Qualitative Protocol Development Tool

The research protocol forms an essential part of a research project. It is a full description of the research study and will act as a ‘manual’ for members of the research team to ensure adherence to the methods outlined. As the study gets underway, it can then be used to monitor the study’s progress and evaluate its outcomes.

The protocol should go into as much detail about the research project as possible, to enable the review bodies to fully understand your study.

The use of this collated consensus guidance and template is not mandatory. The guidance and template are published as standards to encourage and enable responsible research.

The document will:

- Support researchers developing protocols where the sponsor does not already use a template
- Support sponsors wishing to develop template protocols in line with national guidance
- Support sponsors to review their existing protocol template to ensure that it is in line with national guidance.

A protocol which contains all the elements that review bodies consider is less likely to be delayed during the review process because there will be less likelihood that the review body will require clarification from the applicant.

We would appreciate self-declaration of how you’ve used this template so we are able to measure its uptake.

Please indicate the compatibility of this template with any existing templates you already use by stating one of the following on the front of each submitted protocol:

- **This protocol has regard for the HRA guidance and order of content.**

FULL/LONG TITLE OF THE STUDY

A feasibility trial of remotely-delivered Video Interaction Guidance [VIG] for families of children with a learning disability referred to specialist mental health services

SHORT STUDY TITLE / ACRONYM

The **VIG**™-LD Study

315829 PROTOCOL V1.3 06FEB2024

RESEARCH REFERENCE NUMBERS

IRAS Number:	315829
SPONSORS Number:	T-2045
FUNDERS Number:	NIHR203051

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

Zaiba Khan

....

Name (please print):

ZAIBA KHAN...

Position: Sponsorship Officer...

Date:
06/02/2024

Chief Investigator:

Signature:

Name: (please print):

...............Dr Vasiliki Totsika............

Date:
06/02/2024

LIST of CONTENTS

KEY STUDY CONTACTS

Insert full details of the key study contacts including the following

Chief Investigator	Dr Vasiliki Totsika v.totsika@ucl.ac.uk 020 7679 9002
Study Co-ordinator	Dr Charmaine Kohn CKohn@Tavi-Port.nhs.uk
Sponsor	Tavistock and Portman NHS Foundation Trust, Research and Development, Noclor Research Support Service, 1st Floor, Bloomsbury Building, St Pancras Hospital, 4 St Pancras Way, London, NW1 0PE E: sponsor.noclor@nhs.net T: 020 7350 8507
Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	NIHR Research for Patient Benefit (RfPB) Grant. Reference NIHR 203051
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Committees	Project Management Group (PMG): led by Totsika, includes all co-investigators (see above) plus Study Co-ordinator Contact: VIG-LD@tavi-port.nhs.uk Trial Steering Committee (TSC): chaired by Dr Aditya Sharma (aditya.sharma@ncl.ac.uk; Child and Adolescent Psychiatrist). Members: Dr Cliona McDowell (Statistician), Dr Joanna Garstang (Paediatrician) and Ms Kathryn Cahalin (Parent Expert)

	Parent/Carer Advisory Group (PCA): led by Grant (Gemma.Grant@thecbf.org.uk), PPI lead. The PCA includes 10 parent/carers of children with a learning disability.

STUDY SUMMARY

Study Title	A feasibility trial of remotely-delivered Video Interaction Guidance [VIG] for families of children with a learning disability referred to specialist mental health services
Internal ref. no. (or short title)	VIG-LD
Study Design	Feasibility RCT with embedded process evaluation and a parallel feasibility economic evaluation
Study Participants	Parents who have a 6-12 year old child with a learning disability who has been referred to specialist mental health services
Planned Size of Sample (if applicable)	N=50
Follow up duration (if applicable)	6 months
Planned Study Period	July 1st 2022 – December 31st 2024
Research Question/Aim(s)	Research objective: To determine the feasibility of a randomised controlled trial evaluation of remotely delivered Video Interaction Guidance (VIG) to parents of children with LD referred to specialist child mental health services. Primary feasibility questions: 1. Participant recruitment rate 2. Study retention at 6 months follow-up 3. VIG completion rate (3 out of a maximum 5 VIG cycles completed) Secondary feasibility questions: 1. Completeness of outcome measures (useable items) 2. Acceptability of VIG to parents, the barriers and facilitators of engaging with remote VIG 3. Acceptability of VIG to clinicians, the barriers and facilitators of offering VIG remotely 4. Feasibility of remote implementation in terms of 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

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NIHR Research for Patient Benefit (RfPB)	

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor is responsible for the management and design of the study; for ensuring the resources required for initiation are in place and applicable regulatory approvals have been received before the study commencing and that the arrangements are in the place for monitoring and ensuring the study is compliant with Good Clinical Practice and all applicable regulations. The sponsor will also confirm there is a clear dissemination and data retention plan once the study has closed.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

1. Parent/Carer Advisory group (PCA): led by Ms Gemma Grant (study co-investigator) who is the PPI lead: the PCA will be set up to include up to 10 parents of children with a learning disability. The PCA will advise on study materials, recruitment processes, data analysis and dissemination content and strategy. Two parents from the group will contribute directly to the academic paper during dissemination. Some admin support with PCA meetings may be provided by study research staff. Grant will be the main link between the PCA and the Study Management Group (see below), feeding the PCA's feedback to the study team.
2. Project Management Group (PMG): led by Totsika, the PMG includes all co-investigators (Hassiotis, Gomes, Kennedy, Absoud, McNamara, Randell, Casbard, Grant and Levitt) and Study Co-ordinator. The PMG is responsible for the design and timely conduct of all aspects of the study.
3. Trial Steering Committee (TSC): the TSC will provide independent oversight on the conduct of the feasibility trial, including providing an independent view on the progression criteria outcomes. Admin support for the meetings will be provided by the study staff, and Dr Totsika will be attending the TSC meetings.

PROTOCOL CONTRIBUTORS

The contributors to this protocol are all the study co-investigators. The CI has led on the design of the study, and will lead on the conduct, data analysis and interpretation, manuscript writing and dissemination of the results. Co-investigators will collaborate on all these tasks. All final decisions regarding the study design and conduct are made by the CI/Sponsor and the Funder is not involved.

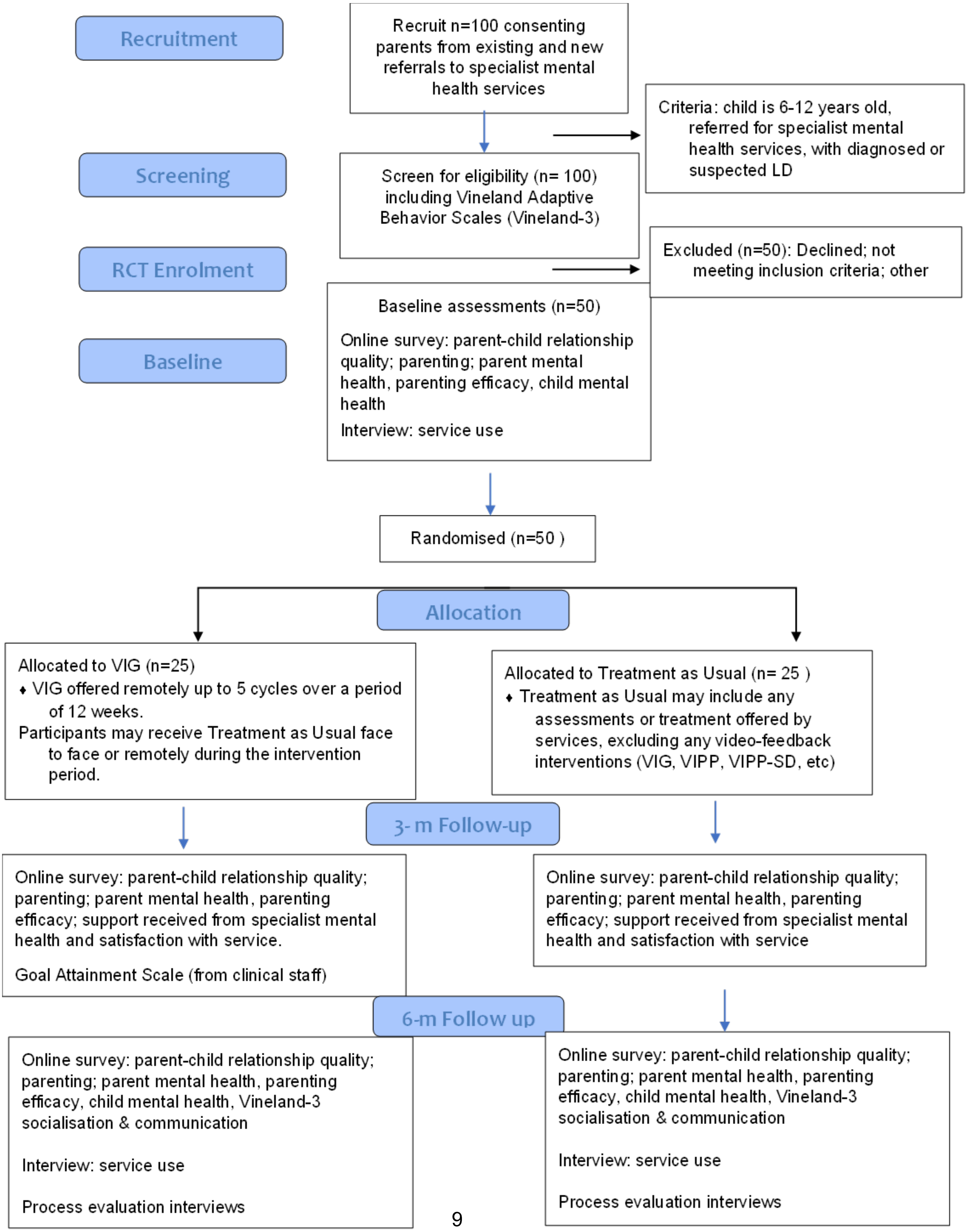
Members of the public have contributed to the design of the study as outlined in this protocol and will contribute to the conduct of the study. Parents of children with a learning disability who had received the intervention (VIG) were interviewed when the study was being designed (with funding and support from the North London Research Design Service). Similarly, several VIG practitioners were interviewed about their experience of delivering VIG remotely during the pandemic or their experience delivering VIG to families of children with a learning disability. Several aspects of the study design have been informed by these interviews.

