbare. En pragmatisk

tilnærming ble vurdert som nødvendig i RCT studien. Artikkel II og III: Pasientene rapporterte å ha den største byrden i form av redusert mental helse relatert livskvalitet emosjonelt stress, men familiemedlemmene hadde symptomer på depresjon. Å være kvinne, ha symptomer på depresjon og angst, og lavere nivå av resiliens var signifikant assosierte med dårligere mental helse relatert livskvalitet hos pasienter og familiemedlemmer. Den randomiserte kontrollerte studien viste ingen ekstra fordel av å delta i et familietiltak med 8 samlinger, i tillegg til å få spesialisert poliklinisk oppfølging.

List of papers

1. Rasmussen MS, Andelic N, Nordenmark TH, Arango-Lasprilla JC, and Soberg HL. 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. *Cogent Medicine* 2019; 6:1, 1607433
2. Rasmussen MS, Arango-Lasprilla JC, Andelic N, Nordenmark TH, Soberg HL. Mental health and family functioning in patients and their family members after traumatic brain injury: A cross-sectional study. *Brain Sciences* 2020;10 (10):670.
3. Rasmussen MS, Andelic N, Pripp AH, Nordenmark TH, Soberg HL. The effectiveness of a family-centred intervention after traumatic brain injury—a pragmatic randomised controlled trial. **Status:** under review in *Journal of Clinical Rehabilitation*.

Abbreviations

ABI	Acquired brain injury
ACRM	American Congress of Rehabilitation Medicine
AIS	Abbreviated Injury Scale
CBT	Cognitive behavioral therapy
FACES IV	Family Adaptability and Cohesion Evaluation Scale – fourth edition
FCS	Family Communication Scale
FSS	Family Satisfaction Scale
GCS	Glasgow Coma Scale
GOSE	Glasgow Outcome Scale Extended
GOS	Glasgow Outcome Scale
CGB	Caregiver Burden Scale
GAD-7	Generalized Anxiety Disorder – 7
GSE	General Self-Efficacy Scale
HISS	Head Injury Severity Scale
ICD-10	International Classification of Diseases - 10 th edition
ICC	Intraclass correlation coefficient
ICF	International Classification of Functioning, Disability and Health
IQR	Interquartile range
ITT	Intention-to-treat
LOC	Loss of consciousness

OUH	Oslo University Hospital
PHQ-9	Patient Health Questionnaire – 9
RROM	Patient-reported outcome measure
PPCS	Persistent Post-Concussion Symptoms
QOLIBRI	Quality of Life after Brain Injury
RLAS	Rancho Los Amigos Scale
RSA	Resilience Scale for Adults
RPQ	Rivermead Post-Concussion Symptoms Questionnaire
SD	Standard deviation
SF-36	36-item Short Form Health Survey
TBI	Traumatic brain injury
TBIFSI	Traumatic Brain/Spinal Cord Injury Family System Intervention
TBI SES	Traumatic Brain Injury Self-Efficacy Scale
WHO	World Health Organization

1 Introduction and background

This thesis describes a family intervention after traumatic brain injury (TBI) (1) and includes a systemic understanding of TBI as a family experience. Persons with TBI of all severities may experience cognitive, emotional, and behavioral changes that interfere with daily life (2). Family members constitute an important source of support for the injured person, and the family's ability to adjust and manage the challenges related to TBI influence the patient's recovery (3). The sudden onset of TBI disrupt family dynamics and family roles and increases the risk of unhealthy family functioning (4, 5). Furthermore, reduced health-related quality (HRQL) of life is reported by both patients (6, 7) and family members (8, 9). Family members may experience persistent caregiver burden (10, 11) and psychological distress (12).

Recovery after TBI therefore entails a complex interplay between individual and contextual factors that requires a systemic approach in TBI rehabilitation (13). Health professionals are encouraged to involve the family members as much as possible in the rehabilitation process and to pay attention to all family members' needs (14, 15). To meet the often long-lasting needs of families and individuals after TBI, researchers, medical professional, and policy makers have advocated for coordination in health services and collaboration across different health care sectors (14, 16, 17).

When this research project commenced in 2016, the knowledge gap in TBI rehabilitation was characterized by a lack of family system approaches (18). The existing evidence for family interventions was insufficient with regard to identification of key components that targeted the needs of the family as a whole, and there was a paucity of longitudinal data and controlled studies (18).

Conducted in collaboration with a municipal health care service, the present research project was designed as a two-armed RCT focusing on persons with TBI and their family members. Through a feasibility study, a cross-sectional study, and an RCT of a family-centered intervention, this PhD project generated knowledge about the feasibility and effectiveness of a manualized family intervention in improving individual and family functioning after TBI. By including responses from both patients and family members, the project overall aim was to contribute to a better understanding of the consequences of TBI on the family system.

1.1 Definition and classification of TBI

TBI is defined as “*an alteration in brain function, or other evidence of brain pathology, caused by an external force*” (19). Alteration in brain function refers to any of the following signs: a period of loss or decreased level of consciousness, loss of memory for events before or after the injury, neurological deficits, and alteration in mental state at the time of injury (19). In the World Health Organization’s (WHO) International Statistical Classification of Diseases and Related Health Problems (ICD-10), injuries to the head are described with diagnostic codes ranging from S06.0 to S06.9 (brain concussion; brain contusion; other intracranial injuries, including subarachnoid, subdural, and extradural hematomas, and diffuse injuries) and T90 (sequelae of injuries to the head) (20).

The severity level of TBI is determined based on patient history, clinical examination, and imaging results from computed tomography (CT) and magnetic resonance imaging (MRI) (21). The classification of injury severity primarily relies on clinical examination using the Glasgow Coma Scale (GCS) score, (22) loss of consciousness (LOC), and length of post-traumatic amnesia (PTA) (23). Table 1 gives an overview of the classification of TBI severity based on clinical measures.

Table 1 Classification of TBI based on clinical measures (24)

Clinical measure	Mild TBI	Moderate TBI	Severe TBI
Glasgow Coma Scale Score	13–15	9–12	3–8
Post-traumatic amnesia	≤ 24 h	>24 h to < 7 d	> 7 d
Loss of consciousness	≤ 30 min	>30 min to < 24 h	> 24 h

Other instruments used to classify TBI include the Abbreviated Injury Scale (AIS) (25) and the Head Injury Severity Scale (HISS) (26). The AIS-head is an anatomic measurement for classifying and ranking the severity of head injuries based on neuroimaging, operative, or autopsy findings (25).

The HISS utilizes the GCS score for severity and adds a second dimension to account for the presence of risk factors to classify closed head injuries with regard to prognosis and treatment (26). Based on the HISS scale, the Scandinavian Neurotrauma Committee guidelines for initial management after minimal, mild, and moderate TBI were published in 2000 (27). They were published to improve the quality of identification of patients at increased risk of developing intracranial hematoma based on the presence of risk factors such as skull fracture, brain contusions, reduced level of consciousness or a history of LOC (27). Another distinction used to classify the severity of mild TBI was proposed by Williams et al., who labeled closed head injuries with evidence of intracranial brain lesions as “complicated mild TBI” due to the increased risk of behavioral sequela and disability in this patient group (28).

There is no clear consensus on the definition of mild TBI and there is a wide variety of diagnostic criteria. Mild TBI and concussion are often used interchangeably, although concussion is more commonly used in the context of sporting injuries (29).

Today, a widely applied definition of mild TBI is the one proposed by the American Congress of Rehabilitation Medicine (ACRM). They defined mild TBI as a traumatically induced physiological disruption of brain function, identified by at least one of the following signs: (a) LOC < 30 minutes, (b) PTA < 24 hours, (c) any alteration in mental state at the time of accident, (d) transient or not transient focal neurological deficits, and (e) a GCS of 13-15 after 30 minutes (30). This definition was later revised by the WHO Collaboration Center Task Force on Mild Traumatic Brain Injury (31). The ACRM and WHO definitions are similar but utilize different descriptions of the altered mental state, and different time frames for GCS score assessment (32). The ACRM’s definition proposes assessing the GCS score after 30 minutes post-injury, but the WHO’s definition proposes doing so after 30 minutes post-injury or upon admission (31).

1.2 Epidemiology

The estimated annual incidence rate of new TBI cases worldwide is 50–60 million, approximately 90% of which are classified as mild TBI (33). In the European Union alone, the number of new TBI cases is approximately 2.5 million each year (33). In a review of Peeters et al., the incidence rate of hospital-admitted TBI in Europe was 262 per 100,000 per

year (34). However, discrepancies in diagnostic criteria and imaging modalities inject uncertainty into the estimation of TBI incidence, in particular pertaining to cases of mild TBI because many do not enter the medical care system and remain undiagnosed (29). A recent literature review found the incidence of hospital-admitted mild TBI to be 200 to 300 per 100,000 individuals (35). A study from mid-Norway identified 732 patients with mild TBI admitted to hospitals or municipal emergency departments over a period of 1.5 years, two-thirds of whom did not require hospitalization (36).

In Norway, the incidence rate of hospital-admitted TBI in the Oslo region was 83.3/100,000 per year, with falls being the most common cause of injury (37). This incidence was found to be lower compared to previous studies from Scandinavia and Northern Europe (37). A more recent study on hospital-admitted individuals with TBI with findings of intracranial injury identified an average of 431 cases per year from 2015 to 2019 in southeast Norway (38).

Today, falls have overtaken road accidents as the leading cause of injury, and there has been an increase in the mean age of those sustaining TBI (35, 39). This change is especially evident in high-income countries, such as Norway, probably as the result of increased elderly populations and improved traffic safety and road standards (34).

1.3 Impact of TBI on the injured person

TBI is a leading cause of death and disability worldwide (40, 41). Nevertheless, TBI has been labeled a “silent epidemic” because of society’s unawareness of its societal and economic burden (42). The patient group is heterogeneous, and the sequelae of TBI and course of recovery exhibit individual variations (33). Rather than being viewed as a single event, TBI has been described as a chronic and evolving neurological condition that negatively affects personal, familial, and social matters (43). To address all TBI consequences is beyond the scope of this thesis. In the following sections, I report some of the common consequences of TBI as found in the literature, with a focus on individual and family consequences.

Outcome after TBI is a multidimensional construct, and different outcome measures have been developed to increase knowledge about TBI consequences and recovery (44). The Glasgow Outcome Scale (GOS) and the Glasgow Outcome Scale Extended (GOSE) are

among the most widely used measures to assess overall global functioning in terms of overall disability and the patient's ability to return to normal life (45). Other outcomes include assessments of neuropsychological impairments, psychological status, TBI symptom burden, return to work, relationship/family stability and functioning, and HRQL of life (44). The wide range of outcome measures reported in the TBI literature reflects the multifaceted impact of this condition, and the use of a single outcome measure is insufficient to capture the total burden of TBI (33).

A TBI of any severity can cause various physical, cognitive, emotional, and behavioral impairments in the injured individual (46). Physical symptoms may include motor and sensory deficits. Cognitive symptoms can include impaired attention, memory, information processing speed, and executive functioning. Further, behavioral changes can manifest as personality changes, impulsivity, apathy, and emotional changes can be anger, irritability, depression, and anxiety (46). The prognosis for mild TBI is generally good, with most patients recovering within weeks or days (47). Yet, a significant proportion of injured individuals, approximately 10%–20%, experience persistent somatic (headaches, dizziness, fatigue, and vision and auditory disturbances), cognitive (memory, attention), and emotional (depression, anxiety, and emotional lability) complaints (48).

When symptoms persist for more than 3 months following a mild TBI, the patient's condition is often labeled as Post-Concussion Syndrome (48). However, post-concussion symptoms are not exclusive to mild TBI; they are present in all TBI populations (49, 50). Today, the term Persistent Post-Concussion Symptoms (PPCS) rather than post-concussion syndrome is frequently used to describe symptoms and complaints present months after the injury (48). The experience of PPCS after mild TBI does not correspond with the anticipated course of recovery, and may lead to insecurity, avoidance of activities, decreased social interaction, and increased emotional distress (51).

Individuals with moderate to severe TBI may undergo intensive medical procedures and long-term specialized follow-ups. Most improvements are evident within 6 months to a year after the injury (52). However, research has demonstrated that both improvement and decline in functioning may appear many years later (46, 53). In a Norwegian context, a study on 163 individuals with severe TBI found that, at 1 year post-injury, 85% of patients had regained independence in daily life activities (54). However, studies on patients with moderate to

severe TBI have revealed that a significant proportion of individuals with TBI exhibit long-term cognitive impairments (55), reduced work capacity, and impaired physical and mental HRQL (56). International studies on moderate to severe TBI have revealed similar long-term results (57-60).

Despite regaining independence in personal daily life activities after moderate to severe TBI, a substantial proportion of individuals continue to exhibit reduced participation in work and leisure activities leading to less community reintegration and problems in social relationships years after the injury (57, 61). Even in the cases of mild TBI, individuals experience long-lasting functional impairments. In the TRACK-TBI study on individuals with mild TBI, 23% had not return to full functional status (as assessed by the GOSE) one year after the injury, and nearly half of the individuals reported reduced life satisfaction (62). Furthermore, in a study by Theadom et al., individuals with mild TBI had significantly poorer level of participation in the community and in social relationships four years after the injury when compared to matched controls (63). Thus, long-term restrictions in activity and participation can occur after any severity of TBI. This may also negatively impact the family members and the overall family functioning.

Either as an emotional response to an awareness of disability or as a direct consequence of the injury itself, individuals with TBI face an increased risk of developing psychiatric conditions such as depression and anxiety (64, 65). Prevalence rates vary across studies, but a systematic review that included adults with TBI of all severities, found a prevalence of 21 % for anxiety disorders and 17 % for depression disorders in the first year after TBI (66).

Recovery after TBI is complex and depends on injury-related factors, demographic factors, pre-injury and post-injury functioning, and family and social support (33). In general, injury-related factors, such as acute GCS score, PTA, and length of stay in an intensive care unit, have been shown to be significantly associated with long-term global functioning (GOSE), cognitive functioning, and productivity outcomes after moderate to severe TBI (55, 59, 67-69). Significant demographic factors include age, race, and level of education (70).

Concerning mild TBI, demographic factors like age and educational level have been associated with functional outcomes (71, 72). Pre-injury and post-injury psychological and

physical problems and more severe acute symptom burden have been shown to be significantly associated with poorer functional outcomes and PPCS (50, 71, 73).

In summary, the consequences of TBI and the course of recovery are dependent on biological, social, and psychological factors, and the impact of these factors on individuals varies (74, 75). The problems patients with TBI experience lead to restrictions in activity and participation and constitute a significant burden to both patients and families. Because problems caused by TBI can manifest in several ways, it may take time for the injured person and their family to become aware of them, especially after milder injuries (76). In the following section, I will describe the impact of TBI on the family, focusing on family functioning.

1.4 Impact of TBI on the family

Over years, researchers' interest in the impact of TBI on the family has increased (76-79). Importantly, the research have concerned ways that health professionals can intervene to support families following TBI (13-15). Here, research that specifically address the impact of TBI on the family and family functioning are presented. The next section examines family responses following TBI from a theoretical perspective.

Family reactions after TBI are dependent upon various factors, and some families, such as those with small children, little social support, or financial problems, may be more vulnerable than others to the changes induced by TBI (80). Family functioning before and at the time of injury might be a significant factor when assessing family functioning after TBI, but results on pre-injury family functioning are limited and inconsistent. One study found that approximately one-third of caregivers either experienced unhealthy family functioning or had a history of psychiatric problems before the injury (81), which potentially made them more vulnerable to the consequences of TBI. Healthy pre-injury family functioning and caregivers' perceived social support have been associated with better home and social reintegration in patients with mild to moderate TBI, but not for those with severe TBI (82). In a study on patients with mild TBI, 62% of the participant reported unhealthy family functioning at time of admission to the emergency department (83). However, family functioning was not

significantly associated with self-reported post-concussion symptoms or functional and participation outcomes at 3-months post-injury (83).

After a TBI, families may face an uncertain course of recovery. Relief over the fact that the injured person survived may be mixed with feelings of loss and grief in response to the ways the injury has changed the patient and the family life (84). TBI can have profound impact on all family members and cause elevated levels of psychological distress (85, 86), as well as significant caregiver burden (11, 87). Consequently, many families are at risk for becoming more isolated from their social network in the aftermath of TBI (88).

Because the response from a single family member may not be representative of the family system as a whole, it has been emphasized that research on family functioning should include reflections from more than one family member (89, 90). A limitation in much of the existing literature is that most studies rely on responses from either the patient or the primary caregiver (91) and thus fail to assess family functioning from a systemic perspective. Furthermore, a paucity of longitudinal data plagues the existing literature (91).

TBI can disrupt family dynamics. This can manifest as enmeshment, overprotectiveness, rigidity, increased frequency of family conflicts, and reduced ability in effective problem-solving (92). Some studies have demonstrated that 30% to 68% of families reported unhealthy family functioning following TBI (5, 85, 93, 94). When unhealthy patterns in the family are established they do not necessarily resolve with time; in fact, longitudinal studies have demonstrated that unhealthy family functioning tends to persist over time (4, 5). In the study by Ponsford and Schönberger, approximately one-third of the caregivers to individuals with severe TBI reported unhealthy family functioning at both 2-years and 5-years follow-up (5).

By including responses from patients and caregivers within the same family, Gan et al. were among the first to explore family functioning after acquired brain injury (ABI) from a family systems perspective (95, 96). They uncovered discrepancies between patients and family members, with the family members reporting significantly more distressed family functioning than the patients (95) and that the family as a unit reported more distressed family functioning than the general population (96).

However, results on family functioning vary across studies. In some studies, over half of the caregivers of individuals with TBI reported unhealthy family functioning (85, 93). By

contrast, some families seem to adjust well in the aftermath of TBI. For example, two studies from Latin America have found generally healthy family functioning and high levels of family communication after TBI (97, 98). In a Latin American study by Lehan et al., the authors found high agreement on family functioning within 68% of the dyads (98). Similarly, studies in the Australian context found that the average level of family functioning was within the healthy range (86, 99).

Research has demonstrated that there are reciprocal relationships between the patients' well-being, the caregivers' health and functioning, and family functioning (99-102). Cognitive and behavioral changes in the injured individual are associated with more unhealthy family functioning (4, 5, 86), which in turn is associated with reduced mental health in caregivers (93, 97, 103). Furthermore, unhealthy family functioning has been shown to negatively affect rehabilitation outcomes in the injured individual (104, 105).

To get a holistic picture of how a TBI affect the family, it is necessary to explore the family system from different perspectives. Families may experience an abundance of needs following TBI, such as the need for information, practical assistance, and emotional support (106). Furthermore, social support has shown to alleviate the adverse effects of TBI on the family members' mental health and the overall family functioning (93, 101). Thus, paying attention to all family members' needs and engaging the family as a whole in the rehabilitation process are important and have been associated with better overall family functioning and improved well-being in family members and patients (93, 94, 107, 108).

As the existing literature demonstrates, TBI represents a family challenge that strains not only the patient but their family members as individuals and the family as a unit. Although the literature is clear regarding the importance of family support following TBI, there is a need for studies on interventions aimed at supporting the family as a unit that include perspectives from more than one member of the family and that examine change in family functioning over time. Having provided this summary of common impacts of TBI on the family, in the next section, I provide a description of the theoretical background for this family systems perspective.

1.5 Theoretical background for family systems and functioning

1.5.1 Defining family

Family can be defined in several ways (109). The biological family may be seen simply as two or more individuals related by blood or marriage. However, family can also be defined more broadly. The functional family may be defined according to personal preference and include anyone who provides support and is actively involved in a person's life (109).

1.5.2 The family system

In addition to taking a best evidence approach, rehabilitation should be grounded in a theoretical perspective (110). In accordance with the shift from a mechanistic to a systemic understanding of health and functioning, an ecological perspective may serve as a theoretical background that offers a systematic way of understanding family responses following TBI and the development of rehabilitation interventions (110). From the ecological perspective, an individual's life spans a number of different contexts at the micro, meso, and macro levels (111). For instance, the respective levels are recognized in rehabilitation that involves individuals (patients and family members) at the micro level, service provision/providers at the macro level, and policies and the meso level (111). The ecological perspective situates human behavior and functioning in the context of reciprocal relationships between individual and environmental factors (110).

Family systems theory is founded in the ecological framework (112). Central to all systems theories is the concept of interrelatedness and a view of the system as a whole. The family system is characterized by the following key elements (113):

- a) A family system consists of a group of people psychologically and behaviorally connected to each other.
- b) Multiple interactions exist within the family system and between the members, such as husband-wife, and parent-child dyads. These interactions constitute sub-systems within the larger family system.

- c) A change of behavior in one of the members of the system necessarily leads to a change in behavior of all members of the same system.
- d) All family systems are unique and dynamic, develop over time, and can adapt and adjust to altering life-events.

Family structure concerns the members of the system (114). Invisible boundaries exist between and around the family members, separating the family system from its social context and enabling the family to create a sense of family identity. The *family functioning* is a multidimensional construct comprising cohesion, flexibility, communication and problem-solving styles, affective expression, and behavioral control (114).

In the present research project, aspects of family functioning are described and assessed based on the Systemic Circumplex Model developed by Olson et al (115). The model incorporates three dimensions of family functioning: cohesion, adaptability, and communication. Balanced levels of cohesion and adaptability characterize healthy family functioning.

Cohesion is the level of emotional connectedness and commitment, and the number of shared interests among family members. It is divided into four levels: disengaged, separated, connected, and enmeshed. Balanced levels of cohesion fall between the separated and connected levels (115).

Adaptability is the level of flexibility in the family system - that is, the ability of a dyad or a family system to change power structures, roles, and rules to adapt to internal or external changes. Level of flexibility is divided into four levels: rigid, structured, flexible, and chaotic. Balanced levels of flexibility fall between the structured and flexible levels (115).

Family communication is considered a facilitating dimension because it enables changes in the dimensions of cohesion and flexibility. Positive communication includes empathy, reflective listening, and supportive comments that facilitate sharing feelings, needs, and preferences among family members. Lastly, family members' satisfaction with aspects of the family's functioning provides insight into the desired and actual patterns of family functioning (115).

An underlying assumption within the circumplex model is that all family systems are dynamic and can be changed over time (115). This assumption supplies the rationale for intervening

within families to improve family functioning. Such intervention is of particular importance when family systems face sudden and unforeseen events, such as TBI (113, 116).

The consequences of TBI on the family have been described in terms of stress and coping, where TBI represents the stressor to the family system (80). Coping efforts represent the family's reaction and can be adaptive, such as creating new roles, and maladaptive, such as developing unhealthy family functioning and managing tasks poorly. From the system perspective, a TBI will affect the members of the family system and the system as a whole (80). Therefore, a TBI requires all family members to adapt and adjust to maintain growth and stability in the system.

Incongruence between the members of a dyad with regard to appraisal of an illness or injury and its symptoms influences the management of the illness and dyadic health (117). Similar appraisals among family members manifest as a mutual responsibility and engagement in the management of any illness or injury (117). This has been demonstrated in TBI research, where shared appraisals concerning the TBI have been shown to positively influence satisfaction with life and family adjustment (89, 118).

1.5.3 A strength-based family approach to TBI rehabilitation

At the meso level, health professionals can engage the family members as active participants in the rehabilitation process following a TBI while recognizing their capacity to persevere despite adversity (14, 119). Consistent with an ecological perspective and with an increased interest in a systemic approach to rehabilitation, the capacity-building family system assessment and intervention model by Dunst and Trivette can serve as a framework to promote a family-centered approach to TBI rehabilitation (120). This model, presented in Figure 1, originally developed as a model for families with children who require long-term care, may serve as an illustration of a strength-based family-approach in the TBI rehabilitation process because it places the family at the center of that process (120) The model comprises the following four elements:

- Capacity building, which refers to promotion rather than prevention. Capacity building focuses on the competencies and strengths of the family's functioning, and includes both relational practices (empathy, active listening, and respect) and participatory practices (engagement of family members to use their strength and abilities).
- Family concerns and priorities, which refers to the family's desires and goals and thus should receive attention in rehabilitation work with families.
- Family member abilities and interests, which refers to the identification and facilitation of the family members' competencies and strengths to meet the demands they face.
- Supports and resources, which refers to both the formal and informal resources that are available to the family. The intention is to obtain and use social supports that enable the family to manage challenges themselves (120).

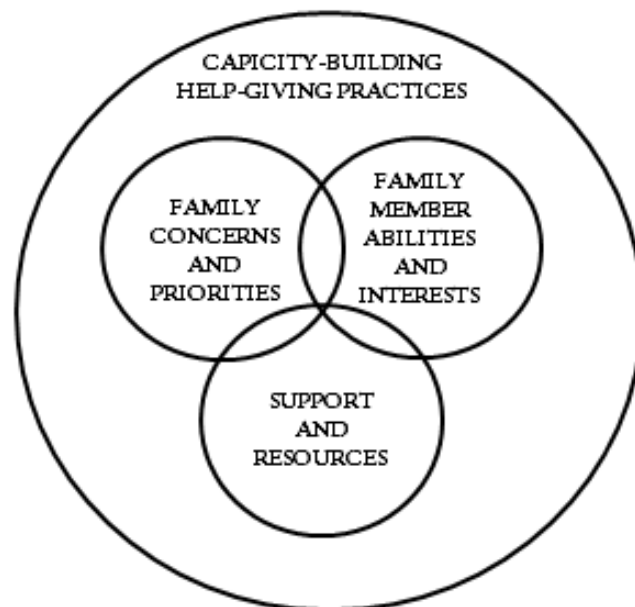


Figure 1. The capacity-building family system intervention model. Reproduced with permission from the author and Taylor & Francis Copyright Clearance Center (120).

Based on the presented theoretical perspectives, supporting families after TBI presupposes the engagement of and interaction with all family members. By applying a systemic approach, health professionals can recognize patients' and families' concerns, priorities, needs, and strengths, which is the starting point for working with families under a strength-based approach and from an ecological perspective.

This chapter has demonstrated that an ecological and systemic framework can help reach an understanding of family responses and TBI outcomes as the result of a complex relationships. That is, family functioning and behavior are the combination of individual and environmental characteristics. In this framework, the three contextual levels—the individuals, the health professionals who assist them, and the rehabilitation policies to improve positive outcomes—are all embedded in the rehabilitation process (111). In the chapter that follows, I provide a brief description of rehabilitation in general and the rehabilitation chain following TBI.

1.6 Rehabilitation after TBI

In Norway, rehabilitation has been defined as targeted, coordinated, continuous, evidence-based collaboration processes between patients, caregivers, and service providers in different social arenas (121). The aim of these processes is to assist individuals in achieving the best possible level of functioning, coping, independence, and participation in studies, work, social life and community activities (121). Clinical decisions and the provision of services in the TBI rehabilitation field should be based on the best available evidence (110, 122).

A biopsychosocial approach to health and functioning was proposed by the WHO's International Classification of Functioning, Disability and Health (ICF) system where functioning comprises body structures, activities, and participation. (123). Disability is the result of bodily impairments, activity limitations, and participation restrictions. Additionally, functioning is influenced by contextual factors in the environment and the individual. Environmental factors comprise physical, social, and attitudinal factors, including the family (123). The ICF has been applied and supported in the literature as a tool for the classification and description of health, functioning, and disability following TBI (56, 124), and health professionals are encouraged to situate the rehabilitation efforts in contexts relevant to the individual (110).

The increased interest in psychosocial factors has been reflected in Norwegian governmental documents, which emphasize that rehabilitation services should be individualized and provided in arenas that are familiar to the patient (16, 125). Further, the recognition of family members being the most important resources of informal care has led to the development of rights and guidelines that include addressing the caregivers' needs (126).

The recognition of the family context as the essential social unit, and thus the most valuable source of support for patients, impelled the shift toward a more family-centered approach in TBI rehabilitation (112). Families should be an integral part of the rehabilitation process, and several studies have provided practical and clinical advice regarding how this can be achieved (14, 15). In sum, these studies have identified approaches from the family therapy field, communication skills that facilitate a trusting relationship between professionals and family members, education, skill-building, and support that involve families in the rehabilitation process.

According to a recent systematic review, learning strategies for solving problems and cognitive behavioral therapy can reduce PPCS and psychological distress, as well as improve quality of life compared with usual care after mild TBI (127). In an earlier systematic review comprehensive interdisciplinary rehabilitation in the post-acute phase was more promising compared to medical interventions in the acute phase (128). A Norwegian RCT of a multidisciplinary rehabilitation program was found effective in reducing the number of post-concussion symptoms in patients with mild TBI who exhibited PPCS 2-months post-injury (129).

OUH is the Level 1 trauma center in southeastern Norway. For patients with severe TBI, early interdisciplinary rehabilitation usually begins at the OUH intensive care unit before discharge to specialized rehabilitation hospitals or local hospitals (130). After being hospitalized for treatment and/or observation in the acute phase, patients with PPCS symptoms following mild to moderate TBI are offered services at the OUH outpatient clinic specialized in TBI rehabilitation (131). The follow-up services will be described in more detail later in the Method section (*4.9.3 Study arms*), in this thesis.

In the following section, I highlight the theoretical constructs that are linked to health and functioning and that were at the core of the present research project. Although they may

contain overlapping phenomena, I have divided them for the purpose of this thesis because they describe the general domains of the outcome measures used in this research project.

1.7 Health-related quality of life

HRQL is a multidimensional construct that reflects health status in terms of physical, mental, and social functioning from the individual's point of view (132). It is considered an important outcome because it adds unique information - beyond objective clinical measures - regarding a person's subjective well-being, functioning, and the effect of treatment (133). Health status, functional status, quality of life, and satisfaction with life are interdependent because they all refer to the concept of health (133). In this thesis, however, I utilize the term HRQL because the focus of the study is the individual's sense of health and well-being in terms of physical, mental, and social functioning.

HRQL measures are often administered as generic or condition-specific patient-reported outcome measures (PROMs) (133). Generic instruments enable comparisons between groups and conditions. One of the most widely used generic instruments, also employed in the present research project, is the 36-item short health survey (SF-36), which assesses functioning and well-being across different health concepts and produces one mental and one physical summary score (134).

1.7.1 HRQL in individuals following TBI

HRQL has been measured in the TBI population to quantify the subjective burden of the injury (132). Research has demonstrated that individuals with TBI report worse HRQL, especially in the physical, emotional, and social functioning domains, compared to other non-clinical and clinical comparison groups (6, 7, 135, 136). The impact of TBI on HRQL has shown variations according to injury severity. For example, a large cohort study, including all severities of TBI, found that the moderate to severe TBI group demonstrated significantly poorer HRQL than the mild TBI group, and only the group with mild TBI improved to levels comparable with the general population at 1 year post-injury (7). However, the presence of PPCS has been associated with reduced HRQL after mild TBI (137, 138).

Several factors have been associated with reduced HRQL in individuals with TBI including female gender (7), lack of involvement in productive and community activities, more functional impairments (6, 56, 139, 140), and symptoms of depression and anxiety (6, 141-143). Family support and higher levels of family satisfaction have been shown to positively influence HRQL (142, 144).

1.7.2 HRQL in family members following TBI

Studies have shown that caregivers of individuals with TBI report diminished HRQL in the acute phase after severe TBI (145, 146). Although significant improvements may occur within the first year (9), evidence suggests that caregiver HRQL remains below the general population norms years after moderate to severe TBI.(8, 9, 147) Concerns about social and emotional health, feeling overwhelmed by responsibilities, lack of personal time, and disruption of one's anticipated life course are factors that interfere with HRQL in caregivers after TBI (148, 149).

Several factors have been shown to be negatively associated with HRQL in family members, such as symptoms of depression and anxiety (150-152), increased levels of caregiver burden (153), and cognitive and behavioral impairments in the injured family member (87). Although results are mixed, some evidence suggests that those who spend the most time caring for the injured family members are at particular risk of increased psychological distress and reduced HRQL (3, 85, 154). Contrarily, having access to social support has been shown have a positive impact on caregivers' HRQL following TBI (153, 155).

1.8 Caregiver burden

Caregiver burden is a multidimensional concept that encompasses many domains, and it is one of the most frequently reported caregiver outcomes in the TBI literature (156). Caregiver burden refers to the physical, psychological, emotional, social, and financial stressors caused by providing care for someone (157). In the literature, it is often described as the objective or subjective burden on caregivers. Objective burden refers to the physical or instrumental

provision of aid, such as the number of hours spent caregiving, whereas subjective burden refers to the emotional and psychological impact of caregiving (157).

1.8.1 Caregiver burden after TBI

Most studies concerning caregiver burden have been conducted on caregiver populations tending to patients with moderate to severe TBI. Studies have revealed that approximately 50% of caregivers report significant caregiver burden in the first year after severe TBI (87, 158). Some evidence suggests that elevated levels of caregiver burden persist or even increase over time (11, 159), whereas a longitudinal study from Paris-TBI study found a significant decrease in the subjective caregiver burden from 1 to 4 years post-injury (10).

Lower functional level (as assessed with GOSE) (11) and cognitive and behavioral problems in the injured person are associated with higher levels of caregiver burden (87, 100). One study indicated that caregiver burden may increase over time as the family members become more aware of the cognitive and behavioral changes caused by the injury (160). Lack of social network and feeling lonely are likewise associated with increased caregiver burden (11).

Although measures of caregiver burden provide information regarding the stress associated with the caregiving task, such measures do not capture caregiver the strength and resources available to them (161). As noted in the coping review of Baker et al., a paucity of research has focused on positive factors that contribute to better outcomes among caregivers (156). Therefore, in the following section, I draw on the field of positive psychology to describe two such factors.

1.9 Resilience and self-efficacy

Positive psychology comprises the study of positive experiences and traits in individuals, as well as the contextual factors that facilitate their development (162). Underlying this is the observation of individuals' ability to exhibit continued trajectories of healthy functioning in the face of adversity (163). Healthy functioning and well-being are not merely the absence of

adversity in life, but an individual's capacity to live a pleasant, engaged, and meaningful life (162).

Resilience is a construct that refers to the possession of protective traits and habits that promote stable mental and physical functioning in the face of adversity (163, 164). Resilience is not limited to an individual's inherited characteristics, it also comprises a process of adjustment and acquisition of skills that can be learned and modified through familial, social, and relational factors (164). Resilient people tend to exhibit greater optimism and experience more positive emotions. They also tend to organize their lives more effectively and place greater value on support from family and friends (165).

Self-efficacy refers to an individual's personal beliefs and confidence in taking control of their motivation, behavior, and the social environment to achieve desirable outcomes (166). It can be considered a resilient quality and is mediated through four processes; previous positive experiences, observation of others performing the same task, being encouraged by others, and positive emotional arousal related to the task (167). Hence, cognitive, motivational, affective, and decisional processes explain how people contribute and act to shape their life circumstances.

1.9.1 Resilience and self-efficacy following TBI

The increased focus in the TBI literature on the assessment and identification of protective factors like resilience and self-efficacy is evident (154, 168-170). It has been argued that health professionals can promote resilient qualities in both individuals and families through strength-based approaches, including skill-building, cognitive behavioral therapy (CBT), and emotional support. (170). Such approaches fit well with the capacity-building family intervention model described earlier (120). From the family system perspective, resilience comprises family communication patterns, problem-solving styles, and family identity (171, 172).

The roles of resilience and self-efficacy in TBI rehabilitation has emerged in the TBI literature over the last decade. One study found that individuals with moderate to severe TBI demonstrated lower levels of resilience compared to the general population early after the

injury (173). However, a Norwegian study found that a resilient adaption to emotional distress was the most common trajectory in individuals with mild to severe TBI in the long-term (174). Higher levels of resilience have been shown to significantly contribute to increased participation, community reintegration, and HRQL in individuals with TBI (175-177), as well as fewer complaints following mild TBI (178). A study that specifically examined self-efficacy after ABI found that individuals with higher self-efficacy coped better with their brain injury reported better HRQL (179).

Concerning caregivers and family members, recent studies have demonstrated that higher levels of resilience in family members are significantly associated with lower levels of caregiver burden, increased hope, and better HRQL (180-183). Furthermore, a study by Scholten et al. found that higher levels of self-efficacy gave better personal and family adjustment at 6-months post-ABI (118).

The growing consensus that protective factors, such as resilience and self-efficacy, help both patients and families to better adjust to the changes caused by TBI has led to increased attention towards strength-based rehabilitation interventions (168, 171). In the following section I describe the existing evidence for family-centered interventions following TBI and give a short description of some of the components that are recommended for such interventions.

2 The evidence for family-centered interventions following TBI

To date, the evidence for family-centered interventions following TBI has been inconsistent. There are several reasons for this, including large variations in the intervention structures, selection of outcomes, methodologies, and reporting of results (18, 184, 185). Consequently, developing recommendations based on the existing literature is challenging because the studies are difficult to compare.

Before the commencement of the present research project, researchers had pointed to poor methodological quality in family intervention studies (18, 186). A critical review of the literature on family and caregiver interventions found that very few interventions targeted families after ABI (18). Moreover, the researchers identified a lack of interventions that had a

family system approach as opposed to working with the primary caregiver only. Similar conclusions were later made by Kreutzer et al. (107). They found that surprisingly few family intervention studies had examined the effects of interventions on family functioning, and the relevant studies were limited by small sample sizes and lack of standardized treatment (107).

To my knowledge, one systematic review of caregiver and dyad intervention after TBI (184) and one scoping review of family-oriented interventions following ABI have been published since the present research project was started (185). The scoping review of family-oriented interventions following ABI identified very few studies that reported on family functioning outcomes despite that the studies included in this review had a family-oriented approach (185). Of the 89 studies included in the review, only 20 % targeted patients with TBI and their family members. Intervention structure and components varied, but education and emotional support were the most recurrent components in the family-oriented interventions (185).

In their systematic review, Kreitzer et al. included caregiver and dyad intervention studies on patients with moderate to severe TBI (184). Of fourteen studies published before 2017, five studies involved both the patient and a family member. Kreitzer et al. found that four out of five dyad studies showed positive results in caregiver outcomes. Education and skill-building were the most recurrent components in the interventions described. In general, many of the studies were limited by insufficient descriptions of theoretical background and lack of standardization (184).

In addition to the review papers described, several non-systematic searches were conducted related to this study to identify relevant RCTs of family interventions following TBI and ABI published after commencement of the present research project. Seven relevant publications were identified, including four RCTs (187-190), one controlled study (191), and one RCT pilot study (192). Five of the studies described single-family format interventions (187, 188, 191-193) All the interventions described were complex in nature, but the selections of outcome measures differed, making comparisons difficult. However, when relevant they will be used in the discussion section of this thesis.

2.1 Components of family-centered interventions following TBI

In general, complex interventions that incorporate several components have been considered beneficial in the family system approach to TBI rehabilitation (13, 17). In particular, adopting elements from the couples and marriage therapy field have been recommended because the systemic understanding of family functioning is essential in these approaches (13, 90, 194). Further elaborating on couples and family therapy is beyond the scope of this thesis, but in this section, I briefly describe some of the components and approaches utilized in interventions targeting TBI patients and their families. Although the components are not mutually exclusive, I describe them separately because they reflect those included in the family intervention used in this research project.

Education/psychoeducation: Education describes efforts to provide families with appropriate information about TBI and the consequences of such injuries (13). Educational components are often combined with other therapeutic approaches, such as CBT and problem-solving (18, 195).

Cognitive behavioral therapy: CBT seeks to modify behavior by helping individuals to identify and change unhelpful thought patterns, and recognizing the relationships between thoughts, feelings, and behaviors (196). CBT components comprise both skill-building and problem-solving approaches.

Skill-building: Skill-building includes efforts to teach patients and families practical skills that are necessary to manage the consequences of TBI and promote changes in the family (13). Skill-building approaches might include communication training, managing stress and emotional regulation, problem-solving skills, and CBT strategies (13, 17).

Problem-solving/solution-focused therapy approaches: Problem-solving can be viewed as a self-management approach to identify problems, find solutions, and set and revise goals and action plans (197). The inclusion of problem-solving components in caregiver interventions following TBI has shown promising results (156, 198). Solution-focused therapy approaches aims to empower people to actively use their strengths and competencies to focus on solutions rather than problems (17).

Emotional support: Emotional support can be provided by health professionals and peers and involves encouraging and supporting the family's ability to cope, respecting patients' and family members' individuality, and listening to and talking with all those affected by the TBI (13).

2.2 Rationale for the current study

The awareness of the impact of TBI on the entire family and of the family's significant influence on recovery following TBI have led to the call for family systems interventions (17, 92, 186, 199). In particular, family interventions have been found to be important in the later stages of recovery, when the TBI patients return home and resume family roles (17). The low degree of generalizability of much of the published research on family-centered interventions has resulted in mainly descriptive data (185). The current research project sought to increase the evidence-based knowledge about the feasibility and effectiveness of family-centered interventions for TBI patients and their families from the family system perspective. Because family structure and perceived family needs exhibit cultural variations (106), it is crucial to evaluate family interventions in various cultural contexts. Furthermore, few family intervention studies have been conducted in Scandinavia; thus, the present research project could contribute to increased knowledge about individual and family functioning after TBI in a context where formal health services are well developed.

2.3 The Traumatic Brain Injury/Spinal Cord Injury Family (System) Intervention

The intervention at scope in the present research project was the Traumatic Brain/Spinal Cord Injury Family (System) Intervention (TBIFSI) (1). It is theoretically founded in family systems theory, and includes approaches from couples and family and therapy, education, skill-building, CBT strategies, and emotional support. The TBIFSI is standardized and described in an intervention manual but is individually tailored by giving the families the opportunity to share and discuss the specific challenges they face. The TBIFSI manual is published as supplementary material in the paper by Stevens et al. (1).

Intervention aims: By addressing family needs, the intervention aims to improve individual and family functioning. More specifically, the intervention aims to increase consensus and shared understanding of TBI-related challenges; improve interpersonal communication, family cohesion, and flexibility; clarify family boundaries, improve coping and problem-solving skills; and reduced the frequency of family conflicts.

Intervention structure: The intervention has a single-family format and consists of eight 90-minute face-to-face sessions with a fixed structure. Each session starts with a relevant quote that is discussed by the family members. The sessions are devoted to providing knowledge about the specific topic, in addition to practicing skills and strategies. Each session ends with an assignment of a home task, and the families are encouraged to apply the strategies learned to relevant daily life situations.

Intervention providers/group facilitators: The TBIFSI is designed for allied health professionals who are trained in the intervention and have clinical experience in family work.

Timing of delivery: According to the TBIFSI manual, it is recommended that families receive the intervention from 6 months and up to 12 months post-TBI, when the patients have been discharged from post-acute rehabilitation to their homes (1). An overview of session topics is displayed in Table 2.

Table 2 Overview of topics covered in the TBIFSI sessions (1).

Session	Topic	Content
1	Introduction	Information about the study. Introduction and overview of expectations and completion of start-of-treatment questionnaires.
2	Making meaning	Extracting beliefs and experiences related to traumatic brain injury.
3	Shifting focus	Positive changes after traumatic brain injury. Understanding the relationship between thoughts, feelings, and behavior.
4	Managing emotions	Physiological changes when emotions escalate. Recognizing “warning signs” of emotional escalations. Strategies for overcoming negative emotions.
5	Communicating effectively	Fighting fairly. Communication danger signs. Strategies for effective communication.
6	Finding solutions	Moving from a problem-oriented to a solution-oriented perspective. Formulating useful goals. Problem-solving skills.
7	Making boundaries	Externalizing the problems. Education on healthy vs. unhealthy family dynamics. Importance of self-care.
8	Summarizing and farewell	Summary of skills learned. Feedback from the participants. Completion of 2-months follow-up questionnaires.

3 Thesis aims

The overall aim of this thesis was to determine the effectiveness of the theory-based, multi-professional family-centered intervention, TBIFSI, for adult patients with TBI and their family members in improving individual and family functioning. It was hypothesized that the participants in the intervention group would report positive changes in mental HRQL, emotional functioning, resilience, self-efficacy, and family functioning and dynamics compared to the control group. Furthermore, it was hypothesized that the caregivers in the intervention group would report reduced caregiver burden compared to the controls. The terms “overall mental health” and “mental HRQL” are used interchangeably in the respective papers, and they both refer to the primary outcome, the Mental Component Summary on the SF-36, in this research project. When describing the thesis aims, I will use the term “mental HRQL”.

This thesis includes three paper, and the specific aims of each papers were as follows:

3.1 Paper I

Title: *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.*

Paper 1 had four aims, all related to feasibility aspects of the intervention arm of the RCT. The objectives were to evaluate (1) the families' willingness and ability to attend the intervention sessions; (2) the appropriateness of intervention topics, including the need for cultural adjustments; (3) the collaboration mode with the municipal clinicians and leadership structure of the sessions, and (4) the appropriateness of data collection methods, including the respondents' understanding of and response to the selected self-reported questionnaires.

3.2 Paper II

Title: *Mental health and family functioning in patients and their family members after traumatic brain injury: A cross-sectional study.*

Paper II had two aims. The first was to describe the characteristics of the patients with TBI and their family members involved in the RCT, including aspects of mental HRQL and family functioning. The second aim was to examine which individual-functioning- and family functioning-related factors were associated with mental HRQL in patients and family members.

3.3 Paper III

Title: *The effectiveness of a family-centered intervention after traumatic brain injury – a pragmatic randomized controlled trial.*

The overall aim of Paper III was to determine the effectiveness of the TBIFSI, provided in addition to specialized follow-ups at an outpatient clinic, on mental HRQL, caregiver burden, family functioning, and TBI-specific HRQL compared to a control group. Additionally, we sought to investigate within-group differences from start of treatment to 2-months follow up, i.e. in the treatment period.

In the following chapter, I describe how these studies were conducted.

4 Materials and methods

4.1 Research design

This research project was designed as an RCT with two arms. The three papers included in this thesis employed the following study designs:

Paper I was a descriptive non-randomized feasibility study.

Paper II was a cross-sectional study and presented data collected at the first assessment point (start of treatment) in the RCT.

Paper III described a two-armed open-labelled RCT with follow up at start of treatment and a 2- and 8-months follow-up.

4.2 Ethics and registration

The RCT was pre-registered at ClinicalTrials.gov with the identifier NCT03000400. Prior to commencing the study, ethical clearance was obtained from the Norwegian Regional Committee for the Medical Research Ethics (REC) of southeastern Norway (#2016/1215) and project approval was obtained from the OUH Data Protection Office. The project was funded by the DAM Foundation under grant number: 2016/ FO77196 by grant application through the National Association of the Traumatically Injured LTN.

The OUH was the research manager of this project, and Professor Helene L. Soberg, Ph.D., was the project manager and main supervisor. Professor Nada Andelic, Ph.D., M.D., and Associated Professor and neuropsychologist Tonje H. Nordenmark, Ph.D., were co-supervisors. A statistician from the University of Oslo contributed with statistical modelling. A psychologist and two students were research assistants whose main responsibility was to administer data collection and management. A project group was established where I worked with the supervisors, health professionals from the collaborating municipal health care service, and a user representative from the National Association of the Traumatically Injured. The study was conducted according to the Declaration of Helsinki and written informed consent was obtained from all participants.

4.3 Recruitment procedure and settings

Paper I: From September to October 2016, patients and family members were recruited through a municipal rehabilitation service for persons with an ABI in Southeastern Norway. Participants with TBI were approached for participation and were given information about the feasibility nature of the study by municipal health professionals and/or the Ph.D. candidate and included after given oral consent.

Papers II and III: From January 2017 to June 2019, patients were recruited from a specialized TBI outpatient clinic at the OUH, Department of Physical Medicine and Rehabilitation. Patients are referred to the outpatient clinic after being hospitalized for observation and/or acute treatment at the OUH or by their general practitioner in case of PPCS pressure and a protracted course of recovery after mild to moderate TBI. Patients were assessed for eligibility by a physiatrist and the Ph.D. candidate. Eligible patients received oral information about the study and a written invitation letter, enclosing consent. A written reminder was sent once to patients that did not respond to the initial invitation. The patients selected their family member(s) for participation. After consenting to participation, families were randomized to the intervention and the control group.

4.4 Inclusion and exclusion criteria

Paper I: Patients were considered eligible for the feasibility study if they met the following inclusion criteria: a) had been diagnosed with a TBI, b) were between 16 and 65 years old, c) lived at home, and d) received or had received rehabilitation from the municipal health care service. Family members nominated by the patients were eligible if they: a) were related to the patient by blood/marriage, b) lived in the same household as the injured person, and c) were between 16 and 65 years old. Exclusion criteria were as follows: a) inability to speak/read Norwegian, b) pre-injury learning disability, c) ICD-10 diagnosis of severe psychiatric or degenerative neurological illness; d) ongoing substance abuse, and e) family in which other family members require professional care.

Papers II and III: Patients in the RCT study had to meet the following inclusion criteria: a) aged between 16 and 65 years; b) be diagnosed with TBI of any severity according to the

ICD-10 classification system (S06.0–S06.9), c) have a Rancho Los Amigos Revised Scale score of 8, corresponding to purposeful and appropriate cognitive and behavioral functioning (200), d) be 6 to 18 months post-injury, e) be home dwelling. The family members were considered eligible if they: a) were between 18 and 65 years old and b) were actively involved in the patients' daily life with weekly contact. The exclusion criteria that applied to all the eligible participants were: a) inability to speak/read Norwegian, b) a pre-injury learning disability, c) an ICD-10 diagnosis of severe psychiatric or degenerative neurological illness, d) ongoing substance abuse, and e) family in which other family members required professional care.

4.5 Randomization and blinding

A computer-generated list with random block sizes of four to eight was used to randomize families (1:1) in the RCT. The randomization process was performed by an independent researcher and the families were provided information about group allocation by the Ph.D. candidate. Blinding of the participants and rehabilitation professionals with regard to group allocation was not possible in this study. However, the data were entered and managed with coded group allocation in the database by an independent research assistant, and the code was not broken until the primary analysis of the data from the first to the last follow up was completed. The randomization was performed before the first assessment point in the RCT, and thus, was not a baseline per definition according to the statistician. We labeled the first assessment point as “start of treatment”.

4.6 Study participants

Paper I: Of three eligible families, two individuals with TBI (one woman and one man) and four family members (two women and two men) consented to participate in the study. Ages ranged from 16 to 56 years with a mean (SD) of 40.3 (16.3) years. One individual had a severe TBI (GCS 3) and was 5 years post-injury, and one individual had a mild TBI (GCS 15) and was 1 year post-injury.

Papers II and III: A total of 278 patients were identified and assessed for eligibility, of which 251 met the inclusion criteria and were invited to participate. A total of 67 patients 69 family members consented to participation and were randomized to intervention (n = 33 families) and control (n = 34 group). Six families withdrew after randomization and before start of treatment, leaving 30 families in the intervention group and 31 families in the control group. A total of 124 participants (61 families) completed the assessment at start of treatment. Figure 2 displays flow chart for the RCT study with study recruitment and retention flow. Table 3 provides the sociodemographic characteristics and outcome measures scores of the participants in the RCT collected at start of treatment. There were no statistically significant differences between the groups at start of treatment.

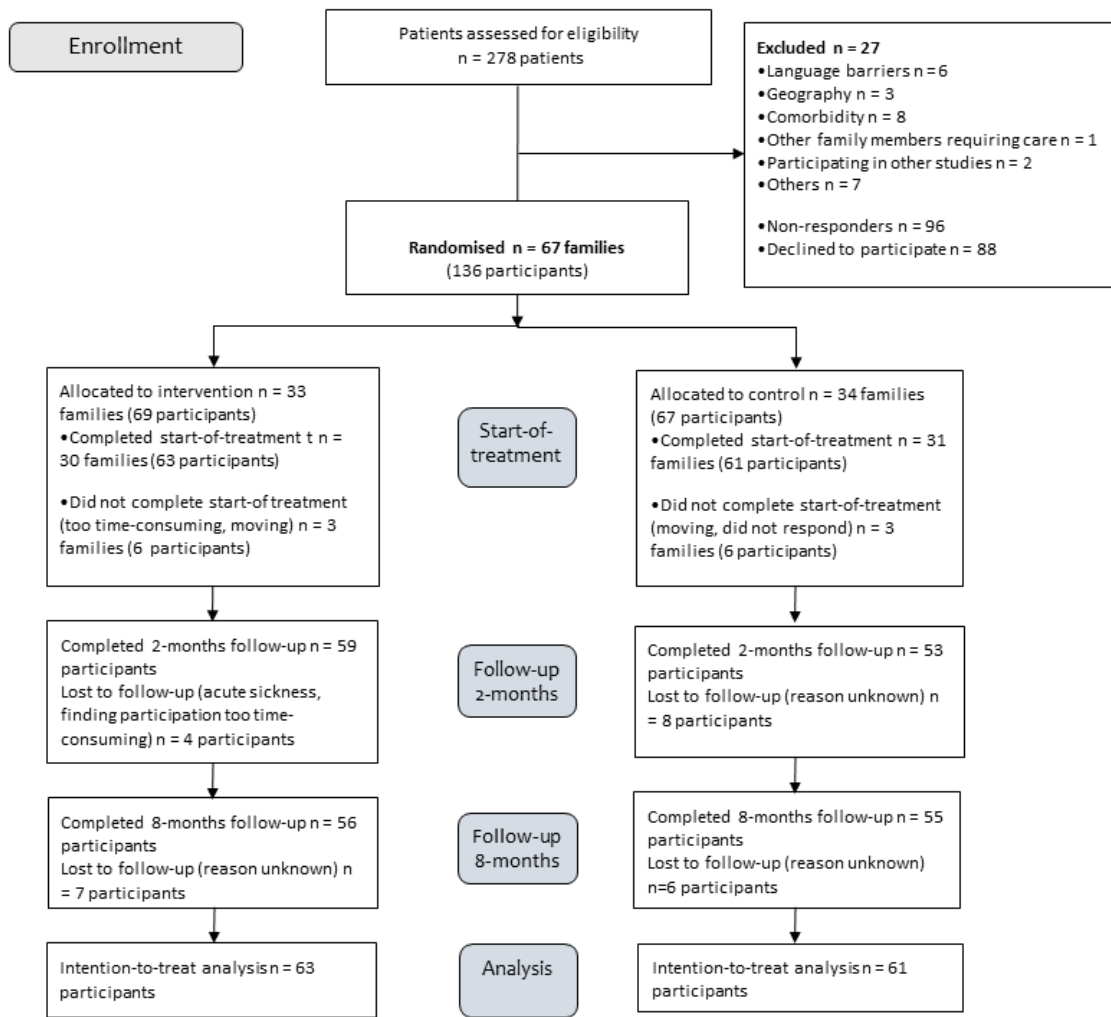


Figure 2 Flow chart of recruitment RCT

Table 3 Sociodemographic characteristics and outcomes at start of treatment

Variables	All n = 124		Intervention n = 63		Control N = 61	
	Patients (n = 61)	Family members (n = 63)	Patients (n = 30)	Family members (n = 33)	Patients (n = 31)	Family members (n = 30)
Age, years, mean (SD)	43.8 (11.2)	42.6 (11.3)	45.0 (11.8)	43.5 (12.2)	42.6 (10.3)	41.6 (10.0)
Female sex, n (%)	33 (54.1)	33 (52.4)	15 (50.0)	18 (54.5)	18 (58.1)	15 (50.0)
Married/cohabitating, n (%)	59 (96.7)	61 (96.8)	29 (96.7)	32 (97.0)	30 (96.8)	29 (96.7)
Kinship to the patient						
Spouse/partner, n (%)		58 (92.1)		29 (87.9)		29 (96.7)
Parent, n (%)		1 (1.6)		1 (3.0)		
Child, n (%)		4 (6.3)		3 (9.1)		1 (3.3)
Length of relationship in years						
< 1 year, n (%)	3 (5.0)	3 (4.9)	3 (10.3)	3 (9.4)		
1-5 years, n (%)	7 (11.9)	8 (13.1)	3 (10.3)	4 (12.5)	4 (13.3)	4 (13.8)
> 5 years, n (%)	49 (83.1)	50 (82.0)	23 (79.3)	25 (78.1)	26 (86.7)	25 (86.2)
Living with injured person, n (%)		57 (90.5)		28 (84.8)		29 (96.7)
Numbers in household, mean (range)			3.0 (0-6)		3.1 (1-6)	
Level of education						
Low, n (%)	16 (26.2)	15 (23.8)	9 (30.0)	9 (27.3)	7 (22.6)	6 (20.0)
High, n (%)	45 (73.8)	48 (76.2)	21 (70.0)	24 (72.7)	24 (77.4)	24 (80.0)
Preinjury employment status						
Employed/studying, n (%)	57 (93.4)		27 (90.0)		30 (96.8)	
Not employed, n (%)	4 (6.6)		3 (10.0)		1 (3.2)	
Post-injury employment status						
Employed/studying, n (%)	5 (8.2)	53 (84.1)	5 (16.7)	27 (81.8)		26 (86.7)
Partly sick-leaved, n (%)	33 (54.1)	4 (6.3)	12 (40.0)	1 (3.0)	21 (67.7)	3 (10.0)
Sick-leaved, n (%)	23 (37.7)	6 (9.5)	13 (43.3)	5 (15.2)	10 (32.3)	1 (3.3)
Injury characteristics						
Time since injury months, median (IQR)	11.4 (8.4, 15.9)		11.4 (8.3, 15.3)		11.4 (8.5, 16.8)	
GCS, median (IQR)	15 (14, 15)		15 (11.8, 15.0)		15 (14, 15)	

Mild TBI (GCS 13-15), n (%)	50 (82.0)				22 (73.3)		28 (90.3)	
Moderate TBI (GCS 9-12), n (%)	2 (4.9)				3 (10.0)			
Severe TBI (GCS 3-8), n (%)	8 (13.1)				5 (6.7)		3 (9.7)	
AIS, median (IQR), n (%)	1 (1, 3)				2 (2.0, 3.3)		1 (1.0, 2.0)	
Findings on CT/MRI, n (%)	18 (29.5)				11 (36.7)		7 (22.6)	
Falls, n (%)	23 (37.7)				11 (36.7)		12 (38.7)	
Traffic accidents, n (%)	19 (31.1)				10 (33.3)		9 (29.0)	
Mechanical object/force, n (%)	14 (23.3)				6 (20.0)		8 (25.8)	
Violence, n (%)	2 (3.3)				1 (3.3)		1 (3.2)	
Others, n (%)	3 (4.9)				2 (6.7)		1 (3.2)	
RPQ (n = 56) (mean, SD)	27.7 (11.1)				29.9 (10.9)		25.8 (10.9)	
Self-reported comorbidities, n (%)	11 (18.6)				6 (20.0)		5 (16.1)	
Outcome measures, mean (SD)								
Mental HRQL (MCS)	41.8 (9.9)	47.7 (9.0)	42.8 (10.4)	47.9 (9.8)	40.9 (9.4)	47.5 (8.3)		
Caregiver burden (CGB)		2.1 (0.6)		2.1 (0.6)		2.0 (0.5)		
Family functioning (FACES IV)	3.0 (1.1)	3.1 (1.2)	3.0 (1.1)	2.9 (1.2)	3.0 (1.2)	3.3 (1.1)		
Family communication (FCS)	65.7 (26.3)	66.4 (25.0)	67.1 (27.0)	61.1 (26.7)	64.4 (26.9)	72.3 (21.8)		
Family satisfaction (FSS)	55.6 (28.7)	55.3 (26.4)	56.9 (30.8)	50.9 (24.1)	54.4 (26.9)	60.2 (28.3)		
TBI specific HRQL (QOLIBRI)	58.1 (16.1)		59.2 (18.4)		57.0 (13.7)			
Depression (PHQ-9)	9.6 (5.1)	6.3 (4.3)	9.1 (5.7)	6.5 (4.2)	10.1 (4.5)	6.2 (4.4)		
Anxiety (GAD-7)	6.0 (4.2)	4.9 (3.7)	6.4 (4.5)	4.8 (3.3)	5.6 (3.9)	5.1 (4.2)		
Resilience (RSA)	107.2 (16.6)	113.9 (16.2)	107.9 (17.6)	116.3 (15.6)	106.4 (15.8)	111.3 (16.7)		
Self-efficacy (GSE)	30.1 (5.1)	31.8 (4.5)	30.0 (5.0)	31.3 (4.6)	30.1 (5.2)	32.3 (4.4)		

Abbreviations: GCS, Glasgow Coma Scale score; AIS, Abbreviated Injury Scale score; CT/MRI, Computed tomography/Magnetic resonance imaging; RPQ, Rivermead Post-Concussion Questionnaire; MCS, Mental Component Summary; CGB, Caregiver Burden Scale; FACES, Family Adaptability and Cohesion Evaluation Scale; FCS, Family Communication Scale; FSS, Family Satisfaction Scale, PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalized Anxiety Disorder Scale-7; RSA, Resilience Scale for Adults; GSE, General Self-Efficacy scale; IQR, interquartile range; SD, standard deviation

4.7 Data collection methods

Data were collected from the patients' medical records and through PROMs. A short questionnaire was designed for the purpose of collecting sociodemographic data at start of treatment.

4.7.1 Paper I

Data to evaluate the pre-defined success criteria comprised registration of attendance rate and home task completion, the participants' feedback, and notes made by the health professionals. The data were registered continuously throughout the study. Sociodemographic characteristics were collected and the participants filled out the PROMs in the first and the last session of the TBIFSI. Injury-related data were obtained from medical records.

4.7.2 Paper II and III

In the RCT study, the participants answered the PROMs at the three following time points: start of treatment, at 2-months (after completion of the TBIFSI), and 8-months follow-up, with similar time points for the control group. The participants in the control group received the PROMs at start of treatment and at 2-months follow up by mail, which contained an instruction letter. At 8-months, all participants received the questionnaires by mail and were offered a follow-up consultation by a physiatrist at the outpatient clinic. The planned 2-months and 8-months follow up were median 2.7 (IQR 2.3, 3.8) and 9.2 (IQR 8.2, 9.9) months after start-of-treatment, respectively.

The sociodemographic variables and outcome measures collected and presented in paper I, II, and III are displayed in Table 4.

Table 2 Sociodemographic variables and outcome measures presented in the respective papers (I, II, III)

Variable	Patients	Family members	Paper
Personal factors			
Age	X	X	I, II, III
Sex	X	X	I, II, III
Level of education	X	X	I, II, III
Pre-injury employment/studies	X		II, III
Current employment/studies	X	X	I, II, III
Self-reported comorbidities	X		II, III
Family factors			
Kinship to the injured person		X	I, II, III
Marital status	X	X	I, II, III
Number of people in the household	X		II, III
Living in the same household as the injured person		X	I, II, III
Injury-related factors			
Date of injury	X		I, II, III
Cause of injury	X		II, III
Glasgow Coma Scale score	X		I, II, III
Abbreviated Injury Scale Head Score	X		II, III
Rivermead Post-Concussion Questionnaire score	X		II, III
Intra cranial injury/findings on CT/MRI	X		II, III
Intracranial surgery	X		II,
Length of hospital stay (in days)	X		II, III
Patient-reported outcome measures - functioning			
Mental Component Summary	X	X	I, II, III
Caregiver Burden Scale		X	I, III
Family Adaptability & Cohesion Evaluation Scale, fourth edition	X	X	I, II, III
Quality of Life after Brain Injury questionnaire	X		I, II, III
Patient Health Questionnaire-9	X	X	II, III
Generalized Anxiety Disorder Scale	X	X	II, III
General Self-Efficacy Scale	X	X	II
Resilience Scale for Adults	X	X	II, III

The sociodemographic variables were registered as follows: age, sex, level of education (high/low), self-reported comorbidities (no/yes), pre-injury and current employment/studies (employed/partial sick-leaved/sick-leaved).

The family variables included kinship to the injured family member (spouse/parent/child), marital status (married/partner/single), and length of relationship (< 1 y/ 1-5 y/ > 5 y), living

in the in same household as the injured person (no/yes), and the reported number of people living in the household.

Injury-related variables were obtained from the patients' medical journal record, and included: date of injury, cause of injury (fall/traffic accident/mechanical object/violence/others), neuroimaging results of intracranial injury (no/yes), intracranial surgery (no/yes), length of hospital stay (days); GCS score (22), the AIS head score (25), and post-concussion symptoms assessed with the Rivermead Post-Concussion Symptoms questionnaire (RPQ) (201).

The GCS is a clinical instrument for assessing the depth and length of impaired consciousness and coma (22). Three different components are examined; eye opening, verbal response, and motor response. The scale range from is 3 to 15, where scores 3-8 indicate a severe TBI, scores 9-12 indicate a moderate TBI, and scores 13-15 indicate a mild TBI (22). The Abbreviated Injury Scale (AIS) Head score is a standardized classification system for rating injuries to the head on an ordinal scale from 1 (minor) to 6 (fatal) (25).

The Rivermead Post-Concussion Questionnaire assesses post-concussion symptoms (201), and was scored before first assessment point in the RCT. This is a 16-item scale that assesses the extent to which physical, cognitive, and behavioral symptoms during the past 7 days have been a problem compared to pre-morbid levels. The total score is the sum of all single scores, except for ratings of 1, which indicates that the symptom is no longer a problem. The total score ranges from 0 (best) to 64 (worst) (201).

4.8 Patient-reported outcome measures (PROMs)

Several self-reported outcome measures were used in the present research project, as recommended for evaluating complex interventions to increase the chance of capturing potential effects (202). The selection of outcome measures was based on several considerations. First, outcome measures were selected based on recommendations in the intervention manual with regard to targeted constructs. Second, psychometric qualities were considered and outcomes were selected based on reliability, validity, and responsiveness (203). Third, the selection of outcome measures was based on the Traumatic Brain Injury

(TBI) Outcomes Workgroup's recommendations of outcome measures used in the TBI research (44). The scores on the PROMs at start of treatment are displayed in Table 3.

4.8.1 Primary outcomes measures

Two primary PROMs were selected for this research project.

The Medical Outcomes 36-Item Short Form Health Survey

HRQL in patients and family members was assessed with the Medical Outcomes 36-Item Short Form Health Survey (SF-36), version 2 (134). This is a generic self-reported instrument for assessing HRQL within the following eight dimensions of functioning: physical functioning (PF), role physical function (RP), bodily pain (BD), general health (GH), vitality (VT), social functioning (SF), role-emotional function (RE), and mental health (MH). Total score ranges from 0 (worst) to 100 (best). Two global summary scores can be aggregated, namely the Physical Component Summary (PCS), which comprises the PF, RP, BD, and GH subscales, and the Mental Component Summary (MCS), which comprises the VT, SF, RE, and MH subscales (134). The PCS and MCS scores are transformed into T-scores based on US normative data with a mean value of 50 and a SD of 10. Scores below < 40 are considered impaired HRQL (204). The SF-36 is frequently used in TBI populations and has demonstrated good internal consistency with Cronbach's alphas ranging from 0.68 to 0.92 (132). The internal consistency of the MCS and PCS have been found satisfactory in a recent Norwegian study on individuals with moderate to severe TBI (205). The MCS was the primary outcome of interest in this study with a Cronbach's alpha of 0.82. In addition, the GH subscale was reported in Paper II to describe general health perceptions in the study population at the start of treatment.

License to use this questionnaire was obtained from the QualityMetric, Optum, Eden Prairie, MN, USA (license number QM051514). The PRO CoRE 1.5 software program's Smart Measurement System was used when scoring the data.

The Caregiver Burden Scale

Subjective caregiver burden was assessed with the Caregiver Burden Scale (CGB). This is a generic 22-item scale developed to capture subjectively experienced burden in caregivers (206). It and it has been used in relation to various diagnoses and disabilities. The CGB assesses burden in the following five domains: general strain (8 items), isolation (3 items), disappointment (5 items), emotional involvement (3 items), and environment (3 items).

Each item is answered from 1 to 4 (not at all, seldom, sometimes, and often). The total score ranges from 22 (worst) to 88 (best), and the total burden is expressed as the mean score of the 22 items. The mean score can be interpreted as follows: 1.00-1.99 points as low burden, 2.00-2.99 points as moderate burden, and 3.00-3.99 points as high burden (207). The CGB scale has previously been applied to Norwegian caregivers of individuals with severe TBI and demonstrated good internal consistency with Cronbach's alphas from 0.81 to 0.94 for the five dimensions (208).

4.8.2 Secondary outcome measures

The Family Adaptability and Cohesion Evaluation Scale – fourth edition

Family functioning was assessed with the Family Adaptability and Cohesion Evaluation Scale, fourth edition (FACES IV) (209). The FACES IV is a 42-item scale consisting of two balanced scales (flexibility and cohesion) and four unbalanced scales (disengaged, chaos, enmeshed, and rigid). The scales are used to capture the level of flexibility and cohesion within couples and family systems and include a circumplex ratio score ranging from 0 (worst) to 10 (best) attributed to the level of cohesion and flexibility within a family. A circumplex ratio score ≥ 1 indicates equal amounts of balance and unbalance in the family system. The circumplex ratio score was used in the present research project. In addition, family communication was assessed with the 10-item Family Communication Scale (FCS), which assesses communication skills within the family. Satisfaction with aspects of the family functioning was assessed with the 10-item Family Satisfaction Scale (FSS). All items are on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The raw scores of the FCS and FSS were recoded into percentile scores ranging from 10 (worst) to 99 (best).

The FACES IV has good construct validity, reliability and internal consistency with Cronbach's alphas ranging from 0.77 to 0.93 (209, 210).

The FACES IV was translated into Norwegian in conjunction with the present research project and with permission of the developer (see Appendix) (211). The questionnaire was translated into Norwegian by a professional translation agency. It was then reviewed by a professional family therapist and researcher to ensure proper terminology. Back translation was performed by a bilingual psychologist whose first language is Norwegian and whose second language is English. Inconsistencies were resolved in consensus meetings.

The Quality of Life after Brain Injury Questionnaire

Condition-specific HRQL in patients was assessed with the Quality of Life after Brain Injury (QOLIBRI) questionnaire (212). This is a 37-item questionnaire, comprising six subscales. Four subscales assess satisfaction with life and include cognition, self, daily life and autonomy, and social relationships. Two subscales assess how bothered the individual is regarding emotions and physical problems. The response scale ranges from 1 (not at all) to 5 (very). The scores on the two bothered subscales are reversed, and a total score is calculated ranging from 0 (worst) to 100 (best) (212). A score below 60 is suggested as a cut-off for impaired HQOL (204). The Norwegian version of QOLIBRI has been validated and has demonstrated satisfactory psychometric properties with Cronbach's alphas of 0.75 to 0.96 for the different subscales (213).

4.8.3 Additional outcome measures

The Patient Health Questionnaire – 9

Symptoms of depression were measured with the Patient Health Questionnaire-9 items scale (PHQ-9), which is used to evaluate the severity of depressive symptoms during the last two weeks (214). Responses range from 0 (not at all) to 3 (nearly every day). The total score range is from 0 to 27 points and can be interpreted as: mild symptoms (5–9 points), moderate symptoms (10–14 points), moderately severe symptoms (15–19 points), and severe symptoms

(20–27 points). The psychometric properties of the scale are satisfactory (214), and it has been proven as a valid and reliable measure for assessing symptoms of depression in TBI populations (215).

The Generalized Anxiety Disorder Questionnaire – 7

Symptoms of anxiety were measured with the Generalized Anxiety Disorder Questionnaire – 7 item scale (GAD-7) (216). The GAD-7 is used to assess symptoms of anxiety over the last 2 weeks. Responses range from 0 (not at all) to 3 (nearly every day). The total score ranges from 0 to 21 points and can be interpreted as follows: mild symptoms (5–9 points), moderate symptoms (10–14 points), and severe symptoms (15–21 points) (216). The GAD-7 has demonstrated satisfactory psychometric properties with Cronbach’s alphas ranging from 0.89 to 0.92 (216, 217).

The General Self-Efficacy Scale and the TBI Self-Efficacy Scale

Self-efficacy was assessed by using both a generic self-efficacy instrument and by an instrument specifically developed for individuals with TBI.

The General Self-Efficacy Scale (GSE) assesses the extent of a person belief in their own competence to handle stressful events and demands (218), and it was applied to both patients and family members. The GSE is a 10-items scale with responses ranging from 1 (not at all true) to 4 (exactly true), and scores ranging from 10 (worst) to 40 (best). The GSE scale has shown good internal consistency with Cronbach’s alpha values of 0.86–0.94 (219).

TBI-specific self-efficacy was assessed using the TBI Self-Efficacy Scale (TBI SES) (220). The TBI SES assesses the degree to which individuals experience to be capable to manage symptoms related to TBI, and consists of 6 items rated from 0 (worst) to 10 (best). Higher scores indicate higher levels of self-efficacy (220). Psychometric properties have not previously been reported for this scale. The TBI SES was not included in the papers and will not be presented further in this thesis.

The Resilience Scale for Adults

The Resilience Scale for Adults (RSA) assesses protective factors in individuals (165). This 33-item scale covers five dimensions (perception of self/future, social competence, family cohesion, social resources, and structured style). The responses are made on a 5-point scale, with total scores from 0 (worst) to 165 (best), and the scale has demonstrated good internal consistency with Cronbach's alphas ranging from 0.76 to 0.87 (221). The RSA was applied to both patients and family members.

4.9 Statistics

4.9.1 Sample size and power estimation

Sample size was determined based on the primary outcomes. For the MCS on the SF-36, the study on patients with moderate to severe traumatic brain injury by Andelic et al. was used (56) and we inserted 44 points (SD 12) with a difference of 5 points between the groups. With a power of 80% ($1-\beta$) and a significance level of 0.05, the predicted sample size was 66 patients, with 33 families in each arm of the RCT. For the CGB scale, we used Manskow et al.' study on Norwegian caregivers of persons with severe traumatic brain injury was used (208). A reduction of 0.4 points on the CGB scale was equal to a moderate effect size, and the power calculation yielded a sample size of 126 caregivers. We estimated that there would be two family members per patient.

4.9.2 Statistical analysis

Descriptive statistics were presented with means and standard deviations of normally distributed continuous data and medians and interquartile ranges (IQR) of skewed data. Categorical variables were presented as proportions in frequency (n) and percentage (%). Comparisons between groups were examined using parametric statistics for normally distributed continuous data and non-parametric analyses for skewed continuous data. Assumptions for normality of the data were evaluated by Kolmogorov-Smirnov test and/or

inspection of frequency distributions, histograms, and Q-Q plots. Cross tabulations and Pearson's chi-square test were used to assess differences in categorical variables. Missing items were replaced with the mean score of the scale or subscale. All tests were 2-sided and assumed a significance level of $p = 0.05$. Assumptions of all statistical tests were not violated.

Paper I: Descriptive statistics were used to present personal, sociodemographic, and injury-related variables. Median scores and IQR of the primary and secondary outcome measures were presented.

Paper II: Descriptive statistics were used to present personal, sociodemographic and injury-related variables, in addition to scores on the outcome measures. Internal dependency within families was evaluated by calculating the intraclass correlation coefficient (ICC). Based on an ICC value of 0.11, the internal dependency within the same family was considered low (222). Differences between patients and family members were examined using independent t-tests. Univariate analyses were carried out to examine associations between independent variables and the dependent variable MCS on the SF-36. Independent variables with a p-value of ≤ 0.1 were selected as potential candidate variables for the linear multiple regression analysis, and a maximum of ten independent variables were determined based on the sample size (223). Correlations between independent variables were evaluated by performing Spearman's Rho test, and independent variables with a correlation coefficient of >0.7 were not entered together in the multiple regression. Multicollinearity was evaluated with the variance inflation factor, and normality assumptions were assessed by inspection of the histogram and Q-Q plots. The assumptions of the regression model were not violated. Model estimates and statistics were presented with unstandardized beta coefficients with 95% confidence intervals (CIs), R^2 , adjusted R^2 , and F-value.

Paper III: A linear mixed model for repeated measurements with a random intercept was carried out to examine between-group mean differences on the primary and secondary outcome measures at all assessment points of the RCT. The main effect of treatment, the main effect of time, and the interaction term between treatment and time were applied as fixed effects in the statistical model. Random effects were the subjects. Results were presented as mean differences with 95% CIs for all three assessment time points. The analysis was conducted with an intention-to-treat (ITT) approach.

The statistical analyses were carried out using the Statistical Package of Social Sciences (SPSS) software (Chicago, IL, USA) version 25 and StataCorp LLC (STATA) software (College Station, Texas, USA) version 16.

4.9.3 Study arms

This section gives a description of the treatment provided in the two study arms of the RCT. In both the intervention and the control group, patients received the regular follow-ups carried out by the multidisciplinary team at the specialized TBI outpatient clinic at OUH. The follow-ups consisted of one-to-one contacts and an educational group. The aims of the specialized follow-ups were to provide advice and support to the individuals with TBI with regard to managing symptoms and finding balance between rest and activity, and to provide psychoeducational support to resume daily life activities and return to work. The educational group comprised four 2-hour group sessions for the patients, each led by different multidisciplinary team members. In the group sessions, the patients were provided with information about the consequences of TBI and advice on how to return to daily life activities and work. Additionally, patients are given the opportunity to share experiences, thoughts, and concerns with each other in the educational group.

In total, the patients attended consultations with the following individuals and groups during the RCT period (n [%]): educational groups 10 (16%); examination and individual consultations by psychiatrist 59 (97%); occupational therapist 21 (35%); social worker 21 (35%); psychologist 16 (26%); neuropsychologist 8 (14%); and physical therapist 15 (26%). No statistically significant differences were evident in the amount of received treatment at the outpatient clinic between the intervention and the control group.

Intervention arm

The families in the intervention group were supplied with the family intervention, TBIFSI (1). The Ph.D. candidate, a physical therapist with MSc in rehabilitation and clinical experience from specialized and primary health care service, was the group facilitator responsible for delivering the intervention. A nurse and an occupational therapist from a municipal health care service attended as co-facilitators for ten of the families in the intervention group. All

group facilitators had received a 2-day training course in the intervention from one of the intervention developers followed by training sessions and participated in the feasibility study of the intervention.

Control arm

The family members in the control group were invited to attend an educative group-session of 2.5 hours. The group session was led by an occupational therapist and a neuropsychologist from the multidisciplinary team. In this group session, the family members were given information about TBI and its common consequences, and information about resuming daily life activities, but not specifically about family functioning.

4.9.4 Treatment fidelity

To evaluate the main group facilitators' adherence to the TBIFSI manual, a municipal health professional evaluated fidelity based on elements published in a previous publication by Winter et al. (188). The elements comprised the following: a) explained purpose of each session clearly, b) used appropriate pace and language, c) showed sensitivity to the participant responses, d) responded clearly to participants' questions, e) demonstrated overall fidelity to the TBIFSI manual, and f) explained the next step of the intervention. The fidelity items were rated as poor, good, or excellent by a municipal health professional after completion of the family intervention for nine (30%) of the families in the intervention group. All items concerning fidelity were rated as excellent by the municipal health professional. As part of the evaluation of fidelity, the participants in the intervention group were asked to rate their satisfaction with the TBIFSI sessions, and with the group facilitators' delivery of the sessions after completion of the intervention. A numeric scale from 0 (not at all satisfied) to 10 (very satisfied) were used for the purpose. The participants were very satisfied with the intervention sessions (mean score of 9.3; SD 0.9) and with the way the sessions were delivered by the group facilitator(s) (mean score of 9.6; SD 0.6).

5 Summaries of papers

5.1 Paper I

This study aimed to evaluate the feasibility of the Norwegian version of the family intervention and the study procedures of the intervention arm in the RCT, including the participants' willingness and ability to attend in the TBIFSI sessions, appropriateness of intervention topics, the leadership structure of and collaboration mode with the municipal health professionals, and the data collection methods.

Two families were included, comprising six persons with a mean (SD) age of 40.3 (16.3) years. One individual with mild TBI (GCS 15) and one individual with severe TBI (GCS 3) were included who were 1 year and 5 years post-injury, respectively. Both individuals with TBI reported physical, cognitive, and behavioral problems that they attributed to the TBI. Three out of four family members lived in the same household as the injured individual. The families received the family intervention over the course of 8 to 10 weeks.

Overall, the families expressed finding the topics relevant and recognizable, which was in line with the health professionals' impression and was supported by a high attendance rate (98%) and home task completion (100%). However, feedback from the participants indicated the need for minor adjustment of wording and language tone in examples provided in the sessions. Furthermore, the need for individual adjustments to compensate for potential cognitive impairments after TBI became evident. Some logistic challenges with regard to finding time to attend the sessions were expressed by both the families and the municipal health professionals. The collaboration mode with the municipal health professionals and leadership structure of the sessions worked well. The participants answered the outcome measurements within the given time frame of 70 minutes and with <10% missing variables.

With minor modifications of the Norwegian version of the TBIFSI, the family intervention and study procedures of the intervention arm of the RCT were feasible. To reduce the burden for the families and succeed in recruiting families for the larger scale trial, a pragmatic approach with applied flexibility in intervention delivery was considered necessary in the RCT. The effectiveness of the family intervention is explored in the RCT and presented in Paper III in this thesis.

5.2 Paper II

The aim was to describe aspects of mental health and family functioning in home-dwelling patients with TBI and their family members, and to explore individual-functioning- and family-functioning-related factors that were associated with mental health in patients and family members.

Start of treatment assessments were obtained from 61 patients (54.1% women) with a mean (SD) age of 43.8 (11.2) years, and 63 family members (52.4% women) with mean (SD) age of 42.6 (11.3) years. At start of treatment, the median (IQR) time since injury was 49 (36, 69) weeks. Most patients (82 %) had sustained a mild TBI as classified by GCS and AIS scores, and 92 % of the family members were spouses/partners of the injured individual and most had been in the relationship for more than 5 years.

Independent sample t-tests showed that at start of treatment the patients reported significantly worse in: mental HRQL on the MCS (mean diff. 5.9 points, $p = 0.001$), general health on the GH subscale (mean diff. 8.6 points, $p < 0.001$), symptoms of depression on the PHQ-9 (mean diff. 3.3, $p < 0.001$), resilience on the RSA (mean diff. 6.7, $p = 0.025$), and self-efficacy on the GSE (mean diff. 1.7, $p = 0.044$) compared to the family members. Among the family members, 57 % reported mild to moderate symptoms of depression. Multiple linear regression analysis revealed that gender ($\beta = 2.56$ and $p = 0.038$), depression ($\beta = -0.79$ and $p < 0.001$), anxiety ($\beta = -0.64$ and $p = 0.003$), and resilience ($\beta = 0.12$ and $p = 0.007$) were significantly associated with mental health (MCS on the SF-36). These factors explained 56% of the variance in the MCS variable, and the model was statistically significant ($p \leq 0.001$).

In conclusion, the main disease burden was on the patients at start of treatment in the RCT, but the family members reported emotional distress in terms of depressive symptoms. Being female, having more severe symptoms of depression and anxiety, and exhibiting lower levels of resilience were significantly associated with reduced mental health in both patients and family members.

5.3 Paper III

The primary aim was to determine the effectiveness of the TBIFSI in improving mental HRQL, TBI-specific HRQ, caregiver burden, and family functioning, communication, and satisfaction. We hypothesized that significant improvements in mental HRQL, TBI-specific HRQL, caregiver burden, and family functioning would be evident in the intervention group when compared to the control group. The secondary aim was to examine within-group differences in individual and family functioning in the treatment period (i.e., from start of treatment to 2-months follow-up).

Sixty-one patients and 63 family members recruited from the outpatient clinic at OUH were allocated to the intervention group (n=30 families), consisting of specialized follow ups for the patients and the TBIFSI, and the control group (n=31 families), consisting of specialized follow ups for the patients and a 2.5 hour group session for the family members. A mixed model analysis with a repeated measurement design and ITT approach showed no significant mean differences between the intervention and the control group at any of the three assessment points in the RCT ($p > 0.05$). From start of treatment to the 2-months follow-up, the participants in the intervention group significantly improved by 2.4 points ($p = 0.028$) on the MCS, -0.2 points ($p = 0.003$) on the CGB, 0.23 points ($p = 0.027$) on the FACES IV circumplex ratio, 6.8 points ($p = 0.002$) on the FCS, and 5.7 points ($p = 0.030$) on the FSS. Significant within group improvements in the control group were observed on the QOLIBRI with a change in mean scores of 6.1 points ($p = 0.002$) from start of treatment to the 2-months follow-up.

In conclusion, receiving a theory-based eight-session TBIFSI in addition to specialized TBI outpatient follow-ups was not superior to receiving specialized follow-ups only, in improving individual and family functioning in patients with mild to severe TBI and their family members. Within-group changes implied that the TBIFSI might have contributed to an acceleration of the recovery process during the intervention period.

6 Discussion and main findings

Several methodological aspects and study limitations are discussed in the respective papers included in this thesis. In the following section I elaborate further on some methodological considerations related to the three papers included in this thesis that should be taken into account in the interpretation of the results.

6.1 Methodological considerations

6.1.1 External and internal validity

External validity refers to the extent to which the results are applicable across contexts and clinical practice settings (224). The CONSORT guidelines emphasize the importance of providing a description of the contextual factors, such as study setting and data collection to make it possible to evaluate external validity. Internal validity refers to the reliability and accuracy of data to provide answers about cause-effect and is related to study design and the control of confounding factors (224). In these sections, I discuss aspects of external and internal validity in light of the pragmatic elements of this research project.

The present research project was designed as an RCT, which is considered the most rigorous design in evaluations of new treatment approaches due to the control of confounding factors (224). Although the intervention group received an extra 12-hour family intervention, the patient in both groups received ordinary multidisciplinary treatment at the outpatient clinic. Control groups that receive comprehensive treatment may lead to reduced effect sizes compared to RCTs where control groups receive little or no treatment (225). The study was carried out in a clinical setting, which one could consider to increase the external validity of the results within the specialized rehabilitation context. However, the comprehensive treatment as usual provided in this study might reduce the generalizability of the results to other contexts.

As recommended in guidelines for the evaluation of complex interventions (226), we conducted a feasibility study as preparation of the RCT. Feasibility studies are small studies done before larger scale trials to assess the elements of an intervention or of study procedures

(227). The 2-day training course in advance followed by the feasibility study allowed us to practice on the intervention manual and the study procedures of the intervention arm, which contributed to increased internal validity in the RCT. This study also enabled us to make appropriate modifications of the Norwegian version of the TBIFSI, which can be considered a strength because complex intervention often need to be adjusted to the context in which it is provided (226).

Further, intervention fidelity was evaluated by measurement of task completion, and the overall adherence to the TBIFSI was evaluated as satisfactory. The families reported satisfaction with the sessions and the group facilitators' delivery of them. This contributed to both internal validity (adherence to the intervention manual) and to external validity (possibility to replicate the treatment) (228).

The feasibility study showed that a pragmatic approach in the RCT was necessary to reduce the families' burden of participation and to succeed with recruitment of families in the RCT. Pragmatic trials differ from an explanatory trials in that they endeavor to achieve similarity to normal clinical practice, unlike explanatory trials which aim to provide answers about whether an intervention works under ideal circumstances (229). Similarity to regular clinical practice increases the generalizability of results, but may decrease the internal validity because the study conditions are less controlled (229). However, an RCT does not need to be either exclusively pragmatic or exclusively explanatory, but may comprise qualities of both (230), as was the case in the present research project and will be elaborated upon further.

6.1.2 Eligibility criteria and study population

We included patients who had an ICD-10 diagnosis of TBI of any severity, however, with a Rancho Los Amigos score of 8 as a criteria for cognitive functioning. Including a mixed group of patients with different injury severities have been considered a limitation because it merges different perspectives (91). However, the heterogeneity of the patients in the RCT can be considered a pragmatic element that may have increased external validity because it reflected the heterogeneity found in the larger TBI population.

The main cause of injury among the patients were falls, which aligns with the findings in epidemiological TBI injury profiles (35, 231). Furthermore, the distribution of TBI severities found in the present study was consistent with that reported in other studies on patients admitted to trauma centers (34). The patients with mild TBI represented the proportion of patients who exhibit PPCS and thus were not representative of the larger mild TBI population. However, this larger mild TBI group might not experience extra strain on the family members and family system. Approximately 50% of the included patients were women, which was higher than reported in other studies on hospital-admitted patients with TBI (231). However, according to data from the Quality Registry for the outpatient clinic at OUH, 10% more women than men are referred to the outpatient clinic (reference: personal communication with the Quality Registry staff).

All patients were recruited from the same outpatient clinic, specialized in TBI rehabilitation. The results may not be applicable to other clinical settings such as municipal health care settings. However, patients with mild to moderate TBI were also referred to the outpatient clinic by their general practitioner in case of PPCS. Consequently, the validity of our results are not limited to those admitted to emergency room/trauma/hospitals because they also encompassed patients that did not seek immediate medical assistance after the TBI.

Although we included patients of all TBI severities in this study, the more severely injured were the minority. Caution should therefore be applied when generalizing the results to families facing more severe injuries. Furthermore, although we applied a broad definition for "family member" and allowed for various kinships, most patients selected their partner or spouse for participation. Consequently, our results may not necessarily be applicable to other family members, or the extended family. We excluded individuals with insufficient command of Norwegian, ongoing substance abuse, and families providing extensive care to other family members. Hence, our inclusion criteria were not merely pragmatic in nature, but the study population may be representative of an adult population with TBI, and in particular those with mild complicated TBI that experience PPCS.

6.1.3 Collaboration with the municipal health care service and choice of intervention facilitators

Involvement of municipal health professionals was particularly relevant in this research project because the TBIFSI was designed to be delivered by allied health professionals in different contexts (1). Furthermore, the timing of intervention delivery at 6 to 18 months post-injury was set to a stage of the recovery process when many of the formal rehabilitation services should be provided by the municipal health care service. None of the health professionals had extensive psychological or family therapy expertise. Nevertheless, the intervention providers in this study reflected health professions commonly found in the municipal setting, which may have contributed to external validity and could be considered a pragmatic element of this study. Research have also demonstrated that non-psychologists can take on new roles and apply psychological techniques, such as CBT with adequate training and supervision (232).

6.1.4 Self-reported outcome measures:

The selection of PROMs in this study was based on the recommendations in the literature (44), concept targeted in the TBIFSI, as well as measurement properties of the instruments. Thus, we selected outcome measures that reflected a broad range of health and functioning, as is recommended for the evaluation of complex interventions (202). However, there are some methodological considerations pertaining to the use of PROMs as outcomes.

Using the generic SF-36 as one of our primary outcomes enabled us to compare mental HRQL between patients and family members and could allow for further comparison across conditions and populations. Moreover, the combination of a generic and a TBI-specific HRQL instrument provided a health profile of the patients that covered areas typically affected by TBI, which aligns with recommendations for assessment of HRQL in TBI individuals (132, 204).

Caregiver burden is a central concept in the ABI literature (156). However, there is no clear consensus on how the term should be defined or what it entails (157). Various instruments have been employed in research, which can make comparison of results difficult. The burden

on caregivers might also be reflected in other outcome measures, including measures that capture symptoms of depression and anxiety.

The FACES IV is considered a valid and reliable instruments for assessment of family functioning (209, 233). It does not provide any instructions to the respondents for how the family should be defined, and thus; we do not know whether the responses on this questionnaire reflected mainly the couples that participated in the study or whether they included the more extended family. Furthermore, some participants may have considered being asked about family functioning personal. This could have led to a social-desirability response bias (234), reflecting desired or socially accepted family patterns rather than the actual family functioning.

Moreover, the process of filling out the FACES IV and the other PROMs may have generated discussions and raised awareness of family concerns among the participants in the control group as well. In another RCT of a stroke intervention for families, participants in the control group reported that the assessments facilitated reflections, adjustments, and help-seeking behavior (235), which is also a possibility in the present RCT.

6.1.5 Statistical considerations

Sample size and power calculation

For the feasibility study described in Paper I, no formal sample size calculation was performed. Recommendations for sample sizes in pilot and feasibility studies are inconsistent but because such studies may serve several purposes it depend on the study objectives (236). The sample size in the feasibility study corresponded to 6% of the estimated sample size in the intervention arm of the RCT and was a result of a limited number of eligible patients in the recruitment setting, a shortage of research time line, and the access to human and financial resources. The small sample size clearly limited the external validity of our findings. However, it was in line with a recommendation for sample sizes in pilot studies described in a study by Stallard et al., who suggested a sample size of 0.03-times the sample size planned for the larger scale trial (237).

The sample size calculation in the RCT (Papers II and III) was determined based on the primary outcome measures, the MCS and the CGB scale. The calculation for the MCS estimated 66 patients, equal to 33 families in each study arm. We succeeded in reaching the estimated sample size of patients but were not able to include the estimated sample size of two family members per patient. Thus, the RCT was inadequately powered for the CGB outcome measures, which increased the risk for making a Type II error. That is, to not reject the hypothesis of no statistical difference or effect when such difference or effect does exist (223).

Randomization and blinding

We used a computer-generated list with random block sizes of four to eight for randomization of families in the RCT. The use of random block sizes reduced the risk of predicting allocation sequences (238). However, a limitation of the study design was that the first assessment point was after the families had been allocated. Knowledge of group allocation might have influenced the participants' responses to the PROMs and the internal validity. However, this decision was based on consideration of burden for the participating families, and for logistics and administrative purposes. Furthermore, blinding of participants and health professionals to group allocation was not feasible in this study, but the data were collected and managed by blinded research assistants and the group allocation code was not broken until the primary analyses at the 8-months follow-up was completed.

Recruitment of families

Slow inclusion was a challenge in this study, with the final response rate corresponding to 27% of all eligible patients. Recruitment challenges are common in many clinical trials, and it has been suggested that less than half of all eligible participants will consent to participation (239). The most common reasons given for declining participation in the present RCT were lack of time and finding the intervention too comprehensive. The recruitment was further complicated by the fact that the study design required participation from both the patients and at least one family member. The high rate of non-responders may have limited generalizability.

