A Goal-Oriented Randomized Controlled Intervention in the Chronic Phase of Traumatic Brain Injury

Feasibility, Patient-Reported Problem Areas, and Goal Attainment

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Foreword

When interviewing for the position of a Ph.D.-candidate for this project I first met the project investigators Cecilie and Marianne. I could feel how important the project was to them and made them a promise that this project would be as important to me, and that I would stay involved for however long it might take to finish. I entered the project in the planning phase, and it started out with a bang with an excellent seminar with kind guidance by our collaborator Laraine Winter. The first few months was spent translating material and adapting the intervention to a Norwegian context, which involved long academic (and non-academic) discussions with Post. Docs. Solveig, Marit and Ingerid. We were all excited when we sent out invitations to participants in the feasibility trial in December 2017. Being able to co-operate and co-adjust as therapist during the feasibility trial was an amazing learning experience, and I felt so lucky to be part of such an engaged group of rehabilitation professionals. We were ready to start recruitment for the main RCT-study in June 2018. The amount of logistics involved in organizing and conducting a randomized controlled trial with 120 participants was a challenge that I was lucky to be part of, as it allowed me to feel an intense sense of involvement in all parts of this study. Being allowed to grow as a clinical psychologist specializing in neuropsychology while collecting research data, by being allowed to get involved in so many lives and destinies of participants and their families, was highly motivating and is at its core the most meaningful part of this process for me. Hurdles were overcome, with pacing recruitment to a therapist burden that the four of us could manage and dealing with a pandemic when we thought we were only a few months from completing the recruitment. The covid-19 pandemic was certainly an extra strain for many of our participants, and we were challenged to find safe ways of continuing delivering our intervention. Being forced, but also allowed, to test the intervention by adding a video conference component was both daunting and exciting, as it may provide important information on an entirely different mode of implementation of rehabilitation in this patient group. During the past four years I was thus allowed to get intimately involved with every nook and cranny of conducting a larger scale RCT while also doing my best to help people in vulnerable life situations. Looking back at that first interview, I feel I can safely say that this project has become as important to me as to those making it possible by hours and hours of work to plan it and secure funding. Seeing first-hand how many people living with persistent symptoms after TBI and their families are left to themselves, I hope that the work that we have done can help shed light on their situations and their unmet need for support.

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This thesis could not have been written without the support from and efforts of many individuals that I now wish to thank.

First and foremost, I would like to extend my gratitude to *the patients and their families* who have participated in this research project. Without them, none of this would have been possible. I am honored that I have been allowed to share in their lives and that they have shown such a willingness to contribute to research on long term consequences of TBI, even those who have felt abandoned by health care services for several years. I deeply hope that this work can have an impact on the care for TBI in the chronic phase in Norway.

I could not have finished this thesis without the amazing support I have received from my four supervisors. To my main supervisor, *Cecilie Røe*, thank you so much for always having my back, pushing me forward, and always finding the time for even my most trivial challenges along the way. Your wealth of knowledge, work capacity and mental processing speed is highly impressive, and always makes academic discussions a learning experience.

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To my co-supervisor *Marit Vindal Forslund*. I admire your balance of rigor and warmth through everything that you do. Thank you for reminding me (many times, at any hour) that the first rule of research is that every process than you would hope and for always grounding me. These years have been filled with so many shared hours of diligent work and discussions, but also with food, travel, dancing, and celebration. For that I am forever grateful, and I look forward to all the fun that is yet to come.

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Several senior researchers have contributed substantially to this project. I wish to thank *Nada Andelic* for sharing in your wealth of knowledge, always expressing high beliefs in me, and your attitude towards promoting young researchers. *Solrun Sigurdardottir, Helene Søberg* and *Unni Sveen* have all been important collaborators who have shared their ideas and expertise, and who have helped with important multidisciplinary discussions along the way. Our international collaborator *Laraine Winter* has been invaluable in both planning this study and by in-depth feedback on papers. I hope to see you in Norway again soon.

As a Ph.D.-candidate I have been employed by the *Department of Physical Medicine and Rehabiltiation* at Oslo University Sykehus HF, Ullevål. I have been enriched in these years by a stimulating environment of so many accomplished and friendly colleagues. I am thankful to be part of this department. Particularly, I wish to thank the colleagues who have contributed to data collection in this project; *Mari, Emilie, Silje, Solrun, Camilla, Pernille* and *Benedikte*.

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Abbreviations

ABI – acquired brain injury

ADL – activities of daily living

BRIEF-A – Behavior Rating Inventory of Executive Function-Adult

CONSORT - The Consolidated Standards of Reporting Trials

COPM – Canadian Occupational Performance Measure

CVLT-II – California Verbal Learning Test-second edition

D-KEFS – Delis-Kaplan Executive Function Systems

EQ-5D – EuroQol-5 dimensions

GAD-7 – Generalized Anxiety Disorder-7 item

GAS – goal attainment scaling

GOSE – Glasgow Coma Scale - Extended

GCS – Glasgow Coma Scale

HRQOL – Health-related quality of life

ICF – International classification of functioning, disability and health

LOC – Loss of consciousness

OUH – Oslo University Hospital

PART-O – Participation Assessment with Recombined Tools-Objective

PCRS – Patient Competency Rating Scale

PHQ-9 – Patient Health Questionnaire-9 item

PTA – Post traumatic amnesia

PTSD – post-traumatic stress disorder

QOLIBRI-OS – Quality of Life after Brain Injury-Overall Scale

RCT – randomized controlled trial

RPQ – Rivermead Post-concussion Questionnaire

SD – standard deviation

SF-36 – Medical Outcome Survey Short Form-36

SMART – Specific, measurable, attainable, relevant, timed

SPIRIT - the Standard Protocol Items: Recommendations for Interventional Trials

TBI – Traumatic brain injury

U.K. – the United Kingdom

U.S. – the United States (of America)

WAIS-IV – Weschler Adult Intelligence Scale-fourth edition

WHO – World Health Organization

Thesis summary

A broad range of symptoms may be expected in patients experiencing a traumatic brain injury (TBI), and for some these difficulties persist for decades after their injury. Further, many individuals with TBI and their families report long-term unmet health care needs. The variability in expected symptoms post TBI is high, which necessitates an individualized approach in assessing and treating these patients. Further, to improve the patient-centeredness and personal relevance of rehabilitation approaches, treatment should be goal-oriented and conducted within the context of the patient's everyday life. This thesis was written in the context of a randomized controlled trial (RCT) that aims to investigate the efficacy of a goal-oriented and home-based rehabilitation intervention for individuals in the chronic phase of TBI. The overall aim of the thesis is to cover knowledge gaps about treatment needs and options in the chronic phase of TBI by developing an individualized rehabilitation intervention with suitable goal attainment measures to be evaluated in an RCT. This thesis displays the feasibility testing (paper I), the study protocol (paper II), the utility of an individualized assessment approach (paper III), and the goal attainment in the intervention group (paper IV).

The first aim was to investigate the feasibility of the intervention delivery. Paper I displayed that although the intervention was considered feasible and acceptability was high, some amendments was needed before establishing the final protocol for the RCT. As a result of the feasibility trial, eligibility criteria were amended, the baseline assessment was abbreviated, and the included outcome measures and their order were modified.

Paper II displays the full study protocol for the RCT, including study design, setting, intervention content and planned analyses for the efficacy evaluation of this trial.

In paper III, an individualized approach (Target Outcomes) to attain information about main patient-reported problems areas after TBI was evaluated and compared to standardized outcome measures. In total 120 individuals with persistent symptoms at least two years after a TBI was included. Target Outcomes were reported in the domains of cognitive, physical, emotional, and social functioning, and covered 24 distinct sub-categories. Further, comparison with standardized measures displayed that the Target Outcome approach provided a more detailed picture of the problem profile of each participant. It was concluded that this approach might be a useful addition to assessing idiosyncratic TBI-related difficulties that may aid clinicians and researchers in planning interventions for these patients.

Paper IV displayed goal attainment results from the intervention group of the RCT. Goal attainment was high and all 59 patients displayed overall improved goal attainment at the final

intervention session. Goal attainment did not vary depending on the type of goal, i.e., goals within different domains (cognitive, physical, emotional, social) were attainable at the same levels. Individuals who were less educated, experienced less cognitive and executive impairments, and had high outcome expectation at session 3 showed higher goal attainment at session 8. These findings should be considered preliminary, and more research on indicators of goal attainment is warranted.

In summary, this thesis displays insights into the delivery of an individualized approach to rehabilitation in the chronic phase of TBI. It provides a transparent look into aspects of conducting a RCT such as feasibility testing and protocol establishment. It also expands current knowledge about individualized approaches that may aid in the planning and delivery of rehabilitation interventions for patients in the chronic phase of TBI, ensuring the delivery of an evidence-based and patient-centered intervention. Individualized and patient-centered approaches are considered crucial to improve outcomes in the chronic phase of TBI.

The efficacy evaluation of the RCT is pending the completion of final outcome assessments and results are expected to be available in 2022.

List of papers

This thesis is based on the following four papers referred to by their Roman numerals I-IV.

Paper I

Borgen, I. M. H., Løvstad, M., Røe, C., Forslund, M. V., Hauger, S. L., Sigurdardottir, S., Winter, L., & Kleffelgård, I. (2020). Needs and treatment options in chronic traumatic brain injury: A feasibility trial of a community-based intervention. *Cogent Medicine, 7*(1). https://doi.org/10.1080/2331205x.2020.1731222

Paper II

Borgen, I. M. H., Løvstad, M., Andelic, N., Hauger, S., Sigurdardottir, S., Søberg, H. L., Sveen, U., Forslund, M. V., Kleffelgård, I., Lindstad, M. O., Winter, L., & Røe, C. (2020). Traumatic brain injury-needs and treatment options in the chronic phase: Study protocol for a randomized controlled community-based intervention. *Trials, 21*(1), 294-308. https://doi.org/10.1186/s13063-020-4195-5

Paper III

Borgen, I. M. H., Kleffelgård, I., Hauger, S. L., Forslund, M. V., Søberg, H. L., Andelic, N., Sveen, U., Winter, L., Løvstad, M., & Røe, C. (2021). Patient-Reported Problem Areas in Chronic Traumatic Brain Injury. *Journal of Head Trauma Rehabilitation.* Published online ahead of print. https://doi.org/10.1097/htr.0000000000000744

Paper IV

Borgen, I. M. H., Hauger, S. L., Forslund, M. V., Kleffelgård, I., Brunborg, C., Andelic, N., Sveen, U., Søberg, H. L., Sigurdardottir, S., Røe, C., & Løvstad, M. (2021). Goal attainment in an individually tailored and home-based intervention in the chronic phase after traumatic brain injury. Under review in *Journal of Clinical Medicine*.

1 Needs Description and Motivation

Traumatic brain injury (TBI) is the leading cause of death and disability in young adults and is one of the most debilitating health conditions for all age groups. TBI is thus a disorder with high societal costs, especially considering the number of young individuals who live with consequences of the disorder for decades (James et al., 2019). The impact of TBI on individuals has been extensively documented, and includes medical, physical, cognitive, emotional, and social difficulties, resulting in reduced functioning and participation. Research on treatment options for TBI has largely focused on the acute and sub-acute phases of the disorder. At the same time, studies have documented that many individuals with TBI experience long-term unmet health care needs, especially related to cognitive, emotional, and social functioning. An added challenge is that TBI is a highly heterogeneous condition, and treatment must be individualized to target the specific deficits the individual and their family experience. As TBI is now recognized as a chronic disease impacting individuals and their families for decades, there is a need for high-quality studies that evaluate the effectiveness of targeted interventions well-suited for persistent TBI symptoms. Although some studies have shown that rehabilitation can have positive effects on quality of life and participation even years after the TBI occurs, high-quality research on treatment options for TBI in the chronic phase is still needed (Maas et al., 2017). This thesis aims to cover knowledge gaps within the field of needs and treatment options for TBI in the chronic phase.

2 Introduction

2.1 TBI Definition, Epidemiology, and Classification

TBI is "an alteration in brain function, or other evidence of brain pathology, caused by an external force." (Menon et al., 2010, p. 1637). The cause of injury varies by age, with falls being the most prominent cause in children, adolescents, and older adults, while road traffic accidents are the most common cause in young adults (Peeters et al., 2015). TBI occurs in all age groups, but adolescents and young adults tend to sustain more TBIs, as do the elderly (Andelic, Anke, et al., 2012; Kraus & McArthur, 1999). TBI occurs approximately two times more often in men than in women, although reported male-to-female ratios range from 1.2:1 to 4.6:1 (Peeters et al., 2015).

Estimated prevalence (the number of patients living with the injury at a specified point in time) and incidence (number of new cases within a specified point in time) of TBI varies among studies due to differences in demographic characteristics, inclusion criteria, and injury severity (Kraus & Chu, 2005; Maas et al., 2011; Peeters et al., 2015; Tagliaferri et al., 2006), and emergency department and hospitalization rates may provide the most reliable estimates. Incidence rates of TBI-related emergency department visits in the U.S. was 2.87 million in 2014, 801.9 per 100 000, an increase compared to 2006 (Peterson et al., 2019), and earlier estimates (120/100 000; Kraus & Chu, 2005). A systematic review of the epidemiology in Europe from 16 different countries showed an overall incidence rate of 262 per 100 000 (Peeters et al., 2015). A Norwegian study documented an annual incidence of hospitalized TBI in the metropolitan area to be 83.3/100 000 (Andelic et al., 2008). The prevalence of TBI-related disability in the United States (U.S.) alone has been estimated to be between 3-5.3 million (Thurman, 1999; Zaloshnja et al., 2008), while conservative estimates suggested that more than 7.7 million individuals were living with TBI-related deficits in Europe (Tagliaferri et al., 2006).

TBI is commonly classified as mild, moderate, or severe, based on the level of consciousness in the acute phase as assessed with the Glasgow Coma Scale (GCS; Teasdale & Jennett, 1974) with a minimum score of 3 and a maximum score of 15, supplemented with the length of loss of consciousness (LOC) and post traumatic amnesia (PTA). Table 1 displays an overview of the criteria for classification of TBI severity. The mild injuries dominate, comprising 80-90% of the cases, while moderate to severe TBI represent 10-15% of all TBIs (Andelic et al., 2008; Ma et al., 2014; Maas et al., 2008; Tagliaferri et al., 2006). The level of consciousness is a good estimate for mortality, with an overall mortality rate of 15/100 and significantly higher risk of mortality in moderate and severe TBI (Brown et al., 2004). There are however several challenges regarding classification of injury severity, as simple and pragmatic tools might over-simplify the complex nature of TBI, and more comprehensive assessment methods incorporating several differing approaches might be too complex to implement in clinical practice (Steyerberg et al., 2019; Tenovuo et al., 2021). Duration of PTA has been shown to be a better predictor of long-term outcome than acute GCS (Sherer et al., 2002; Willemse-van Son et al., 2007; Wood, 2008), but injury severity alone seems to be a poor predictor of long-term disability and service needs in TBI survivors (Ponsford et al., 2008; Vallat-Azouvi et al., 2021; Willemse-van Son et al., 2007; Wood, 2008). Yet, universally accepted more complex models for long-term outcome is still lacking.

Table 1. Severity classification of TBI in the acute phase. Adapted from Voss et al. (2015).

	GCS	LOC	PTA
Mild	13-15	0-30 minutes	< 1 day
Moderate	9-12	>30 minutes to < 24 hours	> 1 day to < 7 days
Severe	3-8	>24 hours	> 7 days

GCS=Glasgow Coma Scale. LOC=loss of consciousness. PTA=post-traumatic amnesia

2.2 Pathophysiology of Acute TBI and Mechanisms in the Chronic Phase

TBI involves both a primary injury and secondary systemic and cellular mechanisms. Primary injuries may be both focal, such as a contusion or hematoma; or diffuse, such as axonal strain. These primary mechanisms are irreversible and only the object of preventative strategies (Walker & Tesco, 2013). Acute TBI care involves reducing the impact of secondary effects in the brain initiated by the primary injury. Secondary effects may involve edema, increased intracranial pressure, hemorrhage, excitotoxicity, and inflammation. These detrimental processes underly synaptic and cellular dysfunction, cell death and traumatic axonal injury. Over the past decades, acute trauma care has improved with decline in mortality for TBI patients (Gerber et al., 2013; Lu et al., 2005; Stein et al., 2010), which entails an increasing number of individuals living with sequelae post-TBI. Integrated medical, neurosurgical treatment and early rehabilitation has been shown to provide TBI survivors better functional outcomes (Andelic, Bautz-Holter, et al., 2012). A wealth of research has been focused on understanding mechanisms of TBI and treatment options in the acute and sub-acute phases. However, less attention has been paid to long-term consequences of TBI.

Earlier, TBI was by many considered as an isolated event, an occurrence to cause some temporary or permanent damage to the brain, requiring immediate care. More recently, several researchers and clinicians have postulated a view of TBI as an occurrence that sets into motion a chronic disease process (Corrigan & Hammond, 2013; Masel & DeWitt, 2010, 2014; Wilson, Stewart, et al., 2017). The mechanisms of how TBI can lead to chronic neurodegeneration are not fully understood, but several disease processes in the brain have been implicated (Masel & DeWitt, 2014). Both animal models and studies of humans 1-2 years post-TBI have suggested that apoptotic cell death may continue to occur after TBI for months or even years (Beattie et al., 2002; Williams et al., 2001; Wilson et al., 2004). Inflammation in response to the TBI has further been documented several months and years post-TBI (Engel et al., 2011; Gentleman et al., 2004; Helmy et al., 2011) and as late as 22 years post-injury (Maxwell et al., 2006). Additionally, long-term reduction of cerebral blood flow (Ge et al., 2009; Terayama et al., 1991), as well as ongoing denervation and reinnervation of axons leading to shorter neuronal life spans (Dalakas, 1995) might play a role in the chronic disease processes post-TBI.

Evidence that TBI has long-term devastating consequences can also be found in the literature on mortality and morbidity post-TBI. Individuals suffering from a TBI have 2.0-2.5 times the risk of mortality at one year or more post injury and a decreased life expectancy by about 7 years (Harrison-Felix et al., 2004; Harrison-Felix et al., 2009; McMillan et al., 2011). This likely is in part due to increased risk of post-injury morbidity. TBI is a major risk factor for disorders such as epilepsy (Hauser et al., 1991), Alzheimer’s dementia and non-Alzheimer’s dementia (Jellinger et al., 2001;

Lye & Shores, 2000; Schofield et al., 1997), brain tumors (Chen et al., 2012), disorders related to post-traumatic hypopituitarism (Schneider et al., 2007), Parkinson's disease (Bower et al., 2003), as well as a range of psychiatric disorders including major depression, as well as psychotic and anxiety disorders (Fleminger, 2008; Ponsford et al., 2018; Zasler et al., 2007).

In addition to pathophysiological consequences and multimorbidity, individuals living with TBI often experience a wealth of direct and indirect symptoms of their condition. These difficulties must be considered in a lifespan perspective, as they have currently been documented up to 30 years post TBI (Colantonio et al., 2004; Himanen et al., 2006; Hoofien et al., 2001; Wood & Rutterford, 2006b). The sequelae are further impacted by many diverse factors, making outcomes of TBI heterogeneous and complex. To better understand outcome post TBI, a theoretical framework is needed to aid interpretation of empirical and clinical findings.

2.3 Outcome after TBI

2.3.1. The Biopsychosocial Model

As TBI-related disability is a result of a complex interplay of multiple factors and expected outcomes are heterogeneous in nature, there is a need to apply a broad theoretical framework to assist understanding of post-TBI consequences and treatment needs. The highly influential biopsychosocial model was proposed by Engel (1977) and postulates that biological, psychological, and social factors interact in the creation of symptoms and disease. Biological factors are any factors relating to the physical body. Psychological factors comprise of any subjective experiences, including mental states, thoughts, feelings, perceptions, intentions, and behaviors. Social factors include life events, interpersonal experiences, social circumstances, and sociocultural influences (Karunamuni et al., 2021). The biopsychosocial model was developed in response to dissatisfaction with a pure biomedical model of illness and has gained substantial influence within the field of rehabilitation (Barnes, 2003; Wade & Halligan, 2017). As a result, patients are not seen as passive recipients of treatment and advice delivered by an expert professional. Instead, they are active participants in their own rehabilitation, both by delineating what is of personal relevance to themselves and by describing what they wish to achieve given their idiosyncratic context. Further, this entails that health care professionals are expected to not only address specific deficits, but also evaluate how the deficits interact with emotional, behavioral, and social functioning (Wilson, 2008). More recently, a holistic biopsychosocial model has been suggested by Wade (2015), which takes into account aspects such as life stage, time since injury, quality of life and choice. The biopsychosocial model is used as a descriptive foundation of the International Classification of Functioning, Disability and Health (ICF; World Health Organization, 2001). The ICF is an international framework and classification system for health, health-related states, and outcomes. The ICF has two interacting components: functioning and disability, and contextual factors. Within the component of functioning and disability there are domains relating to body functions and structures, as well as activities and participation. Contextual factors include both environmental factors, such as physical and social environments, and personal factors, such as age, gender, habits, coping and self-efficacy. The ICF has been used to assess disability post-TBI and is considered a useful framework to fully understand the burden after TBI for patients and families (Andelic et al., 2010; Laxe et al., 2015; Laxe et al., 2014; Laxe et al., 2013).

Interpreting outcomes post-TBI in both research and clinical settings may be aided by the application of the biopsychosocial model. For example, biological factors such as type of injury (Maas et al., 2007), presence of concurrent injuries (Schonberger et al., 2011) and injury severity (de Guise et al., 2016; Dikmen et al., 2010; Rapoport & Feinstein, 2000; Sigurdardottir et al., 2009) have been shown to influence functional outcome, as well as be related to poorer employment outcome (Avesani et al., 2005; Brown et al., 2005; Doctor et al., 2005; Howe et al., 2018; Machamer et al., 2005; Ponsford et al., 1995; Schonberger et al., 2011) and reduced cognitive functioning (Green et al., 2008). However, it is by now well known that outcomes after a TBI are not only the result of the head injury itself, but that many psychological and contextual factors play important roles in recovery (Cooper-Evans et al., 2008; Ponsford, 2014). The interacting nature of factors related to long-term disability post-TBI are not yet fully understood, but current perspectives will be outlined below.

2.3.2 Long-Term Disability After TBI

TBI might affect the individual in domains such as physical, cognitive, emotional, and social functioning, and impact their ability to participate in work, in their families and in their communities. This section will provide an overview of current knowledge about long-term TBI-related disability.

Physical difficulties such as balance difficulties, dizziness, abnormal movement, and sensory and motor impairments are frequent after TBI, as well as fatigue and headache (Jourdan et al., 2018). Visual difficulties including accommodative dysfunction, convergence insufficiency and visual field loss are also common after TBI (Merezhinskaya et al., 2019). As many as 50% of individuals experience sleep difficulties post-TBI, with an increased risk of difficulties with sleep maintenance, excessive sleepiness, early awakenings, and reduced sleep efficiency (Mantua et al., 2018; Mathias & Alvaro, 2012). Even though physical difficulties typically improve during the first year post-TBI, longitudinal studies have shown that a surprising number of difficulties, such as dizziness and balance problems, sensory difficulties, fatigue, pain, and headaches persist over time (Jourdan et al., 2016; Mollayeva et al., 2014; Olver et al., 1996; Ponsford, Downing, et al., 2014).

As with physical difficulties, cognitive impairments after TBI often improve within the first 1-2 years, and then are considered relatively stable (Christensen et al., 2008; Finnanger et al., 2013).

This entails that a broad range of cognitive difficulties are expected to persist, which has been documented at 3, 5 and 10 years post-injury in moderate-severe TBI (Dikmen et al., 2003; Marsh et al., 2016; Ponsford, Downing, et al., 2014; Rabinowitz et al., 2018; Rabinowitz & Levin, 2014; Ruet et al., 2019; Sigurdardottir et al., 2020). Most frequently, deficits in areas of processing speed, attention, memory, and executive functioning are found post-TBI (Boake et al., 2001; Dikmen et al., 2003; Dikmen et al., 1995; Draper & Ponsford, 2008; Green et al., 2008; Jourdan et al., 2016; Lehtonen et al., 2005; Millis et al., 2001; Novack et al., 2001; Satz et al., 1998; Sigurdardottir et al., 2015; Spitz et al., 2012). In severe TBI, there is evidence that as many as 60-65% of individuals experience long-term cognitive difficulties, and that some experience generalized intellectual disabilities (Dikmen et al., 2003; Rabinowitz & Levin, 2014; Wood & Rutterford, 2006b). Cognitive impairments matter for individuals with TBI, as they may interfere with their ability to return to their normal life, such as independence in complex instrumental activities of daily living (ADL), employment, and social life (Colantonio et al., 2004; Dikmen et al., 2003; Olver et al., 1996; Ponsford, Downing, et al., 2014; Powell et al., 2007). Further, slowed information processing and executive dysfunction has been shown predict poorer functional outcomes (Azouvi et al., 2016; Ruet et al., 2019; Spitz et al., 2012; Vallat-Azouvi et al., 2021). In addition, many individuals with TBI have impaired awareness of their difficulties, which often is a result of complex mechanisms involving organic, cognitive, and psychological factors (FitzGerald et al., 2012; Flashman & McAllister, 2002; Hart et al., 2005) that may persist over time (Kelley et al., 2014). Impaired awareness post-TBI has been shown to impede rehabilitation efforts, hamper community integration and increase caregiver burden (Abreu et al., 2001; Brown et al., 2019; Chesnel et al., 2018; Robertson & Schmitter-Edgecombe, 2015).

Emotional difficulties are common after TBI and include increased rates of psychiatric disorders. As many as ~50% have been shown to satisfy criteria for major depressive disorder within the first year after TBI (Bombardier et al., 2010; Gould et al., 2011a; Whelan-Goodinson et al., 2009), and the presence of depressive symptoms has been shown to increase in the first three years following TBI (Ashman et al., 2004). High rates of depression have been documented as late as 10-30 years post-injury (Draper et al., 2007; Hoofien et al., 2001; Koponen et al., 2002), as well as increased suicidal ideation (Bahraini et al., 2013). Depression has been shown to negatively affect recovery, reduce social functioning and increase risk of re-hospitalization, and should thus be managed (Beedham et al., 2020). Anxiety symptoms and disorders are also common post-TBI (Osborn et al., 2016), but rates vary between 17-57% among studies evaluating anxiety symptoms at 1-30 years post-TBI (Gould et al., 2011a; Koponen et al., 2002; Whelan-Goodinson et al., 2009). Anxiety is associated with poorer functional outcomes, and reducing the impact of depression and anxiety in the chronic phase of TBI may lead to better global functioning (Ruet et al., 2021). Rates of post-traumatic stress disorder (PTSD) have been documented to be high in military populations suffering from TBI but has more recently been shown to be elevated also in civilian TBI populations (Iljazi et al., 2020; Loignon et al., 2020; Van Praag et al., 2019). Although evidence is more conflicting (Ponsford et al., 2018; Van Reekum et al., 2000), some studies have reported increased risk of substance use disorders and psychosis post-TBI (Alway et al., 2016; Molloy et al., 2011; Orlovska et al., 2014; Zgaljardic et al., 2015). Importantly, comorbid psychiatric issues and substance abuse post-injury may exacerbate other difficulties, increasing overall disability (Jourdan et al., 2017), and some evidence suggests a delayed onset of several psychiatric disorders post-TBI, which highlight the importance of long-term evaluation in the TBI population (Alway et al., 2016; Ponsford et al., 2018).

More recently, social cognitive difficulties have been recognized as a long-term consequence in many individuals with TBI. Social cognition refers to the ability to perceive social information, mentalize or understanding one's own and other's feelings, thoughts, and intentions, and responding appropriately by regulating one's feelings and behavior (Adolphs, 2003; Cassel et al., 2019). Individuals with TBI may experience emotional lability, irritability, apathy, childishness, and reduced empathy for others, and these difficulties tend to persist over time (Benedictus et al., 2010; Cassel et al., 2019; Hanks et al., 1999; Ietswaart et al., 2008; Jourdan et al., 2016; Milders, 2019; O'Connor et al., 2005; Stefan & Mathe, 2016). Irritability and anger are frequently reported after TBI and may in accordance with the biopsychosocial model be result of a complex combination of factors, including damages to frontal brain networks, personality traits, comorbid anxiety or depression, poor emotional perception, cognitive deficits and negative social experiences (Arciniegas & Wortzel, 2014; Feng et al., 2021; Hart et al., 2017; Kim et al., 1999; Neumann et al., 2015, 2017a, 2017b; Yang et al., 2013). Social cognitive impairments may in part underlie the rates of social isolation, reduced social participation, difficulties with developing and maintaining relationships and loneliness commonly seen to persist post-TBI (Bier et al., 2009; Dikmen et al., 2003; Draper et al., 2007; Engberg & Teasdale, 2004; Hoofien et al., 2001; Jourdan et al., 2016; Ponsford, Downing, et al., 2014; Winkler et al., 2006; Wise et al., 2010; Wood & Rutterford, 2006c).

Social cognitive difficulties affect not only the individual with TBI but their family and friends as well. Overall, caregiver burden is considered high, with caregivers reporting high rates of psychological distress and reduced quality of life (Anke et al., 2020; Kreutzer et al., 2009; Kreutzer, Serio, et al., 1994; Norup et al., 2015). Although relationship disruption rates (e.g., divorce) have been shown to be similar to the general population (Forslund, Arango-Lasprilla, Roe, Perrin, & Andelic, 2014; Hammond et al., 2021) and many families cope surprisingly well with the consequences of TBI, quality of relationships may decline, and the combination of increased reliability on family members and changes in behavior and personality of the individual with TBI may increase family stress over time (Manskow et al., 2017; Ponsford, 2014). The presence of social cognitive difficulties may particularly impact the family system and increase caregiver burden (Anderson et al., 2002; Kreutzer, Gervasio, et al., 1994; Saban et al., 2015; Sander et al., 2013).

The impact of the broad range of symptoms that may occur post-TBI is evident when considering overall disability seen in studies of global functioning after TBI. Most individuals with a mild TBI are likely to regain full functioning and return to work within the first year of injury (Cassidy et al., 2014), while only about 50% of the individuals with moderate to severe TBIs have favorable outcomes at 6-12 months post-injury (Murray et al., 1999; Sigurdardottir et al., 2009; Singh et al., 2019). Importantly, although some improve, the larger proportion of TBI patients remain at the same overall gross level of functioning as one year post injury, and some even deteriorate over time (Forslund et al., 2019; Hammond, Grattan, et al., 2004; Marquez de la Plata et al., 2008; Pretz & Dams-O'Connor, 2013). Naturally, disability levels matter to individuals and families post-TBI, and overall disability has been shown to predict health-related quality of life (HRQOL) which is typically reduced post-TBI (Andelic et al., 2009; Grauwmeijer et al., 2014; Jourdan et al., 2016; Tsyben et al., 2018). HRQOL should be considered a multidimensional concept that considers how symptoms or illness impacts on a person's perception of their own well-being (Cella, 1994). In TBI, this is further complicated by impairments in executive functioning and self-awareness, which may lead to individuals reporting a higher HRQOL than would be expected (Cicerone et al., 2004; Pettemeridou et al., 2020).

Another important aspect to consider is that of participation. In the ICF, participation is defined as "involvement in life situations" (p.10), and participation restrictions are described as difficulties an individual might have with such involvement. Participation is important to patients themselves and has been shown to be more strongly related to quality of life than ADL or global functioning (Dijkers, 1997; Huebner et al., 2003; Steadman-Pare et al., 2001). In stark contrast, rehabilitation services may often be evaluated and funded based on outcomes related to physical rather than social health (Dijkers et al., 2000), perhaps as a vestige of the biomedical model still being influential in health care funding. Measuring participation in life areas such as work, social life, and leisure activities post-TBI thus seems highly important, especially as there is evidence that participation difficulties typically persist for decades (Hoofien et al., 2001). Studies investigating participation after TBI have shown overall reduced participation in leisure activities and social life after TBI (Erler et al., 2018; Hammond, Hart, et al., 2004; Larsson et al., 2013; Olver et al., 1996; Sander et al., 1996; Temkin et al., 2009). Return to work is an integral part of participation (Wagner et al., 2002; Webb et al., 1995) and may hold a unique meaningfulness for patients after TBI (Bryson-Campbell et al., 2013; Klepo et al., 2020). Rates of work participation has varied among studies, but many have documented that fewer than half of those with moderate-severe TBI are able to return to stable work participation (Forslund, Arango-Lasprilla, Roe, Perrin, Sigurdardottir, et al., 2014; Howe et al., 2018; Kreutzer et al., 2003; Machamer et al., 2005; Novack et al., 2001; Ownsworth & McKenna, 2004; Ponsford et al., 1995; Pössl & Jürgensmeyer, 2009; Sherer et al., 2002).

2.3.3 Contextual Factors Influencing Disability After TBI

As outline above, disability after TBI is heterogeneous, and in accordance with the biopsychosocial model, different symptoms act together to create the summed challenges individuals experience in their lives at home, at work and in their community. This leaves disability post-TBI multi-factorial and adding to this complexity is the fact that factors outside the injury itself and its direct consequences are known to influence disability. As previously mentioned, in the ICF these contextual factors are often referred to as personal factors, such as age, gender and coping, and environmental factors, such as social support and access to services.

Of personal factors, age seems to be the strongest predictor of outcome in moderate-severe TBI, with increased risk of poor outcome with old age (Brown et al., 2005; Dikmen et al., 2010; Green et al., 2008; Hukkelhoven et al., 2003; Keyser-Marcus et al., 2002; LeBlanc et al., 2006; Livingston et al., 2005; Marquez de la Plata et al., 2008; Mushkudiani et al., 2007; Nakase-Richardson et al., 2011; Ponsford et al., 1995; Schonberger et al., 2011). Interestingly, older age might protect against psychiatric comorbidity and relationship disruption following TBI (Hammond et al., 2021; Senathi-Raja et al., 2010), possibly as the patients might have reached more life goals and have stronger relationships prior to injury (Ponsford, 2014). Gender does not alone predict outcome well, and studies have displayed diverging results as to the influence of gender on outcome (Davis et al., 2006; Farace & Alves, 2000; Willemse-van Son et al., 2007). Higher pre-injury intelligence may be related to better long-term cognitive outcome (Raymont et al., 2008), and pre-injury higher education has been shown to be related to better outcome in areas such as cognition, employment, social functioning, and community integration (Draper & Ponsford, 2008; Hoofien et al., 2002; Raymont et al., 2008; Wood & Rutterford, 2006a). Genetic factors, such as the presence of the Apolipoprotein E4 allele have been suggested to have a negative influence on outcome post-TBI (Alexander et al., 2007; Baguley et al., 2000; Jordan, 2007; Ponsford et al., 2011; Teasdale et al., 1997). Personality factors and self-efficacy further seem to impact outcomes post-TBI (Wood, 2008), and the use of non-productive emotion-focused or avoidant coping strategies such as worry, self-blame, substance use, and wishful thinking also has been found to be related to poorer outcomes (Anson & Ponsford, 2006; Curran et al., 2000; Sigurdardottir et al., 2014; Spitz et al., 2013; Tomberg et al., 2007; Wolters et al., 2010). Pre-injury psychiatric history further influences psychological adjustment post-injury (Bombardier et al., 2010; Gould et al., 2011b; Schonberger et al., 2011; Whelan-Goodinson et al., 2008). Pre-injury substance abuse is a significant predictor of long-term disability and reduced productivity post-TBI (Dikmen et al., 2010; Jourdan et al., 2017; Willemse-van Son et al., 2007). An added challenge is that individuals in vulnerable life situations seem to be particularly prone to sustain TBIs, such as individuals with previous drug and alcohol abuse, psychiatric disorders, individuals from lower socioeconomic groups, or who have had previous head injuries or unstable employment (Kraus & McArthur, 1999; Robinson & Jorge, 2002), and these factors may further have a negative impact on recovery post-TBI (MacMillan et al., 2002).

One important environmental factor is access to social support, which has been shown to be the most important predictor of long-term emotional well-being after TBI. Both the amount and the quality of social support seem essential for individuals post-TBI (Kendall & Terry, 2009; Stalnacke, 2007; Tomberg et al., 2005). The living environment may play a role in access to social support, as living in rural areas has been shown to increase social support seeking, and in turn increase quality of life (Farmer et al., 2005). Further, the living environment itself may either be a facilitator or barrier for the individual with TBI, as they may need an environmental structure that match their level of competency post-injury. Some environments may present with more barriers than others, e.g., barriers at the workplace or in complex social situations are expected to be larger for individuals with TBI, while home or indoor setting may provide higher amounts of informal help and supervision, representing a more facilitating environment (Jourdan et al., 2016). One study (Whiteneck et al., 2004) found that the most frequently reported environmental barriers one year post-TBI were related to transportation, aspects of the surroundings such as noise, lightning and crowding, government policies, attitudes met at home, and the natural environment. Further, facing these barriers was correlated with reduced quality of life and social participation. Structural factors such as funding of and access to rehabilitation services may further impact individuals with TBI, as access to rehabilitation is known to improve outcomes after TBI.

2.4 Rehabilitation in the Chronic Phase of TBI

The definition of rehabilitation has been a subject of contention. A recent terminological analysis found that 187 definitions of rehabilitation currently exist in the English language (Arienti et al., 2020). An ongoing Cochrane Rehabilitation project aims to define rehabilitation in the health care context for scientific purposes. A provisional definition was published in October 2020 (Negrini et al., 2020), and the final definition is pending validation. In this provisional definition, rehabilitation is defined as a:

> Multimodal person-centered process including functioning interventions targeting (1) body functions, and/or (2) activities and participation, and/ or (3) the interaction with the environment (Intervention) aimed at optimizing functioning (Outcome) in (1) persons with health conditions (a) experiencing disability or (b) likely to experience disability, and/or (2) persons with disability (Population). (p.659)

In Norway, the legal regulation “Regulation of habilitation and rehabilitation” (Forskrift om habilitering og rehabilitering, 2018) states that rehabilitation should be based on the individual patient’s life situation and goals, and that rehabilitation is:

> A goal-oriented collaborative process between patients, users, caregivers, and service providers in various arenas. The processes are characterized by coordinated, continuous, and knowledge-based actions. The aim is that the individual patient and user, who has or is at risk of developing limitations in their physical, psychological, cognitive, or social functioning, shall be given the opportunity to achieve their best possible functional and coping skills, independence and participation in education, work, social life, and society at large. (§3, *my translation*).

This description is not unlike the provisional definition by the Cochrane group, though more specific. Wade (2021) argues that rehabilitation can be described, but not defined. In his description of rehabilitation, he describes that the main goal of rehabilitation is to optimize a patient’s quality of life and social integration. Further, he argues that rehabilitation is a problem-solving process, delivered in a person-centered way, within the context of a biopsychosocial model of illness. He also notes that rehabilitation should be tailored to the patient’s priorities, needs and goals (Wade, 2020). Within this thesis, rehabilitation is defined as suggested by the Cochrane group, but the more explicit understanding of its content and purpose is in line with the descriptive qualities suggested by both the Norwegian regulation and Wade.

As documented above, individuals with TBI experience long-term consequences of their condition, and it thus stands to reason that they may need long-term support from health care services. One main concern after TBI is to increase participation and quality of life for patients (Jourdan et al., 2017), and rehabilitation services should be provided to help individuals meet their idiosyncratic goals. Also, any rehabilitation intervention targeting TBI sequelae needs to be individualized because of the heterogeneous and multifactorial complaints expected to prevail after injury. The use of a biopsychosocial model as a backdrop for the experienced difficulties may aid in tailoring rehabilitation interventions. Further, as individuals with TBI and their families gradually try to return to their everyday lives, they may experience different issues at differing times during recovery. Life events and increasing age further implies that the life stage they are at needs to be considered when developing rehabilitation strategies (Wade, 2015). This means that there is a need to adjust rehabilitation efforts in accordance with changes in functional capacity over time (Jourdan et al., 2017), and not just evaluate needs for rehabilitation and its delivery based on reports from early assessments post-TBI.

2.4.1 Unmet Needs in the Chronic Phase of TBI

Unmet health care needs in the chronic phase of TBI have been documented in several studies and across countries. Needs relating to physical functioning, such as delivery of physical therapy, have been shown to be covered more often than needs relating to emotional, cognitive, and vocational deficits (Andelic et al., 2021; Andelic et al., 2014; Corrigan et al., 2004; Heinemann et al., 2002; Mahoney et al., 2021; Schulz-Heik et al., 2017). Further, individuals with psychological difficulties or cognitive impairments might be less likely to receive rehabilitation (Andelic et al., 2021; Miller et al., 2017; Schulz-Heik et al., 2017), which is troubling as these are common sequela post-TBI. Further, individuals with TBI might be at risk of not receiving rehabilitation services because of comorbid psychiatric disorders, while either not receiving psychiatric care because of their brain injury or receiving care that is not properly tailored to their cognitive impairments. Importantly, receiving needed services is related to higher life satisfaction (Brown & Vandergoot, 1998; Pickelsimer et al., 2007). One qualitative study suggested that while needs in the acute and subacute phase of brain injury typically are related to survival and re-establishment of functional abilities, needs in the chronic phase are related to psychosocial recovery, which includes aspects such as awareness, acceptance, adjustment, and balance (Stiekema et al., 2020). As mentioned above, organizational factors such as access to rehabilitation services may play a role in the unmet needs reported in the chronic phase of TBI. For example, insufficient funding and availability of rehabilitation services targeting cognitive complaints may be the cause of unmet needs, despite the patient or family reporting need for such services (Jourdan et al., 2015). One study found that health care access, but also other environmental barriers such as the physical environment, informational sources, social attitudes, public policy, in-home assistance, and transportation availability, were related to unmet rehabilitation needs (Mahoney et al., 2021). Further, there seem to be a discordance between the ideal of helping individuals re-enter into their daily lives, and the community services provided, with funding favoring specialized medical services over community re-entry services (Jourdan et al., 2015)

The delivery of rehabilitation services is dependent on contextual factors such as geographical region, type of health care system and public policy. In Norway, there is universal access to health care services. While specialized rehabilitation services at the hospitals are responsible for acute and post-acute care and rehabilitation, the municipal and primary health care services are primarily responsible for long-term follow-up after TBI in Norway. If organizational factors were the main reason for unmet health care needs, and lack of sufficient rehabilitation services was due to financial restraints and scarce resources, one would expect to find fewer unmet needs of rehabilitation services in higher income countries with universal access such as Norway, which is not the case. On the contrary, a recent study documented low frequency in delivery of rehabilitation services in Norway.

The authors concluded that the delivery of services did not reflect the impairments expected in this sample of mostly severe TBI, which may indicate insufficient delivery of rehabilitation services in the long-term for patients with moderate-severe TBI in Norway (Andelic et al., 2020). The Norwegian Directorate of Health launched a plan for increasing support for rehabilitation services between 2017-2019. However, a recently published report showed that fewer patients received specialized rehabilitation services in 2019 than in 2015, and that there are large discrepancies between regions in provision of rehabilitation services (Helsedirektoratet, 2020b). Unequal geographic provision of rehabilitation services has been shown in other countries as well (Kamenov et al., 2019). Further, an independent review of the rehabilitation plan displayed systematic weaknesses in rehabilitation services in Norway including the need to clarify responsibilities between the specialized and municipal health care services and poor coordination of services (Helsedirektoratet, 2020a). The organization of rehabilitation of services in Norway may be an important barrier for patients post-TBI and explain the relatively high levels of unmet needs. Perhaps the knowledge about long-term consequences of TBI and unmet needs has yet to fully impact all levels of health care services, but also to gain political traction necessary to ensure funding of long-term services for individuals with persistent difficulties post-TBI. In the National Health and Hospital plan for 2020-2023 (2019) closer collaboration between municipal and specialized health care services, and technological improvements to make specialized health care services available to patients in their homes, are set forth as main goals. Such policies may impact future rehabilitation services to individuals with chronic TBI in Norway. To ensure that rehabilitation services are prepared for this task, there is a need to expand the knowledge on effective treatment options for these individuals in the chronic phase, and robust research designs that can document effectiveness of interventions seem an important step in the right direction to ensure that patients and their families get the help they need.

2.4.2 Current Knowledge About Rehabilitation of Long-Term Consequences of TBI

In 2017, the World Health Organization (WHO) launched the initiative “Rehabilitation 2030: A call for action”, aiming to draw attention to the worldwide unmet rehabilitation needs (World Health Organization, 2017). One recommendation was that rehabilitation interventions of high methodological quality should form the evidence base of rehabilitation. Despite the ample evidence of persistent difficulties after TBI, the research on effective treatment options for these deficits are to a large degree characterized by heterogeneity in study populations, types of interventions tested, and outcome measures used. This section will provide an overview of the current knowledge base regarding rehabilitation of long-term consequences post-TBI.

For individuals with TBI whom experience persistent difficulties, there is evidence that rehabilitation efforts can be effective in the chronic phase. Several observational studies have documented that rehabilitation at one year or more post-injury is associated with positive changes in community reintegration, productivity and functional independence (Cicerone et al., 2004; Geurtsen et al., 2011; Jourdan et al., 2017; Sander et al., 2001; Seale et al., 2002) even in the chronic phase of severe TBI (High et al., 2006). This indicates that gains in important domains for individuals with TBI is possible even in a stable phase many years after the injury. In their randomized controlled trial (RCT) of a comprehensive and holistic rehabilitation program compared to standard multidisciplinary for TBI, Cicerone et al. (2008) included a population of TBI survivors where more than half of the sample were at one year or more post-injury. Participants receiving the intensive rehabilitation program showed larger gains in community integration, quality of life and self-efficacy for managing their symptoms compared to standard treatment, and treatment effects were maintained at 6-months follow-up. The Cognitive Rehabilitation Task Force of the American Congress of Rehabilitation Medicine Brain Injury Interdisciplinary Special Interest Group recommended in their systematic review as a practice standard that post-acute, holistic neuropsychological rehabilitation targeting cognitive, emotional, and interpersonal difficulties should be provided after moderate to severe TBI (Cicerone et al., 2011). This recommendation was recently updated and confirmed (Cicerone et al., 2019) to specify that evidence now suggests this practice standard should be applied regardless of injury severity or time since injury and is also relevant for non-traumatic acquired brain injuries (ABIs). A practice recommendation was included that these interventions should be goal directed and target individualized client-centered goal setting to enhance independence and occupational functioning.

2.4.2.1 Goal oriented rehabilitation. To improve outcomes and increase the patient-centeredness of rehabilitation, goal-oriented rehabilitation has been proclaimed as the main approach to rehabilitation in recent years (Wilson, 2008). Schut and Stam (1994) were perhaps the first to describe how goal-oriented rehabilitation addresses several challenges in delivery of rehabilitation, such as patient motivation and interprofessional teamwork. In the context of goal-oriented rehabilitation, a goal was described by Playford et al. (2009) as “how things will be at some specified time in the future and it is a desired state that requires both action and effort” (p. 338). Goal-oriented rehabilitation has been shown to increase patient satisfaction and adherence (Levack et al., 2006) and improve self-efficacy, health-related quality of life and emotional status, although there is a need for more methodologically rigorous studies (Levack et al., 2015). Evidence further suggests that goal setting might be fundamental in changing human behavior, which is often an aim in rehabilitation (Siegert et al., 2004).

Although goal-based rehabilitation has been a popular approach over the past decades, conceptual terms typically vary among studies, and theoretical frameworks are often not described (Playford et al., 2009; Scobbie et al., 2009; Siegert & Taylor, 2004). A clearer theoretical framework may, however, facilitate clinical implementation and research. Scobbie and colleagues (2009) conducted a systematic review identifying important theories of behavior change. They identified three main theories: Social Cognitive Theory (Bandura, 1997), Goal Setting Theory (Locke & Latham, 2002), and Health Action Process Approach (Schwarzer, 1992), and proposed a theoretical framework compiling these theories to improve the theoretical underpinning of goal setting in clinical rehabilitation. They argued that goal setting seems to involve two separate phases; a motivational phase where outcome expectancy and self-efficacy play important roles, and an action phase which involves action planning, feedback and the handling of barriers and setbacks. Theories related to the concept of self-regulation has further been proposed as relevant to goal-oriented rehabilitation. Self-regulation theories assume that human behavior is goal-directed, that individuals often strive towards simultaneous goals, and that their ability to attain goals are determined by their skill at regulating their emotions, cognitions, and behavior. Further, they suggest that goal attainment, motivation and affect interact. Siegert and colleagues (2004) argued that goal-oriented rehabilitation need to account for both the motivation of the patient and affective responses to goal-directed behavior in accordance with self-regulation theories. They suggested that setting rehabilitation goals may increase optimism, willingness to change and compliance, and that improving these motivational aspects may lead to better rehabilitation outcomes. Within the same theoretical framework Hart and Evans (2006) suggested that individuals with TBI might be particularly prone to difficulties in goal activities, as cognitive deficits may impair their ability to set and achieve goals, and negatively influence goal-directed behavior, arguing the need to consider these difficulties when applying goal setting with individuals with TBI.

Further, goal-oriented rehabilitation has been thought to be the epitome of actively engaging patients in treatment, i.e., to increase the patient-centeredness of interventions. This is accordance with the shift towards shared decision making and patient empowerment in rehabilitation (Barnes, 2003; Edwards & Elwyn, 2009). According to Wilson (2008), rehabilitation should always be structured as a collaborative effort where the patient, therapist and family members or others close to the patient decide on relevant functional goals. Person-centered rehabilitation has been shown to have positive effects on occupational performance and rehabilitation satisfaction (Yun & Choi, 2019), and is thought to be a key to successful goal setting (McClain, 2005; Wade, 2009). However, two systematic reviews have shown that goal-oriented rehabilitation may be less person-centered than intended (Rosewilliam et al., 2011; Sugavanam et al., 2013). A survey of health care professionals displayed little real involvement of the patient in establishing goals and evaluating their progress, and further that few used formal methods to evoke goals and only half shared the goals with the patient, despite considering their work approach patient-centered (Holliday et al., 2005). This suggests that barriers to ensuring the patient-centeredness of goal-oriented rehabilitation should be recognized.

Patients might have varying interest in being directly involved in goal setting depending on their situation (Playford et al., 2009). Further, they may adopt a passive role when entering rehabilitation based on previous experiences with health care systems (McClain, 2005), e.g., by simply confirming goals suggested by therapists (Parry, 2004). In addition, patients with cognitive impairments are susceptible to be poorly involved in goal setting (Hersh et al., 2012). This lack of active participation on behalf of the patient might lead to goals being established that might not be those the patient him- or herself is most interested in. For example, therapists might suggest some types of goals, e.g., goals related to mobility, while ignoring areas that might be important to patients, such as psychological well-being (Wressle et al., 1999). Reduced awareness is a particular challenge in the TBI population, as the patient might be less motivated to establish goals in areas that they do not perceive as a major concern, but that therapists or family members consider most troublesome. They might also want so set goals that are considered unrealistic by family member and care providers. Patients and therapists might also have different expectations of recovery (Bendz, 2000), leading to disagreements between patients and clinicians on what constitutes realistic goals. Thus, a structured approach should be applied in goal setting, and patient-centeredness should be an ongoing focus during the delivery of goal-oriented interventions.

One widely used approach to goal setting in rehabilitation has been the SMART goal approach. SMART is an acronym, that typically entails establishing goals that are Specific, Measurable, Achievable, Relevant and Timed, although many other variations of the meaning of these letters exist (McPherson et al., 2014; Wade, 2009). Further, there is no one true way to establish SMART goals and use these in rehabilitation, although several authors have suggested clinically relevant approaches. For example, Bovend'Eerdt et al. (2009) suggested a practical way of registering SMART goals, which entails the following steps: 1) identify target activity, 2) identify support needs, 3) quantify current behavior level, 4) set a deadline. However, the SMART goal approach has also met some critique. Some have argued that the approach might lead therapists to be rigid in their approach with patients, being overly concerned with goals being achievable or specific enough, resulting in goals that lack meaning to the patients, leaving them in a passive role (Barnard et al., 2010; Leach et al., 2010). Hersh and colleagues (2012) suggested the “SMARTER”-framework as an addition to SMART goals and described their framework as a guide to the goal setting process itself to ensure higher patient involvement, while Wade (2009) suggested that the SMART goal approach should be adopted in a more flexible manner, guiding clinical decision making, but not being applied so rigidly that it hampers collaborative goal work with patients. The application of SMART goals thus entails a need to ensure patient involvement, as with other goal-oriented approaches.

To evaluate outcomes in goal-oriented rehabilitation, there is a need for specific measures that evaluate the patient’s improvement on the specific problems targeted in treatment (Turner-Stokes, 2009; Wade, 2009). However, few studies report results on goal attainment (Liu et al., 2004). Although some elements have changed from the original usage suggested by Kiresuk and Sherman (1968), Goal Attainment Scaling (GAS) remains one of the foremost chosen methods for scoring of goal attainment (Grant & Ponsford, 2014). Using GAS entails establishing five levels of goal attainment for each goal. GAS is thus subjective for each individual and specific to each goal. GAS has been shown to be reliable, valid and has satisfactory responsiveness. In addition, its sensitivity to change has been shown to be higher than that of many standardized measures such as questionnaires (Hurn et al., 2006). A systematic review of goal-setting methods for chronic health conditions (Stevens et al., 2013) showed that while GAS was the second most popular goal-setting instrument, the Canadian Occupational Performance Measure (COPM; Law et al., 1990) was the measure most frequently applied. However, while the COPM is restricted to goals in areas of self-care, productivity and leisure, GAS can be used within any domain. In a later scoping review (Prescott et al., 2015) GAS was identified as the most used goal setting tool in ABI rehabilitation.

In summary, goal-oriented interventions might be particularly well suited for patients living with long-term consequences of TBI, as it allows for tailoring rehabilitation strategies to the specific difficulties experienced by the patient and their family members. Efforts should be taken to ensure patient-centered intervention delivery, and structured methods should be applied to ensure a systematic approach to both defining goals and evaluating their attainment.

2.4.2.2 Community-Based Rehabilitation. Typically, rehabilitation interventions have been delivered in a clinical setting at a hospital. However, the true nature of difficulties after TBI might be most evident in the patient's own living and social environments. As argued above, the living environment of the individual with TBI might include important barriers, and environmental support from friends and families should be combined with rehabilitation efforts to ensure higher motivation and treatment adherence (Gagnon et al., 2016). Further, in TBI, the capacity to handle environmental demands might be impaired because of TBI-related deficits. This is in line with Lewin's (1935) person-environment fit concept. This theory suggests that the alignment of abilities of a person and the environmental demands is necessary to achieve optimal outcomes. As barriers at home and in the community might in themselves be a source for intervention, the individual's community may be the optimal context for the delivery of rehabilitation in the chronic phase of TBI. Additionally, the multi-factorial nature of expected persistent deficits typically reported, such as decreased quality of life and reduced participation in everyday life, further suggest that the patient's living environment would be a suitable context for the delivery of rehabilitation interventions. Despite this, most interventions studies are still conducted in a hospital setting (Roe et al., 2019).

A systematic search of community-based interventions for ABI that included individuals with TBI at least 6 months post-injury was conducted as part of a systematic review (Hauger et al., 2021). Table 2 displays an overview of study designs, etiologies, intervention types, outcomes, and if any, what types of goal setting was applied in the studies including TBI populations. Although there seems to be an increased research effort in evaluating community-based rehabilitation, there is at present a very high heterogeneity in study populations, intervention programs, and outcome measures. Hence, drawing overarching conclusions about the effectiveness of community-based programs for individuals in the chronic phase of TBI is impossible. However, the search revealed that while many programs were adopted for TBI specifically, several were also applied for a range of ABI etiologies. As some have argued that rehabilitation efforts should be applied to ameliorate specific difficulties experienced by individuals, and not be based on diagnosis or etiology alone (Wade et al., 2010), it seems prudent that long-term consequences that are prevalent in all ABIs may be targeted using the same interventions. One example is the RCT by Carnevale et al. (2006) of a behavioral intervention that targeted behavioral difficulties for patients with TBI and other ABIs. This study applied psychoeducation and individualized behavioral plans to target behaviors and found a significant between-group difference in frequency of problem behaviors post-trial.

Powell and colleagues (2002) conducted an RCT involving an outreach community program for individuals with severe TBI. The outreach intervention aimed to improve independence, inactivity, participation, and psychosocial well-being. The intervention included individualized treatment tailored to the diversity of impairments and psychosocial problems presented by individuals with TBI and included a written short-term goal ("contractually organized goal setting"). While 54 individuals received the intervention program, 56 participants were allocated to a control group receiving one home visit and an information booklet, in addition to treatment as usual. After the intervention, the intervention group showed an increased overall community integration and increased ADL functioning compared to controls. Further, the authors found that time since injury did not predict the effectiveness of treatment, which is in accordance with previously mentioned guidelines that suggest that rehabilitation intervention could and should be provided to individuals with unmet needs regardless of time since injury.

Winter and colleagues (2016) conducted an RCT including 81 veterans and their family members in the U.S. All veterans had mild-severe TBI and lived with persistent TBI-related difficulties. Participants in the intervention group received eight home visits by occupational therapists. The aim of the sessions was to assess current functioning, establish goals relevant to the individual and use action planning in alleviating TBI-related difficulties. The intervention was shown to be effective in both the alleviation of patient-nominated TBI-related difficulties and in increasing community-integration. In addition, high levels of acceptability were reported for patients and family members. Although the result of this trial seems promising, the authors noted a need to replicate the findings in a civilian population. Further, 69% of the participants in the study had mild TBI, but more promising results were seen among the more severely injured participants (L. Winter, personal communication, 4. September 2017). The intervention designed by Winter and colleagues conformed to the evidence outlined in this section, i.e., their intervention was *individualized* to target the specific needs of each patient given their idiosyncratic context, it was *patient-centered* and *goal-oriented*, and it took into consideration the environmental context of the patient as it was *home-based*. Hence, the program developed by Winter and colleagues was translated and adapted to a Norwegian context by our research group, and a SMART goal approach and GAS was added to the protocol. The study aims to evaluate the effectiveness of this intervention program in a universal access health care systems for civilians with more severe injuries.

Table 2. Studies of community-based rehabilitation interventions ≥6 months post-TBI.

Author (year), country	**Study design, n, etiology**	**Time since injury, inclusion of family member**	**Intervention dose**	**Short description of intervention and control group content**	**Goal setting method**	**Outcomes**	**Results**
Bedard et al. (2014), Canada	RCT, n=105, TBI	IG mean (y): 4.5, no	10 sessions, 12 weeks	Mindfulness CBT vs. waitlist	Not applied.	Depressive symptoms, mindfulness	Significant between-group differences on main depression scale maintained at 3 months, but not on other self-reported depression or mindfulness measures.
Behn et al. (2019), UK	Controlled trial, n=21, mixed ABI	Mean (y): 11.9, no	10 sessions, 6 weeks	Project-based group program vs. waitlist	GAS	Participation in conversation, QoL	Significant between-group differences on some of the conversation measures, no differences on QoL measures. Improvements on GAS as rated by both participant and conversation partner.
Bell et al. (2005), U.S	RCT, n=171, TBI	Unknown, yes	Calls at 2- and 4-weeks post discharge and at 2, 3, 5, 7 and 9 months	Scheduled telephone intervention vs. TAU	Goal setting based on Motivational Interviewing	Functional status, community reintegration QoL and vocational status.	Significant between-group differences on functional status and QoL, but not on community reintegration or vocational status
Bell et al. (2011), U.S.	RCT, n=433, TBI	Unknown, yes	Calls at 3-4 days, 2-, 4-, 8-, and 12- weeks and 5-, 7-, 9-, 12-, 15-, 18-, and 21-months post discharge	Scheduled telephone intervention vs. TAU	Goal setting based on self-management training	Functional status, community participation, QoL and vocational status	No significant between-group differences
Bourgeois et al. (2007), U.S.	Controlled trial, n=46, TBI	IG mean (y): 9.7, yes	Calls 4-5 days per week till goals reached: mean number of sessions 11.8(4.7)	Spaced retrieval memory training vs. didactic strategy training (no spaced retrieval)	Three memory goals identified by participant, caregiver and therapist and logged	Frequency of reported memory problems, goal mastery, memory strategy used, generalization of strategies and QoL	Significant between group differences in goal mastery and strategy use, but not on memory functioning, generalization of strategies or QoL.

Brown et al. (2015), U.S.	RCT, n=257, TBI	Unknown (>1 year post-injury), yes	4 sessions, 4 months	Curriculum-based vs. self-directed advocacy training	"Setting advocacy goals" mentioned, but not elaborated on.	Advocacy behavior	No significant between-group differences
Carnevale et al. (2006), U.S.	RCT, n=41, mixed ABI	Mean (y): 7.6, yes	4 weekly sessions + 8 individualized sessions, 3 months	Natural setting behavior management vs. education only vs. waitlist	No formal goal setting method applied, but target behavioral plan	Frequency of target problem behaviors, caregiver stress, aggression	Significant between-group differences of target behaviors at 3-months follow up, no other significant differences.
das Nair and Lincoln (2012), UK	RCT, n=72, mixed ABI	IG mean (m): 127.7, no	10 group sessions + 2 individual sessions, 12 weeks	Compensation memory training vs. restitution memory training vs. self-help group	Not applied.	Several memory outcomes, mood, adjustment and ADL	Significant group differences in use of internal memory aids only favoring intervention groups.
Fann et al. (2015), U.S.	RCT, n=100, TBI	Mean (y): 3.3, yes	12 sessions, 3 months	Telephone-based CBT vs. in-person CBT vs. TAU	Written therapeutic goals	Several depression outcomes, QoL and functional impairment	No significant between-group differences except for patient reported experience of improvement and satisfaction with care.
Grill et al. (2007), Germany	Controlled trial, n=1534, mixed ABI	Mean length of stay (d): 90.9, yes	Individualized intervention dose based on discharge FIM-score, 2 years	Coordinated advisory program vs. TAU	Not applied.	Functional independence, readmission to acute hospital and survival	Significant between-group improvements in functional independence and survival, but increased readmission rates.
Hanks et al. (2012), U.S.	RCT, n=96, TBI	Unknown, yes	Recommended 18 contacts, mean number of sessions was 5.4 (range:1-66), 1 year	Peer mentoring program vs. TAU	Not applied.	Community Integration, coping style, behavioral control, physical functioning, alcoholism	Significant between-group differences in behavioral control, alcohol use, emotion-focused and avoidance coping, and QoL. No group differences in community reintegration, depression, and anxiety.
Heinemann et al. (2004), U.S.	Controlled trial, n=319, TBI	Median (y): 1.4, no	Median 35.0(31.9) hours of case management, 9 months	Comprehensive case-management vs. TAU	Not applied.	Addiction severity, community reintegration, QoL, vocational status	Significant differences between the two groups were either not found on outcome measures, or the two groups differed significantly already at the time of inclusion, not corrected for in the statistical analysis.

Ownsworth et al. (2008), Australia	RCT, n=35, mixed ABI	Mean (y): 5.3, yes	8 sessions, 2 months	Occupation-based support vs. group-based intervention vs. combined intervention	COPM	Goal attainment, behavioral competency, community reintegration	No between-group differences on COPM. No other comparisons reported, only within group differences reported.
Powell et al. (2002), UK	RCT, n=110, TBI	Median (y): 1.4, no	2-6 hours weekly. Mean duration 28 weeks	Outreach goal-based intervention vs. TAU and single visit	Contractually organized goal setting	ADL, community reintegration, functional independence, depression, anxiety	Significant between-group differences on ADL, overall community integration, self-organization, and psychological well-being subscales. No significant differences found on socializing, productive employment, anxiety, or depression.
Raina et al. (2016), U.S.	RCT, n=41, TBI	IG mean (m): 9.9, no	16 sessions, 2 months	Fatigue-management program vs. health education program	Goal setting based on Problem Solving Therapy	Fatigue measures	No significant between-group differences (feasibility study, between group differences were secondary aim and study was underpowered)..
Rietdijk et al. (2020), Australia	Controlled trial, n=51, TBI	IG mean (m): 12, yes	10 sessions	Social communication skills training vs. TAU	Not applied.	Participation and support in conversation	Improved casual and purposeful conversation on 5 of 8 ratings. Treatment effect not maintained for two measures at 3-month follow-up.
Trexler et al. (2016), U.S.	RCT, n=44, mixed ABI	IG mean (d): 63.2, no	Unknown intensity, 15 months	Resource facilitation vs. TAU	Documentation of return-to-work goals not otherwise specified	Vocational independence and time to return to work, participation, psychological distress	Significant between-group differences in rate and timing of return to productive community-based work and increased rates of competitive employment. No significant differences in psychological distress or home/community participation.
Winter, Moriarty, Robinson, et al. (2016), U.S.	RCT, n=81, TBI	Mean (y): 10.0, yes	8 sessions, 4 months	Goal-based intervention with action planning and strategy training vs. TAU	COPM	Community integration, difficulty handling target problem areas, functional competency	Significant between-group differences on community integration and target problem areas. No significant differences in functional competency.

Abbreviations: ABI=acquired brain injury, ADL=activities of daily living, COPM=Canadian Occupational Performance Measure, d=days, GAS=Goal Attainment Scaling, IG=intervention group, m=months, QoL=quality of life, RCT=randomized controlled trial, TAU=treatment as usual, TBI=traumatic brain injury, U.K.=United Kingdom, U.S.=United States, y=years

2.5 Study Rationale and Thesis Aims

In summary, TBI may have a broad range of consequences for individuals and their families, impairments may be long-lasting, and treatment needs may change over time. Although much effort has been put into expanding the knowledge about TBI consequences, there is a lack of high-quality studies that document effectiveness of interventions, particularly in the chronic phase.

This thesis was conducted within the context of a larger trial: "Traumatic Brain Injury; Needs and Treatment Options in the Chronic Phase. A Randomized Controlled Community-based Intervention", which has the overall aim of evaluating the effectiveness of a goal-oriented, home-based intervention program inspired by Winter and colleagues (2016). The trial was further conducted within a framework for evaluating complex interventions as suggested by The Medical Research Council (Craig et al., 2008). Therefore, the specific aim of this thesis was to provide a transparent overview of the adaption and delivery of a complex (rehabilitation) intervention for individuals in the chronic phase of TBI, highlighting important aspects for consideration in both research and clinical practice. The specific aims of the included papers were:

(1) To adapt and evaluate the intervention feasibility in the context of universal health care and a civilian population in Norway (paper I)
(2) To adapt the protocol, procedures, and content of the RCT accordingly (paper II).
(3) To evaluate an open-ended approach of individually reported problem areas in the chronic phase of TBI, as compared to standardized assessment (paper III)
(4) To evaluate SMART goals and goal attainment in the intervention group (paper IV).

3 Materials and methods

3.1 Study Design and Setting

The setting of this study was Oslo University Hospital (OUH). OUH is the major trauma referral center in South-East Norway serving TBI victims in need of neurosurgical assessment. Table 3 displays an overview of designs, participant characteristics, and outcome measures in Paper I, III and IV. The feasibility trial (paper I) was a one-group pre-post study evaluating the feasibility of the intervention arm of this RCT. The protocol article (paper II) describes the two-group RCT with assessments at baseline (T1), 4-5 months (post-intervention; T2) and 12-months post inclusion (follow-up; T3). Inclusion criteria were (i) a TBI diagnosis in the acute phase and radiologically verified intracranial injury, (ii) aged 18-72 years at time of inclusion and at least 16 years of age at time of injury (iii) living at home, and (iv) having ongoing TBI-related difficulties (included cognitive, emotional, or physical problems, reduced mental and/or physical health and/or difficulties with participating in activities with family, friends or in the community). Exclusion criteria were (i) severe ongoing psychiatric disorders or neurological disorders that may confound outcome, (ii) inability to participate in goal setting process, (iii) insufficient understanding of Norwegian language, (iv) active substance abuse or violent tendencies that would put therapists at risk during home visits, and (v) inability to give informed consent. If participants had a family member willing to participate, the family member was included as a co-participant. The eligibility criteria were the same in the feasibility trial (paper I) except inclusion criterion (ii), which was “aged 16-80 years at time of injury”. The effectiveness of the RCT as such will be evaluated after all participants have completed all outcome assessments (estimated December 2021). Paper III represents a cross-sectional evaluation of the participants included the RCT and paper IV a pre-post evaluation of the participants in the intervention group.

Table 3. Design, participant characteristics and outcome measures in paper I, III and IV.

	Paper I	**Paper III**	**Paper IV**
Design	feasibility trial	cross-sectional	one group pre/post
Time points included	T1-T3	T1	T1, sessions 1-8
Participants	n=6	n=120	n=59
Age in years, mean (SD)	52.8 (14.6)	45.2 (14.4)	43.1 (13.6)
Gender (men), n (%)	5 (83%)	85 (71%)	43 (73%)
Education years, median (IQR)	13.5 (12-15)	12 (12-15)	12 (12-15)
Employed part-time or full-time, n (%)	4 (67%)	59 (49%)	29 (49%)
Time since injury in years, median (IQR)	8 (7.5-8.5)	4 (3-6)	4 (3-6.25)
Acute Glasgow Coma Scale score, median (IQR)	7 (5.25-8)	9 (5-14)	8 (5-14)
Mild complicated, n (%)	0 (0%)	41 (34%)	16 (27%)
Moderate, n (%)	0 (0%)	18 (15%)	9 (15%)
Severe, n (%)	6 (100%)	54 (45%)	30 (51%)
NA, n (%)	0 (0%)	7 (6%)	4 (6%)
Family members included, n (%)	3 (50%)	78 (65%)	39 (66%)
Questionnaires			
Quality Of Life In Brain Injury Overall Scale (QOLIBRI-OS)		X	
Participation And Recombined Tools-Objective (PART-O)	X	X	
Rivermead Post-Concussion Questionnaire (RPQ)	X	X	X
Patient Health Questionnaire 9-item (PHQ-9) scale	X	X	X
Generalized Anxiety Disorder 7 item (GAD-7) scale		X	X
Patient Competency Rating Scale (PCRS)	X	X	
EuroQol-5D (EQ-5D)		X	
Behavior Rating Inventory of Executive Functioning-Adult (BRIEF-A)		X	X
The Medical Outcome Survey Short Form-36 (SF-36)	X		
Semi-structured Interviews			
Target Outcomes	X	X	
Glasgow Coma Scale Extended (GOSE)	X		
Neuropsychological tests			
Weschler Adult Intelligence Scale-IV (WAIS-IV): Block Design, Vocabulary, Coding, Symbol Search	X		
WAIS-IV: Similarities, Matrices	X	X	X
WAIS-IV: Digit span		X	X
California Verbal Learning Test-II (CVLT-II)	X	X	X
Delis-Kaplan Executive Functions System (D-KEFS): Trail Making Tests 1-5, Color Word Interference Tests 1-4	X	X	X
Intervention Group Outcomes			
Goal Attainment Scaling (GAS)	X		X
Acceptability Scale	X		

3.2. Participants and Recruitment

3.2.1 Participants and Recruitment, Feasibility Study (Paper I)

For the feasibility study, 19 eligible participants were identified from a previous study (Andelic, Anke, et al., 2012) and invited by letter. Of these, eight eligible participants were invited to a baseline assessment at OUH, and six of these and three family members fulfilled criteria and provided informed consents. Participant characteristics are presented in Table 3.

3.2.2 Participants and Recruitment, RCT (Paper III-IV)

Potentially eligible participants to the RCT were identified by the principal investigator by screening of previous study registers and hospital records for the past 10 years. Potentially eligible individuals (n=555) were invited by letter to participate in the study and called to ask about their interest in participating. One researcher had a designated responsibility to screen participants by phone. Participants who appeared eligible after the initial telephone screening were invited to OUH for a baseline assessment (T1) where eligibility was confirmed and written informed consent established. Figure 1 contains a flow chart for participants included in the RCT. A total of 120 participants and 78 family members were randomized. Participant characteristics are displayed in Table 3 for both the full study population (paper III), and the intervention group (paper IV).

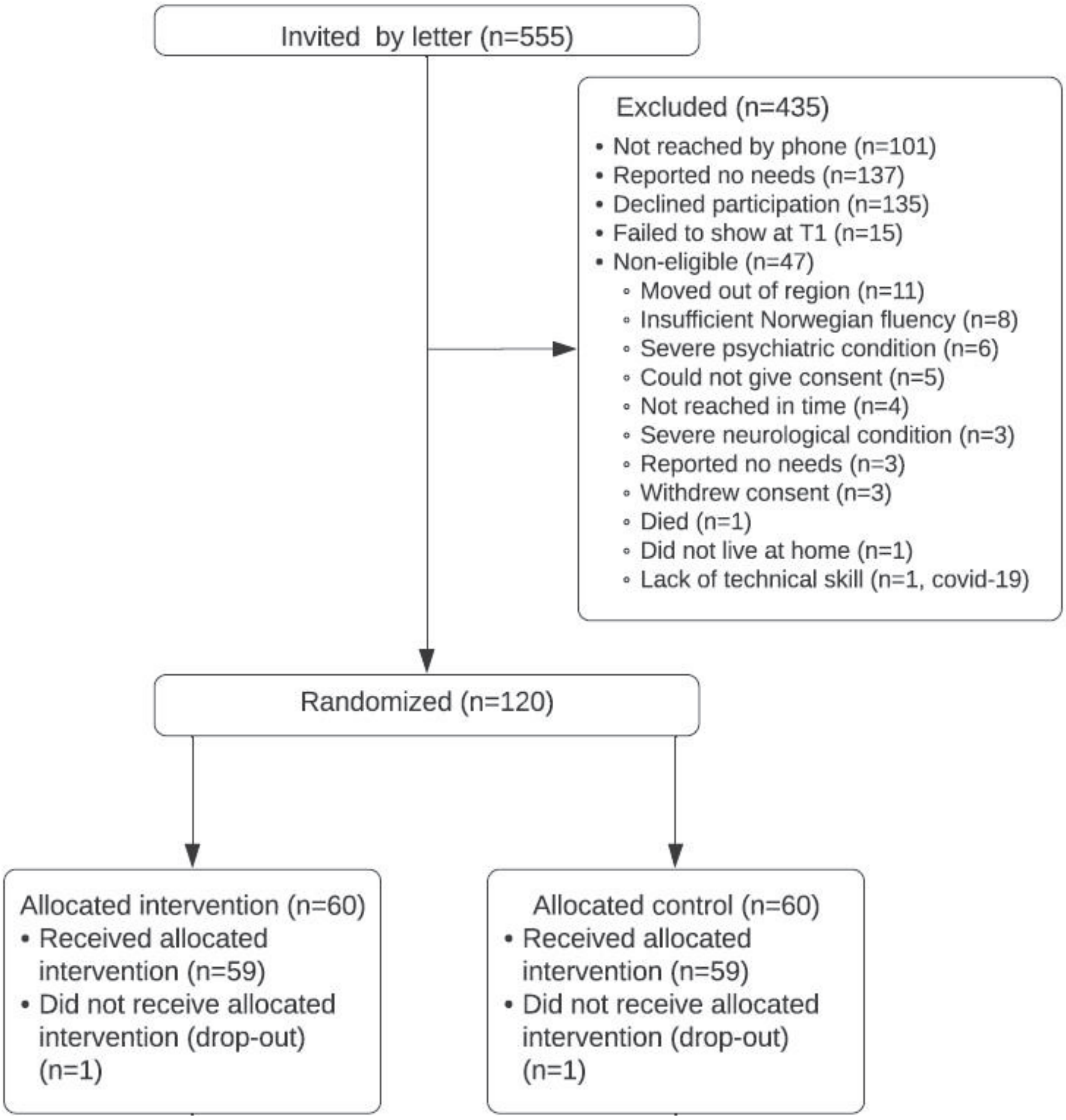

Figure 1. Flowchart[1].

3.3 Randomization and Blinding

Participants were randomized 1:1 to either intervention or control group. An independent statistician created a web-based randomization sequence with variable block sizes. This sequence was stored in a database only accessible to the principal investigator, and the sequence could only be accessed sequentially. Study therapists conducting baseline assessment assigned a randomization number to eligible participants. This number was different than their participant ID to ensure concealment. Randomization number was sent to

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[1] The flowchart only includes the RCT timepoints that are part of this thesis, i.e., not follow-up assessments (T2 and T3). Results from these timepoints will be published elsewhere.

the principal investigator who reported the allocation back to the therapist. Blinding of participants and therapists was not possible, but outcome assessors were blinded.

3.4 Data collection and Procedures

3.4.1 Baseline Assessment (T1)

Baseline assessment was conducted by one of the four therapists delivering the intervention took between 3-5 hours. The following sociodemographic variables were recorded at baseline: age, gender, marital status, number of children, educational level, medical comorbidities, and current employment including disability details. Information regarding injury characteristics, clinical severity (GCS), and neuroimaging results were collected from medical journals. Some measures were administered at T1 only to provide a thorough description of the sample. This included a neuropsychological screening battery and the Behavior Rating Inventory of Executive Function Adult Version Self-Report (BRIEF-A; Roth et al., 2005). The NPCS Clinician Form "needs" (Turner-Stokes & Siegert, 2012) was administered to register health care service needs at T1 but is not included in paper I-IV.

3.4.1.1 Neuropsychological Screening Battery. Neuropsychological tests were administered at T1 only to provide patient characteristics and to guide intervention delivery. The battery included tests of intellectual ability (Block Design, Matrices, Vocabulary and Similarities from the Weschler Adult Intelligence Scale-fourth edition, WAIS-IV; Wechsler, 2008), processing speed (Coding and Symbol Search from WAIS-IV, Trail Making Tests 1-3 and 5 and Color Word Interference Tests 1-2 from the Delis Kaplan Executive Function System, D-KEFS; Delis et al., 2001), verbal attention and working memory (Digit Span from WAIS-IV), verbal learning and memory (California Verbal Learning Test-second edition, CVLT-II; Delis et al., 2000) and executive functioning (Trail Making Test 4 and Color Word Interference Tests 3-4 from D-KEFS). The tests Block Design, Vocabulary, Coding and Symbol Search was included in paper I only, while Digit Span was included in paper II-IV only.

3.4.2 Outcome Measures

Some outcome measures related to health care provision and family members were not included in paper I-IV, but was collected as part of the RCT. The Needs and Provisions Complexity Scale (NPCS; Turner-Stokes & Siegert, 2012) Clinician Form "gets" was administered to register health care services received at T1-T3. For participants with family members included, an adapted version of the Quality of Relationship scale used by Winter and colleagues (2016) was administered. In addition, family members filled out two questionnaires regarding the participant's functioning; the BRIEF-A Informant Form and the Patient Competency Rating Scale (PCRS) Relative Form (Prigatano, 1986), as well as three questionnaires pertaining to their own functioning; the visual analogue scale from EuroQol-5 Dimensions (EQ-5D; Brooks, 1996), Patient Health Questionnaire-9 item (PHQ-9; Kroenke et al., 2001) and the Caregiver Burden Scale (Elmstahl et al., 1996). This section details measures applied in paper I-IV.

3.4.2.1 Questionnaires. All questionnaires administered in both the feasibility trial and the RCT are listed in Table 3. The RCT has two primary outcome measures; participation as measured by the Participation And Recombined Tools-Objective (PART-O; Whiteneck et al., 2011) and TBI-specific quality of life as measured by the Quality Of Life after Brain Injury Overall Scale (QOLIBRI-OS; von Steinbüchel et al., 2012). Outcome measures were administered at all time points (T1, T2 and T3) in a standardized order of administration.

PART-O. The PART-O is a 17-item questionnaire developed based on three common measures of participation in TBI and relates to chapters 6-9 in the activities and participation component in the ICF (Whiteneck et al., 2011). The PART-O aims to determine an objective measurement of participation by asking respondents to report the frequency or amount of time spent in differing activities. As such, the PART-O does not pertain to the individual's satisfaction with their participation. Three subdomains have been identified: productivity, social relationships, and "out and about" (participation in a range of activities of community life). In addition to a summary total score, a balanced t-score algorithm has been developed to enable the evaluation of whether participation in different domains is equal and balanced (Bogner et al., 2011). The PART-O has shown satisfactory construct and concurrent validity and excellent inter-rater reliability (Bogner et al., 2017; Whiteneck et al., 2011). The PART-O was used in a Norwegian translation.

QOLIBRI-OS. The QOLIBRI-OS is a 6-item questionnaire indexing brain injury specific HRQOL. The questionnaire includes questions about physical, cognitive, emotional, personal, and social functioning, as well as everyday functioning, current situation, and prospects. Respondents indicate their level of satisfaction in these areas on a Likert-scale from 1 ("Not at all") to 5 ("very") (von Steinbüchel et al., 2012). A total percentage scale from 0-100 (worst-best) is calculated. A total score >60 is considered normal, while a score of 52-60 is considered borderline and a cut-off of <52 is used as an indicator of low or impaired HRQOL (Wilson, Marsden-Loftus, et al., 2017). The QOLIBRI-OS has displayed good reliability (Cronbach's alpha=0.86, test-retest reliability=0.81) and good construct validity in a sample of TBI patients. It also correlates highly (r=0.87) with the total score of the full version of the scale (QOLIBRI; von Steinbuchel et al., 2010) and displays moderate to strong Spearman correlations with other measures often used in the TBI population. A validation study concluded that the QOLIBRI-OS can be used as a brief index for HRQOL in TBI (von Steinbüchel et al., 2012). Other studies have shown that the QOLIBRI-OS has good criterion validity in a sample of subarachnoid hemorrhage (Wong et al., 2014). The QOLIBRI-OS Norwegian version was administered which has been validated in a stroke population (Heiberg et al., 2018).

EQ-5D-5L. The EQ-5D (Brooks, 1996) is a generic health status measure. Respondents indicate their level of problem on a scale from 1 ("no problem") to 5 ("inability"/"extreme problem") on five dimensions; mobility, self-care, daily activities, pain, and anxiety/depression. In addition, they are asked to indicate their self-perceived health status on a visual analogue scale from 0 (worst health imaginable) to 100 (best health imaginable). The EQ-5D is available in a large number of languages and is often applied in TBI samples (Nichol et al., 2011). The EQ-5D has shown sufficient validity in a broad range of patient groups and in different countries (Janssen et al., 2013), and acceptable reliability (Long et al., 2021), also in its Norwegian version (Stavem et al., 2001). The EQ-5D enables health economic calculations, like the calculation of quality-adjusted life years (QALYs), and is one of the most used tools for calculating QALYs in Norway (Wisloff et al., 2014). An ongoing study aims to create a Norwegian value set and scoring algorithm (Hansen et al., 2020). The 5-level version of EQ-5D was applied in the current study.

SF-36 (Paper I Only). In the feasibility trial, the Medical Outcome Survey Short Form-36 (SF-36; Ware & Sherbourne, 1992) was administered as a measure of HRQOL. The instrument measures HRQOL in eight distinct domains and has shown moderate internal consistency in all domains (Cronbach's alpha= 0.68-0.92; Polinder et al., 2015). The questionnaire has been shown to be a reliable and valid measure of HRQOL in the TBI population (Findler et al., 2001). A license was obtained from the QualityMetric, Optum, Eden Prairie, MN, U.S. (license number QM051514).

RPQ. The Rivermead Post-concussion Questionnaire (RPQ; King et al., 1995) is a 16-item questionnaire assessing the levels of post-concussion symptoms within the past week. Respondents indicate the severity of difficulties on a Likert scale from 0 (“Not experienced at all”) to 4 (“severe problem”). Scores of 1 (“same as before the injury”) are removed from calculations of the total score of 0-64. The validity of its total score has been discussed (Eyres et al., 2005; Potter et al., 2006). The 16 items can be divided into three separate domains; physical, cognitive and emotional symptoms (Smith-Seemiller et al., 2003). Scorings of minimal (0-12), mild (13-24), moderate (25-32) and severe (>32) symptom levels have been suggested (Potter et al., 2006). The RPQ has shown good inter-rater reliability and test-retest reliability with Spearman correlations of 0.87 and 0.90, respectively. The RPQ was used in its validated Norwegian version (Ingebrigtsen et al., 1998).

PHQ-9. The PHQ-9 (Kroenke et al., 2001) was administered to assess self-reported depressive symptoms. Level of nine depressive symptoms within the past two weeks are scored on a Likert scale from 0 (“not at all”) to 3 (“nearly every day”). Total scores range from 0-27, and established levels are set at 5 (mild), 10 (moderate), 15 (moderate-severe) and 20 (severe depressive symptoms). The PHQ-9 has demonstrated excellent internal reliability (Cronbach’s alpha = 0.86-0.89) and excellent test-retest reliability and good construct and criterion validity (Kroenke et al., 2001). The PHQ-9 has been demonstrated as a valid tool for detecting depression in TBI (Fann et al., 2005). The PHQ-9 was used in its validated Norwegian version (Wisting et al., 2021).

GAD-7. The General Anxiety Disorder – 7 item (GAD-7) scale (Spitzer et al., 2006) was used as a measure of self-reported anxiety-related symptoms. Respondents rate the frequency of symptoms within the past two weeks on a Likert-scale from 0 (“not at all”) to 3 (“nearly every day”). A score of 5 indicates mild symptoms, 10 indicates moderate symptoms and 15 indicates severe symptoms. The scale has demonstrated excellent internal consistency (Cronbach’s alpha = 0.92) and good test-retest reliability (intraclass correlation = 0.83), as well as satisfactory criterion, construct, factorial, and procedural validity (Spitzer et al., 2006). The GAD-7 is in common use in TBI population (Boulton et al., 2019) and was used in a validated Norwegian version (Johnson et al., 2019).

PCRS. The PCRS (Prigatano, 1986) is a 30-item scale measuring functional capacity in everyday life. The items pertain to four main domains: performance in ADL, as well as cognitive, emotional, and interpersonal functioning (Leathem et al., 1998). Respondents indicate their performance on a Likert Scale from 1 ("cannot do") to 5 ("can do with ease"). The PCRS was originally developed to measure awareness difficulties in patients with cerebral dysfunction by comparing scores from the participant and relative or clinician versions. In the current RCT, the questionnaire is used both as a measure of functional capacity and a measure of awareness difficulties for participants who have a family member co-participating. The PCRS has been shown to have good reliability, validity, and responsiveness (Prigatano et al., 1990; Sherer et al., 2003), as well as moderate reliability between patient and relative forms and high internal consistency (Hellebrekers et al., 2017). The Norwegian version of the PCRS has been validated for use in the chronic phase of TBI in Norway (Sveen et al., 2015).

BRIEF-A. The BRIEF-A (Roth et al., 2005) is a 75-item self-report measure concerning executive functioning in everyday life. Items are scored on a 3-point scale ("never", "sometimes" or "often"). The BRIEF-A yields a composite index score, Global Executive Composite (GEC), and two sub-index scores; Behavioral Regulation Index (BRI) and Metacognition Index (MI), based on nine clinical subscales. The questionnaire has three validity scales. The BRIEF-A is widely used and has been shown to have satisfactory validity and reliability (Roth et al., 2005). The BRIEF-A has demonstrated higher ecological validity than neuropsychological tests in some studies (Hagen et al., 2016; Isquith et al., 2013), but has also met critique for being more highly correlated with measures of overall symptom level and emotional distress than performance-based measures of cognitive functioning (Hagen et al., 2019; Løvstad et al., 2016). The BRIEF-A was administered in its official Norwegian version (Nicholas & Solbakk, 2006).

3.4.2.2 Semi-Structured Interviews. ***GOSE.*** The Glasgow Outcome Scale-Extended (GOSE; Wilson et al., 1998) is a semi-structured interview that assesses global functioning after TBI. The scale is administered by health care professionals interviewing patients or their proxies. Questions pertain to their level of ability in a range of areas; consciousness, independence at home, ability to travel independently, employment, social and leisure activities, relationship skills and post-concussive symptoms interfering in everyday life. Patient outcome is rated by the interviewer by categorizing the patient as in one of the following categories (GOSE score): upper good recovery (8), lower good recovery (7), upper moderate disability (6), lower moderate disability (5), upper severe disability (4), lower severe disability (3), vegetative state (2), or dead (1). The GOSE has been shown to have high validity and reliability (Levin et al., 2001; Narayan et al., 2002; van Baalen et al., 2006).

The GOSE was used in its official Norwegian translation (Roe et al., 2008). In both the feasibility trial and the RCT, the GOSE was administered to patients, with available proxies (family members) being asked to elaborate in separate interviews when clinicians suspected impaired awareness or felt the need to gain additional information. Overall functioning was used to establish the GOSE score, while mechanisms (TBI-related only, other injury, or mixed) was denoted.

Target Outcomes. Target Outcomes were based on the approach used by Winter, Moriarty, Robinson, et al. (2016). Participants were interviewed at baseline by asking: "What is the main problem caused by your TBI that you have experienced in the past month?". Participants were then asked about their second and third most troubling TBI problem in the same manner. Their responses were written down by interviewers. They were asked to rate their difficulty in handling the problems on a Likert-scale from 0 ("not difficult at all") to 4 ("very difficult"). Separate interviews were held with family members, who were asked to nominate what they saw as the patients´ three main problems. Family members were also asked to score the level of difficulty for both the problem areas suggested by themselves and the ones suggested by the participant.

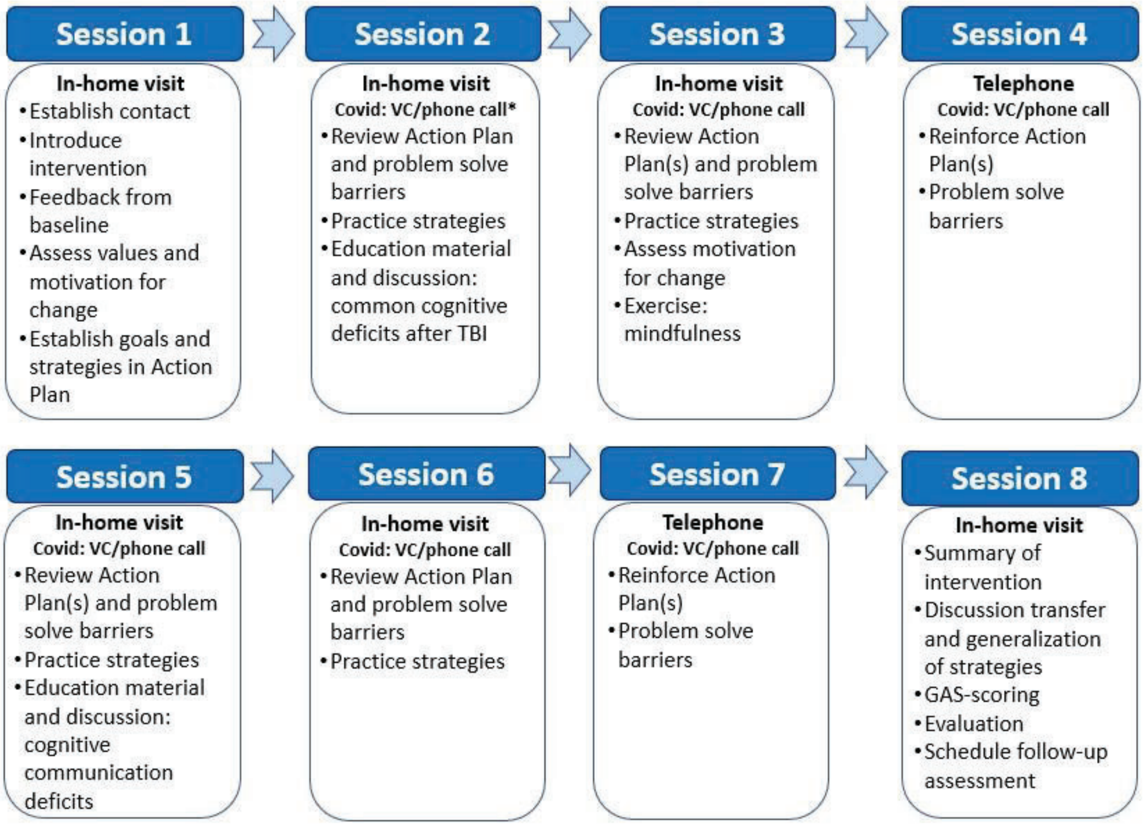
3.4.2.3 Outcome Measures Specific to the Intervention Group. Measures of goal attainment and satisfaction with the intervention was only collected in the intervention group. GAS (Kiresuk & Sherman, 1968) was applied as a measure of goal attainment. Five levels of goal attainment were agreed on between therapist and participant for each specific goal set during the intervention. Baseline GAS scores could be either -2 or -1 and was established together with SMART goal in sessions 1-5. At the final session (session 8), the current level of goal attainment was scored in collaboration with participants and family members and could be either -2 or -1 (no change or deterioration), 0 (expected level) or +1 or +2 (above expected level). The use of GAS was guided by current recommendations (Malec, 1999; Turner-Stokes, 2009; Wade, 2009)

The acceptability scale was adapted from the study by Winter, Moriarty, Robinson, et al. (2016), translated by our research group. As the original version only asked therapists to evaluate acceptability, and we wished to elicit the patients´ experience as well, we developed a participant reported version. These adaptations were discussed with Laraine Winter. Acceptability was thus rated by participants and family members using a 10-item version of the scale with responses scored on a Likert scale from 0 ("not at all") to 4 ("extremely"). The therapist also filled out two 17-item therapist version of the scale evaluating perceived acceptability for the participant and family member separately.

3.5 Interventions

3.5.1 Intervention Group

The intervention was inspired by the Veteran's In-home Program delivered in the study by Winter, Moriarty, Robinson, et al. (2016). Their intervention manual was translated and adapted to a Norwegian context by the research group and the manual was evaluated in the feasibility trial (paper I). The program had three main phases, which included i) the identification of target problems with activities in everyday life, ii) establishment of specific goals aimed at ameliorating the problems, and iii) development of an action plan including strategies to reach the goal. The SMART-goal approach was applied to establish goals, and GAS was used during this process as described above. Participants were free to choose what problem areas they would prefer to work on and could set a maximum of five goals during sessions 1-5. During goal establishment, therapists asked the participant (and family member) about what kind of change would be meaningful to them, identified current barriers and probed for current adaptive strategies. The action plan included strategies based on both current adaptive strategies, suggestions from participants and family members, and therapist suggestions. Intervention strategies suggested by therapists were ideally built on evidence-based strategies for the relevant problem, given availability of evidence-based guidelines for the problem in question. Cognitive strategies were based on recommendations by the Cognitive Rehabilitation Task Force (Cicerone et al., 2019; Cicerone et al., 2011), the American Congress of Rehabilitation Medicine (Haskins et al., 2012), and Guidelines for Cognitive Rehabilitation following TBI, guidelines that are the result of international expert panel on cognitive rehabilitation (Ponsford, Bayley, et al., 2014; Tate et al., 2014; Togher et al., 2014). Depressive and anxiety-related symptoms were mainly managed using techniques from cognitive behavioral therapy (Beck & Beck, 1995) and behavioral activation (Lejuez et al., 2011), while issues relating to identity and self-concept was dealt with using recommended therapeutic strategies from the field of brain injury rehabilitation (Gracey et al., 2008; Myles, 2004; Ruff, 2013; Wilson et al., 2009; Yeates et al., 2008). Muscle relaxation and mindfulness techniques were applied to improve stress management. The therapist actively addressed the action plans during sessions to probe for goal progression, barriers and need for revision of or new strategies. In addition, all participants received psychoeducation about common cognitive deficits post-TBI, mindfulness techniques and social communication difficulties. Although the intervention was manualized, it allowed for a high level of flexibility and individualization necessary to tailor the intervention to the specific goals for each participant. If the participant had a family member co-participating, they were invited to participate in all sessions as feasible and to actively contribute their perspectives and suggestions. When relevant, collaboration with other family members, local health personnel, employers, or labor and welfare coordinators was initiated. The intervention was delivered during a 4-month period and consisted of eight sessions. Originally, six sessions were conducted at home, while two sessions were delivered by phone. Participants could choose to receive the intervention at the outpatient clinic at OUH if they preferred so. Home visits typically lasted two hours, while phone sessions typically were shorter (about one hour). The Covid-19 pandemic necessitated more flexibility in the mode of delivery for sessions delivered from mid-March 2020. To adhere to social distancing recommendations, a minimum of two home visits were conducted, and the other sessions were delivered by videoconferencing or by phone. Figure 2 displays an overview of the intervention sessions including these adjustments. Thorough logging was conducted to document session delivery, including session length, themes covered, notes about goal progression, and contact with other health personnel or caregivers. These data are not included in paper I-IV but will be published as part of a planned process evaluation. Four therapists were responsible for intervention delivery, and each participant was assigned one therapist that conducted all sessions. The two junior therapists (medical doctor and clinical psychologist) and two senior therapists (neuropsychologist and physical therapist) conducted meetings as necessary (weekly-monthly) to discuss action plans, clinical challenges and to ensure reliability of delivery. In addition, 10% of sessions were supervised by a senior researcher evaluating treatment fidelity.



**Delivery format was adjusted due to the Covid-19 pandemic, i.e., videoconference (VC) and phone calls replaced some home visits to reduce risk of infection.*

Figure 2. Intervention sessions.

3.5.2 Control Group

The control group received treatment as usual. This was chosen to evaluate whether the intervention was better or equal to current clinical practice. In Norway, the municipalities are responsible for long-term follow-up after TBI, and the amount of care received typically varies depending on needs and geographical location. This entails that some might receive no follow-up for their TBI, while others may receive follow-up from municipal rehabilitation services.

3.6 Statistical Analysis and Considerations

3.6.1 Sample Size

Sample size was calculated using G*Power (Faul et al., 2007) based on two-sided t-tests. As there were two primary outcome measures, a p-value of .025 was used and an alpha of .80. A deductive approach was used for calculations as there was a lack of previous research providing information about change scores for the primary outcomes. Meaningful group differences of 12% for the QOLIBRI-OS with pooled standard deviation (SD) of 20%

was assumed, and difference of 1.8 on the PART-O (pooled SD of 3). With an assumed attrition rate of 10% at T3, 60 participants should be included in each intervention arm.

3.6.2 Data Analysis and Statistics

All data analyses were conducted using SPSS version 25 (IBM, 2017), 26 (IBM, 2018), and 27 (IBM, 2019). Descriptive data was provided for patient characteristics, feasibility measures and outcome measures in paper I. Paper II presented the planned statistical analyses for the evaluation of the effectiveness of the intervention. Paper III presented descriptive data for patient characteristics and Target Outcomes. In paper IV, goal attainment was reported descriptively, while comparisons of goal attainment by goal domain was investigated using a Kruskal-Willis H-test (non-normality distribution). Indicators of goal attainment was investigated using univariate and multiple linear regression analyses.

3.7 Ethical Considerations

The study was presented to the Norwegian Regional Committee for Medical and Health Ethics (number 2017/1081) and was approved by the Data Protection Office at OUH (2017/10390). The study was conducted according to the ethical guidelines of the Helsinki declaration (World Medical Association, 2013). All individuals in contact with participants were health care professionals complying to Norwegian laws of confidentiality for health care personnel. All participants were assigned an unidentifiable study ID number and de-identified data was electronically stored at secure servers at OUH in accordance with the approval from the Data Protection Office.

One main concern in conducting an RCT-study is the care provided for the control group, as an inclusion criterion was the experience of ongoing difficulties. The management of health care needs in both groups was discussed before trial start-up to ensure satisfactory ethical standards. Firstly, no concurrent treatment was withdrawn for any participants, but were instead registered as part of the protocol. Secondly, medical, or psychiatric issues (e.g., severe depressive symptoms or suicidal ideation, newly emerging medical conditions etc.) uncovered at baseline assessment where postponing treatment would be unethical were handled immediately following trial procedures (i.e., referral to relevant specialist, contacting general practitioner). In addition, all participants were assessed thoroughly at baseline, and a written report concerning current symptomatology and cognitive status was sent to each participants' general practitioner. Any ethical dilemmas regarding the care for the control group was discussed with the project investigators and senior researchers throughout the study period. After T3 data had been collected, all control group participants were offered an extra follow-up for evaluation of further rehabilitation needs or more basic guidance regarding current TBI related problems after trial completion and referred accordingly if deemed necessary. In cases where problems were specific and referral options lacking, some control participants received short-term follow-up by intervention therapists. The user organization in Norway, the Norwegian Association of Persons with Injuries, LTN ("Personskadeforbundet LTN") was closely involved in the development of the study protocol and during trial preparation. User representatives will also be invited to participate in the dissemination of trial results.

4 Results

4.1 Paper I. Needs and Treatment Options in Chronic Traumatic Brain Injury: A Feasibility Trial of a Community-Based Intervention

The aim of this paper was to evaluate the feasibility of trial procedures and intervention delivery in the Norwegian context, in accordance with recommendations of the Medical Research Council for the evaluation of complex interventions (Craig et al., 2008). The following objectives were evaluated: (i) screening and recruitment procedures, (ii) baseline and follow-up assessments, (iii) intervention delivery, (iv) acceptability, and (v) order of outcome measures. Six participants (5 males) with severe TBI aged 35-78 years received the intervention.

(i) Screening and recruitment procedures were found satisfactory. The inclusion criteria of having a family member co-participating adopted by Winter and colleagues was abandoned during trial initiation, as the screening process revealed that several single individuals reporting a clear need for rehabilitation did not have family members that could participate in the study. The feasibility study showed that intervention delivery was feasible without family members, based on therapist feedback and comparable outcomes among participants with and without included family members. However, family members were recognized as important collaborators when available. Inclusion and exclusion criteria were also updated to specify that participants should be at least 16 years old at the time of injury and aged 18-72 at the time of inclusion. This was specified as to exclude pediatric TBIs, as persons who have suffered a pediatric TBI might differ in symptomatology from those who suffer a TBI as adults. We also wished to diminish the risk of including participants with neurodegenerative disorders more typically found in the elderly population, even more so in the elderly TBI population, which is not easily diagnosed in early phases. An upper age limit was thus set.

(ii) The baseline assessment was found to be too time consuming and burdening, and hence in need of reduction. Thus, four neuropsychological tests were abandoned, and the SF-36 was replaced by the QOLIBRI-OS and EQ-5D in the final RCT protocol.

(iii) Intervention delivery was found to be feasible. Therapist burden, i.e., time spent traveling and delivering the intervention, was found to be high, and planning was necessary to ensure therapist logistics during the future definitive RCT.

(iv) Acceptability reported by participants, family members and therapists were considered high, and comparable to the acceptability reported by Winter and colleagues.

(v) The order of outcome measures was amended. Target Outcomes were replaced as a primary outcome measure. The feasibility study revealed that target outcomes nominated at baseline often was inconsistent with what the participant wished to work on during the intervention. In addition, the reliability of severity ratings could be questioned in cases of impaired awareness and no comparative rating from family members. However, Target Outcomes were thought to provide important information regarding idiosyncratic problem profiles and was retained as a secondary outcome measure. Instead, the QOLIBRI-OS and the PART-O were chosen as primary outcome measures for the future definitive RCT, and the GAD-7 added to include a measurement of anxiety-related symptoms.

In summary, the feasibility trial showed that the intervention was feasible and acceptable in the Norwegian context. No adverse effects were observed. The feasibility trial had important implications for the planned RCT, and amendments regarding eligibility criteria, baseline assessment and outcome measures were adapted before trial commencement.

4.2 Paper II. Traumatic Brain Injury—Needs and Treatment Options in the Chronic Phase: Study Protocol For a Randomized Controlled Community-Based Intervention

The full protocol for the final RCT was published in line with Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (Chan et al., 2013). The protocol paper details trial design and procedures, intervention content and outcome measures. See earlier description in section 2.1 for a summary of the final RCT design.

4.3 Paper III. Patient-Reported Problem Areas in Chronic Traumatic Brain Injury

The aim of this paper was to assess the problem areas nominated by patients with TBI and their family members in the chronic phase. Further, we wanted to compare the self-prioritized problems with difficulties captured by standardized measures to evaluate whether any additional information was gained by using the Target Outcome approach.

Target Outcomes were reported by 120 participants and 78 family members. The Target Outcomes were related to cognitive, physical, emotional, and social difficulties. Target Outcomes were linked to 12 chapters and 112 distinct categories in the ICF, while standardized measures only covered 10 chapters and 28 categories. Some aspects of post-TBI adjustment were found to be insufficiently covered by the ICF classification, such as identity issues, lack of meaningful activities and feeling lonely.

In summary, we found that the Target Outcomes approach was a useful addition to standardized assessment of persistent TBI symptoms. Although standardized outcomes ensured that the full spectrum of problems experienced by the patients and their family members were assessed, it did not always sufficiently cover issues that were relevant to participants´ everyday lives. Target Outcomes was found to be useful in assessing what problems patients and family members wanted to work on in rehabilitation in the chronic phase of TBI.

4.4 Paper IV. Goal Attainment in an Individually Tailored and Community-Based Intervention in the Chronic Phase After Traumatic Brain Injury

The aim of this paper was to evaluate goal attainment in a home-based rehabilitation program using SMART goals and GAS. Further, the nominated goals were categorized and goal attainment per domain compared. Indicators of goal attainment were investigated.

In total, 151 goals were set among 59 completers in the intervention group of the RCT. Goal attainment was high, as 93.3% of goals showed improvement in goal attainment from goal establishment to the last intervention session. Goals were divided into four domains: cognitive, physical/somatic, and emotional difficulties, as well as social functioning and participation. No significant differences were found in goal attainment between goals in different domains, suggesting that the intervention was successful in targeting a broad range of difficulties with equal levels of attainment. Further, an exploratory analysis showed that years of education, cognitive impairment, self-reported executive dysfunction, and outcome expectations were indicators of goal attainment.

5 Discussion

This thesis confirms that patients with TBI may have idiosyncratic difficulties that last for a long time after injury. Overall, the papers included in this thesis exemplify the types of deficits that may have a lasting impact post-TBI, and further how these deficits may be ameliorated by addressing them using goal setting and evidence-based rehabilitation strategies.

5.1 Discussion of Main Findings

5.1.1 Feasibility of the Intervention (Paper I)

According to guidelines for evaluating complex interventions (Craig et al., 2008), the feasibility of a complex intervention should be evaluated before initiating a full-scale RCT. The term "complex intervention" encompasses many different types of interventions, including interventions that have many interacting components, high demands on recipients or deliverers, often with multiple target groups and numerous outcome measures. Rehabilitation interventions clearly fit within this framework. Hence, paper I aimed to describe the first step in conducting the RCT; assessing its feasibility. Although the intervention program was based on a previous RCT, there were several differences in delivery of these to interventions to suggest that feasibility should be assessed before trial initiation. Firstly, the RCT by Winter and colleagues was conducted within the Veterans Affair services in the U.S. Military populations will vary from civilian samples, e.g., as injury mechanisms differ, and differing rates of PTSD are expected (Lamberty et al., 2013; Loignon et al., 2020). Secondly, the proportion of participants with mild TBI was 69% in the Winter study, and it was expected to be lower in the current sample as we were recruiting from OUH, admitting patients in need of neurosurgical assessment. Thirdly, the team of therapists in the Winter study included occupational therapists only, while in the current trial the team consisted of a medical doctor, a physiotherapist, a psychologist, and a neuropsychologist. Finally, the U.S. and Norway differ regarding health care organization and access to care, and the context of delivery may also impact trials (Wade et al., 2010). In addition to expected differences in the sampling and context, the manual from Winter and colleagues was translated and adapted to a Norwegian context. The application of SMART goals and GAS was added to the protocol to ensure standardization of goal setting.

Conducting a feasibility study prior to the future definitive RCT also had other important benefits. As the team of four therapists was set ahead of trial initiation, the feasibility trial allowed each therapist to work in pairs with one another during the feasibility trial. This allowed calibration and practice of procedures, ensuring reliability in intervention delivery in the final RCT. Further, it allowed us to assess the full trial protocol. This led to important amendments in several aspects of the trial that was thought to ensure a higher quality RCT. For example, the feasibility trial displayed the need for shorter baseline procedures to alleviate participant burden. For a patient group where one would expect high levels of fatigue, this was important. The feasibility trial also allowed us to pilot procedures relating to recruitment and screening, which was important for logistics ahead of the RCT. Importantly, outcome results from T2 and T3 assessment was reported to allow for full transparency of findings and hypothesis testing left to the main study as recommended in the literature (Arain et al., 2010; Lancaster, 2015; Lancaster et al., 2004; Thabane et al., 2010).

Several amendments to eligibility criteria were deemed necessary based on the feasibility study. Firstly, the study by Winter and colleagues had as an inclusion criterion that a family member should co-participate in the study. This was done to reinforce intervention strategies, keep family members informed and address their needs (Winter, Moriarty, Robinson, et al., 2016). However, the feasibility screening of participants revealed that several patients reported a clear need for rehabilitation but had no available family members. Three of the otherwise eligible participants lived far away from their family and did not want to involve friends in their rehabilitation. This was initially surprising, as Winter and colleagues reported that only 7% in their sample were excluded as they could not nominate a family member. This might be due to cultural differences in family structures between Norway and the U.S., as well as their recruitment from urban Philadelphia, where individuals may live closer to their family members. Norway is geographically large, but has few inhabitants, which leaves distance between family members common. It was decided that the ethics of delivering rehabilitation services to those in need weighed heavier than the absolute criterion of having a participating family member. However, family member inclusion was thought beneficial, and participants were encouraged to let available family members co-participate. Family members should be considered a resource in rehabilitation, and some studies have suggested that family member involvement improves outcomes (Foster et al., 2012; Sherer et al., 2007). Importantly, outcomes were similar in the feasibility trial for participants with and without family members, and therapists reported that the intervention delivery was feasible without family members. In the final sample for the RCT (see paper III), 65% of the participants had an actively participating family member. Further, analyses of predictors of goal attainment (paper IV) displayed that family member inclusion was not related to goal attainment.

Further, the oldest participant in the feasibility study displayed signs of an undiagnosed neurodegenerative disorder that did not become apparent until several sessions had taken place. Symptoms of neurodegenerative disorders such as dementia might be hard to differentiate from cognitive deficits expected after severe TBI during a baseline assessment. To reduce the risk of inclusion of patients with neurodegenerative disorders which may confound outcomes, it was decided to add an upper age limit of 72, which is the working age limit in Norway.

Lastly, a limitation of the feasibility trial was that neither the timeline nor available participants for this study allowed for a full piloting of the RCT. This entailed that we were unable to evaluate aspects such as the responsiveness of outcome measures and re-adjustment of sample size.

5.1.2 Research Transparency and Pre-Publishing of the Study Protocol (Paper II)

To improve knowledge about effective intervention programs for individuals in the chronic phase of TBI there is a need for more studies that are conducted with methodological rigor. This RCT applied several methodological approaches to ensure unbiased results, such as randomization, blinding of outcome assessors and the use of standardized outcome measures. However, although the RCT design is thought to be the gold standard of evaluating the efficacy of health care interventions, many RCTs are inadequately reported in journals. This is a problem as it leaves doubt about the methodological rigor of the trials, and hampers replication and implementation. Lack of methodological rigor can produce biased results, which in turn may have negative effects on decision making in health care (Moher et al., 2010). The Consolidated Standards of Reporting Trials (CONSORT) statement is a guideline developed in 1996 (Begg et al., 1996) to increase the quality of reporting of RCT and was last updated in 2010 (Schulz, Altman, Moher et. al., 2010). The reporting of results of this trial (paper I, III and IV) was done in accordance with CONSORT-guidelines. Moreover, it is recommended that RCTs are registered ahead of time in study registers such as Clinicaltrials.gov, and that study protocols that display full procedures are published ahead of time according to SPIRIT guidelines (Chan et al., 2013). Publishing hypotheses and planned statistical analyses before trials further reduces the risk of publication bias and cherry picking of results, and the pre-publishing of protocols enables the transparent sharing of information about the trial that might not fit into later publications, but that will be important to readers so they can evaluate the quality of the study (Wade et al., 2010). The RCT was prospectively registered in Clinicaltrials.gov (NCT03545594) and Paper II provided such an overview of all planned procedures in the RCT.

5.1.3 Evaluating Problem Profiles in the Chronic Phase of TBI (Paper III)

Paper III evaluated the use of the Target Outcome approach, in relation to problems reported on standardized measures at baseline assessment (T1) using the ICF as a framework. Although the approach is based on open-ended responses by participants and family members, the reported problems converged on similar problem areas across a broad range of participants. This allowed us to establish domains and categories for the reported problems. In our sample, 77% of participants and 60% of family members reported at least one difficulty relating to cognitive impairments. Among these, memory difficulties and executive dysfunction were two of the most frequently reported problems. However, the most frequently reported problem by both participants and family members was related to reduced capacity and fatigue, and physical difficulties were nominated by 81% of participants and 72% of family members. Interestingly, the frequency of reported problems related to emotional and social functioning was higher among family members (49% and 40%, respectively) than among participants (38% and 24%). Other studies have shown that individuals with TBI may underreport emotional and behavioral difficulties compared to family members (Hart et al., 2003; Marsh & Kersel, 2006; Winter, Moriarty, Piersol, et al., 2016). This displays the importance of collecting separate information from family members themselves, as emotional and behavioral difficulties may be especially burdensome for family members (Sander et al., 2013) and addressing these symptoms in rehabilitation may be important to increase patient participation (Winkler et al., 2006). However, our sample size did not allow to check statistically whether the apparent differences in reporting between participants and family members were significant. In some cases, it may be that the differing reporting of main problems are due to different perspectives of the same underlying issue. For example, many symptoms of TBI are "invisible", such as fatigue. Thus, participants might have nominated fatigue as a main problem, citing consequences such as reduced social participation, while the family member report reduced social participation as a main problem as this is more externally evident. Further, the categorization of problem areas was done in this publication to enable the reporting of problem profiles, however, the main strength of clinical application of Target Outcomes in treatment planning remains the ability to individually inform rehabilitation efforts.

By comparing the self-nominated problem areas to problems captured by standardized outcome measures such as questionnaires and neuropsychological tests, it became evident that the full range of problems were not captured by the standardized assessment. Using the Target Outcome approach gave a more detailed picture of the difficulties patients and family members were experiencing post-injury. Further, some of the reported problems, such as feeling like a burden, loneliness, lack of a meaningful everyday life and identity difficulties were found to be poorly reflected in the ICF. These types of difficulties may, however, be crucial to some individuals with TBI. Although changes in emotional functioning and personality may be troublesome for the family as mentioned above, the TBI survivor him- or herself might experience emotional distress when they must get used to living their life with a range of impairments, for some causing challenges related to self-identity. Such difficulties are sometimes forgotten in the rehabilitation literature (Gracey et al., 2008). A recent qualitative meta-synthesis (Villa et al., 2021) suggests that both the awareness of deficits, loss of autobiographical memories, loss of autonomy, loss of roles and activities, other's responses to changes and social rejection underlie challenges with self-identity post-TBI. These types of challenges may in part explain reports of feelings of a less meaningful life post-TBI (Thomas et al., 2014). Importantly, these kinds of emotional sequela post-TBI are different from psychiatric disorders and may become a persistent burden for patients. Further, these types of emotional adjustment difficulties might be seen in other conditions than TBI and should be included in the ICF framework.

However, standardized measures provide important and necessary information regarding impairment, as they include clinical cut-offs and normative data. The current work should not be read as an argument to not perform standardized assessments with validated clinical tools, as standardized outcome measures have many advantages, and should always be part of TBI assessment (Tate et al., 2013). However, impairment-focused evaluations may not be the best foundation for treatment planning if the goal is improved everyday functioning. Adding patient-centered outcomes such as the Target Outcomes approach may improve relevance of trials and translation of findings (Frank, Basch & Selby, 2014). From a Norwegian neuropsychological perspective, many neuropsychological evaluations are strongly founded on standardized assessment such as neuropsychological tests. However, these assessments might overlook issues important to the patient, and thus conclusions about treatment needs might be underspecified. Target Outcomes were included as a secondary outcome measure in the current trial and was part of a larger protocol consisting of a range of questionnaires and neuropsychological tests. Its responsiveness and predictive value will be evaluated.

5.1.4 Goal Attainment in the Intervention Group (Paper IV)

In paper IV, goal attainment in the intervention group was investigated. The paper gave an overview of goal domains and categories and exemplified the use of action planning in the intervention. The high level of goal attainment found among participants was encouraging. Of all 151 goals scored at the last intervention sessions, only nine were scored as unchanged since the goal was set, and only 1 goal was scored with a negative goal attainment. We cannot preclude that the high goal attainment might in part be due to bias in GAS scaling or scoring, e.g., the therapist may have underestimated the participant, and thus set a lower level of expected attainment than could be realistically expected, or the other way around. However, therapists were instructed to establish GAS levels based on levels of improvement patients themselves explained would be meaningful to them, and that in turn were viewed as realistic. Therapists held frequent meetings with one another to ensure reliability in establishment of GAS, and a database was established where all previous goals and accompanying GAS were registered. This allowed for reliability in the ways GAS was established across therapists. Overall, the high levels of goal attainment were interpreted as the intervention being successfully tailored to lead to meaningful change in goal areas for participants. This was also consisted with verbal feedback from participants and family members.

However, the use of GAS has been hotly debated in the literature, and its benefits and potential pitfalls should be considered. The advantage of GAS is thought to be that:

(1) GAS allows for scoring of the specific areas that are most relevant in the case of each specific patient, thus allowing for individuality in outcomes. This means that the same level of attainment might be seen as a success for one patient, and a fiasco for another, and thus allows for scaling the attainment levels according to each individual’s prerequisite (Rockwood et al., 1997). In the current study, therapists suggested GAS levels based on input both from participants and family members, as well as information from baseline assessment and clinical evaluation of the patient’s level of functioning. For example, two patients with memory-related goals could still differ vastly. If one had mild memory impairment and the

other had severe memory impairment, scaling would be different. For the first patient, expected goal attainment might be higher, and rely on being able to remember activities using internal strategies and without help from others, while for the other patient, improved goal attainment might only be realistic with high levels of external support which would then be specified in the GAS.

(2) GAS enables measuring rehabilitation efforts that are not easily captured by standardized measures. For example, while specific short-term goals might be important to patients and their families, standardized measures such as questionnaires may only contain a few relevant questions pertaining to these goals, and the change reported herein might be lost in the averaged total scores reflecting items of no relevance to patients (Turner-Stokes, 2009). Measuring patient-centered outcomes such as GAS and Target Outcomes in the current study seems highly important considering the problem areas and goals nominated by patients. For example, for a patient working on goals related to social communication, irritability, and sleep, only a very few items on the included standardized outcome measures might be relevant to capture changes in these domains. The sole use of standardized measures may thus occlude clinically meaningful change, i.e., improvements that make a difference in the specific patient's situation (Wade, 2005).

(3) The requirement of making deliberate decisions on what is expected for each goal can both be seen as honing clinical reasoning for the therapist, as well as being informative for both the patient and their families (Rockwood et al., 1997). Therapists in this study reported that GAS was seen as informative and motivating for some patients, while others found it to be too complex and needed high level of assistance to understand and provide information during GAS-scaling. GAS was recorded in the action plan in as clear a language as possible, and the participant always had a copy of this available. Further, therapists reported that establishment of GAS could sometimes be time-consuming and could sometimes not be completed within the same session as establishment of the respective SMART goal. Therapists then recorded current level of functioning and level of meaningful change as reported by participants and family members, and then returned in the next session with distinct suggestions for GAS to be discussed and approved by the participants. Regarding the scoring of GAS at the final intervention session, this was completed by asking the participant directly to evaluate their own performance and suggest their attainment level. In cases where the participant displayed reduced awareness, therapists and family members interacted with participants to establish an agreement on the level of goal attainment. For

instance, if the patient indicated they no longer had any problem with irritability (a much higher goal attainment than expected; +2), family members were asked to provide input. If the therapist felt that the level of goal attainment suggested by the patient was incorrect, this was discussed openly, e.g., by commending the patient for the improvement he had achieved, while suggesting that there might still be a little work to be done. Final GAS-scores were in most cases established as a consensus between patient, family member, and therapist, while in a few cases (patients with severe amnesia) final GAS-scores were resolved by the therapist and family member. All therapists had experience with working with patients with TBI and impaired awareness was regularly discussed during team meetings.

Despite its fortune, GAS also has some inherent challenges. For example, the quantitative nature of GAS might suggest a higher level of precision than is the case. The use of non-vague anchors to establish goal levels, such as the use of percentages, have been suggested to ameliorate this challenge (Malec, 1999), and was applied in the current study. Further, some aspects of GAS such as the use of T-scores to evaluate goal attainment has met critique as this entails mathematical calculations on ordinal values (Tennant, 2007), and the use of T-scores was dropped completely from the current study due to these methodological challenges. GAS further demands reliability at many levels; the therapist must be reliable both in identification of goals, scaling the GAS, scoring of baseline levels, and scoring of outcomes. Although some have recommended that the GAS outcome scoring be completed by independent clinicians or researchers (Malec, 1999), this was not feasible in the current study. Importantly, in this study GAS was not applied in isolation, but was an addition to a range of standardized outcome measures according to recommendations (Malec, 1999; Turner-Stokes, 2009). In future publications, the GAS results will be compared to outcome measured by standardized measures, such as the primary outcomes related to HRQOL and participation. Previous studies have shown that positive goal attainment results may be important to patients and caregivers but may not be indicative of improvements in overarching domains such as participation and quality of life. Two prospective Dutch studies of outpatient rehabilitation programs in the chronic phase of ABI displayed improvement on individual's goals using GAS, but no higher participation or quality of life (Brands et al., 2013; Rasquin et al., 2010). Lastly, inherent in measuring goal attainment comes the added challenge that different goals with different levels of complexity might be compared, e.g., goal attainment in re-learning to tie your shoes might be compared to attainment in work participation. Although GAS allows for the weighting of goals to adjust for this, this approach has largely been abandoned as its uncertain whether it provides any meaningful addition to scoring procedures and it further prolongs and complicates the scaling process (Bovend'Eerdt et al., 2009; Malec, 1999; Rockwood et al., 2003; Rockwood et al., 1997; Turner-Stokes, 2009). Weighting of goals was thus not applied in the current study. However, the use of the SMART goal approach in this study in conjunction with GAS is thought to have enabled higher comparability across goals. In summary, although there seem to be many current issues with GAS, it is nonetheless viewed by some as the current best alternative in ensuring that the goal progress of patients is measurable (Grant & Ponsford, 2014).

Although the goal setting approach applied in the current study was based on recommendations for collaborative goal setting (Bovend'Eerdt et al., 2009; Malec, 1999; Turner-Stokes, 2009), therapists sometimes reported that establishing “true” SMART goals could be challenging. Ensuring wording that would be specific and measurable seemed to sometimes result in goals that participants found overly complicated or less meaningful than goals put in their own words. It has been suggested that a too rigid approach to the SMART goal approach might be demotivating to patients (Wade, 2009). Thus, the SMART approach was applied in a flexible manner to increase patient involvement. Often, this meant that goals were specific, but they were not constructed in such a narrow manner so that they lost meaning for the patient. For example, one participant had executive and behavioral difficulties, including impulsivity, reduced awareness, and difficulties with social cognition. He described problems with feeling misunderstood or rejected socially. The SMART goal was framed as “feel like I’m coping better in social situations”, while strategies were related to behavioral dysregulation and social skills training. In many cases, the goal could only be described as “SMART” when viewed alongside the GAS, but as all goals had accompanying GAS-scores, this was viewed as increasing meaningfulness of goals for clients, while still ensuring specificity and measurability that allowed for tracking of the goal attainment progress.

Importantly, goal attainment did not vary significantly between goal domains, i.e., there did not seem to be a bias in what types of goals were successful across participants, e.g., cognitive goals were attained at the same level as physical goals. Low frequency of goal sub-categories meant that we lacked statistical power to analyze whether there were significant differences among lower-level goal categories, e.g., whether goals related to memory were more attainable than goals related to executive dysfunction. Some goals were infrequent, such as goals related to language, identity, and behavioral dysregulation. These areas of functioning were also infrequently reported as main problems in our sample (paper III). However, it cannot be ruled out that some types of goals were established less frequently because they are more complex, which may lend themselves more poorly to a structured goal setting method (Wade, 2009). In some cases, therapists reported that themes such as acceptance of life changes, awareness and identity were ongoing topics during intervention sessions, but that participants did not nominate these as goals in themselves. This implies that not all the rehabilitation processes were measured with SMART goals and GAS. However, when comparing Target Outcomes reported in our sample at baseline (paper III) and goals set during the intervention (paper IV), a large overlap was seen. This suggests that the goals set during the intervention mostly met the challenges reported by individuals and family members at baseline. Further, the topics touched on in each session were recorded in therapist logs, and a future planned process evaluation may shed further light on "silent" processes such as recurring themes that might not have been established as SMART goals. The specific nature of the SMART goal approach may however also be an advantage, as it may allow working on overarching issues such as awareness and identity through management of the specific everyday manifestations of these issues. Many patients will not be able to profit from abstract therapeutic conversation and thus need help in working concretely with their problems. For example, one participant had persistent difficulties with reduced empathy, egocentrism, and anger, which negatively impacted his family situation. He had some awareness of these difficulties, but also displayed signs of feeling threatened when confronted with this by his spouse. By working on goals relating to coping with feelings of irritability and improving communication within the family, he described becoming more aware of how his TBI-related symptoms affected his family and the need to keep working on his emotional and social skills. On an anecdotal note, the wife of this participant reported at T3 assessment that he had kept working on these issues ever since.

Finally, we wished to investigate indicators of goal attainment. There is currently a lack of knowledge about factors that may predict goal attainment, precluding strong hypotheses based on existing knowledge. Paper IV thus contained an explorative approach using univariate linear regression models to investigate potential explanatory variables in our sample. The significant factors were then included in a multiple linear regression model, that showed an explanatory power of 23.4% of the variance. The low level of explained variance implies that many relevant factors were not included in this model. However, it is not unusual that models of human behavior explain a lower percentage of variance (O'Grady, 1982). Yet, these analyses must be interpreted cautiously, as 1) our sample was small (n=59) and 2) using univariate regression models may overestimate the explanatory effect of variables. Nonetheless, the analysis suggested that years of education, level of cognitive impairment and outcome expectations are potential factors of relevance to goal attainment in patients with TBI. The fact that outcome expectations may impact goal attainment is considered an interesting and novel finding. This finding is in line with the theoretical framework suggested by Scobbie and colleagues (2009), that suggest the first phase of goal setting involves a motivational phase were outcome expectancy may play an important role in ensuring the patient's engagement in the goal setting process. Factors such as therapeutic alliance and self-efficacy and motivation might be potentially relevant for rehabilitation and are often not included as measures in rehabilitation studies, including in this study. However, the change in outcome expectation from session 1 to session 3 could theoretically very well be related to therapeutic alliance (Tsai et al., 2014), as patients felt more comfortable with the rehabilitation process and their therapist. Therapeutic alliance has started to gain some interest in the field of rehabilitation (Sherer et al., 2007), although it has been most researched in the field of psychotherapy. Factors important across therapeutic approaches such as empathy, goal consensus, positive regard, and collaboration have been shown to be some of the most predictive factors of intervention efficacy in psychotherapy (Norcross, 2002; Norcross & Wampold, 2011). Further, while recording of outcome expectations might be rare within the field of rehabilitation, focusing on outcome expectancies early on is an established recommendation in psychotherapy (Constantino et al., 2011). It is not unlikely that these factors may be relevant also to rehabilitation interventions, and our finding suggest that patients might benefit from rehabilitation therapists assessing and addressing outcome expectancies early on. However, research to fully understand how outcome expectancies, therapeutic alliance, self-efficacy, and motivation are relevant to rehabilitation is lacking.

5.2 Methodological Considerations

5.2.1 General Considerations in Rehabilitation Research

A recent scoping review aiming to identify challenges in the field of rehabilitation research (Arienti et al., 2021) identified factors such as lack of definition of core outcome sets, lacking descriptions of intervention content, low methodological quality, lack of blinding and adequate randomization, difficulties with recruitment and description of study samples and low clinical practice applicability. These factors have been debated in the field of rehabilitation research for the past decades, and although there might be solutions for some of these issues, others might not be so easily solvable. In the present study we (1) used standardized outcome measures suitable for the TBI population, (2) included a thorough description of the intervention content and the study sample, (3) applied strict randomization procedures, and (4) applied methods rooted in clinical practice and thus hopefully avoided several of the methodological pitfalls outlined by Arienti and colleagues.

As outlined in this thesis, outcomes after TBI are a result of the complex interplay between the head injury, premorbid and post-injury individual factors and the context the individual operates within, including their social support network. The aim of applying an RCT design in the current study was to ensure that factors which may influence outcome that are unrelated to the intervention would be accounted for. RCTs have the benefit of randomly selecting individuals to different treatment conditions, which may, if the randomization is successful and the number of participants adequate, ensure a distribution of individuals with similar characteristics in all study groups. The RCT has been considered the "gold standard" in clinical research (Moher et al., 2010). However, although RCTs in fields such as pharmacology often are successful in controlling for most extraneous factors outside treatment, conducting RCTs in the field of rehabilitation has many challenges. For example, identifying the active ingredients and evaluating which mediating factors should be investigated. These concerns are not specific to the field of TBI but is relevant in many disorders that are heterogeneous and multi-factorial in nature (Wittink et al., 2008). Indeed, one of the main challenges in rehabilitation research remains the identification of what the "active ingredients" of rehabilitation are, i.e., what specific component have a therapeutic effect (Whyte & Hart, 2003). In the present study, we build on research as well as clinical experience regarding "active ingredients". Yet, the subsequent changes in outcome could be hard to predict when we still do not fully understand what makes rehabilitation effective. This entail that it might be necessary to include several outcome measures that measure both direct and indirect effects of the intervention (Wade et al., 2010). In the current study, both direct measures (GAS, symptom burden) and indirect measures (HRQOL and participation) were included. As previously mentioned, factors such as engagement in treatment and strength of therapeutic alliance may be considered active ingredients in rehabilitation but might be hard to measure and control for. Further, rehabilitation is considered a process consisting of many components, and it is the sum of these components that are thought to be effective, and isolated evaluations of specific components should perhaps not be undertaken (Wade et al., 2010). In the current study, the delivery of interventions by four different therapists with differing behavior might further make interventions less comparable across participants, as might the individualization of treatment content. However, it has been suggested that the individualization of rehabilitation intervention to suit the individual patient might be one of the most important active ingredients there is (Whyte & Hart, 2003). The nature of TBI further necessitates this high level of individualization as the treatment must be tailored to the specific difficulties experienced by the specific patients. In other words, the current study undertook not only the treatment of one specific sequela post-TBI (e.g., depression), but instead aimed at tailoring the intervention strategies to a broad range of problems. A consequence of this is that studies such as this may not ever achieve the level of strict control and comparability across patients that is expected in other fields.

Further, unlike in double-blinded placebo trials of drugs or sham surgery studies, patients are expected to be active contributors during rehabilitation treatment. This entails that blinding of patients and therapists is both impossible and unwanted, and was thus not done in the current RCT. Instead, the outcome assessors were blinded to group allocation. In addition, some have argued that although an RCT design may have benefits in increasing the internal validity of studies, RCTs in the field of rehabilitation might be so far removed from clinical practice that external validity is threatened (Schutz et al., 2008). Pragmatic trials have been suggested as a possible solution to this challenge, as these are designed to test interventions in a real-world setting (Ford & Norrie, 2016). Conducting a pragmatic trial involves a more naturalistic choice of participants, conducting the intervention in a setting close to usual care, having a more flexible approach to delivery and adherence and choosing outcome measures that are directly relevant for the participants (Ware & Hamel, 2011). Pragmatic trials may however lead to lower internal validity because study conditions are less controlled (Lurie & Morgan, 2013). However, a trial does not necessarily need to be one or the other but can consist of elements from both approaches (Treweek & Zwarenstein, 2009). This RCT could be considered a semi-pragmatic trial, in that it involved some pragmatic aspects in sampling and intervention delivery, while also comprising eligibility criteria, randomization, and manualized delivery.

5.2.2 External Validity

External validity concerns whether results could be applicable to individuals outside the study population or in a different context (Fletcher et al., 2005). An important aspect of relevance to external validity is the representativeness of the study sample. Out of 555 invited to participate by letter, 454 were reached by phone. In accordance with Data Protection laws in Norway, we were unable to collect data on participants that could not be reached or that declined participation. Thus, out of the 454 reached by phone, 135 declined participation, without divulging their reasons. Further, 15 did not show up for baseline assessment despite consenting initially, and another 4 participants could either not be reached or not scheduled for a baseline before trial recruitment ended. As we could not investigate possible differences between the unreachable or declining individuals and the rest of our sample, a potential bias cannot be ruled out. Further, 137 individuals reported no need for further rehabilitation services. The 163 individuals showing interest in the trial constitutes 29.3% of the 555 invited participants, which is in line with a Norwegian study showing that about 30% have unmet health care needs in the chronic phase of TBI (Andelic et al., 2014). Of these 163, 43 participants did not fulfill eligibility criteria. The most common reasons for exclusion were unavailability (had moved out of South-East region of Norway, n=11), severe ongoing neurological or psychiatric disorder including substance abuse (n=9), insufficient fluency in Norwegian (n=8) and inability to provide informed consent (n=5). Based on this, results from this trial may not be representative for individuals with ongoing severe neurological or psychiatric disorders or substance abuse, who are insufficiently fluent in Norwegian or that are unable to give informed consent. Also, the upper age limit of 72 years applied in the RCT may have decreased the ecological validity of the trial, as efficacy of the intervention cannot be established for patients above working age. Further, to ensure that participants were in a stable phase of TBI and to decrease likelihood of concurrent rehabilitation interventions that might confound outcome, 2 years post-injury or more was set as an inclusion criterion in this trial. This was based on a pragmatic definition of chronic disability applied by the Norwegian Labor and Welfare Administration, where disability is defined as deficits that persist for at least two years, or deficits that are expected to be persistent. It also accounts for the period when most individuals with TBI in Norway receive rehabilitation services, and thus reduced the risk of participants receiving similar rehabilitation programs that might have confounded outcome. Thus, trial results may not be representative for individuals who are less than 2 years post-injury. Further, one inclusion criterion was ongoing difficulties relating to the TBI, which implies that the current sample is representative only of the proportion of TBI patients who experience ongoing, adverse consequences of their injuries for two years or longer.

Paper III gives an outline of the 120 participants randomized in the RCT. Their mean age was 45.2 years, and a large proportion were men (71%). This is in accordance with epidemiological studies of TBI in Europe (Peeters et al., 2015). Injury causes were as expected mainly transport-related and falls. Considering that this was an adult sample, the cause of injury was proportionate to what is expected in Norway (Andelic et al., 2008). While 36% had a mild complicated TBI, 16% were categorized as moderate TBIs and 48% as severe TBI was determined based on their GCS within the first 24 hours after injury. Including all severities was seen as a strength, as we know that injury severity alone is a poor predictor of outcome. Yet, requiring verified intracranial injury implies exclusion of mild uncomplicated TBI, but renders the sample representative for a Trauma Center population. This might limit the relevance of study results to individuals suffering from prolonged symptoms after concussions. In our sample, the median education level in years was 12 (IQR: 12-15) and 34% had higher education. Based on numbers from Statistics Norway, 34.1% of the general Norwegian population has a college or university degree. A large proportion of our sample was not currently working (51%), while the rest were employed either full-time or part-time. This is in accordance with previous studies showing that about half return to work and remain working after moderate to severe TBI (Howe et al., 2018). Hence, this sample was thought to be representative of persons with mild complicated to severe TBI in the chronic phase whom experience ongoing rehabilitation needs in Norway.

5.2.3 Internal Validity

Internal validity relates to whether results are true for the studied sample, i.e., whether sources of bias are kept to a minimum (Fletcher et al., 2005). As mentioned, pragmatic aspects of this trial might have resulted in sources of bias that should be highlighted.

Randomization was conducted by an independent researcher and fully concealed from therapists evaluating patients at baseline. Further, randomization was not performed until after baseline, which ensured no source of bias in therapist evaluations at baseline. As detailed above, blinding of participants in rehabilitation trials is unwanted as they are expected to be active participants in their rehabilitation. However, outcome assessors collecting data at T2 and T3 were blinded to allocation.

The control group in this trial received standard treatment, i.e., any care usually provided in community. This lack of active treatment in the control group might be a source of bias, as participants in the control group may have had more negative appraisals being reminded about their unmet needs at baseline and did not receive additional follow-up during the intervention period (see section 5.5). Further, participants and therapists in the intervention group might have been influenced by beliefs about intervention efficacy, which might influence outcomes (Houben et al., 2005; Wade et al., 2010). However, the time frame and funding of this trial did not allow for an active control condition. The "treatment as usual" control condition did however allow for comparison between standard care for TBI patients in the chronic phase in Norway and the intervention, which was the purpose of this trial. It is also a known challenge within rehabilitation research to design an active control condition that includes only incidental effects of the intervention and not the active ingredients, as these are most often unknown (Hart & Bagiella, 2012). Further, concurrent treatment was not stopped in any of the groups, which could be a source of bias. However, any concurrent treatment was thoroughly logged at all time points so that this can be controlled for when evaluating between-group differences.

The attendance in the intervention group was high. One participant missed 6 sessions (drop-out), and three participants missed 1 session, providing a total attendance rate of 98.3%. Outcome assessments at T2 have been completed with data missing for 5% of participants. T3 assessment has currently been completed for 102 participants, with 8 (7%) missing their evaluation and 10 participants still waiting to complete assessments. The overall attrition rate needs to be evaluated when T3 outcome assessments have been completed.

To ensure satisfactory treatment fidelity, 10% of all home visits were assessed for fidelity by a senior therapist. The planned process evaluation will shed further light on details about the intervention delivery.

5.2.4 Outcome Measures

Choosing outcome measures in rehabilitation trials is a daunting task and warrants further discussion. The scope of potentially relevant measures for TBI is enormous (Tate et al., 2013). As discussed previously, measuring clinically meaningful differences might be hard when pooling responses on standardized measures, as only a few items on any given measure might be relevant for each patient. This study thus aimed at including both patient-centered outcomes such as GAS and Target Outcomes, as well as standardized measures. GAS was however only administered in the intervention group as establishing goals and GAS in the control group was seen as being an integral part of the intervention to be tested (Hart & Evans, 2006). As a result of the feasibility study (paper I), Target Outcomes was replaced as the primary outcome measure. One aspect was that despite intended as a measure of problems participants wanted to work on, several participants ended up choosing goals relating to problems they either did not think of during the baseline assessment or felt uncomfortable divulging during the first meeting. Lack of awareness also seemed to influence reporting of Target Outcome severity in the feasibility trial, and the methodological qualities of its severity rating was questioned. Lack of awareness may also be an issue on other outcome measures in this trial as it might make individuals reporting of their own level of functioning less reliable. Family member reports will be available for a proportion (65%) of this sample, but these reports are likely influenced not only by the patient's functioning, but further the family members level of exposure to behaviors the questionnaires ask about, as well as their own personality, emotional adjustment and in some cases, their own agenda (Ponsford, 2014). Response bias should also be considered as control participants were aware of their group allocation, and many participants had cognitive deficits, which may impact responses (Bogner et al., 2017).

As increasing quality of life and participation is a main goal of rehabilitation in the chronic phase of TBI, these were chosen as primary outcome measures in the RCT instead of Target Outcomes. When considering outcomes relating to participation, it is important to note that there is no consensus on what constitutes ideal participation (Bogner et al., 2011). Post-TBI, one of the challenges in participation might be the decreased capacity to uphold activities in different life areas. Some might return to work, but this may involve reduced participation in other important life areas such as with family, friends, and leisure activities. It seems that the balancing of life roles has higher predictive value for life satisfaction and subjective well-being (Bohle et al., 2004; Hammig & Bauer, 2009), and objective measures of participation should be considered together with the individuals' subjective perspectives on what constitutes ideal participation. The PART-O measures participation quantitatively, and a limitation of this study is a lack of a qualitative measure of participation. The use of brain injury-specific HRQOL measure rather than a generic one has been recommended to fully assess the subjective impact of TBI (von Steinbüchel et al., 2020; von Steinbüchel et al., 2012), and for this reason the SF-36 was replaced by the QOLIBRI-OS after the feasibility trial. A broad range of measures were applied in the current study. According to Wade et al. (2010), four types of outcomes are relevant in rehabilitation: participation, ability to undertake subjectively important tasks, minimization of physical and emotional symptoms and minimization of family stress. This trial includes measures of all these aspects. Also, final conclusions regarding the choice of outcome measures are pending the analysis of the results of the RCT regarding both primary and secondary outcomes.

5.5 Ethical Remarks

Several ethical issues are relevant in this trial. Firstly, potential participants were invited based on the knowledge that a proportion of patients live with persistent TBI-related deficits and unmet needs. However, it is not unlikely that some of the participants contacted would rather be left alone and no longer be considered a "patient with TBI". Receiving the study invitation and phone call may thus have been upsetting for some. Also, participants allocated to the control group spent several hours at baseline assessment divulging their unmet needs, only to receive no immediate additional treatment (see section 2.7).

Several participants that were contacted reported needs for services but did not fulfil eligibility criteria. In these cases, general practitioner's or other involved health care personnel were contacted by the research team with information about the unmet needs. Some received contact information or referrals to relevant health care services such as psychiatric care and family services. In a few instances when local services were not provided and the individual was considered unable to navigate these services, the individual was offered one or two sessions with rehabilitation personnel working in the trial to ensure the initiation of relevant local follow-up.

Importantly, in a few cases therapists reported ethical conflicts in delivering the pre-specified number of sessions outlined in the manual. For some, the number of sessions were seen as being too few to address all important issues troubling the participants and their families. In these cases, the therapists expressed that they wished they could have continued the intervention for some more sessions. This mirrors ethical difficulties experienced by clinicians working with limited resources. For a few other participants, therapists described how issues were resolved within fewer sessions than was suggested, and that the participant and family member might have been spared participating in all eight sessions.

The intended purpose of this study was to allow for co-operation with local health care personnel involved in the care of participants. Therapists reported that getting relevant services involved could be time-consuming and, in a few cases, it became apparent that the individual had needs that could not be covered by the available local services. This was seen as ethically challenging, as it might have been disparaging for participants to learn that their municipality did not offer services that they were made aware of needing. This too, mirrors a current reality for many clinicians, e.g., having to discharge patients from rehabilitation with substantial difficulties they might suspect the patient will not receive help for.

Another concern is that of family members. Many family members expressed gratitude for receiving support in handling their loved one’s TBI-related difficulties. Some did, however, report that they felt frustrated that it was once again the injured individual him- or herself that was receiving treatment, inquiring when they would receive more attention as caregivers. Although caregiver needs were attempted to be addressed as part of the intervention, the participant was nevertheless the main target. The addition of parallel caregiver support groups or similar could have been applied to better address the needs of family members.

6 Conclusions

This thesis has provided a transparent overview of an RCT evaluating the efficacy of a goal-oriented and home-based intervention aiming to ameliorate persistent TBI-related difficulties and improve participation and quality of life. This intervention was shown to be feasible in a Norwegian context with minor adjustments. Further, as the RCT was founded in the understanding that rehabilitation should be patient-centered, this thesis outlined an assessment tool (Target Outcomes) that might assist clinicians in tailoring rehabilitation strategies to the specific difficulties experienced as the most important by the patient and their family. Lastly, this thesis displayed how an individualized and knowledge-based treatment approach resulted in high levels of goal attainment among participants in the intervention group.

7 Implications and Future Perspectives

This thesis has displayed promising preliminary results from the RCT. The overall efficacy evaluation of the trial is pending final assessments. If the trial displays efficacy (intervention is beneficial under the ideal circumstances of the trial), the effectiveness of the intervention (its benefits under normal circumstances) should be considered. Although research is meant to influence the practice field, there are many hinders to successful implementation of health care interventions (Straus et al., 2013). The pragmatic aspects of this trial may aid in this respect. For example, the inclusion of patients with comorbid conditions such as anxiety and depression mirrors clinical practice, and overall, our sample was found to be quite representative for the population seen at OUH with ongoing rehabilitation needs.

Importantly, even in a wealthy country such as Norway, long-term rehabilitation services have been deemed insufficient to cover the needs of individuals with moderate-severe TBI (Andelic et al., 2020). This thesis contributes to this knowledge base by providing important information about the idiosyncratic needs of individuals with unmet rehabilitation needs in Norway. Lack of knowledge among local service providers about long-term consequences of TBI, especially "invisible" consequences such as difficulties with cognitive, emotional, and social functioning, may indeed be part of the problem. Also, the lack of available services to target many of these needs is discouraging. Hence, dissemination of results from this RCT to national providers and policy makers seems an important future initiative. Further, unmet needs are influenced by health policy, including lack of funding of relevant services and lack of financial incentives to provide long-term care for patients. To ensure better care for these individuals, a dynamic collaboration between specialized rehabilitation professionals and local services is needed. Further, this RCT was conducted in accordance with developments and recommendations suggested in guidelines for rehabilitation published by The Norwegian Directorate of Health (Helsedirektoratet, 2012). These guidelines suggested that rehabilitation actions should be transferable to the everyday situation of the service user, that user involvement is a key approach, that the user receives knowledge-based interventions of high quality and that ambulatory services should be provided. This RCT thus displays a potential mode of delivery of rehabilitation services answering a defined need in Norway. Collaboration between specialized and local healthcare providers was proven feasible in the present study. However, the therapists reported that collaboration was most easily established for the participants with the most severe injuries, where services were already provided, and that the coordination with local services was time-consuming. Hence, the present study clearly informs us that sufficient time should be spent on ensuring coherent collaboration between service providers. Further, this study calls for improved follow-up of health care needs after TBI, and specifically community-based services should be provided to patients with ongoing needs, including those with less severe injuries. Future research is needed to inform how the municipal services might be structured to meet these needs.

This work also points to several knowledge gaps within the rehabilitation literature. Neither the explicit active ingredients of rehabilitation interventions nor which outcome measures best capture rehabilitation efforts are currently known, and more research is needed. Also, the sensitivity and reliability of patient-centered outcomes such as Target Outcomes needs to be established. Further, factors known to influence outcomes in the field of psychotherapy, such as motivation, self-efficacy and outcome expectancies have received little attention in the field of rehabilitation. It is however not unlikely that these factors may influence rehabilitation outcomes, and more research is needed to guide clinicians in which, if any, of these factors should be addressed in rehabilitation. Lastly, it could be argued that the individualized and patient-centered approach adopted in this RCT might be a relevant treatment approach for other conditions with persistent symptoms, e.g., other ABIs and neurological conditions. The current study might serve as a model of how to engage patients, families, and local healthcare providers in a structured manner to improve everyday functioning within the context of their living environment. However, the utility of this approach in patients with other conditions will need to be evaluated in separate high-quality studies. For example, an ongoing research project in Norway is inspired by our study and the study of Winter and colleagues. This RCT will evaluate the efficacy of this intervention adapted for children with ABIs in the chronic phase (see clinicaltrials.gov NCT04798859).

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8 Appendix. Papers I-IV

Cogent Medicine

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Needs and treatment options in chronic traumatic brain injury: A feasibility trial of a community-based intervention

Ida Maria H. Borgen, Marianne Løvstad, Cecilie Røe, Marit V. Forslund, Solveig L. Hauger, Solrun Sigurdardottir, Laraine Winter & Ingerid Kleffelgård |

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PHYSIOLOGY & REHABILITATION | RESEARCH ARTICLE

Needs and treatment options in chronic traumatic brain injury: A feasibility trial of a community-based intervention

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Abstract: Lifelong changes may be expected after sustaining a traumatic brain injury (TBI). Research on relevant treatment options in the chronic phase of TBI is lacking. An innovative, home-based intervention program was developed in the US and showed to be effective among US veterans who had sustained a TBI. However, the cross-cultural applicability and effectiveness are unknown. The aim of the present study is to evaluate the feasibility in a Norwegian population before a future definitive randomized controlled trial (RCT). Six participants with severe TBI in metropolitan Oslo, Norway, were recruited and received the intervention. Primary feasibility objectives were to evaluate (i) recruitment and screening procedures, (ii) baseline and follow-up assessments, (iii) intervention delivery, (iv) acceptability, and (v) order of primary and secondary outcome measures. No adverse effects of the intervention were uncovered. Baseline assessment was found to be too long. Intervention delivery was feasible and acceptability high. Outcome measures were reviewed and amendments were deemed necessary. An individually tailored, goal-

ABOUT THE AUTHOR

The current trial is part of a larger collaborative research project conducted by the Department of Physical Medicine and Rehabilitation at Oslo University Hospital (OUH) and Sunnaas Rehabilitation Hospital. The authors contribute to several multidisciplinary research groups, including “Rehabilitation after trauma” at OUH that aims to generate knowledge about neurotrauma, treatment and rehabilitation, with a main focus on traumatic brain injury (TBI), and Research Centre for Habilitation and Rehabilitation Models & Services funded by the Norwegian Research Council to strengthen research in rehabilitation services. The project is further conducted in collaboration with Laraine Winter, who developed the intervention program and evaluated its effectiveness in Philadelphia, USA. The larger research project will contribute to the knowledge on how rehabilitation services could be provided by specialist health care institutions in Norway for patients with chronic TBI, and might inform more generally on provision of ambulatory rehabilitation services for comparable patient groups.

PUBLIC INTEREST STATEMENT

Traumatic brain injury is a leading cause of disability worldwide. Studies have shown that people might experience several challenges even years after their injury. However, few studies have evaluated relevant treatment options for the individuals and their families after they have returned to their homes and daily living. This study aimed to evaluate whether a home-based rehabilitation program tailored to each individual’s activity challenges was feasible in the context of a universal access health-care system in Norway. The study showed that this eight-session treatment program was feasible, but that some adjustments in regards to measurements and inclusion criteria were necessary. With these amendments, a full-scale trial was initiated, aiming to recruit 120 individuals and include a comparison group to evaluate effectiveness.

focused intervention program was deemed feasible in a population of severe TBI and the preliminary results seem promising. The feasibility trial led to important amendments to inclusion criteria, baseline assessment and outcome measures that were adapted before the RCT study commenced. The RCT-study started recruitment in June 2018.

Subjects: Rehabilitation Medicine; Research methods; Community Health; Rehabilitation Medicine

Keywords: Traumatic Brain Injury; community-based rehabilitation; in-home rehabilitation; feasibility trial

1. Introduction

1.1. Background

Traumatic brain injury (TBI) is a leading cause of death and disability worldwide (Langlois, Rutland-Brown, & Wald, 2006; Tagliaferri, Compagnone, Korsic, Servadei, & Kraus, 2006), and often leads to persistent difficulties with cognitive, emotional and vocational functioning, as well as reduced community integration and quality of life (Andelic et al., 2009; Brooks, Campsie, Symington, Beattie, & McKinlay, 1986; Dikmen, Machamer, Powell, & Temkin, 2003; Forslund et al., 2014; Hoofien, Gilboa, Vakil, & Donovick, 2001, Jourdan et al., 2018; Olver, Ponsford, & Curran, 1996; Ponsford, Draper, & Schonberger, 2008; Ruttan, Martin, Liu, Colella, & Green, 2008). One of the groups with the highest prevalence of TBI is young adults (Barker-Collo, Wilde, & Feigin, 2009; Fail, Xu, Wald, & Coronado, 2010; Langlois, Kegler, Butler, & Gotsch, 2003) who may live with TBI-related sequelae for decades or throughout life. This entails both severe alterations of the lives of survivors and their families, and incurs high societal costs. For some, TBI should thus be viewed as a chronic disease process rather than a single event. Also, while many individuals experience improved function, others seem to decline in function over time (Corrigan & Hammond, 2013; Masel & DeWitt, 2010; Pretz & Dams-O'Connor, 2013).

Recent studies have suggested that health-care services offered in the chronic phase of TBI are often related to physical functioning, while needs related to cognitive, emotional and vocational difficulties are more often unmet (Andelic, Soberg, Berntsen, Sigurdardottir, & Roe, 2014; Heinemann, Sokol, Garvin, & Bode, 2002; Jennekens, de Casterle, & Dobbels, 2010; Koskinen, 1998; Olver et al., 1996; Prang, Ruseckaite, & Collie, 2012; van Walsem et al., 2020). This discrepancy between perceived needs and delivery of health-care services suggests that effort should be made to better tailor rehabilitation services in the chronic phase of TBI. This also involves bridging the gap between the rehabilitation services being offered by specialized health care and community-based services. Further, rehabilitation in this phase may entail incorporating aspects that receive less attention during the acute and subacute phases, such as the patient's living environment, access to social support, motivation and community reintegration (Gagnon, Lin, & Stergiou-Kita, 2016; Sherer et al., 2015).

High quality controlled studies evaluating treatment strategies in the chronic phase of TBI should inform treatment planning, but few such studies exist (Ponsford, Harrington, Olver, & Roper, 2006; Powell, Heslin, & Greenwood, 2002). One exception is a recent treatment intervention study performed by Winter et al. (2016), which included 81 military veterans with mild to severe TBI. Applying an innovative in-home-program with an individualized approach to each participant, the authors targeted current TBI-related problem areas, as well as daily functioning and community integration. The intervention was delivered in collaboration with family members, and consisted of eight intervention sessions delivered over a 4-month period. The treatment group was compared to a control group that received their usual care in the Veterans Affairs medical rehabilitation service. The intervention group showed significantly higher community re-integration and less difficulty in managing targeted outcome areas compared to the control group. Despite these encouraging results, the authors emphasized the need for replication in a civilian population. Further, 70% of the participants had a diagnosis of mild TBI, and the intervention program should be evaluated in a population with moderate and severe TBI. In addition, service delivery might be different in a public health-care system with universal access, like the one in Norway.

A future definitive randomized controlled study (RCT) aiming to include these perspectives has been planned in Norway, and the protocol has been translated into Norwegian in close collaboration with Winter and her colleagues. The intervention will include eliciting Target Outcome areas, that is, current TBI-related problems in everyday life, which participants nominate in their own words at the baseline assessment, in addition to rating the difficulty in handling the problem. This approach seems especially suitable considering that TBI is expected to cause a broad range of possible problems, allowing the intervention to be tailored to the individual's needs and assessing changes in the severity of the problem. The intervention will address the nominated Target Outcome areas using a SMART-goal approach, which entails establishing goals that should be Specific, Measurable, Achievable, Realistic/Relevant and Timed (Bovend'Eerdt, Botell, & Wade, 2009). Goal Attainment Scaling (Malec, 1999) will accompany each goal, and therapists will collaborate with participants and family members to develop evidence-based strategies to ameliorate the specific problem area. Further, the Target Outcome-approach allows for assessment of changes in severity pre- and post-treatment to assess the effectiveness of the intervention in light of the heterogeneous nature of long-term sequelae after TBI.

In line with the recommendations of the Medical Research Council (Craig et al., 2008), a feasibility trial was performed. The primary objectives of this feasibility trial were to evaluate the screening and recruitment procedures, baseline and follow-up assessments, intervention delivery, acceptability and order of outcome measures in order to inform the future definitive RCT.

2. Methods

2.1. Trial design

The feasibility trial applied a one group pre-post design, including a baseline assessment (T1) and follow-up assessment immediately after the intervention (T2) as well as 8 months after the end of the intervention (T3). The study was approved by the Data Protection Office at Oslo University Hospital (OUH), Norway (2017/10390).

2.2. Procedures

This feasibility study mirrored assessment procedures planned for the future RCT in order to evaluate the protocol. Baseline data (T1) were collected through consultations with both participants and family members. A neuropsychological screening battery was used at baseline for descriptive purposes. The intervention sessions were performed between T1 and T2. Consultations with participants and family members were repeated for outcome assessment at T2 and T3. Table 1 lists all outcome measures planned for the future definitive RCT, with a focus on the use of measures with satisfactory psychometric properties.

2.3. Participants

Nineteen eligible participants, who sustained a severe TBI in 2009–2010 in the Oslo area, were identified from participants in the multicenter study previously conducted at OUH (Andelic et al., 2012). All participants were invited to participate by letter that included informed consent forms. A scripted telephone interview was performed to screen for inclusion- and exclusion criteria, and assess willingness to participate. The initial inclusion criteria were: (i) TBI diagnosis established in the acute phase, with radiologically verified intracranial injury, (ii) age 16–80 years at the time of injury, (iii) minimum 2 years since time of injury, (iv) ongoing self-reported TBI-related cognitive, emotional and/or physical problems, and/or reduced physical and mental health, and/or difficulties with participation in activities with family, friends and/or in the community, (v) living at home, and

Table 1. All measures used at baseline (T1) and outcome (T2) assessments

	Instruments	Purpose	T1	Session 8	T2 & T3
Baseline data	Baseline form	Collect data on demographics and comorbid illnesses	x		
	CVLT-II (Delis, Kramer, Kaplan, & Ober, 2000)	Evaluate verbal learning and memory	x		
	TMT 1–5 and CWIT 1–4[1] (Delis, Kaplan, & Kramer, 2001)	Evaluate processing speed, mental flexibility and inhibition	x		
	Coding & Symbol Search[2] (Wechsler, 2008)	Evaluate processing speed	x		
	Similarities, Vocabulary, Matrix Reasoning, Block Design[2] (Wechsler, 2008)	Provide an IQ-estimate, evaluate verbal and non-verbal cognition	x		
	BRIEF-A, Self-report Form (Roth, Isquith, & Gioia, 2005)	Self-reported executive dysfunction in everyday life	x		
Participant outcome measures	RPQ (King, Crawford, Wenden, Moss, & Wade, 1995)	Self-reported TBI symptoms	x		x
	PHQ-9 (Kroenke, Spitzer, & Williams, 2001)	Self-reported depressive symptoms	x		x
	SF-36 (Ware, Sherbourne, & The, 1992)	Self-reported health-related quality of life	x		x
	PCRS, Patient Form (Prigatano et al., 1986)	Self-reported functional competency in daily activities	x		x
	PART-O (Whiteneck et al., 2011)	Self-reported participation	x		x
	NPCS, Clinician Version (Turner-Stokes & Siegert, 2012)	Semi-structured interview of health care services provided, and clinician evaluated needs for services	x		x
	GOSE (Jennett & Bond, 1975)	Semi-structured interview of global outcome after brain injury	x		x

(*Continued*)

	Instruments	Purpose	T1	Session 8	T2 & T3
	Target Outcome severity (ordinal scale from 0: "not at all"—4: "severe")	Three TBI-related activity problems currently experienced by the participant, self-reported in open question form	x		x
	GAS (Malec, 1999)	Goal attainment at end of intervention		x	
	Acceptability-Scale (Winter et al., 2016), 10-item Participant Form (ordinal scale from 0: "not at all" to 4: "extremely")	Participant-reported acceptability at end of intervention		x	
	Acceptability-Scale (Winter et al., 2016), 17-item Therapist Form, (ordinal scale from 0: "not at all" to 4: "extremely")	Therapist-reported acceptability for participant		x	
Family member outcome measures	PCRS, Relative Form (Prigatano et al., 1986)	Informant-reported functional competency in daily activities	x		x
	BRIEF-A, Informant Form (Roth et al., 2005)	Informant-reported executive dysfunction in everyday life	x		
	PHQ-9 (Kroenke et al., 2001)	Self-reported depressive symptoms	x		x
	Caregiver Burden Scale (Elmståhl, Malmberg, & Annerstedt, 1996)	Self-reported caregiver burden	x		x
	Target Outcome severity, Informant reported	Three TBI-related activity problems reported by family member	x		x
	Target Outcome severity, Informant scored	Family member's severity rating of participant's Target Outcomes	x		x

(Continued)

Table 1. (*Continued*)

	Instruments	Purpose	T1	Session 8	T2 & T3
	Acceptability-scale (Winter et al., 2016), 10-item Family Member Form (ordinal scale from 0: “not at all” to 4: “extremely”)	Family member reported acceptability at end of intervention		x	
	Acceptability-Scale (Winter et al., 2016), 17-item Therapist Form	Therapist-reported acceptability for family member		x	

[1] Delis–Kaplan Executive Function System (D-KEFS), [2] Wechsler Adult Intelligence Scale, Fourth Edition (WAIS-IV). BRIEF-A = Behavior Rating Inventory of Executive Functioning-Adult version, CVLT-II = California Verbal Learning Test-II, CWIT = Color Word Interference Tests, GAS = Goal Attainment Scaling, GOSE = Glasgow Outcome Scale-Extended, NPCS = Needs and Provision Complexity Scale, PART-O = Participant Assessment with Recombined Tools-Objective, PCRS = Patient Competency Rating Scale, PHQ-9 = Patient Health Questionnaire, RPQ = Rivermead Post-Concussion Symptoms Questionnaire, SF-36 = The Medical Outcomes Short Form-36, TMT = Trail Making Test.

(vi) having a family member that could participate during the intervention sessions. Exclusion criteria were: (i) ongoing severe psychiatric disorders, (ii) comorbid neurological illness that could confound outcome, (iii) inability to participate in goal-setting process, (iv) inability to provide informed consent, and (v) insufficient understanding of the Norwegian language to understand intervention instructions and to complete the assessment protocol. Eligible participants were invited to complete T1 assessment at the outpatient clinic at OUH. All eligible participants and participating family members returned the written informed consent forms at T1.

2.4. Intervention

2.4.1. Framework

The intervention consisted of six in-home visits and two telephone contacts, and was delivered over a period of 4 months. Four therapists were responsible for intervention delivery. The therapists included one psychologist and one physician (junior therapists), and one neuropsychologist and one physiotherapist (senior therapists with >10 years’ experience from neuro-rehabilitation). The intervention delivery to individual participants was performed by two collaborating therapists, in order to ensure uniform treatment delivery and to increase learning. In most cases, senior and junior therapists were paired together, in order to increase reliability in the future definitive RCT-study. Therapists and study PI and co-PI (authors CR and ML) met once every or every second week for consensus discussions and supervision. A major focus in these consensus meetings was to ensure that the professional background of the therapist did not lead to lack of adherence to protocol, and to ensure common procedures for establishment of treatment plans. The TBI expertise in these meetings was considered to be high. All participants were either medical doctors, psychologists or physiotherapists. Four of the consensus participants have Ph.D.’s in the field of acquired brain injury and all participants expect the junior therapists (authors IMHB and MVF) have extensive experience from neurorehabilitation.

2.4.2. Content

During the in-home visits, therapists collaborated with the participant and family member to identify relevant goals (usually related to the Target Outcomes nominated at baseline). A SMART-goal approach was adopted (Bovend’Eerdt et al., 2009). For each established SMART-goal, an accompanying Goal Attainment Scaling (GAS; Malec 1999) was developed to establish a quantifiable measure of goal achievement. The expected level of goal achievement was set to

"0", while higher levels of goal achievement than expected were set to "+1" and "+2", and lower levels than expected were set to "-1" and "-2". Next, an Action Plan was established, which included strategies to be used by the participant to achieve his or her SMART-goals. In addition to profitable strategies suggested by participants and family members, the therapist would suggest evidence-based strategies (Beck, 1995; Cicerone et al., 2011; Gracey et al., 2008; Haskins, Cicerone, & Trexler, 2012; Lejuez, Hopko, Acierno, Daughters, & Pagoto, 2011; Myles, 2004; Ponsford et al., 2014; Ruff, 2013; Tate et al., 2014; Togher et al., 2014; Velikonja et al., 2014; Yeates, Gracey, & Mcgrath, 2015), including environmental modifications and compensatory strategies. Strategy training was a main focus throughout the intervention, in addition to identification of obstacles to adaptive use of strategies and discussion regarding generalizability and transferability of strategies and new skills. Goal attainment and acceptability were evaluated during the last in-home visit (session 8). Figure 1 shows an overview of the intervention sessions.

One area of interest in the feasibility trial was to explore the degree to which cooperation with local health professionals was relevant and feasible. Participants were asked to name a current health-care provider at T1, and all agreed that this person could be contacted for collaboration throughout the intervention. In cases where other relevant collaborators were discerned during the intervention, therapists had the opportunity to contact these if the participant consented and the contact seemed relevant.

2.5. Feasibility

The following methodological approaches were used to assess the primary objectives of the feasibility trial:

(i) Screening and recruitment procedures were evaluated by assessing the scripted telephone interview, consent rate and time to recruit.

(ii) The T1, T2 and T3 assessments were examined for time consumption and participant burden, including ease of filling out questionnaires and burden of the neuropsychological screening battery.

(iii) Intervention delivery was evaluated based on consensus meetings, and included discussion about the appropriateness of the intervention procedures, ease of establishing SMART-goals and GAS and how the collaboration with family members and local health professionals worked in practice. Therapist burden was assessed by looking at time spent per intervention session and travel time to each appointment.

(iv) The number of sessions attended by both participants and family members was recorded. Further, the acceptability of the intervention was assessed by scores on the Acceptability scale. At T3, participants were asked about their willingness to partake in future research studies.

(v) The order of primary and secondary outcome measures was evaluated by looking at the consistency between Target Outcome areas reported at baseline, and the goal-setting process, as well as the burden to complete outcome assessments.

3. Results

3.1. Participants

Figure 2 displays a flow chart for the feasibility trial. Participants' age ranged from 35 to 78 years, and 5/6 were males. Three of the participants were injured in falls, while three were injured in transport-related accidents. Lowest GCS during acute care was 3, 6, 7, 7, 8 and 8 for the participants. Time since injury ranged from 91 to 104 months (approximately 7.5–8.5 years). Minimum level of education was high school (12 years). One participant was retired and one participant received disability pension. The other participants had 40% to 100% paid employment. Three were married and three were single. Participant characteristics were evaluated at baseline assessment.

Figure 1. Overview of the intervention sessions.

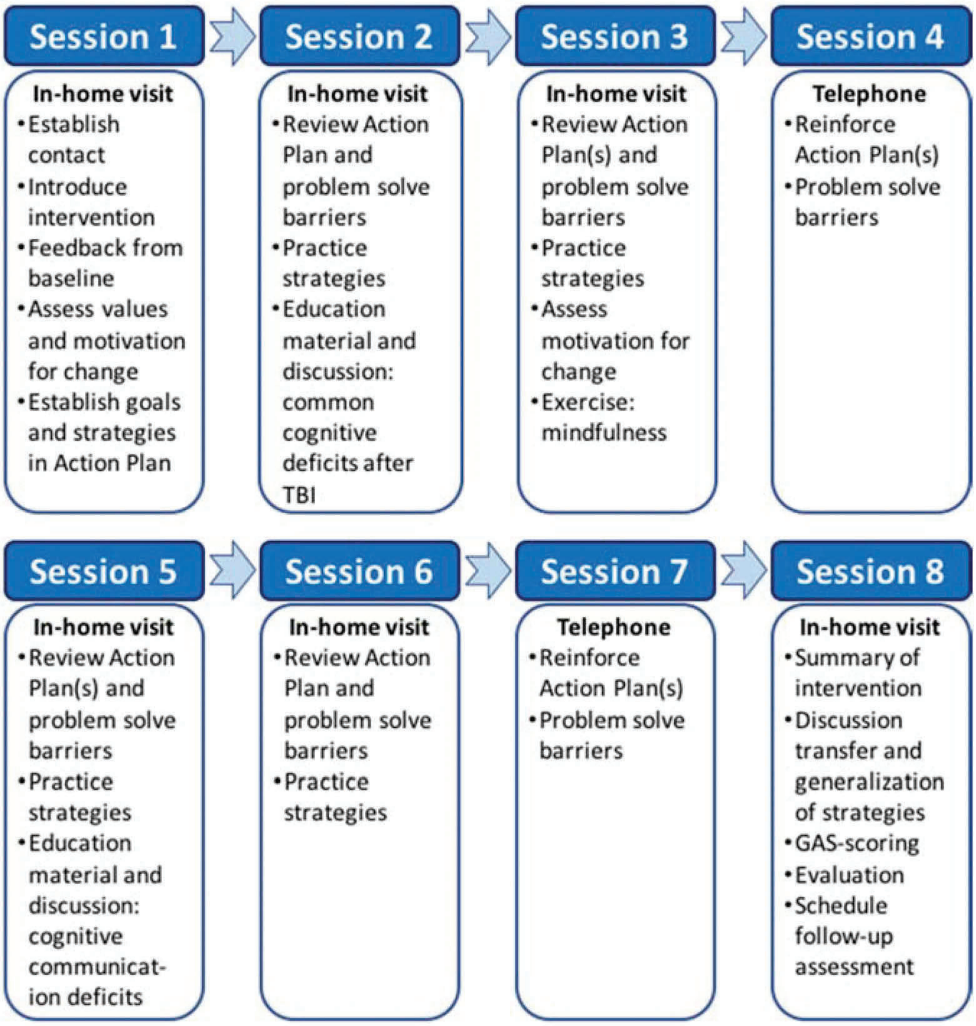

Table 2 provides information about the global outcome, neuropsychological functioning and the Target Outcomes nominated by participants.

3.2. Feasibility

3.2.1. Objective 1: recruitment and screening procedures

The recruitment phase took place in December 2017-February 2018. The same therapist screened all 19 participants, and the prepared screening form was deemed satisfactory. The consent rate was at 40% for this sample. Half of the eligible participants were not able to appoint a family member for participation, because they were single, living far away from other relatives and did not want to include friends in the study as this was seen as too high of a burden on the friendship. This was surprising, given that Winter et al. (2016) reported that only 7% of their patients were not able to include a family member. However, they recruited participants in the densely populated Philadelphia metropolitan region, and networks might be more available than in more rural Norway. We thus decided to evaluate feasibility both for patients with and without family members included. The three married participants nominated their spouses as a participating family member. All family members nominated by participants consented to participate.

3.2.2. Objective 2: baseline and follow-up assessments

Scripts to ensure reliable delivery were evaluated and judged satisfactory with only minor revisions. The baseline assessment took between 4 and 5 h, with a mean of 4.5 h and tired the participants. The burden of the neuropsychological battery was found to be high. Some of the tests were deemed redundant in that they mainly provided measures of the same cognitive functions. T2 and T3 evaluations took between 1 and 2 h for all participants, which was considered acceptable.

3.2.3. Objective 3: intervention delivery

Intervention delivery was conducted from February to June 2018. Therapists gave feedback that the intervention seemed suitable for the patient group and that both participants and family members contributed in a meaningful way to establish goals, discuss strategies and challenges to goal achievement. Five participants were able to nominate SMART-goals. However, the oldest participant displayed difficulties with collaborating in the goal-setting process, and therapists described possible signs of a progressive neurological disorder. The manual advised that the maximum number of SMART-goals should be seven, but the actual number of SMART-goals established was three for all participants. Although the manualized approach to intervention delivery was seen as ensuring treatment fidelity, therapists reported that the manual also allowed for individual adjustments that were deemed both necessary and advisable in the context of rehabilitation for the patient group. Further, therapists described the need to be more guiding in the goal establishment process for participants with more severe cognitive deficits. Table 3 displays the SMART-goals and GAS-score outcomes from session 8.

In-home visits ranged from 100 to 150 min, while phone sessions ranged from 40 to 90 min. The total travel time for in-home visits ranged from 40 to 120 min. Some strategies entailed therapists

Figure 2. Flowchart.

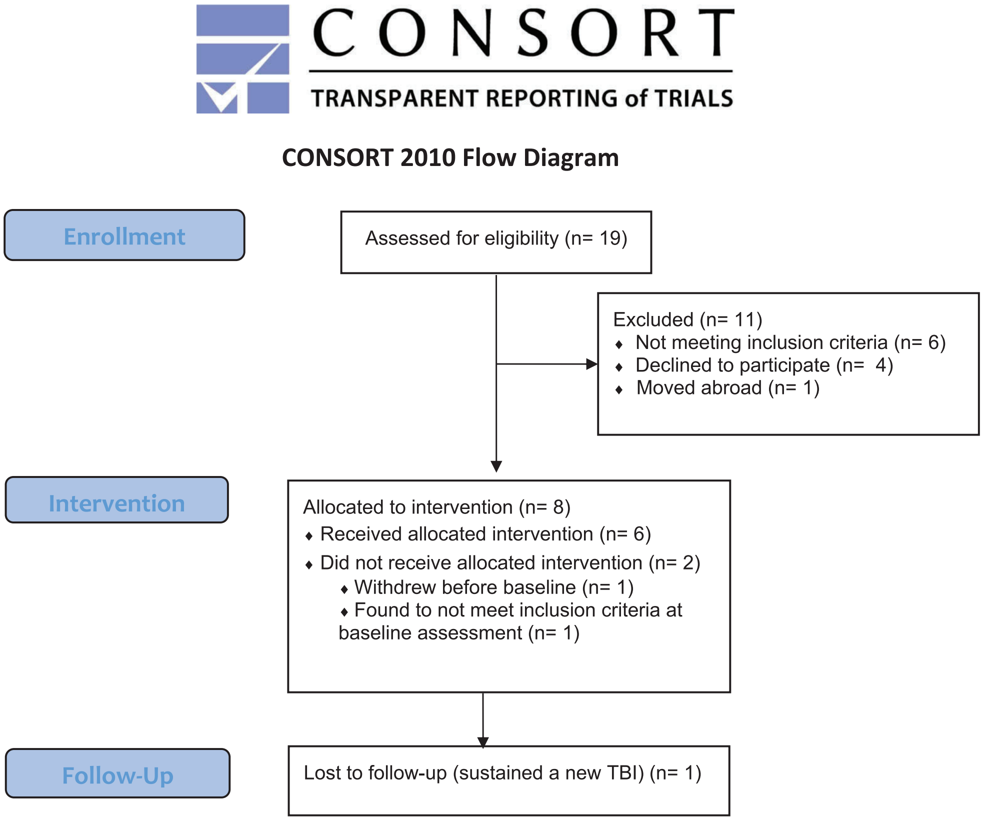

Table 2. Baseline characteristics of six participants

No.	GOSE score	Problem areas identified on the GOSE	Neuropsychological functioning	Target outcome areas
1	6*	Reduced work capacity, reduced social participation, angry outbursts toward family members and reduced memory	Reduced processing speed and executive dysfunction	1: Reduced memory 2: Reduced physical activity level 3:Angry outbursts
2	6	Reduced social participation, mood changes, depressive thoughts	Difficulties with word mobilization	1: Fatigue and dysregulated sleep 2: Depressive thoughts 3: Reduced social participation
3	6	Difficulties with emotional regulation, dizziness and problems with memory and concentration	Reduced processing speed, visual cognition and mental flexibility	1: Reduced ability to plan complex tasks 2: Reduced memory 3: Inability to handle sudden changes
4	6	Reduced work capacity, less social participation, irritability, reduced attention, headache, fatigue	Reduced verbal abstraction	1: Reduced ability to initiate tasks 2: Fatigue and sudden sleeping 3: Irritability
5	6	Reduced work capacity, double vision and reduced memory	Reduced processing speed, learning, memory, attention, mental flexibility	1: Reduced memory 2: Reduced mental flexibility 3: Reduced balance
6	6	Reduced work capacity, less social participation, angry outbursts toward family members and reduced memory	Reduced mental speed, visual attention and mental flexibility	1: Reduced attention 2: Mental and physical fatigue 3: Reduced memory

GOSE: Glasgow Outcome Scale-Extended. *GOSE 6 = Moderate Disability at an Upper Level.

being in contact with participants outside the direct contact during planned sessions, e.g., for one participant, the therapist called the participant approximately once a week to enable training on note-taking during telephone calls. None of the participants received follow-up from local health personnel at the time of inclusion. For three participants, therapists made contact with relevant health-care professionals involved in the participant's community care. One participant sustained a new TBI right before the last intervention session, which was postponed and shortened to avoid unnecessary burden for the participant, and therapists had closer contact with the family member for guidance in handling the sub-acute phase after injury to ensure proper follow up. For two participants, therapists were in contact with their labor and welfare coordinators to discuss further strategies for work training and provide necessary information about TBI.

3.2.4. Objective 4: acceptability

Participants attended 100% of all sessions; one participant did, however, postpone the last intervention session for 6 months due to unrelated health issues. Family members attended 100% of the in-home visits. Four versions of the Acceptability scale were applied; one Participant Form, one Family Member Form, one Therapist Form for the participant and one Therapist Form for the family member (see Table 2). On the Acceptability scale (ranged 0–4), higher scores reflect higher acceptability. On the Participant Form, the acceptability items of "felt bored or uninterested" and "preferred the 'old way' of doing activities" showed the highest scores among all participants (all scored 4, reversed), whereas the single item with the lowest score among participants was "opportunity to give feedback on therapist suggestions" (score range 3 to 4). The mean acceptability score for the six participants on the Participant Form was 3.58 out of the maximum score of 4. On the Therapist Form, the therapists scored the participants highest on "expressed the need for more information". The therapists scored two participants to 1 on an item related to their ability to communicate effectively with the therapist. The mean acceptability score on the Therapist Form for participants was 3.38. Mean acceptability score on the Family Member Form was 3.70, and mean score on the Therapist Form for family members was 3.57. Both family members and therapists displayed the lowest scores on the item related to the family member providing feedback to suggestions made by the therapist. The five participants who completed T3 assessment all answered yes to a question regarding if they would have participated in a similar study at a later point if asked.

3.2.5. Objective 5: order of primary and secondary outcome measures

Target Outcome severity was intended as the primary outcome measure in the future definitive RCT. For the four participants who completed their T2 assessment immediately after the end of the intervention, seven Target Outcome severity scores indicated less difficulty managing the Target Outcome, three indicated increased difficulties and two indicated no change (see Table 4). At T3, 3 severity scores were improved compared to T2, 7 were unchanged, while 2 scores were worse than at T2 and 3 scores were reverted to baseline levels. However, reduced awareness and response shift was found to be possible confounders. For example, for one participant that displayed reduced awareness, the selected Target Outcomes was rated as "a little problematic" at T1. Family member scoring of the same Target Outcomes gave indications that these low scores might be due to a lack of awareness. In addition, participants with increasing self-awareness during intervention might have reported more "appropriate" scoring of Target Outcome severity at T2 and T3 (as opposed to at T1), which then could make comparison with the T1 reporting difficult. Further, as participants were allowed to nominate SMART-goals that were unrelated to Target Outcomes from T1, this outcome measure did not seem well tailored to capture meaningful changes related to the intervention. For example, one participant reported frustration that he could not report back the significant change he had experienced with his difficulties with anger management, as he had not initially nominated this as a Target Outcome at T1.

However, most participants reported fewer problems with handling their targeted problem areas at follow-ups, with the biggest (mainly positive) change occurring from T1 to T2. Table 4 and Table 5 displays scores on outcome measures for all participants. TBI-related and depressive symptoms as well as participation tended to show favorable outcomes at T2, but tended to revert at T3. Functional competency, quality of life and Target Outcomes, on the other hand, appeared to depict a positive change that kept up at T3. As previously stated, the intention of this trial was not to evaluate the effectiveness of the intervention due to small sample size. However, it will be important to evaluate both immediate effectiveness and how the changes are maintained over time in the future definitive RCT.

3.3. Harms

No harms or unintended effects were reported.

4. Discussion

The intervention was found to be overall feasible in a population of severe TBI. Nevertheless, we discovered several elements in need of amendments.

4.1. Recruitment and screening procedures

The screening form was considered satisfactory for the future RCT. The consent rate in this sample was 40%, which is in line with the percentage reporting unmet needs for rehabilitation in the chronic phase of TBI (Andelic et al., 2009).

Table 3. SMART-goals and GAS-score outcomes for each participant

No.	SMART-goal #1	GAS-score #1[A]	SMART-goal #2	GAS-score #2[A]	SMART-goal #3	GAS-score #3[A]
1	Remembering appointments in everyday life	+1	Gain control over frustration and irritability in everyday life	+1	Stabilize mood in everyday life	+1
2	Increase communication skills during conflicts within the family	+2	Manage stress better in everyday life	0	Increased social contact outside core family network	+2
3	Plan execution of complex tasks before initiating the task	−2[B]	Gain overview of daily activities	−2[B]	Control anger when interrupted while completing task	−2[B]
4	Increased structure in everyday tasks and initiate planned tasks	+1	Stabilize circadian rhythm and increased quality of sleep	+1	Experience everyday life as more meaningful	+2
5	Remember more of what has happened during the day	+2	Immediately write down important messages and information during phone calls	+1	Increased social contact	0
6	Register and stop irritability before having an angry outburst	+2	Increased participation and sense of accomplishment during social activities	+1	Register and cope with negative emotions	+2

Possible GAS-scores: −2 = much less than expected, −1 = somewhat less than expected, 0 = expected level, +1 = somewhat more than expected, +2 = much more than expected. [A]Outcome at session 8. [B]Participant sustained a new TBI before session 8 and experienced increased difficulties in all problem areas with SMART-goals and GAS.

Screening revealed that several participants were unable to nominate a family member for participation to the study. Further, these individuals reported high motivation for participation and stated a clear need for rehabilitation. The feasibility trial enabled evaluating the intervention delivery for these participants as well. Therapists reported that the intervention delivery was feasible without a family member. Moreover, participants without family members showed comparable goal attainment and acceptability scores to those who had family members participating in this sample. Based on these results, a consensus was reached that the intervention is feasible without the family member participation, and that future participants without family members should be included. At the same time, family member participation was found beneficial, so inclusion of family members is recommended if available in the future definitive RCT.

Due to an increased risk for neurodegenerative disorders confounding outcome with higher age, an age limit was discussed and deemed appropriate. An upper limit of 72 years was thus set for the future definitive RCT, an age which corresponds with the retirement age in Norway. Furthermore, the lower age limit was redefined as to ensure that the TBI occurred after the age of 16, thus excluding pediatric TBIs.

4.2. Baseline and follow-up assessments

Baseline assessment posed a burden on participants and needed reduction. The IQ-estimate was considered less important than providing information regarding specific cognitive deficits, as this is relevant to tailored treatment planning. Also, several neuropsychological measures seemed to address the same functional areas. This battery was thus abbreviated, removing four of the nine tests (Vocabulary, Block Design, Coding and Symbol Search from the WAIS-IV). Similarities and Matrix reasoning were kept in order to have a general idea of level of abstract thinking. A measure of attention was deemed lacking and relevant for the population, and the Digit Span from the WAIS-IV was added.

A decision was made that the SF-36 should be replaced by Quality of Life after Brain Injury Overall Scale (QOLIBRI-OS; von Steinbuechel et al., 2012) and EQ-5D (Brooks, 1996). These measures are both shorter and easier to complete for the participants, which further decreases the participant burden. Moreover, these instruments have the added benefit of providing a diagnosis-specific measure of the quality of life; they have been more newly developed and are considered to have good validity and reliability (Janssen et al., 2013; von Steinbuechel, 2014; von Steinbuechel et al., 2016).

4.3. Intervention delivery

The translated and adapted manual was deemed satisfactory with minor revisions. The manual allows for individualized sessions, but includes suggested scripts that are optional. This approach was deemed clinically sound, as the level of cognitive function among the participants varied widely. Therapist burden is considered high in this study, taking into account time to travel, time spent during home visits and time spent planning sessions, contacting local professionals and participating in consensus meetings for supervision. Furthermore, the burden related to travel time will increase in the future definitive RCT as the geographical area covered in the current study was restricted to <1-h travel each way. The geographical area supported in the RCT will be larger, with travel times up to 4 h each way, and the feasibility trial was considered helpful in logistics planning in preparation for the RCT. Consensus meetings and group discussions of clinical challenges were deemed useful and will be continued in the RCT, in order to uphold shared clinical understandings of intervention content and maintain common prioritizations during goal setting. An interesting finding was that the prioritized goals by patients in this sample were mainly related to difficulties with cognitive, emotional and social functioning, areas shown in previous studies to be prominent after TBI, but receive less attention than, e.g.,, physical difficulties (Andelic et al., 2014). This suggests that the intervention is suitable for targeting some of the unmet needs reported in the literature in this population. To our knowledge, no comparable interventions exist in Norway. The intervention is feasible, but is also costly, as travelling time to participants results in a time-consuming intervention. Given that the future RCT provides proof of efficacy, a cost-effectiveness analysis will be performed.

4.4. Acceptability

Acceptability was high and comparable to scores in the Winter study (Winter et al 2016). Items with lower scores for both participants and family members were the ability to give feedback to therapist suggestions. This result might reflect a dilemma therapists had in balancing the need to be sensitive to feedback, while also structuring the intervention sessions in accordance with the manual and pre-defined time limit. Although therapists are encouraged to continue to be sensitive to this issue, no major changes are suggested. Lengthening intervention sessions further is not recommended, as intervention sessions >120 min were reported by therapists to be too tiring for participants.

4.5. Order of primary and secondary outcome measures

Target Outcome severity was evaluated for appropriateness as a primary outcome measure in the future definitive RCT. However, the feasibility trial demonstrated some uncertainties as to the appropriateness of retaining this measure as the sole primary outcome measure. Firstly, participants varied in how they reported Target Outcomes, i.e., both the broadness of the problem areas and evaluation of their severity. This led to some difficulties in comparing scores both within and across participants. The range of the severity scale (0–4) was considered restrictive, possibly failing to detect nuances in difficulty. Further, as described above, reduced awareness of deficits provided an additional issue during both baseline and outcome assessments. Making the decision to remove family member participation as an inclusion criterion (see above) entails that family member scores might not be provided for all participants in the future definitive RCT. Overall, it seemed prudent to replace Target Outcome severity as a primary measure, while retaining it as secondary outcome.

Table 4. Outcome scores at baseline (T1) and 4-month (T2) and 12-month (T3) assessments

Outcome measure	Participant 1			Participant 2			Participant 4			Participant 5			Participant 6		
	T1	T2	T3	T1	T2	T3	T1	T2[2]	T3	T1	T2	T3	T1	T2	T3
Target Outcome #1 severity (0–4, best-worst)	1	2	1	2	1	2	4	1	1	1	1	1	2	1	1
Target Outcome #2 severity (0–4, best-worst)	1	2	0	3	1	2	4	1	1	3	1	2	2	1	1
Target Outcome #3 severity (0–4, best-worst)	3	1	1	1	1	2	2	1	2	2	1	1	2	3	2
RPQ Sumscore (0–64, best-worst)	14	0[1]	14	22	16	20	27	7	31	14	4	10	33	29	26
PHQ-9 Sumscore (0–27, best-worst)	5	6	3	12	5	8	11	2	7	1	1	1	11	7	10
PCRS Participant Sumscore (0–150, worst-best)	108	114	126	125	117	123	118	128	125	127	128	132	106	108	113
PART-O total mean score (0–5, worst-best)	1.85	2.23	2.41	2.54	2.42	2.39	1.96	2.08	2.04	0.91	1.40	0.96	1,83	1,84	1.72

Possible Target Outcome severity scores: 0 = not at all, 1 = slightly, 2 = moderately, 3 = quite a bit, 4 = extremely. [1]We have reason to believe that these responses on Rivermead were not valid due to a misunderstanding while filling out this questionnaire. [2] The participant delayed the last intervention session and completed the outcome measures from T2 8 months after inclusion. PART-O = Participation with Recombined Tools-Objectives, PCRS = Patient Competency Rating Scale, PHQ-9 = Patient Health Questionnaire 9 items, RPQ = Rivermead Post-concussion Symptoms Questionnaire.

Table 5. SF-36 subscale scores for all participants at T1, and T3

SF-36 subscale scores[1]	Participant 1			Participant 2			Participant 4			Participant 5			Participant 6		
	T1	T2	T3	T1	T2	T3	T1	T2[2]	T3	T1	T2	T3	T1	T2	T3
Physical functioning	85	90	95	100	95	100	90	95	95	85	90	95	80	90	95
Role physical	0	0	50	100	100	100	0	100	100	75	100	100	75	25	100
Bodily pain	41	52	41	100	100	100	12	72	72	100	100	100	41	51	52
General health	60	65	72	72	92	97	27	82	52	62	85	90	65	57	47
Vitality	45	50	50	45	65	55	15	80	60	55	65	60	40	50	50
Social functioning	50	75	87.5	87.5	75	62.5	0	100	100	100	100	100	50	50	75
Role emotional	33.3	33.3	66.6	66.6	100	66.6	100	100	100	100	100	100	66.6	100	100
Mental health	68	68	72	60	76	60	40	96	80	84	88	80	68	76	72

[1] All subscales are transformed scores and range from 0 to 100 (worst-best). [2] The participant delayed the last intervention session and completed the outcome measures from T2 at 8 months after inclusion.

Reduced quality of life and participation are commonly reported problem areas in the chronic phase of TBI. Early rehabilitation seldom targets these areas, but interventions delivered in the chronic phase should entail targeting these important areas. Thus, measures of quality of life (QOLIBRI and EQ-5D) and participation (PART-O) were chosen as primary outcomes for the future definitive RCT. These are included as common data elements (CDE) recommendations for TBI outcomes and are considered methodologically strong (Maas, Harrison-Felix, & Menon et al., 2010; Wilde et al., 2010).

During analysis of feasibility data, researchers were alerted to a possible bias in assessment of mental health, as only depressive symptomatology was being assessed, not anxiety. After TBI, the risk of depression is higher than in the average population, but so is the risk for anxiety-related disorders (Sigurdardottir, Andelic, Roe, & Schanke, 2013). Symptoms of anxiety were also detected during intervention delivery for several participants, and the Generalized Anxiety Disorder seven-item (GAD-7; Spitzer, Kroenke, Williams, & Lowe, 2006) was thus added to the protocol. This 7-item questionnaire is unlikely to increase participant burden noticeably.

4.6. Limitations

The current feasibility trial has several limitations. Firstly, it only included six participants. Secondly, the sample for this trial was rather selective, and generalizability might thus be limited.

5. Conclusion

The present home-based rehabilitation program was feasible with civilian persons having sustained a TBI in Norway. Participants reported high acceptability and the process of setting SMART-goals and Goal Attainment Scaling was deemed suitable, feasible and acceptable. The feasibility trial led to important amendments to inclusion criteria, baseline assessment and outcome measures that were adapted before the RCT study commenced. The RCT study started recruitment in June 2018.

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Competing Interests
The authors declare no competing interest.

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Protocol
Protocol for the future definitive RCT study has been submitted to the journal Trials. The protocol is registered at ClinicalTrials.gov NCT03545594. Protocol for the feasibility study is available by contacting the first author.

Authors' Contributions
CR, ML, and SS are senior researchers in the project and developed the design of the feasibility trial based on LW's research and with her collaboration. IMHB is a doctoral fellow, while MVF, SH and IK are post-doctoral fellows in this project and they have piloted all procedures and contributed to the final study design and methods. All authors helped draft the manuscript and consent to publication. All authors read and approved the final manuscript.

Ethical Approval
The study has been presented to the Norwegian Regional Committee for Medical and Health Research Ethics (REK) (REK number 2017/1081) and approved by the Data Protection Office at OUH (2017/10390). The project will be conducted according to the ethical guidelines of the Helsinki declaration. Information about the study will be presented to the participants in written and oral form. Written informed consent will be obtained, and the right to withdraw from the project at any time without any explanation necessary will be emphasized. All participants will be assigned an identification number, and all the questionnaires and datasets will

be anonymized. Only the project team will have access to the document that links study identifiers with participant names.

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Trials

STUDY PROTOCOL Open Access

Traumatic brain injury—needs and treatment options in the chronic phase: Study protocol for a randomized controlled community-based intervention

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Abstract

Background: Traumatic brain injury (TBI) is often associated with life-long medical, cognitive, emotional, and behavioral changes. Although long-lasting disabilities are expected, research on effective treatment options in the chronic phase of TBI is scarce.

Methods/design: This study protocol describes a randomized controlled trial (RCT) aimed at evaluating the effectiveness of a goal-oriented and community-based intervention for increasing community integration, quality of life, and functional independence in the chronic phase of complicated mild to severe TBI. Participants will be recruited from Oslo University Hospital, Norway. Patients aged 18–72 years living at home with MRI/CT-verified intracranial abnormalities, a TBI diagnosis, a time since injury of ≥ 2 years, and who experience either current TBI-related problems or restrictions in community integration will be included. The 120 participants will be randomized 1:1 to either (a) an intervention group, which will receive an in-home intervention program over 4 months, or (b) a control group receiving standard care in the municipalities. The intervention will consist of six home visits and two telephone contacts with a rehabilitation professional. A SMART-goal approach will be adopted to target the individual's self-reported TBI difficulties in everyday life. Primary outcomes will be self-reported quality of life and participation. Secondary outcomes include symptom burden, emotional functioning, and clinician-assessed global outcome and need for rehabilitation services. Outcomes will be evaluated at baseline and 4–5 and 12 months after baseline. Caregiver burden and general health will be assessed in participating family members. Goal attainment and acceptability will be evaluated in the intervention group. A process evaluation will be carried out to evaluate protocol adherence, and a cost-effectiveness analysis will be applied if the intervention is found to be effective.

(Continued on next page)

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(Continued from previous page)

Discussion: The current study provides an innovative approach to rehabilitation in the chronic phase of TBI evaluated using an RCT design that may inform treatment planning, health policies, and coordination of patient care. Further, the study may demonstrate new modes of establishing collaboration and knowledge transition between specialized rehabilitation facilities and local rehabilitation services that may improve patient outcomes.

Trial registration: ClinicalTrials.gov, NCT03545594. Registered on June 4th, 2018.

Keywords: Brain injury, In-home rehabilitation, Community-based rehabilitation, Chronic phase, Health-care services, Outcome measures

Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

Title {1}	Traumatic brain injury: needs and treatment options in the chronic phase. Study protocol for a randomized controlled community-based intervention.
Trial registration {2a and 2b}.	ClinicalTrials.gov, NCT03545594. Registered on June 4th, 2018. https://clinicaltrials.gov/ct2/show/NCT03545594
Protocol version {3}	07/02/2020, version 3.0.
Funding {4}	The project is funded by the Research Council of Norway, project number 260673/H10.
Author details {5a}	[1]Department of Physical Medicine and Rehabilitation, Oslo University Hospital, Norway. [2]Department of Psychology, Faculty of Social Sciences, University of Oslo, Norway. [3]Institute of Clinical Medicine, Faculty of Medicine, University of Oslo, Norway. [4]Department of Research, Sunnaas Rehabilitation Hospital, Nesoddtangen, Norway. [5]Center for Habilitation and Rehabilitation Models and Services (CHARM), Institute of Health and Society, University of Oslo, Norway. [6] Faculty of Health Sciences, Oslo Metropolitan University. [7]Department of Health Sciences in Gjøvik, Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology. [8]Philadelphia Research and Education Foundation. [9]Nursing Service, Department of Veterans Affairs Medical Center, Philadelphia, PA, USA
Name and contact information for the trial sponsor {5b}	Not applicable.
Role of sponsor {5c}	Not applicable.

Background

Rationale {6a}

Traumatic brain injury (TBI) is associated with lifelong medical, cognitive, emotional, and behavioral changes and is a leading cause of death and disability worldwide [1, 2]. An estimated 3.17 million people in the United States alone are living with TBI-related disabilities [3], and estimates for the European Union are approximately 7.7 million individuals [4, 5]. Research has demonstrated persistent difficulties in areas including cognitive, vocational, and emotional functioning, as well as reduced quality of life and community integration at both 3–5 [6–10] and 10 years' post-injury [11–14]. Some experts have argued that TBI should be thought of as a chronic disease process, indicating that a long-term perspective is necessary when planning and providing health-care services for individuals with TBI [15, 16].

Although a large knowledge base exists regarding treatment in the acute and sub-acute phases of TBI [17–20], we are still in the early stages of bringing rehabilitation programs closer to community services and in providing the needed rehabilitation in the chronic phase. Reports from user organizations point towards a major dilemma in TBI treatment, in that extensive medical treatment is provided only in the early phases, after which many patients feel that they are left to deal with chronic adversity on their own [21]. A Norwegian study showed that 5 years after moderate to severe TBI, approximately one-third of the individuals reported their self-perceived health-care needs were unmet [22]. Further, services offered in the chronic phase most often target physical functioning, whereas needs related to cognitive, emotional, and vocational difficulties are more often unmet [9, 23–26]. Despite these trends in service delivery, several studies have documented the efficacy of rehabilitation programs aimed at remediation of specific domains, such as memory, attention, and executive and emotional functioning [19, 27].

Following TBI, there is a need to consider the patient's functioning and goals with an ecological perspective in the community, as impaired functional competency and restrictions in participation are more visible in the patient's living and social environments than in clinical settings. The patient's self-defined problems and goals of care should be targets of intervention. These individual preferences, in addition to environmental support from the family and social networks, must be aligned in order to improve treatment relevance, motivation, and adherence [28]. Furthermore, the living environment should be a target for intervention to match the patient's level of competency if needed [29]. The role of the home environment in everyday function and well-being is based on Lewin's person–environment fit concept [30], which concerns the interaction between personal competence and environmental press (i.e., the demands from the environment that support or challenge performance of daily activities). A good fit between the person's competence and environmental press results in optimal outcomes—positive affect and adaptive behavior. When an individual's competence is impaired (as with chronic TBI), the range of acceptable environmental press becomes narrower. Because environment forces may either support or create a barrier to positive outcomes, the home environment should be targeted for intervention. Despite this, health-care and social-support services are rarely individually tailored or delivered in the patient's home environment, and high quality controlled studies targeting the effects of community-based rehabilitation are scarce [31, 32]. Further, although rehabilitation services in the acute and sub-acute phase are often delivered in a specialized rehabilitation setting, rehabilitation services in the chronic phase are typically delivered by primary health-care professionals. The World Health Organization's 2030 rehabilitation strategy [33] encourages a strong cooperation between different levels of health care to ensure effective and more integrated rehabilitation services for users. Systematic knowledge transition from specialized rehabilitation services to the primary-care services is considered essential to ensure coherency in rehabilitation services provided in different phases of TBI.

Hence, the current study aims to evaluate an in-home rehabilitation program tailored to the individual's TBI-related difficulties in the chronic phase. This randomized controlled trial (RCT) was inspired by a home-based rehabilitation study by Winter et al. that included 81 veterans with TBI in a two-group RCT [29]. While the control group received treatment as usual (TAU), the intervention group followed an eight-session, home-based rehabilitation program delivered in the veterans' homes and in close collaboration with a family member. The intervention was person-centered, focusing on targeted activity problems identified by the veterans, and used an action plan that included goals and tailored strategies to fit the individual's physical and social environments. Their study documented the efficacy of the in-home program guided by the person–environmental fit model and showed significantly higher community reintegration and less difficulty managing targeted problems in the treatment group, compared with controls. However, since the study only included military veterans with TBI, the authors emphasized the need for replication with civilians. Almost 70% of participants in Winter et al.'s study had mild TBI, and additional investigation is needed in larger populations, including individuals with moderate-to-severe TBI. Furthermore, the Winter et al. study did not include long-term follow-up or process or cost-effectiveness evaluations. Finally, health-care delivery and social-security systems, as well as culture, differ between countries. For instance, Norway is a welfare state with a public health-care system and may not be comparable to the US veteran system. Hence, the study protocol by Winter et al. was adapted according to cultural issues and differences in the target population. The aim of the current study is to evaluate a community-based, individualized, and goal-oriented intervention targeting civilians with complicated mild to severe TBI in Norway.

Objectives {7}

Our specific hypotheses are:

> H1: Person-centered intervention targeting the participant's problems in functioning in their living environment will result in improved quality of life and participation compared with treatment as usual (TAU).
> H2: Person-centered intervention will result in a lower burden of self-reported TBI-related problems compared with TAU.
> H3: Person-centered intervention will result in improved physical and mental health compared with TAU.
> H4: Person-centered intervention will result in fewer unmet health-care needs compared with TAU.
> H5: Person-centered intervention will be a cost-effective alternative compared with TAU.
> H6: Patients, family members, and rehabilitation professionals involved will be satisfied with the intervention program.

Trial design {8}

The study is a two-group RCT with a mixed-methods design. Figure 1 displays standard protocol items according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [34, 35]. Potentially eligible participants will be invited by letter and screened by phone for inclusion and exclusion criteria. A baseline

		STUDY PERIOD				
	Enrollment	**Baseline assessment**	**Allocation**	**Intervention**	**Outcome assessment**	
TIMEPOINT		***T1 minimum 2 years post injury***			***T2 immediately following in-home intervention (4 months after T1)***	***T3 8 months following in-home intervention (12 months after T1)***
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation			X			
INTERVENTIONS:						
In-home intervention				X		
Treatment as usual				X		
ASSESSMENTS:						
Primary outcome measures *(TBI-related quality of life, participation)*		X			X	X
Secondary outcome measures *(target outcome severity, TBI-related symptoms, physical and mental health, global outcome, received health care services)*		X			X	X
Other measures *(neuropsychological tests, self-reported executive functioning)*		X				
Determination of costs		X			X	X

Fig. 1 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)

assessment (T1) will be conducted using measures of cognitive, emotional, and physical functioning as well as functional competence, participation, current use of health-care services, and main activity problems. Subsequently, participants will be randomized to intervention or TAU groups. Further assessments will be carried out 4–5 (T2) and 12 months (T3) after baseline. The timing of the T2 assessment will be aimed to correspond to the approximate end of the intervention for the intervention group. Use of health-care services will be registered and mapped according to the International Classification System for Service Organization in Health-related Rehabilitation (ICSO-R) [36] over the study period in both groups.

In line with the new Medical Research Council guidance [37], a feasibility study [38] was conducted to evaluate inclusion criteria, feasibility of intervention manual, and outcome measures, as well as acceptability. The feasibility study included six individuals with severe TBI, and intervention delivery was concluded in June 2018.

Methods/design

Study setting {9}

Oslo University hospital (OUH) is the trauma referral center in South-East Norway, serving more than half of the Norwegian population (> 2.5 mil). Assessments will be conducted at an outpatient clinic at OUH, and intervention sessions will be delivered in the participant's home. The intervention may also be delivered at the outpatient TBI clinic at OUH if requested by the participant.

Eligibility criteria {10}

The study will include patients from OUH with a TBI diagnosis and CT/MRI-verified intracranial abnormalities. Participants must be 18–72 years of age at inclusion, ≥ 16 years of age at the time of the injury, at least 2 years' post-injury at study inclusion, and living at home. The participants must report ongoing TBI-related cognitive, emotional, and/or physical problems, and/or reduced physical and mental health, and/or difficulties with participation in activities with family, friends, and/or in the community (based on interview and the standardized questionnaires at baseline). If the participants have a family member or friend closely involved in their lives, the family member/friend will be asked to participate as well. Participants with severe progressive neurologic disorders or severe psychiatric disorders that would confound outcome assessments will be excluded as well as those unable to provide informed consent or participate in a goal-setting process. Participants with insufficient fluency in Norwegian to allow for communication with therapists and outcome assessors or that have active substance abuse or violent tendencies that would put therapists at risk during home visits will also be excluded.

Patient characteristics

The following sociodemographic variables will be recorded at baseline: age, gender, marital status, living arrangement, educational level, and current employment status. Medical variables will be obtained from the medical journal and include comorbidity, injury characteristics, and clinical severity (Glasgow Coma Scale Score, length of posttraumatic amnesia), neuroimaging results, and primary rehabilitation services received. A neuropsychological test battery will be conducted at baseline (T1) to assess cognitive functioning and guide intervention strategies. The battery consists of tests of abstract reasoning (Similarities and Matrix Reasoning from the Wechsler Adult Intelligence Scale (WAIS-IV) [38]), verbal learning and memory (California Verbal Learning Test-II [39]), and attention span (Digit Span, WAIS-IV [40]) as well as processing speed, mental flexibility, and inhibition (Trail Making Tests and Color Word Interference Tests from the Delis-Kaplan Executive Function System (D-KEFS) [41]). A questionnaire regarding executive functioning in everyday living will also be administered at T1 (the Behavior Rating Inventory of Executive Function Adult Version (BRIEF-A) Self-Report [42]).

If inclusion of a family member is possible, participants will answer a short questionnaire pertaining to the quality of their relationship with their family member (adapted version of the Quality of Relationship scale used by Winter et al. [29]) and the family member will be asked to fill out the BRIEF-A Informant Form [42].

Careful consideration has been given to the selection of neuropsychological tests and questionnaires included for patient characteristics in relation to patient burden, and order of administration will be standardized and checked for missing data during administration.

Who will take informed consent? {26a}

Signed written informed consent forms will be collected from all participants and participating family members by the therapist conducting the baseline assessment.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Not applicable.

Interventions

Explanation for the choice of comparators {6b}

A comparison group receiving treatment as usual was chosen to assess whether the intervention is better or at least equivalent to current clinical practice in Norway (see "Background and rationale").

Intervention description {11a}

Patient-centered intervention The intervention is modeled after the Winter et al. study [29] and will consist of eight sessions (six in-home visits of approximately 2-h duration and two telephone contacts). The intervention will be delivered over a period of approximately 4 months and, when possible, in collaboration with a family member/friend who is involved in the participant's everyday life. An overview of the intervention sessions is displayed in Fig. 2.

To increase the proficiency of the goal-setting process, a SMART-goal approach will be used. SMART goals need to be specific, measurable, achievable, realistic/relevant, and timed [43]. Goal attainment scaling (GAS) [44] will be applied during the establishment of SMART goals to provide a quantifiable measure of goal achievement at the end of the intervention.

The intervention will be conducted in three phases: (1) identification of target problem areas (target outcomes) that disrupt activities of everyday life; (2) establishment of SMART-goals and GAS; and (3) development of an action plan containing evidence-based strategies to mitigate the reported problems, including environmental modifications and compensatory strategies. The intervention sessions will include strategy training, identification of obstacles to goal achievement, and guidance in generalization and transferability of new skills. The manual provides a framework for the intervention; however, the specific content of the action plan will be highly

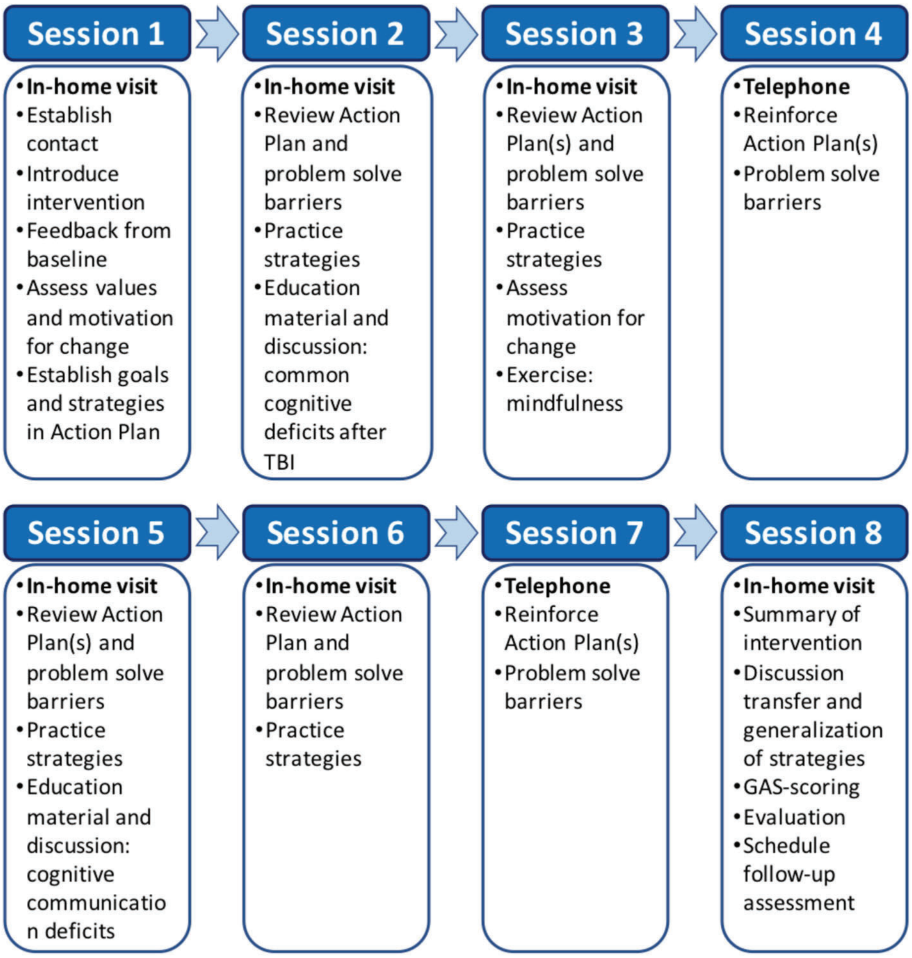


Fig. 2 Overview of intervention sessions

individualized, as it is based on problem areas nominated by the participant.

Based on the most commonly occurring long-term symptoms after moderate-to-severe TBI [8–14, 23] in addition to the experiences of Winter et al. [29] and our feasibility study, target outcomes and defined SMART goals are expected to be related to the following: cognitive (e.g., memory, attention, executive functioning, self-awareness, and social communication); physical (e.g., sensory and motor deficits, fatigue, dizziness, sleep disorders, reduced balance, and visual problems); emotional (e.g., anxiety or depressive symptoms secondary to injury, and stress management); and interpersonal problems (e.g., reduced awareness of deficits, personality changes, disinhibited behavior, apathy, and irritability). To ensure high-quality interventions, the study will include components from evidence-based treatment programs within relevant functional domains, enabling the adaptation of specialized rehabilitation programs to the home setting. Interventions in the areas of memory, attention, executive functioning, symptom awareness, and social communication will be provided according to recommendations by the Cognitive Rehabilitation Task Force [27] and the INCOG Guidelines for Cognitive Rehabilitation following TBI [45–48], as well as the recommendations by the American Congress of Rehabilitation Medicine [49]. Muscle relaxation and mindfulness techniques will be used to address problems with stress management. Regarding symptoms of anxiety and depression, techniques derived from cognitive behavioral therapy [50] and behavior activation [51] will comprise the main theoretical approaches, although an eclectic stance will be taken (e.g., in cases when threats to identity and self-concept are seen to be more readily addressed using other therapeutic approaches) [52–55]. All participants will be provided with hand-out materials and psychoeducation concerning common cognitive impairments in the chronic phase of TBI, cognitive communication difficulties, and an introduction to mindfulness exercises as a stress management technique.

When relevant and feasible, family members or local health professionals who are involved in the care of the participants will be invited to participate during the intervention sessions. At baseline assessment, participants can nominate their primary local health-care professional to join the intervention sessions if they wish. For participants without a local health-care professional but considered to be in need of establishing contact with primary care services, the therapist will establish such contact in collaboration with the patient's general practitioner to ensure lasting knowledge transference.

Four therapists (a psychologist, neuropsychologist, physician, and physiotherapist) will be responsible for the delivery of the intervention.

Treatment as usual The control group will continue to receive their usual health-care and rehabilitation services provided in the municipality. In Norway, the municipalities are mainly responsible for follow-up in the chronic phase of TBI. This follow-up will potentially vary greatly depending on the needs of the individual and what municipality they live in, ranging from no follow-up to regular contact with local rehabilitation teams. The services provided for each individual in the control group will be thoroughly logged at all follow-ups to allow comparison with the intervention group regarding content, professionals involved, etc. Any concurrent treatment of this type will not be discontinued in any group due to ethical considerations.

Criteria for discontinuing or modifying allocated interventions {11b}

All therapists are trained health-care professionals and rehabilitation professionals. Any cases of adverse effects of the intervention will be discussed in the research group, and suitable actions for the participant in question will be ensured. If signs of severe psychiatric symptoms, including suicidal ideation, are detected during contact with participants, the therapist will immediately consult with senior researchers who are specialist medical doctors and psychologists. Procedures for this are part of the manual.

Strategies to improve adherence to interventions {11c}

The principal investigators in collaboration with senior TBI researchers will supervise the therapists. Further, senior researchers will evaluate treatment fidelity by attending 10% of all in-home visits and will attempt to detect and alert to possible bias reflecting therapists' professional backgrounds. Any need for adjustments in the protocol will be discussed and resolved in project meetings throughout the project period.

Relevant concomitant care permitted or prohibited during the trial {11d}

Participants will not be withdrawn from any concurrent treatment during the trial.

Provisions for post-trial care {30}

Need for further follow-up will be evaluated in the control group after the end of the trial, and they will be referred and treated accordingly.

Outcomes {12}

The primary outcome measures are measures of participation (PART-O) [56] and TBI-specific quality of life (QOLIBRI) [57]. Secondary outcomes include the severity of target problem areas (target outcomes), goal attainment, need for rehabilitation services, global outcome, symptom burden, physical and mental health, self-awareness, and satisfaction with the intervention. All outcome measures will be administered at all time points (T1–T3), and order of administration will be standardized. Table 1 provides a list of all instruments that will be used as outcome measures, including references to their psychometric properties. To assess goal achievement and satisfaction with the intervention, two measures (acceptability-scale and GAS scores) can only be measured in the intervention group. Although comparison with the control group is not possible on these measures, they will still provide important information regarding goal attainment and treatment acceptability. The selection of outcome measures has been thoroughly planned according to patient and family member acceptability and time needed for completion.

Participant timeline {13}

A study flowchart is provided in Fig. 3.

Sample size {14}

Sample size calculations were conducted using G*Power [71]. The sample size calculation was based on a power of 0.8 and a p value of 0.025 as there are two primary outcomes. Two-sided t-tests were used as the basis for the analysis, and a meaningful group difference of 12% for QOLIBRI (pooled SD 20%), and a difference of 1.8 for the Part-O (pooled SD 3), were assumed. With this, 54 patients would be required in each group. With an assumed attrition rate of 10% at T3, 60 participants will be included in each intervention arm.

Recruitment {15}

Potentially eligible participants will be invited by letter and screened by phone for inclusion and exclusion criteria. Eligibility will be confirmed at baseline assessment before participants are randomized. Potential participants will be recruited from previous research studies conducted at OUH and, if necessary, from the outpatient TBI department at OUH and Sunnaas Rehabilitation Hospital to reach the target sample size.

Table 1 Outcome measures

Outcome measure	Measures
Primary outcome measures	
Participation	Participation Assessment with Recombined Tools- Objective (PART-O) [56, 58]
Quality of life	Quality of Life After Brain Injury (QOLIBRI) Overall Scale [57, 59]
Secondary outcome measures	
Individually identified target functional domains and their severity	Target outcomes and their severity, as rated on a Likert scale from 0 to 4 (0 = not difficult at all, 4 = extremely difficult), based on Winter et al. [29]
Goal achievement*	Goal Attainment Scaling (GAS) [44]
Symptom burden	Rivermead Post-Concussion Questionnaire (RPQ) [60]
Needs for rehabilitation and social support	Needs and Provision Complexity Scale-Clinician version [61, 62]
Global outcome	Glasgow Outcome Scale-Extended (GOSE) [63, 64]
Emotional functioning (depressive and anxiety symptoms)	Patients Health Questionnaire (PHQ-9) [65] Generalized Anxiety Disorder (GAD-7) scale [66]
Physical and mental health and quality-adjusted life years (QALYs)	EQ-5D [67]
Competency in daily activities	Patient Competency Rating Scale (PCRS) Patient Form [68, 69]
Acceptability of intervention assessed by patient, family member and health professional*	Acceptability Scale (Scale used by Winter et al., adapted and translated into Norwegian) [29]
Family member outcomes	
Participant's competency in daily activities, participant's self-awareness	PCRS Relative Form [68, 69]
Caregiver burden	Caregiver Burden Scale [70]
Family member depressive symptoms	PHQ-9 [65]
Family member general health	EQ-5D VAS-scale (0 = worst health possible, 100 = best health possible) [67]

* Only assessed in the intervention group

Assignment of interventions: allocation

Sequence generation {16a}

Participants will be randomly allocated in a 1:1 ratio to either group. A web-based block randomization will be generated by an independent statistician prior to trial start-up to ensure randomization and complete allocation concealment. Variable block size (generated by Stata version 15) will be applied.

Concealment mechanism {16b}

The allocation sequence will be stored in a database that can only be accessed by the study principal investigator (PI). Neither the therapists assigning participants to randomization nor the outcome assessors have access to this data base. The PI can only access the numbers sequentially.

Implementation {16c}

Eligible patients will be identified by the study PI (author CR) from previous studies and the outpatient clinic at OUH. After an initial gross screening by the study PI, further recruitment is performed by the four therapists delivering the intervention. The therapist will assign a randomization number that is different from the study ID number. The randomization number will be sent by web to the study PI who will access the randomization list generated by the statistician to provide information about the allocation and report that to the therapist.

Assignment of interventions: Blinding

Who will be blinded {17a}

Blinding of the participants and therapists is not possible; however, the outcome assessments at T2 and T3 will be conducted by independent assessors blinded to participants' group assignment. Researcher blinding during statistical analyses will be achieved by reassigning participant ID numbers. To further ensure blinding, an independent researcher will run the main analyses regarding between-group effects.

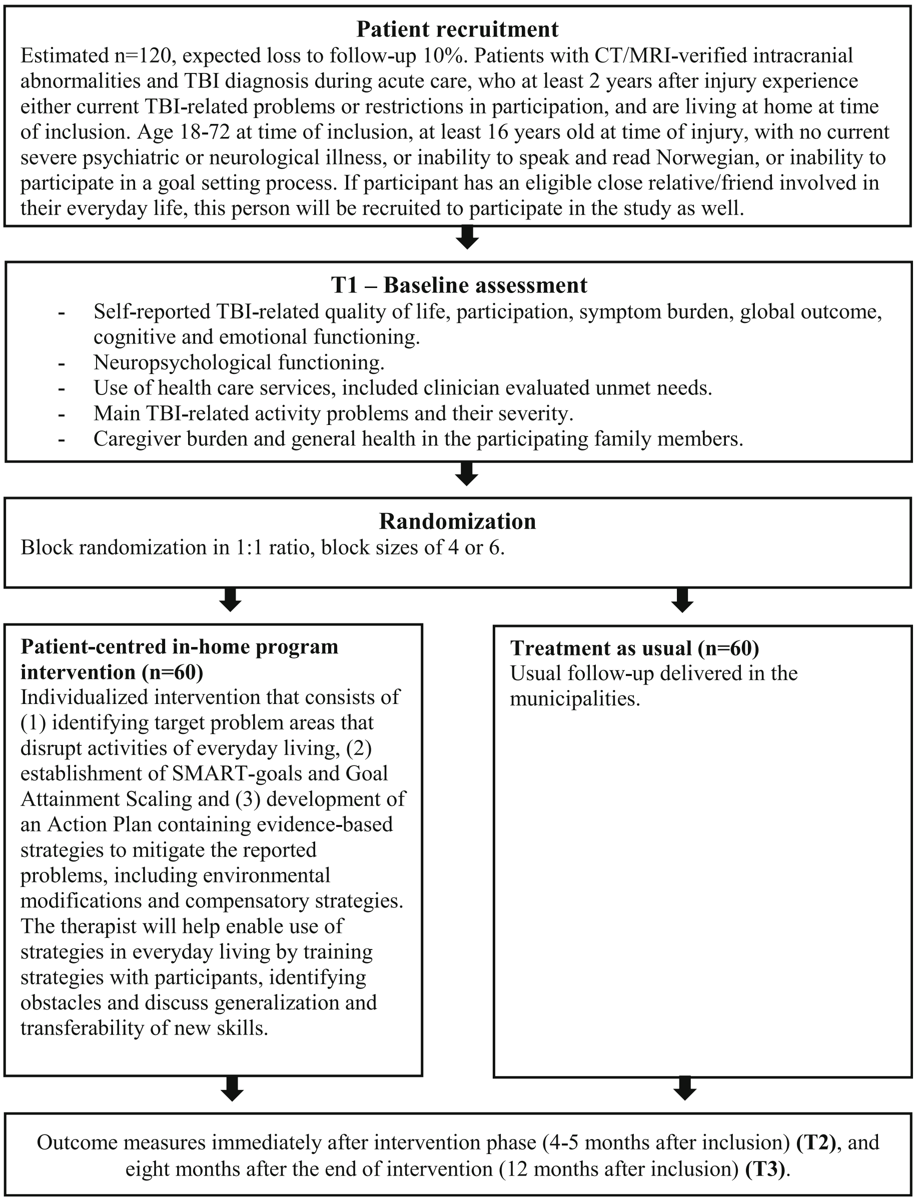
Procedure for unblinding if needed {17b}

There is no need for unblinding procedures in this trial.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Outcome assessors will be trained in the administration of all outcome measures. The estimated time for completion of the data collection is 3–5 h for T1 and 1–2 h for T2 and T3. Most questionnaires and semi-



Patient recruitment

Estimated n=120, expected loss to follow-up 10%. Patients with CT/MRI-verified intracranial abnormalities and TBI diagnosis during acute care, who at least 2 years after injury experience either current TBI-related problems or restrictions in participation, and are living at home at time of inclusion. Age 18-72 at time of inclusion, at least 16 years old at time of injury, with no current severe psychiatric or neurological illness, or inability to speak and read Norwegian, or inability to participate in a goal setting process. If participant has an eligible close relative/friend involved in their everyday life, this person will be recruited to participate in the study as well.

T1 – Baseline assessment

- Self-reported TBI-related quality of life, participation, symptom burden, global outcome, cognitive and emotional functioning.
- Neuropsychological functioning.
- Use of health care services, included clinician evaluated unmet needs.
- Main TBI-related activity problems and their severity.
- Caregiver burden and general health in the participating family members.

Randomization

Block randomization in 1:1 ratio, block sizes of 4 or 6.

Patient-centred in-home program intervention (n=60)

Individualized intervention that consists of (1) identifying target problem areas that disrupt activities of everyday living, (2) establishment of SMART-goals and Goal Attainment Scaling and (3) development of an Action Plan containing evidence-based strategies to mitigate the reported problems, including environmental modifications and compensatory strategies. The therapist will help enable use of strategies in everyday living by training strategies with participants, identifying obstacles and discuss generalization and transferability of new skills.

Treatment as usual (n=60)

Usual follow-up delivered in the municipalities.

Outcome measures immediately after intervention phase (4-5 months after inclusion) **(T2)**, and eight months after the end of intervention (12 months after inclusion) **(T3)**.

Fig. 3 Study flowchart

structured interviews used have been translated into Norwegian and validated in previous studies, with a few exceptions. The NPCS is currently being validated in Norwegian conditions. The acceptability scale and Quality of Relationships scale from Winter et al. were translated into Norwegian by our research group and have not yet been validated. Likewise, the Veteran's In-home Programme Manual developed by Winter et al. was translated into Norwegian and adjusted to the Norwegian setting. The translated manual was evaluated in a feasibility study in which all sessions where conducted by two of the therapists together, ensuring adherence to the manual and reliability as well as identifying necessary adjustments to the Norwegian version before recruitment for the RCT.

Plans to promote participant retention and complete follow-up {18b}

One specific researcher has been assigned administrative responsibility for follow-up of all participants to ensure adherence to planned timing of follow-ups (T1, T2, and T3) in both the treatment and control group to ensure call-backs. Any deviation from the standard timing of outcome assessments due to practical or other reasons will be discussed in the study group.

Data management {19}

All data material will be recorded with a participant ID and will be unidentifiable, and only the researchers working in the project group will have access to lists that link participant numbers with names. De-identified data will be electronically stored on the research server at OUH and will be deleted 5 years after the project has ended. The final dataset will be available to researchers actively contributing to statistical analyses and publications. Data entry will be controlled by initial exploratory analyses, including range checks and double data entry, in order to promote data quality.

Confidentiality {27}

Information about participants will be handled by health-care professionals adhering to Norwegian law on confidentiality. Information that could contribute to breach of confidentiality will not be published without the express consent of the individuals in question. Data are stored in accordance with Norwegian Data Protection Law.

Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in this trial or future use {33}

Not applicable.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Descriptive statistics will be used to depict demographics, injury characteristics, and service delivery at baseline as well as acceptability in the intervention group.

The effect of the intervention will be assessed by linear mixed-effect models fitting the primary outcome variables to account for repeated measurements by patients. Time and time-by-treatment interaction will be used as fixed effects in these models. The linear mixed model will give estimated mean values with 97.5% confidence intervals for all time points (T1, T2, and T3) for each group. Estimates of mean between group changes from T1 to T2 and T2 to T3 will also be provided. The analysis of primary interest in establishing treatment efficacy is a time × group interaction in the direction of the intervention group improving above the levels of the control group at T3. Due to two primary outcomes, a significance level of $p < 0.025$ will be applied.

Methods for additional analyses (e.g., subgroup analyses) {20b}

Individual and treatment-related predictors for goal attainment will be assessed by multivariable regression analysis in the intervention group. Intention-to-treat analyses will be performed in all analyses adjusted for sociodemographic and service-content variables from the ICSO-R.

Process evaluation analysis

The participation rate, numbers of consultations, the direct and indirect time related to each consultation, the kinds of problems presented, completion of intervention according to protocol, and any reasons for non-compliance will be assessed. Ten percent of intervention sessions will be overseen by a senior researcher aiming to evaluate treatment fidelity. The participants in the intervention group will rate their degree of belief that the rehabilitation program will help on a scale from 1 to 10 (worst to best) during sessions 1 and 3. After completion of the intervention, the participants and family members will be asked to evaluate the intervention as well as their satisfaction (acceptability).

Health economic analysis

To determine the cost-effectiveness if the intervention proves to be effective (i.e., at least a moderate effect size on one of the primary outcomes), a statistical analysis of costs will be performed. The total costs will be calculated by adding up direct health-care costs, direct non-health costs, and indirect costs. As the distribution of costs can be skewed, differences in costs between groups will be calculated by means of bootstrapping. A cost-utility analysis will relate the difference between the intervention and control group to changes in utility. This will result in costs per quality-adjusted life years (QALY). QALYs can be derived from the EQ-5D data. Standard discounting will be performed for both costs and outcomes together with sensitivity and uncertainty analyses to gain insight into the generalizability of the economic evaluation.

Interim analyses {21b}

No interim analyses will be conducted.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Missing data will be handled by multiple imputations for all analyses except the mixed-model analyses, in which missing data will be handled by the analysis using the maximal likelihood approach under the assumption of missing at random.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

The translation and adaptation of the intervention program, as well as monitoring of the research process, were performed in close cooperation with the user organization Norwegian Association of People with

Injuries, LTN (https://www.personskadeforbundet.no). The Data Protection Office at OUH has reviewed and accepted the trial and will be consulted for any ethical considerations.

Composition of the data monitoring committee and its role and reporting structure {21a}

Because of the small size of the study and the timing of the intervention and follow-ups (4 months' intervention, assessment at 4–5 months and 12 months), we are documenting each intervention and follow-up by date and time to ensure adherence to protocol. Based on this, an external committee was deemed unnecessary.

Adverse event reporting and harms {22}

Any adverse events will be registered and reported in future publications.

Frequency and plans for auditing trial conduct {23}

Not applicable.

Plans for communicating important protocol amendments to relevant parties (e.g., trial participants, ethics committees) {25}

Important protocol modifications will be reported to the Data Protection Office at OUH and amendments will be made to the trial registry (Clinicaltrials.gov).

Dissemination plans {31a}

Trial reports and other dissemination documents will be written according to the Consolidated Standards of Reporting Trials (CONSORT) statement to facilitate transparency and critical appraisal of the trial [72]. Authorship criteria will adhere to the International Committee of Medical Journal Editors (ICMJE) recommendations [73]. Publications are planned for journals in the fields of neurology, neuropsychology, and rehabilitation. Results will further be disseminated at relevant conferences, national and international meetings, and expert forums. The results will be shared with the user organization and its members as well as policy makers as part of the renewal of rehabilitation services.

Discussion

This project is innovative in its focus on rehabilitation goals with subjective and long-term relevance to each patient and in the establishment of close collaboration between different levels of health care. The RCT design will enable the establishment of the efficacy of the intervention and, if effective, include a cost-effectiveness analysis. In addition to replicating the effectiveness of the program found by a previous study within a universal health-care system, it will provide knowledge of the suitability of the intervention in civilians living with more severe TBIs, as well as provide information about the effectiveness of the intervention 8 months following treatment. To our knowledge, this is one of the first studies to use a manualized and individualized approach to rehabilitation intervention in the chronic phase of TBI with standardized outcome measures. Hence, the study might potentially have important implications on treatment options and delivery in the chronic phase of TBI that may inform policy and treatment planning [32]. The in-home rehabilitation approach is individually tailored and not only applicable to a TBI population; thus, the findings of this study will bear relevance to other conditions involving chronic neurological deficits and have innovation potential in establishing new modes of collaboration and knowledge transition between specialized acute and post-acute neurosurgical and rehabilitation facilities and rehabilitation services in the municipalities. Users will be involved in all phases of the project, which is in line with recommendations to include users' perspectives in the development of treatment strategies [74]. The study will also contribute to increased research collaboration among universities, colleges, and primary-care services in the municipalities.

Limitations

The protocol has several limitations. The individualized nature of the intervention will make it challenging to compare across participants. As previously discussed, however, individualizing the treatment based on the participant's own goals and competency is a major strength, as it enhances motivation and ensures delivery of relevant treatment. Using the combination of target outcomes, SMART goals, and GAS further enables statistical comparisons across individualized outcomes. Blinding of therapists and participants will not be possible in this study, but outcome assessors and researchers conducting the statistical analyses will remain blinded to group allocation. A further limitation is that all main outcome measures are self-report measurements, which may pose a problem in cases of reduced self-awareness (an issue in all TBI research). However, GAS will be included as a secondary outcome measure in the intervention group, and inclusion of family members when possible will ensure comparable data to assess self-awareness. In addition, the follow-up period of 12 months includes a risk of drop-out. The therapists will be flexible with the timing of interventions and assessments to prevent participants from withdrawing from the study. In the Winter et al. study, dropouts were mainly seen in the participating family members, and a more flexible approach to family member involvement has therefore been adopted in the current study. Further, dropouts will be evaluated as part of the process evaluation.

Trial status

Protocol version 3.0. Recruitment for the RCT began in June 2018 and will continue until target sample size has been reached, estimated by the end of 2020.

Abbreviations

BRIEF-A: Behavior Rating Inventory of Executive Function Adult Version; CONSORT: Consolidated Standards of Reporting Trials; CT: Computed tomography; CVLT: California Verbal Learning Test; D-KEFS: Delis-Kaplan Executive Function Systems; GAD-7: Generalized Anxiety Disorder seven-item scale; GAS: Goal Attainment Scaling; GOS-E: Glasgow Outcome Scale-Extended; ICMJE: International Committee of Medical Journal Editors; ICSO-R: International Classification System for Service Organization in Health-related Rehabilitation; MRI: Magnetic resonance imaging; NPCS: Needs and Provision Complexity Scale; OUH: Oslo University Hospital; PART-O: Participation Assessment with Recombined Tools-Objective; PHQ-9: Patient Health Questionnaire-9; QALY: Quality-adjusted life years; RCT: Randomized controlled trial; REK: Regional Ethics Committee; RPQ: Rivermead Post-concussion Questionnaire; SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials; TAU: Treatment as usual; TBI: Traumatic brain injury; WAIS-IV: Weschler Adult Intelligence Scale-fourth edition

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Not applicable.

Authors' contributions {31b}

CR, ML, NA, SS, SH, US, HS, and MØL developed the application with a preliminary study protocol based on LW research and with her collaboration. IMHB is a doctoral fellow, while MVF, SH, and IK are post-doctoral fellows in this project and they have piloted all procedures and contributed to the final study design and methods. All authors helped draft the manuscript and consent to publication. All authors read and approved the final manuscript.

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Availability of data and materials {29}

Not applicable.

Ethics approval and consent to participate {24}

The study has been presented to the Norwegian Regional Committee for Medical and Health Research Ethics (REK; number 2017/1081) and approved by the Data Protection Office at OUH (2017/10390). The project will be conducted according to the ethics guidelines of the Helsinki declaration [75]. Signed written informed consent forms will be collected from all participants and participating family members. Individuals will be informed that their participation is voluntary and they can withdraw from the study at any time without repercussions. Participants will not be withdrawn from any concurrent treatment during the trial. All participants will be assigned an identification number, and all the questionnaires and datasets will be anonymized. Only the project team will have access to the document that links study identifiers with participant names.

Consent for publication {32}

Norwegian consent form is available upon request.

Competing interests {28}

The authors declare that they have no competing interests.

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Publisher's Note

III

J Head Trauma Rehabil

Patient-Reported Problem Areas in Chronic Traumatic Brain Injury

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Objective: The aims of this study were to (1) assess self-reported main problem areas reported by patients with traumatic brain injury (TBI) and their family members in the chronic phase, and (2) compare the self-prioritized problems with difficulties captured by questionnaires and neuropsychological screening through linking to the International Classification of Functioning, Disability and Health (ICF). **Setting:** Outpatient clinic at the Oslo University Hospital, Norway. **Participants:** In total, 120 patients with TBI were recruited, of whom, 78 had a participating family member. Eligibility criteria were a clinical TBI diagnosis with verified intracranial injury, living at home, aged 18 to 72 years, 2 years or more postinjury, and experiencing perceived TBI-related difficulties, reduced physical and mental health, or difficulties with participation in everyday life. Patients with severe psychiatric or neurological disorders or inability to participate in goal-setting processes were excluded. **Design:** Cross-sectional. **Main Measures:** Target Outcomes, that is, 3 main TBI-related problem areas reported by patients and family members, collected in a semistructured interview; standardized questionnaires of TBI-related symptoms, anxiety, depression, functioning, and health-related quality of life; neuropsychological screening battery. **Results:** Target Outcomes were related to cognitive, physical, emotional, and social difficulties. Target Outcomes were linked to 12 chapters and 112 distinct categories in the ICF, while standardized measures only covered 10 chapters and 28 categories. Some aspects of post-TBI adjustment were found to be insufficiently covered by the ICF classification, such as identity issues, lack of meaningful activities, and feeling lonely. **Conclusion:** The Target Outcomes approach is a useful assessment method in a population with chronic TBI. The standardized questionnaires capture the spectrum of problems, whereas the Target Outcomes approach captures the prioritized individual problems hindering everyday life after TBI. While the standardized measures are an irreplaceable part of the assessment, Target Outcomes ensures patient involvement and may help clinicians better tailor relevant rehabilitation efforts.

Key words: *chronic TBI*, *community-based rehabilitation*, *outcome measurement*, *Target Outcomes*, *traumatic brain injury*

TRAUMATIC BRAIN INJURY (TBI) can lead to a broad range of persistent difficulties, including deficits in physical, cognitive, emotional, and social functioning and quality of life.[1–4] While some regain preinjury levels of functioning, others live with TBI-related sequelae for many years, of whom some experience deterioration over time.[5,6] More recently, TBI has been classified as a chronic disease with lifelong and dynamic consequences for health and well-being.[7,8] Furthermore, in accordance with the International Classification of Functioning, Disability and Health (ICF)[9] model, outcomes after TBI are influenced by personal

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and environmental factors. As outcomes after TBI are heterogeneous, there is a need to identify each patient's specific difficulties and evaluate their individual rehabilitation needs.

There is a range of available measures suitable for patients with TBI, including questionnaires and performance-based tests. The use of standardized measures has many benefits, such as reliable assessment of clinically relevant symptoms, standardization across patients, access to normative data, and clinical cutoffs. Such measures are invaluable in diagnostic assessment but might not fully capture the patient's self-identified problems. Asking open-ended questions is necessary to ensure adequate measurement of prioritized TBI difficulties and individual tailoring of treatment. Furthermore, family members or others close to the patient should be asked to provide information about ongoing difficulties, especially since patients with TBI might have reduced awareness of their symptoms, and caregivers may have differing perspectives about the patients' everyday functioning. Wade[10] argued that outcomes in rehabilitation research should also aim to address activity changes evident to the individual and their families to ensure the validity and feasibility of trials. However, there is a lack of consensus on systematic ways to collect self-reported high-prioritized problem areas in rehabilitation.

Gitlin and colleagues[11] proposed that assessing improvements in patients' main problems should be used to evaluate treatment effects in patients with dementia. They used Target Outcomes, which was based on the Target Complaints approach used in psychotherapy.[12] To measure Target Outcomes, patients and family members were asked open-ended questions about their 3 main problems and then rated their difficulty in managing the problem on a 10-point Likert scale. More recently, this approach was used as the primary outcome measure in a randomized controlled trial (RCT) of home-based rehabilitation for veterans with TBI by Winter and colleagues.[13] The study showed a decrease in the difficulty of handling Target Outcomes in the intervention group. Furthermore, the Target Outcomes were categorized and showed disparities between patient and family reporting.[14] The authors concluded that the Target Outcomes approach elicited novel insights into the challenges experienced in living with chronic TBI and were a sensitive measure of change in the ability to manage these symptoms. However, they did not systematically compare the information gained in Target Outcomes with that from established standardized measures. To enhance comparability of health information, linking procedures have been developed within the framework of ICF,[15] which could be applied to analyze the conceptual content across patient-reported information and questionnaires.[16]

OBJECTIVES

An RCT inspired by the study of Winter and colleagues[13] is currently being conducted in a sample of Norwegian civilians living with chronic TBI-related difficulties. This article aims to assess the utility of Target Outcomes by describing and categorizing the prioritized problem areas reported by the patients and family members. A second aim is to compare the patient-reported problem areas with symptoms captured by standardized questionnaires and a neuropsychological screening battery to assess the utility of Target Outcomes as a supplement to established measures by linking to the ICF classification. The hypotheses were that patients and family members would report Target Outcomes related to physical, cognitive, emotional, and interpersonal domains and that patient-reported Target Outcomes would capture problem areas not covered by the standardized measures.

METHODS

This article adheres to Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for observational studies.[17] The study was approved by the Data Protection Office at Oslo University Hospital (OUH) (2017/10390).

Study design, setting, and participants

Data collection was part of a larger randomized controlled study evaluating the effectiveness of home-based rehabilitation in chronic TBI including 120 patients recruited at OUH in 2018-2020. The study protocol provides additional information regarding the study design.[18] Inclusion criteria were age 18 to 72 years, a TBI diagnosis with computed tomography/magnetic resonance imaging–verified intracranial injuries 2 or more years ago, living in a noninstitutional setting, and reporting ongoing TBI-related difficulties, including reduced physical or mental health and/or reduced participation in daily activities. Exclusion criteria were severe neurological or psychiatric illness that would confound outcome, inability to cooperate in the goal-setting process (eg, severely reduced awareness and no available collaborators), insufficient fluency in Norwegian, or ongoing violent tendencies or substance abuse that would put study personnel at risk. If the patient had a close family member or friend whom they would like to participate, this person was included. The patients and family members provided written consent. This article presents cross-sectional data collected at study inclusion (pretreatment). This baseline assessment was conducted at OUH in an outpatient setting and took approximately 4 hours. The order of administration of questionnaires,

TABLE 1 Patient characteristics ($N = 120$)

All participants (*N* = 120)	Mean (SD)/*n* (%)/ median (range)
Age, y	45.15 (14.44)
Number of men	85 (71%)
Education level	
≤10 y	10 (8%)
11-13 y	69 (58%)
14-16 y	24 (20%)
≥17 y	17 (14%)
TBI severity by GCS score[a,b]	9.3 (4.3)
Mild complicated	41 (36%)
Moderate	18 (16%)
Severe	54 (48%)
Time since injury,[c] y	4 (2-24)
Cause of injury[d]	
Transport-related accident	50 (43%)
Fall	39 (34%)
Violent incident	9 (8%)
Other (sports- or leisure-related)[e]	18 (15%)
Work status	
Full-time employment	30 (25%)
Part-time employment[f]	29 (24%)
100% disability pension	55 (46%)
Retired	6 (5%)

Abbreviations: GCS, Glasgow Coma Scale; TBI, traumatic brain injury.

[a] GCS score: mild, 13-15; moderate, 9-12; severe, 3-8.

[b] $n = 113$.

[c] $n = 119$.

[d] $n = 116$.

[e] All injury causes that could not be classified as a fall, transport-related, or violent incident were classified as "other" and included sports-related and injuries sustained during leisure activities.

[f] Part-time employment was prioritized over part-time disability, that is, most of the participants in this category also received disability benefits.

semistructured interviews, and neuropsychological assessment was standardized across patients to avoid bias.

In total, 555 potentially eligible patients identified from outpatient department records were contacted by phone to evaluate eligibility. Of these, 101 did not respond, 137 reported no needs, and 135 declined participation. Furthermore, 33 were excluded by phone screening and 15 did not attend baseline despite initial consent. At baseline, 14 were excluded according to the eligibility criteria, resulting in a final inclusion of 120 patients and 78 family members. Sample characteristics are displayed in Tables 1 and 2.

Mapping to the ICF and linking procedures

TABLE 2 Family member characteristics ($N = 78$)

Participants with family members (*N* = 78)	Median (range)/ *n* (%)
Relationship to family members	
Spouse	58 (74%)
Parent	12 (15%)
Other	8 (10%)
Family member age, y	48.5 (19-76)
Family member work status	
Employed/student	58 (74%)
100% disability pension	10 (13%)
Sick leave	2 (3%)
Applying for work	2 (3%)
Retired	5 (6%)
Homemaker	1 (1%)
Time spent with participant	
Daily contact	66 (85%)
Weekly contact	10 (13%)
Less than weekly contact	1 (1%)
Unknown	1 (1%)

To enable comparison between the patient reported main problem areas (Target Outcomes) and the standardized questionnaires and neuropsychological assessment (aim 2), we mapped the information to the ICF. We used the components "body functions" and "activities and participation" and second to fourth levels for more specified information (see Figure 1 for an overview of the ICF framework). This was done in accordance with established ICF linking rules[15]: the meaningful concepts of the patient-reported problem areas were identified and coded by 2 independent researchers (I.K. and C.R.). Linking of the standardized questionnaires and neuropsychological assessments was based on existing literature and supplemented by coding when necessary (I.K. and C.R.). Disagreements were resolved by consensus and in cooperation with a third researcher (H.S.).

Measures

Target Outcomes

Target Outcomes were derived from a semistructured interview. The patients were asked: "What is the main problem caused by your TBI that you have experienced in the past month?" Their open-ended responses were written down by the interviewers. This process was then repeated, eliciting the second and third most troubling problem areas. If a family member participated, the family member was also independently asked to report 3 main problem areas they considered most important for the patient. The interviews were conducted separately to ensure that both the patient and the family member felt free to provide their subjective perceptions, without consideration of the other's reaction. Target Outcomes were documented by the interviewer, with the wording being as close to the participants' choice of words as possible.

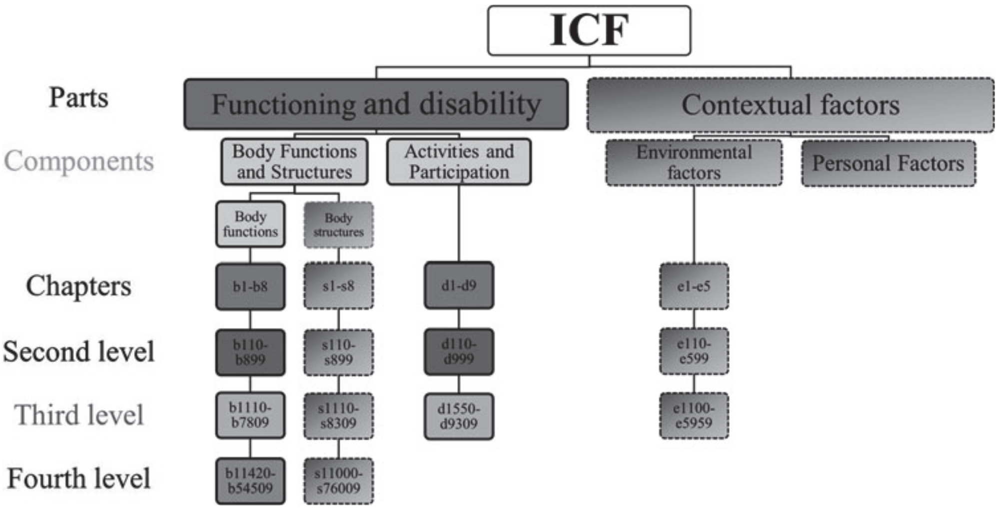

Figure 1. Structure of the ICF.[9]

Development of Target Outcomes categories

To address the first aim, a coding scheme was developed to categorize the individually reported Target Outcomes based on the written notes from the interviews. Two investigators (S.H. and I.M.H.B.) developed these Target Outcomes categories using the approach described by Winter and colleagues.[14] This entailed that Target Outcomes categories were constructed so that similar problem areas were grouped together, e.g., tinnitus and visual deficits were grouped together within the category sensory difficulties, while being distinct from dizziness or motor impairments. The Target Outcomes categories were thereafter classified within distinct domains in accordance with Winter and colleagues, but one category (interpersonal) was renamed in accordance with the ICF model (social function and participation). The process of establishing data-driven Target Outcomes categories and domains was consensus-based, and disagreements were resolved by discussions in the research group.

In addition, the meaningful concepts of the Target Outcomes were identified on the basis of the written notes and linked to ICF. In total, 65% of the ICF categories were identified independently by 2 researchers (I.K. and C.R.) with complete overlap.

Standardized measures

Questionnaires

Standardized questionnaires were administered in their validated Norwegian versions (see Table 3). The questionnaires were chosen on the basis of the recommendations of Common Data Elements,[41] measures in clinical use in Norway, and experience with problem areas of individuals with chronic TBI. Several of the standardized questionnaires had previously been linked to the ICF (see Table 3). For 4 of the questionnaires (see Table 3), the existing linking was restricted to the component or chapter level and was in the present study supplemented with linking the meaningful concepts in the items to the ICF second- to fourth-level category according to the linking rules[15] by 2 authors (I.K. and C.R.).

Neuropsychological assessment

Cognitive function was evaluated by a neuropsychological screening battery consisting of measures of auditory attention and working memory (Weschler Adult Intelligence Scale-IV; WAIS-IV Digit Span),[35] verbal learning and memory (California Verbal Learning Test-II; CVLT-II),[37] abstract thinking (WAIS-IV Similarities and Matrices),[35] and psychomotor speed and executive functioning (Trail Making Tests and Color Word Interference Test from the Delis-Kaplan Executive Function System; D-KEFS).[38] Existing linking to the ICF was applied (see Table 3).

Data analysis and statistics

Statistical analyses were conducted in IBM SPSS version 25.0. Descriptive data for Target Outcomes categories are provided in number (%). The ICF categories linked to the Target Outcomes reported by patients were compared with the ICF categories linked to the standardized measures.

RESULTS

Aim 1: Target Outcomes domains and categories

All patients reported 3 Target Outcomes, while 5 family members only reported 2. Four domains were identified: (1) cognitive functioning, (2) physical functioning, (3) emotional functioning, and (4) social functioning and participation (see Table 4). Furthermore,

TABLE 3 *Standardized measures with ICF chapters and categories*

Measures	Assessment domains	ICF components and categories
Questionnaires		
Rivermead Post-Concussion Questionnaire (RPQ)[19]; 16 items	TBI-related symptoms—physical, emotional, and cognitive postconcussive symptoms[20]	Body functions[21]; *b130, b134, b140, b144, b152, b1600, b210, b21020, b2401, b28010, b280, b5350*[a]
9-item Patient Health Questionnaire (PHQ-9)[22]; 9 items	Depressive symptoms	Body functions[23]*; b122, b130, b147, b152, d175, d310*[a]
7-item Generalized Anxiety Disorder (GAD-7)[24]; 7 items	Anxiety-related symptoms	Body functions; b152[21]
Patient Competency Rating Scale (PCRS)[25]; 30 items	Originally developed to assess self-awareness, also measures competence in daily activities[26]	Body functions[21]; activities and participation (d1-d9)[27]*; b144, b152, b164, b3504, d355, d475, d540, d630, d640*[a]
Quality Of Life In Brain Injury Overall Scale (QOLIBRI-OS)[28]; 6 items	Brain injury-related quality of life	Body functions (b1-b2); activities and participation (d3-d9)[29, b]
EuroQol-5D (EQ-5D)[30]; 5 items + VAS	Health-related quality of life	Activities and participation (d4-d6); b152, b280[31]
Participation Assessment with Recombined Tools–Objective (PART-O)[32]; 17 items	Frequency of participation in 3 life areas: productivity, social participation, and community life	Activities and participation (d6-d9)[21,33]
Behavior Rating Inventory of Executive Functioning–Adult (BRIEF-A)[34]; 75 items	Executive difficulties in everyday life	Body functions (b1)[21]*; b140, b144, b152, b164*[a]
Neuropsychological tests		
Weschler Adult Intelligence Scale-IV (WAIS-IV)[35]	Verbal and visual reasoning, auditory attention, working memory	Body functions; b140, b156, b160, b167[36]
California Verbal Learning Test-II (CVLT-II)[37]	Verbal learning and memory	Body functions; b144[21]
Delis-Kaplan Executive Function System (D-KEFS)[38]	Psychomotor speed and executive functioning	Body functions; b140, b164[21,31,39]

Abbreviations: ICF, International Classification of Functioning, Disability and Health; TBI, traumatic brain injury; VAS, visual analog scale.
[a] All items marked in italics are linked by the authors.
[b] Based on the full version of the QOLIBRI.[40] The QOLIBRI-OS is less specific but was deemed to cover the mentioned ICF chapters, while more specific categories were not included.

24 Target Outcomes categories were established (see Table 4) within these domains. Patients and family members reported problems within all domains, while the most frequently reported problem categories were related to reduced capacity/fatigue, memory difficulties, and problems related to cognitive aspects of executive functioning.

Aim 2: Comparison between Target Outcomes and standardized measures

The meaningful concepts in the Target Outcomes were linked to 12 chapters and a total of 112 ICF categories, of which 61 of them were at the third or fourth level (see Supplemental Digital Content 1, available at: http://links.lww.com/JHTR/A494, and https://apps.who.int/classifications/icfbrowser for a detailed description of the categories). Meaningful concepts were identified for all Target Outcomes. Yet, the wording and context of some of the expressed experiences were found to be insufficiently covered by the ICF categories. Specifically, this was relevant for lack of interest or apathy, identity issues, feeling worthless or like a burden, loneliness, lack of meaningful activities, inability to contribute, and difficulties accepting life changes. Although the standardized questionnaires covered 10 chapters of the ICF, only 28 second- to fourth-level categories were covered. The neuropsychological assessment covered another 4 second-level categories (see Supplemental Digital Content 1, available at: http://links.lww.com/JHTR/A494). When comparing the reported second-level ICF categories in the Target Outcomes with the standardized measures, a total of 20 (17%) patients did not have their body function issues covered and 67 (56%) did not have their activities and participation issues covered by the

TABLE 4 *Target Outcomes categories for patients ($N = 120$) and family members ($N = 78$)*

Target Outcomes categories by domain	Example	Patient, *n* (%)	Family, *n* (%)
Cognitive difficulties		92 (77%)	47 (60%)
Attention difficulties	Difficulties with concentration, distractibility	26 (22%)	9 (12%)
Reduced processing speed	Increased time to complete tasks	7 (6%)	2 (3%)
Memory difficulties	Forgetting appointments, tasks, or names	44 (37%)	18 (23%)
Visuospatial difficulties	Difficulties with navigating surroundings	2 (2%)	1 (1%)
Language difficulties	Word-finding difficulties, aphasia	6 (5%)	3 (4%)
Cognitive aspects of executive functioning	Difficulties with planning/organizing, problem solving, initiating tasks, mental flexibility, reduced awareness, impulsivity	35 (29%)	31 (40%)
Physical difficulties		97 (81%)	56 (72%)
Reduced capacity and fatigue	Reduced energy, mental fatigue, difficulties with initiating physical exercise	61 (51%)	38 (49%)
Pain	Headache, migraine, other pain	17 (14%)	11 (14%)
Sleep difficulties	Disrupted circadian rhythms, prolonged time to fall asleep, disrupted sleep	19 (16%)	7 (9%)
Difficulties with motor functions	Reduced walking function, reduced hand function	11 (9%)	6 (8%)
Sensory difficulties	Visual deficits, tinnitus, light sensitivity, noise sensitivity	18 (15%)	9 (12%)
Difficulties with dizziness and balance	Reduced balance, fall tendencies, vertigo	20 (17%)	9 (12%)
Difficulties with natural functions	Increased frequency of urination, reduced sexual drive	2 (2%)	1 (1%)
Emotional difficulties		46 (38%)	38 (49%)
Emotion perception and regulation	Mood swings, lack of empathy, emotional blunting, apathy	9 (8%)	8 (10%)
Irritability[a]	Anger, irritability at home, work, or while driving	13 (11%)	17 (22%)
Anxiety	Anxiety, worrying about the future	14 (12%)	6 (8%)
Depressive thoughts and feelings	Increased number of negative feelings, rumination, hopelessness	9 (8%)	7 (9%)
Difficulties with coping with stress	Difficulties handling unforeseen events, increased levels of stress	3 (3%)	2 (3%)
Difficulties with identity, acceptance, and sense of self	Changes in family roles, difficulties with own identity postinjury, feelings of worthlessness, loss of self-confidence, difficult to accept life changes	5 (4%)	6 (8%)
Social function and participation		29 (24%)	31 (40%)
Behavioral dysregulation	Socially inappropriate behavior, behavioral rigidity, acting childish	3 (3%)	9 (12%)
Social communication difficulties	Conflicts with other, difficulties communicating needs to others, difficulties taking turns in conversation, frequent misunderstandings	4 (3%)	10 (13%)
Reduced self-sufficiency	Difficulties managing own life, loss of driver's license, dependence on others	6 (5%)	1 (1%)
Reduced social participation	Spending less time with friends, loneliness	13 (11%)	16 (21%)
Lack of meaningful activities	Feeling like everyday life is "empty" and missing meaningful activities	4 (3%)	0 (0%)

[a] Irritability was chosen as a separate category from "emotion perception and regulation" because it was reported frequently as a specific problem by both patients and family members.

standardized measures. When considering third- or fourth-level categories, 113 (94%) patients did not have their body function covered by the standardized measures and 27 (23%) patients had uncovered activities and participation concepts. This suggests that Target Outcomes covered several areas that the standardized measures missed.

DISCUSSION

The aim of this article is to assess the utility of the Target Outcomes approach for a population of civilians living with chronic TBI. We specifically wished to investigate *what information* this approach would elicit and further *how different* this information was from what is obtained by using standardized measures commonly used in the field of TBI.

The first aim was to describe and categorize prioritized problem areas reported by patients with TBI and their family members. The same domains were identified as in the study by Winter and colleagues,[14] and in both studies, 2 of the most frequent responses were related to memory problems and difficulties with executive functions. However, the names of Target Outcomes categories identified differed somewhat between the studies, as did which difficulties included within each category. However, 18 of 24 categories were found to be comparable across the studies. The 6 nonoverlapping categories only reported by Winter and colleagues included poor self-care, obsessiveness, drinking problems, spending too much money, driving problems, and poor appetite. Instead, reduced mental speed, visuospatial difficulties, difficulty handling stress, difficulties relating to identity and acceptance, as well as lack of a meaningful everyday life, were identified only in our study. In addition, the Target Outcomes category with most frequent nominations in our study was fatigue. In the study by Winter and colleagues, fatigue was part of the category "other physical problems" together with dizziness, loss of dexterity, and seizures. Despite this, the category was only the fifth most frequent. These differences between the studies might be explained by individuals with more severe injuries being included in our population and perhaps differences between civilian and military populations. Our sample seems to be representative of civilian populations of patients with chronic TBI regarding injury severity and cause, as well as educational level, and about 50% being employed. In addition, cultural differences between the United States and Norway, as well as differing theoretical perspectives and professional background among researchers, might further explain the identification of somewhat differing Target Outcomes categories.

The inclusion of family member respondents was found to often provide more in-depth details about the patients' level of functioning and broaden the perspectives provided by patients. The differing perspectives by patients and family members on what constitutes the main problems post-TBI might be important in guiding treatment planning. No distinct Target Outcomes categories were reported by family members beyond those that were reported by the patients themselves on a group level in the current study, while 10 categories in the study by Winter and colleagues were reported solely by family members. Previously, Winter and colleagues[42] have described differing patterns of reporting for patients and family members relating to domains of functioning.

The second aim was to compare the Target Outcomes with the standardized measures. The results showed that Target Outcomes provided a more detailed problem description, that is, covering more ICF categories at all levels than the standardized measures. However, the ICF framework did have shortcomings regarding areas of functioning that were important to the patients with TBI, such as difficulties related to identity, loss of meaning, and loneliness. Thus, there seems to be a subgroup of patients experiencing their main problems in areas that could easily be overlooked if only relying on standardized measures. Issues related to identity, role changes, and psychological adaptation to a life with altered functioning are common. To summarize the issues at a group level, the measures need to combine personality, emotional, and higher cognitive functions, and in TBI research, this is perhaps best captured in qualitative studies,[43] as the issues are difficult to measure with objective standardized measures and will be unique to each patient. Importantly, these difficulties reflect disruptions of the adaptation to a life with chronic TBI symptoms, thus differing from emotional difficulties as seen in psychiatric disorders. Previous studies have documented limited access to services to address emotional difficulties post-TBI.[44,45] Living with adjustment-related emotional symptoms after TBI may be long term and may at worst increase over time and lead to deterioration of mental health if these individuals do not meet the criteria for psychiatric treatment and if the rehabilitation services fail to acknowledge and address these problems. It is noteworthy that the ICF classification does not cover these issues that are important not only after TBI but also in the chronic phase of many injuries or diseases of varying causes. As patients in the current study were at 2 to 24 years postinjury, it is evident that these issues may remain undetected or inadequately treated for several years after injury, despite having received rehabilitation after TBI.

Clinicians usually talk with patients to identify their individualized needs and wishes; however, this process could be supported by using a structured approach such as Target Outcomes. Furthermore, the same approach could be used to systematically collect information from caregivers, who additionally might have their own uncovered support needs. This approach could support clinicians in establishing a prioritized list of problems and enable the establishment of patient-centered treatment goals, which is in line with recommendations for rehabilitation, that is, that it should be patient-centered and goal-oriented.[46,47]

The Target Outcomes approach could likewise be a useful addition to TBI research. TBI research frequently involves testing of specific treatments to ameliorate specific problems, often identified and measured by standardized questionnaires and neuropsychological evaluations. However, as demonstrated by the current study, these standardized measures and accompanying interventions might not capture and target the problems that patients and their families would prioritize as most important in rehabilitation. To ensure patient-centered research that is easily transferrable to clinical practice, this emphasizes the relevance of research on individualized intervention programs for patients with TBI. For patients with specific problems, the sensitivity of detection of change in rehabilitation target outcomes might be lower in standardized measures using summary scores that include items of varying relevance than for individualized measures directly targeting the problem. The Target Outcomes approach also includes a severity rating by the respondents, enabling assessment of change posttreatment relevant for both research and clinical practice purposes. Another outcome measure based on patient-reported difficulties recently shown to be applicable in a population of acquired brain injury[48] is the Patient Specific Functional Scale (PSFS).[49] However, the PSFS is activity-based whereas the Target Outcomes approach allows for the identification of a broader range of problems.

The Target Outcomes approach was found to be easily completed by both interviewers and respondents. It ensures that the user's perspectives are emphasized and might elicit specific difficulties of importance when planning rehabilitation for patients with TBI in their individualized context in the chronic phase. These results do not diminish the importance of standardized outcomes in research or clinical practice, as they are recommended in both diagnostic assessment and treatment planning.[21] However, choosing relevant outcome measures for individuals with TBI can be a challenging task. Tate and colleagues[21] identified 728 different outcome measures in the field of TBI in their systematic review and concluded that choosing outcomes might be especially difficult in cases of new or rare problems. As evidenced by the current findings and recognized in the field of TBI rehabilitation, neither use of the ICF nor the use of standardized measures guarantees that one obtains all relevant information from the patient. This highlights the ingenuity of using the Target Outcomes approach in addition to the use of standardized measures in treatment planning to avoid burdening patients and families with an excessive number of questionnaires.[10]

LIMITATIONS

This is to our knowledge the first study to systematically compare information from open-ended questions to patients with TBI about their self-reported main problems with standardized measures. However, several limitations should be considered. First, our sample must be considered as a subgroup of patients with TBI who still experience difficulties at least 2 years postinjury, and the method is probably superfluous for patients experiencing only minor problems related to their injury, such as those with mild noncomplicated TBI (not included in the current sample). A second limitation is the choice of the ICF classification. Although the framework allows comparisons of different outcomes after TBI, the ICF framework does not capture all problems reported by the patients at the personal level, and other models that address issues outside the domains covered by the ICF should be considered. Furthermore, the standardized measures compared with Target Outcomes in this study are based on a selection of measures used in an ongoing RCT. The list of measures available for the TBI population is long,[41] and other measures might capture areas of difficulties not covered by our selection. However, the quite large number of standardized measures in this study is based on recommended measures for the TBI population, and additional measures would have increased the burden to patients. Finally, the Target Outcomes were written down by interviewers and not recorded verbatim. This might involve some translational process by the interviewer; however, the framing of the question and the order of administration were standardized to reduce this bias. In addition, this interaction between the patient and the therapist mimics that of normal clinical practice, increasing the external validity of the study and making the results more easily transferrable to use in clinic practice.

CONCLUSION

The Target Outcomes approach was found to be useful in extracting individualized problems that were important to patients with TBI and their family members. The approach also seemed to elicit a range of difficulties not captured by the standardized measures used in research and clinical practice, such as difficulties relating to identity and adjustment to life post-TBI. Although standardized measures are crucial, there is a need for supplementary methods to guide targeted rehabilitation efforts in the chronic phase of TBI.

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Goal attainment in an individually tailored and home-based intervention in the chronic phase after traumatic brain injury

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Abstract: Traumatic brain injury (TBI) is a heterogeneous condition with long-term consequences for individuals and families. Goal-oriented rehabilitation is often applied, but there is scarce knowledge regarding types of goals and goal attainment. This study evaluates goal attainment in persons in the chronic phase of TBI whom have received an individualized, SMART goal-oriented and home-based intervention, compares goal attainment in different functional domains, and examines indicators of goal attainment. Goal Attainment Scaling (GAS) was recorded in the intervention group (n=59) at the final session. The goal attainment was high, with 93.3% increased goal attainment across all goals at the final session. Level of goal attainment was comparable across domains (cognitive, physical/somatic, emotional, social). Years of education, cognitive impairment, self-reported executive dysfunction, and therapy expectations were indicators of goal attainment. These results support high level of goal attainment in patients with TBI participating in home-based, goal-oriented rehabilitation program in the chronic phase. Tailoring of rehabilitation to address individual needs for home-dwelling persons with TBI in the chronic phase represents an efficient health care service.

Keywords: Traumatic brain injury, goal-oriented rehabilitation, home-based rehabilitation, community-based rehabilitation, SMART, GAS, goal attainment scaling

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1. Introduction

Traumatic brain injury (TBI) is a costly condition with long-lasting impact for many individuals [1-3]. Persons who suffer a TBI might experience a variety of consequences, including difficulties with physical, cognitive, emotional, behavioral, vocational, and social functioning. Many experience persistently reduced quality of life and restrictions in community participation [4-9]. Families are also affected and may have to adapt to a new life with their injured family member being dependent on their assistance and support [10-14]. It has been increasingly recognized that TBI is a chronic condition with multiple and interacting effects on health and wellbeing [15-18], as a significant proportion of patients continue to experience life-long difficulties and impaired functional status [8, 19-22]. A challenge in rehabilitation after TBI is the heterogeneous nature of sequelae. Also, the patient's specific difficulties interact with contextual and psychosocial factors [25, 26]. Hence, many individuals are in need for long-term support from health care services. Evidence suggests that rehabilitation can be effective in reducing symptom burden and in improving participation and quality of life also for those who experience persisting symptoms [23, 24]. However, evidence suggests that one third of patients with chronic TBI have unmet needs related to cognitive, emotional, and vocational functioning [27], and that certain symptoms, such as neuropsychiatric sequelae might often be overlooked in rehabilitation [28].

Rehabilitation efforts have become increasingly focused on enhancing patient involvement [29], and person-centered rehabilitation has been shown to have positive effects on occupational performance and rehabilitation satisfaction [30]. Goal-oriented rehabilitation with patient involvement is considered a key approach to rehabilitation [31, 32], and has been shown to increase patient satisfaction and adherence [33], as well as improve self-efficacy, health-related quality of life and emotional status. There is however a need for more methodologically rigorous studies involving the use of individualized and specific treatment goals [34]. Herein, there is a specific need to investigate the utility of goal-oriented approach in tailoring rehabilitation efforts to the heterogeneous functional difficulties due to persistent TBI-symptoms to target patients' unmet needs.

Although goal-oriented rehabilitation seems promising in chronic TBI, there might also be individual differences in the suitability of the approach. Many advocate that a high level of patient-involvement is necessary in goal-oriented rehabilitation [32, 35-37], and that patients with cognitive impairments are susceptible to be less involved in goal setting [38]. Cognitive impairment might thus lead to difficulties both with setting goals and with achieving them and should be explored when evaluating goal attainment [39]. Some studies have identified fatigue and emotional difficulties as potential barriers to early goal-oriented rehabilitation [40]. In addition, individual factors such as self-efficacy, tenacity, and motivation have further been identified as potential moderators of goal attainment [39, 41, 42]. To our knowledge, a systematic investigation of the degree to which cognitive impairment, emotional distress, demographic factors (i.e., age, gender, education), and/or injury related variables predict goal attainment in the chronic phase of TBI has not yet been explored.

Despite the focus on goal-oriented rehabilitation over the past decades, conceptual terms vary, theoretical frameworks are often lacking [43, 44], and there is a need to evaluate goal attainment [36, 45], as goal attainment is rarely reported [46]. The SMART goal approach is frequently applied, i.e., setting goals that are Specific, Measurable, Achievable, Relevant and Timed. Further, the use of Goal Attainment Scaling (GAS) [47] to measure goal attainment seems to be the best available alternative [48]. GAS is a systematic scoring of individualized goals in specific areas, which allows comparison of goal attainment across individualized goals and patients. GAS has been shown to be reliable, valid and to have satisfactory responsiveness, as well as being sensitive to change [49]. Recently, Trevena-Peters, McKay [50] published results from a randomized controlled trial (RCT) supporting the effectiveness of an intervention to improve activities of daily living during post traumatic amnesia, providing detailed results from GAS. A feasibility study of a project-based intervention for acquired brain injuries also detailed goal attainment results [51]. However, the studies neither provided information on attainability of goals in distinct domains, nor did they investigate predictors of goal attainment.

The current study is modeled after a goal-oriented, home-based rehabilitation program shown to be effective in improving TBI-specific problem areas nominated by participants and which was shown to be highly acceptable for both patients and family members [52]. The current study represents an expansion and development of this approach in a different cultural setting (i.e., Norway), in a civilian sample, and with more severe injuries. The design was expanded by including SMART goals and GAS scoring, resulting in the combination of an individually targeted and standardized intervention approach.

1.1 Aims

The primary aim was to evaluate goal attainment in persons with persistent symptoms of TBI in the chronic phase. We hypothesized that participants would achieve goal attainment at expected levels. A second aim was to explore the functional domains of SMART goals established in the chronic phase, and to determine whether goal attainment varied according to functional domains. We hypothesized that SMART goals would be related to physical/somatic, cognitive, emotional, and social problem areas typically seen in the chronic phase of TBI, and that goal attainment was achievable in all functional domains. Thirdly, we explored variables that might be associated with goal attainment, such as age, injury severity and cognitive and emotional functioning. Existing literature does not give reason for a strong hypothesis regarding this aim; hence this approach was considered exploratory in nature.

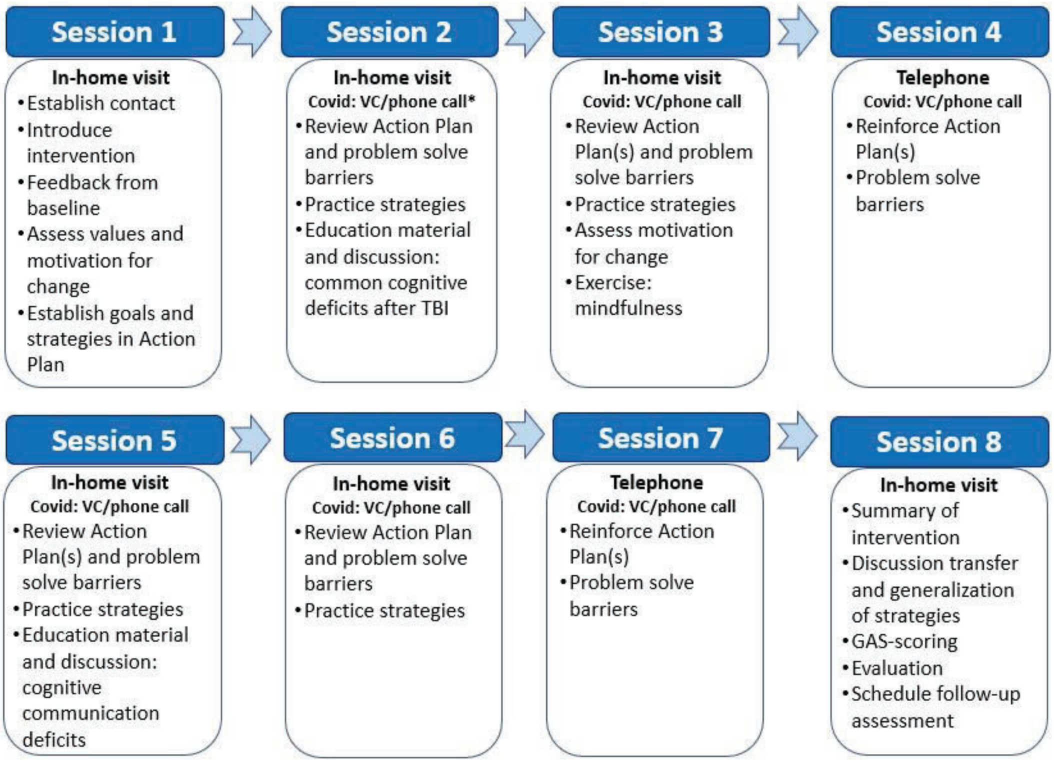
2. Materials and Methods

2.1 Participants

Participants were recruited from a two-group RCT conducted in Oslo, Norway. A detailed description of the study design is provided elsewhere [53]. Recruitment took place between June 2018 and December 2020. Between-group results of this trial will be published pending completion of 12 months follow-up assessments. Eligible participants were invited by letter, screened by phone and if eligible, invited to a baseline assessment at Oslo University Hospital (OUH). A family member was also invited if possible. Eligibility criteria were patients aged 18-72, with a TBI diagnosis with intracranial abnormalities verified by either computed tomography or magnetic resonance imaging. The participants had to be ≥16 years old at the time of injury, at least two years post-injury, and be living at home. Further, they had to report ongoing TBI-related problems and/or reduced physical and mental health and/or difficulties with participation in their everyday life. Exclusion criteria were severe progressive neurologic or severe psychiatric disorders (including active substance abuse and violence), inability to provide informed consent, inability to participate in a goal-setting process, or insufficient fluency in Norwegian. After baseline assessment, participants were randomized 1:1 to either the control group or the intervention group by an independent researcher using a randomly generated number sequence. Only patients randomized to the intervention group established SMART goals with subsequent GAS, hence only results from the intervention group is reported in the current paper (n=60).

2.2 Intervention

The intervention group received a home-based intervention consisting of eight contacts over a 4-month period. Initially, six home visits and two telephone calls were carried out. Due to the Covid-19 pandemic, some patients were followed up by phone only during the initial Norwegian lockdown in March-May 2020. A pragmatic solution was adapted to continue recruitment during the pandemic, and most participants included from May-December 2020 (n=17) were offered one to two home visits (first, ± last), while six to seven meetings were conducted by videoconference or telephone. Figure 1 displays an overview of the intervention sessions. Four therapists delivered the intervention: a medical doctor, a psychologist, a physiotherapist, and a neuropsychologist, all four with TBI rehabilitation expertise. Each participant was followed up by the same therapist throughout the intervention.



**Delivery format was adjusted due to the Covid-19 pandemic, i.e., videoconference (VC) and phone calls replaced some home visits to reduce risk of infection.*

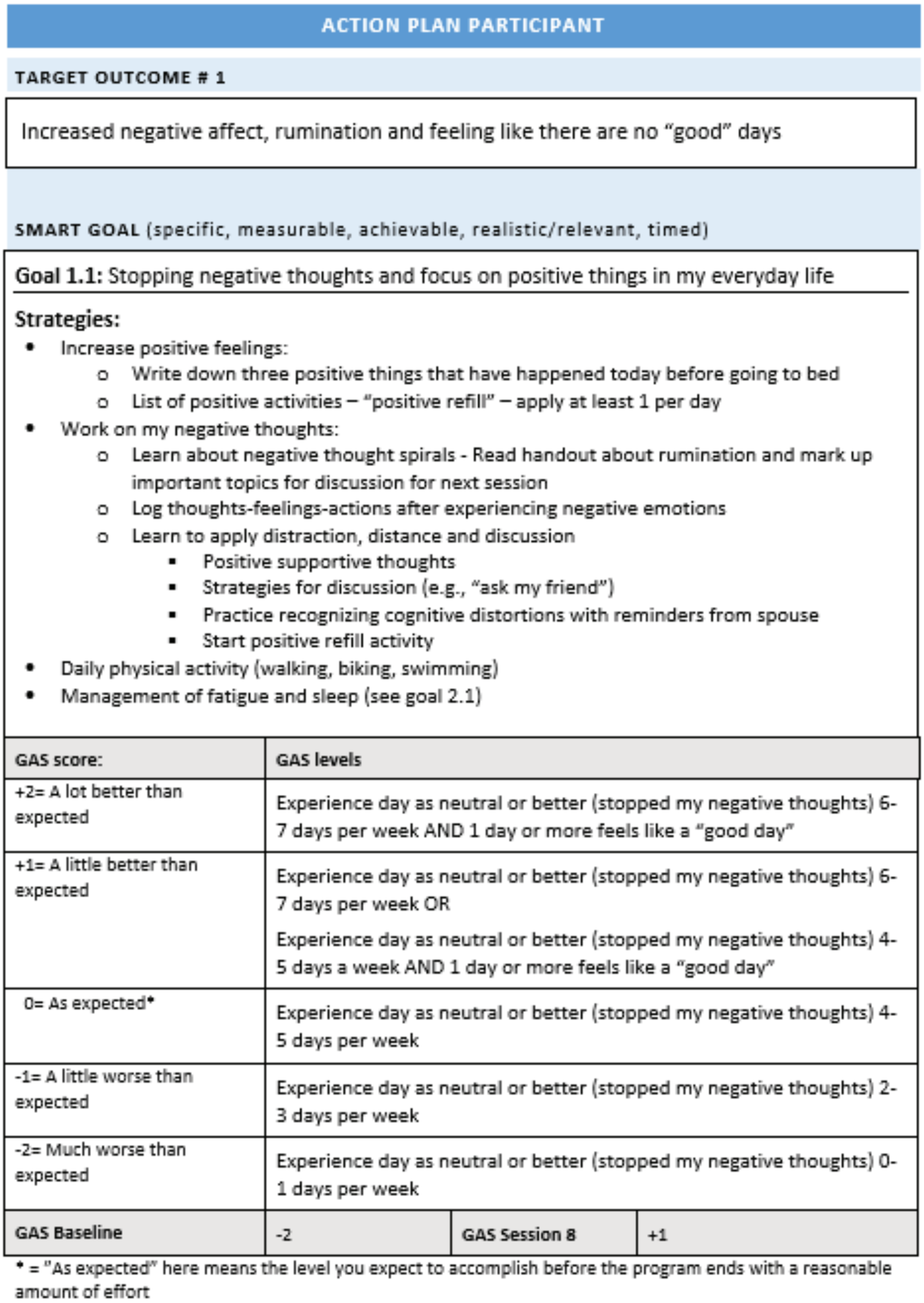
Figure 1. Overview of intervention sessions.

The intervention was manualized and based on the study by Winter et al. [52]. It contained three phases: 1) identification of target problem areas, 2) establishment of SMART goals and Goal Attainment Scaling for the selected target problems, and 3) development of an Action Plan consisting of strategies to achieve the goal. Figure 2 displays an example of an action plan. Goals were established through brainstorming between the patient, therapist, and family member, and included identification of needs for support, barriers to change and current adaptive strategies to be built upon. There was no upper limit on the number of SMART goals for each patient, but new goals were not established after session 5. The process of establishing SMART goals, GAS and Action plans was based on recommendations for collaborative goal setting from several authors [45, 54, 55]. Patients were presented with visual and verbal information about the SMART approach to goal setting, and the SMART approach was applied in a flexible manner to increase patient involvement. Specific and written strategies to be employed to reach the SMART goals were established, based on collaborative interactions between participants, family members and therapists. Therapists suggested a range of therapeutic strategies based on the current evidence base for the specific target problem area, and a list of common strategies was built up throughout the study related to recurring functional areas of SMART goals. Therapists reviewed and updated these strategies, and specific interventions were adopted to the individual needs of each patient. For details, see study protocol [53]. Team meetings were held on a regular basis, ensuring calibration of manual adherence across therapists. Ten percent of the sessions were observed by a senior professional with TBI expertise to evaluate treatment fidelity.

2.3 Outcomes

2.3.1 Goal attainment scaling

The main outcome measure in this study was goal attainment as measured by GAS-scores, where five levels of goal attainment was agreed upon and established for each goal. GAS is thus subjective for each individual and goal specific. The expected level of goal attainment (scored as 0) was recorded, as well as two levels below the expected level (-1, -2; with baseline level being one of these) and two levels above the expected level (+1, +2). Baseline levels were set to -2 in cases where deterioration was impossible, and otherwise set to -1. To enhance precision, GAS levels were defined as specifically as possible, e.g., using percentages or number of days within the past week, as recommended by Malec [55]. Figure 2 displays an action plan example. GAS was scored at the last session (session 8) for all goals. Patients were asked to evaluate their goal attainment and suggest their current level. In cases of reduced awareness or other factors influencing the patient reporting of goal attainment, therapist and family members interacted with the patient to establish consensus.



ACTION PLAN PARTICIPANT

TARGET OUTCOME # 1

Increased negative affect, rumination and feeling like there are no "good" days

SMART GOAL (specific, measurable, achievable, realistic/relevant, timed)

Goal 1.1: Stopping negative thoughts and focus on positive things in my everyday life

Strategies:

- Increase positive feelings:
    - Write down three positive things that have happened today before going to bed
    - List of positive activities – "positive refill" – apply at least 1 per day
- Work on my negative thoughts:
    - Learn about negative thought spirals - Read handout about rumination and mark up important topics for discussion for next session
    - Log thoughts-feelings-actions after experiencing negative emotions
    - Learn to apply distraction, distance and discussion
        - Positive supportive thoughts
        - Strategies for discussion (e.g., "ask my friend")
        - Practice recognizing cognitive distortions with reminders from spouse
        - Start positive refill activity
- Daily physical activity (walking, biking, swimming)
- Management of fatigue and sleep (see goal 2.1)

GAS score:	GAS levels		
+2= A lot better than expected	Experience day as neutral or better (stopped my negative thoughts) 6-7 days per week AND 1 day or more feels like a "good day"		
+1= A little better than expected	Experience day as neutral or better (stopped my negative thoughts) 6-7 days per week OR Experience day as neutral or better (stopped my negative thoughts) 4-5 days a week AND 1 day or more feels like a "good day"		
0= As expected*	Experience day as neutral or better (stopped my negative thoughts) 4-5 days per week		
-1= A little worse than expected	Experience day as neutral or better (stopped my negative thoughts) 2-3 days per week		
-2= Much worse than expected	Experience day as neutral or better (stopped my negative thoughts) 0-1 days per week		
GAS Baseline	-2	GAS Session 8	+1

* = "As expected" here means the level you expect to accomplish before the program ends with a reasonable amount of effort

Figure 2. Action plan example with SMART goal, strategies, and GAS.

Descriptive data are provided to evaluate the number of goals with goal attainment at the expected level or above, as well as goals with less than expected levels of attainment. As baseline GAS varied between -2 and -1, change scores were deemed to best describe goal attainment. GAS change scores were calculated as the difference between baseline and session 8 scores, and could thus vary between -1 (deterioration) and +4 (maximum improvement).

2.3.2 SMART goal categorization

To describe the functional domains covered by SMART goals, goals were categorized by two independent researchers (authors I. M. H. B. & S.L.H). The categories were established earlier in the study to classify the target problem areas nominated by patients and family members, based on procedures described by Winter, Moriarty [56] and the International Classification of Functioning (ICF). See Borgen, Kleffelgaard [57] for an overview over this categorization of target outcomes. Twenty-four categories were established, which covered four overarching domains: cognitive, physical/somatic, emotional, and participation/social functioning. There was full agreement on categorization for 92% of the goals, and disagreements were resolved by consensus in the research group.

2.3.3 Identification of indicators of goal attainment

Indicators of goal attainment were chosen within the domains of demographic variables, injury characteristics, intervention-related factors, cognitive functioning, global outcome, and self-reported symptoms. Demographic data, i.e., age, work status, and educational level was collected at baseline. Injury-related factors (i.e., injury severity, time since injury and cause of injury) were retrieved from medical records. Intervention-related factors included whether a family member participated and treatment expectation, the latter measured at session 1 and 3 by asking participants to rate their expectation that the intervention would be useful for them on a Likert-scale from 1-10. See Table 1 for an overview of standardized measures of global functioning, cognition and self-reported symptoms and their scorings.

Table 1. Standardized outcomes and their applied scaling.

Assessment domain	Measure name	Score used (min.-max.)
Global Outcome	GOSE [58]	Total score (3-8)
Cognitive functioning		
Verbal and visual abstraction/reasoning	Similarities and Matrices, WAIS-IV [61]	A dichotomized impairment variable was established, where impairment was defined as at least two test results being ≤1.5 standard deviation below the normative mean (no/yes) [59,60]
Verbal attention and working memory	Digit Span, WAIS-IV [61]	
Verbal learning and memory	CVLT-II [62]	
Processing speed, mental flexibility, and inhibition	Trail Making Tests 1-5 and Color Word Interference Tests 1-4, D-KEFS [63]	
Self-reported symptoms		
Post-concussive symptoms	RPQ [64]	Total score (0-64)

Fatigue	RPQ item [64]	Item score (0, 2-4)
Depressive symptoms	PHQ-9 [65]	Total score (0-27)
Anxiety-related symptoms	GAD-7 [66]	Total score (0-21)
Overall psychiatric distress	PHQ-9 [65] and GAD-7 [66]	Score of ≥10 on either scale (no/yes) [65,66]
Self-reported executive dysfunction	BRIEF-A [67]	Global Executive Composite t-score (0-100)

BRIEF-A= The Behavioral Rating of Executive Functions – Adult version, CVLT-II= California Verbal Learning Test-II, D-KEFS= Delis-Kaplan Executive Functioning Systems, GAD-7= Generalized Anxiety Disorder 7-item, GOSE=Glasgow Outcome Scale Extended, PHQ-9= Patient Health Questionnaire 9-item, RPQ= Rivermead Post-Concussion Symptoms Questionnaire, WAIS-IV= Weschler Adult Intelligence Scale IV

2.4 Statistical methods

All statistical tests were conducted in SPSS, version 26. Descriptions of patients and categorization of goals, as well as within-group changes in goal attainment from session 1 to session 8 are provided with descriptive statistics. Goal-attainment per goal was not normally distributed, and Kruskal-Wallis H test was chosen to explore differences in goal attainment between domains. Distribution of GAS scores was assessed by visual inspection of QQ-plots.

To determine indicators of GAS change scores, two analytical approaches were performed using multiple linear regression analyses. In the first approach, known indicators of GAS change scores based on theoretical, empirical, and clinical experience ("expert model") were included in a multiple regression analysis. In the second explorative approach all explorative variables associated ($p<0.20$) with GAS change scores from univariate regression analyses were included ("explorative model"). The chosen explorative variables are outlined above. One factor from each domain was chosen to avoid multicollinearity. Further, multicollinearity among exploratory variables was checked using Pearson correlation coefficient (r) of 0.7 as a cut off. The results from linear regression analyses were reported by regression coefficient (β) with 95% confidence interval (CI) and explained variance (R^2). Missing values of exploratory variables were 5% missing for cause of injury and 6% missing for injury severity. These data were multiple imputed under the assumption of missing at random. All available data were used to generate 15 imputed datasets. The results from each imputed dataset were combined to present single estimates.

2.5 Ethics

The study was approved by the Data Protection Office at OUH (2017/10390). The trial was registered at ClinicalTrials.gov, NCT03545594.

3. Results

3.1 Participants

Sixty participants were randomized to the intervention group. One withdrew after session 2 due to personal reasons, while the 59 remaining participants completed the intervention (session 8) and are included in the analysis. Thirty-nine (66%) had a participating family member, of whom 28 (72%) were spouses or domestic partners, 6 (15%) were parents and 5 (13%) were other family members, such as siblings. Patient characteristics are reported in Table 2. In total, 56 (94%) participants participated in all 8 sessions, while 3 completed 7 sessions. Average length of intervention was 124 days (SD=11.32; ~4 months).

Table 2. Patient characteristics.

Characteristics		**mean(SD)/median(range)/n(%)**
Demographics		
Age, y		43.12 (13.61)
Gender, male		43 (73%)
Education, y		12 (10-20)
Marital status	Single	21 (36%)
	Married/domestic partner	32 (54%)
	Other (widowed, divorced, separated)	6 (10%)
Injury-related factors		
Injury severity (GCS)*		8 (3-15)
	Mild	16 (27%)
	Moderate	9 (15%)
	Severe	30 (51%)
	NA	4 (6%)
Cause of injury**	Fall	17 (29%)
	Transport-related	24 (40%)
	Violence	4 (7%)
	Other†	11 (19%)
	NA	3 (5%)
Time since injury***, y		4 (2-23)
Work participation		
Work percentage		0 (0-100)
Work status	Works full-time	16 (27%)
	Works part-time	13 (22%)
	Disability/sick leave/retired	30 (51%)

*n=55. **n=56. ***n=58. †:sports- and leisure activities. GCS=Glasgow Coma Scale, SD=standard deviation, y=years

3.2 SMART goals

In total, 151 unique SMART goals were established and rated at session 8, with a mean of 2.61 (SD=0.72, range: 1-4) per participant.

3.2.1 Goal attainment

At session 8, 41 (27%) goals were scored at expected levels of goal attainment (score 0), 55 (36%) goals were scored a little better than expected (score +1) and 42 (28%) goals were scored much better than expected (+2). Only 11 (7%) goals were scored a little worse than expected (-1), and 2 (1%) goals were scored as much worse than expected (-2) at session 8.

The median overall GAS change score was 2 (range: -1.0 - 4.0). At session 8, 141 (93.3%) of the goals showed positive goal attainment (i.e., change scores 1-4), while 1 (0.7%) goal was with a worse goal attainment than at baseline, and 9 (6.0%) goals were scored with no change from baseline. At the individual level, the mean GAS change score per participant (n=59) was 2.22 (SD=0.91), and mean improvement per participant ranged from 0.5 to 4.0, i.e., all participants improved on at least one of their goals. The mean GAS change score at the individual level is visualized in Figure 3.

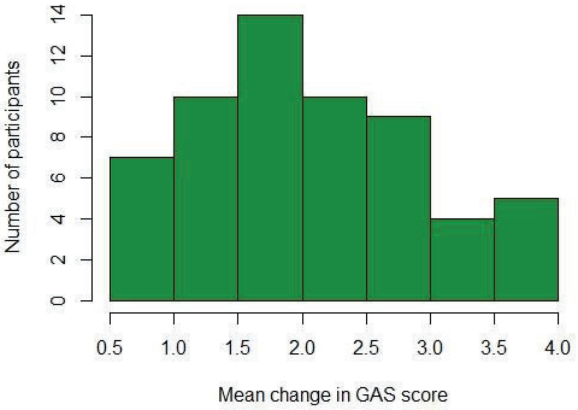


Figure 3. Mean individual change in GAS scores, across all 151 goals.

3.2.2 SMART goal domains and categories

Table 3 displays the 151 SMART goals sorted by domains and sub-categories, with corresponding goal attainment. The most frequent SMART-goal categories were related to reduced capacity and fatigue, memory difficulties and sleep problems. A Kruskal-Wallis H test was run to determine if there were differences in GAS change scores across the four goal domains, i.e., cognitive (n=38), physical/somatic (n=53), emotional (n=35), and social (n=25). Median GAS change scores were the same for all domains (2), with no significant differences between them ($\chi^2(3) = 2.674$, $p = .445$).

Table 3. SMART goal categories and goal attainment at final session.

	Below expectation	At expectation	Above expectation	Total
Domain/Category (number of participants)	*n*	*n*	*n*	*n*
Cognitive difficulties	**4**	**11**	**23**	**38**
Attention difficulties (n=5, 9%)	1	2	4	7
Memory difficulties (n=15, 25%)	3	6	11	20
Language difficulties (n=1, 2%)	0	0	1	1
Cognitive aspects of executive functioning (n=10, 17%)	0	3	7	10
Physical/somatic difficulties	**5**	**13**	**35**	**53**
Reduced capacity and fatigue (n=21, 36%)	2	7	13	22
Pain (n=4, 7%)	0	0	4	4
Sleep difficulties (n=11, 19%)	1	1	10	12

Difficulties with motor functions (n=6, 10%)	0	5	3	8
Difficulties with dizziness and balance (n=7, 12%)	2	0	5	7
Emotional difficulties	**2**	**8**	**25**	**35**
Emotion perception and regulation (n=3, 5%)	0	0	3	3
Irritability (n=9, 15%)	1	3	6	10
Anxiety (n=9, 15%)	0	2	8	10
Depressive thoughts and feelings (n=8, 14%)	0	2	6	8
Difficulties with coping with stress (n=3, 5%)	1	1	1	3
Difficulties with identity, acceptance, and sense of self (n=1, 2%)	0	0	1	1
Social function and participation	**2**	**9**	**14**	**25**
Behavioral dysregulation (n= 1, 2%)	0	0	1	1
Social communication difficulties (n=10, 17%)	0	3	6	9
Reduced self-sufficiency (n=4, 7%)	0	2	2	4
Reduced social participation (n=4, 7%)	0	1	3	4
Lack of meaningful activities (n=6, 10%)	2	3	2	7
Total	**13 (8.6%)**	**41 (27.2%)**	**97 (64.2%)**	**151**

Number of participants with goal within each category is given in the left column. Goal attainment levels at session 8 are given as "below expectation" (score -2 or -1), "at expectation" (score 0) and "above expectation" (score +1 and +2). The total number of goals per domain/category registered at each level of attainment are given in n (%).

3.3.3 Indicators of goal attainment

The "expert model" included age, gender, injury severity, total RPQ-score, and presence of cognitive impairment. The model showed an R2= .062, F (5, 49) = .652, p = .662.

As the model showed low predictive value, i.e., only predicted 6.2% of the total variance, univariate regression models were run to determine which explanatory variables should be included in the exploratory model. Results are presented in Table 4.

The final exploratory model of factors with a significance level <0.2 thus included years of education, presence of cognitive impairment, self-reported executive function (BRIEF-A GEC t-score) and treatment expectation at session 3. This model showed R^2 of .234, F (5,51) = 3.111, *p* = .016. Complete-case (Table 4) and imputed models (data not shown) showed similar results.

Table 4. Univariate regression analyses of goal attainment at final session (n=59).

Exploratory variables	**B**	**95% CI**	**Significance**	**R square**	**Decision**
Demographic factors					
Age	.001	-.017 to .019	.891	.000	Discard
Gender	.284	-.249 to .818	.290	.020	Discard
Education (in years)	*-.086*	*-.185 to .014*	*.091*	*.049*	*Keep*
Percentage work participation (%)	.001	-.004 to .007	.595	.005	Discard
Injury-related factors					
GCS score	.002	-.055 to .059	.944	.000	Discard
Cause of injury (fall)	-.144	-.931 to .642	.702	.009	Discard
Months since injury	.002	-.002 to .006	.383	.014	Discard
Functional status/symptoms at baseline					
Global functioning (GOSE)	-.056	-.303 to .191	.651	.004	Discard
Neuropsychology – overall impairment	*-.316*	*-.790 to .157*	*.186*	*.030*	*Keep*
Self-reported symptoms at baseline					
Post-concussion symptoms (RPQ total score)	.008	-.012 to .028	.437	.011	Discard
Fatigue (RPQ item)	.074	-.098 to .247	.391	.013	Discard
Depression (PHQ-9 total score)	.005	-.038 to .049	.809	.001	Discard
Anxiety (GAD-7 total score)	-.014	-.071 to .043	.625	.004	Discard
Psychiatric symptoms (PHQ-9 and/or GAD-7 ≥ 10)	.133	-.372 to .638	.600	.005	Discard
Executive dysfunction (BRIEF-A GEC)	*-.020*	*-.046 to .007*	*.140*	*.039*	*Keep*
Intervention factors					
Treatment expectation at session 1	-.006	-.130 to .118	.920	.000	Discard
Treatment expectation at session 3	*.123*	*-.010 to .256*	*.070*	*.057*	*Keep*
Family member participation	.045	-.461 to .551	.858	.001	Discard

Italics display results at acceptable p-value (<.20) to be carried forward. BRIEF-A=Behavioral Rating Inventory of Executive Functioning-Adult version. GAD-7=Generalized Anxiety Disorder 7-items, GCS=Glasgow Coma Scale, GEC=Global Executive Composite, GOSE= Glasgow Outcome Scale Extended, PHQ-9=Patient Health Questionnaire 9-item, RPQ=Rivermead Post Concussion Questionnaire.

4. Discussion

This study aimed at evaluating goal attainment across goal domains in patients receiving an individually tailored, home-based rehabilitation intervention. We also explored indicators of goal attainment at the final session.

Goal attainment was very high. All participants had a positive total goal attainment change score, which means that all participants improved on at least one of their goals. The high levels of goal attainment found across patients with different injury severity, time since injury, current level of functioning and different goal domains indicated that the intervention format is well suited for many individuals in the chronic phase of TBI. We believe that the high level of patient involvement in this study might have resulted in the high goal attainment seen, as suggested in the literature [68]. Additionally, setting goals and GAS has been shown to be effective in and of itself [69], which may have contributed to the results.

Goals were categorized as related to either cognitive, physical/somatic, emotional, or social functioning. The level of goal attainment was equal across goal domains, which implies that the intervention was sufficiently tailored to allow participants to work effectively on a broad range of issues. Most goals were set related to physical/somatic functioning, especially regarding fatigue and sleep. Examples of such goals were "prevent episodes of fatigue >6 (VAS) during the week" and "maintain a circadian rhythm and get up at a fixed time". Within the domain of cognitive functioning most goals were related to memory and cognitive executive functioning and included goals such as "establish routines to ensure finding my belongings" and "get started on everyday tasks and stop postponing things". Goals regarding emotional functioning were most often related to anxiety and irritability and included goals such as "be less bothered by worrisome thoughts when going to bed" and "prevent and deal with episodes of irritability/anger in a calm manner". Within the social domain goals were most frequently related to social communication difficulties and included goals such as "contribute to a more open and positive family communication" and "manage to stop losing track and veering off-topic during conversations".

During baseline assessment in the RCT, patients and family members nominated target problem areas relating to TBI. A previously published paper [57] describes domains and categories of these problem areas. The problem areas reported at baseline were highly similar to the SMART goal areas reported in the current paper. A few problem areas reported at baseline were however, not developed into SMART goals, i.e., visuospatial difficulties, reduced processing speed, difficulties with sensations and difficulties with natural functions. Further, some goal areas were not frequently established, such as goal related to identity difficulties and behavioral dysregulation. This may suggest that some problem areas are less easy to translate to SMART goals. Importantly, the initial problem areas nominated by participants do not always represent problems they end up wishing to work on later in the rehabilitation process. For example, it might be that an increased working alliance with the therapist allows the participant and family members to delve into problems they do not disclose during the first meeting. This was reported by therapists in the current study, and by therapists in the study by Winter and colleagues [70].

The initial investigation of indicators of goal attainment based on theoretical, empirical, and clinical perspectives, yielded a low predictive model explaining only 6.2% of the total variance of goal attainment in this sample. As the knowledge base about predictors of goal attainment is scarce, an exploratory approach was warranted to generate new hypothesis for future work. This approach suggested that being less educated, having good cognitive and executive functioning as well as high rehabilitation expectations were related to positive goal attainment. This finding should be interpreted with caution as there is a risk of overestimating the association of single explanatory variables in univariate regression analyses, and future investigation is needed. Further, it should be noted that although the exploratory model is significant, the explained variance is still modest (23.4%), which implies that there are factors associated with goal attainment that were not included in the current model.

The fact that both demographic factors, TBI-related deficits, and factors relating to the intervention itself may play a role in goal attainment is, however, not surprising but clinically very important. Rehabilitation is a complex, multifaceted process that involves many interacting factors, and the identification of active ingredients in rehabilitation interventions is notoriously difficult [71]. It is not surprising that individual factors may be associated with intervention outcomes. In our exploratory model, neither age, gender nor employment status predicted goal attainment. However, individuals with lower educational levels displayed higher goal attainment. This finding was surprising, and we do not currently have any strong hypothesis regarding this result. The finding might even be spurious, in that education is a proxy for a third and unknown variable. This finding needs replication. Interestingly, no injury-related factors were predictive of goal attainment. This could suggest that at the chronic stage of TBI, factors such as injury severity and time since injury does not play an important role in who benefits from every-day oriented goal-based rehabilitation approaches. This supports the findings by Cicerone and colleagues that individuals with ongoing TBI-related difficulties should be offered support and may benefit also in the chronic stage, even years after the injury [23, 24]. Additionally, both performance-based cognitive impairments and self-reported executive dysfunction were shown to be detrimental to goal attainment. This supports previous findings that cognitive impairment may hinder setting and achieving goals [38, 39]. Despite previous findings that fatigue, and emotional difficulties may be barriers to early goal-oriented rehabilitation in patients with stroke [72], these factors did not significantly predict goal attainment in the current study. It may be that initial levels of fatigue and emotional distress is a larger barrier to benefit from rehabilitation during early recovery and are more addressable as the target of SMART goals later on.

The finding that a positive expectation in that the treatment could be beneficial during the third but not during the first session, was predictive of goal attainment, was highly interesting. The finding may suggest that patient expectations are essential for goal attainment. However, as the wording of this question was the degree to which the participant expected that they would benefit from participating in the program, and that this belief was only predictive after participating in two or more sessions (and not at the very first session), it is likely that their response was influenced by their perceived level of therapeutic alliance. Although therapeutic alliance has received most attention in the field of psychotherapy, it has also been recognized as an important factor in brain injury rehabilitation (see [73] for a discussion). However, positive expectations might also be related to factors not measured in the current study. For example, level of self-awareness may influence therapeutic alliance [74]. It may also be that expectations of change were influenced by the level of participant self-efficacy caused by the experienced improvement or lack thereof during the first three sessions. Both self-efficacy, tenacity and motivation has been previously shown to be predictive of goal attainment [32, 39, 41, 42]. Future investigations should include measures of both therapeutic alliance, self-efficacy, and self-awareness in addition to change motivation to provide a clearer understanding of this interesting finding. The finding also indicated that treatment expectations should be discussed with patients early on in treatment, as it may play a role in treatment outcome. In summary, despite being exploratory, the current analyses provide hypotheses for further investigation of indicators of goal attainment. Such investigations might be highly important to ensure a better understanding of what helps and what hinders goal attainment in rehabilitation, which again could help improve outcomes and ensure necessary tailoring of interventions.

4.1 Limitations

This work has some limitations that should be recognized. Firstly, the comparability of goal attainment across patients when delivering an individualized intervention is always uncertain, and although the intervention was manualized, the specific content was tailored to the individual patient. However, the individualized nature of the intervention is also thought to be a major strength, given the heterogeneous nature of long-term symptoms of TBI, and because it allows participants to define for themselves what areas are important for them to work on, further enhancing patient involvement. Secondly, the efficacy of this intervention has not yet been established. Although this study is based on a similar RCT which did demonstrate significant between-group effects [52], effects have not yet been investigated in our sample pending final outcome assessments. This entails that although participants in the intervention group display high levels of attainment on specific goals, we do not yet know whether goal attainment is associated with improved global outcomes regarding e.g., participation and quality of life. However, high goal attainment is an important positive finding regardless of group comparisons on more global outcome measures. Thirdly, the sample may not be representative of patients with TBI in general. Rather, the study included those who continue to experience TBI-related challenges in everyday life and who were motivated to participate in rehabilitation. Thus, the sample is considered representative of patients seen in specialized rehabilitation clinics. Further, GAS-scoring has some limitations, including that reliability in identifying goals, establishing, and scoring GAS might be an issue. In this study, GAS scoring was conducted by the therapists, as scoring by a blinded third party was not feasible. How to best compute GAS scores across goals and individuals is also disputed, which is the reason that GAS change scores were applied instead of t-scores, as these are controversial [75]. In addition, it is important to note that the problem categories used in the current paper were based on previous work by our research group using a data-driven approach. Different approaches could be applied that might have resulted in somewhat different categorization of goals. There is currently no gold standard in taxonomies for goal categorization, although some suggestions have been made elsewhere [76, 77].

5. Conclusions

This study provides a transparent look at a goal-oriented approach in delivering rehabilitation interventions in the chronic phase of brain injury. Goal attainment was high, and goals were related to a broad range of problem areas typically identified in the chronic phase of TBI. Further investigation is needed to make strong conclusions regarding indicators of goal attainment, but the current study suggests that both individual, injury-related, and therapeutic factors are at play. The findings have clinical utility for therapists working with acquired brain injuries in general and other conditions where an individualized approach to treatment is warranted.

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