

Caregivers to patients with severe traumatic brain injury

A national prospective study on caregiver burden, life satisfaction and health care experiences.

Unn Sollid Manskow

A dissertation for the degree of Philosophiae Doctor –October 2016

Caregivers to patients with severe traumatic brain injury

A national prospective study on caregiver burden, life satisfaction and health care experiences.

Unn Sollid Manskow

Department of Rehabilitation, University Hospital of North Norway

Faculty of Health Sciences, Department of Clinical Medicine

UiT, The Arctic University of Norway

Tromsø, Norway 2016



Acknowledgements

First of all, I will thank my supervisor Audny Anke for engaging me in this project and supporting me all the way through this journey. You have given me a lot of new knowledge, good and clarifying discussions, supported me in both up and down periods, and always with a positive attitude. Thank you for believing in me and for your care for me as a person.

A huge thank to my co-supervisor Elin Damsgård for your support all the way and for our fruitful discussions and feedback, you have seen things with “new eyes” and have given me a lot of new knowledge through our cooperation.

I also wish to thank my dear friend and colleague Dr. Mary Braine for all your help and professional support, your clinical knowledge within this theme of research has been important to me.

Thanks to Oddgeir Friborg for your positive attitude and help with not only the statistics and methods, but also for your interest and insight in our area of research. Also thanks to Cecilie Røe for your contribution and helpful feedback on our articles in this thesis and for always being positive to participate.

Thanks to all members of the steering committee in the national multicenter study on “Rehabilitation after severe traumatic brain injury” for help and support especially in the first article.

I also want to thank my colleagues at UNN, IHO and EPINOR for all your support.

Thanks to the Northern Norway Regional Health Authorities for funding the study.

A huge thank goes to my husband Snorre for all your love and unconditional support, for good discussions at home and for being there for me in both good and not so good times. Love and thanks to all our children for their support, love and always having faith in me.

Last but not least, my appreciation goes to all the participants for making this project possible.

Tromsø 22.10.16

Unn Sollid Manskow

Table of Contents

Sammendrag	3
Summary	5
List of papers	7
Abbreviations	8
1. Introduction	9
1.1 Severe traumatic brain injury (TBI)	9
1.2 The impact on family members	10
1.3 Family systems theory	11
1.4 Caregiver burden	12
1.4.1 Caregiver burden related to severe TBI.....	13
1.4.2 Predictors of caregiver burden.....	14
1.5 Life satisfaction	16
1.6 Satisfaction and experiences with health care	17
1.6.1 Family members' experience with in-hospital health care after severe TBI.....	17
2.0 Aim and objective of the thesis	21
3. Material and methods	22
3.1 Study design and inclusion criteria	22
3.2 Data collection	22
3.3 Participants	23
3.4 Ethical considerations	25
3.5 Assessment of caregivers	25
3.5.1 Caregiver Burden Scale (CBS)	25
3.5.2 Life satisfaction	26
3.5.3 Social network.....	27
3.6 Assessment of patients at baseline and 1-year follow-up	27
3.6.1 Acute injury severity variables at baseline.....	27
3.6.2 Functional level at 1-year follow-up.....	28
3.7 Development of the Family members' Experiences with in-hospital Care Questionnaire in severe Traumatic Brain Injury (FECQ-TBI)	28
3.8 Statistical analysis	30
4. Results	33
4.1 Paper I	33
4.2 Paper II	34
4.3 Paper III	34
5. Discussion of methodological considerations	36
5.1 Systematic error	36
5.2 Validity of measurements	37
5.2.1 Validity of caregiver burden measures	37
5.2.2 Validity of the life satisfaction measure	38
5.2.3 Validity of social network questions	38
5.3 Study design	39
5.4 Generalizability - external validity of the results	39
5.5 Causality - internal validity of the results	40
6. General discussion of results	42
6.1 Level of caregiver burden	42

6.2 Predictors of caregiver burden.....	45
6.3 Life satisfaction and the association with caregiver burden	47
6.4 Experiences with in-hospital health care.....	48
7. Clinical implications and conclusion	52
7.1 Clinical implications.....	52
7.2 Conclusions	53

References

Papers I-III

Appendix A-D

Sammendrag

Bakgrunn: Alvorlig traumatisk hjerneskade (TBI) er en utfordring innen folkehelse da det ofte har store konsekvenser for pasienten og familien i lang tid etter skaden. Å undersøke faktorer relater til pårørendes omsorgsbelastning, livstilfredshet og erfaringer med helsetjenesten er essensielt for å gi en optimal behandling, rehabilitering og omsorg for både pasienten og familien.

Formål: Å beskrive omsorgsbelastning og prediktorer for opplevd belastning 1 og 2 år etter skade, undersøke endring og stabilitet i omsorgsbelastning og livstilfredshet fra 1 til 2 år.

Utvikle et validert verktøy for å vurdere pårørendes erfaringer med helsetjenesten.

Metode: Norsk prospektiv multisenter kohorte som inkluderte totalt 122 pårørende av pasienter med alvorlig TBI. Nittito pårørende fylte ut et strukturert spørreskjema som undersøkte grad av omsorgsbelastning og prediktorer for omsorgsbelastning 1 år etter skade. Åtti pårørende deltok ved både 1 og 2 år der vi undersøkte endring i omsorgsbelastning og livstilfredshet over tid samt pasient og pårørenderelaterte faktorer assosiert med omsorgsbelastning. Vi utviklet og evaluerte de psykometriske egenskapene til the Family Experiences of in-hospital Care Questionnaire in severe Traumatic Brain Injury (FECQ-TBI). Eksplorerende faktoranalyse ble utført for å undersøke skalaens struktur, datakvalitet og analyser av intern konsistens og validitet.

Resultater: Artikkel I rapporterte en moderat til høy omsorgsbelastning hos 50 % av deltagerne 1 år etter skade. Gjennomsnitt score av Caregiver Burden Scale (CBS) viste en moderat omsorgsbelastning. Lineær regresjonsanalyse viste at et dårlig sosialt nettverk og å ta vare på en pasient med større funksjonsproblemer var signifikante prediktorer for en høy omsorgsbelastning. Artikkel II rapporterte en signifikant høyere omsorgsbelastning og lavere livstilfredshet ved 2 år sammenlignet med 1 år etter skade. Tretti prosent rapporterte en økning i belastning mens 55 % hadde en stabil omsorgsbelastning fra 1 til 2 år. Logistisk

regresjonsanalyse viste at ensomhet var en signifikant prediktor for en økning i belastning.

Artikkel III beskriver utviklingen av spørreskjemaet FECQ-TBI. Prinsipalkomponent analyse av det utviklede spørreskjemaet identifiserte seks delområder: akutt organisering og informasjon, rehabilitering organisering, rehabilitering informasjon, utskrivelse, fasiliteter sykehus-pasient og fasiliteter sykehus-familien. Spørsmål relatert til den akutte fase var sammenlignbar med spørsmål innenfor de to delområder av rehabilitering (organisering og informasjon). Alle delskalaer hadde Cronbach's alpha verdier > 0.80 , som bekreftet god intern konsistens. Hypotesetesting støttet begrepsvaliditeten.

Konklusjon: Pårørende til pasienter med alvorlig traumatisk hjerneskade rapporterer en moderat til høy omsorgsbelastning i lang tid etter skaden, med klinisk signifikant økning i belastning og reduksjon i livstilfredshet over tid. FEQC-TBI viste gode psykometriske egenskaper og begrepsvaliditet. Dette støtter bruken av FEQC-TBI for å kartlegge pårørendes vurdering av kvaliteten på behandling og omsorg gitt på sykehus. Resultatene kan ha klinisk betydning da en mer familiesentret akutt behandling og rehabilitering samt en langsiktig oppfølging kan forebygge omsorgsbelastning over tid. Å identifisere pårørende til pasienter med funksjonsproblemer, er i risiko for sosial isolasjon og et dårlig sosial nettverk er nødvendig.

Summary

Background: Severe traumatic brain injury (TBI) is a major public health challenge as it often has huge consequences for the patient and the family for a long time after the injury. To reveal factors affecting caregiver burden, life satisfaction and experiences with in-hospital health care is essential to be able to provide optimal treatment, rehabilitation and care for the patient and caregivers.

Objective: To describe caregiver burden and predictors of burden 1 year post injury, to investigate change and stability of caregiver burden and life satisfaction over time. To develop a validated tool to assess family member's in-hospital health care experiences.

Methods: A Norwegian prospective cohort multicenter study including a total of 122 caregivers to patients with severe TBI. Ninety-two participants completed a structured questionnaire assessing caregiver burden and predictors of burden 1 year post injury. Eighty participated at both 1 and 2 years post injury assessing caregiver burden and life satisfaction over time and patient and caregiver related predictors of burden. We developed and psychometrically evaluated the Family Experiences of in-hospital Care Questionnaire for family members of patients with severe Traumatic Brain Injury (FECQ-TBI). Exploratory factor analysis were used to examine scale structure, in addition to screening for data quality and analysis of internal consistency and validity.

Results: Paper I reported a moderate and high caregiver burden in 50 % of the participants at 1 year post injury. Mean score of the Caregiver Burden Scale (CBS) showed a moderate burden. Linear regression analyses revealed that poor social network and taking care of a patient with more functional problems were significant predictors of a high burden. Paper II reported significantly higher caregiver burden and lower life satisfaction at 2 years compared to 1 year post-injury. Thirty percent reported an increase in burden while 55 % had a stable burden from 1 to 2 years. Logistic regression analysis revealed loneliness as a significant

predictor of an increase in burden. Paper III describes the development process of the FECQ-TBI. Principal component analysis of the developed questionnaire extracted six subscales: acute organization and information, rehabilitation organization, rehabilitation information, discharge, hospital facilities-patient and hospital facilities-family. Items related to the acute phase were comparable to items in the two dimensions of rehabilitation (organization and information). All subscales had Cronbach's alpha coefficients > 0.80 , confirming the internal consistency. Hypothesis testing supported construct validity.

Conclusion: Caregivers of patients with severe TBI experiences a considerable caregiver burden long time post injury, with a clinical significant increase in burden and a decrease in life satisfaction over time. The FECQ-TBI showed good psychometric properties and construct validity, supporting the use of the FEQC-TBI to assess quality of in-hospital care from a family perspective. The results may have clinical implications as improved family-centered acute and rehabilitative care and a long-term follow-up can prevent the perceived caregiver burden over time. To identify caregivers to patients with functional problems and at risk of social isolation and a poor social network is needed.

List of papers

This thesis are based on the following papers:

Paper I.

Manskow US, Sigurdardottir S, Roe C, et al. Factors Affecting Caregiver Burden 1 Year After Severe Traumatic Brain Injury: A Prospective Nationwide Multicenter Study. *J Head Trauma Rehabil.* 2015;30(6):411-423.

Paper II.

Manskow US, Friberg O, Roe C, et al. Patterns of change and stability in caregiver burden and life satisfaction from 1 to 2 years after severe traumatic brain injury: A Norwegian longitudinal study. *Accepted, june 2016*

Paper III.

Anke A, Manskow US, Friberg O, et al. The family experiences of in-hospital care questionnaire in severe traumatic brain injury (FECQ-TBI): scale structure and validity. *Submitted.*

Abbreviations

ABI: acquired brain injury

AIS: Abbreviated Injury Scale

ANOVA: Analysis Of Variance

CBS: Caregiver Burden Scale

EFA: exploratory Factor Analysis

FECQ-TBI: The Family Experiences of in-hospital Care Questionnaire in severe Traumatic Brain Injury

GCS: Glasgow Coma Scale

GOSE: Glasgow Outcome Scale Extended

ISS: Injury Severity Scale

LCFS: the rancho Level of Cognitive Functioning Scale

LSD: Least Significant Difference

OR: Odds Ratio

PBS: Perceived Burden Scale

PCA: Principal Component Analysis

SD: Standard Deviation

SPSS: Statistical Package for the Social Sciences

SWLS: Satisfaction with Life Scale

TBI: Traumatic Brain Injury

sTBI: severe traumatic brain injury

UiT: UiT The Arctic University of Norway

ZBI: Zarit Burden Inventory

1. Introduction

1.1 Severe traumatic brain injury (TBI)

Severe TBI occurs when the brain is exposed to external trauma, and the most common causes include traffic accidents and falls. TBI is recognized as a major public health issue, and the WHO estimates that the prevalence of TBI will increase to become the 5th most common cause of death worldwide within a few years (Sundstrom et al., 2005, Hyder et al., 2007). The severity of TBI is categorized into minor, moderate and severe injury, and about 15% of patients admitted to a hospital with TBI have a severe injury (Ingebrigtsen et al., 1998). The mean age of those injured is around 30 years; men are three times more exposed to TBI than women, and the mortality due to severe TBI is approximately 30% (Sundstrom et al., 2005). The incidence of hospital-admitted severe TBI in Norway is reported to be between 4-5/100,000 each year (Andelic et al., 2012).

The range of possible impairments following severe TBI is extensive: cognitive losses can affect memory, visual perception, attention, concentration, problem solving, abstract reasoning, planning, information processing and organization (National Institutes of Health, 1999). Physical effects may include hemiparesis, visual deficits, bowel and bladder dysfunction, muscle spasticity, seizures and sensory impairments in touch, vision, pain, and temperature (Lynch, 1986). Psychological changes can affect behaviour (impulsivity, aggression, lability, withdrawal) and personality (depression, anger, denial, passivity, dependency, low self-esteem) (Cunningham et al., 1999).

TBI patients require long-term intensive care and rehabilitation, and the impairments after injury can affect the patient, family and social network for a long period of time. The patients often experience a reduced functional level, limitations in activity and participation in daily life activities over time or for the rest of their life (Zaloshnja et al., 2008, Christensen et al., 2008). TBI is considered to represent a “silent epidemic”, as society seems to be unaware

of the magnitude of its socioeconomic consequences (Roozenbeek et al., 2013). In Norway, there are no established family programmes or structured follow-up routines available after severe TBI in the four trauma centres included in this study. Only one of the main rehabilitation hospitals does arrange a seminar for family members three times a year and reports a close connection and collaboration with family members during the patients' stay.

1.2 The impact on family members

The family members and/or caregivers are an important component of the patient's treatment and rehabilitation process, and they function as an extension of the health care system, especially after returning home (Ramkumar and Elliott, 2010). Unlike other neurological diseases such as dementia and stroke, severe TBI is a sudden event that often results in a variety of deficits, particularly affecting cognitive, behavioural and psychosocial outcomes. These deficits are often invisible to others, which make it especially challenging for both the patient and the family.

Since the 1970s, a substantial amount of literature on the impact of severe TBI on family members has pointed to a high level of caregiver burden, diminished life satisfaction, unmet family needs, adaptation to new roles, anxiety, depression, social isolation, emotional difficulties and challenges with family functioning (Oddy et al., 1978, McKinlay et al., 1981, Gillen et al., 1998, Douglas and Spellacy, 1996, Braine, 2011, Kolakowsky-Hayner et al., 2001, Livingston et al., 1985, Kreutzer et al., 2009, Norup et al., 2011, Holm et al., 2009). In the late 1970s, the term "carer" appeared in the literature; until then, carers were not visible in policy and research activities because it was expected that being a carer was part of family life, an informal role, and thus a private not a public matter (Braine and Wray, 2016). The definition of a caregiver varies across studies, and no rigorous definitions are found in the

literature; however, most studies agree that the individual must not be paid to provide care (Greenwood et al., 2008).

In this thesis, a caregiver is understood to be the primary and informal (unpaid) family member or acquaintance of an individual who, due to illness or disability, depends on their support to perform a variety of tasks, such as personal care, assistance, emotional problems and others. An informal caregiver can be a son, daughter, husband/wife, mother/father, close friend, uncle/aunt or other family member.

1.3 Family systems theory

To provide a more holistic understanding of the impact a severe TBI has on the caregivers, family systems theory was chosen as a theoretical framework for this thesis. Family systems theory is previously used for family intervention after TBI and is seen as important for health professionals to be able to understand the family dynamics (Rosenthal and Young, 1988). The theory views the family as a multidimensional and complex unit with an identity of its own that is simultaneously dynamic when exposed to events that provoke changes in the family structure (Rosenthal and Young, 1988, Leaf, 1993).