During development of the present protocol, members of the PCA provided further feedback on the study design which resulted in some small changes to the design proposed here compared to the funding application (change of one measure, removal of another) as well as on all participant-facing CRFs which resulted in changes in the language used, where possible.

KEY WORDS: Video Interaction Guidance, video-feedback intervention; learning disability (intellectual disability), specialist mental health services.

STUDY FLOW CHART

The CONSORT-style flowchart shows the process of the feasibility trial in more detail.



Recruit n=100 consenting parents from existing and new referrals to specialist mental health services

Criteria: child is 6-12 years old, referred for specialist mental health services, with diagnosed or suspected LD

Screen for eligibility (n= 100) including Vineland Adaptive Behavior Scales (Vineland-3)

Excluded (n=50): Declined; not meeting inclusion criteria; other

Baseline assessments (n=50)

Online survey: parent-child relationship quality; parenting; parent mental health, parenting efficacy, child mental health

Interview: service use

Randomised (n=50)

Allocated to VIG (n=25)

- VIG offered remotely up to 5 cycles over a period of 12 weeks.

Participants may receive Treatment as Usual face to face or remotely during the intervention period.

Allocated to Treatment as Usual (n= 25)

- Treatment as Usual may include any assessments or treatment offered by services, excluding any video-feedback interventions (VIG, VIPP, VIPP-SD, etc)

Online survey: parent-child relationship quality; parenting; parent mental health, parenting efficacy; support received from specialist mental health and satisfaction with service.

Goal Attainment Scale (from clinical staff)

Online survey: parent-child relationship quality; parenting; parent mental health, parenting efficacy; support received from specialist mental health and satisfaction with service

Online survey: parent-child relationship quality; parenting; parent mental health, parenting efficacy, child mental health, Vineland-3 socialisation & communication

Interview: service use

Process evaluation interviews

Online survey: parent-child relationship quality; parenting; parent mental health, parenting efficacy, child mental health, Vineland-3 socialisation & communication

Interview: service use

Process evaluation interviews

Please note the acronyms stand for:

VIG: Video Interaction Guidance

VIPP: Video feedback Intervention to promotion Positive Parenting

VIPP-SD: Video feedback Intervention to promotion Positive Parenting and Sensitive Discipline

STUDY PROTOCOL

A feasibility trial of remotely-delivered Video Interaction Guidance [VIG] for families of children with a learning disability referred to specialist mental health services

1 BACKGROUND

What is the problem being addressed?

There are about 300,000 children with a learning disability in England. Learning disability often co-occurs with other neurodevelopmental conditions, e.g., autism. Challenging behaviours and mental health problems are 3-4 times higher in children with a learning disability (LD) compared to typically developing children (Einfeld et al., 2011; Totsika et al., 2011a). By 5 years of age, as many as 88% of these children present clinical levels of hyperactivity, conduct problems and emotional problems (Emerson & Hatton, 2007; Totsika et al., 2011b). By mid-childhood (age 11-12), levels of challenging behaviours and mental health problems are still significantly higher than in typically developed children (Bailey et al., 2019; Emerson & Hatton, 2007). One in seven children with a mental health problem is a child with LD.

The quality of the parent-child relationship and parenting are risk factors for challenging behaviours and mental health problems in these families (Rodas et al., 2016; Rodas et al., 2020; Totsika et al., 2014; Totsika et al., 2020). Children with LD are at higher risk of negative parenting and poorer parent-child relationships: there is more conflict and less closeness compared to other families (Totsika et al., 2014).

The COVID-19 pandemic has further exacerbated difficulties for these families with an increase noted in both child mental health problems and challenging behaviours as well as a deterioration in parental mental health and further strain on family relationships due to restrictions and disruption in service access (Paulauskaite et al., 2021).

Children with LD with challenging behaviour or mental health problems are referred to specialist child mental health services for treatment and support. Specialist mental health services are increasingly under strain (NHS Digital, 2020a), with therapy waiting time approaching 12 months; these issues have been exacerbated due to the pandemic. Remote family interventions could be an effective solution for both families and specialist mental health services (Aref-Adib & Hassiotis, 2021). The NHS long-term plan proposes digital interventions should be adopted to ease the pressure on specialist child mental health services. The Children's Commissioner (Children's Commissioner for England Office, 2021) highlights that, post-pandemic, remote interventions are even more crucial for achieving the NHS long-term plan. Where staff have had the experience of remote interventions (during the pandemic), they are keen to adopt them as a regular service offer, because they could improve access, waiting times and non-attendance rates (Sheehan et al., 2021).

Why is this research important?

Challenging behaviours and mental health problems in children with LD can lead to family breakdown and children have to move to specialist residential schools or inpatient units. Seventy per cent of about 6,000 children in residential schools are there because of challenging behaviour (Lenehan & Gerachty, 2017). Such placements cost up to £500m a year (Lenehan & Gerachty, 2017). A placement in Assessment and Treatment Units (ATUs) is estimated at £5m over three years per child (Lenehan, 2017). There are 250 children in ATUs (NHS Digital, 2020b). Parents say 'there is a better way' to support these children and families.

To minimise use of out-of-home placements, NICE (2018) emphasises the need for services to provide skilled support so that families can manage effectively at home. Typically, specialist mental health services offer parents psychoeducation, either group or individual. Group parenting programmes are one option but evidence highlights very low access (Sapiets et al., 2022), high drop-out rates linked to perceived poor match to family needs (Kleefman et al., 2014), and parent preference for personalised support that is flexibly delivered in the family's own environment and adapted to the family's needs (Coulman et al., 2020; Stanford et al., 2020). Individual psychoeducation could be personalised, but as a non-manualised approach, it can vary in content thus not necessarily targeting family mechanisms that maintain adverse child outcomes. There is, therefore, a clear need to develop the evidence base for remotely delivered, personalised family interventions that target mechanisms that contribute to child outcomes. Our proposal aligns with DHSC's Mental Health Research Goals (2020-30) for research on child mental health (Goal 1) and on improving access to mental health services (Goal 4) through family and parenting support. Our proposal addresses priorities 4 and 5 in the James Lind Alliance top 10 priorities for child mental health research.

2 RATIONALE

Video feedback interventions show promise for child mental health. Video feedback interventions tend to be brief, personalised, strengths-based interventions that use videotaped successful moments of parent-child interaction as a therapeutic tool (Kennedy & Underdown, 2018). Video Interaction Guidance (VIG) is the video feedback intervention most widely used in the UK. Based on Trevarthen's theory of inter-subjectivity that describes how parents communicate successfully with their infants, VIG aims to increase attuned interactions between two communication partners (Kennedy & Underdown, 2018).

Three systematic reviews, one of which is a Cochrane review for children under 5, identified significant gains in the quality of the parent-child interaction and improvements in child attachment following video feedback interventions (Balldin et al., 2018; Fukkink, 2008; O'Hara et al., 2019). As a result, NICE recommends video feedback interventions for pre-schoolers at risk of social-emotional problems (2012), and children with attachment difficulties (2016). The body of evidence is not specific to VIG as, to date, no effectiveness trial of VIG has been conducted. Further, the evidence is not specific to LD or other neurodevelopmental conditions, though video feedback is promising for this population and warrants further study (Barlow et al., 2016). Reflecting the lack of robust evidence for this population, NICE guidelines for autism services (2015) indicate video feedback interventions may be “considered”, albeit not yet recommended.

Moreover, the evidence available is not specific to child behaviour and mental health problems. However, research on mechanisms of risk suggests that video feedback interventions may benefit families directly through improvements in parent-child relationship, and indirectly through improvement in child challenging behaviours or mental health (Rodas et al., 2016; Rodas et al., 2020; Totsika et al., 2014; Totsika et al., 2020). We demonstrated that parent-child relationship in families of children with LD is a risk factor for challenging behaviours between 5 and 11 years (Totsika et al., 2014; Totsika et al., 2020).

Specialist mental health services are beginning to offer VIG to families of children with LD and comorbid conditions aged 6 years and over. One of the advantages of VIG over other approaches is that it does not require adaptation for different child populations. Though VIG shows promise and it is used in some services, we do not yet know whether it is widely acceptable to families and feasible to implement across specialist services. VIG has never been evaluated in specialist mental health services. To date, only two small studies of VIG have been conducted: a small pilot trial (N=31) with preterm neonates (Barlow et al., 2016), and a small (N=19), uncontrolled feasibility study with infants (Chakkalackal et al., 2017).

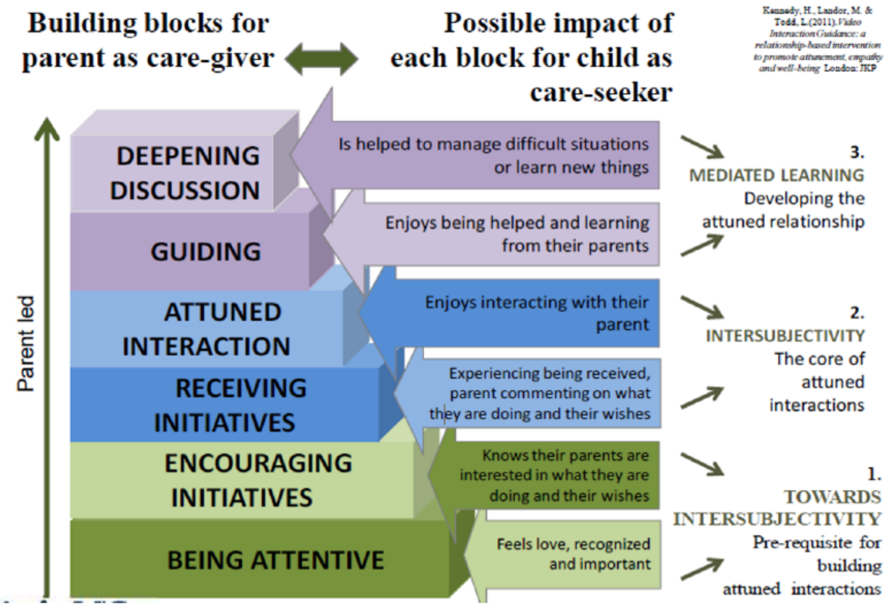
A feasibility trial is therefore needed to determine: the acceptability of remote VIG in this population as evidenced by both recruitment rate and engagement with the intervention. Parents referred to specialist services for child problems may prefer support focused on the child only; parents may not want remote therapy (Paulauskaite et al., 2021); previous studies included only an immediate follow up (Barlow et al., 2016; Chakkalackal et al., 2017), but VIG outcomes should be measurable in the medium term at 6 months follow-up (Balldin et al., 2018; O’Hara et al., 2019); and an appropriate primary outcome for a definitive evaluation, as evidenced by stakeholder perspectives on perceived impacts and levels of completeness of child outcome measures.

Since March 2020, VIG therapists have delivered VIG remotely. AVIGuk (the Association of Video Interaction Guidance that accredits all UK VIG practitioners - https://www.videointeractionguidance.net/) already provides guidance on delivering VIG through Microsoft Teams or Zoom. An NIHR-funded study (PI Professor Nicola Yuill, Sussex) analysed remote VIG sessions and compared them with face to face sessions, as well as interviewed therapists on their experience of remote VIG (http://www.sussex.ac.uk/psychology/chatlab/projects/zoomorroom). The study did not look at VIG with parents of children with LD, but VIG as used in the non-LD population. The study recently evidenced (2021) that the key therapeutic mechanisms of VIG (shared warmth, shared balance, individual responsiveness, and others) are present at similar levels when VIG is offered remotely compared to face to face. Therapists who used VIG remotely during lockdown provided insight on ways to enhance remote delivery. Importantly, 82% of VIG therapists wanted to continue providing VIG remotely after the pandemic.

3 THEORETICAL FRAMEWORK

The theoretical underpinnings of Video Interaction Guidance stem from Colwyn Trevarthen's theory of inter-subjectivity, which aimed to describe the development of shared understanding between a mother and an infant through the way the mother responds to the infant's communicative initiatives (Kennedy & Underdown, 2018). Some of the key propositions of this theory is that the positive communicative interactions are built when the mother is attentive and responds to the child's communicative attempts in an attuned way. Doing this systematically and consistently allows dyads to move beyond attuned communication towards 'mediated learning'. This is a theoretical concept derived from Vygotsky's work that suggests that, during interactions between parents and children, the parent needs to provide enough 'scaffolding' to the child to help them move forward independently; if they provide too little the child will fail and if they provide too much support, there is no learning happening. The schema below shows the theoretical underpinnings of VIG (copied from VIG training materials provided by AVIG-uk: https://www.videointeractionguidance.net/). Drawing on these, VIG theorists propose that children who feel listened to by their parents are more likely to listen to parent instruction. Where parents provide a consistent 'foundation of love, play and work, they are more likely to find managing problematic behaviour easier' (Kennedy & Underdown, 2018, pp. 226-227).

Figure 1: Schematic representation of the main theoretical constructs behind Video Interaction Guidance



Kennedy, H., Landor, M. & Todd, L.(2011). *Video Interaction Guidance: a relationship-based intervention to promote attunement, empathy and well-being* London: JKP

4 RESEARCH QUESTION/AIM(S)

To determine the feasibility of a randomised controlled trial evaluation of remotely delivered Video Interaction Guidance (VIG) to parents of children with LD referred to specialist child mental health services.

4.1 Objectives

Primary feasibility questions:

1. Participant recruitment rate
2. Study retention at 6 months follow-up
3. VIG completion rate (3 out of a maximum 5 VIG cycles completed)

Secondary feasibility questions:

1. Completeness of outcome measures (useable items)
2. Acceptability of VIG to parents, the barriers and facilitators of engaging with remote VIG
3. Acceptability of VIG to clinicians, the barriers and facilitators of offering VIG remotely
4. Feasibility of remote implementation in terms of 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

4.2 Outcome

The overall objective of the study will be to determine, following pre-specified criteria, whether we can proceed to a full trial without any modifications, with some modifications (and which ones), or whether a full trial of VIG-LD should not be pursued. The primary outcomes relate to feasibility of delivery and evaluation of remote VIG including: recruitment and retention, adherence (completion rate) and acceptability (of intervention, outcome measures and study processes).

4.3 Intervention

During VIG, the therapist meets with the parent to take a short video of the parent interacting with the child. This first meeting lasts about 20 minutes. At the second meeting (the week after), the parent and the therapist view select moments of the video, with a focus on moments when the interaction between parent and child is 'better than usual'. The therapist gently guides the parent to identify these moments and to identify how the parent's own behaviour contributes to successful and positive interactions. This second meeting is called shared review and lasts 40 minutes. The two meetings are called one VIG cycle. Three VIG cycles will be offered (standard practice), with an option for up to 2 additional cycles if the therapist or parent requests. An introductory and revision meeting take place around the cycles. The total maximum length of the intervention is 12 weeks.

Meetings typically take place in the parent's house or the clinic. When VIG happens remotely meetings take place over Teams or Zoom. For the purposes of this study, sites are being asked to offer VIG primarily remotely. However, if both the therapist and the parent consider a face to face meeting necessary to make the intervention more accessible, the first meeting for capturing the video (half of the 1st cycle) may take place face to face. Parents in the VIG group would also receive any other face-to-face or remote support made available by CAMHS during this 12-week period.

VIG is offered in few services so far, mostly face to face. Clinical services that offer VIG obtain consent from parents including for the video part which is integral to the mechanism of the intervention. Sites offering VIG and any other intervention as part of their usual support would be managing themselves the informed consent process with their clients. As an additional precaution, we added a clause in the study's consent form for participants in the VIG group to consent to being videotaped, in case any of the clinical sites do not have formal consenting processes for their interventions.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

Study Design: A feasibility randomised controlled trial of 50 parents allocated on a 1:1 basis into intervention or treatment as usual (TAU), with an embedded process evaluation. We will collect service use data for cost comparison in a parallel feasibility economic evaluation. This will be conducted by a series of questionnaires and interviews.

Randomisation

Randomization will take place after participants have consented to the study and have had their eligibility confirmed by the screening process. Participants will be randomized on a 1:1 basis to the two study arms (VIG+ treatment as usual vs treatment as usual). The randomisation will be performed by the study statistician at the Cardiff Centre for Trials research.

Data collection methods:

From study participants:

- **Interviews:** Parents will be interviewed to determine eligibility to be included in the study; in addition to a few questions matching the inclusion/exclusion criteria, parents will be administered the Vineland-3 (Sparrow et al., 2016) to determine their child's overall adaptive skills score. Parents who enter the study will be interviewed to measure their levels of service use (CA-SUS; Byford et al., 1999) at baseline (before randomisation) and 6 months after randomisation.
  For the process evaluation, **approximately** 10 parents (five from each group) and approximately eight clinical staff (including VIG clinicians and Service Managers) will be interviewed at the 6-month follow up (semi-structured interviews) to investigate their experience of the study (intervention and evaluation acceptability); perceived effectiveness of VIG and implementation issues (VIG group only); barriers and facilitators for engagement with VIG (VIG group only), and contextual service factors that affect VIG delivery (VIG group only). Interviews will take place over the telephone or an online video platform (Teams or Zoom). Interviews will last between 30 minutes to one hour.
- **Questionnaires**: Participants will be invited to complete questionnaires at baseline (before randomisation) and at two follow-up timepoints, 3- and 6-months post-randomisation: Parent-Child Relationship Scale (Pianta, 1992); parent mental health (PHQ-4; Kroenke et al., 2009); parenting (Alabama Parenting Questionnaire; Essau et al., 2006); parenting efficacy (Parenting Sense of Competence; Johnston & Mash, 2020); and child mental health (Developmental Behaviour Checklist-2 – DBC2 (not measured at 3-months); Gray et al., 2018). At 6-months, the survey will also include Vineland-3 items related to child socialisation and communication skills. At 3-months an additional question will measure the ways participants have been supported by specialist mental health services over the preceding 3-month period, so as to describe the content of Treatment as Usual (TAU) and VIG. Participants' satisfaction with specialist mental health services' input (both groups) will be measured using the 9-item 'Satisfaction with Care' sub-scale of the Experience of Service Questionnaire (ESQ; Brown et al., 2014). We envisage questionnaire completion to take place through an online survey link set up in Qualtrics; participants will also be offered a choice of completing the questionnaires offline (emailed a measure pack) or arranging a tele/video conference with the researcher to go through measures. Participants will be asked to complete the questionnaires within a 3-week window of either side of the follow-up date. Questionnaire completion will take up to an hour each time point.

Appendix 2 summarises data collection from study participants.

From service providers:

- **Survey:** VIG practitioners will provide data (through Qualtrics) on the Goal Based Outcomes Scale (3 months) for the VIG group only.
- **Interviews**: For the process evaluation, VIG therapists (approx. N=5) and service managers (approx. N=3) will be interviewed on their acceptability of the study processes; their perceived effectiveness and implementation issues in relation to VIG offered remotely; barriers and facilitators for engagement with VIG, and contextual service factors that affect VIG delivery.

Participant compensation: There is a small ‘thank you’ voucher for parents’ time to do the research: £10 for screening and then £20 for each data collection (baseline, 3 and 6 months follow up, total £60). An additional £10 data top up could be offered to some participants who need data to fill in the surveys. For parents and clinicians who participate in the process evaluation interviews a ‘£20’ thank you gift voucher will be offered. Compensations are managed by the research team.

Data management and storage: Data will be entered in Qualtrics by participants directly. Participants will be invited via a secure link to complete the questionnaires in Qualtrics; participants can complete Qualtrics questionnaires on their smart phones, PCs, tablets or other electronic devices. Information entered in Qualtrics is then saved directly onto a database. To be able to link the signed informed consent with the baseline and subsequently the two follow up surveys, Qualtrics requires setting up a non-anonymous link between all these elements (these are effectively treated by Qualtrics as four separate surveys). Participants will enter personal data in the consent form and one aspect of their personal data is carried over to the next survey (e.g., email address) so the participant can check it’s really them and change their information if they wish. When linked in this way, Qualtrics data are not downloaded all in a single database but separately to protect participants. To further protect participant anonymity, links to surveys are personalised (and emailed to each participant directly), rather than copied on websites or other open invitations. Personal identifying data downloaded from Qualtrics (names, email addresses, telephone numbers) will be kept in a password-protected database separate from the other study data. Study databases will be pseudonymised, i.e., participants will be allocated a code.

The study email address and the Study Co-ordinator’s phone number will be provided for parents who need support/have queries or who for whatever reason would prefer to complete the questionnaires in an interview (in this instance the researcher would ask the questions one by one and enter the data directly in the database). Interviews will be transcribed by the Study Co-ordinator or Research Assistants: these will be Master’s-level students from UCL who will be on Research Placement with the project (annual commitment) or UCL Master’s students doing their dissertation in this study. The team will not use external service providers for transcription. Excel will be used for quantitative data storage. Microsoft Word and NVivo will be the software used for qualitative (including interview files) data storage, assistance with transcription, and qualitative analysis. No visual recordings of interviews will be stored. Transcripts will be anonymised by removal of any identifiable information from the text and a pseudonym used in place of real names. Audio recordings of interviews will be deleted once the transcript of the interview is completed.

At the end of the data collection period, pseudonymised databases will be shared with UCL for analysis. The data transfer will take place via UCL's Data Safe Haven, a secure data transfer system that encrypts data in transit. The Data Safe Haven has been certified to the ISO27001 information security standard and conforms to NHS Digital's Information Governance Toolkit.

Prior to quantitative analysis, the CI (Totsika) and Study Co-ordinator will review the data for any participants who display highly unique 'special characteristics' who may be vulnerable to secondary identification due to their uniqueness. In such cases, the participant will be further protected by analysis criteria being amended so as not to highlight the unique characteristic. For example, if there is only one child from a specific ethnic background, with a specific condition, attending a special needs school then descriptive analysis criteria may be amended so as to reduce exposure in final analysis. Where we publish verbatim quotes from the qualitative analysis, these will be linked to a pseudonym (made up name or code), and pseudonyms will not be linked to participant information in publications.

Intervention fidelity: We will estimate whether VIG is being delivered with fidelity by scoring VIG practitioners using a standardised form. As part of routine clinical practice, VIG practitioners provide support to parents through a process called shared review (see 4.3). Practitioners record themselves when they do a shared review for the purposes of discussing their practice with their VIG supervisor (i.e., recordings of shared reviews are done by VIG practitioners are part of regular clinical practice – not as part of the study). To estimate fidelity, 25 shared reviews will be randomly selected among the 75-125 shared reviews likely generated during the course of the study. Levitt (the co-investigator who is an expert on VIG and a VIG supervisor) will code the 25 shared reviews using a standardised form called the Skills Development Scale (VIG-SDS) as she is watching them live/providing supervision in real time. No file transfer is required for this activity: all fidelity coding will take place in real time during supervision meetings. Each VIG practitioner owns and retains their own VIG shared review videos.

The Skills Development Scale (VIG-SDS) includes 11 items rated on a 0-6 scale. VIG-SDS indicates what score is expected from the VIG practitioner dependent on their level of expertise. These scores will be used to estimate fidelity. Scoring the VIG-SDS does not require any information about the parent.

Data Analysis:

Quantitative data will be analysed using descriptive statistics (frequencies, means, standard deviations). Qualitative data will be analysed guided by the MRC framework for process evaluation (Moore et al., 2015): the analysis will combine a bottom-up with a top-down approach to identify key themes emerging in the data across process evaluation domains of context, implementation and mechanisms of impact.

More detail on the proposed analysis to address the primary and secondary feasibility questions is provided here:

Recruitment: The study will note the number of referrals directly from clinicians, the number of people on mailing lists emailed study information, the number of interested parents undergoing screening, number ineligible, reasons for ineligibility, numbers who consent to be randomised, numbers and reasons for refusal to be randomised. The recruitment rate will be estimated from 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. The criterion to be met is that at least 50% of eligible parents participate, i.e., N=50 from 100 eligible).

Study retention: 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. The criterion to be met is that at least 70% of recruited participants are retained at 6m follow up. The percentage of participants who at 6 month follow up provided data on the DBC2 among those recruited (likely primary outcome in the final trial) will be estimated.

VIG completion: the number of recruited participants who received 3 VIG cycles among the recruited intervention group. The criterion to be met here is that at least 80% of participants receive 3 VIG cycles. VIG cycle completion is defined as one meeting to take a video and one meeting to go through the shared review.

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. The definition of 'useable' data will be pre-specified for each measure in the data analysis plan and it will correspond to having enough items to allow for the calculation of a total or subscale score.

Health economics data analysis: The health economic analysis will take the health and social care perspective. VIG practitioners and other health and social care service use will be costed using unit costs of health and social care (PSSRU; https://www.pssru.ac.uk/project-pages/unit-costs). The total cost of remote delivery of VIG will be reported as well as the extent to which this differs from the costs of providing TAU.

Acceptability of VIG: framework analysis of qualitative data from interviews with parents, VIG therapists and service managers. Acceptability of VIG will be coded with reference to an established framework for assessing intervention acceptability (Sekhon et al., 2017). Thematic analysis will identify key barriers and facilitators for remote VIG separately by stakeholder group.

Feasibility of remote implementation: Thematic analysis of qualitative data from interviews with parents and therapists in terms of stakeholders' perceived effectiveness, likely adaptations and any unintended implementation failures. Quantitative data on VIG fidelity will be estimated by determining the percentage of shared reviews with a VIG-SDS score at the level expected for level of training the practitioner has had. Patient satisfaction with VIG will be measured by summing the 9 ESQ Satisfaction with Care items and comparing them between the two groups (Brown et al., 2014).

Progression to a final trial: A traffic light system will determine readiness for a definitive RCT. It is anticipated that of about 100 families consenting to the study, at least 50 families will be recruited. A hypothesis testing approach will be used to determine the feasibility of recruitment (Lewis et al., 2021): A green signal for recruitment rate is defined as recruiting more than 50% of eligible families, 35-50% amber; and <35% red. With 90% power and 5% one-sided alpha, 97 families will need to be approached. If recruitment is within the amber zone, but above the critical value of 42, then minor changes will be required to improve recruitment, if recruitment is <42 then major changes will be required.

Traffic light signals (Avery et al., 2017) for study retention and VIG completion: A green signal for study retention rate will be to retain >70% of participants at 6m follow-up (60-69% amber, <60% red). A green signal for VIG completion will be >80% completing 3 VIG cycles (65-79% amber; <65% red). These three primary feasibility outcomes will be the basis for determining whether progression to a full trial is possible.

A green signal for measure completeness will be 100% - 80% of useable data for DBC2 scores (likely primary outcome in full trial). Any measure with <70% useable data will be reconsidered.

6 STUDY SETTING

Study settings are specialist mental health services (NHS). There are mainly two types of specialist mental health services in the NHS. The first type includes Child and Adolescent Mental Health Services (CAMHS) specific to children with an intellectual disability/learning disability (often referred to as LD CAMHS) or CAMHS that include a neurodevelopmental pathway for children with LD and/or other comorbidities such as autism or ADHD. The second type of specialist mental health services is found in specialist paediatric neurodevelopmental services that include a pathway for child behaviour/mental health problems. Children with an intellectual disability are referred to specialist mental health services for high levels of challenging behaviour or because they are suspected of mental health problems. Where the service includes a diagnostic pathway, children may be referred to for assessment for suspected neurodevelopmental disabilities. In the latter services, diagnostic assessments may be accompanied (in parallel or later) by a referral to the service's mental health pathway if challenging behaviours or mental health problems are identified on referral/on first assessment. Specialist CAMHS services tend to accept children from the age of 6 years. Specialist paediatric neurodevelopmental services accept children from a wider age range. The study will recruit from new and existing referrals to these settings.

It is anticipated 5-7 sites will be take part in the study throughout England (multi-centre study). Each site will undertake the same activities (recruitment to the study, offer of VIG to the intervention group, offer of Treatment as Usual to the intervention and comparison groups). Sites may already have one or more trained VIG therapists – may be already offering VIG as part of their therapeutic pathways or may not have any trained VIG therapists- may not offer VIG as part of their standard offer.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

The population for this study includes parents of 6-12 year-old children with a learning disability who have been referred to specialist mental health services. Eligible participants will be identified amongst the waiting lists of specialist mental health services (new or existing referrals) and will be screened according to the study inclusion/exclusion criteria specified below.

7.1.1 Inclusion criteria

1. Be a parent aged at least 18 years of age.
2. The parent has a child who is aged between 6 and 12 years (up to one day before 13th birthday on screening day).
3. 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.
4. 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 conditions (autism). Children with LD and co-occurring conditions are eligible.
5. The child has a composite score of <80 on Vineland Adaptive Behavior Scales (Vineland-3 30) indicating significant developmental delay.
6. The child has been referred to a specialist child mental health service (new or existing referral).

7.1.2 Exclusion criteria

1. Another sibling participates in the trial.
2. The child lives with the parent <50% of the time,or is in a 24hr 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.

7.2 Sampling

7.2.1 Size of sample

As this is a feasibility RCT, no power calculation was used to estimate the target sample size. The recruitment rate of similar studies (Chakkalackal et al., 2017; Coulman et al., 2020) was examined to determine an appropriate recruitment rate for the current study. Subsequently we estimated the adequacy of the proposed recruitment target to address the study's research questions. It is anticipated that of about 100 families consenting to the study, at least 50 participants will be recruited to the study. A hypothesis testing approach will be used to determine the feasibility of recruitment (Lewis et al., 2021). This is one of the three primary research objectives: A green signal for recruitment rate is defined as recruiting 50% of eligible families, 35-50% amber; and <35% red. With 90% power and 5% one-sided alpha, 97 families will need to be approached. If recruitment is within the amber zone, but above the critical value of 42, then minor changes will be required to improve recruitment, if recruitment is <42 then major changes will be required.

7.2.2 Sampling technique

Convenience sampling will be used: among those eligible to participate (7.1), those who express an interest in the study and fulfil the inclusion criteria will be recruited.

7.3 Recruitment

The local Research Delivery Team associated with each study site Trust will assist the clinicians with identification, approaching, informing and recruiting participants into the study. This is where Trust- employed research staff are considered part of the clinical team.

Potential participants will be initially identified by clinical teams or local Research Delivery Teams. Identification can occur either directly by clinicians during routine clinical contact or through site mailouts to patients on their referral list or waiting list or their active case load list.

In addition, the local Research Delivery Team will be able to contact potentially eligible participants directly from service lists or active case load lists to gauge interest in participating in the study. In either case, potential participants will be provided with brief information about the study including those cases referred by a Participant Identification Centre (PIC). Both clinicians and local Research Delivery Team members will receive guidance information on study inclusion/exclusion criteria. Supporting information will also be provided to PICs regarding the study should they wish to refer a parent of a child who may be suitable (outlined in section 7.3.1). To determine who clinical teams or local Research Delivery Teams should contact, the main criteria are: children need to be between 6 and 12 years old and have a confirmed or suspected learning disability, and have been referred to the service (or be on the waiting list or the active case list). Up to three attempts will be made to directly contact the parent/carer to introduce the study. After three unsuccessful attempts to make contact, no further contact will be attempted.

Parents who receive the information about the study and are interested will be required to contact the VIG-LD researchers directly or seek support from the clinical team or local Research Delivery Team (i.e., their expression of interest to be emailed to the VIG-LD researchers on their behalf with the parent cc'd into the email).

VIG-LD researchers will contact all participants who actively express their interest by contacting the study email address or mobile telephone number. The VIG-LD researchers will respond to the email or text message by offering to discuss the study further. For any interested parent, up to three attempts will be made to contact the potential participant either by email or phone call. If the potential participant does not respond to the researcher's response to the initial expression of interest after three contacts, the potential participant will not be contacted further. For those participants who respond to the researcher's response to their initial expression of interest, a time will be arranged to discuss the study and go through the Participant Information Sheet.

7.3.1 Sample identification

Identification of potential participants: Route 1 – Sites and local Research Delivery Teams:

Sites and local Research Delivery Teams will be provided with a study summary and a step by step guide to identifying potential study participants. The VIG-LD research team will request that the information is distributed to clinicians (site Principal Investigators), administrators and local Research Delivery Teams members for each site. The key criteria at this stage are: the child's age, the fact that the child's been referred to the site, and the child is suspected or identified with a learning disability.

Within clinical teams, the responsible clinician can pass on the study brief directly to parents during the context of a consultation if the three key criteria mentioned above are present. The parent can then opt to contact the VIG-LD research team as outlined in 7.3

Clinical and local research delivery teams will identify potential participants within the referral/mailing lists and email and/or call them directly to introduce the study and provide the study brief. The parent can then opt to contact the VIG-LD research team as outlined in 7.3.

Identifying information of potential participants will not be shared with the VIG-LD research team during recruitment. An exception to this will be where a potential participant expresses an initial interest about the study to the site clinician/administrator/ Research Delivery Teams member and asks for help contacting the research team: the site clinician/administrator/ Research Delivery Teams member could then use the research study email to contact the VIG-LD researchers cc-ing in the potential participant with their permission (i.e., the potential participant contacting the research team together with a site clinician/administrator/ Research Delivery Teams member). The process will then continue as outlined in 7.3.

Identification of potential participants: Route 2- Patient Identification Centres:

Patient Identification Centres (PICs) will be provided with a brief study summary and a step by step guide to identifying potential study participants. The VIG-LD research team will request that the information is distributed to clinicians and administrators in each PIC. For PICs, the key criteria are: the child's age, the child is identified or suspected of having a learning disability; the

PIC would like to refer the child to a specialist mental health service (site) for any reason matching the clinical eligibility criteria (e.g., because there are concerns about the child's mental health or the levels of challenging behaviour or other clinical reasons that warrant a referral to specialist mental health).

The responsible clinician or PIC administrator will refer the child to the site making a note in their referral that the parent might be a potential study participant.

On receipt of the referral, the site administrator/local Research Delivery Team member will contact the potential participant and provide the study brief, similar to the process described above. The potential participant can then opt to contact the VIG-LD research team as outlined in 7.3

As with sites, PICs will not pass to the VIG-LD research team identifying information of potential study participants.

Additional support with recruitment at PICs may be provided by the local Research Delivery Team operating at the study sites. On this occasion, participant identifying information will again not be passed to the VIG-LD research team directly, unless the potential participant expresses an interest about the study to the local Research Delivery Team member and asks for help contacting the research team: the local Research Delivery Team member could then use the VIG-LD research study email to contact the VIG-LD researchers cc-ing in the potential participant with their permission (i.e., the potential participant contacting the VIG-LD research team together with the local Research Delivery Team). The process will then continue as outlined in 7.3.

Signposting of potential participants

The VIG-LD research team and charity partners (Challenging Behaviour Foundation and other charities or organisations supporting families of children with a learning disability) will advertise the study using social media (e.g., Twitter) signposting potential participants to the study's landing page (hosted by the Challenging Behaviour Foundation and UCL) where they can access further information about the study (the study brief and a video explaining the study) and contact their local clinical teams (sites for the study) to be connected to the study.

Screening of potential participants:

The screening assessment will take place over a telephone or video-conference meeting with the VIG-LD researchers. The VIG-LD researchers will go through the screening items using a standardised screening form (but delivered where possible as a conversation). The VIG-LD researcher will also complete the Vineland during the meeting. If the Vineland cannot be completed in one appointment, a second telephone appointment will be offered. The majority of the screening meetings will be undertaken by the Study Co-ordinator so as to provide parents with a single named contact, and a consistent experience. If demand for screening exceeds capacity and to avoid delays for the participants, we will engage local Research Delivery Teams and/or research assistants to conduct study screening processes.

Telephone interviews will be offered at a time that suits the parent, even if is after 5pm so as to enable participation from parents who may be single carers (Coulman et al., 2020). We followed NIHR guidance for research with under-served populations (NIHR, 2020a) guidance for COVID-19 inclusive research (NIHR, 2020b) and evidence from our research on barriers to accessing telehealth during COVID-19 (Paulauskaite et al., 2021) and trials of parenting interventions (Coulman et al., 2020).

To support parents who may not adequately understand verbal explanations or written information in English, all study materials have been reviewed by the Parent Carer Advisory Group and simplified language used throughout. In addition, a recruitment video will be developed to address issues with literacy potential participants may have. On first contact, the Study Co-ordinator (or research assistant/ local Research Delivery Team member) will ask if participants feel comfortable reading and speaking in English. If not, the participant will be ask whether they usually require help with written or spoken English and whether they have people available to help with this study. The Study Co-ordinator (or research assistant/ local Research Delivery Team member) will support participants with literacy issues by offering to complete measures talking through the questionnaires instead of parents filling in a Qualtrics survey. The study does not actively exclude people with difficulties with written or spoken English, although the support we can offer is flexibility in the data collection. The study has not been funded to cover interpreter or translation costs.

Once screening for eligibility has taken place and eligibility is confirmed, the Study Coordinator (or research assistant/ local Research Delivery Team member) will provide each participant with two standardised letters; one addressed to the GP and a Child Notification Letter. The purpose of both letters is to explain the aim and purpose of the study, provide information concerning the role of the participating parent and the contact details of the Study Coordinator. Participants are made aware that it is their decision to provide the letter to their GP should they choose to. The Child Notification Letter is developed in Easy Read format. Two versions have been developed; version one is designed for younger children (6-9 years) and version two for older children (10-12 years). We followed NHS England guidelines on Accessible Information and utilised images to support child comprehension of the information. Parents are encouraged to go through the letter with their children and support their children should their children wish to directly contact the Study Coordinator.

Identification of Process Evaluation interview participants:

Potential interview participants will be identified randomly from parents who were deemed eligible at time of screening. Stratification methods will be employed to ensure a balanced sample across factors such as VIG receipt and site. Clinical service staff will be approached for an interview if they provided VIG to at least one family, ensuring at least one practitioner is recruited per site. Service Managers will all be invited to interview.

Data related to recruitment:

Aggregated anonymous data will be collected from each site on the number of families they emailed or gave the study brief. This information will be collected from sites on a monthly basis.

When potential participants contact the research team, a Microsoft Excel secure database will be created to retain the information on recruitment and screening including identifying information of eligible participants and recruited participants. Participant identifying information will be deleted after completion of the study and publication of outputs (funder report and academic paper; summer 2025).

7.3.2 Consent

Written informed consent will be obtained from all study participants prior to *any* data collection, including screening. A Participant Information Sheet will be given to interested participants when they first contact the research team expressing an initial interest about the study (see 7.3) and it will be discussed with them when they meet with the researcher a few days later. Potential participants will have an opportunity to ask questions during that meeting as the researcher will go through the PIS with them. A link to the informed consent form will be emailed to them at the end of that first meeting (and the PIS again). The email address will have been made available by the potential participant when they first contacted the VIG-LD researcher expressing their interest in the study. The consent form was designed following HRA/MHRA guidelines on e-consent.

An 'Independent' survey will be set in Qualtrics just for the consent form: independent here means that it will include just the consent form not the subsequent questionnaires that need to be completed by study participants. The Qualtrics link will be emailed to the potential participant. The participant will have to read and initial the statements and then write their name as signature in this electronic document. The participant will also enter the code for SITE ID that they first encountered in the VIG-LD study brief (given by the site) and then again at the researcher's response to their initial Expression of Interest.

If for whatever reason participants cannot complete the consent in Qualtrics they will be provided with an editable offline version of the consent that they could sign by hand or offline and return by email: the participant could sign by hand and then email the team a photograph of the hand-signed consent or the participant could fill in their name electronically and then save it as a PDF to email it back to the VIG-LD research team.

Once received signed, a copy of the completed consent form as well as the Participant Information Sheet will be emailed to the consenting participant (for their records) and a copy will be retained in the research team (securely stored in the Tavistock server and separate from other data).

Participants will be asked to complete and send the signed consent within 24 hours of the meeting (if it is a working day). Participants will be asked to volunteer reasons for not consenting to participation if they choose. If the consent form is not received, the VIG-LD researcher will contact the potential participant three more times spread over a three week period. If a potential participant does not respond following the 3rd attempt they will not be contacted again.

As the parent is the participant in the present study, child assent will not be sought. However, consenting and eligible parents will be provided with a Child Notification Letter that explains the purpose and process of the study to children. The participant will be encouraged to go through the Child Notification Letter with their child. The letter includes information on how to contact the Study Coordinator if the child wishes to do so.

A separate consent form will be obtained for those who will participate in the process evaluation interviews; these will be both clinical service staff and parents. For this part of the study, a separate Participant Information Sheet and Consent form are available

Due to the aims and context of the research, monitoring of participants' capacity will not be undertaken. After consent, continued capacity will be assumed. However, help resources will be available through their clinical team should a participant require support due to loss of capacity.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

There are three potential risks to participants in this study:

1) The protection of their personal information and the provision of informed consent for participation: participants will be provided with clear information on the mechanisms associated with the protection of their personal information in the Participant Information Sheet. Participants need to provide written informed consent to participate in the present study. A Data Management Plan will be developed to guide all aspects of data management and data analysis prior to data collection.
2) Psychological distress during data collection: as participants will be invited to provide information about their child's behaviours that challenge and mental health, it is likely they might experience mild psychological distress associated with reflecting on their own mental health and the challenging behaviours of their child while filling in the relevant questionnaires. The Participant Information Sheet alerts participants to this risk and directs them to resources and support available by the charity Cerebra (that is independent of this study) as well as to their GP or collaborating clinical sites teams. The study team have developed a letter addressed to the GP informing of the nature of the study and what participation involves. Parents are provided with a copy of this letter once their participation is confirmed and have the choice to share with their own GP as desired.
3) Disclosure of issues that have safeguarding implications during data collection processes: data collection involves interviews with participants. In the event of disclosure of an issue that has safeguarding implications (adult safeguarding or child safeguarding), the researcher will raise the issue with their line manager (both the study CI and Dr Kennedy) immediately following the disclosure and no later than 24 hours after the disclosure. Trust policy will be followed should the matter need to be escalated further by contacting safeguarding@tavi-port.nhs.uk

Potential risks to researchers in this study:

There is minimal risk to the researchers themselves as all research will be done remotely. Researchers will be offered supervision and are able to contact the CI after data collection appointments if they need support. If the Study Coordinator is in need of additional support, they have access to other members of the Co-Investigators team which includes two psychiatrists. If the Research Assistants require support, they are able to contact the Study Coordinator who is also a qualified therapist and provider of supervision.

All members of the research team collecting data from participants directly will receive training on Good Clinical Practice, Data Protection and Safeguarding.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from an NHS Research Ethics Committee (REC) for the study protocol, informed consent forms and other relevant documents associated with this protocol.

- Any amendments, with the agreement of the sponsor, will be submitted to the relevant regulatory body. Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- The Chief Investigator will produce annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

- Before any site can approach participants about the study, the Chief Investigator/Principal Investigator will ensure the study has gained HRA approval and REC favourable opinion.
- For any amendment to the study, the Chief Investigator in agreement with the sponsor will submit information to the HRA and REC for them to issue approval for the amendment. The Chief Investigator will work with sites (relevant R&D departments) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study.

Amendments

The Project Management Team in collaboration with the Sponsor will determine whether an amendment is substantial or non-substantial. The guidance below will be followed: https://www.hra.nhs.uk/approvals-amendments/amending-approval/examples-of-substantial-and-non-substantial-amendments/

Following the decision, the Study Co-ordinator will amend the protocol and any associated documents and will notify the REC following the process described in the REC's initial decision letter/the Amendment Tool.

Version numbers and dates on documents will be used to identify the most recent protocol and documents. A separate document listing all amendments with dates and version numbers will be used to facilitate the process.

8.3 Safety Reporting

In the unlikely event that any Serious Adverse Events (SAEs) related to the intervention or research procedures should occur, the CI is responsible for ensuring that all staff involved in this study are familiar with the content of this section. Cis are responsible for notifying the Study Co-ordinator and CI. All SAEs must be reported immediately (and within 24 hours of knowledge of the event) to the sponsor by the study team. SAEs will be assessed at all follow-up time points, and intervention delivery staff will be trained to report these directly to the study team at any point during the study. Rates of SAEs by study arm will be reported to the TSC, and if required, to the REC. Additional information about the potential harm of the intervention will be collected through qualitative interviews with all stakeholders.

8.3.1 Definitions

Term	**Definition**
Adverse Event (AE)	Any untoward medical occurrence in a participant administered an intervention which are not necessarily caused by or related to the VIG.
Serious Adverse Event (SAE)	Any adverse event that - • Results in death • Is life-threatening* • Required hospitalisation or prolongation of existing hospitalisation** • Results in persistent or significant disability or incapacity • Consists of a congenital anomaly or birth defect • Other medically important condition***

*Note: The term 'life-threatening' in the definition of serious refers to an event in which the study participant was at risk of death at the time of the event or it is suspected that used or continued used of the product would result in the participants death; it does not refer to an event which hypothetically might have caused death if it were more severe.

** Note: Hospitalisation is defined as an inpatient admission, regardless of the length of stay, even if the hospitalisation is a precautionary measure for continued observation. Pre-planned hospitalisation e.g. for pre-existing conditions which have not worsened, or elective procedures, does not constitute an SAE.

*** Note: other events that may not result in death, are not life-threatening, or do not require hospitalisation, may be considered as an SAE when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

8.3.2 Causality

The assessment of whether or not an SAE is a consequence of receiving the intervention will be provided by the CI.

Relationship	**Description**	**Reasonable possibility that the SAE may have been caused by the intervention?**
Unrelated	There is no evidence of any causal relationship with the intervention	No
Unlikely	There is little evidence to suggest there is a causal relationship with the intervention. There is another reasonable explanation for the event (e.g. the participant's clinical condition, other concomitant treatment).	No
Possible	There is some evidence to suggest a causal relationship with the intervention. However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant treatments).	Yes
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.	Yes
Definite	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.	Yes

8.3.4 Reporting procedures

Any queries concerning adverse event reporting should be directed to the Study Co-ordinator.

All SAEs, whether expected or not, should be recorded on the relevant report form and followed up to resolution wherever possible. The CI (or delegated member of the SMG) should sign and date the SAE reporting form to acknowledge that they have performed the seriousness and causality assessments. SAEs should be reported from time of signature of informed consent, throughout the treatment period.

An SAE form is not considered as complete unless the following details are provided:

- Full participant study number
- A Serious Adverse Event
- A completed assessment of the seriousness, and causality as performed by the CI (or another appropriately qualified individual on the delegation log).
- Only reports of related and unexpected SAEs should be submitted to the REC. These should be sent within 15 days of the CI becoming aware of the event.

8.4 Peer review

The study was reviewed by an independent advisor from the North Thames Research Design Service who reviewed the application and protocol. This took place prior to and in parallel to the process of applying for NIHR RfPB support.

In addition, the study was reviewed by anonymous reviewers during the grant funding process. Comments from the reviewers were passed on by the NIHR RfPB panel and these led to various modifications of the study design.

