

BMJ Open Paediatric goal management training in patients with acquired brain injury: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Compromised integrity of the brain due to paediatric acquired brain injury (pABI) has been associated with cognitive impairment, particularly executive dysfunction, in addition to somatic and emotional symptoms and reduced everyday function. Goal Management Training (GMT) is a cognitive rehabilitation intervention for improving executive function (EF) that has received empirical support in studies of adults with ABI. The purpose of the present study is to determine the efficacy of a recently developed paediatric version of GMT (pGMT) for children and adolescents with ABI and reported executive dysfunction.

Methods and analysis This study protocol describes a parallel randomised controlled trial including allocation concealment and assessor blinding. Eighty survivors after pABI, aged 10–17 years at the time of intervention, will be recruited. Participants will be randomly allocated to either pGMT (n=40) or a psychoeducative control intervention (n=40; paediatric Brain Health Workshop). Both interventions consist of seven group sessions for participants and parents, followed by external cueing and telephone counselling. The study also includes involvement of teachers. Assessments will be performed at baseline, immediately postintervention and at 6 months' follow-up. Primary outcome measure will be changes in daily life EF as reported by parents (The Behavior Rating Inventory of Executive Function). Secondary outcomes include other assessments of EF (neuropsychological tests and questionnaires). Furthermore, we aim to assess generalisation effects of pGMT on other cognitive functions, as well as emotional, behavioural, adaptive and family function, academic performance, fatigue and quality of life.

Ethics and dissemination Results from this study will be disseminated to relevant research, clinical, health service and patient communities through publications in peer-reviewed and popular science journals, in addition to presentations at scientific conferences. The study will be conducted in accordance with the Helsinki declaration and the Ethical Research Involving Children (ChildWatch International and Unicef). In accordance to Good Clinical Practice our study includes safety and quality monitoring guarantees in compliance with research ethics and safety. The trial will be reported in accordance with

Strength and limitations of this study

- **Quality of design.** A robust randomised controlled design, entailing an active control intervention, blinding of assessors, a well-defined primary outcome (with ecological validity) and a large sample size.
- **Quality of intervention.** Implementation of a theoretically based and manualised cognitive rehabilitation programme (Goal Management Training) already shown to be effective in adults, now adapted to children and enhanced by external cueing, counselling and involvement of parents and teachers.
- **Outcome.** Comprehensive outcome assessments including sustainability of effect (6 months follow-up).
- **Participant heterogeneity** may be regarded both as a limitation, with risk of effects in subsets of the study population being disregarded as null effects, and strength if results show effect across these differences (ie, generalisability).
- Another limitation is the risk of non-adherence to the interventions and loss of participants to follow-up due to comprehensive and time-consuming interventions.

the Consolidated Standards of Reporting Trials 2010 statement and Standard Protocol Items for Reporting in Trials recommendations, in addition to being registered at ClinicalTrials.gov. The study has been approved by the Regional Committees for Medical and Health Research Ethics Norway (2017/772).

Trial registration number NCT03215342.

INTRODUCTION

Acquired brain injury (ABI) is a diverse condition resulting from either traumatic brain injury (TBI) or non-traumatic injuries such as brain tumour, stroke, hypoxia or infections/inflammation to the brain. It is one of the leading causes of death and disability for children and adolescents.^{1 2} Although survival rates from paediatric ABI (pABI) is



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increasing with advances in prehospital care, surveillance and medical treatment, the possibility of poor outcome after survival remains. Indeed, pABI constitutes a major disruption to child development and may affect cognitive, behavioural, emotional, social as well as academic function.^{3–11} Previous assumptions that injuries early in life resulted in less adverse outcomes have been challenged by more recent research, suggesting that the young brain in fact may be vulnerable to more severe, diffuse and enduring deficits.^{12–15} Psychiatric disorders frequently follow pABI and occur at significantly higher rates than after orthopaedic injury without brain injury.¹⁶ The negative impact of pABI on social function and behaviour has been highlighted by several studies.^{3 4 11 17} Further, fatigue is a problem encountered by a significant proportion of pABI patients and is associated with poor academic achievement, limited physical activity and socioemotional problems.^{18 19} Moreover, poor postinjury family environment and resources have been shown to have negative effects on long-term social outcomes after early brain insult.¹⁵ Finally, following pABI, as many as 50% may experience persistent cognitive impairment, with a significant higher risk of executive dysfunction.^{8 9 20 21}

