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A study to test the methods and costs of an online programme for adolescents who have survived a brain injury: Teen online problem solving (TOPS-UK)

Submission date
12/06/2017

Recruitment status
No longer recruiting

Registration date
13/06/2017

Overall study status
Completed

Last Edited
18/03/2020

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
In the UK, a child injures their brain every 30 minutes through accident or illness. Many can survive brain injury but it can lead to devastating and life-long impacts on the child and their family. Brain injury can affect thinking, emotion, behaviour and relationships. This can impact the child's ability to cope with school, home life, future employment and independence. Families are also more likely to experience mental health difficulties and parental separation, which can further affect how well a child recovers. Researchers have developed an internet-based treatment for children who have survived such brain injuries called TUPs-UK. This treatment teaches problem-solving skills in response to specific everyday difficulties and is used at home for 10-16 weeks with weekly therapist support. Research on children with traumatic brain injury suggests that those who completed treatment, compared to those who were given general self-help, improved in their ability to plan, organise, problem-solve, and manage mood and behaviour. Families also experienced less stress and better mental health. However, there are still questions about the treatment and if it will have similar benefit for all types of brain injury (e.g.stroke, infection, tumour), if it can improve other aspects of life (e.g.improved quality of life) and if it cost effective. The aim of this study is to find out whether it is possible to identify and recruit adolescents and their families with brain injuries via the NHS, and establish if they find the treatment and research measures acceptable, in order to undertake a larger study to assess the benefit of the internet based treatment.

Who can participate?
Adolescents aged 12 to 18 who have a brain injury and executive function difficulties and their families

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the TOPS-UK programme which they access online in addition to their usual treatment. This requires weekly 1-hour sessions over 10-16 weeks which help adolescents develop skills to cope with

problems. The participant and their parent/carer work together and they will be supported by a weekly Skype or FaceTime session with a research coach. Any support they usually receive (for example, seeing a psychologist or speech therapist) continues as usual. Those in the second group receive their usual treatment. Participants and their families are followed up 1 week after the programme with online questionnaires to assess how feasible and acceptable the study is. Participants are also asked to take part in a telephone interview with a researcher to give feedback about being in the study, and (for those who accessed the online treatment programme), how they found the programme.

What are the possible benefits and risks of participating?
There are no notable benefits with participating. Participants may feel tired when completing the TOPS-UK programme or questionnaires. There are risks of this study leading to disagreements within the family however there will be a TOPS-UK coach available to help the family.

Where is the study run from?
This study is being run by the University of Plymouth (UK) with Royal Devon and Exeter Hospital (UK) as its lead site.

When is the study starting and how long is it expected to run for?
December 2016 to March 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Alison Jeffery
alison.jeffery@plymouth.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Alison Jeffery

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Additional identifiers

EudraCT/CTIS number

IRAS number
207736

ClinicalTrials.gov number

Secondary identifying numbers
31846, IRAS 207736

Study information

Scientific Title
Teen Online Problem Solving for adolescents who have survived an acquired brain injury in the UK: a feasibility study (TOPS-UK)

Acronym
TOPS-UK

Study objectives
The aim of this study is to find out whether it is possible to identify and recruit adolescents and their families with brain injuries via the NHS, and establish if they find the treatment and research measures acceptable, in order to undertake a larger study to assess the benefit of the internet based treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Exeter Research Ethics Committee, 05/06/2017, ref: 17/SW/0083

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Children, Primary sub-specialty: General Paediatrics; UKCRC code/ Disease: Injuries and Accidents/ Injuries to the head, Neurological/ Other disorders of the nervous system

Interventions
Current intervention as of 06/12/2018:
Following consent and confirmation of eligibility, participants are allocated to either the treatment or control arm (50:50 ratio) via a web-based system provided by the CTU in conjunction with the trial statistician. Participants (both adolescent and parent), the site research nurse, CTU trial managers and the trial coach (therapist) are informed of the treatment allocation.

Treatment arm: Participants receive the TOPS-UK programme. This is a web-based programme followed weekly by the adolescent and his/her family. The weekly sessions take about one hour each, and help the adolescent to develop skills to cope with everyday problems. These include compulsory sessions on staying positive, steps to problem solving, getting organised, staying in control and taking care of yourself. The adolescent can then choose a further four sessions to suit their own situation from a choice of dealing with fatigue, fear and worry, anger control and communication, listening, talking and reading non-verbal cues, social behaviour and groups, working with school. The final session for all participants summarises the key points from the course. A therapist helps the adolescent and his/her family through weekly Skype or FaceTime calls.

Control arm: Participants receive their usual support only, with no access to the online programme.

The study intervention lasts 16 weeks. The adolescent and his/her family complete 10 sessions, each session lasting one to two weeks, thus allowing time for holidays, illness or to recap a session if necessary. The follow up is at 17 weeks following randomisation (1 week after completion of the intervention programme for those in that arm, and equivalent time for control group). Follow up comprises completion of questionnaires online by both adolescent and parent. All families are asked to participate in qualitative interviews by telephone to ascertain study acceptability and feedback about study participation.

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Control arm: Participants receive their usual support only, with no access to the online programme.

The study lasts 16 weeks. The adolescent and his/her family complete 10 sessions, each session lasting one to two weeks, thus allowing time for holidays, illness or to recap a session if necessary. The first follow up is at 17 weeks following randomisation (one week after completion of the intervention programme for those in that arm, and equivalent time for control group). Follow up comprises completion of questionnaires online by both adolescent and parent. All families in the treatment arm are asked to participate in qualitative interviews by telephone to ascertain study acceptability and feedback about study participation. A selection of 10 families in the control arm are also asked to participate in qualitative telephone interviews to feedback their views on study participation.

The second follow up will be at six months after completion of the first follow up questionnaires. The online questionnaires will be repeated. A subset of 10 families from the treatment arm will be invited to participate in another qualitative telephone interview.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 10/12/2018:
Feasibility of assessing executive function using Behavior Rating Inventory of Executive Function Second Edition (BRIEF-2) completed by parents 17 weeks after randomisation. Executive function assessed using BRIEF-2 is the proposed primary outcome measure for the main trial.

Previous primary outcome measure as of 06/12/2018:
Executive function assessed using Behavior Rating Inventory of Executive Function Second Edition (BRIEF-2); completed by parents at 17 weeks. This is the proposed primary outcome measure for the main trial.

Previous primary outcome measures:
Intervention adherence, feasibility, acceptability and study participation are measured using online questionnaires (non-validated) and telephone interviews at 17 weeks and six months.

Secondary outcome measures
Current secondary outcome measures as of 10/12/2018:
1. Clinician ability to identify participants
2. Feasibility of online screening, consent and randomisation processes
3. Recruitment rate; proportion of eligible patients identified that are recruited
4. Willingness of families to be randomised and complete outcome measures assessed by questionnaire 17 weeks after randomisation and by telephone interviews with families after completion of outcome measures
5. Adolescent and parent acceptability of intervention and outcomes assessed using intervention acceptability questionnaires (adolescent and parent) 17 weeks after randomisation and telephone interviews after completion of outcome measures
6. Coach’s experience of intervention assessed using telephone interview with coach once all TOPS-UK participants have completed intervention
7. Intervention adherence and losses to follow-up assessed using records taken by coach of participation in weekly Skype sessions and use of intervention website (frequency, duration, progression) captured automatically by database throughout 16-week intervention period

8. Completeness of outcome and resource use data collected
9. Parents' and adolescents' experiences of study participation assessed using study participation questionnaires and telephone interviews (adolescent and parent) completed after the end of the trial

Previous secondary outcome measures added 06/12/2018:
1. Clinician ability to identify participants
2. Feasibility of online screening, consent & randomisation processes
3. Recruitment rate; proportion of eligible patients identified that are recruited
4. Willingness of families to be randomised and complete outcome measures
5. Adolescent and parent acceptability of intervention and outcomes
6. Coach's experience of intervention
7. Intervention adherence and losses to follow-up
8. Completeness of outcome and resource use data collected
9. Parents' and adolescents' experiences of study participation

Overall study start date
01/12/2016

Completion date
31/03/2019

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 10/05/2018:
1. Aged 12-18 years
2. Acquired brain injury, including moderate-to-severe TBI
3. Medically stable post-injury/illness onset with cognitive recovery having plateaued
4. Acute medical treatments for primary diagnosis completed
5. Executive function difficulties in the opinion of the local principal investigator
6. Access to the internet
7. Availability of at least one parent/guardian who lives with the adolescent to participate in the study

Previousparticipant inclusion criteria as of 10/05/2018:
1. Aged 12-18 years
2. Acquired brain injury, including moderate-to-severe TBI
3. Medically stable post-injury/illness onset with cognitive recovery having plateaued
4. Acute medical treatments for primary diagnosis completed
5. Executive function difficulties as reported by parents on BRIEF-2
6. Access to the internet
7. Availability of at least one parent/guardian who lives with the adolescent to participate in the study

Previous participant inclusion criteria:
1. Aged 12-16 years
2. Acquired brain injury, including moderate-to-severe TBI
3. Medically stable post-injury/illness onset with cognitive recovery having plateaued
4. Acute medical treatments for primary diagnosis completed
5. Received treatment for acquired brain injury within last 5 years

6. Executive function difficulties as reported by parents on BRIEF-2
7. Access to the internet
8. Availability of at least one parent/guardian who lives with the adolescent to participate in the study

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 25; UK Sample Size: 25

Total final enrolment
12

Key exclusion criteria
1. Insufficient English language or capacity for the parent/child to consent/assent to the study
2. Pre-injury or co-morbid conditions such as sensory impairments and global developmental delay, known to impair engagement with the computer and treatment materials
3. Non-accidental brain injury

Date of first enrolment
01/07/2017

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Devon and Exeter Hospital (Lead site)
Barrack Road
Exeter

United Kingdom
EX2 5DW

Study participating centre
Cambridge Centre for Paediatric Neuropsychological Rehabilitation (CCPNR)
Brookside Clinic
18D Trumpington Road
Cambridge
United Kingdom
CB2 8AH

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
University Hospital Southampton
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Queen's Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Royal Devon & Exeter Hospital

Sponsor details

Barrack Road
Exeter
England
United Kingdom
EX2 5DW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03jrh3t05

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study team will prepare a plain English summary of the study results, which will be sent to the study participants as soon as possible after the end of the study.

The final results of the study will be disseminated via presentations at appropriate scientific meetings and conferences (e.g. International Paediatric Brain Injury Society, International Neuropsychological Society, World Federation for Neuro-Rehabilitation) and publication in appropriate peer-reviewed journals (e.g. Neuropsychological Rehabilitation, Journal of Head Trauma Rehabilitation or Developmental Medicine and Child Neurology).

Intention to publish date
31/03/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/08/2019	27/08/2019	Yes	No
HRA research summary			28/06/2023	No	No