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Wellbeing in children with neurological conditions

Submission date
09/06/2015

Recruitment status
No longer recruiting

Registration date
25/09/2015

Overall study status
Completed

Last Edited
23/08/2022

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Children with neurological conditions such as epilepsy are significantly more likely to develop mental health difficulties, such as anxiety, depression and behavioural problems than children who do not have neurological conditions. These mental health difficulties can have as big an impact upon quality of life and functioning as the neurological condition itself. There are highly effective treatments for anxiety, depression and behavioural difficulties in children. These include self-help interventions with guidance from a therapist. However, there has been little research to determine whether these interventions work in children who have a neurological condition.
The aim of this study is to assess whether they work in children with neurological conditions and also help us to design a larger scale study. If the results suggest that they do work, then we hope that local child and adolescent mental health services, as well as paediatric services, will be able to offer integrated, affordable, accessible, effective interventions for children with neurological conditions and mental health problems.

Who can participate?
Young people aged 7-18 years old with a neurological condition and waiting for/undergoing assessment/treatment at Great Ormond Street Hospital, London.

What does the study involve?
Participants are randomly allocated to one of two groups: receiving a 10-session guided self-help cognitive behavioural intervention delivered over the telephone over 12 weeks or being in the waiting list group (before receiving the self help intervention).

What are the possible benefits and risks of participating?
We cannot guarantee that the study will help individual families, but the information will help improve the treatment of children with anxiety, low mood or behavioural problems in the context of a neurological illness. There are no specific risks from taking part. The study is a ‘randomised waiting-list controlled study’, which means that a child might not be put into the group that receives the guided self-help intervention that we are testing straight away. However, these participants will still receive the intervention after 12 weeks. If we think that a child needs to meet with someone to discuss their wellbeing sooner (for example if their mood

worsens considerably during this time), then we will refer them to other services that can help. No children will be deprived of an intervention that they would otherwise have received had they not been a part of the study. It is possible that thinking about their life and the effect of having a neurological condition could be upsetting for parents and/or their child. If the questionnaires do cause any distress, we can offer support and think about what further help is needed, including referral to other services if necessary.

Where is the study run from?
Great Ormond Street Hospital, London (UK).

When is the study starting and how long is it expected to run for?
October 2014 to October 2017.

Who is funding the study?
Institute of Child Health, University College London and Great Ormond Street Hospital charity, London (UK)

Who is the main contact?
Dr Sophie Bennett
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

13BS22

Study information

Scientific Title
Guided self-help interventions for psychiatric disorders in children and young people with neurological conditions: a feasibility study assessing symptom improvement on standardised questionnaire measures and a diagnostic screening instrument

Study objectives
A guided self-help treatment for common mental health disorders will be feasible and effective in reducing symptoms of anxiety, depression and/or disruptive behaviour in children and young people who have neurological conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Camden and Islington NRES Committee, London, 09/10/2014, ref: 14/LO/1353

Study design
Feasibility study. Randomised controlled intervention trial comparing a guided self-help intervention with a waiting list control group.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Mental health disorders (anxiety, depression and disruptive behaviour) in children and young people with neurological conditions.

Interventions
Intervention arm: a 10-session guided self-help cognitive behavioural intervention delivered over the telephone over 12 weeks

Comparator: 12-week waiting list

Intervention Type
Behavioural

Primary outcome measure
1. Primary mental health outcome: Strengths and Difficulties Questionnaire (SDQ) total score post-intervention and follow-up (weeks 12 and 24)
2. Primary physical health outcome measure: Paediatric Quality of Life Generic Core Scales (weeks 12 and 24)

Secondary outcome measures
1. Revised Child Anxiety and Depression Scale (12 weeks and 24 weeks)
2. Development and Wellbeing Assessment (12 weeks and 24 weeks)

Overall study start date
01/10/2014

Completion date
01/10/2017

Eligibility

Key inclusion criteria
1. Young people aged 7-18 years
2. With a neurological condition and waiting for/undergoing assessment/treatment at Great Ormond Street Hospital
3. Identified by the DAWBA as meeting criteria for impairing common psychiatric symptoms (anxiety, depression or disruptive behaviour)

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
34

Key exclusion criteria

1. Children/families who do not speak/understand English sufficiently well to access the screening assessments and interventions. This is primarily due to limited funding capacity for interpreters, however should sufficient additional funding be obtained, then we would seek to recruit these families and to hire interpreters to allow equitable access to the intervention.
2. Children who have an intellectual disability at a level meaning that they cannot access the screening and/or intervention. This will be determined by clinical judgement, either prior to screening, if the child is already known to GOSH, or at the initial assessment for guided self-help. This will not be defined by IQ, but by clinical judgement; children will not be excluded because of the presence of an LD per se, but because of being unable to access the materials. People will not be excluded post-testing on the basis of IQ score. Ability to participate may be different for younger children with relatively low IQs, whose parents complete the materials, compared to older children with the same IQ level who need to complete the materials themselves. If the learning disability is identified during the initial assessment (through clinical judgement), young people will be referred to other more appropriate services, as necessary (with the agreement of the family).
3.In phases 2 and 3, children who screen for a severe mental health disorder other than depression, anxiety or disruptive behavioural disorders, or whose screening is otherwise suggestive of risk will be excluded and referred to other services as appropriate. The research team comprises of a number of trained clinicians, who will be well-placed to liaise with, and refer to, other services. This may include (although is not restricted to) local CAMHS, the GOSH Psychological Medicine Team or paediatric psychology. This procedure will also be followed should it become apparent that there is risk, or a requirement for a higher intensity intervention, during the course of guided self-help. Consistent with best practice guidance (e.g. Department of Health, 2007) if the risk is immediate and requires urgent assessment or higher intensity intervention, then children will be referred on as necessary. Liaison will continue until the risk is adequately managed.

Date of first enrolment
01/04/2015

Date of final enrolment
01/11/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Great Ormond Street Hospital for Children
London
United Kingdom
WC1N 3JH

Sponsor information

Organisation
Great Ormond Street Hospital for Children NHS Foundation Trust

Sponsor details
Joint Research and Development Office
Great Ormond Street Hospital for Children NHS Foundation Trust
UCL Institute of Child Health
30 Guilford Street
Bloomsbury
London
England
United Kingdom
WC1N 1EH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03zydm450

Funder(s)

Funder type
Research organisation

Funder Name
Institute of Child Health, University College London

Alternative Name(s)
UCL Great Ormond Street Institute of Child Health, GOS ICH

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Great Ormond Street Hospital Charity

Alternative Name(s)
Great Ormond Street Hospital Children's Charity, GOSH Charity, GOSH

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Following completion of the study in 2017, we will disseminate the findings in a variety of ways including:
• Publication in peer-reviewed scientific journals
• Presentations at relevant national and interventional conferences
• Publication on our research-group website
• Stakeholder Meeting: We will hold a Research Update meeting for participants, stakeholders and non-scientific audiences with PPI involvement

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
Individual participant level data will not be made available as it may identify participants with rare conditions. Data will be held at Great Ormond Street Hospital for Children NHS Foundation Trust.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2018	21/06/2019	Yes	No
Results article	results	05/01/2021	12/01/2021	Yes	No
Protocol article		04/11/2016	23/08/2022	Yes	No
HRA research summary			28/06/2023	No	No