Correspondingly, as discussed in Papers II and III, a possible selection bias might have occurred in this project. A non-responder or volunteer bias occurs when those who consent to participate differs characteristically from those who decline participation (240). This is a potential concern because the families in this study had balanced levels of family functioning and high levels of family communication at start of treatment. It is possible that families who found it too difficult to engage in a family intervention study have more troubled family dynamics, however, we could not collect any data from them. Another explanation of the response rate might be that the patients with mild TBI were all given a good recovery prognosis. Thus, some families might not have felt burdened to the extent that they were in need for a comprehensive family intervention.

Drop out, retention, and attendance rate

In the RCT, 8.8% of the participants withdrew after randomization and before the first assessment point, and 9.7% and 10.5% were lost to follow-up at 2-months and 8-months, respectively (Figure 2). There was no statistically significant difference in drop outs between the intervention and control group. Data from at least one time point were available for 91% of the participants. Loss to follow-up is common in longitudinal studies on persons with TBI across injury severity levels and may impose systematic bias (241, 242). Despite not being clear-cut, it has been suggested that <20% loss to follow-up is considered acceptable regarding external and internal validity (243). The percentage of families discontinuing the family intervention in this study (6.3%) was lower than in other single-family intervention studies that have reported attrition rates of >20% (187, 192, 193).

In general, the attendance rate of the TBIFSI sessions was high, which might be a result of the flexibility applied in the intervention delivery. Four families asked to combine the two first and two last sessions to minimize use of time. Flexibility in interventions is recommended when requiring family members to attend face-to-face sessions (185). According to the TBIFSI manual, the intervention is supposed to be delivered over a course of eight weeks (1), but the flexibility in timing of sessions in the present study resulted in some variation in its duration.

Statistical analysis

In line with the CONSORT recommendations for pilot and feasibility studies (244), predetermined success criteria were used to evaluate feasibility in Paper I. The qualitative and quantitative data were analyzed descriptively. A limitation in the feasibility study was that we did not use quantitative measures for participant satisfaction, acceptability, and applicability, which would have allowed for a more systematic data collection. Nevertheless, the combination of quantitative data (attendance rate) and qualitative feedback (participants' feedback) provided useful information about the feasibility of the TBIFSI. Qualitative data were obtained through open-ended questions to the participants concerning participation, relevance of content, and potential harms and benefits. We only visually inspected median (IQR) scores on the primary and secondary outcome measures because the objective was to evaluate the participants' capacity and ability to fill out the selected PROMs.

Paper II involved a multiple linear regression analysis to examine statistical dependency between independent variables (individual-functioning- and family functioning-related factors) and the dependent variable (MCS on the SF-36). We followed the recommendation of having at least ten observations for each independent variable in the model (223). Age did not fulfill the criteria of $p \leq 0.1$ in the univariate analysis, but was included to adjust for variation in the study population. We combined the patients' and family members' responses in the regression analysis. By doing so, we were not able to include injury-related variables or outcome measures answered by patients or family members only.

In Paper III, a linear mixed model analysis for repeated measurements was performed to account for the hierarchical structure of the data (245). Data were situated at the three following levels: repeated measures (level 1), nested in the subjects (level 2), that were nested within families (level 3). However, because the internal dependency was evaluated as low based on an ICC value of 0.10 (222), the family variable was not included as a random effect in the final model. Further, all participants were analyzed according to an intention to treat approach as recommended by the CONSORT guidelines for parallel-group RCTs (224). We did not adjust for baseline differences in the mixed model analysis according to statistical advice because the first assessment time point was not defined as a baseline per se, and treatment was included as a fixed effect in the mixed level model.

6.2 General discussion

In this section, I first discuss the main results of the feasibility study (Paper I), and this discussion also cover some methodological aspects. Thereafter, I discuss the results from the RCT (described in Papers II and III). As previously mentioned, the MCS on the SF-36 was described using different terms in Paper II (overall mental health) and Paper III (mental HRQL). In the general discussion of the results in this thesis, I use the term mental HRQL when referring to the MCS for the purpose of consistency.

6.2.1 Feasibility of the TBIFSI (Paper I)

Although the TBIFSI was based on evidence-based approaches derived from CBT and family therapy, the intervention was culturally sensitive and originally developed based on experiences from the Latin American rehabilitation field (1). Prior to this study, the TBIFSI had been tested in a small RCT pilot study on eight Latin American families facing spinal cord injury (1). This pilot study demonstrated significant improvements in emotional distress, caregiver burden, and problem-solving skills compared to the control group (1). However, there were large differences in individual and contextual factors between the pilot study and our feasibility study, including patient diagnosis, the family setting, and access to formal rehabilitation services. Furthermore, the Latin American pilot study focused on preliminary effects of the TBIFSI, whereas the present feasibility study addressed the acceptability and study procedure of the intervention arm in the RCT.

Acceptability refers to perceived appropriateness of an intervention and can pertain to the perceptions of both those who receive the intervention and those who deliver it (246). One of the factors that influence families' willingness to engage in research is burden of participation (247). Family interventions that require face-to-face meetings may be a challenge for busy caregivers. Although families in the feasibility study were perceived to be active and engaged in the session, which were supported by the high attendance rate and completion of home tasks, some logistic challenges emerged with regard to scheduling the sessions, similar to what have been described by others conducting family interventions studies (188, 192, 248). We decided to allow for the TBIFSI to be delivered in the families' residences when appropriate to facilitate the attendance.

Despite common cognitive impairments due to TBI, such as memory loss (2), the systematic review by Kreitzer et al. found that few interventions reported modifications to accommodate for such impairments (184). However, the results from the feasibility study indicated that parts of the TBIFSI could be challenging to comprehend and follow due to cognitive impairments after severe TBI. This accentuated the importance of individual adjustments to the content to accommodate unique needs, and for group facilitators to have sufficient knowledge to recognize such challenges.

No clear recommendations exist for timing intervention delivery optimally (247, 249). We used the feasibility study as an opportunity to evaluate whether the intervention could be relevant for family members < 18 years of age and for families in later stages of recovery. Thus, we allowed for the inclusion of a family 5 years post-injury whose participating family member was 16 years old. Although we could not make any definitive conclusions based on the views of this single family, they expressed that the intervention would have been more beneficial at an earlier phase of the recovery. Additionally, the 16-years-old family member stated that he found the intervention less relevant for him at that point.

Based on this, we kept the RCT inclusion criteria for the age of family members between 18 and 65 years, as recommended in the TBIFSI manual. A potential consequence of this decision was that we included few children in the RCT. Because the incidence rate of hospital-admitted patients in Oslo is lower than in other countries (37), we extended the time frame for the maximum time since injury to 18 months to enhance the number of eligible families in the RCT.

Based on the purpose and objectives of feasibility, the study provided us with information about the *à priori* success-criteria. Moreover, because the acceptability and feasibility of interventions vary among different contexts, the present study can contribute to increased knowledge about potential challenges and aspects of feasibility for others planning larger scale trials in similar contexts.

6.2.2 Aspects of mental HRQL and family functioning in patients with TBI and their family members (Paper II)

Paper II presents data from the study participants included in the RCT at the start of treatment, approximately 1 year (median) after the TBI. We found that the patients' mental HRQL was diminished, which was in line with previous research encompassing patients of all TBI severities that have assessed HRQL in the first year after TBI (7, 56, 250). However, Scholten et al. found that HRQL in the group of individuals with mild TBI was comparable to that of the general population one year post-injury (7). However, most patients in the present study had a mild TBI with PPCS, which has been associated with reduced HRQL (137, 138). Furthermore, the patients also reported TBI-specific HQOL below the suggested cut-off on the QOLIBRI (204). The mean QOLIBRI score in the present study was lower compared to another Norwegian study on individuals with mild to severe TBI at 1 year post-injury (58 points vs. 67 points) (213), indicating that TBI posed a significant burden to the patients in the present study. The disruptions to daily activities and role functioning reported after mild TBI and a protracted course of recovery (251), may have negatively influenced the patients mental HRQL.

Regarding family members' mental HRQL, prior studies have reported HRQL in caregivers after severe TBI to be significantly lower than that of the general population in the acute phase after TBI (145) and in later stages of recovery (8, 87). In the present study, most of the family members reported mental HRQL comparable to that of the general population (204). Our findings were aligns with another study that included family members to non-hospitalized individuals with mild TBI where the family members' mental HRQL was comparable to general population levels in the first year (252). After severe TBI, prior studies have found that cognitive impairments and behavioral changes in the injured individuals are negatively associated with the family members' HRQL (9, 87). Because most patients in the present study had mild TBI, it is possible that the family members' mental HRQL might have been less affected than in cases of more severe injuries. This may be because the family members in our study faced less demanding caregiver tasks than caregivers of individuals with more severe injuries. A study by Carlozzi et al. demonstrated that those caring for individuals with less functional impairments exhibited better HRQL than those who cared for individuals with lower functioning (253).

6.2.3 Emotional distress

At start of treatment, the patients' mean score on the PHQ-9 and the GAD-7 indicated mild to moderate levels of depression and mild anxiety. Depression has been found to be prevalent the first year following TBI (64), and especially among those with mild TBI seeking medical treatment and experiencing post-concussion symptoms (75, 254). The presence of PPCS after a mild TBI can lead to a more unpredictable life course, which could explain the findings of increased emotional distress in the patients in the present study. Furthermore, depression and anxiety are common in individuals with TBI across severities (66).

In spite of mental HRQL within the normal range at the start of treatment, the family members' scores on the PHQ-9 indicated increased emotional distress. More than 50% had a mean score above the cut-off for mild depression (214). Elevated levels of emotional distress are consistently reported in prior studies on caregivers to individuals with TBI (12, 86, 255, 256). Jones et al., however, found no increased emotional distress in family members of persons with mild TBI.(252). In a recent study the patients' HRQL was associated with emotional distress in family members, (257), and also reduced social participation in individuals with severe TBI (160) and caregivers' perception of patient depression (258) have been associated with increased psychological distress in family members. This points to the reciprocal relationships of mental health and functioning within the family system, which may be of relevance in this study as well.

6.2.4 Factors associated with mental HRQL in patients and family members

In Paper II, we sought to examine associations between the mental HRQL on MCS and individual-functioning-related factors and family-functioning-related factors. Identifying these factors can enable the design of family interventions that can promote positive outcomes in mental HRQL for both patients with TBI and their family members. As shown in Paper II, mental HRQL on the MCS (SF-36) was explained by the following factors: gender, symptoms of depression and anxiety, and resilience.

Female gender was significantly associated with lower mental HRQL at the start of treatment, which aligns with previous findings on both the general population (259) and on individuals

with TBI (7, 205). Of the individual-functioning-related factors, emotional distress was most strongly associated with reduced mental HRQL. It is well known that psychological distress is associated with HRQL in patients with TBI, (141, 143, 260-262) and in caregivers to individuals with TBI (9, 145, 263). Moreover, resilience was also significantly associated with mental HRQL in patients and family members. Resilience and self-efficacy capture motivational processes and adaptive coping related to the consequences of TBI (177). Both self-efficacy and resilience were included as independent variables in the statistical model presented in paper II, but only resilience was found to be significantly associated with mental HRQL. Other studies on individuals with TBI (264, 265) and caregivers (181, 266) have found similar associations. Our results serve to illustrate the buffering role resilience play towards the adverse effects of TBI, and underpin the value of a strength-based approach in rehabilitation. Patients and family members with higher levels of resilience may have exhibited more optimistic views and applied skills to manage the TBI-related challenges more effectively. Anderson et al. found that resilience was associated with better mental health in family members, mediated through hope (181).

6.2.5 Caregiver burden

Caregiver burden was only discussed briefly in Paper III but is discussed further in this section of the thesis because it was a core concept in this research project. As presented in Paper III, the mean level of CGB at start of treatment corresponded to a moderate level of burden (206), and 62% of the family members scored moderate or higher levels of caregiver burden. As we further explored some of the specific subscales on the CGB scale, not presented in Paper III, we found that the domains isolation and general strain were most affected. Our results aligned with those found in other studies (87, 159, 208). However, these studies included caregivers to individuals with severe TBI, and one might expect the level of caregiver burden to be lower in the present study due to the majority of individuals with mild TBI. Although we included all severities of TBI, our results indicate that even individuals with mild TBI and a protracted course of recovery pose a significant burden to the family members. In the study by Manskow et al., lack of social network strongly predicted caregiver burden at one year post-injury (11). A possible explanation for our findings is that the family

members in our study did experience decreased social participation due to their injured family member, as reflected in the isolation subscale on the CGB.

The caregiver burden improved over time in both groups, and the CGB mean score at the 8-months follow up in the RCT corresponded to a low level of burden. The decreased burden could potentially reflect the natural course of recovery of mild TBI where functioning in daily life and participation restrictions improves over time (267) and thereby lessens caregiver burden. By contrast, studies on caregiver burden after severe TBI have shown that the burden remains elevated or even increases over time (11, 159).

6.2.6 Family functioning, communication, and satisfaction

The family-functioning-related variables (circumplex ratio on the FACES IV and FCS) were not significantly associated with mental HRQL when controlled for other factors in paper II. Other studies have found family functioning to be associated with mental health in patients and family members (97, 268), and a recent study found family functioning to be significantly associated with mental HRQL in individuals with TBI (269). Williamson et al. found that family satisfaction (as assessed by the FSS) had a direct positive affect on HRQL in individuals with moderate to severe TBI.

The average level of family functioning on the FACES was within the balanced and healthy range at start of treatment, although the level of emotional distress indicated that both patients and family members to some extent were burdened. Similarly, other studies have revealed that emotional distress in caregivers to individuals with TBI co-existed with healthy family functioning (85, 97). A possible explanation, also pointed out by Kreutzer et al.(85), is that maintaining healthy family functioning in adverse times might be at the expense of the respective family members' emotional functioning.

The patients and family members had similar perceptions of family functioning, communication, and satisfaction, which indicated high level of agreement. By contrast, others have found that family members reported significantly worse family functioning than did the patients following ABI (95, 270). Gan et al. suggested that the difference could be due to lack of awareness in the patients, as a consequence of the injury (95).

There are several possible explanations for this study's results on family functioning, which were discussed in the methodological section (*Recruitment of families*) regarding inclusion criteria and procedures. In the Latin American studies mentioned earlier, the authors pointed to the strong family bonds and loyalty that characterize Latin American families as a possible explanation for why most families in these studies reported balanced family functioning (97, 98). Strong family bonds and loyalty might also have contributed to balanced family functioning in the participating families in our study.

Furthermore, in contrast to the pilot study on the TBIFSI conducted in a rural setting (1), the present study was conducted in an urban area where people are more likely to be in contact with specialized health services compared to those in rural areas (271). Norway is a welfare state providing comprehensive rehabilitation to individuals with disabilities, including TBI. Therefore, Norwegian families may not face the same demands and responsibilities after TBI as those in more underserved contexts, which could explain lower strain on the family system after TBI. That access to formal rehabilitation services may lead to less family strain after TBI was also suggested in the study by Ponsford et al. (86).

6.2.7 The effectiveness of the family-centered intervention (Paper III)

The main aim of this the research project was to examine the effectiveness of the TBIFSI in improving individual and family functioning. Contrary to our hypotheses, no significant differences between the intervention and control group were evident at any assessment points in the RCT. In general, the existing evidence of the effectiveness for family interventions after TBI is inconsistent (184, 185), and comparing of our results to those of other studies is challenging due to differences in intervention structure, content, and study methodology.

It is difficult to determine the optimal timing for intervention delivery, and prior family intervention studies have included families with a wide range of years since the injury (187, 189, 191). We do not know if the timing was appropriate in the RCT, considering the large number of families that declined participation. However, the high attendance rate in the TBIFSI sessions may indicate that the interventions accommodated some of the families' needs at this point in recovery. By contrast, in a study by Niemeier et al. on a caregiver

intervention provided in the acute phase, approximately one-third of the caregivers discontinued the intervention due to the many new tasks they were facing (192).

Based on the examination of within-group differences in the intervention and control group in the RCT, the results suggest a potential acceleration in recovery for the participants in the intervention group in mental HRQL, caregiver burden, family functioning, communication, and satisfaction from start of treatment to the 2-months follow up. However, these improvements did not continue after the intervention period ended. Our results were similar to those of other, failing, despite significant improvements in the intervention period, to demonstrate sustainable treatment improvements (191, 192). This might indicate that dyadic relationship and family communication are complex, and that mediating and moderating factors should be explored in family functioning after TBI.

Furthermore, although we followed the participants until the 8-month follow up, time needed to make stable behavioral and family changes is unclear and most likely varies individually (272). We do not know the extent to which the families in the present study were able or willing to apply and continue to use the learned skills and strategies after completion of the TBIFSI. In the study by Kreutzer et al., the authors suggested a maintenance session could have facilitated further improvements (191). This could have been pertinent in the present study as well.

The level of family functioning, as assessed by cohesion and flexibility, remained relatively stable throughout the study period. Assessment of family functioning is considered important for identifying resources and strengths within the family system, and aligns with the capacity-building family intervention model (120). This study was one of few family intervention controlled studies that have examined its effects on family functioning after TBI. Other studies did not have an RCT design, and none of them found change in the family functioning. (107, 273, 274). It might be that more time was needed in the present study to observe changes in the family system.

Furthermore, the balanced levels of cohesion and flexibility reported by the participants at start of treatment might have made improvements through the intervention more challenging to achieve than if the intervention had been provided to families that were more troubled. Additionally, a consequence of being provided with knowledge about family functioning,

such as about family boundaries and communication styles, is that the families might have become more aware of family challenges and issues, which might have reduced the hypothesized improvements in this study. Related to this, an RCT of a mentoring program for families facing TBI, the caregivers who participated in the mentoring program reported more family dysfunction than those in the control group (275).

The outpatient multidisciplinary follow-ups at the outpatient clinic that were offered to all patients in this study entailed elements that might be considered strength-based approaches, such as supporting the patients in resuming daily life activities and handling their PPCS. Consequently, the patients may have applied more beneficial coping strategies, which in turn might have had a positive effect on the family members. Thus, patient and family members may have had many of their needs met through the follow-ups at the outpatient clinic. By contrast, other RCTs of family interventions following TBI/ABI have selected wait-list control groups not receiving any treatment (189, 191, 193).

Contrary to our hypothesis only the patients in the control group showed significant within-group improvement in TBI-specific HRQL on the QOLIBRI during the treatment period (start of treatment to the 2-months follow-up). One might consider that attending an eight-session family intervention, in addition to receiving follow-ups, could have been perceived as a burden rather than an opportunity, reflected in their responses on the QOLIBRI. The presence of typical PPCS such as fatigue, headaches, and poor concentration (267) might have made session attendance demanding. An abbreviated version of the TBIFSI could have been appropriate in this context, considering the total hours of treatment provided to the individuals with TBI in this study.

7 Conclusions and future perspectives

7.1 Conclusions

In conclusion, after minor adjustments the Norwegian version of a manualized, eight-session intervention was feasible in a sample of patients with mild to severe TBI and their family members. Through a pragmatic approach, the TBIFSI could be delivered.

A TBI of any severity had long-term consequences on mental HRQL and emotional functioning in patients, but also to some extent for family members. Symptoms of depression and anxiety, as well as resilience were modifiable factors associated with mental HRQL in patients with mild to severe TBI and their family members.

Receiving the TBIFSI in addition to specialized follow-up at a TBI outpatient clinic did not lead to superior outcomes compared to receiving specialized follow-up only. The TBIFSI may have contributed to an acceleration in recovery, however, the improvements were not sustained beyond the intervention period.

7.2 Future perspectives

Although a great body of knowledge about family and caregiver responses after TBI exist, the complex interactions between family functioning and patients' and family members' mental HRQL should be further explored.

Evaluations of complex interventions for families facing TBI should consider different study designs such as mixed method approaches that may provide more in-depth information about lessons learned and participation experiences of the TBIFSI.

Because an eight-session intervention is time consuming, it can also represent a burden in the rehabilitation process for families. Further research on the TBIFSI could consider delivering the intervention in a multi-family format or testing an abbreviated version of the intervention. In future research of the TBIFSI, delivering the intervention to families with more troubled family functioning is suggested.

Future research should adopt common definitions of family functioning, and aim to achieve consistency in the selection of reliable and valid outcomes of interest to allow comparisons across studies. The results from the RCT described in this project could provide insight for other researchers performing family interventions studies, including on the methodological challenges.

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9 Appendix



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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*Corresponding author: Mari S. Rasmussen, Physical Medicine and Rehabilitation, Oslo University Hospital (Oslo Universitetssykehus), Norway
E-mail: m.s.rasmussen@studmed.uio.no

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Omid Khayat, Liverpool Hope University, Liverpool, UK

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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

Mari S. Rasmussen^{1,2*}, Nada Andelic^{1,2}, Tonje H. Nordenmark¹, Juan C. Arango-Lasprilla^{3,4} and Helene L. Soberg^{1,5}

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 (Kreutzer 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; Friberg, 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
Primary			
SF36 Mental Health Scales	0–100 (worst–best)	X	X
Caregiver burden scale	22–88 (best–worst)		X
Secondary			
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
Additional measures			
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

	Family A	Family 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.

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Competing Interests

The authors declare that they have no competing interests.

Author details

Mari S. Rasmussen^{1,2}
E-mail: m.s.rasmussen@studmed.uio.no
ORCID ID: <http://orcid.org/0000-0003-2794-4768>
Nada Andelic^{1,2}
E-mail: nadand@ous-hf.no
ORCID ID: <http://orcid.org/0000-0002-3719-4406>
Tonje H. Nordenmark¹
E-mail: tofoss@ous-hf.no
Juan C. Arango-Lasprilla^{3,4}
E-mail: jcalasprilla@gmail.com
Helene L. Soberg^{1,5}
E-mail: h.l.soberg@medisin.uio.no
ORCID ID: <http://orcid.org/0000-0001-6908-7480>

¹ Oslo University Hospital, Ullevål, Oslo, Norway.

² Institute of Health and Society, Research Centre for Habilitation and Rehabilitation Models & Services (CHARM), Faculty of Medicine, University of Oslo, Oslo, Norway.

³ BioCruces Health Research Institute, Cruces University Hospital, Barakaldo, Spain.

⁴ IKERBASQUE, Basque Foundation for Science, Bilbao, Spain.

⁵ Faculty of Health Sciences, Department of Physiotherapy, Oslo Metropolitan University, Oslo, Norway.

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.

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Article

Mental Health and Family Functioning in Patients and Their Family Members after Traumatic Brain Injury: A Cross-Sectional Study

Mari S. Rasmussen ^{1,2,*}, Juan Carlos Arango-Lasprilla ^{3,4,5} , Nada Andelic ^{1,2},
Tonje H. Nordenmark ^{1,6} and Helene L. Soberg ^{1,7}

¹ Department of Physical Medicine and Rehabilitation, Oslo University Hospital, P.B. 4950 Nydalen, 0424 Oslo, Norway; nadand@ous-hf.no (N.A.); tofoss@ous-hf.no (T.H.N.); h.l.soberg@medisin.uio.no (H.L.S.)

² Institute of Health and Society, Research Centre for Habilitation and Rehabilitation Models & Services (CHARM), Faculty of Medicine, University of Oslo, 0318 Oslo, Norway

³ Biocruces Bizkaia Health Research Institute, 48903 Barakaldo, Spain; jcalasprilla@gmail.com

⁴ IKERBASQUE, Basque Foundation for Science, 48009 Bilbao, Spain

⁵ Department of Cell Biology and Histology, University of the Basque Country UPV/EHU, 48940 Leioa, Spain

⁶ Department of Psychology, University of Oslo, 0317 Oslo, Norway

⁷ Department of Physiotherapy, Faculty of Health Sciences, OsloMet—Oslo Metropolitan University, 0130 Oslo, Norway

* Correspondence: m.s.rasmussen@studmed.uio.no; Tel.: +47-997-97-575

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Abstract: Traumatic brain injury (TBI) affects the family as a whole. This study aimed to describe and compare mental health and family functioning in TBI patients and their family members, and to identify individual and family-related factors that were associated with mental health. It was conducted at an urban, specialized, TBI outpatient clinic and included 61 patients with mild to severe TBI and 63 family members. Baseline demographics and injury-related data were collected, and the participants answered standardized, self-reported questionnaires 6–18 months post-injury that assessed mental health; general health; family functioning, communication, and satisfaction; depression and anxiety; self-efficacy; resilience; and condition-specific quality of life. The patients reported significantly worse mental health, depression, resilience, self-efficacy, and general health compared with the family members. Patients and family members had similar perceptions, showing balanced family functioning, high family communication levels, and moderate family satisfaction. Factors significantly associated with mental health in patients and family members were depression, anxiety, and resilience, explaining 56% of the variance ($p < 0.001$). Family-related factors were not associated with mental health. The disease burden was mainly on the patients; however, the family members also reported emotional distress. Family-targeted interventions across the TBI continuum should be considered.

Keywords: traumatic brain injury; quality of life; family functioning; rehabilitation

1. Introduction

The consequences of traumatic brain injury (TBI) are multifaceted and affect the patients' family as well [1,2]. Persistent physical, cognitive, and emotional problems have been identified in individuals with TBI of all severities [3]. A previous study demonstrated that up to 20% of individuals with TBI of all severity levels experienced symptoms, such as dizziness, fatigue, headaches, depression, and anxiety, one year after the injury [4]. TBI adversely affects health-related quality of life (HRQL)

across both the mental and physical domains [5], and HRQL is as an important outcome in populations with TBI of all severity levels [6].

When patients return home after the primary rehabilitation period, they often rely on their family members for emotional and practical support in everyday life activities [7]. The family members consequently have a fundamental role in the patients' rehabilitation. The changes in lifestyle and responsibilities of the family members are challenging, and an increased caregiver burden [8–10], diminished HRQL [11,12], and increased levels of emotional distress [13,14] are negative outcomes for the caregivers.

Families are not prepared for the sudden changes caused by TBI; therefore, they are at risk for disrupted family dynamics that may lead to unhealthy family functioning. Researchers have documented a significant and lasting increase in unhealthy family functioning following TBI [15,16]. The stress on the family system seems to be less dependent on the severity of the TBI, but is related to the cognitive, emotional, and behavioral changes in the injured person [17,18]; and there is a reciprocal relationship among TBI-related factors in the injured person, caregiver distress, and family functioning [14,16,19].

To form a more comprehensive picture of the challenges that families face after TBI, it is important to include the perspectives of both the patients and their family members [20]. Previous research has demonstrated that personal, familial, and social characteristics and injury severity affect HRQL, disease burden, and family adjustment after TBI [21–23]. However, there is a paucity of knowledge on mental health and family functioning related to the consequences of TBI, which include the impact on these outcomes for members within the same family system. Thus, the objectives of this study were to:

- (a) Describe and compare aspects of mental health and family functioning in home-dwelling patients with TBI and their family members at 6–18 months post-injury (i.e., the study inclusion time)
- (b) Explore individual- and family functioning-related factors that are associated with mental health.

2. Materials and Methods

2.1. Study Design and Settings

Data were collected from June 2017 to June 2019 at Oslo University Hospital (OUH) in Norway as part of a two-armed, pragmatic, randomized, controlled trial (RCT) aimed at evaluating the effectiveness of a family intervention called the “Traumatic Brain Injury/Spinal Cord Injury Family Intervention” [24]. The intervention was originally developed based on experiences from TBI rehabilitation services in Latin America. Adaptations of the intervention into a Norwegian setting have been published by our group [25]. This study was approved by the Regional Committee for Medical and Health Research Ethics, South-East Norway (approval no. 2016/1215), and the Data Protection Officer at OUH. It was registered at [ClinicalTrials.gov](https://clinicaltrials.gov) with the identification number NCT03000400. The study presented cross-sectional data from the first assessment time point (T1), which we defined as the baseline assessment of the RCT.

2.2. Participants

A total of 251 patients with TBI were approached at the TBI Outpatient Clinic of OUH for participation. Patients are generally referred to this outpatient clinic for follow-ups with a physiatrist and, if needed, with a multiprofessional rehabilitation team consisting of medical doctors, a psychologist, physical therapists, occupational therapists, and a social worker. The patients either were inpatients at the hospital in the acute phase or were referred to the outpatient clinic by their general practitioner. The patients referred to the outpatient clinic with mild TBI had experienced persistent post-concussion symptom pressure. All the patients were evaluated by a physiatrist and were considered eligible based on the following inclusion and exclusion criteria: (a) age between 16 and 65 years; (b) diagnosed with TBI of any severity according to the International Classification of Diseases (ICD)-10 classification system (S06.0–S06.9); (c) a Rancho Los Amigos Revised Scale score of 8 [26]; (d) TBI sustained 6 to 18 months

ago; and (e) were home dwelling. The family members were chosen by the patients and considered eligible if they: (a) were between 18 and 65 years and (b) were actively involved in the patients' daily life with weekly contact. The exclusion criteria that applied to all the eligible participants were: (a) inability to speak/read Norwegian; (b) a pre-injury learning disability; (c) an ICD-10 diagnosis of severe psychiatric or degenerative neurological illness; (d) ongoing substance abuse; and (e) families in which other family members required professional care. Eligible patients and family members received oral and written information regarding the study. All participants provided written informed consent.

2.3. Measures

The following sociodemographic characteristics were recorded: participant role (patient/family member), age (years), sex (female/male), marital status (married/partner/single), length of relationship (<1 year/1–5 years/>5 years), education (dichotomized as low/high with high representing college/university degree), and current work status (full-time work/partial sick-leave/sick-leave). From the patients only, we collected pre-injury work status (not working/working), comorbidities (no/yes), and number of persons living in the household. The following data were collected from the family members: type of relationship with the injured individual (spouse/parent/child) and whether they lived in the same household as the injured individual (no/yes).

The patients' injury-related characteristics included time since injury (in weeks); injury mechanism (fall/traffic accident/mechanical object/violence/others); neuroimaging results of intracranial injury (no/yes); length of hospital stay (days); the lowest Glasgow Coma Scale (GCS) score recorded within the first 24 h after the injury, with scores from 3–8 indicating severe TBI, 9–12 indicating moderate TBI, and 13–15 indicating mild TBI [27]; the Abbreviated Injury Scale (AIS)—head score that is calculated as a standardized approach for categorizing the type and severity of injuries to the head [28]; and post-concussion symptoms assessed with the Rivermead Post-Concussion Symptoms Questionnaire (RPQ) [29]. The RPQ has a scale with scores ranging from 0 (best) to 64 (worst), and the total score was used in the present study. The RPQ has been validated in Norway [30].

HRQL measure: The primary outcome measure was the 36-item Short Form Health Survey (SF-36) Mental Component Summary (MCS) score [31]. The MCS was aggregated from the four mental health scales that are part of the SF-36, Vitality (VT), Social Functioning (SF), Role Limitation Due to Emotional Problems (RE), and Mental Health (MH) scales, as the weighted sum of the subscale scores with a mean value of 50 and a standard deviation of 10. The General Health Scale (GH) of the SF-36, which provides an overall evaluation of the health status, was applied. The MCS and GH each have scores ranging from 0 (worst) to 100 (best). Scores below 40 indicate impaired mental health/general health [32]. The SF-36 has demonstrated good validity, reliability, and responsiveness in TBI populations with Cronbach's alphas ranging from 0.79 to 0.92 [31].

Family functioning measure: The Family Adaptability and Cohesion Evaluation Scale, fourth edition (FACES IV) [33], is a 42-item scale consisting of two balanced scales (flexibility and cohesion) and four unbalanced scales (disengaged, chaos, enmeshed, and rigid). The scales are used to determine the level of flexibility and cohesion within couples and family systems and include a circumplex ratio score ranging from 0 (worst) to 10 (best) that is assigned to the level of cohesion and flexibility within a family; a score of 1 indicates equal amounts of balance and unbalance in the family system. In addition, the Family Communication Scale (FCS) that assesses communication skills within the family and the Family Satisfaction Scale (FSS) that assesses the level of satisfaction with family functioning were used. The raw scores of each scale were recoded into percentile scores ranging from 10 (worst) to 99 (best). FACES IV is proven valid and reliable with Cronbach's alphas ranging from 0.77 to 0.93 [33,34].

Psychological functioning: Depression was measured with the Patient Health Questionnaire-9 (PHQ-9), which is a nine-item screening instrument used to evaluate the severity of symptoms of depression [35]. The scores can be interpreted as follows: no depression (0–4 points), mild (5–9 points), moderate (10–14 points), moderately severe (15–19 points), and severe depression (20–27 points). The psychometric properties of the scale are favorable [35].

Anxiety was measured with the Generalized Anxiety Disorder Questionnaire-7 (GAD-7). This is a seven-item questionnaire that is used to assess symptoms of generalized anxiety [36]. The scores can be interpreted as follows: mild (5–9 points), moderate (10–14 points), and severe anxiety (15–21 points). The GAD-7 has demonstrated excellent construct validity with a Cronbach's alpha of 0.92 [36].

Self-efficacy: The General Self-Efficacy Scale (GSE), which assesses the belief in a person's own competence to handle stressful events and demands, was used [37]. It has 10 items with an ordinal scale from 1 (not at all true) to 4 (exactly true), and scores ranging from 10 (worst) to 40 (best). High reliability and construct validity on this scale have been confirmed in earlier studies, with Cronbach's alpha values of 0.86–0.94 [37].

Resilience: The Resilience Scale for Adults (RSA) was used to assess protective factors in individuals [38]. This 33-item scale covers five dimensions (1A, perception of self; 1B, perception of future; 2, social competence; 3, family cohesion; 4, social resources; and 5, structured style). The scale's scores range from 0 (worst) to 165 (best). The total score was used in this study. The RSA has demonstrated adequate internal consistency with Cronbach's alphas ranging from 0.76 to 0.87 [38].

Condition-specific quality of life measure: The Quality of Life after Brain Injury Questionnaire (QOLIBRI) is a 37-item scale consisting of six subscales that include four satisfaction scales (the Cognition, Self, Daily Life, and Autonomy scales) and two bothered scales (the Emotions and Physical Problems scales) [39]. A total score ranging from 0 (worst) to 100 (best) can be calculated. A score <60 points indicates a reduced quality of life [40]. The Norwegian QOLIBRI has exhibited satisfactory psychometric properties with Cronbach's alphas ranging from 0.75 to 0.96 [41].

2.4. Data Sources

The sociodemographic data were obtained from a self-reported questionnaire developed by the authors (M.S.R. and H.L.S.), whereas the injury-related variables were collected from the patients' medical records. For seven patients, the GCS score was not specified in the medical records and was assigned by a physiatrist (author N.A.) based on the injury descriptions in the patients' medical records. At the study's baseline assessment, all the self-reported outcome measures were filled out after the family had been allocated to the intervention group or the control group in the RCT.

2.5. Study Sample Size

Sample size estimation was based on the primary outcome measure, SF-36 MCS. This was based on a study on Norwegian patients with moderate to severe TBI [42]. An estimated sample size of 66 patients was calculated with $\alpha = 0.05$ and $\beta = 0.2$, taking into consideration a 10% dropout rate.

2.6. Data Analysis and Statistics

All the statistical analyses were performed using IBM SPSS Statistics 25. The distribution of the data was evaluated by using the Kolmogorov–test and/or visual plots. The mean and standard deviation (SD) were used for normally distributed data, and the median and interquartile range (IQR) were used for skewed data. Categorical data are presented as frequencies and percentages.

Missing data were addressed by replacing the missing scores on a scale or subscale with the mean score of the remaining variables if appropriate. Missing data points in the SF-36 were automatically handled by the scoring software program, PRO CoRE 1.5 Smart Measurement System (Optum, Eden Prairie, MN, USA). The data were checked for internal dependency within each family using an intraclass correlation coefficient (ICC), and evaluated as poor with an ICC value of 0.107 [43]. Differences between patients and family members were evaluated by using independent *t*-tests or Mann–Whitney *U* tests. The chi-square test was used to detect group differences in categorical data. Statistical significance was determined by a *p*-value of <0.05.

MCS was the dependent variable in the multiple regression analysis. Univariate linear regressions were used to evaluate associations between the independent variables and MCS. Independent variables with a *p*-value ≤ 0.1 were selected and included in the multiple regression analysis. Age did not fulfill

the inclusion criteria of a p -value of ≤ 0.1 , but was included in the multiple regression analysis to adjust for variations in the population. Correlations between independent variables were evaluated by performing Spearman's Rho test, and variables with an intercorrelation >0.7 were not applied together in the multiple regression analysis. These analyses are not presented. Owing to the intercorrelation between FCS and FSS with a Spearman's rho >0.7 , the FCS score was chosen as the candidate variable in the multiple regression analysis because family communication was at the core of this study and can be seen as a facilitator for family functioning [33].

One hundred twenty-two participants were included in the regression analysis because two respondents were excluded on account of missing data, and we identified a maximum of 10 independent variables to be included in the analysis [44]. A multiple linear regression analysis with a backward approach was conducted to assess the associations among personal factors, individual functioning, and family functioning.

Prior to carrying out the multiple regression analyses, we investigated the possibility of multicollinearity among the independent variables using a variance inflation factor. We controlled for the normality of residuals by inspecting the histogram and quantile-quantile plots. To check for internal validity, the model was run with 1000 bootstrap samples [44]. The results of the multiple regression modeling are presented with R^2 , adjusted R^2 , and unstandardized B coefficients with 95% confidence intervals.

3. Results

In total, 67 patients and 69 family members agreed to participate in this study. Six families withdrew after the randomization for the following reasons: two families moved away, two families thought participating would be too time consuming, and two families did not provide a specific reason, leaving a total of 124 participants at baseline. See Figure 1 for flow chart.

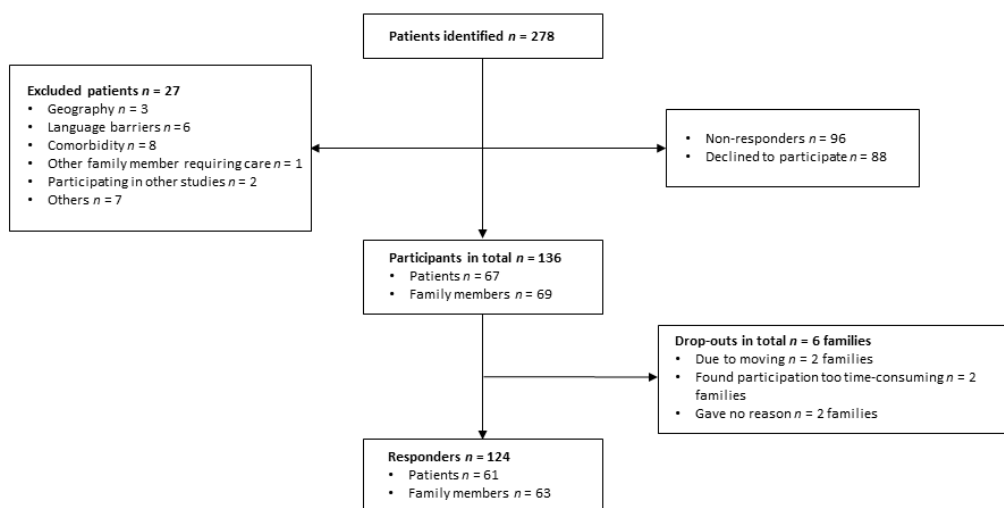


Figure 1. Flow chart.

Table 1 presents the sociodemographic data. Baseline data were collected from 61 patients (54.1% women) with a mean (SD) age of 43.8 (11.2) years and from 63 family members (52.4% women) with a mean (SD) age of 42.6 (11.3) years. There were no significant differences in sex, age, and level of education between the patients and family members. The majority of family members (92%) was spouse/partner of the injured person and more than 80% had been in the relationship for >5 years.

Table 1. Demographic factors of the 61 patients and 63 family members. SD, standard deviation.

	Patients (<i>n</i> = 61)		Family Members (<i>n</i> = 63)	
	Frequency (%)	Mean (SD)	Frequency (%)	Mean (SD)
Age, mean (SD)		43.8 (11.2)		42.6 (11.3)
Sex (% females)	33 (54.1)		33 (52.4)	
Comorbidity	12 (19.6)			
Marital status				
Married	35 (57.4)		37 (58.7)	
Partner/cohabitant	24 (39.3)		24 (38.1)	
Single	2 (3.3)		2 (3.2)	
Length of relationship				
<1 year	3 (5.0)		3 (4.9)	
1–5 years	7 (11.9)		8 (13.1)	
>5 years	49 (83.1)		50 (82.0)	
Living arrangement				
Living in the same household as the patient			57 (90.5)	
Number of people living in the patient's household		3.1 (1.2)		
Education				
Low	16 (26.2)		15 (23.8)	
High	45 (73.8)		48 (76.2)	
Patients' pre-injury work status				
Not working	4 (6.6)			
Working	57 (93.4)			
Current work status				
Full-time work	5 (8.2)		53 (84.1)	
Partial sick-leave	33 (54.1)		4 (6.3)	
Sick-leave	23 (37.7)		6 (9.5)	
Type of relation to the injured				
Partner/spouse			58 (92.1)	
Parent			1 (1.6)	
Child			4 (6.3)	

Injury Characteristics

The injury characteristics are presented in Table 2. The median time since injury was 49 (IQR 36, 69) weeks. The median GCS score was 15 (IQR 14, 15), which corresponds to mild TBI. The median AIS head score of 1 (IQR 1, 3) indicated a mild severity level of injury. Among the 50 (82%) patients who had mild TBI as assessed by the GCS, eight (16%) patients had intracranial injury diagnosed with computed tomography/magnetic resonance imaging (CT/MRI) and were classified as having complicated mild TBI [45]. The main injury mechanisms were falls (37.7%) and traffic accidents (31.1%). The mean RPQ total score of 27.7 (SD 11.1) indicated a higher level of post-concussive symptoms.

At baseline, the patients reported significantly worse scores than the family members on overall mental health on the MCS, general health (GH) (SF-36), depression (PHQ-9), resilience (RSA), and self-efficacy (GSE) (Table 3). On the MCS, the difference was 5.9 points ($p = 0.001$). Overall, approximately one-third of the participants had impaired MCS with scores <40 points.

Table 2. Injury characteristics.

Injury Characteristics (<i>n</i> = 61)	Frequency (%)	Mean (SD)/Median (IQR)
Glasgow Coma Scale score		15 (14, 15)
Mild TBI	50 (82.0)	
Moderate TBI	3 (4.9)	
Severe TBI	8 (13.1)	
AIS head score		1.0 (1, 3)
Intracranial injury	18 (29.5)	
Surgical procedure	8 (13.1)	
Falls	23 (37.7)	
Traffic accidents	19 (31.1)	
Mechanical object	14 (23.0)	
Violence/Assault	2 (3.3)	
Others	3 (4.9)	
Time since injury (weeks)		49.4 (36, 69)
Length of stay (days)		5.4 (range 0–37)
RPQ total score (<i>n</i> = 56)		27.7 (11.1)
Self-reported comorbidities (<i>n</i> = 59)	11 (18.6%)	

TBI, traumatic brain injury; AIS, Abbreviated Injury Scale; RPQ, Rivermead Post-Concussion Symptoms Questionnaire; SD, standard deviation; IQR, interquartile range.

Table 3. Intergroup differences on self-reported outcome measures.

Outcome	Family Members		Mean difference	<i>p</i> -Values
	Patients	Family Members		
SF-36 MCS	Mean (SD) 41.8 (9.9)	Mean (SD) 47.7 (9.0)	5.9	0.001
GH (SF-36)	45.8 (10.6)	54.4 (10.0)	8.6	<0.001
QOLIBRI overall scale	58.1 (16.1)	-	-	-
FACES IV circumplex ratio	3.0 (1.1)	3.1 (1.2)	0.1	0.692
FCS	65.7 (26.3)	66.4 (25.0)	0.7	0.884
FSS	55.6 (28.7)	55.3 (26.4)	0.3	0.946
PHQ-9	9.6 (5.1)	6.3 (4.3)	3.3	<0.001
GAD-7	6.0 (4.2)	4.9 (3.7)	1.1	0.193
RSA	107.2 (16.6)	113.9 (16.2)	6.7	0.025
GSE	30.1 (5.1)	31.8 (4.5)	1.7	0.044

SF-36, short form-36; MCS, Mental Component Summary; QOLIBRI, Quality of Life after Brain Injury Questionnaire; FACES IV, Family Adaptability and Cohesion Evaluation Scale; FCS, Family Communication Scale; FSS, Family Satisfaction Scale; PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalized Anxiety Questionnaire-7; RSA, Resilience Scale for Adults; GSE, General Self-Efficacy Scale; GH, General Health; SD, standard deviation.

Regarding self-reported symptoms of depression on the PHQ-9, 65% of the patients reported scores that indicated mild to moderate depression and 20% reported scores indicating moderately severe to severe depression. Among the family members, 57% reported scores indicating mild to moderate depression and 6% reported scores indicating moderately severe to severe depression. The patients' GAD-7 mean score indicated mild anxiety, whereas the family members' GAD-7 mean score was just below the cut-off score for mild anxiety. Furthermore, 66.7% of the patients reported good GH with scores ≥ 40 points, whereas 90.5% of the family members reported good GH. The patients' mean (SD) total QOLIBRI score was 58.1 (16.1) points, indicating diminished HRQL.

There were no statistical differences in terms of family functioning, communication, or satisfaction at baseline. Overall, the participants perceived their family functioning as balanced with a mean (SD) circumplex ratio score of 3.0 (1.1) for the patients and 3.1 (1.2) for the family members. On average, both the patients and their family members reported having high family communication levels (FCS) and a moderate level of family satisfaction (FSS).

The results of the univariate regression analyses of candidate variables in the multiple regression model that examined factors associated with MCS and the results of the multiple regression analysis are presented in Table 4.

Table 4. Results of the regression analyses and results of the final multiple regression model.

Outcome Variable MCS	Univariate Regression		Multiple Regression Backward		
	B (C.I.)	p-Value	B	p-Value	95% C.I.
Age	0.09 (−0.68, 0.25)	0.265			
Sex (female/male)	3.09 (−0.42, 6.58)	0.084	2.56	0.038	(0.14, 5.0)
Relation (patient/family)	5.85 (2.47, 9.23)	0.001			
FACES IV circumplex ratio	2.37 (0.91, 3.84)	0.002			
FCS	0.08 (0.02, 0.15)	0.018			
FSS	0.11 (0.05, 0.17)	<0.001			
PHQ-9	−1.41 (−1.67, −1.16)	<0.001	−0.79	<0.001	(−1.16, −0.43)
GAD-7	−1.59 (−1.94, −1.25)	<0.001	−0.64	0.003	(−1.06, −0.22)
RSA	0.32 (0.23, 0.41)	<0.001	0.12	0.007	(0.04, 0.21)
GSE	0.96 (0.63, 1.28)	<0.001			
GH (SF-36)	0.43 (0.29, 0.57)	<0.001			
R ²			0.576		
Adjusted R ²			0.562		
F value			39.76	<0.001	

SF-36, short form-36; MCS, Mental Component Summary; FACES IV, Family Adaptability and Cohesion Evaluation Scale, fourth edition; FCS, Family Communication Scale; FSS, Family Satisfaction Scale; PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalized Anxiety Questionnaire-7; RSA, Resilience Scale for Adults; GSE, General Self-Efficacy Scale; GH (SF-36), General Health; C.I., confidence interval.

In the final regression model, sex was the only personal factor that was significantly associated with the MCS, with men having 2.6-point higher scores than women. The individual functioning-related factors that were associated with the MCS were depression on the PHQ-9, anxiety on the GAD-7, and resilience on the RSA, whereas self-efficacy on the GSE and GH on the SF-36 were not associated with the MCS. The family functioning circumplex ratio and FCS scores were not significantly associated with the MCS. The final model accounted for 56.2% of the variance in the MCS ($p < 0.001$).

4. Discussion

In the present study, we focused on aspects of mental health and family functioning in both patients and family members after TBI as part of the baseline assessment of an ongoing RCT. Most patients had mild TBI with persistent symptoms and functional disturbances, and the symptom pressure as assessed with the RPQ at the time of inclusion was higher than that reported in previous studies on mild TBI [4,30].

Both sexes were equally represented, and being male was associated with better mental health in both patients and family members. This finding is in accordance with studies on mental health on the Norwegian general population [46], and with studies on TBI patients, in which women tended to report lower mental health scores and HRQL [5,42]. In addition, previous studies have demonstrated that women caregivers report lower quality of life levels compared with men [47,48].

4.1. Post-Injury Functioning

The patients in the current study reported significantly lower mental health levels compared with the family members; 48% of the patients and 17% of the family members reported poor mental health with MCS scores <40.0 points. A systematic review on HRQL after TBI found that mental HRQL (MCS) was more negatively affected than physical HRQL (PCS) [6]. The patients in this study also reported reduced HRQL as assessed by the QOLIBRI, which is considered to be more sensitive in terms of capturing specific domains often affected by TBI [49].

In previous studies, caregivers of individuals with TBI reported diminished HRQL compared with the general population [11,12]. However, only a few studies emphasized on patients with mild TBI, as in the present study. It is possible that the family members' mental health may have been less affected because they did not have the same caregiver responsibilities or role changes as those of patients with more severe injuries as reported in the Paris-TBI study (47.7 points vs. 36.7 points) [50]. A study on caregivers of persons with mild TBI demonstrated that, at 6 months after the injury, the HRQL reached levels similar to the general population, suggesting that mild TBI has less impact on the family members' mental health compared with more severe injuries [51]. We included family members 6–18 months post-injury supporting this finding on overall mental health; however, this impression was not clear-cut.

Symptoms of depression and anxiety are often described in research on individuals with TBI [52] and caregivers [13]. In the current study, the patients reported significantly worse depressive symptoms than the family members, which is in line with other studies [17,18]. Worse functional status in the injured person and need for supervision have previously been identified as risk factors for caregiver depression [53]. In spite of a possibility of less caregiver challenges than is the case with severe TBI, our results revealed that more than half of the family members experienced some level of emotional distress. Stevens et al. demonstrated that the caregivers' perception of patient depression was the best predictor for depression in caregivers [54].

Based on the regression analysis, depression and anxiety were the two factors that were most strongly associated with mental health on the MCS. Studies have demonstrated that depression negatively affects HRQL in individuals with TBI [42,55,56]. Additionally, in caregivers, improvements in HRQL have been associated with improvements in symptoms of depression and anxiety [57], and strong correlations between depression and HRQL have been identified [58]. Although much of this research refers to patients and caregivers facing moderate to severe TBI, parallel associations were found in our study.

Compared with the patients, the family members reported significantly higher resilience and general self-efficacy. However, when controlled for other factors, only resilience contributed significantly to the variance in mental health, and higher resilience levels were associated with better mental health. Similarly, studies have shown that resilience in caregivers affects hope, which is positively associated with mental health and quality of life, and negatively associated with emotional distress [59,60]. Furthermore, patients with mild to severe TBI have been found to report lower resilience compared with the general population [61], and higher resilience is associated with fewer PCS symptoms after mild TBI [62].

4.2. Family Functioning

Healthy family functioning has been associated with better outcomes for TBI patients [63], and family functioning has shown to be positively associated with the mental health of patients and especially, the caregivers [20,64]. However, in our study, family functioning and communication were not significantly associated with overall mental health when controlled for other factors. On average, the patients and family members had similar perceptions, which showed balanced family functioning, high levels of family communication, and moderate family satisfaction. Even though research shows an increase in unhealthy family functioning after TBI [15,16], our results are in line with those of a study on families living in Latin America using the FACES IV data. The study demonstrated that a large proportion of the families had balanced levels of cohesion and flexibility as well as a high level of communication [65].

In the Latin American study, the authors argued that divergent results on family functioning across countries might be due to differences in family cultures, i.e., the Latin American family culture being characterized by family loyalty and placing the family needs above individual needs [65]. By contrast, families in the western societies have traditionally been characterized by relatively weak family links, where much of the support for family members have been provided by public and private

institutions [66]. Thus, there might be a selection bias of families in the current study. It is conceivable that families who perceive their family communication as good would be more willing to participate in a study potentially involving participation in a family intervention. Families who were more troubled prior to the TBI might find it too challenging to address family problems with the extra strain that TBI might have imposed on the family system as different psychological, financial, and social factors play a role in a couple's willingness to participate in research [67].

Moreover, the patients had undergone follow-up examinations and rehabilitation at a specialized outpatient clinic before being included in the current study. Norway functions as a welfare state that guarantees all its inhabitants approximately the same access to health services. The study was conducted in an urban area, and people living in urban areas are more likely to have contact with specialist physician services compared with people in rural areas [68]. This might explain why the level of strain on family functioning seemed lower in this study compared with studies conducted in countries with limited access to rehabilitation services. Ponsford et al. found that families who had access to comprehensive rehabilitation services after mild to severe TBI on average showed healthy family adjustment after the injury [18].

The current study has some limitations that should be considered. First, the data presented were collected at only one time point, and causality cannot be inferred. Second, the outcomes in the current study were based on self-reported measures; thus, the patients were only screened for depression and anxiety. Third, we did not specifically measure fatigue, which might be associated with mental health after TBI; however, the SF-36 vitality subscale is included in the MCS. Fourth, caution should be applied when generalizing the results of this study to families with moderate and severe TBI only because most of the participants in this study had mild TBI.

A few studies have reported on mental health and family functioning from the perspective of members within the same family system. A strength of this study is that it provides valuable insights into how TBI affects both patients and their closest family members within the same family unit by treating the family as a whole. Finally, this mixed sample of individuals with TBI represented the patients that were admitted to our department, which makes it possible to translate the findings to everyday clinical practice owing to increased external validity.

5. Conclusions

This study demonstrated that TBI, regardless of injury severity level, has lasting consequences on overall mental health and emotional functioning for the patients, but also to some extent for the family members. The disease burden was primarily on the patients as they had significantly lower mental health, overall general health, resilience, self-efficacy, and worse symptoms of depression compared with their family members. The family members reported some symptoms of depression. The participants had similar perceptions showing balanced family functioning. Family communication was perceived as high and family satisfaction as moderate. Sex, depression, anxiety, and resilience were significantly associated with mental health on the MCS, and family-related factors were not associated with the MCS in the regression analysis. Future studies assessing the effectiveness of targeted family interventions aimed at improving mental health in patients with TBI, especially those with a protracted course of recovery, and their family members should be considered.

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The effectiveness of a family-centred intervention after traumatic brain injury – a pragmatic randomised controlled trial

Mari S. Rasmussen^{1,2*}, Nada Andelic^{1,2}, Are H. Pripp³, Tonje H. Nordenmark^{1,4}, and Helene L. Soberg^{1,5}

¹ Department of Physical Medicine and Rehabilitation, Oslo University Hospital, P.B. 4950 Nydalen, 0424 Oslo, Norway.

² Institute of Health and Society, Research Centre for Habilitation and Rehabilitation Models & Services (CHARM), Faculty of Medicine, University of Oslo, 0318 Oslo, Norway.

³ Oslo Centre of Biostatistics and Epidemiology Research Support Services, Oslo University Hospital, P.B. 4950 Nydalen, 0424 Oslo.

⁴ Department of Psychology, University of Oslo, 0317 Oslo, Norway.

⁵ Department of Physiotherapy, Faculty of Health Sciences, OsloMet—Oslo Metropolitan University, 0130 Oslo, Norway.

*corresponding author: Mari S. Rasmussen, e-mail: m.s.rasmussen@studmed.uio.no; Tel.: +47-997-97-575.

Nada Andelic: nadand@ous-hf.no

Are H. Pripp: apripp@ous-hf.no

Tonje H. Nordenmark: tofoss@ous-hf.no

Helene L. Soberg: h.l.soberg@medisin.uio.no

Abstract

Objectives: To determine the effectiveness of a theoretically based family-centred intervention for patients with traumatic brain injury and their family members.

Design: Open-labelled, 2-armed randomised controlled trial.

Settings: Outpatient clinic, municipal premises, and family residences.

Participants: Sixty-one patients (33 women) with mild-to-severe traumatic brain injury, mean age 43.8 ± 12.2 , and 63 family members (33 women), mean age 42.6 ± 11.3 , were recruited and randomly assign to intervention (n = 30 families) and control group (n = 31 families).

Intervention: An 8-session family intervention to improve individual and family functioning was delivered to each family separately. The participants answered self-reported questionnaires at start-of-treatment, a median (IQR) of 11.4 (8.4, 15.9) months post-injury, and at 2 post-intervention follow-ups, 2.7 (2.3, 3.8) and 9.2 (8.2, 9.9) months after start-of-treatment.

Outcome measures: Primary outcome measures were the Mental Component Summary (MCS) on SF-36 and the Caregiver Burden Scale (CGB). Secondary outcome measures were the Family Adaptability and Cohesion Evaluation Scale (FACES) and the Quality of Life after Brain Injury Questionnaire (QOLIBRI). Group differences were analysed with a linear mixed-model analysis for repeated measurements.

Results: No significant between-group differences were found. The intervention group significantly improved on the MCS, the CGB, and FACES in the treatment period, whereas the controls did not. Mean (SE) MCS scores were 47.9 (1.26) and 47.3 (1.27) in the intervention and control group at last follow-up.

Conclusions: Receiving an 8-session family intervention, in addition to specialised follow-ups for the patients, was not superior to follow-ups at a specialised traumatic brain injury outpatient clinic.

Keywords: traumatic brain injury, rehabilitation interventions, family, health related quality of life, randomised controlled trial

Introduction

Traumatic brain injury not only has an impact upon the patients but also upon the patient's family and friends¹. Consequently, interventions to help support the family have been suggested² and have been researched, for example, in relation to patients who have suffered a stroke³. The family serves as the primary support system for patients, and interpersonal relationships are recognised as an important factor influencing all aspects of the rehabilitation process⁴. Despite this, rehabilitation has often been individually oriented, and family members have been treated as passive actors in the process⁵.

Cognitive, emotional, and behavioural changes in the injured person disrupt the family dynamics and lead to persistent, unhealthy family functioning in a significant proportion of families after traumatic brain injury^{6,7}. Diminished health-related quality of life and increased levels of psychological distress are reported by both patients^{8,9} and family members¹⁰.

Increased and persistent levels of caregiver burden in the family members¹¹ might reduce their capacity to care for the injured family member and negatively affect the patient's recovery¹².

Few studies have evaluated the effectiveness of family system interventions, and most study results draw on information from either the patients or the caregiver¹³. Moreover, findings on family functioning are often not reported, and it has been emphasised that studies should report on both patient and caregiver outcomes because the family is a unit¹³. The current evidence for family/dyad interventions after traumatic brain injury are limited by low sample sizes as well as poor fidelity and randomisation techniques^{13,14}. Much uncertainty still exists about the effectiveness of family-centred interventions on patients and caregivers or family members, and there is a need for studies evaluating such interventions.

Hence, the objective of this study was to determine the effectiveness of a theoretically based family intervention for patients with traumatic brain injury and their family members, provided in addition to follow-up treatment for patients at a specialised outpatient clinic. We

hypothesised that there would be significant improvements in the family intervention group for mental health-related quality of life, family functioning, communication, and satisfaction in patients and family members as well as reduced caregiver burden over time for the family members when compared to the control group. Further, we wanted to explore within-group changes in outcomes during the treatment period.

Methods and materials

The Regional Committee for Medical and Health Research Ethics, South-East Norway (#2016/1215), and the Data Protection Officer at Oslo University Hospital approved the study. The study was registered in ClinicalTrials.gov with the identification number NCT03000400 and reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines¹⁵. Oral and written informed consent were obtained from all participants in the study.

This was an open-labelled, 2-armed randomised controlled trial conducted at Oslo University Hospital, Norway, in collaboration with a municipal health care service. Enrolment of families took place from January 2017 to June 2019. The study population included patients admitted to the outpatient clinic for follow-ups after mild-to-severe traumatic brain injury. The patients had been hospitalised for observation/rehabilitation in the acute phase or were referred by their general practitioner in case of persistent post-concussion symptoms. Patients were screened for eligibility upon admission by a physiatrist or by a multidisciplinary team. The included patients selected family members for participation. Family members were defined as any relative, including spouses, partners, parents, adult children, or others actively involved in the patient's daily life.

Inclusion criteria for the patients were the following: a) age between 16 and 65 years; b) diagnosed with traumatic brain injury of any severity according to the International Classification of Diseases (ICD-10) system (S06.0-S06.9); c) a Rancho Los Amigos Revised Scale score of 8¹⁶; d) traumatic brain injury sustained 6 to 18 months ago; and f) home dwelling. Inclusion criteria for family members were the following: a) age between 18 and 65 years; and b) being actively involved in the patient's daily life, with weekly contact.

Patients and family members were excluded in the following cases: a) inability to speak/read Norwegian; b) a pre-injury learning disability; c) an ICD-10 diagnosis of severe psychiatric or degenerative neurological illness; d) on-going substance abuse; and e) having other family members who required professional care.

The families were randomised (1:1) according to a computer generated list with random block sizes of 4 to 8. An independent researcher was responsible for the randomisation process, and first-author MSR contacted the patients and provided information about the group allocation. Blinding the participants and the rehabilitation professionals to the allocation was not possible, but the data were entered and managed with a coded group allocation in the database by an independent research assistant, and the allocation code was not broken until the primary analyses of data from the first to the last follow-up were conducted.

The data collection was administered by an independent research assistant that was blinded with regard to group allocation. The participants answered self-reported outcome measures at 3 different times: at start-of-treatment, at 2-month follow-up (after completion of the family intervention), and at 8-month follow-up after end-of-treatment, with parallel time points for the control group. As the first assessment time point took place after randomisation, it is not per definition a true baseline. Hence, we defined the first assessment as start-of-treatment. The families allocated to the interventions group answered the questionnaires at start-of-treatment and at the 2-month follow-up as part of the first and last sessions of the family

intervention, whereas the families allocated to the control group received the questionnaires by mail, supplied with an information/instruction letter. At the 8-month follow-up, all families received the questionnaires by mail and were offered a final consultation with a physiatrist at the outpatient clinic.

Sociodemographic data were collected by a short questionnaire developed by authors MSR and HLS at the start-of-treatment and included age, gender, marital status, kinship to the injured person, whether family members live in the same household as the patients, number of people in the household, level of education (dichotomized as low/high with high representing college/university degree), patients' pre-injury employment status, current employment status, and patients' self-reported comorbidities. Injury-related variables were obtained from medical records, including time since injury, injury mechanism, neuroimaging results of intracranial injury, length of hospital stay, Glasgow Coma Scale score¹⁷, and the Head Abbreviated Injury Score (AIS)¹⁸. Post-concussion symptom pressure was registered at first follow-up using the Rivermead Post-Concussion Symptoms Questionnaire¹⁹.

The primary outcome measures were the following:

- Mental health related quality of life was assessed with the Mental Component Summary, which is a sum score based on the mental health subscales on the 36-item Short-Form Health Survey (SF-36)²⁰.
- The Caregiver Burden Scale, which is a multidimensional scale/instrument that assesses caregivers' perceived subjective burden within 5 dimensions: general strain, isolation, disappointment, emotional involvement, and environment²¹.

The secondary outcome measures were:

- The Family Adaptability and Cohesion Evaluation Scale, fourth edition, was used to assess level of cohesion and flexibility in the family or couple system²². For research

purposes, a circumplex ratio score ranging from 0 (worst) to 10 (best) is recommended. A score ≥ 1 indicates balanced levels of cohesion and flexibility in the system. In addition, 10 items assess the level of family communication with the Family Communication Scale, and 10 items assess the level of family satisfaction along the Family Satisfaction Scale²².

- The Quality of Life after Brain Injury Questionnaire, designed specifically to assess quality of life after traumatic brain injury, was applied to the patients²³. It consists of 6 subscales that include 4 satisfaction scales (cognition, self, daily life, and autonomy) and 2 bothered scales (emotions and physical problems).

All patients in the study received follow-ups at the specialised outpatient clinic, which comprised a clinical examination and, if needed, follow-ups by a multidisciplinary team consisting of 5 different health professionals. The aim of the follow-ups was to assist the patients' return to daily life activities and work by providing information, support, and recommendations. The outpatient clinic treatment is described in more detail in a study by Howe and colleagues²⁴. In the control group, the family members were invited to attend a 2.5-hour psychoeducational group session conducted by an occupational therapist and a psychologist from the multidisciplinary team. The group session focused on brain anatomy, traumatic brain injury, and post-injury challenges in functioning and in resuming daily life activities and work, but not specifically on family functioning.

In the intervention group, the follow-ups at the outpatient clinic were supplied with the Traumatic Brain Injury/Spinal Cord Injury Family System Intervention²⁵. This is a theoretically based family intervention developed for families facing trauma, comprising eight 90-minute sessions focusing on specific topics. The intervention manual has appeared as

supplementary material in a previous publication²⁵. The family intervention builds on family system theory and evidence-based strategies from cognitive-behavioural therapy and family therapy approaches. The aims described in the manual were to improve patients' and family members' individual functioning and the family functioning and to enact positive changes in communication, level of conflict, family satisfaction, and interpersonal boundaries²⁵. Some minor cultural adjustments to fit the Norwegian context were made in advance of the randomised controlled trial and are described in a previous publication²⁶.

To each family separately, the main group-facilitator (author MSR) delivered the sessions according to the instruction manual, with approximately 1 session per week. The sessions comprised both theoretical and practical components and had a fixed structure but were individually tailored to accommodate each family's unique needs. In the sessions, participants were given the opportunity to share personal experiences and family challenges relevant to their specific situation. Handouts and between-session tasks were provided, and the families were encouraged to apply the learned skills and techniques to real life situations. Based on the families' needs and preferences, the intervention was delivered at the Oslo University Hospital, in the family's home, or in appropriate municipal premises. The group-facilitator scheduled the sessions based on the families' availability. For 10 of the families in the intervention group, a rehabilitation professional (nurse or occupational therapist) from the collaborating municipality attended as co-facilitator. Table 1 provides an overview of the intervention topics.

[Table 1 Overview of intervention topics near here]

All group-facilitators had received training in the intervention, and they participated in a pilot/feasibility study of the family intervention²⁶. Furthermore, elements from a publication by Winter et al.²⁷ were used to assess the main group-facilitator's adherence to the intervention manual and administration of the family intervention. The elements measuring

task completion included the following: a) explained purpose of each session clearly; b) used appropriate pace and language; c) showed sensitivity to the participant responses; d) responded clearly to participants' questions, e) demonstrated overall fidelity to the Traumatic Brain Injury/Spinal Cord Injury Family System Intervention manual; and f) explained next step of intervention. The fidelity items were rated as poor, good, or excellent by a municipal health professional after completion of the family intervention for 9 (30%) of the families in the intervention group. All items concerning fidelity were rated as excellent by the municipal health professional.

Additionally, in the last session of the family intervention, participants were asked to rate the level of satisfaction with the sessions and of satisfaction with the group-facilitator's delivery of the sessions on a numeric scale ranging from 0 (not at all satisfied) to 10 (very satisfied). The participants were very satisfied with the intervention sessions (mean score of 9.3; SD 0.9) and with the way the sessions were delivered by the group-facilitator(s) (mean score of 9.6; SD 0.6).

Statistical methods

Data were analysed with Stata 16 and with an intention-to-treat approach, including all subjects randomised regardless of group, compliance with treatment, or withdrawals.

Descriptive statistics were used to describe the study population, and demographic variables were compared using χ^2 , Mann-Whitney U tests, or t-tests, as appropriate. Continuous variables were presented as mean and standard deviation (SD) or median and interquartile range (IQR), and categorical variables were presented as frequency and percentage.

Sample size was determined based on the primary outcomes. For the Mental Component Summary on the SF-36, the study on patients with moderate to severe traumatic brain injury

by Andelic et al. was used²⁸, and we inserted 44 points (SD12) with a difference of 5 points between the groups. With a power of 80% and a significance level of 0.05, the predicted sample size was 66 patients, with 33 families in each arm of the randomised controlled trial. In addition, we estimated that there would be 2 family members per patient. And for the Caregiver Burden Scale, Manskow and colleagues' study on Norwegian caregivers of persons with severe traumatic brain injury was used²⁹. A reduction of 0.4 points on the Caregiver Burden Scale is equal to a moderate effect size, and the power calculation yielded a sample size of 126 caregivers.

To evaluate the intervention effect, a linear mixed model analysis for repeated measurements with a random intercept was conducted to investigate between-group differences at start-of-treatment and at the 2-month and 8-month follow-ups. The main effect of treatment, the main effect of time, and the interaction term between treatment and time were applied as fixed effects in the statistical model. Random effects were the subjects. Results are presented as mean differences with 95% confidence intervals (CIs) for all 3 assessment time points. All tests were 2-sided and assumed a significance level of $p = 0.05$. Assumptions of all statistical tests were not violated.

Results

Figure 1 shows the flow chart for study recruitment and retention flow. Of the 251 eligible patients, 67 patients and 69 family members consented to participation and were randomised to the intervention group ($n = 33$ families) and control group ($n = 34$ families). Before the assessment at the start-of-treatment, 6 families (8.8 %) withdrew. Data from at least 1 time point were available for 124 participants (91%). In 4 families, the 2 first or last sessions were combined into 1 session pursuant to the families' request to minimise use of time. The families were recruited approximately 1 year post-injury. Median (IQR) in months from start-

of-treatment to 2 months' follow-up was 2.7 (2.3, 3.8) months and 9.2 (8.2, 9.9) months to the 8-month follow-up. No adverse effects were reported during the study.

[Figure 1 CONSORT flow chart near here]

Participant characteristics and injury-related data are displayed in Table 2. There were no significant differences in characteristics or outcome measures at start-of-treatment between the groups. Most patients (82 %) had a mild traumatic brain injury and reported persistent post-concussion symptoms as assessed by the Rivermead Post-concussion Questionnaire. Most family members (92 %) were spouse/partner of the patient.

Results from the multilevel model analysis with between-group mean differences are displayed in Table 3. There were no significant between-group differences on the primary outcome measures, the Mental Component Summary and the Caregiver Burden Scale, at the follow-ups. However, there were significant within-group improvements on the Mental Component Summary ($p = 0.028$) and the Caregiver Burden Scale ($p = 0.003$) from start-of-treatment to 2-month follow-up in the intervention group. Mental health related quality of life and level of caregiver burden improved over time in both groups.