Executive dysfunction following pABI represents one of the most common and disturbing cognitive symptoms, impacting most domains of everyday life.^{9 20 22–24} Executive function (EF) is a blanket term that embodies a collection of inter-related top down processes promoting the control and regulation of cognition (ie, goal-directed attention), emotion and behaviour. In particular, the domain of sustained attention is viewed as crucial to supporting the various EF processes, such as working memory, planning, monitoring, inhibiting and task switching.^{25 26} Thus, executive processes play an essential role in a child's cognitive, behavioural, emotional and social function and development, with executive dysfunction potentially influencing the rehabilitation process, as well as postinjury academic achievement, social relationships, independence and future employment negatively.^{4 8 9 27} Hence, interventions that target EF components, especially supporting the domain of sustained attention, may have the potential to significantly affect everyday function and may as such have life-long effects for children and adolescents with ABI.

As far as we know, there are no widely accepted standardised interventions targeting remediation of executive dysfunction for children and adolescents.^{28–30} In fact, cognitive rehabilitation after pABI varies excessively between region, hospital and community settings.^{31 32} Effect studies of cognitive rehabilitation programme for children and adolescents are confounded with a multitude of challenges, including poor research design, divergent participant aetiologies, methodological inadequacies, lack of psychometrically sound and ecologically valid instruments for cognitive and behavioural assessments and finally inconsistency of outcome measures.^{28 31 33} In a recent systematic review and meta-analysis of cognitive interventions, only 13 randomised controlled studies

were reported with only four including pABI populations, most of which involved computerised training.³⁴ Sohlberg and colleagues²⁹ identified five efficacy studies,^{35–39} evaluating attention training and metacognitive strategy training for children and adolescents with ABI. They conclude that while there is initial support for metacognitive interventions, the studies are not readily replicable as a number of clinical implementation factors were not properly identified.

Since the pABI is acquired during the course of development, this poses a particular challenge in research on this population. Thus, studies need to consider how developmental factors (eg, age at injury and intervention), maturity and awareness and access to early rehabilitation may impact the nature of rehabilitation and recovery. Furthermore, parent involvement in the intervention is highlighted by several studies as important for positive outcomes, especially for transfer to everyday life.^{35 40} The school constitutes another significant learning arena in children's lives, essential for generalisation of intervention effects.⁴⁰ To our knowledge, no previous studies have included parental and teacher components into a randomised controlled trial (RCT) to enhance EF in children.

Cognitive rehabilitation interventions that include metacognitive strategy training and problem-solving strategies have proved effective in treating EF impairments post-ABI in adults, with evidence of transfer to other domains such as quality of life (QoL) and emotional health.^{41 42} One of the best validated interventions for executive dysfunction is Goal Management Training (GMT).^{25 43–47} GMT has received empirical support in studies of adult patients with neurological conditions (eg, ABI) and in healthy elderly adults,^{45 48} with reports of improved sustained and executive attention^{43 49–51} and reduction of executive dysfunction in daily life.^{44 46 52–55} The theoretical foundation of GMT holds that the sustained attention system upholds higher order goals in mind while inhibiting automatic processes.^{25 56} Indeed, improved EF following interventions targeted at improving goal-directed attention regulation, such as GMT, is assumed to be a result of underlying alterations in brain networks supporting sustained attention.^{50 57 58} The element of sustained attention is reinforced through mindfulness training.^{43 59} Furthermore, the participants are taught to be reflective with 'stop-and-think' strategies and thereby also raising awareness of attentional errors that often interfere with and obstruct task completion. Thus, the main objectives of GMT are to train participants to stop ongoing behaviour, to define goal hierarchies and monitor performance.⁴³

As GMT has been shown to improve EF in various adult populations, application to broader patient- and age groups seems feasible. In fact, Krasny-Pacini and colleagues⁶⁰ investigated the efficacy of a multifaceted intervention programme with children with severe TBI (n=5), including a paediatric GMT protocol. The study aimed at involving parents and teachers,^{61 62} but

unfortunately, involvement was low.⁶⁰ Hence, the results of this pilot study were inconclusive, with only partial improvement of EF. The authors argue that the inconclusive results may be due to the inclusion of severe TBI and ‘non-optimally functioning’ families from low socioeconomic background. As GMT is a metacognitive intervention, it requires at least a moderate degree of awareness of deficits.²⁵ As such, the paediatric version of GMT (pGMT) is probably not appropriate for patients with severe impairment (ie, severe TBI). Of, note, a preliminary version of the pGMT protocol to be used in the present study has been piloted on children with brain injuries (n=13) with encouraging findings, suggesting enhanced attentional control and improved daily life EF, as perceived by parents 6 months postintervention.⁶³ In conclusion, there is great need for experimentally derived, prospective studies with randomly assigned experimental and control interventions, well-defined samples and investigator-masked outcome measures for children and adolescents with pABI.^{28 62} It is critical that evidence-based cognitive remediation options are made available for this group.⁶⁴ Given that heterogeneity is a hallmark characteristic of brain injury, larger multisite studies of systematic treatment are recommended to attain the volume and diversity necessary to discern the various factors that enhance intervention efficacy, as well as identify the specific, underlying mechanisms responsible for change.^{28 29 35}

The main objective of this RCT is to determine the efficacy of a modified version of GMT as a group-based treatment programme for children and adolescents with pABI and EF deficits. Furthermore, we are interested in investigating potential transfer effects of pGMT to other central areas of functioning relating to emotional health, fatigue, social function and QoL. The present study aims to address several of the methodological shortcomings in previous studies by having a randomised controlled, multisite trial design, a relatively large sample size, blinded assessments, long-term follow-up, counselling of parents and teachers, in addition to external cueing to facilitate effective goal management in everyday life. The literature shows low correlation between neuropsychological tests and daily life (functional) EF.⁶⁵ Thus, we have chosen a functional measure (The Behavior Rating Inventory of Executive Function (BRIEF))⁶⁶ as a primary outcome, also based on prior research.⁵⁵ The pGMT intervention will be compared with a psychoeducative control intervention (paediatric Brain Health Workshop (pBHW)),²⁵ immediately after the intervention and at 6 months follow-up. The main study hypotheses are:

- ▶ Primary hypothesis: pGMT will result in a greater improvement in EF in daily life as reported by parents (BRIEF), compared with pBHW.
- ▶ Secondary hypothesis: pGMT will result in greater improvements in other EF domains (EF tests and functional EF), as well as emotional, behavioural, adaptive and family function, academic performance,

fatigue, QoL and other cognitive functions, compared with pBHW.

- ▶ Finally, we wish to examine whether there is an association between factors related to patient characteristics such as IQ, demographics and medical variables and treatment outcome.

METHODS AND ANALYSIS

Study design

The proposed study is a parallel RCT, comparing pGMT to an active control intervention (pBHW), using a repeated-measures design across three time-points (preintervention (T1), postintervention (T2) and 6-month follow-up (T3)) (figure 1).

The trial will be conducted and reported according to Consolidated Standards of Reporting Trials guidelines⁶⁷ and Good Clinical Practice (GCP).⁶⁸ The study flowchart is provided in figure 2.

Study setting

Eighty participants with paediatric ABI will be invited to participate in the study based on hospital discharge diagnosis and record information. Interventions will be conducted at two sites in Norway—St Olav’s Hospital (SOH) in Trondheim and Oslo University Hospital, Rikshospitalet (OUH-RH). In addition, patients from the University Hospital of North Norway (UNN) will also be invited to participate. SOH, OUH-RH and UNN are the trauma referral centres for the Central, South-Eastern and Northern regions of Norway, respectively, and have a population base of more than two-thirds of the Norwegian paediatric population. Recruitment started in November 2017 and will continue until the summer of 2019.

Population and eligibility criteria

The study population will consist of children and adolescents diagnosed with ABI resulting from traumatic (TBI) and non-traumatic injuries (brain tumour, stroke, hypoxia/anoxia and brain infections/inflammations) from the age of 10 up to 17 years at the time of the intervention. Participation requires a period of at least 12 months since injury/illness or more than 12 months since ended cancer therapy, in addition to experiencing executive dysfunction in daily life as determined by a semistructured interview. Exclusion criteria are as follows: (1) injury acquired before 2 years of age; (2) cognitive, sensory, physical or language impairment affecting the capacity to attend regular school (ie, primarily follow educational goals of peers and regular classroom teaching) and/or complete the training programme; (3) preinjury neurological disease, severe psychiatric disorder and/or stimulant medication; (4) recently detected brain tumour relapse; (5) unfit for evaluation of outcome (independent evaluation by two investigators) and (6) not fluent in Norwegian.

