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Improving mental health outcomes for adolescents with learning disabilities: a home-base intervention study

Submission date
30/07/2021

Recruitment status
No longer recruiting

Registration date
20/09/2021

Overall study status
Completed

Last Edited
24/05/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Some Individuals with learning disability demonstrate some behaviours that are difficult to manage. Staff in special schools may have techniques to help manage these challenges, but children and adolescents spend most of their time at home and often these strategies are not directly taught to parents. Currently, most interventions to manage behavior that challenges are provided in schools, although those children and adolescents spend only a third of their time in school. Parents are rarely involved in interventions and generalisation to the home situation is very limited. The focus of the proposed study is on helping parents of adolescents with intellectual disabilities (with or without autism) to manage concerning behaviors through home-based interventions. Working with a therapist, parents will establish some goals and strategies to resolve problems they experience with their child. our aim is to provide additional support outside the school environment teaching home-based interventions for parents for this population.

Who can participate?
Families who have a child with learning disabilities with or without autism aged between 11 and 19 years old.

What does the study involve?
Firstly parents will complete a few questionnaires. The questionnaires include questions regarding the child's behaviour and some questions about the particiapnt's home that are relevant to our study. These questionnaires will be used to help us understand the participant's profile of strengths and difficulties. Some questionnaires will help us measure any changes in the participant's behavior or skills during the time they are involved in the study. Then, one of our therapists will visit the participant's home to learn about their behaviour or skills and decide together with the parents what they would like to work on at home. We estimate that interventions could last between 4 to 12 weeks.

What are the possible benefits and risks of participating?
All families in this study will have direct contact with a therapist teaching them to manage

behaviours that challenge or develop their child's functional skills at home. At this stage of the study, we do not know whether the home-based interventions will be helpful but we hope that we will learn information about how to test this properly.

Where is the study run from?
Evelina London Children's Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2021 to May 2023

Who is funding the study?
Guy's and St Thomas' Charity (UK)

Who is the main contact?
Dr Michael Absoud, Michael.Absoud@gstt.nhs.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
299406

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 299406, CPMS 50357

Study information

Scientific Title
AdolesCents Home based InterVEntion Study

Acronym
ACHIEVE

Study objectives
Adolescents with intellectual disabilities (with or without autism) can present with behavior that challenges and/or a mental health condition (such as depression, anxiety, obsessive-compulsive disorder). Currently, most interventions to manage behavior that challenges are provided in schools, although those children and adolescents spend only a third of their time in school. Parents are rarely involved in interventions and generalisation to the home situation is very limited. The focus of the proposed study is on helping parents of adolescents with intellectual disabilities (with or without autism) to manage concerning behaviors through home-based interventions. Our aim is to assess the feasibility and acceptability of teaching home-based interventions for parents for this population. We aim to recruit 60 adolescents aged between 11-19 years who attend local (South London) special school provision but who do not currently benefit from the education and therapy interventions at home.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/10/2021, London - Queen Square Research Ethics Committee (HRA NRES Centre Bristol, 3rd floor, block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8061; queensquare.rec@hra.nhs.uk), ref: 21/LO/0645

Study design
Single-centre interventional

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Adolescents with intellectual disabilities (with or without autism)

Interventions
The primary focus of our study is to provide intervention to individuals with restricted communication, poorly developed functional skills and behaviour that challenges, with parents who are expressing concern about supporting their child at home. This will be delivered by individualised therapy sessions via home-based and video link sessions to families. The sessions will be delivered by the therapists (SLT or OT) and follow similar procedures as face-to-face therapy sessions. The therapists will engage with parents to establish the target areas (up to 3 target areas) to work during the intervention sessions.

The number of interventions sessions will depend on the number and the type of target areas. Interventions session will range between 3 to 10 sessions for each family. Parents will share in setting problem-specific targets for their child. Pre-treatment and immediate post-treatment measures of these targets will be made by the therapists using Goal Attainment Scales (GAS) and COPM.

Intervention Type
Behavioural

Primary outcome measure
Measured pre- and post- intervention:
1. Extent to which patient's individual goals are achieved in the course of intervention measured using Goal Attainment Scaling (GAS)
2. Problematic target areas measured using the COPM in a semi-structured interview

Secondary outcome measures
At baseline and post-intervention:
1. Demographics measured using a questionnaire designed to collect families' demographic information such as first language, ethnicity background.
2. Stress parents are experiencing and what factors are causing this stress measured using the Autism Parent Stress Index (APSI)
3. Mental health and problematic/risky behaviours measured using the Assessment of Concerning Behaviour Scale (ACB)
4. Behavioural and emotional problems measured using the Developmental Behaviour Checklist

(DBC)
5. Personal, social and health service resource usage measured using the Child and Adolescent Service Use Schedule (CA-SUS)

Overall study start date
30/07/2021

Completion date
01/05/2023

Eligibility

Key inclusion criteria
1. Age between 11 and 19 years
2. Clinical diagnosis of learning disabilities with/without autism spectrum disorder
3. Willing to consent to participation and able to engage in intervention at home

Participant type(s)
Patient

Age group
Mixed

Lower age limit
11 Years

Upper age limit
19 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Parents with reduced levels of spoken and/or understanding of English, which would limit participation
2. Children with current child protection issues

Date of first enrolment
22/11/2021

Date of final enrolment
01/04/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Evelina Children's Hospital
Newcomen Centre at St Thomas
Floor 2
Becket House
St Thomas Hospital
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SE1 7EH

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/Home.aspx

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Charity

Funder Name
Guy's and St Thomas' Charity

Alternative Name(s)
Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of the research will be targeted for publication in peer-reviewed journals of general and special interest. The study details and anonymised results will also be presented at relevant conferences and academic or educational meetings.

Intention to publish date
02/04/2024

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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?
HRA research summary			28/06/2023	No	No