In short, four main pillars are included in the theory (Verhaeghe et al., 2005, Rosenthal and Young, 1988): (1) All components within a system are connected. Family relationships occur in several different directions, and the interactions are numerous, i.e., father and mother, child and parents, between child one and child two. (2) The system develops over a life cycle. At each new phase in life and addition to the family (birth of a child, marriage), the family system develops and evolves. (3) A change in one component of the system implies change for all system components. If the rules of the existing patterns within the family are disrupted, this affects not only that person but also all participants within

the system. (4) Every system is unique. One family's system differs from that of another, and the roles within the system differ, meaning that a disruption and its consequences differ.

Applying family systems theory to this thesis, caregivers are conceptualized as components of a family system adapting to a new situation after being confronted with severe TBI. The first pillar within this theory pertains to the relationships between the caregiver, other family members and the person with severe TBI; the whole family is affected. The second pillar has a direct implication on the development of the family, as the sudden event of a TBI can be characterized as a new phase in life for the whole family and also for their social network. In addition, the impact on the caregivers as the patient progresses through different phases of acute treatment and rehabilitation, as well as long-term phases of care, can be linked to this phase. The third pillar implies that each person is affected by the severe TBI in a unique manner, and how the caregiver provide care and adjust to the subsequent changes in life differs for each person in the family. The fourth has direct implications for health care professionals, as each family is different, and thus the roles and degree of disruption after the injury will differ for each family.

1.4 Caregiver burden

Caregiving has become a major healthcare issue and is considered a global health care resource; furthermore, it is recognized that adverse consequences of caregiving may inadvertently affect the care recipient (Mathers and Loncar, 2007). Caregiver burden is one of the most commonly investigated caregiving outcomes and has been a central concept in family caregiving research since the 1960s (Grad and Sainsbury, 1966). There is no uniform or singular definition of caregiver burden, as it has been conceptualized in various ways since the 1960s, and a multitude of definitions have been described (Chou, 2000). Caregiver burden has been defined as the social, psychological, physical, economic or emotional strain that

individuals experience due to providing care (George and Gwyther, 1986). This burden may also accumulate when providing care to an individual over a long period of time (Kasuya et al., 2000).

The literature on burden related to caregivers of patients with TBI is often described to have two distinct components – objective and subjective burden. Objective burden refers to the physical or instrumental provision of aid to care-recipients, e.g., the numbers of hours of care provided, home care needs and observable caregiving tasks (Montgomery et al., 1985). Subjective burden relates to the emotional or psychological impact the objective burden has on caregivers, e.g., anxiety and emotional, relational and social stress (Montgomery et al., 1985). Many different instruments have been used to assess burden in family members of patients with TBI, and this affects the subsequent findings, as they shed light on different aspects of burden depending on which instrument is used. In addition, the use of different instruments warrants attention and caution when interpreting and comparing studies.

In this thesis, caregiver burden is defined as a multidimensional response to various stressors associated with caregiving that affect social, psychological, physical, and emotional aspects of the caregiver's life. The instrument we use to assess burden is directly connected to the experience of caring for a person with severe TBI (i.e., “Do you think that it is psychologically demanding for you to take care of your relative?”) and does not measure levels of anxiety or depression, only the perceived burden.

1.4.1 Caregiver burden related to severe TBI

Thomsen was one of the first to report on family caregivers in 1974, describing heavy strain in family members 2 years post-TBI (Thomsen, 1974). A longitudinal study investigating primary caregivers of patients with severe TBI at 3, 6 and 12 months post-injury found a slightly increased burden after 6 and 12 months (McKinlay et al., 1981). A follow-up study by the same authors revealed that caregivers experienced a significantly higher burden at 5 year

compared to 1 year post-injury (Brooks et al., 1986). Livingston and colleagues investigated 57 caregivers of patients with severe TBI 3, 6 and 12 months post-injury and found a high level of perceived burden at all time points, with a slight increase in burden at 6 and 12 months (Livingston et al., 1985). A study from New Zealand conducted from 6 to 12 months after injury reported that 50% of the caregivers experienced significant burden at both 6 and 12 months post-injury, but the authors found no change in burden over time (Marsh et al., 2002). Another cross-sectional study found a higher burden in caregivers of TBI patients compared to caregivers of patients with other acquired brain injuries (Jackson et al., 2009); in contrast, Sander et al. found a decrease in perceived burden during the first year after injury in their investigation of 69 caregivers at 3 different follow-up times within the first year post-injury (Sander et al., 1997). The population-based French Paris-TBI study reported that 56% of the participants experienced a heavy burden one year post-injury (Bayen et al., 2012).

Additionally, the positive versus negative aspects of caregiving related to severe TBI have been investigated. Two studies from the US reported that the majority of caregivers of patients with moderate/severe TBI had negative experiences related to caregiving (Hanks et al., 2007, Machamer et al., 2002). However, another study reported that 39% of the caregivers experienced negative and 60% positive aspects of caregiving (Knight et al., 1998).

1.4.2 Predictors of caregiver burden

Regarding predictors related to caregiver burden, studies show inconsistent findings. Some have reported that spouses experience a greater burden than parents (Kreutzer et al., 1994, Ponsford and Schonberger, 2010, Thomsen, 1974), while other studies have found no differences in burden depending on the caregiver's relationship to the patient (Ergh et al., 2002, Kreutzer et al., 2009, Norup et al., 2012, Livingston et al., 1985). Two studies have

reported that men experienced more emotional distress than women (Sander et al., 1997, Davis et al., 2009).

Social support is a broad concept that can include all social resources available to an individual, such as interpersonal relationships, health resources and professional support. The concept can also be defined as the individuals' social network, which includes both quantity (number of close friends, frequency of meeting friends) and quality (perceived support) of the caregivers' personal network; this is how we define caregiver's social network in this study (Gottlieb and Bergen, 2010, Anke et al., 1997). Previous research has shown that the perceived support (quality of social network) is not necessarily related to the quantity of social ties (i.e., number of close contacts) (George et al., 1989).

In the literature of caregivers to patients with TBI, Knight and colleagues found no relationship between caregiver burden and lack of a social network (Knight et al., 1998), while other studies indicated that a lack of social network in terms of perceived social support was related to a higher caregiver burden (Kreutzer et al., 2009, Hanks et al., 2007). A review from 2005 reported that young families of patients with TBI who perceived little social support were the most vulnerable to emotional distress (Verhaeghe et al., 2005). Furthermore, some studies have assessed perceived support in addition to loneliness in family members of patients with TBI: Oddy et al. reported loneliness as being the most difficult aspect of social adjustment experienced by caregivers of TBI survivors (Oddy et al., 1985). In a qualitative study on caregivers of patients with acquired brain injury, loneliness was reported to be a key theme contributing to the overwhelming sense of loss and burden (Braine, 2011).

Thomsen was one of the first researchers to report that the personality and emotional changes in patients with TBI contributed more to family burden than their physical and cognitive changes (Thomsen, 1974). Several cross-sectional studies have reported that a patient's neurobehavioral disturbances in the form of cognitive dysfunction and behavioural

changes strongly predicted a heavy burden (Marsh et al., 1998, Ergh et al., 2002, Kreutzer et al., 1994, Machamer et al., 2002). A longitudinal study found patient's behavioural changes to be the strongest predictor of experienced burden during both the first year and at 5 years post-injury (Brooks et al., 1986, McKinlay et al., 1981). Caring for a patient with severe disability, scored with the Glasgow Outcome Scale Extended (GOSE), was shown to be a predictor of caregiver burden in the Paris-TBI study (Bayen et al., 2012).

1.5 Life satisfaction

Life satisfaction is described as a cognitive subjective process in which a person assesses his/her overall satisfaction with current life status in relation to self-defined standards, expectations or their desired life status (Dijkers, 1999). In this thesis, life satisfaction was defined as the caregiver's view of general satisfaction with his or her life. Few studies have reported on life satisfaction at several time points in caregivers of patients with TBI. One study found diminished life satisfaction in family members of patients with TBI several years after injury compared to the reported levels pre-injury (Kolakowsky-Hayner et al., 2001).

A large longitudinal study assessed life satisfaction in caregivers 1 and 2 years post-injury and reported that patients' functional status, drug use and neurobehavioral problems were predictors of a low satisfaction with life, although there were no changes in life satisfaction scores over time (Livingston et al., 2010). Another longitudinal study showed no difference in life satisfaction compared to normative data 1, 2 or 5 years post-injury, although taking care of a patient with a low functional level and spending more time on care were predictors of a lower life satisfaction (Kreutzer et al., 2009). The cross-sectional and longitudinal studies assessing caregiver burden and life satisfaction referred to in this chapter are presented in detail according to their methods, participants and outcomes in Table 1.

1.6 Satisfaction and experiences with health care

Studies assessing the satisfaction and experiences with health care are usually conducted with patients and not family members. In most studies, a high proportion of overall satisfaction with health care are reported (Jenkinson et al., 2002, Garratt et al., 2005, Lee et al., 2008). The challenge with overall satisfaction assessments is that a high satisfaction score does not necessarily indicate the quality of health care because satisfaction results are likely to be less sensitive to specific problems (Jenkinson et al., 2002). Experiences with health care services are recognized as key dimensions of health care quality, and this is true among family members as well (Dodek et al., 2004). Although experience with concrete events is more valid and easier to interpret than satisfaction ratings, family experiences represent a complex concept, as they include comparisons of the family members' experiences with their own subjective standards. Patient and family health care experiences are used internationally to evaluate and compare health care services (Lee et al., 2008, Pettersen et al., 2004).

1.6.1 Family members' experience with in-hospital health care after severe TBI

Family members are especially important in providing support and care for the patient who has suffered from a severe TBI, and they often act as the patient's representative as the primary caregiver (Dodek et al., 2004). Family members' experiences with in-hospital health care is a vital indicator of the quality of health care provided to both the patient and the family. During the patient's in-hospital stay, family members may have needs and specific experiences that can change across treatment phases (Rotondi et al., 2007). It is common to describe these experiences and needs of family members in terms of the following phases post-TBI: the acute phase (1), in-hospital rehabilitation (2), the discharge phase (3), and the time after discharge (4). However, no validated multidimensional scales evaluating adult family members' experiences and satisfaction with acute care and rehabilitation after TBI are

to date available.

Most studies investigating family members' experiences in the acute treatment and rehabilitation stages of the patient with TBI are qualitative and suggest important areas for quality of care, including information from staff and the organization of services. The earliest studies on this topic were conducted in the 1970s: Panting and Merry (1972) investigated 31 relatives of patients with TBI who were admitted to a rehabilitation centre. They reported that more than half of the relatives felt that the support provided was inadequate because they received insufficient information regarding the prognosis and the difficulties that might be encountered (Panting and Merry, 1972). Thomsen (1974) found that a lack of information throughout the patient's clinical treatment was common among relatives of patients with TBI (Thomsen, 1974).

One qualitative study reported a lack of information in both the acute and rehabilitation phases related to both practical information and information regarding the consequences of brain injury, which caused anxiety among the family members (Smith and Smith, 2000). A Canadian study interviewed 25 family members at discharge from the ICU and discharge from acute care (Keenan and Joseph, 2010). They identified several needs, including advice on managing their new life and the need for information, professional support and hope. In addition, the needs changed over time throughout the different phases of the patients' in-hospital stay (Keenan and Joseph, 2010).

Another study explored family members' experiences during the patient's rehabilitation process with a questionnaire and reported that 25% received inadequate information about transfers within health care services and fewer than 20% received any formal support (O'Callaghan et al., 2011). Families and patients were also not informed about their rights during this dramatic life event, and carers' satisfaction with health care services declined throughout the patients' care pathway as their responsibility for the patient increased

(O'Callaghan et al., 2011). Turner et al. interviewed 13 family members of patients with acquired brain injury (ABI) and reported that caregivers experienced financial strain when transitioning from hospital- to home-based care because the family member had to stop working to provide full-time care. In addition, the process of reimbursement and issues related to insurance felt overwhelming (Turner et al., 2007). One longitudinal study in Australia investigated 83 family members' experiences from in-patient rehabilitation until discharge to home and reported that lower ratings of transition success were associated with greater stress among caregivers (Nalder et al., 2012).

As the literature indicates, there is a particular challenge in providing information to family members through the phases of the patient's in-hospital stay. Family members' in-hospital experiences could be important for their long-term confidence, support, and thus caregiver burden and potentially life satisfaction, in addition to health care indicators of the quality of in-hospital care.

Table 1. Cross-sectional and longitudinal studies on caregiver burden and/or life satisfaction in caregivers of patients with moderate to severe TBI.

Study	N	Patient population	Time post injury	Instrument	Burden ¹	Life satisfaction ^{1,2}
Oddy (1985)	23	sTBI	7 yrs	WSRS	17 %	-----
McKinlay (1981)	55	sTBI	3, 6 and 12 months	Likert	69%, 73%, and 75 %	-----
Jackson (2009)	222	TBI, ABI	3 months-44yrs	CBI	44 %	-----
Sander (1997)	69	sTBI	0-3, 6-18, 18 months	SBM	na	-----
Brooks (1986)	42	sTBI	1 and 5 yrs	Likert	57% and 89 %	-----
Marsh (2002)	52	sTBI	6 and 12 months	CQ	50%	-----
Marsh (1998)	66	sTBI	6 months	CQ	50 %	-----
Machamer (2002)	180	mTBI, sTBI	6 months	BQ	24 %	-----
Knight (1998)	52	sTBI	6 years (mean)	CBS	39 %	-----
Kreutzer (1994)	62	TBI	1.5-60 months	BSI	33 %	-----
Kreutzer (2009)	273	TBI	1, 2 or 5 years	BSI, SWLS	18 %	22 %
Ergl (2002)	60	mTBI, sTBI	5 years (mean)	BSI	53 %	-----
Thomsen (1974)	50	sTBI	4,5 months, 2,5 yrs	na	na	-----
Livingston (2010)	336	TBI	1 and 2 yrs	SWLS	-----	39 % and 41%
Livingston (1985)	57	sTBI	3, 6 and 12 months	PBS	na	-----
Hanks (2007)	60	mTBI, sTBI	6 months – 15 years	CAS	90 %	
Davis (2009)	114	mTBI, sTBI	12 months	MAS	NA	-----
Bayen (2012)	66	sTBI	12 months	ZBI	56 %	-----
Kolakowsky-Hayner (2001)	57	TBI	4 years or more	Life satisfaction	-----	40 %

¹ Including studies investigating caregiver burden, strain and/or distress.

² In longitudinal studies, the proportion reporting burden and life dissatisfaction at each time point is presented.

Abbreviations: na, not applicable; mTBI, moderate traumatic brain injury; ABI, acquired brain injury; CBI, Carer Burden Interview; SBM, Subjective Burden Measure; CQ, Caregiver Questionnaire; CBS, Care Burden Scale; SWLS, Satisfaction with Life Scale; CAS, Caregiver Appraisal Scale; MAS, Modified Appraisal Scale; PBS, Perceived Burden Scale

2.0 Aim and objective of the thesis

The main aim of this thesis was to explore caregiver burden and life satisfaction in caregivers of patients with TBI up to 2 years post-injury and to develop an instrument to assess family members' experiences with in-hospital health care after severe TBI.

The primary objectives of this thesis were as follows:

- 1) To assess the level of caregiver burden and factors affecting caregiver burden one year after severe traumatic brain injury.
- 2) To investigate the patterns of change and stability in caregiver burden and life satisfaction from 1 to 2 years post-injury in caregivers of patients with severe TBI and the factors associated with changes in caregiver burden.
- 3) To develop and validate the Family members' Experience with in-hospital Care Questionnaire (FECQ-TBI).

3. Material and methods

3.1 Study design and inclusion criteria

The study was a prospective population-based, multicentre cohort study covering all regions of Norway. All participants were caregivers of patients who were ≥ 16 years of age with severe TBI occurring from January 2009 to January 2012. All patients were admitted to 1 of the 4 trauma referral centres in each of the 4 health regions in Norway. The inclusion criteria for the present study were as follows:

1. A caregiver of a patient included in the national multicentre study on severe TBI in Norway (“Rehabilitation after severe traumatic brain injury. A Norwegian multicentre study”). The inclusion procedure for patients in the national multicentre study was as follows: age ≥ 16 years, admitted to one of the Norwegian trauma referral centres within 72 hours of injury, and unsedated Glasgow Coma Scale (GCS) score of ≤ 8 during the first 24 hours post-injury (Andelic et al., 2012).
2. Caregiver listed as the patient’s closest family member or acquaintance either by the patient and/or in the patient’s medical records.
3. Caregiver age ≥ 18 years.

3.2 Data collection

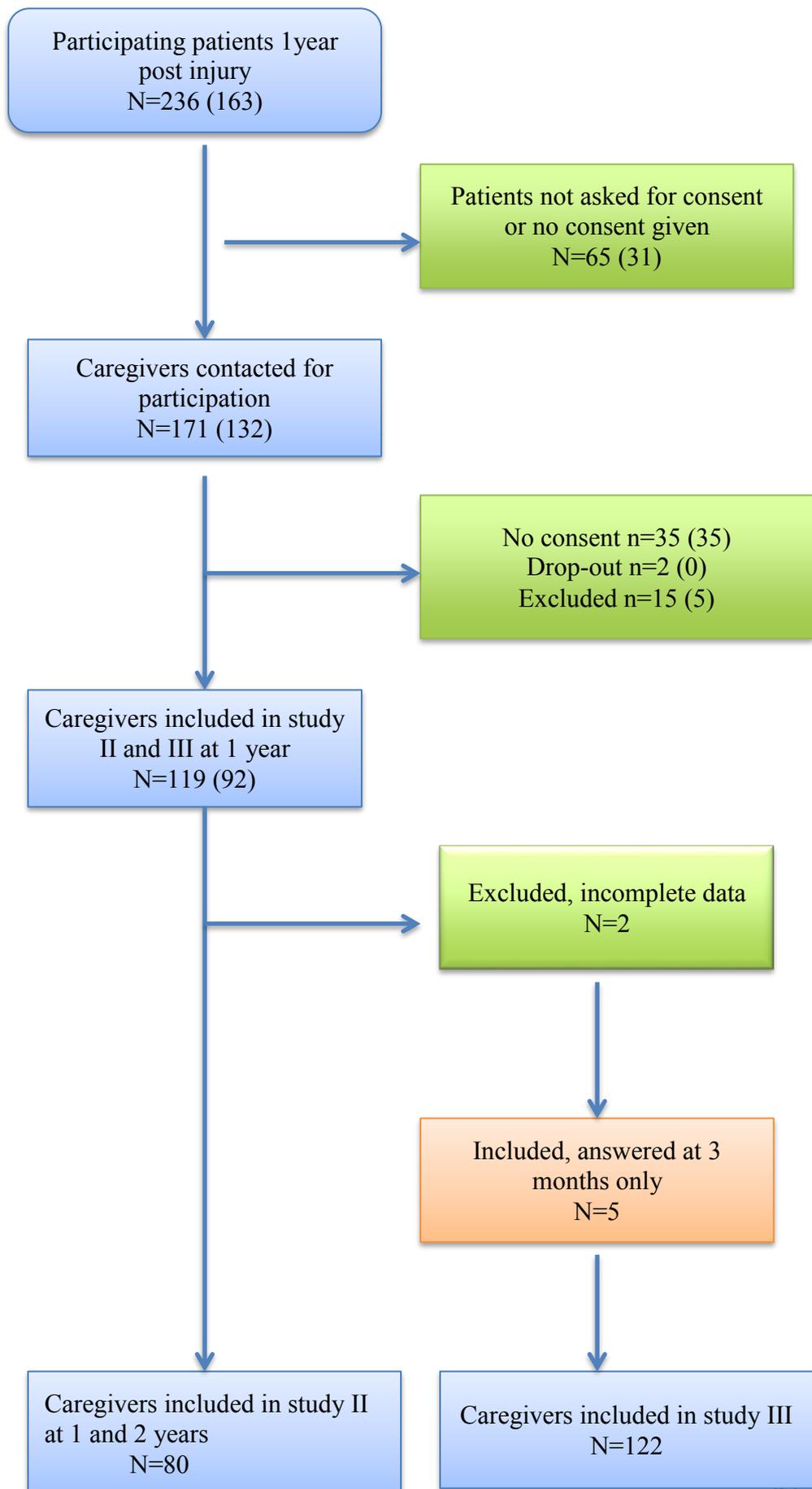
At the time of inclusion or at the 12-month follow-up, the patient was asked to name the closest family member or acquaintance who could be contacted for possible participation in the present study. Patients who agreed to involve the caregiver gave written informed consent, which was collected by a project coordinator in each regional trauma centre (Appendix B). If the patient was unable to give this consent due to cognitive impairment, the family member answered on his/her behalf. The project coordinator at each of the regional trauma centres was

either a medical doctor, a specialized nurse, a neuropsychologist or an occupational therapist. All project coordinators were specialized within acute care, neurosurgery or rehabilitation medicine and had clinical experience in the treatment and rehabilitation of patients with severe TBI. A project coordinator within each trauma center were responsible for the assessment of patients in both the acute phase and at 3 and 12 months follow-up. Caregivers were contacted by telephone and given information about the study from one of the coordinators within each trauma centre. If the caregiver gave oral agreement to participate, the questionnaires and written consent were sent by mail (Appendix A). A structured self-report questionnaire was used to obtain all information from the caregivers (Appendix C). In this thesis, analysis of information and questions from page 1, 4 and 6-8 in the questionnaire is presented, in addition to a section in page 5 (Life satisfaction). The University Hospital of North Norway was responsible for maintaining a database of all participants. Data on patients were obtained from the national multicentre study on severe TBI (Andelic et al., 2012).

3.3 Participants

A total of 122 family members participated in the study. As illustrated in the flowchart, the number of participants in each of the three papers in this thesis differed, as paper I included participants in only the first two years of the cohort and paper II and III included all family members for the entire cohort (3 years), except for two who were excluded for having incomplete data on the FECQ-TBI (Figure 1). The 15 family members who were excluded from the cohort were caused by: incomplete questionnaires (n=6), patient dead (n=2), no contact information (n=2), 1-year questionnaires filled out at nearly two years post injury (n=5).

Figure 1. Flowchart of participating caregivers in the study cohort. Participants in article I are presented in ().



3.4 Ethical considerations

This study was approved by the Committee for Medical Research Ethics for the southeast of Norway (no. 2009/702) and followed the ethical guidelines of the Helsinki Declaration (Declaration of Helsinki, 2008). All participants had the opportunity to contact the project coordinators if there were any questions about the structured questionnaire. Informed written consent was collected from all participating caregivers. All data were labelled with pseudonyms and were unidentifiable in the analysis and presentation.

3.5 Assessment of caregivers

All data on the caregivers were collected through the structured questionnaire. The following socio-demographic variables were obtained: gender (male/female), marital status (married/cohabitant or single), education (low \leq 12 years, high $>$ 12 years), occupational status (working/studying or not working/studying), relation to the patient (spouse/cohabitant, parent, other (children, siblings, grandparents, friends, other)), living with the patient (yes/no) and time spent with the patient (24 hours/day, 2-10 hours/day, 1 -2 times/week or less). The characteristics of the non-participating caregivers were not available.

3.5.1 Caregiver Burden Scale (CBS)

The CBS is a generic 22-item scale developed to measure different types of subjective caregiver burden (Elmståhl et al., 1996). The CBS has been used to assess caregiver burden in family members of patients with stroke and dementia (Andren and Elmstahl, 2005, Andrèn and Elmståhl, 2008, Dahlrup et al., 2011). A factor analysis of the CBS yielded 5 indices, representing each dimension of the scale: general strain (8 items), isolation (3 items), disappointment (5 items), emotional involvement (3 items), and environment (3 items) (Elmståhl et al., 1996). General strain assesses the caregiver's practical problems, feelings of

tiredness and being worn out, and presence of psychological or health problems stemming from the caregiver role. Isolation assesses whether caregivers avoid and/or experience diminished social contact as a consequence of taking care of the patient. Disappointment assesses the caregiver's feelings of unfairness, isolation, and economic sacrifice. Emotional involvement assesses their experience of feeling ashamed, angry, and embarrassed of the behaviour of the person with TBI. Environment assesses potential problems in the physical environment that could affect the caregiver's ability to take care of the patient (Appendix 1).

Tests of the construct validity and internal consistency of the scale yielded Cronbach's alpha coefficients of 0.70 to 0.87 for all subscales except for environment (0.53) (Elmståhl et al., 1996). The scale has demonstrated good test-retest reliability, with kappa values ranging from 0.89-1.00 for all subscales except for the environment (0.69) (Elmståhl et al., 1996). The items are scored from 1 to 4 (1, not at all; 2, seldom; 3, sometimes, 4, often), and the total score for the scale ranges from 22-88. A high score indicates a high burden. Because the subscales consist of a different number of questions, an index score was calculated by using the sum score of each subscale divided by the total number of items. An index score of 1.0-1.99 indicated a low burden, 2.0-2.99 a moderate burden, and 3.0-3.99 a high burden (Elmståhl et al., 1996, Bergstrom et al., 2011).

3.5.2 Life satisfaction

Life satisfaction was measured with one global item: "In general, how satisfied are you with your life now?" The item was rated on a 5-point ordinal scale: 1 (very dissatisfied), 2 (dissatisfied), 3 (neither satisfied nor dissatisfied), 4 (satisfied) and 5 (very satisfied). This item has previously been used and has shown validity for caregivers after traumatic brain injury (Kolakowsky-Hayner et al., 2001).

3.5.3 Social network

Five questions related to the caregiver's personal social network were included in the analysis. Questions assessing the quantity of the social network included the following: (1) How many people live in the same household as you?; (2) Approximately how many close friends and relatives do you have—people you feel comfortable with and can confide in? (none, one, several); and (3) How often do you meet friends and relatives with whom you do not live, for example, visiting each other's homes, going out together, talking on the phone? (once a week, less than once a week but at least once a month, less than monthly). The quality of social network questions included the following: (1) Do you ever feel lonely? (never or rarely, sometimes, often) and (2) Do any of the people close to you give you attention and take interest in what you do? (none or little, some, a lot) (Anke et al., 1997). Social network quality indicates the concept of perceived social support (Barrera, 1986).

3.6 Assessment of patients at baseline and 1-year follow-up

All information about the patients was collected through the Norwegian multicentre study on patients with severe TBI (Andelic et al., 2012). The demographic variables were age, gender (male/female), level of education (low \leq 12 years, high $>$ 12 years) and marital status (married/cohabitant, single).

3.6.1 Acute injury severity variables at baseline

Acute injury severity was assessed by the most commonly used scale that has previously been validated: the abbreviated injury severity scale (AIS) (AAAM.org., 2008). The AIS head score was used in the present study to indicate the severity of brain injury; a higher severity score indicates a progressively more severe injury. The Glasgow Coma Scale (GCS) was used

to assess the patient's level of consciousness in the acute phase of TBI, and the lowest GCS score within the first 24 hours was recorded (Teasdale and Jennett, 1974).

3.6.2 Functional level at 1-year follow-up

The GOSE was scored with a structured interview and used to evaluate patient's functional level at the 1-year follow-up (Wilson et al., 1998). The GOSE categorizes patient status into one of eight categories: dead (1), vegetative state (2), lower severe disability (3), upper severe disability (4), low to moderate disability (5), upper to moderate disability (6), low to good recovery (7), and upper good recovery (8) (Wilson et al., 1998). The Rancho Levels of Cognitive Functioning (LCFS) is a rating scale used to evaluate recovery from traumatic brain injury based on cognitive and behavioural factors (Gouvier et al., 1987). The scale is divided into 8 stages, from coma to appropriate behaviour and cognitive functioning. Satisfactory test-retest and inter-rater reliability as well as concurrent and predictive validity have been reported for this scale. In this study, only the 12-month LCFS scores were assessed. The patient characteristics did not differ between the participants and non-participants, except that the proportion of male patients was higher in the former.

3.7 Development of the Family members' Experiences with in-hospital Care Questionnaire in severe Traumatic Brain Injury (FECQ-TBI)

A literature search was first developed, and the multidimensional Parent Experience of Paediatric Care questionnaire (PEPC) was used as a starting point. PEPC has previously been found to have good validity, is not disease-specific and is available in Norwegian (Garratt et al., 2007). The PEPC questionnaire contains 25 items covering six subscales: organization, information about examinations and tests, physician services, nursing services, information about discharge and hospital facilities. In addition, the PEPC contains several other single

questions that were of interest in the development of the FECQ-TBI: nine items about health care delivery, overall satisfaction with care and how the parents were treated, the extent to which parent expectations were met, the extent of poor treatment, information about medication, and the extent of problems with staff. A good validity, internal consistency and test-retest reliability of the PEPC have been reported (Garratt et al., 2007, Garratt et al., 2011).

The FECQ-TBI was further developed on the basis of a focus group interview with three family members of patients with severe TBI in northern Norway who had received in-patient rehabilitation. Focus group interviews are useful for generating a deeper understanding of the phenomena relevant to the particular study objective, such as questionnaire construction, and are also suitable for examining whether questionnaire items are appropriately formulated (Malterud, 2012, Kreuger and Beerman, 2000). Furthermore, a small pilot study (n=3) of the questionnaire was conducted in which family members commented on the relevance and intelligibility of the questions and evaluated the response options of each item. Small changes to the wording were made, and one item was removed; therefore, the complete questionnaire consisted of 55 items and was named the FECQ-TBI (version 1). Four items were yes/no questions regarding the use of a diary in the ICU and whether children were involved in the acute and rehabilitation department. The other 51 items were all related to their experiences and satisfaction with care.

Furthermore, some of the wording was modified, mostly changing “nurse” or “doctor” to “staff” and “child” to “patient”. All 11 questions regarding the acute care department were also asked with identical phrasing regarding the rehabilitation department. We added 9 items regarding experiences with the rehabilitation department as a result of the focus group interview (items 12-20, Appendix C). Additionally, new items that emerged from the focus group interview were added to the original PEPC scales: discharge-related information and

hospital facilities. Items related to discharge and hospital facilities were analysed as distinct concepts. Four overall single-item questions were identical to the corresponding questions on the PEPC questionnaire, and three were added in this study: transfer between departments, financial needs and care of involved children. These items were not suitable for factor analysis and were not meant to be included in the factors or scales. The original scoring method from the PEPC was preserved; each item was scored from 1 (worst experience) to 5 (best experience). Items related to experiences with provided health care ranged from 1 (not at all) to 5 (to a very large extent). Negative items were re-coded before summation; a higher score represented a better experience. The FECQ-TBI (version 1) was mailed to 171 family members, and data were collected from family members 3 and 12 months post-injury for patients injured in 2010 and only at 12 months post-injury for other patients. The data collected 12 months post-injury were preferred in this study.

3.8 Statistical analysis

Statistical Package of Social Sciences (SPSS) software (Chicago, IL, USA) version 22 and 23 was used for all statistical analyses. Descriptive statistics of the participants were presented as the mean, SD or as proportions of subjects. Cross-tabulations with χ^2 tests were performed for nominal data. Assumptions of a normal distribution were visually inspected and tested using a skewness test statistic. Non-parametric statistical analysis was conducted when the data were not normally distributed. Independent sample t-tests, analysis of variance (ANOVA) or paired sample t-tests were used to compare the means between 2 or more groups. Correlation analysis was performed with Spearman's rho for non-parametric data.

In paper I, the relationship between relevant patient and caregiver variables and CBS scores were explored using ANOVA, and non-parametric analyses were applied when the data were not normally distributed (Mann-Whitney U-test or Kruskal-Wallis test). LSD post hoc test

was applied to analyse pairwise comparisons. In the multivariate analysis, a Bonferroni corrected significance level of <0.01 was applied with respect to multiple testing. The internal consistency of the CBS was assessed using Cronbach's alpha, with a level > 0.70 considered acceptable. To analyse the relationship between the independent variables and the 5 CBS subscales, linear multiple regression analyses were performed with backward stepwise regression. Independent variables with correlation coefficients greater than or equal to 0.70 were not entered together in the regression analysis. GOSE scores at 3 and 12 months were highly correlated (Spearman's $\rho=0.74$); therefore, GOSE scores at 12 months were used in the regression analysis. Age, gender and independent variables that were significantly associated with the CBS total score and in one or several of the CBS indices in the univariate analysis were entered in the regression analysis.