Sample size

The proposed study aims at recruiting a total of 80 children and adolescents with pABI. Based on previous

Study period							
	Enrolment (n=80)	Allo- cation	Baseline assessment	Intervention period		Outcome assessment	
				Inter- vention (3 weeks)	Counselling and external cueing (5 weeks)		
Time point	>12 months post injury >12 months after completed medical treatment		T1			T2 (imme- diately post interve- ntion, max 12 weeks after T1)	T3 (6 months post interve- ntion)
Enrolment - Eligibility screening interview - Informed consent - Allocation	X						
	X						
		X					
Intervention pGMT (n=40)				X	X		
pBHW (n=40)				X	X		
Assessments <i>Primary outcome measure</i> BRIEF- parent report <i>Secondary outcome measures</i> EF questionnaires and tests (Tab. 1) Questionnaires of cognitive, emotional, behavioural, academic, family and adaptive functioning, fatigue and QoL (Tab. 1)			X			X	X
			X			X	X
			X			X	X

Figure 1 Study period illustrated by SPIRIT figure. BRIEF, Behavior Rating Inventory of Executive Functions; EF, executive function; pGMT, paediatric Goal Management Training; pBHW, paediatric Brain Health Workshop; SPIRIT, Standard Protocol Items for Reporting in Trials.

studies, the estimated annual incidence of TBI in Norway (aged 0–19 years) is 1400.⁶⁹ The prevalence of paediatric brain tumours in Norway is lower, with 40 new cases per year (survival rate is 80%),⁷⁰ with a high proportion of patients suffering from cognitive deficits. Incidence rates for childhood stroke vary from 1.3 per 100 000 to 13.0 per 100 000,⁷¹ while rates of paediatric encephalitis-related hospitalisation range from 3 to 13 admissions per 100 000 children per year (USA and Europe).⁷² Thus, the sample size is considered to be attainable, with reference to the total eligible population. Previous cognitive rehabilitation studies after pABI including metacognitive training have included 29,⁶¹ 32,⁷³ 38³⁹ and 161³⁵

participants. As only one previous single-case study on pGMT in pABI exists to date,⁶⁰ this represents a challenge in estimating the required sample size in this proposed study. To document a clinically relevant effect as experienced by the child/adolescent and their family, we used the Global Executive Composite scale from the parental report on BRIEF⁶⁶ as the main outcome measure in the power analysis. Prior research on the effect of GMT in adults with ABI and spina bifida has reported moderate to large effect sizes. To detect an effect size of $d=0.7$ with a power=0.80 and $\alpha=0.05$, 32 patients are needed in each group.

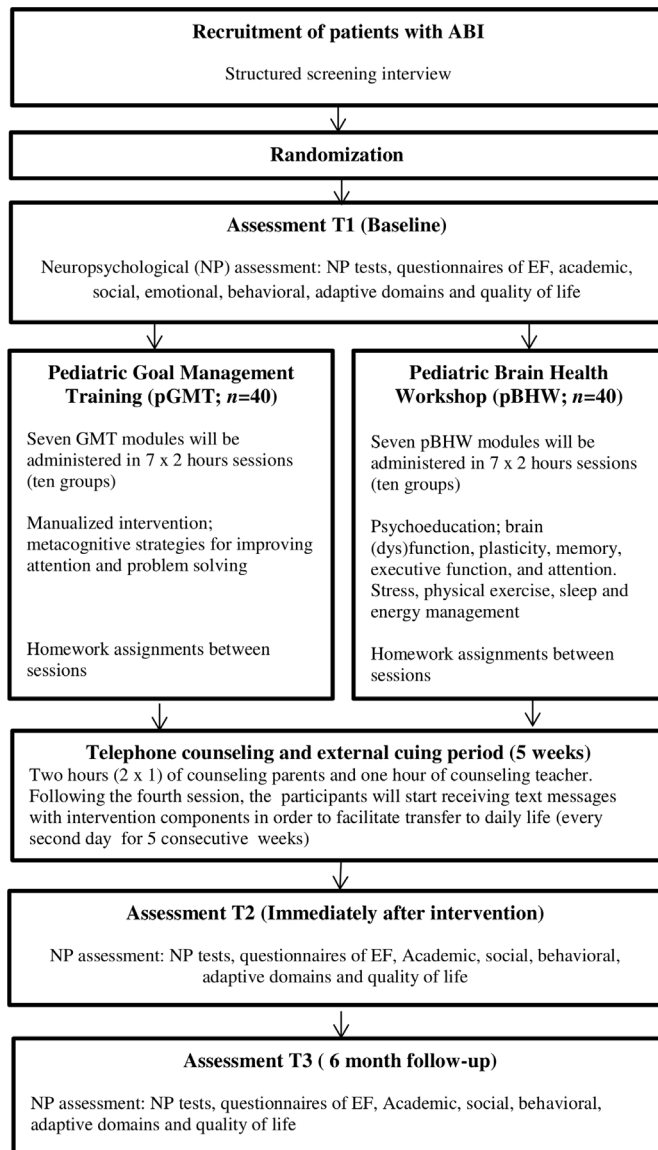


Figure 2 Flowchart for the study protocol. Cognitive Rehabilitation in paediatric ABI—a randomised controlled study. ABI, acquired brain injury; EF, executive function.

Randomisation and blinding

Participants will be randomised to either pGMT or pBWT in a 1:1 ratio, applying block randomisation and stratification by (1) research site (Trondheim or Oslo) and (2) age at the time of intervention (10–13 years or 14–17 years). The Unit for Applied Clinical Research, Norwegian University of Science and Technology will be responsible for the computerised randomisation but will not be involved in determination of participant eligibility, assessment or execution of the interventions. The block size is set to four due to the study design of the treatment. The block randomisation was set up in advance by the allocator and hidden from the executor to minimise the possibility of guessing the next allocation. Blinding will be applied to reduce systematic bias as a result of knowing the treatment allocations, with the following procedures: (1) Families and participants will not be informed about

which intervention they have been assigned to (the term ‘brain training’ will be used consistently in both groups); (2) Test technicians who conduct baseline and follow-up assessments will be blinded to treatment allocation; (3) Therapists who administer the two interventions will be blinded to all test performance and evaluation; (4) The use of the Web Clinical Research Form (WebCRF) system, with data stored anonymously and only biostatistician and research assistant having access, minimises the likelihood of influence by the investigators. Furthermore, the interventions (pGMT and pBHW) will be conducted separately in time on both sites, thus reducing the chance of participants with differing allocations sharing information and experience. Additionally, participants will be explicitly asked not to discuss course content with test technicians assessing them or other potential participants outside of their group.

Procedures

Following a positive invitation response, written informed consent will be required from potential participants (>16 years) or primary caregivers (participants <16 years) before conducting a semistructured interview to determine EF symptoms and information of other inclusion/exclusion criteria that are not included in the hospital records. The interview section concerning daily EF consists of eight specific questions where the caregiver is asked to assess and describe the child’s function, for example: ‘Is it difficult for the child/adolescent to plan school assignments or leisure activities?’. Participants that have surpassed 16 years of age are invited to attend the interview. Successively, individuals that meet inclusion criteria will be designated a study number and randomly assigned to either of the two interventions by a computer-based algorithm in a webCRF. Once the participants have been randomised, a baseline assessment is completed on the first day of admission, prior to the first session of the group intervention, as illustrated in the flow chart in figure 2. Test technicians will receive training in test administration and scoring by a clinical neuropsychologist.

Baseline variables

At baseline (T1), the following information will be recorded in addition to tests included for primary and secondary outcome measures: age, sex, height, weight, medical status (medicines, sleep, appetite, sensory sensitivity), neurological status (cranial nerve, motor function, balance, sensibility), pain and hormone levels (thyroid-stimulating hormone, free thyroxine, adrenocorticotropic hormone, cortisol, insulin-like growth factor one hormone, luteinising hormone, follicle-stimulating hormone and serum osmolality), school attendance and special educational needs, as well as injury characteristics, age of injury and medical treatment. The demographic information will be collected in a standardised interview, medical examination (including neurological screening) by a physician and information in relation to injury/illness and treatment will be extracted from medical records. In

addition, an optional blood test will provide hormonal level status. To provide an IQ estimate, the subscales vocabulary, similarities, digit span, coding, block design and matrix reasoning of the Wechsler Intelligence Scale for Children—Fifth Edition⁷⁴ will be employed.

Primary and secondary outcome measures

The present study intends to investigate effects on a number of central domains pertaining to sequelae after pABI. Hence, a comprehensive assessment battery of common outcome measures has been selected (table 1). The primary outcome measure is the BRIEF, parent report.⁶⁶ BRIEF is an 86-item standardised questionnaire that captures parents perceptions of a child's EF in his or her everyday environment. Each item's frequency of occurrence is rated on a 3-point Likert scale from 1 (never) to 3 (often). It has demonstrated good reliability, with high test-retest reliability ($r_s=0.88$ for teachers, $.82$ for parents), internal consistency (Cronbach's $\alpha_s=0.80-0.98$), and moderate correlations have been detected between teacher and parent ratings ($r_s=0.32-0.34$). The questionnaire has been applied to several clinical groups in Norway.⁷⁵ Secondary outcome measures include: (1) domains specific to EF and (2) those related to other cognitive functions, as well as other functional areas such as emotional health, fatigue, social function and QoL (see table 1). Additionally, we have included measures of EF assumed to be more ecologically valid than traditional neuropsychological tests. Indeed, to better uncover challenges related to EF in daily activities we have translated and included a method that is designed as an ecological, open-ended assessment of EF in children, the 'Children's Cooking Task' (CCT).^{76 77} In addition to evaluating intervention satisfaction after each intervention week, intervention compliance will be assessed by modules completed by each child/adolescent.

Interventions

The intervention programme will be conducted in the same manner at both research sites according to preplanned standardised procedures. The two interventions are matched regarding non-specific factors (eg, structure, intensity, duration and therapist contact). Hence, the pGMT and pBHW protocols are group based and consist of seven modules of approximately 2-hour duration each (figure 3), both with standardised Power-Point slides and participant workbooks. Between sessions, there will be homework assignments aiming to promote generalisation.

Two experienced clinical neuropsychologists will lead the group treatment sessions, each consisting of two to five participants, ideally four. The present study will aim at facilitating transfer from training to real life by including training and education of parents. A 1-hour review of the modules will be given to the parents by the same group therapists subsequent to each of the seven participant sessions, with the opportunity for questions and experience exchange. Following to the fourth session, the

pGMT participants will start receiving a text message stating 'STOP' (a key instruction in pGMT), while the pBHW will get a text message stating 'Brain training' every other day for five consecutive weeks until the end of the intervention period. This constitutes 18 text messages per participant and is included to cue goal management and encourage transfer to daily life.^{78 79} The cueing time will be between 08:00 and 20:00 and will be changed routinely to prevent habituation. Two hours (2×1) of telephone counselling by one of the therapists, including both parent(s) and child when possible, will be conducted following the sessions during a 1-month period. The counselling mainly provides support to promote use of the techniques in everyday life by discussion of how the strategies (pGMT) or lifestyle advice and techniques (pBHW) may be implemented in home and school settings, in addition to clarifying possible obstacles and misunderstandings. Teachers will receive a 1-hour telephone counselling in the same period. The main purpose is to provide a brief review of the specific intervention strategy allocated and thus encourage teachers to consider how the strategies can be implemented in the school setting. In addition, the counselling may contribute to enhanced knowledge of pABI and cognitive dysfunction in general. Pre-determined templates for the telephone counselling of parents/participants and teachers respectively ensures systematic and consistent procedures across sites, with specific protocol for each intervention.

Paediatric Goal Management Training and Paediatric Brain Health Workshop

In pGMT, participants are trained to use strategies such as stopping and orienting to relevant information, partitioning goals into subgoals, encoding and retaining goals, monitoring performance and mindfulness training.⁵⁹ The training also uses discussion of participants' real-life attention deficits, in-session practice on tasks of attention supplemented with periodic alertness cueing and homework assignments. The manualised pGMT protocol is an adaptation of the adult version of GMT which has been translated into Norwegian.^{46 47 63} The modifications of the GMT protocol for children included changes to make materials more child friendly and age appropriate (eg, examples and discussions more related to school and leisure activities). For example, 'The mental blackboard' (ie, working memory) became 'The brain blackboard', and 'The mental laboratory' (a way of thinking about, practising and experimenting with daily life skills) became 'The brain workshop'. Finally, the protocol has been compressed into seven modules (from 9). Following the pilot work by Stubberud and colleagues,⁶³ the protocol has been further revised, primarily by simplifying language, reducing the amount of text, making examples more relevant to child and adolescent activities and adding more visual material. Nevertheless, all sessions will follow the same procedure; introduction to key concepts, practical exercises and discussion using examples from the participants' daily life. Homework assignments will include practical exercises and logging of activity and exercises in mindfulness. Similarly to the development of

Table 1 Measures to be employed in the study

Function	Outcome measure	Ref.
Primary outcome	Executive functioning (EF)	Q
Secondary outcome, specific to EF	Behavioral Rating Inventory of Executive Function, parent report (BRIEF)	66
	BRIEF, self- and teacher report	66
	Dysexecutive Questionnaire for Children (DEX-C), parent- and teacher report	80
	ADHD Rating Scale IV, parent and teacher report	81
	Conners Continuous Performance Test third edition (CPT-III)	82
	Color-Word Interference Test (CWIT 3–4), Delis-Kaplan Executive Function System (D-KEFS)	83
	Behavioural Assessment of the Dysexecutive Syndrome in Children (BADS-C)	80
	Tower of London (TOL)	84
	Trail Making Test 3–4 (TMT 3–4), D-KEFS	83
	Children's Cooking Task (CCT)	77
Secondary outcome related to other functions/ domains	Motor function	NP
	Grooved pegboard	85
	Processing speed	NP
	Coding & Symbol search, WISC-V	74
	Trail Making Test (TMT 1–2), D-KEFS	83
	Working memory	NP
	Color-Word Interference Test (CWIT 1–2), D-KEFS	74
	Verbal learning & memory	NP
	Digit Span, Picture Span, WISC-V	86 87
	Social Cognition	NP
	Childrens Auditory Verbal Learning Test (CAVLT-2)	88
	Mentalization, NEPSY-II second edition (NEPSY - II)	89
	Socio-emotional function	Q
	Achenbach System of Empirically Based Assessment (ASEBA)	90
	Self-esteem /self-efficacy	Q
Harter Self Perception Profile for Children and Adolescents (SPPC-R and SPPA-R)	90	
Quality of life	Q	
Paediatric Quality of Life Inventory (PedsQL)	91	
Fatigue	Q	
PedsQL Fatigue scale	92	
Adaptive and daily living skills	Q	
Health Behaviour Inventory	93	
Family Functioning Scales	93	
Family & Environment	Q	
Center for Epidemiologic Studies Depression Scale (CESD)	94	
Health outcome	Q	
Glasgow Outcome Scale Extended Paediatric (GOS-E Peds)	95	
EQ-5D-Y	CI	
Q	Q	
Baseline variables/ demographics	General ability	NP
Vocabulary, Similarities, Block Design, Matrix Reasoning, Wechsler Intelligence Scale for Children fifth edition (WISC-V)	74	
Clinical assessment	CI	
Clinical and neurological examination with evaluation of hormonal status in peripheral blood as indicated	Standardised interview	

CI, clinical interview; NP, neuropsychological tests; OA, observational assessment tool; Q, questionnaire.

Paediatric Goal Management Training sessions	Paediatric Brain Health Workshop sessions	Inpatient duration
Module 1: The absent mind, the present mind Module 2: Absentminded slip-ups	Module 1: Introduction Module 2: Neuroplasticity	2 days
<i>Approximately 7 days at home including between session-assignments</i>		
Module 3: The automatic pilot Module 4: The brain blackboard	Module 3: Memory I Module 4: Memory II	2 days
<i>Approximately 7 days at home including between session-assignments</i>		
Module 5: State your goal Module 6: Splitting tasks into subtasks Module 7: Checking (Stop!)	Module 5: Executive functioning and attention Module 6: Lifestyle and neuroplasticity I Module 7: Lifestyle and neuroplasticity II	3 days
Two hours (2 x 1) of counselling (parents + child when possible) following the intervention during a 1-month period One hour of counselling teacher in the same period for each child		

Figure 3 Description of the paediatric Goal Management Training and paediatric Brain Health Workshop interventions.

the pGMT, the pBHW is an adaptation of the adult version of BHW which has been translated into Norwegian.⁵⁵ It comprises educational materials addressing brain injury and (dys)function, plasticity, memory and learning, executive function, fatigue and lifestyle interventions (eg, the effect of stress, sleep, exercise and nutrition on brain function) (figure 3). Homework and within-session activities will include sharing of the participant's experiences with the intervention topics in home and school settings, brain games, practical exercises and lifestyle advice, in addition to quizzes testing their acquired knowledge. Furthermore, the participants and parents are invited to discuss how the techniques and advice may be incorporated into their everyday routine.

Statistical analysis

Data analysis will follow the intention-to-treat principle and will be specified in a separate Statistical Analysis Plan. The analysis populations will be defined according to the following strategy: (1) The primary analysis population (modified intention-to-treat) will include all randomised participants who have completed baseline assessments. (2) The per protocol population will include all participants who have missed a maximum of two out of the seven group sessions. Results from all primary and secondary outcome measures will be presented separately by treatment allocation. A description of participant characteristics and baseline measurements will take place when all groups have carried through the baseline assessment (T1). The final analysis of the RCT will be conducted following the 6-month (T3) follow-up for participants, anticipated to be December 2019. For continuous outcomes, results will be presented as means and SD of age-corrected standardised scores defined from normative samples. The primary analyses will be performed by a linear mixed model with time point, intervention and the interaction between intervention and time as

fixed factors. Supplementary analyses will be performed using linear regression. Sensitivity analyses will include adjustment for baseline factors where there is an obvious imbalance between the two groups. For binary outcomes, results will be presented as the number and proportion with impairments for each of the outcomes presented separately by treatment groups. Comparisons between groups will be done by χ^2 tests. Additional sensitivity analyses adjusting for any imbalanced baseline factors will be performed by multiple logistic regression models.^{28 29} Significance level is set to $p \leq 0.05$. Due to the issues of multiple testing in assessment of a number of secondary outcomes, results will be interpreted according to magnitude of the group difference (effect size) rather than relying solely on significance levels.