8.5 Patient & Public Involvement

During development of the study protocol:
Parents with experience of remote VIG and VIG therapists with experience of delivering VIG remotely during the pandemic were interviewed. We spoke to two parents who had received VIG remotely through their educational psychology service. One family had experience of LD CAMHS referral in parallel to the receipt of remote VIG from educational psychology [VIG is currently more widely used in educational psychology, rather than specialist educational services]. Parents shared their experience of the process and reflected on perceived impacts; this helped us shape our draft logic model and identify additional outcomes for measurement (parenting, parenting efficacy). Although going through VIG was a positive and empowering experience for parents, they questioned whether effects lasted – reinforcing the need for us to measure effects in the medium-term. Parents were highly supportive of VIG being integrated in CAMHS. Their experience of CAMHS was mostly negative (for the lack of therapy available). Reflecting on their expectations from CAMHS, they wanted support focused on the child (ideally for someone to intervene on the child to reduce the challenging behaviours). This expectation is incongruent with the family-centred perspective largely adopted by specialist CAMHS services. In relation to this study, it raises questions regarding the acceptability of a parent-focused therapy, such as VIG, a therapy that shines the light on strengths rather than problems. This reinforced the need to consider acceptability as the primary outcome in the feasibility study. Parents were reimbursed for their time through a PPI grant from our Research Design Service.

Consultations included several VIG therapists (all educational psychologists in private or educational settings) with experience of remote VIG, some of whom had experience of VIG with families of children with LD. They reinforced that VIG is highly feasible with these families, even remotely. They were all very supportive of VIG being taken up by more services, so that it is more accessible to parents. Some queried whether remote delivery would be part of the post-pandemic world. Current findings from a VIG therapist survey, though, from Prof Yuill's team (University of Sussex) showed that 82% want to continue remote delivery post-COVID.

During the conduct of the study, a Parent Carer Advisory group including 10 parents of children with learning disabilities advised on study materials associated with this application. As a result of their feedback, the language used in all participant-facing materials was reviewed and some of the measures were changed. The PCA will further advise on recruitment processes, data analysis and dissemination content and strategy. Two parents from the group will contribute directly to the academic paper during dissemination. Our approach to PPI was informed by Staniszewska et al. (2017) The PCA is supported by Gemma Grant, our co-I who is the Children & Young People lead at the Challenging Behaviour Foundation (CBF).

8.6 Protocol compliance

All study researchers will follow the details outlined in the protocol. If any deviations are found, they will be logged into the deviation log and reported to the CI (and if relevant to the site PI). Major protocol deviations will be reported to the sponsor. Deviations which are found to occur frequently will require immediate action and they could potentially be classified as a serious breach.

8.7 Data protection and patient confidentiality

All investigators and research staff will comply with the requirements of the Data Protection Act 2018 and the General Data Protection Regulation (GDPR) with regard the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles throughout the study. Qualtrics will be used to collect part of the data for this study is a secure platform and is GDPR compliant; Qualtrics has been certified to ISO27001 information security standard and also meets the NHS Digital's Information Governance Toolkit standards. The CI will be the data custodian. Tavistock & Portman NHS Foundation Trust & UCL are the joint data controllers of the study.

Of note, recruitment and data collection is undertaken by research staff. Q.5 detailed how data from the various parts of the project will be stored and analysed. As a brief summary here, identifying personal information will be kept separate from all remaining data. Participant IDs will consist of an unrelated sequence of characters (a pseudonymised code) and the key (the link between participant ID and personal identifying information) will be retained separately in a password-protected file in a separate location to the storage of the main study database within secure Tavistock servers. As a further precaution, the CI (Totsika) and Study Co-ordinator will review the data for any participants who display highly unique 'special characteristics' who may be vulnerable to secondary identification due to their uniqueness. In such cases, the participant will be further protected by analysis criteria being amended so as not to highlight the unique characteristic. For example, if there is only one child from a specific ethnic background, with a specific condition, attending a special needs school then descriptive analysis criteria may be amended so to reduce exposure in final analysis. Where we publish verbatim quotes from the qualitative analysis, these will be linked to a pseudonym (made up name or code), and pseudonyms will not be linked to participant information in publications. No visual recordings of interviews will be stored, and audio recordings will be deleted once an anonymised transcript of the interview is completed. Transcripts will be anonymised through the removal of any identifiable information within the text and pseudonyms used in place of real names. Transcripts will be stored as a password protected word file on Tavistock & Portman NHS trusted server.

Participant identifying information will only be accessed by research staff responsible for recruitment (Study Co-ordinator,Totsika and research assistants). Pseudonymised files will be transferred securely to University College London for analysis purposes (see Q.5). Transfer will take place using UCL's Data Safe Haven which encrypts data in transit. Personal identifying information will be retained until the study is complete, the report to funder and academic papers are published (estimated summer of 2025). Pseudonymised data will be retained for a period of at least 20 years in line with the data retention policies in Tavistock & Portman NHS Foundation and University College London. Pseudonymised data will only be shared and retained between the sponsor organisation and UCL. All information above has been provided to study participants in the Participant Information Sheet along with links to Data Retention Policies and the host's Data Protection Officer.

8.8 Indemnity

The NHS indemnity scheme will cover the potential legal liability of the sponsor arising from the design, conduct and management of the study. Non-negligent harm indemnity is not a feature of this study.

Monitoring & auditing: The sponsor (Tavistock & Portman NHS Foundation Trust) is responsible for monitoring and auditing of the research to ensure research conduct is compliant with GCP and all applicable laws and regulations.

8.9 Access to the final study dataset

The study CI (Totsika) and Study Co-ordinator will have access to the full dataset. Co-Is Casbard, Randell and McNamara from the Centre for Trials Research will advise on analyses but will not retain or have access to the final dataset. Any requests to access the final dataset by a 3rd party will be reviewed by the CI. The final dataset will be anonymised. Site PIs will not have access to the final dataset as all study data will be collected by research staff not site staff. The dataset may be used for secondary analyses in the future and, for this, appropriate consent will be obtained by the participants (see relevant informed consent documents).

9 DISSEMINATION POLICY

9.1 Dissemination policy

The study protocol will be made available through the funder's website. The protocol will be registered with the International Standard Randomised Controlled Trial Number Register

(ISRCTN). A final report will be submitted to the funder and this will be made available through the funder's website. A paper with the study findings will be submitted for publication to an academic journal. A summary of the study findings will be emailed to study participants following publication of the report by the study funder and shortly before the planned deletion of all personal identifying information (summer of 2025).

The sponsor will own the data arising from the study. The funder (NIHR) will be named and acknowledged accordingly in any publication.

9.2 Authorship eligibility guidelines and any intended use of professional writers

All investigators and study staff are eligible to participate as co-authors in planned publications. No professional writers will be engaged. To determine eligibility for authorship we will follow the 4 criteria set out by the International Committee of Medical Journal Editors.

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11. APPENDICES

11.1 Appendix 1- Required documentation

Documents required prior to initiating a participating site:

1. CVs: CI and Study Co-ordinator
2. Study brief for sites
3. Study brief for PICS (if relevant)
4. Guide to recruitment for sites/pics (as relevant)
5. Study brief for participants -adapted to the site
6. A screening log for capturing aggregate anonymous activity on study brief sharing

11.2 Appendix 2 – Schedule of Procedures

Participant flow to the study

Sites > Study Brief for participants (mailout or in clinical consultation)

Potential participants contact Researcher (email or phone)

Telephone appointment with researcher to go through PIS and give consent form

Consent signed > Meeting with researcher for screening

Eligible and Consenting Participants				
Procedures	**Screening**	**Baseline**	**3 months**	**6 months**
Vineland Adaptive Behavior Scale 3 Domain-level version	X (interview)			X (socialisation and communication items only – survey)
Demographics		x		
Developmental Behaviour Checklist 2 (DBC2)		x		x
Child-Parent Relationship Scale- Short form (CPRS)		x	x	x
Patient Health Questionnaire-4 item (PHQ-4)		x	x	x
Alabama Parenting Questionnaire – positive parenting and inconsistent discipline		x	x	x
Parenting Sense of Competence (PSEC) – self efficacy		x	x	x
Goal Based Outcomes-Intervention group only			x	
Support from Specialist mental health team and satisfaction with service			x	
Child and Adolescent Service Use Scale (CA-SUS) - Interview		x		x
Parent Interview (Process evaluation)				x
Clinical Staff Interview (process evaluation)				x

13.3 Appendix 3 – Amendment History

Amendment No.	**Protocol version no.**	**Date issued**	**Author(s) of changes**	**Details of changes made**

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.