No significant between-group differences were demonstrated on the secondary outcome measures, the Family Adaptability and Cohesion Evaluation Scale and the Quality of Life after Brain Injury Questionnaire, at 2 months or 8 months. At all assessment time points, both groups reported balanced levels of cohesion and flexibility in the family system, indicated by a mean circumplex ratio score > 1 , as well as high levels of family communication with mean scores on the Family Communication Scale > 62 percentiles²².

From start-of-treatment to the 2-month follow-up, the intervention group had significant improvements in family functioning on the circumplex ratio score ($p = 0.027$), Family Communication Scale ($p = 0.002$), and Family Satisfaction Scale ($p = 0.030$), whereas the

control group did not. The patients in both groups had a mean score < 60 points on the Quality of Life after Brain Injury Questionnaire at start-of-treatment, indicating reduced quality of life³⁰. However, they improved over time, whereas only the patients in the control group had a significant change from start-of-treatment to 2-month follow-up ($p = 0.002$). Within group changes are displayed in Table 4.

[Table 2 near here]

[Table 3 near here]

[Table 4 near here]

Discussion

Contrary to our hypothesis, this clinical trial showed no extra benefit of the 8-session family intervention in addition to ordinary follow-ups at a specialised outpatient clinic on mental health related quality of life, traumatic brain injury specific quality of life, caregiver burden, and family functioning (including communication and satisfaction). However, in the intervention period, there were statistically significant improvements in mental health related quality of life, caregiver burden, family functioning, communication, and satisfaction in the intervention group, indicating that the family intervention possibly contributed with a boost in the recovery process.

Our results differed from those reported in a randomised pilot study of the Traumatic Brain Injury/Spinal Cord Injury Family Intervention on 8 individuals with spinal cord injury and their family members, which demonstrated significant reductions in depression, anxiety, burden, and improved problem-solving skills in favour of the intervention group²⁵. However, contextual factors, such as access to formal health services and injury consequences, were different from those in the present study, making comparison of the results difficult.

In general, comparing family/dyad intervention studies after traumatic brain injury is difficult due to discrepancies in intervention aims and content as well as differences in methodology and outcome measures¹⁴. Interventions aimed at supporting the family often focus on the caregiver only and do not work with patients and caregivers as active participants in the same sessions. Moreover, many intervention studies focus on patient and caregiver outcomes but do not report on outcomes that reflect the family or dyadic health as a whole, such as family functioning¹³.

In the present study, both groups showed improvement over time in mental health related quality of life, and the family members' subjective caregiver burden was reduced in the

follow-up period. This is in contrast to findings in a study on Norwegian caregivers of persons with severe traumatic brain injury, which reported increased caregiver burden 2 years after the injury¹¹. However, most patients in the present study had consequences following mild traumatic brain injury. Although they experienced persistent symptoms, the recovery is generally good for persons with mild traumatic brain injury, and function improves over time³¹. Thus, it might be that the level of subjective caregiver burden also improved over time for the majority of family members in the present study.

Many randomised controlled trials are conducted in clinical settings that offer specialised treatment. If the quality of standard care or “treatment as usual” is comprehensive in randomised controlled trial control groups, the effect sizes might be reduced³². The treatment provided to the control group might have influenced the results in this study, as all patients received the specialised follow-ups. Additionally, family members in the control group also attended the educational group session about traumatic brain injury. Because of this, families in both groups may have experienced that many of their needs were met through specialised follow-ups. Moreover, completing the self-reported questionnaires might have opened up discussions about family functioning and communication for those in the control group. This is an issue also highlighted in a randomised controlled trial of patient and caregiver intervention after stroke, in which some control group participants reported that the assessments promoted reflection, adjustments, and help-seeking behaviour³³.

The mean level of family functioning showed balanced levels of cohesion and flexibility in the family system at start-of-treatment. A selection bias is possible, however, related to those who volunteered to participate in this study. There is a possibility that families with problematic dynamics and more troubled family functioning, who could have benefitted more from the intervention, found it too difficult to address family issues in addition to coping with

the traumatic brain injury. When people voluntarily participate in studies, the researcher cannot be sure whether the participants are those most in need of the intervention³⁴.

Further, participation in the intervention asked families to attend 8 sessions and complete home tasks, and 4 families asked to combine sessions to reduce use of time. Feasibility of recruitment and delivery mode of caregiver and dyad interventions is emphasised in both the stroke and traumatic brain injury literature, as finding time to attend several sessions can be challenging for family members due to busy everyday life schedules^{3, 13}. Moreover, the patients in this study reported traumatic brain injury specific quality of life in the proximity of the suggested cut-off for poor quality of life at the 2- and 8-month follow-ups, as suggested by Wilson and colleagues³⁰. Additionally, the patients in the control group showed a more significant improvement in condition-specific quality of life than the patients in the intervention group. With symptoms commonly experienced after traumatic brain injury, such as fatigue, headache, and poor concentration³¹, attending 8 family sessions might be perceived as a burden rather than an opportunity. An abridged version of the family intervention, adjusted to topics provided as part of the specialised rehabilitation process, might have been more appropriate for this patient group.

Strengths of this study were that we followed the Consolidated Standards of Reporting Trials (CONSORT) statement¹⁵ and that feasibility with regard to delivery of the intervention and outcome assessments were evaluated prior to the full-scale randomised controlled trial²⁶. In addition, this was a pragmatic trial with applied flexibility to accommodate the families' needs and to minimise their use of time and resources. The pragmatic element makes this study relevant to clinical practice. To our knowledge, this is one of the first family-centred intervention studies with an emphasis on patients with mild traumatic brain injury that had a protracted course of recovery.

In addition to the methodological challenges that have been raised in the discussion, the study has some limitations that should be noticed. All participants were recruited from the same specialised outpatient clinic, and the same therapist was responsible for delivering the intervention to all families. Hence, our results may not be generalisable to outpatient clinics with different structures and processes of care. Although we did succeed in recruiting a sufficient number of patients needed in this study, we included fewer family members than estimated, most likely due to cultural factors, such as the typical Norwegian family structure. Further, we had to end the inclusion period after 2.5 years due to the project's time frame. Several outcome measures were used in this study, as recommended when evaluating the effectiveness of complex interventions³⁵. However, recovery after traumatic brain injury is multifaceted, and we cannot be sure we chose the right outcomes to capture the intervention's actual impact. As most patients had sustained a mild traumatic brain injury, precaution should be made when generalising the results to families facing more severe injuries.

Any illness and disability can put stress on the family unit, and the Traumatic Brain Injury/Spinal Cord Injury Intervention could be applied to families dealing with illness and disability in general²⁵. However, many intervention studies focus on a specific condition¹³. With regard to generalisability, future studies should consider including participants with different conditions, such as stroke or traumatic brain injury, or other chronic neurologic conditions, as the families might experience many of the same needs¹³. This could improve transfer of knowledge between different health sectors. Additionally, this is relevant with regard to implementation of interventions in municipal health care settings, as they are less specialised and provide services and support to persons with various conditions and their families. Moreover, planning intervention studies with a mixed methods approach, such as combining quantitative measures with semi-structured interviews, may help to define key components of interventions and should be considered in future research.

From this study we conclude that receiving the theoretically based family intervention, in addition to outpatient specialised follow-ups for patients with traumatic brain injury and their family members, was not superior to only receiving specialised follow-ups in improving mental health related quality of life, traumatic brain injury specific quality of life, caregiver burden, and family functioning after traumatic brain injury. However, our findings imply that the family intervention might have contributed to a boost in individual and family functioning in the intervention period.

Clinical message

- Receiving a theoretically based 8-session family intervention, in addition to specialised follow-ups at a traumatic brain injury outpatient clinic, was not superior to only receiving specialised follow-ups in improving individual and family functioning in patients with mild-to-severe traumatic brain injury and their family members.

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Declaration of conflict of interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Trial registration

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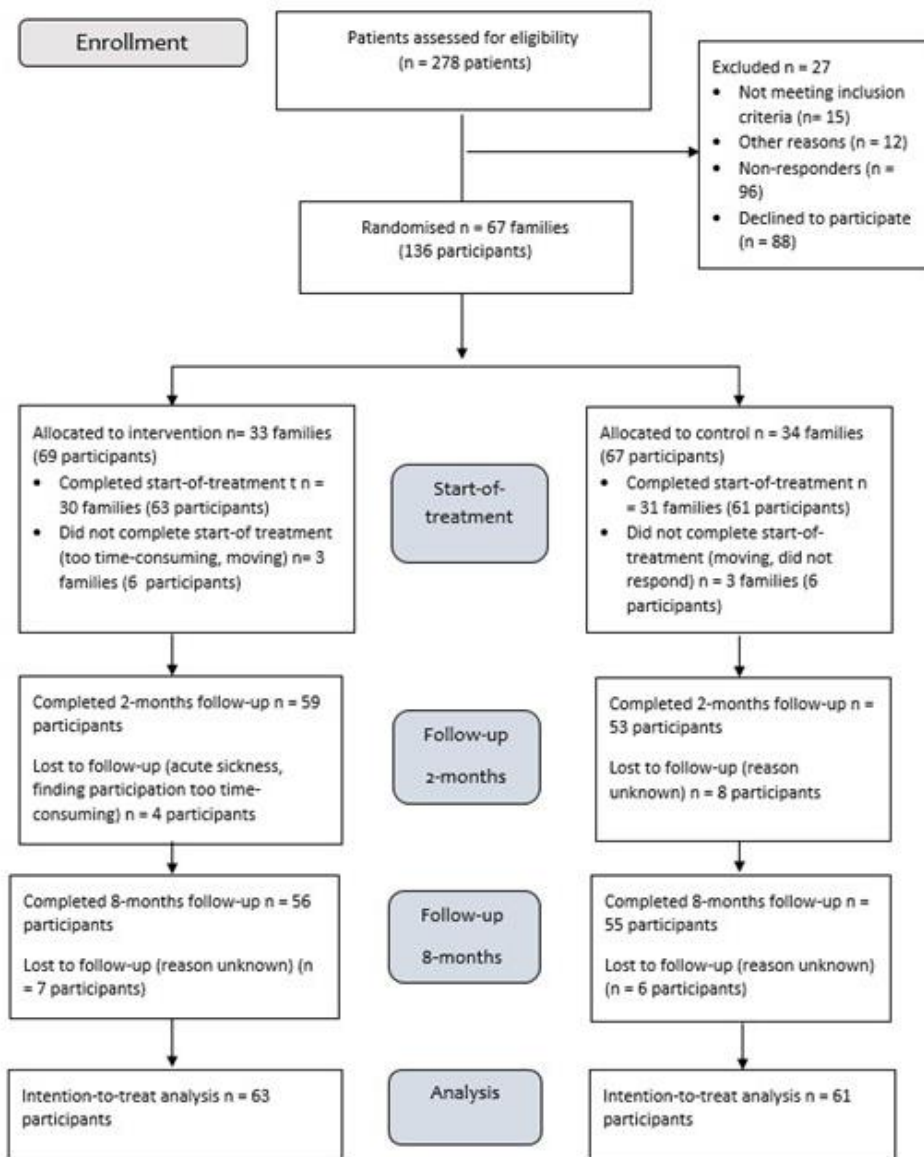


Figure 1: CONSORT flow chart.

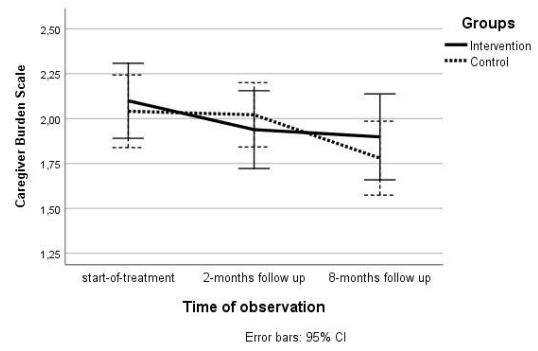
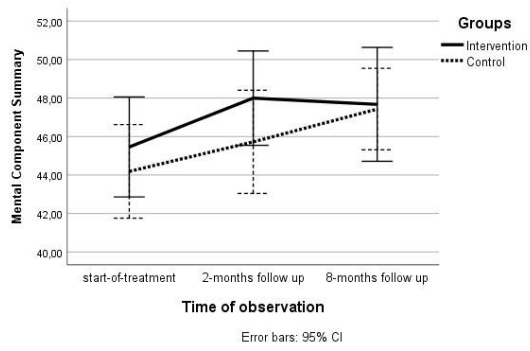


Figure 2 Graphical presentation of mean scores on the primary outcome measures, the Mental Component Summary and the Caregiver Burden Scale, per group on start-of-treatment, 2-months follow up, and 8-months follow up.

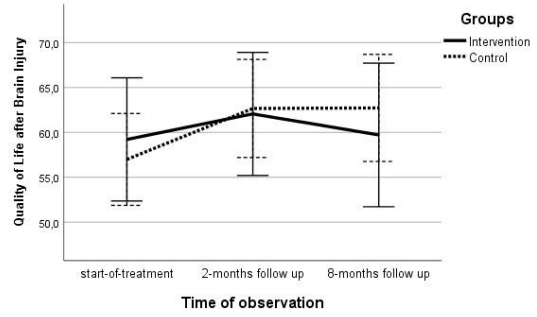
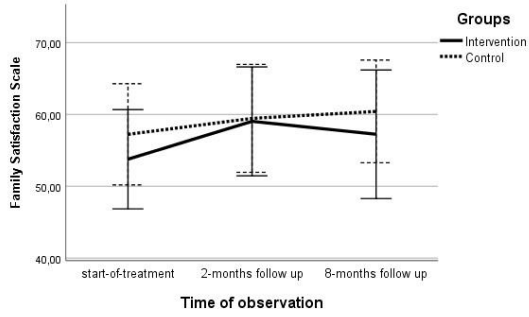
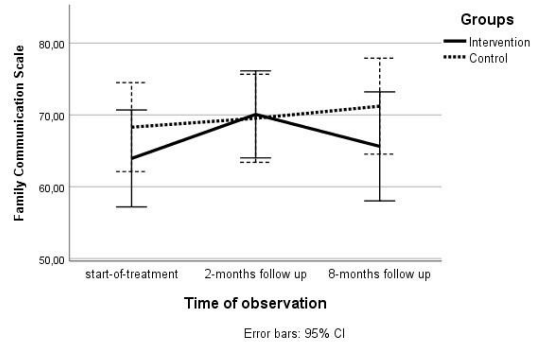
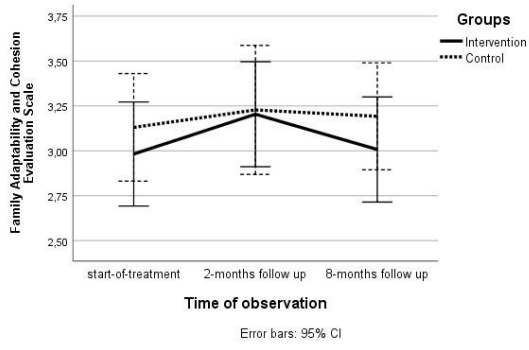


Figure 3 Graphical presentation of mean scores on the primary outcome measures, Family Adaptability and Cohesion Evaluation Scale, Family Communication Scale and Family Satisfaction Scale, per group on start-of-treatment, 2-months follow up, and 8-months follow up.

Table 1: Overview of intervention topics ²⁵.

Session	Topic	Content
1	Introduction	Information about the study. Introduction and overview of expectations and completion of start-of-treatment questionnaires.
2	Making meaning	Extracting beliefs and experiences related to traumatic brain injury.
3	Shifting focus	Positive changes after traumatic brain injury. Understanding the relationship between thoughts, feelings, and behaviour.
4	Managing emotions	Physiological changes when emotions escalate. Recognising “warning signs” of emotional escalations. Strategies for overcoming negative emotions.
5	Communicating effectively	Fighting fairly. Communication danger signs. Strategies for effective communication.
6	Finding solutions	Moving from a problem-oriented to solution-oriented perspective. Formulating useful goals. Problem-solving skills.
7	Boundary making	Externalising the problems. Education on healthy vs. unhealthy family dynamics. Importance of self-care.
8	Summarising and farewell	Summary of skills learned, feedback from the participants, and completion of 2-months follow-up questionnaires.

Table 2: Sample characteristics of the intention-to-treat population at start-of-treatment (n = 124) in personal factors, living arrangements, and injury-related factors.

Variables	Intervention n = 63 participants		Control n = 61 participants	
	Patients (n = 30)	Family members (n = 33)	Patients (n = 31)	Family members (n = 30)
Age, years (mean, SD)	45.0 (11.8)	43.5 (12.2)	42.6 (10.3)	41.6 (10.0)
Female sex, n (%)	15 (50.0)	18 (54.5)	18 (58.1)	15 (50.0)
Married/cohabitating, n (%)	29 (96.7)	32 (97.0)	30 (96.8)	29 (96.7)
Kinship to the patient				
Spouse/partner, n (%)		29 (87.9)		29 (96.7)
Parent, n (%)		1 (3.0)		-
Children, n (%)		3 (9.1)		1 (3.3)
Length of relationship in years				
< 1 year, n (%)	3 (10.3)	3 (9.4)		
1-5 years, n (%)	3 (10.3)	4 (12.5)	4 (13.3)	4 (13.8)
> 5 years, n (%)	23 (79.3)	25 (78.1)	26 (86.7)	25 (86.2)
Living with injured person, n (%)		28 (84.8)		29 (96.7)
Number of family members in the insured's household, mean (range)	3.0 (0-6)		3.1 (1-6)	
Level of education				
Low, n (%)	9 (30.0)	9 (27.3)	7 (22.6)	6 (20.0)
High, n (%)	21 (70.0)	24 (72.7)	24 (77.4)	24 (80.0)
Employment status				
Preinjury				
Employed/studying, n (%)	27 (90.0)		30 (96.8)	
Preinjury not employed, n (%)	3 (10)		1 (3.2)	
Post-injury				
Employed/studying, n (%)	5 (16.7)	27 (81.8)	-	26 (86.7)
Partly sick-leaved, n (%)	12 (40.0)	1 (3.0)	21 (67.7)	3 (10.0)
Sick-leaved 100%, n (%)	13 (43.3)	5 (15.2)	10 (32.3)	1 (3.3)
Injury characteristics				
Time since injury months, median (IQR)	11.4 (8.3, 15.3)		11.4 (8.5, 16.8)	
GCS, median (IQR)	15 (11.8, 15.0)		15 (14.0, 15.0)	
AIS, median (IQR)	2 (2.0, 3.3)		1 (1.0, 2.0)	
Findings on CT/MRI, n (%)	11 (36.7)		7 (22.6)	
Falls, n (%)	11 (36.7)		12 (38.7)	
Traffic accidents, n (%)	10 (33.3)		9 (29.0)	
Mechanical object, n (%)	6 (20.0)		8 (25.8)	
Violence, n (%)	1 (3.3)		1 (3.2)	
Others, n (%)	2 (6.7)		1 (3.2)	
RPQ (n = 56) (mean, SD)	29.9 (10.9)		25.8 (10.9)	
Self-reported comorbidities, n (%)	6 (20.0)		5 (16.1)	

GCS, Glasgow Coma Scale score; AIS, Abbreviated Injury Scale score; CT/MRI, Computed tomography/Magnetic resonance imaging; RPQ, Rivermead Post-Concussion Questionnaire IQR, interquartile range; SD, standard deviation

Table 3: Mean difference for each outcome between the groups (control compared with intervention) at start-of-treatment, follow-up 2-months, and follow-up 8-months using a linear mixed model for repeated measurements.

Measure	Mean difference (95% C.I) between groups, start of treatment	p-value	Mean difference (95% C.I) between groups, 2-months follow-up	p-value	Mean difference (95% C.I) between groups, 8-months follow-up	p-value
MCS	-1.27 (-4.67 to 2.13)	0.464	-1.93 (-5.43 to 1.57)	0.280	-0.61 (-4.11 to 2.90)	0.734
CGB	-0.01 (-0.34 to 0.21)	0.632	0.07 (-0.21 to 0.34)	0.633	-0.01 (-0.29 to 0.26)	0.920
FACES	0.15 (-0.25 to 0.55)	0.470	0.03 (-0.38 to 0.21)	0.871	0.15 (-0.26 to 0.56)	0.482
FCS	4.36 (-0.26 to 0.56)	0.331	-1.81 (-4.42 to 13.14)	0.692	2.75 (-10.77 to 7.14)	0.548
FSS	3.47 (-6.49 to 13.43)	0.495	-0.19 (-10.37 to 10.00)	0.972	1.13 (-9.09 to 11.35)	0.828
QOLIBRI	-2.23 (-10.58 to 6.12)	0.601	0.88 (-7.59 to 9.35)	0.838	1.10 (-7.37 to 9.56)	0.799

MCS, Mental Component Summary; CGB, Caregiver Burden Scale; FACES, Family Adaptability and Cohesion Evaluation Scale; FCS, Family Communication Scale; FSS, Family Satisfaction Scale; QOLIBRI, Quality of Life after Brain Injury Questionnaire.

Table 4: Scores on primary and secondary outcomes at all assessment time points with within-group mean scores and p-values for differences from start-of-treatment to follow-up 2-months and follow-up 8-months, by group.

	Intervention group				Control group					
	Start-of-treatment n = 63	2-months follow-up n = 59	8-months follow-up n = 56	Change from start-of-treatment to follow-up 2-months	Change from start-of-treatment to follow-up 8-months	Start-of-treatment n = 61	2-months follow-up n = 53	8-months follow-up n = 55	Change from start-of-treatment to follow-up 2-months	Change from start-of-treatment to follow-up 8-months
	Mean (SE)	Mean (SE)	Mean (SE)			Mean (SE)	Mean (SE)	Mean (SE)		
MCS (0-100 worst-best)	45.5 (1.21)	47.9 (1.24)	47.9 (1.26)	*2.4	*2.4	44.2 (1.24)	46.0 (1.29)	47.3 (1.27)	1.8	*3.1
CGB (1-4 best-worst)	2.1 (0.10)	1.9 (0.10)	1.8 (0.10)	*-0.2	-0.3	2.0 (0.10)	2.0 (0.10)	1.8 (0.10)	0.0	*-0.2
FACES (1-10 worst-best)	3.0 (0.14)	3.2 (0.15)	3.0 (0.15)	*0.2	0.0	3.1 (0.15)	3.2 (0.15)	3.2 (0.15)	0.1	0.1
FCS (10-99 worst-best)	63.9 (3.14)	70.7 (3.18)	66.7 (3.22)	*6.8	2.8	68.3 (3.19)	68.9 (3.28)	69.5 (3.26)	0.6	1.2
FSS (10-99 worst-best)	53.8 (3.56)	59.5 (3.62)	58.1 (3.67)	*5.7	4.3	57.2 (3.62)	59.3 (3.73)	59.2 (3.70)	2.1	2.0
QOLIBRI (0-100 worst-best)	59.2 (3.01)	62.2 (3.05)	61.0 (3.06)	3.0	1.8	57.0 (3.01)	63.1 (3.06)	62.1 (3.04)	*6.1	*5.1

MCS, Mental Component Summary; CGB, Caregiver Burden Scale; FACES, Family Adaptability and Cohesion Evaluation Scale; FCS, Family Communication Scale; FSS, Family Satisfaction Scale; QOLIBRI, Quality of Life after Brain Injury Questionnaire.

* Significant within-group changes $p < 0.05$