Ethics and dissemination

Data management and monitoring

The study is set up to meet GCP⁶⁸ quality and safety standard. A secure, web-based system (WebCRF) will be used to ensure storage of sensitive information and management of data files. The system ensures quality of data entry and allows for continuous monitoring of the study, as well as enabling download of data files for statistical analyses. Furthermore, participants will be allocated a unique research identification number prior to assessment. Consent form and documents containing personal information will be kept in a locked filing cabinet in a locked office within the hospital. A list of names and corresponding identification numbers will be kept separately and securely in the locked filing cabinet as well as on a password-protected hospital server. An external monitor agreement includes monitoring of protocol adherence, consent, randomisation and assessment of data quality during the study period.

Ethics and safety aspects

The aims and methods in this project are not contrary to legislation, norms or values within the Norwegian society. Lastly, the trial will be reported in accordance with the CONSORT 2010 statement,⁶⁷ in addition to being registered at ClinicalTrials.gov.

Dissemination and user involvement

Research findings from the described study will be disseminated through peer-reviewed research journals, conferences and patient organisations.

Patient and public involvement

Development of cognitive rehabilitation is highly requested by user organisations. We have identified several potential users; patients, their families, patient organisations and municipality services. This study seeks user involvement in all project phases. User involvement was included in the planning process through meetings and interviews with previous patients with pABI, patient organisations and municipality services, as well as execution of pilot studies. As such, the development of the study design, research questions and choice of outcome measures have been informed by patients' priorities, experience and preferences. The patients will not, however, be involved in the recruitment to and conduct of the study. Furthermore, during the execution phase and dissemination phase, an advisory panel with user representatives (participants from pilot study, parents of children with pABI and patient organisations) has been appointed and is scheduled to have regular meetings throughout this phase and will be involved in discussions to improve study design, secure a good consent process, relevant assessment instruments and publication in relevant media. Finally, findings to be made available to the participants at the end of study include main findings, where the information is tailored to the characteristics of the sample, in addition to an offer of receiving feedback on individual results.

DISCUSSION

The proposed study is unique in the field of paediatric cognitive rehabilitation, as it aims to address several limitations of previous studies by applying a robust study design with randomisation to intervention type, large sample size, blinded assessments, involvement of parents and teachers, external cueing and long-term follow-up to obtain solid knowledge on how children and adolescents with ABI profit from systematic cognitive rehabilitation programme. The study will focus on a vulnerable patient population that has EF impairments that impact multiple domains of everyday life. Hence, it is critical that effective cognitive remediation options are made available for this group of patients and their families.^{14 33 40} In fact, family-centred interventions have been increasingly recognised as critical in serving children, particularly young children, with disability.^{68 69} The proposed study

includes heavy involvement of parents and counselling of teachers (ie, 'context sensitive'),^{61 62} which is expected to enhance study adherence and intervention gains. The expected outcome is that pGMT will be more effective in improving EF when compared with pBHW, and that this improvement will generalise to everyday function with potential long-term effects. In the long run, intervention effects may contribute to facilitate completion of education and successful participation in work life and less need of social benefits. It has been suggested that the documented improvements following GMT is a result of underlying alterations in brain networks supporting sustained attention or attentional control.⁶³ The capacity to sustain attention over time (eg, attentional control) is a necessity for reliable goal-directed behaviour. So, by targeting sustained attention, which is heavily emphasised in pGMT, improvements in broader domains of goal-directed functioning may occur. As such, we also expect that the intervention will have a positive impact on emotional health, psychosocial health, family function, QoL and perceived fatigue. The study is expected to have a direct impact on rehabilitation practice and may inform rehabilitation programme and guidelines in the paediatric ABI community. As pGMT specifically addresses deficits in sustained attention to improve EF function, the programme may prove helpful to populations from a host of developmental and other acquired aetiologies with EF challenges.

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Patient consent for publication Parental/guardian consent obtained.

Ethics approval The study has been approved by the Regional Committees for Medical and Health Research Ethics, Norway (2017/772/REK) and is currently

recruiting participants and conducting interventions. The study will be conducted in accordance with the Helsinki declaration and the Ethical Research Involving Children (ChildWatch International and UNICEF).

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