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Remote video interaction guidance for families of children with an intellectual disability who have been referred to specialist mental health services

Submission date
27/10/2022

Recruitment status
No longer recruiting

Registration date
28/12/2022

Overall study status
Completed

Last Edited
20/03/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Behaviours that challenge and mental health problems are 3-4 times higher in children with an intellectual disability (learning disability in UK services) compared to other children. The National Institute for Health and Care Excellence (NICE) recommends that services support families to manage effectively at home. Children with a learning disability and behaviour that challenges or mental health problems are referred to specialist child mental health services for support. Remote therapy could increase the reach of therapies that can help these families. Video Interaction Guidance (VIG) is increasingly used in specialist mental health services to help families. VIG is a brief, personalised, strengths-based intervention: it uses video to identify successful moments of communication/interaction between a parent and a child as a tool to improve parent-child interaction and relationships. To determine if VIG works well as a remote therapy, the first step is to determine if we can recruit parents to a study and if they like VIG.

Who can participate?
Parents or carers of a 6-12 year-old child with a learning disability referred to specialist child mental health services.

What does the study involve?
Parents who are interested meet with a researcher to check if the study is definitely for them (this is called screening). If it is, parents provide information about themselves and their child in two ways: by filling in a survey and doing an interview. This is the first data collection. After this, data collection is repeated 3 months and 6 months later. After the first data collection, a computer decides - by chance - if parents are offered the usual support by their mental health services or the usual support plus VIG.

What are the possible benefits and risks from participating?
Taking part in the research involves completing questionnaires and interviews. We do not anticipate risks from taking part in the research. Some of the questionnaires contain questions

some parents may find upsetting (for example questions about things the child may find challenging or questions about parents' own mental health). We do not yet know if VIG is helpful to families or not. Parents may be selected to be offered VIG or they may not. Participation in the study may not provide parents with a direct benefit except for a modest compensation for their time to contribute to the data collection. By contributing to how future studies are designed and run, parents will be benefiting carers and families like theirs to take part in future trials.

Where is the study run from?
Tavistock & Portman NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2022 to December 2024

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

Who is the main contact?
1. Dr Charmaine Kohn, IDVIG-LD@tavi-port.nhs.uk
2. Dr Vaso Totsika, v.totsika@ucl.ac.uk

Contact information

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Public

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Additional identifiers

Integrated Research Application System (IRAS)
315829

Central Portfolio Management System (CPMS)
54410

Protocol serial number
T-2045

Study information

Scientific Title
A feasibility trial of remotely-delivered video interaction guidance for families of children with a learning disability referred to specialist mental health services: the VIG-LD study

Acronym
VIG-LD

Study objectives
To determine the feasibility of a randomised controlled trial evaluation of remotely delivered video interaction guidance (VIG) to parents of children with learning disabilities (LD) referred to specialist child mental health services

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/12/2022, London - South East Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8120, +44 (0)207104 8177, +44 (0)207 104 8263; londonsoutheast.rec@hra.nhs.uk), ref: 22/LO/0819

Primary study design
Interventional

Study design
Feasibility randomized controlled trial with embedded process evaluation and a parallel feasibility economic evaluation

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Intellectual disability

Interventions
Parents who are interested meet with a researcher to check if the study is definitely for them (screening). If it is, parents provide information about themselves and their child in two ways: by filling in a survey and doing an interview. This is the first data collection. After this, data collection is repeated 3 months and 6 months later. After the first data collection, a computer decides - by chance - if parents are offered the usual support by their mental health services or the usual support plus VIG. The researchers will follow families up to 6 months to measure: how many parents are recruited to the study; how many stay in the study at 6 months and complete the study questionnaires; how many families complete VIG, whether remote VIG is acceptable to families and services, and what factors make it easy or difficult to offer or take up remote VIG. At the end of the study, the researchers will determine, using pre-specified criteria, if they can proceed with testing in a large multicentre trial whether VIG is an effective therapy delivered remotely within specialist mental health services. They will communicate their findings to parents, specialist mental health services and researchers.

Intervention Type
Behavioural

Primary outcome(s)
1. Participant recruitment rate: the number of parents found to be eligible for the trial amongst those undergoing formal screening and the number of those screened who are randomised.
2. Study retention at 6 months follow-up: the percentage of participants who at the 6m follow-up have at least one questionnaire measure completed among all participants who consented to participate in the study.
3. VIG completion rate (3 out of a maximum 5 VIG cycles completed) : How many participants in the VIG group complete the expected 3 cycles of VIG.

Key secondary outcome(s)
1. Completeness of outcome measures: the number of participants who provide useable data on each study measure, estimated separately at each time point for every measure.
2. Acceptability of VIG to parents: analysis of qualitative data to identify what is helpful and/or challenging about engaging with remote VIG
3. Acceptability of VIG to clinicians: analysis of qualitative data to identify what is helpful and/or challenging about offering VIG remotely
4. Feasibility of remote implementation: analysis of qualitative data to describe perceived effectiveness, likely adaptations and any unintended implementation failures.
5. Preliminary assessment of service use and costs of remote delivery of VIG in specialist mental health services: how much it costs services to offer VIG remotely and whether researchers can collect data about the other health and social care services participants used during the study.

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. The parent has a child who is aged between 6 and 12 years (up to one day before 13th birthday on screening day)
2. The parent is the child’s biological, foster, adoptive or step mother or father or any other caregiver. The parent provides informed consent for participation
3. The child has an administratively defined LD: i.e., an administrative label within the education,

health or social care system identifying the child as having LD; or as eligible for neurodevelopmental services; or a diagnosis (learning/intellectual disability or [global] developmental delay for younger children). The child may be diagnosed with additional conditions (e.g., Down syndrome) or co-occurring neurodevelopmental disabilities conditions (autism). Children with LD and co-occurring conditions are eligible.
4. The child has a composite score of <80 on Vineland Adaptive Behavior Scales (Vineland-3 30) indicating significant developmental delay
5. The child has been referred to a specialist child mental health service (new or existing referral)

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Another sibling participates in the trial
2. The child lives with the parent <50% of the time, or is in a 24-h residential placement (inpatient unit or residential school)
3. The parent is receiving another video feedback intervention (e.g., VIPP, VIPP-SD, Marte Meo, Video Parent-Child Interaction) either remotely or in person
4. The family is under active family court proceedings

Date of first enrolment
15/01/2023

Date of final enrolment
28/02/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
-
-
-

England
-

Sponsor information

Organisation
The Tavistock and Portman NHS Foundation Trust

ROR
https://ror.org/04fx4cs28

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from VIG-LD@tavi-port.nhs.uk or the study CI Dr V Totsika. Data may be shared with others at the end of the study (2025) if participants who consented to participate in the present study have also consented for their pseudonymised data to be shared.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/03/2026	20/03/2026	Yes	No
Protocol article		05/12/2024	11/12/2024	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 1.3	06/02/2024	12/03/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes