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A digital parent skills training programme for parents of children with intellectual disabilities

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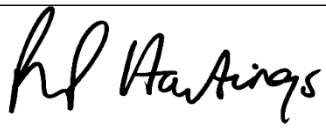
SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigators agree to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the relevant study regulations, GCP guidelines, and relevant SOPs.

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 intervention 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.

Chief Investigators:

Kylie Gray **Name**	 **Signature**	20.12.2023 **Date**
Richard Hastings **Name**	 **Signature**	20.12.23 **Date**

General Information This protocol describes the online Stepping Stones Triple P study, and provides information about the procedures for the study. Every care has been taken in drafting this protocol. However, corrections or amendments may be necessary. These will be circulated to the known Investigators in the study. Problems relating to the study should be referred, in the first instance, to the CIs.

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1 Amendment History

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version.

Amendment No. *(specify substantial/non-substantial)*	**Protocol version no.**	**Date issued**	**Summary of changes made since previous version**
1 (non-substantial)	1.1	07.02.2024	Added name of study manager, and minor edit to description of health economics work on page 11.

2 Scientific Abstract

Background: A high proportion of children with intellectual disabilities (ID) have clinically concerning levels of behaviour problems, coupled with elevated parental psychosocial health difficulties. Digital technology provides an unparalleled opportunity to deliver support interventions for families caring for a child with ID.

Aim: The primary aim of this study is to design a trial to examine the effectiveness and cost effectiveness of the Stepping Stones Triple P (SSTP) online parenting programme. The research team and collaborating organisations will work together to address six specific objectives to inform the design of a randomised controlled trial to achieve this aim. The objectives are:

1 Intervention delivery: Explore views on delivering the SSTP online parent skills programme with or without additional guidance. If consensus is that additional guidance/support is indicated, we will explore questions including how much support, who might deliver such support, and what form this support might take. Revise the current SSTP Logic Model.

2 Optimising engagement: Determine the potential barriers for parents in engaging with and maintaining engagement in a digital self-directed parenting programme and how best to overcome these.

3 Recruitment pathways: Determine the optimal way to recruit parents with a child with ID to a future trial. Explore potential recruitment pathways with practitioners and social care organisations, schools and support and advocacy/community organisations. Build relationships with organisations to facilitate recruitment for a future trial and seek initial agreement for Local Authorities to be involved as sites in a future trial.

4 Outcome measures: Review, seek PPI input about, and determine a candidate set of outcome measures as guided by the revised logic model for SSTP online. Measures will address key outcomes such as child behaviour and emotional problems, parenting practices, parent mental health and wellbeing, and family functioning. Guided by the Logic Model, a primary outcome for a future trial will be selected. Explore data collection tools for a health economics evaluation.

5 Intervention costs: Explore options for funding the intervention costs involved in delivering the SSTP online in the context of a randomised controlled trial.

6 Design of a future trial: Design a future trial to evaluate the SSTP online parent skills training programme.

Methods: We will work together with our PPI partner co-applicant Allard and the Council for Disabled Children (CDC) and PPI co-applicant Griffin to recruit parents to join a co-production group to work in partnership with the study team to address the key questions in relation to Objectives 1-4.

We will recruit up to six practitioners/senior staff from organisations that deliver Triple P and/or Triple P online, local authorities, and community-based organisations delivering parenting/family support for families of children with ID. Practitioners/senior staff will be invited to a consultation group to work with the study team to address Objectives 1-4.

Outputs: Study outputs will include a plan for a randomised controlled trial to examine the effectiveness and cost effectiveness of the SSTP online parent skills training programme, a

SSTP online Logic Model, and a grant application to NIHR HTA. Within the 12 month period, we will also produce a journal article about the PPI co-production process integrated with the consultative model with professionals.

3 Plain English Summary

Many children with learning disabilities have significant behaviour and emotional problems. Parents caring for a child with learning disabilities often have difficulties with their mental health and wellbeing. Parent skills training programmes can help to support families, but accessing such supports can be challenging for parents.

Digital technology, such as virtual and online programmes, is one way to provide support for parents caring for a child with learning disabilities. Accessing programmes online can be easier for families than attending sessions in person.

We want to design a study to test whether an online parent skills training programme called Stepping Stones Triple P can teach parents skills to support their child with learning disabilities and improve their behaviour and emotional problems, and in turn help parents to improve their own mental health and wellbeing. We will work together with parents to design this study. We will also work together with professionals and organisations who support families caring for a child with learning disabilities.

Together with our partner the Council for Disabled Children, we will invite up to six parents to form a co-production group with us to plan a study to test whether the online Stepping Stones Triple P programme can reduce child behaviour and emotional problems, and improve parent mental health and wellbeing. We will also invite six practitioners/senior staff from organisations who provide support and services to families to join a consultation group. These two groups will each work collaboratively with the research team over six meetings to address key questions and design the future study to test the Stepping Stones Triple P online programme.

The co-production and consultation groups will focus on: what should the online Stepping Stones Triple P programme look like and how can it best provide skills training for parents? Would including support and guidance from practitioners be helpful? If it is agreed that additional guidance/support is needed, we will explore questions including how much support, who might deliver such support, and what form this support might take. The groups will also explore potential challenges for parents in engaging with an online support programme and how best to overcome these. We will work together to find out the best ways to test whether the Stepping Stones Triple P online programme works, and in the future how to inform parents about the study and how they can be involved. We will also work with the practitioner consultation group to work out how providers of social care services (for example local authorities) and other community-based support organisations can assist in the delivery and testing of the Stepping Stones Triple P online programme.

At the end of this process, we will be able to design a future study to test the Stepping Stones Triple P online programme and see if it is helpful for children with learning disabilities and those who care for them. We will write an application for funding to do this study. We will also write a report together with our co-production partners about the work we have completed together.

4 Research Plan

Children with intellectual disability (ID) have an IQ <70, with associated deficits in adaptive skills, and their impairments emerge in the “developmental period” – typically considered to be before age 18 years. Data from UK population-based research show that parents, especially mothers, of children with ID are 2-3 times more likely to report elevated or clinically concerning levels of mental health and other psychological problems when compared to parents who do not have a child with ID (1). Population-based data for the UK and other countries suggest that rates of mental health problems at a level of clinical concern range between approximately one third and one half of this population of parents (2). Thus, parents of children with ID represent a high risk population in terms of parental psychosocial (ill)health.

Other population-based data have shown that children with ID are 4-5 times more likely to have a diagnosable mental health disorder (3) compared to other UK children. In addition, high proportions (60-80%) of children with ID in population-based samples have clinically concerning levels of behaviour problems (including hyperactivity and conduct problems) (1). Families of children with ID also face significant social and economic inequalities, including being approximately twice as likely as other families to be experiencing income poverty, low parent education levels, exposure to potentially adverse experiences, and parent unemployment (3). These social and mental health inequalities for children with ID and their parents emerge early in life – by the time the child with ID is 3-5 years of age at the latest (4). Linking multiple risk factors along a developmental pathway, longitudinal data suggest that early family adversity leads to decreased parental well-being that can reduce parent-child relationship quality and increase negative parenting practices, that in turn increase the behavioural and emotional problems of children with ID (5).

Given the research evidence, interventions are needed that target interacting factors in the lives of families of children with ID: family adversity, parenting and parent-child relationships, parent mental health, and child mental health. Although social policy supports are needed to directly reduce family poverty and other social risk factors, all these interacting factors can be improved as primary and secondary outcomes through parenting programmes. Such programmes help to improve parenting and parent-child relationship, directly reducing children’s behavioural and emotional problems. Through these changes, parental mental health can be improved and families may be able to directly improve the adversity factors over which they may have some control. Therefore, parenting programmes may offer a systemic approach to boost the overall well-being of families of children with ID. This potential is recognised in NICE guideline recommendations on behaviours that challenge and mental health problems in children with ID (6, 7). NG11 and NG54 both recommend using behavioural parent training programmes in health and social care contexts – programmes either appropriately adapted from mainstream programmes or designed bespoke for families of children with ID.

Access to appropriate child mental health and parenting supports, however, is also a challenge for families of children with ID. For example, less than 30% of children with ID who also had a diagnosable mental health problem had access to mental health services in the preceding 12 months [3]. Similarly, 29% of families of young children with ID or autism reported direct support for themselves or their child in the preceding 12 months, with only

about 10% reporting that they had received parenting support of any kind (8). One option for increasing reach and removing some, though not all, access barriers is to offer digital (online, or virtual synchronous) interventions for parent carers of children with ID – which may be as effective as existing face-to-face approaches (9). Our research group is also currently conducting a funded systematic review of digital interventions to support families of children and adults with ID or autism [https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=407687], and findings from that review will be fed into the proposed project.

Triple P

One of the parenting interventions highlighted by NICE in NG11 and NG54 is the Triple P system, and specifically the Stepping Stones version for families of disabled children.

Triple P's Stepping Stones intervention (SSTP) has a programme theory that explicitly recognises the interconnection between child and parent outcomes in families of children with ID, and targets changes in parenting that are designed to affect the health of the parent and child (10). SSTP was developed, using parent and professional input, from the mainstream Triple P parenting programmes. SSTP is a fully manualised intervention, with a training programme for practitioners that includes accreditation. SSTP has also been shown to improve behavioural difficulties in children with ID (11-17). SSTP is already being delivered in services across the UK: since 2010, Triple P UK (the only training provider) has trained approximately 1800 practitioners in 856 social care, health, education and charity organisations.

Triple P online

The ever-increasing acceptability of digital technology provides an unparalleled opportunity to deliver parenting interventions for families caring for a child with ID. The Covid-19 pandemic resulted in a rapid shift to deliver social care and health interventions and supports in practice/services, including Triple P programmes, to families online.

Self-directed online Triple P parenting interventions have comparable treatment outcomes to those delivered face-to-face (18-20). Digital interventions broaden accessibility and reduce the well-documented logistical and personal barriers reported in face-to-face treatment (e.g., stigma, cost, travel, childcare). Digital parenting approaches may be desirable for parents caring for a child with ID who require specialized childcare or have physical access needs (27). Self-directed digital parenting programmes provide additional flexibility in terms of completing the skills training modules, but also enable parents to learn at their own pace.

Questions remain about how best to provide digital self-directed parent skills training programmes. Parent engagement is an important factor, with higher rates of attrition prior to intervention commencing in self-directed digital programmes compared to face-to-face (18). Whether there are better outcomes, or interventions are more acceptable, when some practitioner or peer support is added to self-directed digital programmes (to make them "guided") needs further research attention. A study of the Triple P self-directed programme with and without practitioner support reported that parents in the self-directed programme were less likely to complete the online modules, and parents in the self-directed plus practitioner support group were more engaged and satisfied with intervention (28). In other self-guided digital interventions for parents of children with ID, there is also some evidence

that adding (trained) peer support may improve outcomes and was perceived positively (21). Investigating ways to maximise the child, parent and family outcomes from digital programmes warrants further attention.

Despite these encouraging findings, the evidence base for digital, self-directed parent skills training programmes for the parents of children with ID is lacking. One study to date has explored SSTP in an online, self-directed delivery format, with telephone support, finding improvements in child behaviour problems at 3-month follow-up in an Australian study (22).

Children with ID and their parents face significant health inequalities and potential problems accessing appropriate support, a problem which has been exacerbated by the Covid-19 pandemic (23). Digital parenting skills training programmes such as those offered by Triple P, have potential to offer much needed support to families with a child with ID. Triple P online is widely available to families in the UK. It is currently offered to families by 52 Local Authorities in England, providing access to up to 33,000 parents. Triple P International has recently produced new materials for the self-directed online SSTP version of the programme. A robust evaluation of the online Stepping Stones Triple P programme is, therefore, warranted.

Aims and Objectives

The primary aim of this study is to carry out preparatory work towards and to design a trial, with an embedded process evaluation, to examine the effectiveness and cost effectiveness of the Stepping Stones Triple P (SSTP) online parenting programme. The proposed research team and collaborating organisations will work together to address six specific objectives to inform the design of a randomised controlled trial to achieve this aim.

Objective 1: Intervention delivery, and population

We will work in co-production and consultation groups with parents, Triple P and other parenting practitioners, and social care professionals to explore views on delivering the SSTP online parent skills programme with or without additional guidance. If consensus is that additional guidance/support is indicated, we will explore questions including how much support, who might deliver such support, and what form this support might take. Once the format for the digital programme is confirmed, we will revise our existing SSTP Logic Model to incorporate assumptions and process relating to digital delivery and (if indicated) additional guidance/support. We will also explore the specific population that would fit with a Local Authority social care services context; this may include other developmental disabilities in addition to intellectual disability, depending on how services are organised and delivered. As part of this objective we will also survey families and practitioners within Local Authority social care services to understand what current support as usual is for families with a child with ID.

Objective 2: Optimising engagement

In groups with parents and professionals, we will discuss potential barriers for parents in engaging with and maintaining engagement in an online self-directed programme and how best to overcome these. Digital inequity will be one of the issues to be examined. We will develop a plan for the trial application that includes mitigation strategies for all identified barriers.

Objective 3: Recruitment pathways

Objective 3 will determine the optimal way to recruit parents with a child with ID to a future trial. We will explore potential pathways to and rates of recruitment with practitioners and social care organisations (Local Authorities) as well as with school and support and advocacy/community organisations. We will discuss recruitment and how to best inform parents about a future trial with parents. We will also build relationships with organisations to facilitate recruitment for a future trial. Finally, we will also seek initial agreement for Local Authorities to be involved as sites in a future trial.

Objective 4: Outcome measures and identification of a primary outcome
Drawing on our team's experience of working with parents to select outcome measures to evaluate other interventions for parents of children with ID (24) we will review, seek additional PPI input about, and determine a candidate set of outcome measures as guided by the revised logic model for SSTP online. We will also determine the best way to capture these outcomes (e.g. remote data collection). Measures will address key outcomes such as child behaviour and emotional problems, parenting practices, parent mental health and wellbeing, and family functioning. Guided by the Logic Model, a primary outcome for a future trial will be selected and work carried out to explore an appropriate MCID should there not be an established MCID for the selected measure. We will also explore using the same PPI informed approach data collection tools for a future health economics evaluation which will enable us to collect key health and social care resources in a future trial.

Objective 5: Intervention costs
We will explore different options for funding the intervention costs involved in delivering the Stepping Stones Triple P online in the context of a randomised controlled trial.

Objective 6: Design of a future trial and sample size
The final objective involves the design of a future trial with process evaluation to evaluate the Stepping Stones Triple P online parent skills training programme. This will include considering support as usual for families across a range of Local Authorities (informed by the surveys carried out as a part of Objective 1), taking this into account in the design of a future trial. This trial design will also include a sample size calculation based on key information about the selected primary outcome measures and meaningful change.

Overview of Research Design and Methods

Co-production and professionals' consultation groups
We will work together with our PPI partner co-applicant Allard and the Council for Disabled Children and PPI co-applicant Griffin to recruit 4-6 parents who are independent of the study team to join a co-production group to work in partnership with the study team to address the key questions in relation to Objectives 1-4. This will include parents of children from a range of ages, ethnicities, including parents of children who also have autism. We will work with the CDC team and Dr Griffin to identify other key characteristics to consider in recruiting parents in PPI roles.

Co-applicant Griffin will chair the co-production group, supported by CDC/Allard, with agendas and materials for each meeting negotiated with the joint CIs and study manager (research fellow).

We will also recruit up to six practitioners/senior staff from: organisations that deliver Triple P and / or Triple P online, local authorities, and community-based organisations delivering parenting/family support for families of children with intellectual disabilities. These individuals will be recruited via our team's existing networks as well as through Triple P UK's network of practitioners. We will recruit the practitioners from a range of local authorities and service providers. These will all be independent of the study team. Practitioners/senior staff will be invited to a consultative group to work directly with the study team to address the same key questions in relation to Objectives 1-4. The consultative group will be chaired by one of the senior staff members with agendas and materials for each meeting negotiated with the joint CIs and study manager (research fellow).

The co-production and consultative groups will each work collaboratively over a series of six online meetings to address Objectives 1-4. The first meeting will introduce the project and the work of the group. Meetings 2-5 will focus on each of the Objectives 1-4. Summary and feedback will be sought at each meeting, and following reflection, subsequent refinements will be made to the design of a future trial, to then be presented and discussed with the group at the next meeting. The final meeting will present the outcomes of this process and the proposed trial design, with a final opportunity for reflection and feedback. We have successfully used this method for co-production and consultation groups in other NIHR HTA studies (for example NIHR130177, NIHR129804).

Both groups will have clear terms of reference and charters, to be signed by all participants. All meetings will be minuted, with a clear record of decisions made. For each meeting of both groups, the study team will prepare background information and research/practice literature, carry out desk research to inform the discussion, and present options and draft materials for discussion. The minutes (including recommendations/decisions) from each group will be shared with the other group to ensure that there is shared learning to inform all decisions. The study team will also produce an integrated summary of emerging decisions and their rationale, incorporating the work of both groups.

Actions from either group may include gathering new data (e.g., rapid surveys, brief structured interviews with key individuals, other desk research) to inform discussions and decisions. In particular, we anticipate a brief survey of local authority decision makers to assess their interest in being sites in a future trial, and gather information on local process (including family support as usual at each site) and how this might impact on delivery of the trial. Findings from our team's ongoing systematic review of digital interventions for families of children and adults with intellectual disability/autism will also be feed into the work of both groups.

Intervention costs

The study team will work with Triple P UK and local authority representatives to understand the delivery costs associated with Triple P SSTP online. Led by health economics co-I McMeekin, we will generate initial estimates for the cost of any practitioner/peer additional support element that may be added to the intervention. Drawing from the team's networks and the networks of the co-production and consultation groups, we will explore options for funding sources for intervention delivery costs as a part of a future trial (including working with the Director of the NIHR School for Social Care Research). As a part of a brief survey of local authorities' interest in a future trial, we will include questions about their willingness to fund or part-fund intervention delivery costs.

Future trial design and sample size calculation
Through co-I Randell, we will meet regularly with the Cardiff Centre for Trials Research to discuss emerging trial design and feed back these discussions into the co-production and consultation groups for their input. Co-I and statistician Thompson will lead modelling of sample size calculations and assumptions early in the project as study design options emerge and a primary outcome is identified.

A key objective will be to identify an MCID (if one does not already exist) after identification of a suitable primary outcome. We will collate multiple sources of evidence following a triangulation approach (25), beginning with consultation of our co-production and PPI groups, and gathering existing published evidence. The distribution of MCID estimates from both experts and information regarding the variability around estimates would then be used to determine the most conservative sample size.

Analysis
We do not currently anticipate formal research analysis of material generated as a part of the co-production and consultation groups' processes. We will develop detailed notes on each study Objective, the recommendations of each group, how each set of input determines key decisions, and where recommendations are not taken up clear reasons for this (which will always be fed back to group members). Some descriptive analysis will likely be required especially for quantitative data that may be gathered (e.g., summaries of survey responses, summary of routine data from services). Sufficient detail will be recorded to include in a funder end of grant report and also to describe the PPI process fully against GRIPP2 criteria (26).

Outputs
The main output from this study will be a plan for a randomised controlled trial (likely with internal pilot and clear progression criteria) to examine the effectiveness and cost effectiveness of the Stepping Stones Triple P online parent skills training programme, a Stepping Stones Triple P online Logic Model, and an associated grant application to NIHR HTA. Two other outputs are anticipated at this stage: 1. A final funder report about the project, and 2. An academic and/or professional journal article about the PPI co-production process integrated with the consultative model with professionals, led by co-applicant Griffin.

Socioeconomic Position and Inequalities
Parents of children with intellectual disabilities (ID) and the children themselves face a range of social, economic, health, and mental health inequalities as well as problems accessing appropriate supports and services. This proposal overall is thus focused on the development of evidence relating to an intervention that may have potential to reduce some of that inequality for this population. Stepping Stones Triple P has been built from existing mainstream evidence-based parenting programmes, and includes adaptations to facilitate access and engagement of parents of children with ID. Parent psycho-social health and child development and behavioural and emotional problems are also directly targeted within SSTP – two of the areas of inequality faced by the families of children with ID.

Project Timetable and Milestones

The project has a proposed start date of 1 January 2024, continuing for 12 months:

Month(s)	Activities and milestones
Monthly	Study Management Group meetings
-1 to 1	Recruit for co-production and consultation groups
1-2	Recruit study staff, preparing materials for ethics submission.
2	Finalise co-production and consultation group protocols, training for all project staff
3	Meetings 1-2 co-production and consultation groups, processing information
4	Ethics review and approvals. Meeting 3 co-production and consultation groups, processing information
5	Meeting 4 co-production and consultation groups, processing information
6	Meeting 5 co-production and consultation groups, finalise results of co-production/ consultation, begin drafting Stage 1 HTA application
7	Meeting 6 co-production/consultation groups, design trial, finalise future grant team
8	Stage 1 HTA application writing
9	Finalise and submit Stage 1 HTA application
10	Process, and write up project outcomes
11	A final funder report about the project, academic and/or professional journal article, submit HTA Stage 2 application if shortlisted
12	Complete and submit academic and/or professional journal article

5 Safety reporting

There are no expected adverse events (AE) related to the research procedures. Reporting of adverse events is not planned for this study.

6 Protocol/GCP non-compliance

The Chief Investigator should report any non-compliance to the study protocol or the conditions and principles of Good Clinical Practice in writing to the ethics committee and sponsor as soon as they become aware of it.

7 Regulatory Considerations

7.1 Ethical and governance approval

At this stage, we do not anticipate the need for formal research ethics review for the majority of work for this study. All those taking part in co-production and consultation groups will be fully informed about their participation through a Charter that they will sign to indicate their consent/agreement. For the practice as usual survey under Objective 1, we will submit an application to the University of Warwick's Humanities and Social Sciences Research Ethics Committee. If any other new data collection is required, we will review the need for research ethics approval and if so would apply to the same committee.

7.2 Data Protection

The research team will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified, except where specific consent is obtained, or if abusive practice is disclosed that researchers would have a duty to report. Data will be stored in a secure manner and will be registered in accordance with the Data Protection legislation (in accordance with GDPR). Participants will always be identified using a unique PIN. Any identifiable information will not be stored with collected data.

7.3 Indemnity

The University of Warwick has in force a Public and Products liability policy, and a professional Indemnity policy which provides cover for "negligent harm" and the activities here are included with in that coverage subject to the terms, conditions and exceptions of the policy. The University of Warwick does not provide compensation for non-negligent harm.

7.4 Study sponsorship

The University of Warwick will act as Sponsor for study if this is required for HRA approvals, but we do not anticipate this being necessary.

7.5 Funding

The study is funded by National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) programme (Ref NIHR 160414).

8 Study management

The Study Team (ST) will meet weekly and will consist of Gray, Hastings, administrator, research fellow and research assistant. Other co-applicants will join as needed. The Study Management Group (SMG) will consist of all of the investigators, administrator, research fellow and research assistant, and will meet monthly to review progress and address key management issues. The co-production and professionals' consultation groups will develop terms of reference and charters.

9 Publication policy

Outputs from the study will include open access peer reviewed journal articles in international academic journals, presentations at national and international academic conferences and at public engagement/dissemination events. All publications and presentations relating to the study will be authorised by the SMG. A project publications policy and plan will be produced and approved by the SMG.

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