In paper II, the aim was to investigate the patterns of change and stability in the CBS from 1 to 2 years post-injury. We used a version of the distribution-based method to define the minimal clinically important difference between the two follow-up times. We first calculated the standard error of measurement (SEM), indicating the smallest change in raw score that reflected a true change and not a measurement error (Copay et al., 2007). We defined two SEM as the minimal clinically important difference in CBS score, corresponding to a change of 0.30 points. In practice, a change of 0.30 points on the CBS score represented one-half the SD of the total CBS score as the minimal clinically important difference. The change in total CBS score from 1 to 2 years post-injury was tested with a paired sample t-test. Furthermore, a χ^2 test was performed to investigate the longitudinal changes in caregiver burden score between 1 and 2 years, with participants dichotomized into two groups 1 year post-injury: (1) low burden and (2) moderate to high burden. To analyse the relationship between the independent variables and a minimal clinically important change in CBS score, a

binary logistic regression analysis with backward stepwise regression was conducted. The CBS dependent variable was coded as 0 (stable/improved) or 1 (worsened).

In paper III, an exploratory factor analysis (EFA) was used to identify the number of underlying factor structures that adequately summarized the items of the FECQ-TBI. Principal component analysis (PCA) was then conducted to capture all of the variance. The component solution was promax rotated. Components with eigenvalues > 1 were retained, and loadings < 4 were suppressed. As most items were not normally distributed, the PCA was based on Spearman's rank order correlation coefficients. Separate PCAs were conducted on thirty-one items related to caregiver experience in the acute and rehabilitation departments, six items related to discharge and seven items regarding experiences with hospital facilities. The internal consistency of the identified subscales was evaluated by Cronbach's alpha coefficients, with values > 0.70 deemed satisfactory. Construct and criterion-related validity were evaluated by examining the structural relationships (i.e., correlation coefficients) between the subscale scores and the other included measures (Spearman's rank correlations).

4. Results

This chapter provides a summary of papers I-III.

4.1 Paper I

Objectives: To assess the burden experienced by caregivers of patients with severe TBI one year post-injury and to relate this burden to caregiver demographic data and social network and patient demographics, injury severity and functional status.

Results: Ninety-two caregivers completed a structured questionnaire. This study is the first to use the multidimensional CBS for caregivers of patients after severe TBI. The total index score on the CBS (2.1) indicated a moderate burden on average. Caregiver burden was found to be high in 16%, moderate in 34% and low in 50% of the participants. The CBS subscales of general strain and disappointment yielded the highest scores. In the univariate analyses, significant associations with a higher burden were observed in participants who reported a low frequency of meeting friends, experienced loneliness often and were caring for a patient with severe disability ($p < 0.01$). Multiple linear regression analysis revealed that experiencing loneliness was an independent significant predictor of a higher total burden and of each subscale of the CBS ($p < 0.001$). Caring for a patient with more severe disability was an independent predictor of a higher total burden and of each subscale of the CBS ($p < 0.001$), except for emotional involvement. Being married was a significant predictor of higher scores on the subscales isolation, emotional involvement and environment ($p < 0.05$), and a low frequency of meeting friends was significantly associated with isolation and disappointment ($p < 0.05$).

Conclusion: This study highlights different aspects of burden experienced by primary caregivers of adults with severe TBI. Patients' functional status, caregiver's feeling of loneliness and seldom meeting friends and family were predictors of a higher burden. The relationship between different aspects of burden, and relevant predictors may help health care

providers identify caregivers at risk and develop future interventions.

4.2 Paper II

Objectives: To assess the stability and change in burden from 1 to 2 years post-injury and the correlations between the CBS and life satisfaction and to identify significant predictors of a change in burden from 1 to 2 years post-injury.

Results: A total of 119 caregivers participated at 1 year, while 80 participated at both the 1- and 2-year follow-up. Total caregiver burden scores were significantly higher at 2 years compared to 1 year post-injury ($p=0.04$). Using the defined score of minimally clinically important difference, 30% of the participants reported an increase in burden, 55% were stable and 15% had a decrease in burden from 1 to 2 years post-injury. Life satisfaction was significantly lower at 2 years compared to 1 year ($p=0.03$). Logistic regression analysis showed that experiencing loneliness was an independent predictor of increased burden from 1 to 2 years post-injury ($OR=4.35$, $p<0.05$). A significant strong negative correlation was observed between the total CBS score and life satisfaction at both follow-up times (Spearman's $R= -.79$, $p<0.001$ for both).

Conclusion: An increase in caregiver burden, a decrease in life satisfaction and a strong association between burden and life satisfaction may have significant clinical implications. The results demonstrate a need for more long-term follow-up of caregivers and patients that focuses on professional support to relieve the burden and risk of loneliness and social isolation.

4.3 Paper III

Objectives: To describe the development of the Family Experiences with in-hospital Care Questionnaire in severe Traumatic Brain Injury (FECQ-TBI) and to evaluate its validity and

psychometric properties. To date, no established, validated instruments are available to assess family members' experiences during a patient's acute treatment and rehabilitation path.

Results: The questionnaire was returned by 122 caregivers. Principal component analysis extracted six dimensions (eigenvalues > 1.0): acute organization and information (10 items), rehabilitation organization (13 items), rehabilitation information (6 items), discharge (4 items), hospital facilities-patients (4 items) and hospital facilities-family (2 items). Items related to the acute phase were comparable to items in the two dimensions of rehabilitation: organization and information. All six subscales had good internal consistency, with Cronbach's alpha coefficients >0.80. The construct validity was confirmed.

Conclusion: The FECQ-TBI is a self-report measure that assesses important aspects of in-hospital care during the acute and rehabilitation phases from a family perspective. The psychometric properties and construct validity of the questionnaire were good, thereby supporting the use of the FECQ-TBI in assessing the quality of care provided in acute and rehabilitation departments.

5. Discussion of methodological considerations

5.1 Systematic error

In general, one of the weaknesses of observational studies is the risk of different types of bias (Szklo, 2014). Self-report questionnaires, such as those used in the present study, present a source of bias in different ways, and the influences of self-report need to be considered when interpreting the results. Selection bias is a systematic error in a study that is related to the procedures used to select subjects or from factors that influence study participation, and it occurs when the relationships between the associated factors differ between responders and non-responders (Bhopal, 2008, Szklo, 2014). We did not have any information about the caregivers who did not participate, and this could represent a non-response bias or selection bias. However, we did compare the participating patients with non-participating patients and found no differences between the groups, except that the participating group had a higher proportion of male patients.

Additionally, because the structured questionnaire for caregivers was only available in Norwegian, we may have excluded participants with different native languages. There were also a much lower number of participants from one of the four trauma centres in terms of the number of participating patients, which is a potential source of selection bias. A possible bias may also have been introduced in the process of inclusion, as only the family member listed as the primary caregiver could participate: at the time of enrolment at the 1-year follow-up, one family member often volunteered to participate even when more than one family member had attended the follow-up with the patient. This may have led to the inclusion of the most “resourceful” family member.

5.2 Validity of measurements

5.2.1 Validity of caregiver burden measures

The CBS is a non-disease-specific scale that measures burden; it is multidimensional, and the five subscales represent different aspects of both subjective and objective burden. Other uni- or multidimensional scales have also originally been developed for use in geriatric research, mostly for dementia (Bayen 2013, Hanks, 2007). A good validity, reliability and internal consistency have been previously reported for the CBS (Elmståhl et al., 1996). Furthermore, in this study, good internal consistency (scale reliability) was found, with Cronbach's alpha coefficients from 0.81-0.94 on the five subscales of the CBS. However, some of the questions within the CBS seems overlapping between the dimensions; i.e. question 14 "Do you feel lonely and isolated because of your relatives problem?" is in the dimension Disappointment, and not within Isolation. Question 5 "Do you feel tied down by your relatives problem?" is in the dimension General strain, and not within Isolation (see Appendix D).

The CBS contains items mostly measuring subjective burden: "Do you feel lonely and isolated because of your relative's problem?" and "Do you feel that life has treated you unfairly?" However, some items measure objective burden: "Do you find it physically strenuous to take care of your relative?" and "Does the physical environment make it difficult for you to take care of your relative?" Unfortunately, the dimensions within the CBS do not separate subjective and objective burden items, making it difficult to distinguish between objective and subjective burden in the analysis.

In general, there is a weakness in describing caregiver burden in the literature, as to date no uniform or singular definition exists and it has been conceptualized in various ways for decades (Chou, 2000). This explains why there are a multiple different instruments for assessing caregiver burden available, which weakens the possibility to compare across studies, which can make it difficult to argue against policy makers within the health care

system. This can also affect the impact from the present study, as the CBS have not been previously used in other studies investigating family members to patients with severe TBI.

5.2.2 Validity of the life satisfaction measure

The life satisfaction measure used in the present study was a one-item measure that assessed the caregiver's overall satisfaction with life. The use of this single item has previously been confirmed as valid by other researchers (Kolakowsky-Hayner et al., 2001), and its validity is further supported by the high negative correlation to the CBS score found in this study. Our findings also indicate that the single item showed good sensitivity to change. Other studies assessing life satisfaction use more extensive or multidimensional scales to measure this concept, and using a more extensive measure for life satisfaction would have provided more in-depth information regarding the participants' life satisfaction. It would also be possible to compare our results to other studies if a more extensive validated instrument were used. An extensive scale would also provide us the possibility of analysing the association between the patient- and family member-related variables affecting the family member's life satisfaction.

5.2.3 Validity of social network questions

The questions on the family member's social network quality and quantity have not previously been formally validated or analysed for reliability. However, the questions assess both social network quantity and social network quality and have been found to be useful in patients after severe multiple traumas (Anke et al., 1997). Other more structured and validated questionnaires that assess social networks exist, but they do not precisely assess the concept we wished to measure, such as the number of close friends and the frequency of meeting friends. The questions related to social network were self-explanatory and were considered important by our expert group and by the results of a literature review, supporting the content validity of the questions.

5.3 Study design

The prospective longitudinal study design is a strength, as it enables us to investigate outcomes over a period of time as well as the possible associations between factors related to the patient and caregiver and the outcome. The possibility of connecting two parallel cohort studies provides a unique opportunity to identify factors related to caregiver burden and life satisfaction both at a single time point and over time. Although this was a national multicentre study, it had a low number of participants, suggesting the potential for low statistical power in some analyses. This could result in a type 2-error, wrongly accepting a null hypothesis when there actually is a difference.

5.4 Generalizability - external validity of the results

The design of the study as a national prospective multicentre study increases the generalizability of the results as the study captures the population of family members after severe TBI in Norway in a given time period. The use of established and validated instruments, outcome assessments at fixed time points and a homogenous group of participants also makes the results more valid. A known challenge within the literature assessing caregiver burden after TBI is that studies use different time spans for follow-up and different populations within the same study, such as ABI, tumour and spinal cord injuries (Thompson, 2009). The CBS is a generic questionnaire that has also been used to measure burden in other populations, which increases the generalizability of our results and enables comparisons to other caregiver populations within neurological diseases, such as dementia and stroke. The CBS also allows us to compare between Scandinavian countries, as we have almost identical free-of-charge health care systems. It may be difficult to transfer the results presented in this thesis to other cultures and countries due to the differences in health care systems, cultures and economic implications after severe TBI. This limits the generalizability

of the study's findings to (all) other countries or cultures, as they have different support systems in the community and unique customs regarding family involvement (Norup et al., 2015).

There may also be some issues regarding the generalizability of the FECQ-TBI as it is modified for family members after severe TBI in Norway. This can make it challenging to compare to other populations in countries where the patient pathway and health care delivery differs from Norway. However, the FECQ-TBI have good possibilities to be used in family members of other neurological patient groups facing both acute care and rehabilitation, such as stroke, ABI, spinal cord injuries and general trauma patients

5.5 Causality – internal validity of the results

In observational studies, it is not possible to draw conclusions about causality; only associations between the predictors and/or risk factors and the outcome can be made (Bhopal, 2008). One difference between biomedical research and rehabilitation research is that within biomedical research, there are more clear objectives of the outcome (a laboratory value, disease/no disease, life/death), whereas within rehabilitation research, there are several confounding factors and challenges that affect both the patient and the family members. Physiological, psychological, social, emotional, and environmental factors can all affect the family members' experiences.

A limitation in our study is our lack of knowledge of the family member's physical and psychological health both at baseline and at follow-up, their personality traits and coping styles, which are known to impact caregiver burden and life satisfaction (Ponsford and Schonberger, 2010, Simpson and Jones, 2013). Additionally, the disability experienced by the person with TBI may have resulted from many known and unknown factors. Although we assessed the global function of the patient with the internationally validated instrument

GOSE, a limitation of this study is the lack of neuropsychological data on the patients. This would have provided more detailed information about the patients cognitive functioning and behaviour, as these factors are well known to affect the perceived caregiver burden.

6. General discussion of results

6.1 Level of caregiver burden

The caregiver burden analyses showed that caregivers on average experienced a moderate burden both 1 and 2 years post-injury and a clinically significant increase in burden from 1 to 2 years. In paper I, 50% reported a moderate or high burden, and in paper II 30% of the caregivers had an increase in burden from 1 to 2 years post-injury. The proportion of caregivers reporting a high burden in our study (16%) was higher than that found in a Swedish study using the CBS to assess burden in caregivers of patients with dementia (6%) (Andr n and Elmst hl, 2008). This difference may be caused by the nature of the injury, with severe TBI representing a sudden life changing event, in contrast with the more progressive course of dementia. In addition, the impact of patients' age most likely affect the perceived burden, as the patients with severe TBI were younger than the patients with dementia.

Our results regarding the level of caregiver burden at a single time point in paper I and over time in paper II are both in accordance with, and contradictory to, previous studies on caregiver burden after severe TBI. However, the results are difficult to compare directly due to their use of other instruments to assess burden and the different follow-up times. A cross-sectional study from the UK investigated 48 carers of patients with TBI, and 42% of them had an elevated level of strain 9 years after the injury (Boycott et al., 2013). A study from Colombia using the Zarit Caregiver Burden (ZCB) interview with 51 caregivers 7-19 months post-injury reported that 28% experienced a moderate or severe level of burden (Lehan et al., 2012).

An increase in burden from 1 to 5 years post-injury was reported in a study from the UK, whereas Livingston reported a slight increase in burden during the first year post-injury (Brooks et al., 1986, Livingston et al., 1985). Both Brooks and Livingston used a self-designed ordinal scale to assess caregiver burden.. A study from Marsh used an instrument

designed for that particular study to assess burden at 6 and 12 months post-injury and found no change in caregiver burden between the two follow-up times (Marsh et al., 2002). Some of the main challenges within the literature is the many different instruments used to measure this concept, and many of the scales used, are designed for a specific study and not validated (Thompson, 2009). This makes it difficult to compare results between studies.

Only one other study have used the CBS to assess burden in 41 family members of patients with severe TBI: Doser and Norup recently reported a mean caregiver burden of 2.2 at 3-6 years post-injury, which is in accordance with our results at 24 months post injury (Doser and Norup, 2016). We found no differences in the level of caregiver burden regarding how much time the caregiver spent with the patient. Time spent with the patient is considered as an aspect of the objective caregiver burden. Our results conflict with the above mentioned Danish study and a Swedish study using the CBS who both found that spending more time with the patient strongly influenced the experience of caregiver burden (Doser and Norup, 2016, Annerstedt et al., 2000). Our result was surprising as one would expect that spending more time with the patient would lead to a higher caregiver burden. Our finding could be considered as a positive aspect, as spending more time caring for patients with severe TBI also can generate some positive feelings and a closer connection between the family member and the person with severe TBI.

In paper I, 50% of the family members reported a low burden, and in paper II, 55% remained stable in their reported burden from 1 to 2 years. This could reflect resilience in the form of family member's personality traits and coping strategies, which should be further investigated in future research (Bonanno, 2004). To include studies that investigate the positive aspects of caregiving, would add an understanding of the characteristics of the family members and the factors protecting them from the negative aspects of being a family member of a person with severe TBI. The present study did not investigate the factors related to those

experiencing a low caregiver burden, which is a weakness of our study. In accordance with several other studies, the long-term caregiver burden is worth noting and needs to be highlighted to health care providers and future follow-up routines for family members of patients with severe TBI.

In paper I and II we reported that within the different dimensions of caregiver burden, general strain had the highest score at both 1 and 2 years post-injury. In addition, a significant increase in burden over time was observed in the disappointment, emotional involvement and environment dimensions. The previously mentioned Danish study found a similar distribution of scores on the different dimensions as our study; the highest scores were observed in general strain and disappointment, and the lowest scores in emotional involvement and environment (Doser and Norup, 2016). Our results may imply that family members felt tired, worn out and busy and that it was psychologically stressful to care for the person with severe TBI (general strain). Additionally, it can imply that the burden over time is linked to social isolation and a reaction (disappointment) to the lack of improvement or stability in the recovery of the patient and the need to face the reality of the new situation for the family as a whole. This information is useful for health care professionals both in the rehabilitation team and in the community, especially for nurses as this group is the closest to the patient and the family members during the patients stay. In the rehabilitation setting, the team of professionals taking care of the patient must include the family members to a greater extent and provide more information about the injury, both the short- and long-term disabilities.

Kreutzer and colleagues recently reported the effect of an intervention study on education, skill-building and support for 108 families up to 3 months after acquired brain injury (Kreutzer et al., 2015). The treatment group showed an increase in met needs, greater satisfaction with services and reduced burden compared to pretesting. Future studies assessing the long-term effect of such interventions are needed. For district nurses and other health

professionals in the community, more knowledge of the long-term consequences of the injury and the impact on the family is warranted.

According to the family systems theory, this implies that the family system is developing over time and that the family is now faced with a new situation that affects all persons within the family. For health care professionals, it is important to treat the whole family as unique; although one person with severe TBI shares similarities with other patients being treated and rehabilitated, the family structure and order and the disruption to the family will differ from one family to the next. An individual follow-up both in-hospital and in the community that is targeted to each family according to their family structure will be essential.

6.2 Predictors of caregiver burden

In paper I, being married in general was significantly related to a higher burden in some of the burden dimensions, and being a spouse led to a higher burden than being a parent, although this finding was not significant. Doser et al. reported that spouses had a higher burden than parents (Doser and Norup, 2016), which was in contrast to a Dutch study that found no significant relationship between caregiver burden and relation to the patient (Machamer et al., 2002). Our results could imply that being a spouse affects intimate relationships, as patients can differ substantially from their various pre-injury characteristics.

A role change may occur and spouses face responsibility for making decisions on behalf of their husband or wife after severe TBI. The spouse may also be faced with a new role as a single parent, if the injured patient is unable to perform traditional parenting functions. Additionally, it may be easier for parents to accept the dependent role of the patient because they are returning to a previous well-known role. However, parents may not be prepared to lose the independence they had regained in their later life. This is supported by Oddy who notes that a higher burden on spouses can have several explanations; the burden

most likely falls entirely on the one spouse, while with parents, the burden can be shared between both (Oddy et al., 1978).

The results from paper I showed that being a sibling or child of the patient did affect caregiver burden, as those who had “other” relationships to the patient (siblings, children, grandparents, friends) had a higher burden score for emotional involvement compared to spouses and parents. The low number of participants in our study who were siblings or children, may have influenced the results, but one could also posit that children or siblings may be the most affected family member, as the roles and rules within the family are disrupted. A sibling could feel neglected because the parents spend more time with the injured patient, and a child could be faced with assuming a parenting role for the father or mother, disrupting the previous roles and family system.

In paper I, patients’ functional status was significantly associated with a higher caregiver burden at 1 year post-injury. In paper II, an increase in burden from 1 to 2 years showed a tendency towards being associated with patient’s functional level 1 year after injury. Recent results from the Paris-TBI study have also reported that being a family member of a person with disabilities (low GOSE score) predicted a higher caregiver burden (Bayen et al., 2013). Although an association was found between GOSE score and caregiver burden, we did not assess what type of disability, if any, that may have influenced on the perceived caregiver burden as the GOSE is a rather crude instrument to assess global functioning.

Aspects of the caregivers’ social network quality and quantity were associated with caregiver burden in paper I. Feelings of loneliness and decreased contact with family and friends were significant predictors of a higher caregiver burden score. In paper II, the feeling of loneliness was significantly associated with an increase in burden from 1 to 2 years. Although loneliness has been described as low perceived social support and an important indicator of social network quality (Anke et al., 1997), feeling lonely does not necessarily

mean that a person is socially isolated (Nicholson, 2012). In paper I, nearly 20% of the family members reported having contact with friends and family less than weekly. In addition to actual social isolation, the feeling of loneliness may partly reflect an individual's experience of being different from others. Again, this reflects one of the most important points from the family systems theory that every family (member) is unique and their needs are individual. To help improving family members social networks and preventing social isolation may be particularly important in the future.

In paper II, a tendency towards an association between male caregivers and an increase in caregiver burden was found, although this was not significant. A recent review of caregiver burden did not find gender to be a risk factor for increase in burden over time, and this issue should be explored in future studies (Adelman et al., 2014). This could imply that the gender of the caregiver does not necessarily have an impact on the degree or aspects of burden they experience. Although previous studies show that most women are caregivers of a male person with severe TBI (Bayen et al., 2013, Kreutzer et al., 2009, Kolakowsky-Hayner et al., 2001), future studies should identify the possible gender differences, as reactions to this dramatic change in life can differ for women in several ways. One could also posit that it is not gender itself that causes differences in experienced burden, but the disruptions to the family system.

6.3 Life satisfaction and the association with caregiver burden

Not surprisingly, a strong negative correlation was found in paper II between caregiver burden and life satisfaction, implying a high burden correlated to a low life satisfaction and vice versa. As caregiver burden is characterized as a multidimensional response to various stressors (social, psychological, emotional, physiological) related to caregiving, it can be directly transferrable to the caregivers' overall satisfaction with their life in relation to their self-defined standards or expectations. According to the family systems theory, a change in

one component of the system implies a change in all components, meaning that a caregiver's experience of a moderate to high burden affects life satisfaction as well.

6.4 Experiences with in-hospital health care

Paper III describes the development and evaluation of the multidimensional scale FECQ-TBI. This is the first constructed instrument designed for family members after TBI that measures both general satisfaction and experiences in six dimensions from the acute phase of patient's in-hospital stay up to their discharge after rehabilitation. Good psychometric properties and validity were found for this instrument. Because general satisfaction questions regarding treatment often provide high ratings (Becker et al., 2014, Crow et al., 2002), this questionnaire was designed to assess experiences with specific aspects of care, which is important for the improvement of the quality of treatment and care provided.

Patient and family member/parent satisfaction and experiences questionnaires are shown to contain the same or corresponding items in some studies (Bjertnaes et al., 2012). A newly developed instrument for patient experiences with integrated care contains five domains corresponding to coordination between care teams, communication between specialists and the primary doctor and information (Walker et al., 2016). This is comparable to our FECQ-TBI questionnaire, demonstrating the fact that patient experience questionnaires contain many of the same items and themes of experienced care and strengthening the implications of our developed questionnaire.

Experiences with health care are often described as fragmented and disjointed, especially within specialized health care, as departments are divided according to the disease or injury of the patient, and this may contribute to the experience of fragmented health care for both the patients and the family members (Walker et al., 2016). Earlier research has pointed to the lack of information and organization as one of the main challenges for family members as patients

move from, for example, the ICU to the neurosurgical department or from the neurosurgical department to rehabilitation (Dodek et al., 2012).

These results imply that to prepare caregivers for the future and prevent a moderate to high caregiver burden, it is important to perform a structured follow-up of caregivers of severe TBI patients starting with the acute phase of patients' in-hospital stays. Increased levels of stress and anxiety are found among relatives during this phase, which highlights the importance of developing a thorough plan before discharge to home (O'Callaghan et al., 2011). The lack of information, especially related to the phase before discharge to home, is concerning because this is when the caregiver really serves as an extension of the health care system. In addition, family members are faced with the long-term consequences of caregiving once they return to the community, and information about the long-term consequences of the injury and arrangements post-injury for rehabilitation was emphasized when developing the FECQ-TBI.

Other studies reporting family members' experiences after TBI have qualitative designs and focus on the acute phase, the in-patient rehabilitation phase or the period before discharge, although Smith focused on the journey through the health care system (Smith and Smith, 2000, Coco et al., 2011, O'Callaghan et al., 2011, Keenan and Joseph, 2010). Based on these qualitative studies, a more in-depth description of family members' experiences would have been useful. Although we developed a structured questionnaire, a substantial amount of important information is not captured in the items, which is a weakness of validated questionnaires. The family member is not able to describe his/her actual challenges because the items already list potential challenges. For future research, a combination of qualitative interviews and assessments with the FECQ-TBI will be important to gain more insight into the actual experiences of family members.

A recent prospective Australian study investigating 83 family members and 127 patients

with TBI and explored factors associated with perceived success when the patients with TBI were transferred home after their hospital stay (Nalder et al., 2012). Nalder and colleagues reported that the patient's level of psychosocial integration in the community was significantly associated with the family member's perceptions of transition success (Nalder et al., 2012). A further qualitative investigation from the same author reported a lack of adequate information about the content of the rehabilitation, and a decrease in the family member's satisfaction with the care delivered as they progressed from in-patient to community-based rehabilitation.

Based on the previous literature, the FECQ-TBI may contribute to a detailed understanding of family members' experiences in the different phases of health care provided after severe TBI. This knowledge will be important for clinical decision-making and assisting health care professionals provide high quality health care services as it will provide more detailed information on areas in which the in-hospital care, information and organization needs to be strengthened. The impact on the family members as the patient progresses through different phases of acute treatment and rehabilitation, as well as long-term phases of care, is linked to the family systems theory. Each person within the family is affected by the severe TBI in a unique manner, and how family members provide care and adjust to the subsequent changes through these phases, differs. The disruption of the family system after a severe TBI is different for each family, which is essential to understand for health care professionals.

Family members' experiences during a patient's in-hospital stay will most likely affect their experienced caregiver burden and life satisfaction in the longer term post-injury. A positive experience with the in-hospital health care services could help the family members feel more prepared for life after the patient return home, and thus may prevent long-term problems such as high caregiver burden and poor satisfaction with life. The development of

the FECQ-TBI is one component of improving the future care of both patients and families after severe TBI.

7. Clinical implications and conclusion

7.1 Clinical implications

To our knowledge, no structured program for follow-up of the family after TBI exists in any of the four trauma centres in Norway. A structured follow-up of from the acute phase, through rehabilitation and when the patient returns home, seems needed. Identifying caregivers at increased risk of burden in both the early and later phase of a patient's in-hospital pathway is important for preventing caregiver burden and improving the care of both the patient and the family. This can be implemented by using the CBS at different time-points post injury to assess caregiver burden. Our focus on the caregiver's social network as a predictor of burden at both one point in time and between 1 and 2 years post-injury contributes to the literature, as the few previously conducted studies have shown contradictory findings. Assessing the pattern of change and stability in caregiver burden and investigating predictors of a change in burden have not been reported within TBI research to date.

Knowledge on how to support the primary caregivers and other family members in general and especially of persons with acute and chronic neurological diseases, must be included in the education of health care professionals. Health care professionals need to inform and assist the family in their adaption to the new responsibilities and demands of care. This includes nurses, medical doctors, therapists etc. at both the specialized health care but most important health professionals working in the communities.

Identifying, reducing, monitoring and assessing caregiver burden and experiences with health care in family members are important health care issues, and the findings support the need for comprehensive rehabilitation programmes for patients and the family in the chronic phase after severe TBI. A recent Norwegian study shows that under 50 % of patients with severe TBI in Norway are referred directly to a specialized rehabilitation department after acute care (Sveen et al., 2016), in contrast to Denmark where 84 % were admitted to

highly specialized rehabilitation after severe TBI (Odgaard et al., 2015). A future study on caregiver burden and experiences with health care between countries with similar health care systems could be useful to further explore factors influencing on family members perceived burden and experiences with healthcare services.

7.2 Conclusions

This thesis is the first to describe the population of caregivers to patients with severe TBI in Norway. The caregivers experience a considerable caregiver burden long time post injury, with a clinical significant increase in burden and a decrease in life satisfaction over time. A more structured long-term follow-up of the whole family with attention to identify caregivers at risk of social isolation and a poor social network is needed. A future political focus must be to improve the access to and the importance of rehabilitation after a life-changing event as severe TBI, and to include and support the family to a larger degree in the treatment and rehabilitation process. The new developed questionnaire FEQC-TBI makes us able to assess quality of in-hospital care from a family perspective. The results from this thesis can contribute to a more family-centered acute and rehabilitative care that makes them more prepared for the future and to prevent caregiver burden over time.

Reference list

- AAAM.ORG. 2008. The Association for the Advancement of Automotive Medicine. The Abbreviated Injury Scale (AIS) 2005–Update 2008. .
- ADELMAN, R. D., TMANOVA, L. L., DELGADO, D., DION, S. & LACHS, M. S. 2014. Caregiver burden: a Clinical review. *JAMA*, 311, 1052–60.
- ANDELIC, N., ANKE, A., SKANDSEN, T., SIGURDARDOTTIR, S., SANDHAUG, M., ADER, T. & ROE, C. 2012. Incidence of hospital-admitted severe traumatic brain injury and in-hospital fatality in Norway: a National cohort study. *Neuroepidemiology*, 38, 259–67.
- ANDREN, S. & ELMSTAHL, S. 2005. Family caregivers' subjective experiences of satisfaction in dementia care: Aspects of burden, subjective health and sense of coherence. *Scand J Caring Sci*, 19, 157–68.
- ANDRÈN, S. & ELMSTÅHL, S. 2008. The relationship between caregiver burden, caregivers' perceived health and their sense of coherence in caring for elders with dementia. *J Clin Nurs*, 17, 790-9.
- ANKE, A. G., STANGHELLE, J. K., FINSET, A., ROALDSEN, K. S., PILLGRAM-LARSEN, J. & FUGL-MEYER, A. R. 1997. Long-term prevalence of impairments and disabilities after multiple trauma. *J Trauma*, 42, 54–61.
- ANNERSTEDT, L., ELMSTAHL, S., INGVAD, B. & SAMUELSSON, S. M. 2000. Family caregiving in dementia--an analysis of the caregiver's burden and the "breaking-point" when home care becomes inadequate. *Scand J Public Health*, 28, 23-31.
- BARRERA, M. 1986. Distinctions between Social Support Concepts, Measures, and Models. *American Journal of Community Psychology*, 14, 413-445.
- BAYEN, E., PRADAT-DIEHL, P., JOURDAN, C., GHOUT, I., BOSSERELLE, V., AZERAD, S., WEISS, J. J., JOEL, M. E., AEGERTER, P., AZOUVI, P. & STEERING COMMITTEE OF THE PARIS-TBI STUDY 2013. Predictors of informal care burden 1 year after a severe traumatic brain injury: results from the Paris-TBI study. *J Head Trauma Rehabil*, 28, 408–418.
- BAYEN, E., PRADAT-DIEHL, P., JOURDAN, C., GHOUT, I., BOSSERELLE, V., AZERAD, S., WEISS, J. J., JOEL, M. E., AEGERTER, P., AZOUVI, P. & THE MEMBERS OF THE STEERING COMMITTEE OF THE PARI, S. T. B. I. S. 2012. Predictors of Informal Care Burden 1 Year After a Severe Traumatic Brain Injury: Results From the Paris-TBI study. *J Head Trauma Rehabil*.
- BECKER, F., KIRMESS, M., TORNAS, S. & LOVSTAD, M. 2014. A description of cognitive rehabilitation at Sunnaas Rehabilitation Hospital–Balancing comprehensive holistic rehabilitation and retraining of specific functional domains. *NeuroRehabilitation*, 34, 87–100.
- BERGSTROM, A. L., ERIKSSON, G., VON KOCH, L. & THAM, K. 2011. Combined life satisfaction of persons with stroke and their caregivers: Associations with caregiver burden and the impact of stroke. *Health Qual Life Outcomes*, 9, 1.
- BHOPAL, R. 2008. *Concepts of epidemiology. Integrating the ideas, theories, principles and methods of epidemiology.*, Scotland, Oxford University Press.
- BJERTNAES, O. A., SJETNE, I. S. & IVERSEN, H. H. 2012. Overall patient satisfaction with hospitals: effects of patient-reported experiences and fulfilment of expectations. *BMJ Qual Saf*, 21, 39-46.
- BONANNO, G. A. 2004. Loss, trauma, and human resilience: have we underestimated the human capacity to thrive after extremely aversive events? *Am Psychol*, 59, 20-8.

- BOYCOTT, N., YEOMAN, P. & VESEY, P. 2013. Factors associated with strain in carers of people with traumatic brain injury. *J Head Trauma Rehabil*, 28, 106–115.
- BRAINE, M. E. 2011. The experience of living with a family member with challenging behavior post acquired brain injury. *J Neurosci Nurs*, 43, 156–64.
- BRAINE, M. E. & WRAY, J. 2016. *Supporting Families & Carers. A nursing perspective*, UK, CRC Press.
- BROOKS, N., CAMPSIE, L., SYMINGTON, C., BEATTIE, A. & MCKINLAY, W. 1986. The five year outcome of severe blunt head injury: a Relative's view. *J Neurol Neurosurg Psychiatry*, 49, 764–770.
- CHOU, K. R. 2000. Caregiver burden: a concept analysis. *J Pediatr Nurs*, 15, 398-407.
- CHRISTENSEN, B. K., COLELLA, B., INNESS, E., HEBERT, D., MONETTE, G., BAYLEY, M. & GREEN, R. E. 2008. Recovery of cognitive function after traumatic brain injury: a multilevel modeling analysis of Canadian outcomes. *Arch Phys Med Rehabil*, 89, S3-15.
- COCO, K., TOSSAVAINEN, K., JAASKELAINEN, J. E. & TURUNEN, H. 2011. Support for traumatic brain injury patients' family members in neurosurgical nursing: a systematic review. *J Neurosci Nurs*, 43, 337-48.
- COPAY, A. G., SUBACH, B. R., GLASSMAN, S. D., POLLY, D. W., JR. & SCHULER, T. C. 2007. Understanding the minimum clinically important difference: a Review of concepts and methods. *Spine J*, 7, 541–546.
- CROW, R., GAGE, H., HAMPSON, S., HART, J., KIMBER, A., STOREY, L. & THOMAS, H. 2002. The measurement of satisfaction with healthcare: implications for practice from a systematic review of the literature. *Health Technol Assess*, 6, 1-244.
- CUNNINGHAM, J. M., CHAN, F., JONES, J., KRAMNETZ, B., STOLL, J. & CALABRESA, J. 1999. Brain injury rehabilitation: A primer for case managers. In: CHAN, F. & LEAHY, M. J. (eds.) *Health care and disability case management*. Lake Zurich, IL.: Vocational Consultants Press.
- DAHLRUP, B., NORDELL, E., ANDREN, S. & ELMSTÅHL, S. 2011. Family caregivers' assessment of symptoms in persons with dementia using the GBS-scale: Differences in rating after psychosocial intervention—an 18-month follow-up study. *Clin Interv Aging*, 6, 9–18.
- DAVIS, L. C., SANDER, A. M., STRUCHEN, M. A., SHERER, M., NAKASE-RICHARDSON, R. & MALEC, J. F. 2009. Medical and psychosocial predictors of caregiver distress and perceived burden following traumatic brain injury. *J Head Trauma Rehabil*, 24, 145-54.
- DECLARATION OF HELSINKI 2008. Available from: <http://www.wma.net/en/30publications/10policies/b3/>.
- DIJKERS, M. 1999. Measuring quality of life: methodological issues. *Am J Phys Med Rehabil*, 78, 286-300.
- DODEK, P. M., HEYLAND, D. K., ROCKER, G. M. & COOK, D. J. 2004. Translating family satisfaction data into quality improvement. *Crit Care Med*, 32, 1922-7.
- DODEK, P. M., WONG, H., HEYLAND, D. K., COOK, D. J., ROCKER, G. M., KUTSOGIANNIS, D. J., DALE, C., FOWLER, R., ROBINSON, S., AYAS, N. T. & CANADIAN RESEARCHERS AT THE END OF LIFE, N. 2012. The relationship between organizational culture and family satisfaction in critical care. *Crit Care Med*, 40, 1506-12.
- DOSER, K. & NORUP, A. 2016. Caregiver burden in Danish family members of patients with severe brain injury: The chronic phase. *Brain Inj*, 30, 334–342.
- DOUGLAS, J. M. & SPELLACY, F. J. 1996. Indicators of long-term family functioning following severe traumatic brain injury in adults. *Brain Inj*, 10, 819–839.

- ELMSTÅHL, S., MALMBERG, B. & ANNERSTEDT, L. 1996. Caregiver's burden of patients 3 years after stroke assessed by a novel caregiver burden scale. *Arch Phys Med Rehabil*, 77, 177-182.
- ERGH, T. C., RAPPORT, L. J., COLEMAN, R. D. & HANKS, R. A. 2002. Predictors of caregiver and family functioning following traumatic brain injury: social support moderates caregiver distress. *J Head Trauma Rehabil*, 17, 155-74.
- GARRATT, A. M., BJAERTNES, O. A., KROGSTAD, U. & GULBRANDSEN, P. 2005. The OutPatient Experiences Questionnaire (OPEQ): data quality, reliability, and validity in patients attending 52 Norwegian hospitals. *Qual Saf Health Care*, 14, 433-7.
- GARRATT, A. M., BJERTNAES, O. A. & BARLINN, J. 2007. Parent experiences of paediatric care (PEPC) questionnaire: reliability and validity following a national survey. *Acta Paediatr*, 96, 246-52.
- GARRATT, A. M., BJERTNAES, O. A., HOLMBOE, O. & HANSSEN-BAUER, K. 2011. Parent experiences questionnaire for outpatient child and adolescent mental health services (PEQ-CAMHS Outpatients): reliability and validity following a national survey. *Child Adolesc Psychiatry Ment Health*, 5, 18.
- GEORGE, L. K., BLAZER, D. G., HUGHES, D. C. & FOWLER, N. 1989. Social support and the outcome of major depression. *Br J Psychiatry*, 154, 478-85.
- GEORGE, L. K. & GWYTHYER, L. P. 1986. Caregiver well-being: a multidimensional examination of family caregivers of demented adults. *Gerontologist*, 26, 253-259.
- GILLEN, R., TENNEN, H., AFFLECK, G. & STEINPREIS, R. 1998. Distress, depressive symptoms, and depressive disorder among caregivers of patients with brain injury. *J Head Trauma Rehabil*, 13, 31-43.
- GOTTLIEB, B. H. & BERGEN, A. E. 2010. Social support concepts and measures. *J Psychosom Res*, 69, 511-520.
- GOUVIER, W. D., BLANTON, P. D., LAPORTE, K. K. & NEPOMUCENO, C. 1987. Reliability and validity of the Disability Rating Scale and the Levels of Cognitive Functioning Scale in monitoring recovery from severe head injury. *Arch Phys Med Rehabil*, 68, 94-7.
- GRAD, J. & SAINSBURY, P. 1966. Evaluating the community psychiatric service in Chichester: results. *Milbank Mem Fund Q*, 44, Suppl:246-78.
- GREENWOOD, N., MACKENZIE, A., CLOUD, G. C. & WILSON, N. 2008. Informal carers of stroke survivors--factors influencing carers: a systematic review of quantitative studies. *Disabil Rehabil*, 30, 1329-49.
- HANKS, R. A., RAPPORT, L. J. & VANGEL, S. 2007. Caregiving appraisal after traumatic brain injury: the Effects of functional status, coping style, social support and family functioning. *NeuroRehabilitation*, 22, 43-52.
- HOLM, S., SCHONBERGER, M., POULSEN, I. & CAETANO, C. 2009. Patients' and relatives' experience of difficulties following severe traumatic brain injury: the sub-acute stage. *Neuropsychol Rehabil*, 19, 444-60.
- HYDER, A. A., WUNDERLICH, C. A., PUVANACHANDRA, P., GURURAJ, G. & KOBUSINGYE, O. C. 2007. The impact of traumatic brain injuries: a global perspective. *NeuroRehabilitation*, 22, 341-53.
- INGEBRIGTSEN, T., MORTENSEN, K. & ROMNER, B. 1998. The epidemiology of hospital-referred head injury in northern Norway. *Neuroepidemiology*, 17, 139-46.
- JACKSON, D., TURNER-STOKES, L., MURRAY, J., LEESE, M. & MCPHERSON, K. M. 2009. Acquired brain injury and dementia: a comparison of carer experiences. *Brain Inj*, 23, 433-44.

- JENKINSON, C., COULTER, A., BRUSTER, S., RICHARDS, N. & CHANDOLA, T. 2002. Patients' experiences and satisfaction with health care: results of a questionnaire study of specific aspects of care. *Qual Saf Health Care*, 11, 335-9.
- KASUYA, R. T., POLGAR-BAILEY, P. & TAKEUCHI, R. 2000. Caregiver burden and burnout. A guide for primary care physicians. *Postgrad Med*, 108, 119-123.
- KEENAN, A. & JOSEPH, L. 2010. The needs of family members of severe traumatic brain injured patients during critical and acute care: a qualitative study. *Can J Neurosci Nurs*, 32, 25-35.
- KNIGHT, R. G., DEVEREUX, R. & GODFREY, H. P. 1998. Caring for a family member with a traumatic brain injury. *Brain Inj*, 12, 467-481.
- KOLAKOWSKY-HAYNER, S. A., MINER, K. D. & KREUTZER, J. S. 2001. Long-term life quality and family needs after traumatic brain injury. *J Head Trauma Rehabil*, 16, 374-385.
- KREUGER, F. A. & BEERMAN, H. 2000. The screening history of women with cervical cancer in the Rotterdam area. *Eur J Epidemiol*, 16, 641-5.
- KREUTZER, J. S., GERVASIO, A. H. & CAMPLAIR, P. S. 1994. Patient correlates of caregivers' distress and family functioning after traumatic brain injury. *Brain Inj*, 8, 211-230.
- KREUTZER, J. S., MARWITZ, J. H., SIMA, A. P. & GODWIN, E. E. 2015. Efficacy of the Brain Injury Family Intervention: Impact on Family Members. *J Head Trauma Rehabil*, 30, 249-60.
- KREUTZER, J. S., RAPPORT, L. J., MARWITZ, J. H., HARRISON-FELIX, C., HART, T., GLENN, M. & HAMMOND, F. 2009. Caregivers' well-being after traumatic brain injury: a Multicenter prospective investigation. *Arch Phys Med Rehabil*, 90, 939-946.
- LEAF, L. E. 1993. Traumatic brain injury: affecting family recovery. *Brain Inj*, 7, 543-6.
- LEE, D. S., TU, J. V., CHONG, A. & ALTER, D. A. 2008. Patient satisfaction and its relationship with quality and outcomes of care after acute myocardial infarction. *Circulation*, 118, 1938-45.
- LEHAN, T., ARANGO-LASPRILLA, J. C., DE LOS REYES, C. J. & QUIJANO, M. C. 2012. The ties that bind: the relationship between caregiver burden and the neuropsychological functioning of TBI survivors. *NeuroRehabilitation*, 30, 87-95.
- LIVINGSTON, L. A., KENNEDY, R. E., MARWITZ, J. H., ARANGO-LASPRILLA, J. C., RAPPORT, L. J., BUSHNIK, T. & GARY, K. W. 2010. Predictors of family caregivers' life satisfaction after traumatic brain injury at one and two years post-injury: a Longitudinal multi-center investigation. *NeuroRehabilitation*, 27, 73-81.
- LIVINGSTON, M. G., BROOKS, D. N. & BOND, M. R. 1985. Patient outcome in the year following severe head injury and relatives' psychiatric and social functioning. *J Neurol Neurosurg Psychiatry*, 48, 876-881.
- LYNCH, R. T. 1986. Traumatic brain injury: Implications for rehabilitation counselling. In: RIGGAR, T. F., MAKI, D. R. & WOLF, A. W. (eds.) *Applied rehabilitation counseling*. New York: Springer.
- MACHAMER, J., TEMKIN, N. & DIKMEN, S. 2002. Significant other burden and factors related to it in traumatic brain injury. *J Clin Exp Neuropsychol*, 24, 420-33.
- MALTERUD, K. 2012. Systematic text condensation: a strategy for qualitative analysis. *Scand J Public Health*, 40, 795-805.
- MARSH, N. V., KERSEL, D. A., HAVILL, J. A. & SLEIGH, J. W. 2002. Caregiver burden during the year following severe traumatic brain injury. *J Clin Exp Neuropsychol*, 24, 434-447.

- MARSH, N. V., KERSEL, D. A., HAVILL, J. H. & SLEIGH, J. W. 1998. Caregiver burden at 6 months following severe traumatic brain injury. *Brain Inj*, 12, 225-38.
- MATHERS, C. D. & LONCAR, D. 2007. Neurological Disorders: Public Health Challenges. In: ORGANIZATION, W. H. (ed.). Geneva, Switzerland: World Health Organization.
- MCKINLAY, W. W., BROOKS, D. N., BOND, M. R., MARTINAGE, D. P. & MARSHALL, M. M. 1981. The short-term outcome of severe blunt head injury as reported by relatives of the injured persons. *J Neurol Neurosurg Psychiatry*, 44, 527-533.
- MONTGOMERY, R. V., STULL, D. E. & BORGATTA, E. F. 1985. Measurement and the analysis of burden. *Res Aging*, 7, 137-52.
- NALDER, E., FLEMING, J., FOSTER, M., CORNWELL, P., SHIELDS, C. & KHAN, A. 2012. Identifying factors associated with perceived success in the transition from hospital to home after brain injury. *J Head Trauma Rehabil*, 27, 143-53.
- NATIONAL INSTITUTES OF HEALTHS 1999. Report of the NIH consensus development conference on the rehabilitation of persons with traumatic brain injury. Bethesda, MD: U.S. Department of Health and Human Services.
- NICHOLSON, N. R. 2012. A review of social isolation: an important but underassessed condition in older adults. *J Prim Prev*, 33, 137-152.
- NORUP, A., KRISTENSEN, K. S., SIERT, L., POULSEN, I. & MORTENSEN, E. L. 2011. Neuropsychological support to relatives of patients with severe traumatic brain injury in the sub-acute phase. *Neuropsychol Rehabil*, 21, 306-21.
- NORUP, A., PERRIN, P. B., CUBEROS-URBANO, G., ANKE, A., ANDELIC, N., DOYLE, S. T., CRISTINA QUIJANO, M., CARACUEL, A., MAR, D., GUADALUPE ESPINOSA JOVE, I. & CARLOS ARANGO-LASPRILLA, J. 2015. Family needs after brain injury: a Cross cultural study. *NeuroRehabilitation*, 36, 203-214.
- NORUP, A., WELLING, K. L., QVIST, J., SIERT, L. & MORTENSEN, E. L. 2012. Depression, anxiety and quality-of-life among relatives of patients with severe brain injury: the Acute phase. *Brain Inj*, 26, 1192-1200.
- O'CALLAGHAN, A. M., MCALLISTER, L. & WILSON, L. 2011. Experiences of care: perspectives of carers of adults with traumatic brain injury. *Int J Speech Lang Pathol*, 13, 218-26.
- ODDY, M., COUGHLAN, T., TYERMAN, A. & JENKINS, D. 1985. Social adjustment after closed head injury: a Further follow-up seven years after injury. *J Neurol Neurosurg Psychiatry*, 48, 564-568.
- ODDY, M., HUMPHREY, M. & UTTLEY, D. 1978. Stresses upon the relatives of head-injured patients. *Br J Psychiatry*, 133, 507-13.
- ODGAARD, L., POULSEN, I., KAMMERSGAARD, L. P., JOHNSEN, S. P. & NIELSEN, J. F. 2015. Surviving severe traumatic brain injury in Denmark: incidence and predictors of highly specialized rehabilitation. *Clin Epidemiol*, 7, 225-34.
- PANTING, A. & MERRY, P. 1972. The long term rehabilitation of severe head injuries with particular reference to the need for social and medical support for the patient's family. *Rehabilitation*, 38, 33-37.
- PETTERSEN, K. I., VEENSTRA, M., GULDVOG, B. & KOLSTAD, A. 2004. The Patient Experiences Questionnaire: development, validity and reliability. *Int J Qual Health Care*, 16, 453-63.
- PONSFORD, J. & SCHONBERGER, M. 2010. Family functioning and emotional state two and five years after traumatic brain injury. *J Int Neuropsychol Soc*, 16, 306-317.
- RAMKUMAR, N. A. & ELLIOTT, T. R. 2010. Family caregiving of persons following neurotrauma: Issues in research, service and policy. *NeuroRehabilitation*, 27, 105-112.

- ROOZENBEEK, B., MAAS, A. I. & MENON, D. K. 2013. Changing patterns in the epidemiology of traumatic brain injury. *Nat Rev Neurol*, 9, 231–236.
- ROSENTHAL, M. & YOUNG, T. 1988. Effective family intervention after traumatic brain injury; theory and practice. *Journal of Head Trauma Rehabilitation*, 3, 42-50.
- ROTONDI, A. J., SINKULE, J., BALZER, K., HARRIS, J. & MOLDOVAN, R. 2007. A qualitative needs assessment of persons who have experienced traumatic brain injury and their primary family caregivers. *J Head Trauma Rehabil*, 22, 14-25.
- SANDER, A. M., HIGH, W. M., JR., HANNAY, H. J. & SHERER, M. 1997. Predictors of psychological health in caregivers of patients with closed head injury. *Brain Inj*, 11, 235–249.
- SIMPSON, G. & JONES, K. 2013. How important is resilience among family members supporting relatives with traumatic brain injury or spinal cord injury? *Clin Rehabil*, 27, 367-77.
- SMITH, J. E. & SMITH, D. L. 2000. No map, no guide. Family caregivers' perspectives on their journeys through the system. *Care Manag J*, 2, 27-33.
- SUNDSTROM, T., SOLLID, S. & WESTER, K. 2005. [Deaths from traumatic brain injury in the Nordic countries, 1987–2000]. *Tidsskr Nor Laegeforen*, 125, 1310–1312.
- SVEEN, U., ROE, C., SIGURDARDOTTIR, S., SKANDSEN, T., ANDELIC, N., MANSKOW, U., BERNTSEN, S. A., SOBERG, H. L. & ANKE, A. 2016. Rehabilitation pathways and functional independence one year after severe traumatic brain injury. *Eur J Phys Rehabil Med*.
- SZKLO, M. N., J. 2014. *Epidemiology. Beyond the basics.*, US, Jones & Bartlett Learning.
- TEASDALE, G. & JENNETT, B. 1974. Assessment of coma and impaired consciousness. a Practical scale. *Lancet*, 2, 81–84.
- THOMPSON, H. J. 2009. A critical analysis of measures of caregiver and family functioning following traumatic brain injury. *J Neurosci Nurs*, 41, 148–158.
- THOMSEN, I. V. 1974. The patient with severe head injury and his family. A follow-up study of 50 patients. *Scand J Rehabil Med*, 6, 180-3.
- TURNER, B., FLEMING, J., CORNWELL, P., WORRALL, L., OWNSWORTH, T., HAINES, T., KENDALL, M. & CHENOWETH, L. 2007. A qualitative study of the transition from hospital to home for individuals with acquired brain injury and their family caregivers. *Brain Inj*, 21, 1119-30.
- VERHAEGHE, S., DEFLOOR, T. & GRYPDONCK, M. 2005. Stress and coping among families of patients with traumatic brain injury: a review of the literature. *J Clin Nurs*, 14, 1004–1012.
- WALKER, K. O., STEWART, A. L. & GRUMBACH, K. 2016. Development of a survey instrument to measure patient experience of integrated care. *BMC Health Serv Res*, 16, 193.
- WILSON, J. T., PETTIGREW, L. E. & TEASDALE, G. M. 1998. Structured interviews for the Glasgow Outcome Scale and the Extended Glasgow Outcome Scale: Guidelines for their use. *J Neurotrauma*, 15, 573–585.
- ZALOSHNIJA, E., MILLER, T., LANGLOIS, J. A. & SELASSIE, A. W. 2008. Prevalence of long-term disability from traumatic brain injury in the civilian population of the United States, 2005. *J Head Trauma Rehabil*, 23, 394-400.

Manskow US, Sigurdardottir S, Røe C, Andelic N, Skandsen T, Damsgård E, Elmståhl S, Anke A.

Factors affecting caregiver burden 1 year after severe traumatic brain injury: A prospective nationwide multicenter study. *J Head trauma Rehabil*, 30, 411-423.

Manskow US, Friborg O, Røe C, Braine M, Damsgård E, Anke A.

Patterns of change and stability in caregiver burden and life satisfaction from 1 to 2 years after severe traumatic brain injury: A Norwegian longitudinal study.

Accepted, june, 2016

Paper III

Anke A, Manskow US, Friborg O, Røe C, Arntzen C.

The Family Experiences of in-hospital Care Questionnaire in severe Traumatic Brain Injury (FECQ-TBI): A validation study. *Submitted, 2016*

Appendix A

Consent of participation caregiver

Forespørsel om deltakelse i forskningsprosjektet

”Pårørende ved traumatisk hjerneskade. En nasjonal studie”

Bakgrunn og hensikt

Det er et spørsmål til deg om å delta i en forskningsstudie som undersøker situasjonen til de nærmeste når en i familien får en alvorlig traumatisk hjerneskade. Studien vil øke kunnskapen om hvilke behov pårørende har og hvordan disse er ivaretatt, og vil kunne bidra til å bedre dagens behandlings- og rehabiliteringstilbud. Studien er nasjonal, det vil si at alle helseregioner i Norge deltar. Universitetssykehuset Nord-Norge HF (UNN) er hovedansvarlig for studien.

Hva innebærer studien?

Som nærmeste pårørende ber vi deg om opplysninger om hvilke behov du opplever etter skaden og hvordan disse er ivaretatt, i tillegg til en evaluering av hvor tilfreds du er med ulike sider av helsetjenestens tilbud. Studien vil også kartlegge pårørendes livskvalitet, psykiske helse og opplevde støtte fra omgivelsene. Det registreres hvilken relasjon du har til pasienten (eks. ektefelle, datter, sønn), alder, kjønn og utdanning og yrkesmessig situasjon. Alle registreringer foregår ved hjelp av spørreskjema som du selv fyller ut 12 og 24 måneder etter skaden. De som er pårørende til personer som skades i januar 2010 eller senere, vil også bli spurt om å fylle ut spørreskjema etter 3 måneder. Personen som har fått en hodeskade er forespurt om å delta i en studie som registrerer forløp over tid og behandlingstilbud.

Mulige fordeler og ulemper

Studien medfører ingen form for risiko eller ubehag annet enn at du fyller ut spørreskjemaene. Selv om enkelte spørsmål berører følsomme sider ved livssituasjonen, oppleves dette erfaringsmessig lite belastende. Det vil bli gitt veiledning og støtte ved behov. Mange pårørende synes det er bra å bli spurt om egen situasjon. Studien vil gi bedre kunnskap om problemer hos familiemedlemmer ved alvorlig hodeskade, og vil kunne bidra til å bedre tilbudet til familier som kommer i en lignende situasjon.

Hva skjer med informasjonen om deg?

Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Informasjonen som samles vil bli slettet innen utgangen av 2022.

Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse

Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for videre behandling. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte Audny Anke, overlege dr.med. tlf. 95936333, Universitetssykehuset Nord-Norge (UNN).

Ytterligere informasjon om studien finnes i kapittel A – utdypende forklaring av hva studien innebærer.

Ytterligere informasjon om personvern og økonomi finnes i kapittel B

Samtykkeerklæring følger etter kapittel B.

Kapittel A- utdypende forklaring av hva studien innebærer

Den som er registrert som nærmeste pårørende til pasienter innlagt med alvorlig traumatisk hjerneskade ved Universitetssykehusene i Tromsø, Trondheim, Bergen og Oslo blir forespurt om deltakelse. Det vil kun være pårørende til pasienter som inkluderes i oppfølgingsstudien ”Rehabilitering etter alvorlig traumatisk hjerneskade”, som vil bli inkludert i denne studien. Dersom du gir ditt samtykke, vil du få spørreskjema til utfylling (3), 12 og 24 måneder etter skaden. Skjemaene vil være vedlagt en frankert svarkonvolutt.

Bare pårørende til pasienter som er i live på undersøkelsestidspunktene vil bli kontaktet.

Kapittel B – Personvern og økonomi

Personvern

Opplysninger som registreres om deg er i hovedtrekk hentet fra det spørreskjemaet du fyller ut. De opplysninger du gir vil bli analysert i sammenheng med informasjon om pasientens skade, funksjon, medisinske behandling og rehabilitering.

All informasjon om deg aidentifiseres og studiens medarbeidere og forskere får kun tilgang til aidentifisert informasjon.

Databehandlingsansvarlig for studien er Universitetssykehuset Nord-Norge ved administrerende direktør.

Retten til innsyn og sletting av opplysninger om deg og sletting av prøver

Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi

Studien finansieres gjennom forskningsmidler fra stiftelsen Helse og Rehabilitering.

Informasjon om utfallet av studien

Du har som deltaker rett til å få informasjon om studiens resultater.

Ansvarlige for studien er:

Prosjektleder, overlege dr.med. Audny Anke

Universitetssykehuset Nord-Norge, tlf. 77 62 80 41, mobil tlf. 95936333

Kontaktperson ved

Ullevål universitetssykehus: Professor dr.med. Cecilie Røe og overlege dr.med. Nada Andelic

St Olavs Hospital: Overlege Toril Skandsen

Haukeland universitetssykehus: Overlege dr.med. Jan Sture Skouen og overlege Tina Ader

Kongsgård rehabiliteringssenter: Overlege Rein Knoph

Sunnaas sykehus: Sjefpsykolog dr.philos. Anne-Kristine Schanke

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Appendix B

Concent patient

IDNR.:

**Tilleggsinformasjon til pasienter som deltar i den vitenskapelige studien
”Rehabilitering etter alvorlig traumatisk hjerneskade, en nasjonal multisenterstudie”**

Nærmeste pårørende til de som er skadet har ofte spesielle utfordringer. Vi ønsker din tillatelse til å kontakte vedkommende.

Hvis du gir tillatelse, vil pårørende bli spurt om å delta i en studie som undersøker erfaringer med helsetjenesten, behov og følelsesmessige forhold. Pårørendes erfaringer vil bli sett i sammenheng med din situasjon og behandlingstilbudet. Studien heter ”Pårørende ved traumatisk hjerneskade”.

Det vil være helt frivillig for dem å delta og det vil ikke få noen konsekvenser for din behandling.

Ansvarlig for studien er:

Audny Anke, overlege dr.med., Rehabiliteringsklinikken, Universitetssykehuset Nord Norge, 9038 Tromsø. Tlf. 77 62 80 40, mobil tlf. 95936333.

- Jeg har mottatt skriftlig og muntlig informasjon og samtykker for at min nærmeste pårørende blir forespurt om å delta i studien ”Pårørende ved traumatisk hjerneskade”.

Pasientens signatur

Dato

Stedfortredende samtykke når berettiget, enten i tillegg til personen selv eller istedenfor

(Signert av nærstående, dato)

Appendix C

Questionnaire to participants

Pårørende ved hodeskade

En nasjonal multisenterstudie

Skjema 1

PERSONLIGE OPPLYSNINGER

- Mann Kvinne
 Gift/Reg.partner Samboende Enslig

Mitt forhold til den som har hatt en skade. Jeg er:

- Ektefelle/Mann Søster
 Ektefelle/ Kone Barnebarn
 Samboer Venn
 Sønn Nabo
 Datter Andre
 Bror

UTDANNING OG YRKE

Hva er din høyeste fullførte utdanning? (sett ett kryss)

- Grunnskole 7-10 år, framhaldskole eller folkehøyskole
 Yrkesfaglig videregående skole, yrkesskole eller realskole
 Allmennfaglig videregående skole eller gymnas
 Høyskole eller universitet
 Hvilket yrke har du, eller hadde du tidligere (før du eventuelt ble arbeidsledig, permittert, trygdet eller pensjonert)

ARBEIDSSTATUS

- I arbeid / Yrkesaktiv Alderspensionist
 Under utdanning Arbeidsledig
 Hjemmearbeidende Sykemeldt
 Førtidspensionert/ufør Annet

TID SAMMEN MED DEN SOM ER SKADET

Bor du i samme hus/ leilighet som den som har hatt en skade?

- Ja Nei

Hvor mye tid tilbringer du sammen med personen som har hatt en skade pr. døgn?

- Alle dager hele døgnet
 6-10 timer pr.døgn
 2-6 timer pr.døgn
 1-2 ganger ukentlig
 Mindre enn 1 gang ukentlig

Formålet med spørreskjemaet er å gi helsepersonell bedre forståelse av situasjonen til familie og/eller venner av personer som har hatt en alvorlig skade. Din utfylling av skjemaet vil være til stor nytte for å kunne gi et best mulig behandlings- og rehabiliteringstilbud i fremtiden, både til den som har hatt en skade og pårørende.

Spørreskjemaet har flere deler. Første del omhandler din utdanning, yrkessituasjon, familie og det sosiale nettverket. Neste del er et skjema som omhandler familiens behov, og deretter er det registreringer av belastninger hos pårørende og sinnsstemning/ følelser. Den siste delen av spørreskjemaet omhandler hvilke erfaringer du har fra sykehusoppholdet.

Takk for at du bidrar!

SOSIALT NETTVERK

Hvor mange personer bor det i husstanden din?

Hvis du ikke bor alene, hvem bor du sammen med?

- Ektefelle
 Samboer
 Andre
 Venn(er)
 Barn
 Foreldre
 Svigerforeldre

Omtrent hvor mange nære venner har du – personer du trives sammen med og kan snakke fortrolig med? (du kan regne med slektninger dersom du ønsker det)

Ingen En Flere Antall

Hvor ofte treffer du venner og slektninger, for eksempel på besøk hos hverandre, for å gå ut sammen, snakke i telefonen?

- Minst en gang i uken
 Sjeldnere enn hver uke, men minst en gang i måneden
 Sjeldnere enn hver måned

Er det noen blant dem som står deg nær, som viser deg oppmerksomhet og er interessert i det du holder på med?

- Viser ingen eller lite varme og interesse
 Ja, viser noe varme og interesse
 Ja, viser mye varme og interesse

Forekommer det at du føler deg ensom?

- Aldri/ sjeldent Av og til Ofte

(Anke AG et al., J Trauma 1997)

FAMILIENS BEHOV

Familie og/eller venner av personer som har hatt en alvorlig skade, opplever ofte at de selv har spesielle behov. Disse behovene blir ikke nødvendigvis dekket mens pasienten er under rehabilitering, og behovene endres gjerne over tid. Vi er interessert i å finne ut om dine behov blir dekket. All informasjon fra deg vil hjelpe oss til bedre å forstå behovene til din familie og til andre pårørende av personer som har vært utsatt for alvorlige skader.

For hvert av spørsmålene nedenfor ber vi om at du vurderer om behovene er dekket eller ikke. Sett ett kryss i svaralternativene. **JA** hvis behovet er dekket, **DELVIS** hvis behovet bare er delvis dekket og **NEI** hvis behovet ikke er dekket i det hele tatt.

Er dette behovet dekket?	Ja	Delvis	Nei
1 å se at pasientens behov og ønsker blir respektert av medisinsk personale, pedagogisk personale eller rehabiliteringspersonalet.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2 å få informasjon hver dag om hva som blir gjort for pasienten.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3 å gi uttrykk for min mening daglig til andre som er involvert i pasientens pleie, rehabilitering eller opplæring.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 å bli informert om alle endringer i pasientens medisinske status.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5 å få forsikring om at pasienten får best mulig medisinsk behandling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6 at fagfolk forklarer ting på en måte jeg kan forstå.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7 at mine spørsmål blir besvart på en ærlig måte.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8 å få vite at mine meninger blir tatt i betraktning i planleggingen av pasientens behandling, rehabilitering eller opplæring.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9 å ha kontakt med fagfolk som kan bistå med råd eller tjenester når pasienten trenger hjelp.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10 å få fullstendig informasjon om den medisinske behandlingen av alvorlige skader (f.eks. medisiner, injeksjoner eller operasjoner).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11 å få fullstendig informasjon om pasientens fysiske problemer (f.eks. svakhet, hodepine, svimmelhet, problemer med synet eller problemer med å gå).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12 å få fullstendig informasjon om pasientens problemer med tenkning (f.eks. forvirring, hukommelse eller kommunikasjon).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13 å få fullstendig informasjon om stoff- eller alkoholproblemer og behandling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14 å få vite hvor lenge man tror pasientens ulike problemer vil vare.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15 å få vite hva som bør gjøres når pasienten er oppskaket eller oppfører seg underlig.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16 å få informasjon om pasientens framgang i rehabilitering eller opplæring.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17 å få hjelp til å finne ut hvor mye pasienten kan klare på egen hånd.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18 at det er tilstrekkelige ressurser til pasienten (f.eks. rehabiliteringstilbud, fysioterapi, rådgivning, jobbveiledning).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Er dette behovet dekket?		Ja	Delvis	Nei
19	tilstrekkelige ressurser til meg selv eller familien (f.eks. økonomisk eller juridisk rådgivning, lindrende behandling, rådgivning, pleie eller omsorg på dagtid).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20	hjelp i huset (f.eks. til innkjøp, rengjøring, matlaging osv.).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21	hjelp fra andre familiemedlemmer til å ta vare på pasienten.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22	tilstrekkelig hvile eller søvn.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23	å få en pause fra mine problemer og oppgaver.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24	å være sammen med venner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25	å ivareta mine egne behov, interesser eller min jobb.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26	at min ektefelle forstår hvor vanskelig det er for meg.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27	at min partner/kjæreste eller mine venner forstår hvor vanskelig det er for meg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28	at andre familiemedlemmer forstår pasientens problemer.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29	at pasientens venner forstår hans/hennes problemer.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30	at pasientens arbeidsgiver, kolleger eller lærere forstår hans/hennes problemer.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31	å snakke om mine følelser overfor pasienten med noen som har opplevd det samme.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32	å snakke om mine følelser overfor pasienten med venner eller familien.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33	å bli forsikret om at det er vanlig å ha sterke negative følelser overfor pasienten.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34	hjelp til å overvinne usikkerhet og frykt med tanke på fremtiden.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35	hjelp til å være forhåpningsfull med tanke på pasientens fremtid.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36	hjelp til å forberede meg for det verste.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37	å bli oppmuntret til å be andre om å hjelpe til.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

FNQ: Utviklet av Rehabilitation Psychology & Neuropsychology Service, Department of Physical Medicine and Rehabilitation, Virginia Commonwealth University, Richmond. Oppdatert 2/08. (Oversatt av Anke, UNN HF).

BELASTNING HOS PÅRØRENDE

		Nei, ikke i det hele	Nei, ikke i særlig grad	Ja, til en viss grad	Ja, i høy grad
1	Føler du deg trøtt og overarbeidet?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Føler du deg ensom og isolert på grunn av ditt familiemedlem sitt problem?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Synes du at du må ta for mye ansvar for ditt familiemedlems ve og vel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Føles det iblant som om du vil flykte fra hele den situasjonen du er i?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Står du overfor rent praktiske problemer i omsorgen som du synes er vanskelig å løse?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Kan du bli såret og sint på ditt familiemedlem?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	Synes du at din helsetilstand lider av at du har tatt hånd om ditt familiemedlem?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	Har ditt familiemedlems problem ført til at omgangen med andre, for eksempel slekt og venner, har minsket for deg?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	Finnes det noe i boligen til ditt familiemedlem som gjør det vanskelig å ta hånd om han eller henne?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	Føler du deg bundet av problemet til ditt familiemedlem?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	Føler du deg brydd av ditt familiemedlems oppførsel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	Fører ditt familiemedlems problem til at du ikke kan gjøre det du hadde tenkt å gjøre på denne tiden i livet?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13	Synes du det er fysisk anstrengende for deg å ta deg av ditt familiemedlem?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	Synes du at ditt familiemedlem tar så mye tid at du ikke får tilstrekkelig tid for deg selv?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15	Er du urolig for at du ikke skal kunne ta hånd om ditt familiemedlem på riktig måte?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16	Hender det at du skammer deg over ditt familiemedlem sin oppførsel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17	Er det noe i omgivelsene rundt hjemmet til ditt familiemedlem som gjør det vanskelig å ta vare på han eller henne?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18	Har det vært et økonomisk offer for deg å ta vare på ditt familiemedlem?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19	Synes du det er psykisk belastende for deg å ta vare på ditt familiemedlem?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20	Har du iblant en følelse av at livet behandler deg urettferdig?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21	Hadde du tenkt deg at livet skulle være annerledes i den alderen du er nå?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22	Unngår du å invitere hjem venner og bekjente på grunn av ditt familiemedlem sitt problem?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SINNSSTEMNING/FØLELSER

1 **Jeg er nervøs eller anspent**

- For det meste
- Ofte
- Noen ganger
- Ikke i det hele tatt

2 **Jeg gleder meg fremdeles over ting jeg pleide å glede meg over**

- Avgjort like mye
- Ikke fullt så mye
- Bare litte grann
- Ikke i det hele tatt

3 **Jeg har en urofølelse som om noe forferdelig kommer til å skje**

- Helt sikkert og svært ille
- Ja, men ikke så veldig mye
- Litt ille, men det bekymrer meg ikke så mye
- Ikke i det hele tatt

4 **Jeg kan le og se det morsomme i alle situasjoner**

- Like mye som jeg alltid har gjort
- Ikke like mye nå som før
- Avgjort ikke så mye nå som før
- Ikke i det hele tatt

5 **Jeg har hodet fullt av bekymringer**

- Veldig ofte
- Ganske ofte
- Av og til
- En gang i blant

6 **Jeg er i godt humør**

- Aldri
- Noen ganger
- Ganske ofte
- For det meste

7 **Jeg kan sitte i fred og ro og kjenne meg avslappet**

- Ja, helt klart
- Vanligvis
- Ikke så ofte
- Ikke i det hele tatt

8 **Jeg føler meg som om alt går langsommere**

- Nesten hele tiden
- Svært ofte
- Fra tid til annen
- Ikke i det hele tatt

9 **Jeg føler meg urolig liksom jeg har sommerfugler i magen**

- Ikke i det hele tatt
- Fra tid til annen
- Ganske ofte
- Svært ofte

10 **Jeg har sluttet å bry meg om hvordan jeg ser ut**

- Ja, helt klart
- Jeg bryr meg ikke så mye som jeg burde
- Det kan nok hende at jeg ikke bryr meg nok
- Jeg bryr meg like mye om utseendet som jeg alltid har gjort

11 **Jeg føler meg rastløs som om jeg stadig må være i aktivitet**

- Uten tvil svært mye
- Ganske mye
- Ikke så veldig mye
- Ikke i det hele tatt

12 **Jeg ser med glede frem til hendelser og ting**

- Like mye som jeg alltid har gjort
- Heller mindre enn jeg pleier
- Avgjort mindre enn jeg pleier
- Nesten ikke i det hele tatt

13 **Jeg kan plutselig få en følelse av panikk**

- Uten tvil svært ofte
- Svært ofte
- Ikke så veldig ofte
- Ikke i det hele tatt

14 **Jeg kan glede meg over en god bok eller et radio- eller TV-program**

- Ofte
- Fra tid til annen
- Ikke så ofte
- Svært sjeldent

Hospital Anxiety and Depression Scale
(Zigmond and Snaithe, 1983)

GENERELL LIVSTILFREDSHET

Generelt, hvor tilfreds er du med livet ditt nå?

- Meget fornøyd
- Fornøyd
- Verken fornøyd eller misfornøyd
- Misfornøyd
- Meget misfornøyd

ERFARINGER UNDER SYKEHUSOPPHOLDET

Dette skjemaet skal bare fylles ut dersom den personen som fikk hodeskaden har avsluttet det første oppholdet på sykehus (både akuttavdeling og eventuelt rehabiliteringsenhet).

Vi vil gjerne høre om dine erfaringer som pårørende ved sykehusoppholdet. Vi er interessert i å få vite hvilke erfaringer dere som nære pårørende har fra ulike faser av sykehusoppholdet. Altså fra både akuttavdelingen og fra rehabiliteringsavdelingen. Hvis den skadde har vært innlagt flere ganger, svar på spørsmålene på bakgrunn av det første oppholdet.

		Svært misfornøyd	Ganske misfornøyd	Verken fornøyd eller misfornøyd	Ganske fornøyd	Svært fornøyd
1	Alt i alt, hvor fornøyd eller misfornøyd er du med den pleien, behandlingen og rehabiliteringen den skadde fikk ved sykehuset. (Svar samlet for både den akutte fasen og rehabiliteringsfasen.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Alt i alt, hvor fornøyd eller misfornøyd er du med hvordan du ble behandlet som pårørende?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Dine erfaringer fra den første fasen, for eksempel intensivavdelingen, kirurgisk avdeling eller annen avdeling enn en rehabiliteringsenhet:

		Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad
3	I hvilken grad opplevde du at det var én lege som hadde hovedansvaret for den skadde?	<input type="checkbox"/>				
4	I hvilken grad opplevde du at det var en fast gruppe pleiepersonale som tok hånd om dere?	<input type="checkbox"/>				
5	I hvilken grad opplevde du at de ansatte samarbeidet om den behandlingen og pleien den skadde fikk?	<input type="checkbox"/>				
6	Opplevde du at behandlingen, pleien og rehabiliteringen den skadde fikk i den akutte fasen fulgte en gjennomtenkt plan?	<input type="checkbox"/>				
7	Fikk du vite det du synes var nødvendig om resultater av prøver og undersøkelser i denne fasen?	<input type="checkbox"/>				

I hvilken grad synes du at personalet... (sett kun ett kryss per spørsmål)

		Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad
8	Tok hensyn til deres familiesituasjon?	<input type="checkbox"/>				
9	Hadde omtanke og omsorg for <u>den skadde</u> ?	<input type="checkbox"/>				
10	Hadde omtanke og omsorg <u>for deg som pårørende</u> ?	<input type="checkbox"/>				
11	Var interessert i å høre dine oppfatninger som pårørende?	<input type="checkbox"/>				
12	Ga deg forklaringer og informasjon som du forstod?	<input type="checkbox"/>				
13	Virket faglig dyktige?	<input type="checkbox"/>				
14	Ble det ført dagbok mens den skadde var på intensivavdelingen?	<input type="checkbox"/>	Ja	<input type="checkbox"/>	Nei	

Denne siden fylles ut hvis den skadde var innlagt på en rehabiliteringsavdeling.

Hva er dine erfaringer fra rehabiliteringsavdelingen/enheten?

		Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad
15	I hvilken grad opplevde du at det var én lege som hadde hovedansvaret for den skadde?	<input type="checkbox"/>				
16	I hvilken grad opplevde du at det var en fast gruppe pleiepersonale som tok hånd om dere?	<input type="checkbox"/>				
17	I hvilken grad opplevde du at det var en fast gruppe annet behandlingspersonell (eks. fysioterapeut, ergoterapeut, sosionom, logoped) som tok hånd om dere?	<input type="checkbox"/>				
18	I hvilken grad opplevde du at de ansatte samarbeidet om den behandlingen og pleien den skadde fikk?	<input type="checkbox"/>				
19	Opplevde du at behandlingen, pleien og rehabiliteringen den skadde fikk i rehabiliteringsfasen fulgte en gjennomtenkt plan?	<input type="checkbox"/>				
20	I hvilken grad følte du deg trygg på at den skadde fikk nødvendig behandling, pleie og rehabilitering?	<input type="checkbox"/>				
21	I hvilken grad fikk du forklart hensikten med den rehabiliterende behandlingen den skadde fikk?	<input type="checkbox"/>				
22	Opplevde du at de ansatte engasjerte seg i den skaddes situasjon?	<input type="checkbox"/>				
23	Opplevde du at du hadde én fast kontaktperson på rehabiliteringsavdelingen?	<input type="checkbox"/>				
24	I hvilken grad fikk du informasjon om rettigheter pasienten har (eks. yrkesrettede tiltak, trygder, forsikringer, sosiale tjenester)?	<input type="checkbox"/>				
25	Fikk du vite det du synes var nødvendig om resultater av prøver og undersøkelser?	<input type="checkbox"/>				

I hvilken grad synes du at personalet... (Sett kun ett kryss per spørsmål)

		Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad
26	Tok hensyn til deres familiesituasjon?	<input type="checkbox"/>				
27	Ga avlastning/ hjelp med den skadde i løpet av oppholdet?	<input type="checkbox"/>				
28	Informerte om hva du kunne bidra med som pårørende på sykehuset?	<input type="checkbox"/>				
29	Hadde omtanke og omsorg for <u>den skadde</u> ?	<input type="checkbox"/>				
30	Hadde omtanke og omsorg for <u>deg som pårørende</u> ?	<input type="checkbox"/>				
31	Var interessert i å høre dine oppfatninger som pårørende?	<input type="checkbox"/>				
32	Ga deg forklaringer og informasjon som du forstod?	<input type="checkbox"/>				
33	Virket faglig dyktige?	<input type="checkbox"/>				
34	Var samkjørte når de ga informasjon om den skadde?	<input type="checkbox"/>				
35	Ble det ført dagbok mens den skadde var på rehabiliteringsavdelingen?	<input type="checkbox"/>	Ja	<input type="checkbox"/>	Nei	

Hva synes du om følgende forhold ved rehabiliteringsavdelingen?

		Svært dårlig	Ganske dårlig	Både/og	Ganske bra	Svært bra
36	Renholdet	<input type="checkbox"/>				
37	Bad-/dusj-/toalettforhold	<input type="checkbox"/>				
38	Roen på pasientrommet	<input type="checkbox"/>				
39	Maten til den som var skadet	<input type="checkbox"/>				
40	Aktivitetstilbud for den som var skadet (spill, kulturtilbud, turer, video, andre sosiale aktiviteter)	<input type="checkbox"/>				
41	Maten til pårørende	<input type="checkbox"/>				
42	Hvilerom og overnattingstilbud til pårørende	<input type="checkbox"/>				
43	Hadde den som var skadet et eget rom? <input type="checkbox"/> Ja <input type="checkbox"/> Delvis <input type="checkbox"/> Nei					

Spørsmålene nedenfor gjelder tiden før hjemreise

		Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad
44	Ble du som pårørende tatt med på råd og ivaretatt i planlegging av utskrivningen?	<input type="checkbox"/>				
45	Fikk du informasjon du mente var nødvendig om tiden etter utskrivning?	<input type="checkbox"/>				
46	Var du ved hjemreisen trygg på at du kunne klare den nødvendige oppfølgingen av den som var skadet?	<input type="checkbox"/>				
47	Hadde den skadde fått nødvendig opplegg for videre rehabilitering?	<input type="checkbox"/>				
48	Fikk du informasjon om hva du kunne gjøre hvis det ble problemer eller noe ekstra skjedde etter at dere kom hjem?	<input type="checkbox"/>				
49	I hvilken grad fikk du informasjon om konsekvensene av hodeskaden – på kort og lang sikt?	<input type="checkbox"/>				

Spørsmålene nedenfor gjelder sykehusoppholdet som helhet

		Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad
50	Mener du at den skadde på noen måte ble feilbehandlet (etter det du selv kan bedømme)?	<input type="checkbox"/>				
51	Ble du sint, opprørt eller skuffet over personalet i løpet av oppholdet?	<input type="checkbox"/>				
52	Oppløpde du uheldige episoder i forbindelse med flytting fra en avdeling til en annen, eller fra et sykehus til et annet?	<input type="checkbox"/>				
53	Ble dine økonomiske behov ivaretatt?	<input type="checkbox"/>				
54	Var det barn involvert? <input type="checkbox"/> Ja <input type="checkbox"/> Nei					
55	Hvis ja, ble barna ivaretatt?	<input type="checkbox"/>				

Vennligst sjekk at alt er fylt ut. Send skjemaet sammen med et underskrevet eksemplar av samtykkeskjemaet. Bruk den vedlagte frankerte svarkonvolutten. Takk for innsatsen og lykke til videre!

Appendix D

The Caregiver Burden Scale (English version)

The Caregiver Burden Scale

General strain

1. Do you find yourself facing purely practical problems in the care of your relative that you think are difficult to solve?
2. Do you think you have to shoulder too much responsibility for your relative's welfare?
3. Do you sometimes feel as if you would like to run away from the entire situation you find yourself in?
4. Do you feel tired and worn out?
5. Do you feel tied down by your relative's problem?
6. Do you find it psychologically stressful trying to take care of your relative?
7. Do you think your own health has suffered because you have been taking care of your relative?
8. Do you think you spend so much time with your relative that the time for yourself is insufficient?

Isolation

9. Do you avoid inviting friends and acquaintances home because of your relative's problem?
10. Has your social life, e.g. with family and friends, been lessened?
11. Has your relative's problem prevented you from doing what you had planned to do in this phase of your life?

Disappointment

12. Do you have a feeling that life has treated you unfearly?
13. Had you expected that life would be different than it is at your age?
14. Do you feel lonely and isolated because of your relatives problem?
15. Do you find it physically strenuous trying to take care of your relative?
16. Have you experienced economic sacrifice because you have been taking care of your relative?

Emotional involvement

17. Are you sometimes ashamed of your relatives behavior?
18. Do you ever fell offended and angry with your relative?
19. Do you feel embarrassed by your relative's behavior?

Environment

20. Does the physical environment make it troublesome for you taking care of your relative?
21. Do you worry about not taking care of your relative in the proper way?
22. Is there anything in the neighbourhood of your relative's home making it troublesome for you to take care of your relative?

