

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

Submission date 30/07/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 20/09/2021	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/05/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 participant'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

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

299406

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

11 years

Upper age limit

19 years

Sex

All

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**

United Kingdom

England

Study participating centre

Evelina Children's Hospital

Newcomen Centre at St Thomas

Floor 2

Becket House

St Thomas Hospital

London
United Kingdom
SE1 7EH

Sponsor information

Organisation

Guy's and St Thomas' NHS Foundation Trust

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

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?
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HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes