DAISY

PROTOCOL

Title page

A randomised controlled trial of a digital parent support programme for parents of children with intellectual disabilities: The Digital Family Support study

Short title/acronym: DAISY

Protocol version number and date

Protocol version number:	V1
Protocol version date:	01/04/2026

Research reference numbers

IRAS number:	350650
Sponsor/RG number:	RG_25-109
REC reference number:	
Public registry number:	
Funder number:	NIHR168754

Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the CI agrees to adhere to the signed University of Birmingham's sponsorship CI declaration.

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

Full project title:	A randomised controlled trial of a digital parent support programme for parents of children with intellectual disabilities: The Digital Family Support study
Protocol version number:	V1.0
Protocol version date:	

Chief Investigator (CI)	
Name:	Professor Kylie Gray
Date:	
Signature:	

Sponsor statement

Where the University of Birmingham takes on the sponsor role for protocol development oversight, the signing of the IRAS form by the sponsor will serve as confirmation of approval of this protocol.

Table of contents

Key contacts

Role/function	Contact details
Professor Kylie Gray, Chief Investigator	k.m.gray@bham.ac.uk
Professor Richard Hastings, (Co-Investigator)	r.hastings@bham.ac.uk
Dr Paul Thompson, (Co-Investigator), Associate Professor in Applied Statistics, University of Birmingham	p.a.thompson@bham.ac.uk
Dr Jeanne Wolstencroft, (Co-Investigator), Research Fellow, University College London	j.wolstencroft@ucl.ac.uk
Dr Kathryn Hudson, (Co-Investigator) Commissioner expertise & Chair of Professional Advisory Committee .	KathrynHudson@Hudsoncoachingconsulting.co.uk
Ms Amanda Allard, (Co-Investigator), Director, Council for Disabled Children	aallard@ncb.org.uk
Ms Elizabeth Randell, (Co-Investigator), Research Fellow, Centre for Trials Research, Cardiff University	RandellE@cardiff.ac.uk
Miss Mia Sydenham, (Co-Investigator), Senior Data Manager, Centre for Trials Research, Cardiff University	SydenhamM@cardiff.ac.uk
Dr Jeremy Segrott, (Co-Investigator), Reader, Lead Process Evaluation, Centre for Trials Research, Cardiff University	SegrottJ@cardiff.ac.uk
Ms Saira Minhas, (Co-Investigator), PPI Representative	s.minhas.2@bham.ac.uk
Dr Joanna Griffin, (Co-Investigator), PPI Representative	j.k.e.griffin@bham.ac.uk
Dr Nicola McMeekin, (Co-Investigator), ResearchFellow, Health Economist, University of Glasgow	Nicola.Mcmeekin@glasgow.ac.uk
Dr Paula Foscarini-Craggs, Research Associate, Centre for Trials Research, Cardiff University	Foscarini-CraggsP@cardiff.ac.uk
Dr Wendy Powell, Research Associate, Centre for Trials Research, Cardiff University	PowellW1@cardiff.ac.uk
Emma Scripps, Research Fellow, University of Birmingham	e.scripps@bham.ac.uk
Rovan Bahnassy, Research Associate, University of Birmingham	R.m.bahnassy@bham.ac.uk

Project summary

Development phase	Phase III
Trial design	A two-arm parallel group, 1:1 randomised controlled effectiveness trial of Stepping Stones Online plus Usual Support (US) versus US alone
Trial participants	Parent carers of children with intellectual disability between the ages of 2-11 years
Planned sample size	432
Planned number of sites	N/A
Inclusion criteria	Participants are eligibility if they meet the following criteria 1. Family has child aged 2-11 years with an intellectual disability; 2. The identified child with intellectual disability meets the following: a. has a diagnosis or is in the process of exploring a diagnosis or the child's presentation is related to intellectual and/or severe developmental disabilities – including but not restricted to 'Learning Disability', Global Developmental Delay, Pervasive Developmental Delay or Special Educational Needs AND b. Has a Adaptive Behavior Composite score on the Vineland Adaptive Behaviour Scales (VABS-3, Comprehensive Interview Form) of <80; 3. A biological, step, adoptive, foster parent carer available to complete the intervention and study measures; 4. Parent carer English language ability sufficient to engage with the Stepping Stones Online programme; 5. Parent carer aged ≥18 years old; 6. Parent carer(s) concerned about the child with intellectual disability's behavioural and /or emotional problems; 7. Parent carer lives in England; 8. Parent carer able to provide informed consent.
Exclusion criteria	1. Child with intellectual disability is in 24-hour residential placement; 2. Child with intellectual disability is in a foster placement due to end before the 12-month post-randomisation follow-up data collection point; 3. There are current child protection concerns relating to the child with intellectual disability that have been indicated to research team at the point of recruitment; 4. The family is not in a position to engage with the intervention (for example family is in crisis) 5. Another parent carer in the family has already been recruited into the trial; 6. Parent carer is unable to access the internet despite support provided; 7. Families where one or more parent has received a multi-session parenting programme covering similar content to Stepping Stones Online over the previous 12 months; 8. Families where one or more parent is currently receiving a multi-session parenting programme covering similar content to Stepping Stones Online or any multi-component manualised family intervention, such as for example Multi-Systemic Therapy, Stepping Stones Triple P; 9. Primary residence outside of England.
Treatment duration	Between 4-12 months
Follow-up duration	12 months
Planned trial period	42 months

Primary objective	Does Stepping Stones Online and access to usual supports (US) lead to improvements in the behavioural and emotional problems of children with intellectual disabilities compared to US alone at 12 months post randomisation?
Secondary objectives	• Does Stepping Stones Online and US lead to lower levels of parental psychological distress, and other secondary outcomes compared to US alone? • Does Stepping Stones Online and US lead to higher levels of child adaptive skills compared to US alone? • Are the outcomes for parent carers and children moderated by the severity of the child's communication impairment? • Are the outcomes for parents and children moderated by parent carers expectations of treatment outcome? • Does Stepping Stones Online and US lead to a change in the use of health and social care services by the family compared to US alone? • What is the cost-effectiveness of Stepping Stones Online and US in comparison to US alone? • To what extent is Stepping Stones Online received and delivered as intended, and what are the key influences, including variations across context? • How do intervention change mechanisms operate, including parent carers' experiences, and perceived value of the Stepping Stones Online intervention?
Primary outcomes	Child behaviour and emotional problems at 12 months post randomisation, measured by the parent carer total behaviour problems score from the parent carer Developmental Behavior Checklist (DBC2-P)
Secondary outcomes	a) Parent wellbeing - Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) b) Parenting practices – Parenting Scale Short Form (PS-SF) c) Parent psychological distress – Kessler 6 (K6) d) Parent social isolation - UCLA three-item Loneliness Scale (UCLA-LS) e) Parenting emotion regulation – from the Bangor Mindful Parenting Scale (BMPS) f) Parent-child relationship quality – Child Parent Relationship Scale (CPRS) g) Parent empowerment - Parenting Sense of Competence Scale (PSOC scale) h) Child adaptive functioning – GO4KIDDS <u>Health economics measures:</u> i) Parent quality of life – EQ-5D-5L j) Child quality of life (parent carer report) – EQ-5D-Y-3L, Paediatric Quality of Life Inventory (parent carer report) (PedsQL) k) Resource use – Client Service Receipt Inventory (CSRI) <u>Process evaluation</u> l) Parent adherence to intervention m) Fidelity of implementation of parent support sessions
Intervention	Stepping Stones Online (SSOL) is designed to support and empower parent carers of a child with intellectual disability aged 2-11 years by increasing their confidence and skills in managing behavioural and emotional problems and promoting positive child behaviour. There are 9 skills modules and a concluding module each taking 30-60 min to complete. Parent carers will be encouraged to complete the programme in 4 months but will have access for 12 months.

Funding and support in kind

Funder(s)	Financial and non-financial support given
NIHR	
Department of Health England	Intervention costs

Role of sponsor and funder

The Sponsor has/will be delegating certain responsibilities to Cardiff University/CTR(CU), the CI, and other stakeholder organisations as appropriate in accordance with the relevant agreement that is informed by regulation and trial type.

The University of Birmingham will act as Sponsor for this trial and will provide indemnity and compensation in the event of a claim for negligent harm. We are partnering with the Centre for Trials Research (CTR) which is a registered CTU. Trial oversight will be provided by the Project Team, Trial Management Group, and Data Monitoring and Trial Steering Committees. Membership charters will be drawn up for the TMG and both independent committees.

Roles & responsibilities of management committees/groups & individuals

Project Team (PT): This group will deal with the day-to-day running of the project and will report to the TMG. The Trial/Study Manager will be responsible for organising weekly project team meetings, inclusive of the Chief Investigators and directly employed staff.

Trial Management Group (TMG): The TMG will comprise Chief and Co-Investigators, and directly employed staff. This group will meet 4-6 weekly to set up the study, monitor progress and deal with issues as they arise, paying particular attention to timescales. TMG members will be required to sign up to the remit and conditions as set out in the TMG Charter.

Trial Steering Committee (TSC): A TSC will be established and will meet 4 times during the project. The TSC will comprise at least 5 independent members, including an independent Chair, 2 independent parent carers, and independent statistician. Members will be chosen in such a way as to ensure we have a representative group of appropriate stakeholders, including experts and at least one parent/carer. The TSC will have supervisory responsibility for the study. The Chief Investigators and if appropriate one or more co-investigators or key research staff will attend as observers. TSC members will be required to sign up to the remit and conditions as set out in the TSC Charter.

Data Monitoring and ethics Committee (DMEC): The DMEC (comprised of an independent statistician who will act as Chair; and at least three other independent members,) will also meet at least 4 times during the study and will report directly to the TSC. DMEC members will be required to sign up to the remit and conditions as set out in the DMC Charter.

Public involvement group

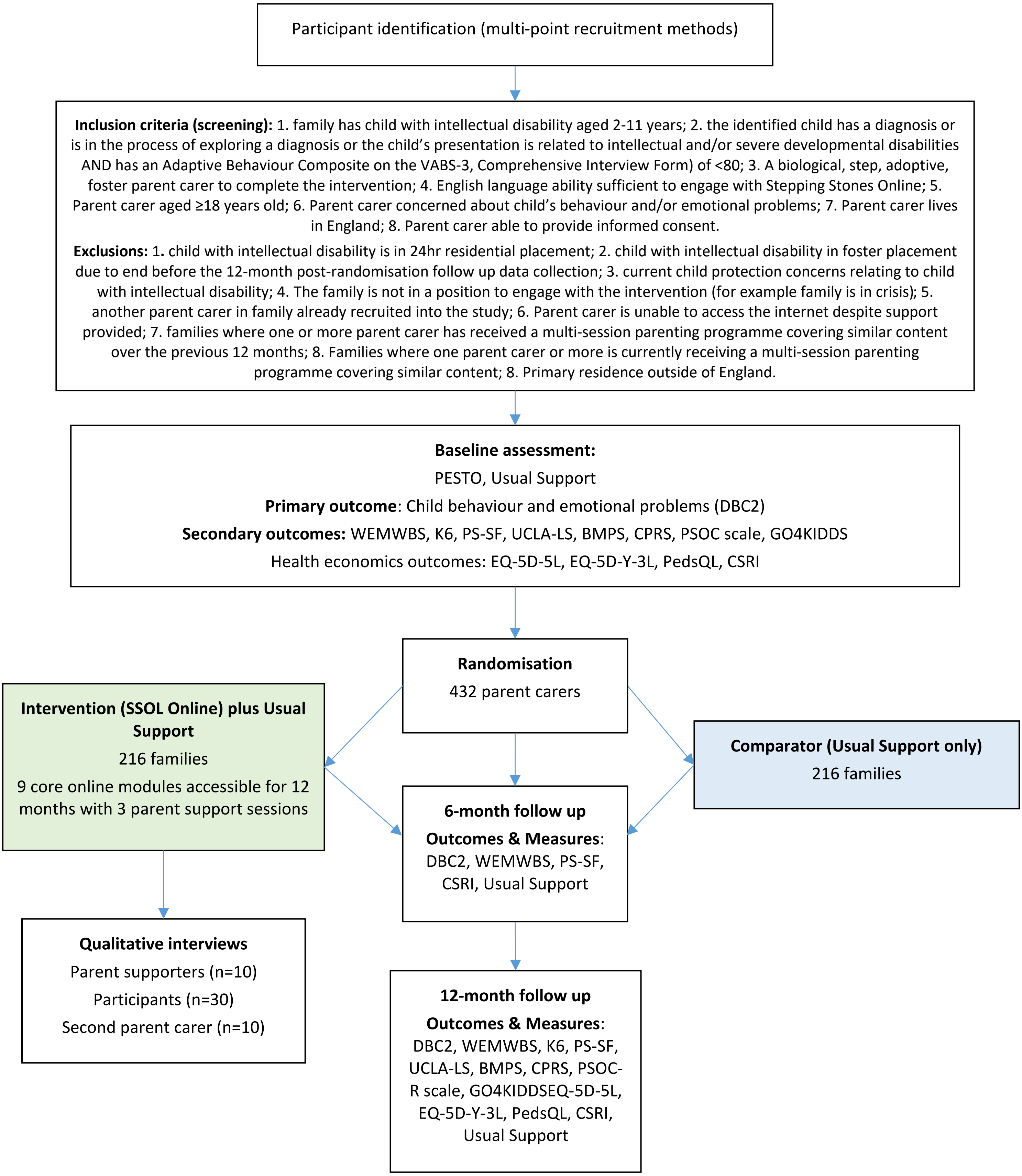
Parent Carer Advisory Group (PCAG): PPI input for the study will be achieved in part through the PCAG of 8parent carers from a diverse range of backgrounds, co-chaired by PPI co-investigators and parent carers Griffin and Minhas. This group will advise the TMG, with clear processes for documenting input and actions. Additional PPI input will be included from the TSC.

Professionals Advisory Group (PAG): Professionals, consisting of social care commissioners and senior managers to advise the TMG throughout the trial, with a specific focus on dissemination and development of future implementation in social care services. The PAG will consist of professionals with a range of experiences, backgrounds, and expertise of working with diverse communities. This group will be chaired by co-investigator Hudson with commissioner expertise.

Protocol contributors

Key words

Project flow chart



Participant identification (multi-point recruitment methods)

Inclusion criteria (screening): 1. family has child with intellectual disability aged 2-11 years; 2. the identified child has a diagnosis or is in the process of exploring a diagnosis or the child's presentation is related to intellectual and/or severe developmental disabilities AND has an Adaptive Behaviour Composite on the VABS-3, Comprehensive Interview Form) of <80; 3. A biological, step, adoptive, foster parent carer to complete the intervention; 4. English language ability sufficient to engage with Stepping Stones Online; 5. Parent carer aged ≥18 years old; 6. Parent carer concerned about child's behaviour and/or emotional problems; 7. Parent carer lives in England; 8. Parent carer able to provide informed consent.

Exclusions: 1. child with intellectual disability is in 24hr residential placement; 2. child with intellectual disability in foster placement due to end before the 12-month post-randomisation follow up data collection; 3. current child protection concerns relating to child with intellectual disability; 4. The family is not in a position to engage with the intervention (for example family is in crisis); 5. another parent carer in family already recruited into the study; 6. Parent carer is unable to access the internet despite support provided; 7. families where one or more parent carer has received a multi-session parenting programme covering similar content over the previous 12 months; 8. Families where one parent carer or more is currently receiving a multi-session parenting programme covering similar content; 8. Primary residence outside of England.

Baseline assessment:

PESTO, Usual Support

Primary outcome: Child behaviour and emotional problems (DBC2)

Secondary outcomes: WEMWBS, K6, PS-SF, UCLA-LS, BMPS, CPRS, PSOC scale, GO4KIDDS

Health economics outcomes: EQ-5D-5L, EQ-5D-Y-3L, PedsQL, CSRI

Randomisation

432 parent carers

Intervention (SSOL Online) plus Usual Support

216 families

9 core online modules accessible for 12 months with 3 parent support sessions

Comparator (Usual Support only)

216 families

6-month follow up

Outcomes & Measures: DBC2, WEMWBS, PS-SF, CSRI, Usual Support

Qualitative interviews

Parent supporters (n=10)

Participants (n=30)

Second parent carer (n=10)

12-month follow up

Outcomes & Measures: DBC2, WEMWBS, K6, PS-SF, UCLA-LS, BMPS, CPRS, PSOC-R scale, GO4KIDDSEQ-5D-5L, EQ-5D-Y-3L, PedsQL, CSRI, Usual Support

Protocol

1. Background

Intellectual disability is a developmental condition first occurring before age 18 and associated with low intellectual ability and low levels of everyday adaptive skills. Intellectual disability is the internationally used term, although the term learning disability is typically used in the UK health system.

Thirty-eight to 49% of children with intellectual disabilities (ID) have clinically significant levels of behaviour and emotional problems, significantly higher than typically developing children (14%) (1). Parents of children with intellectual disability are themselves 2-3 times more likely to report elevated levels of mental health and other psychological problems compared to parents who do not have a child with intellectual disability (2). Decreased parental well-being can reduce parent-child relationship quality and increase negative parenting practices, in turn increasing the behavioural and emotional problems of children with intellectual disability (3).

Despite these clear support needs, access to appropriate child and parenting supports can be challenging for families of children with intellectual disability (4). For example, in the UK only 29% of families of young children with Intellectual disability 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 (4).

The increased risk of poorer outcomes for children with intellectual disability and their parents, along with the limited access to support, means that evaluating scalable interventions for this population is of critical importance. One option for increasing reach and removing access barriers is to offer digital interventions for parent carers of children with Intellectual disability. Consistent with NICE priorities (5-7), digital interventions have the potential to support family carers and prevent the development of more severe behaviour and emotional problems, and subsequently reduce pressure on specialist services.

Under the Children and Families Act 2014 and Special Educational Needs and Disability (SEND) Regulations 2014, local authorities in England publish a Local Offer of services to support children with intellectual disability and their families. Local Authorities include in this Offer parenting and family support, including access to online/digital programmes. In England, the Care Act (2014) and accompanying statutory guidance (2024) also requires local authorities to provide support for the wellbeing of carers. Similar responsibilities are also outlined in other UK nations (e.g. the Mental Health and Wellbeing Strategy (2023) in Scotland, and the Social Services and Wellbeing Act (2014) in Wales).

Although Local Offers include the potential to access online parenting support programmes, none are evidence-based for supporting families of children with ID. One promising intervention is Stepping Stones Online (8). This online parenting support programme aims to address behavioural and emotional problems in children with intellectual disability. Stepping Stones Online is adapted from Triple P Online (TPOL) – a non-disability-focused parenting programme (9). Parenting programmes, including Stepping Stones Online and TPOL, are recommended in NICE guidelines for children with intellectual disability (5, 7) and TPOL is already delivered by 52 English Local Authorities. However, Stepping Stones Online has not been evaluated in the UK.

Evidence supports TPOL as an effective programme for improving both parent and child outcomes (10). A controlled evaluation comparing the effectiveness of Triple P standard (in person delivery) and TPOL found that online programme delivery was similarly effective in improving child behaviour problems and parenting practices compared to in-person delivery (11), while demonstrating lower programme and delivery costs (12).

There is also evidence for the effectiveness and acceptability of Stepping Stones Online, delivered in a face-to-face group or individual format with a professional (13-17).

However, professional-delivered programmes can be inaccessible for many parent carers of children with intellectual disability. 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 intellectual disability who require specialized childcare or have physical access needs (18). 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.

However, how best to provide digital self-directed parent support programmes is a key question. Parent engagement is a critical factor, with higher rates of attrition prior to intervention commencing in self-directed digital programmes compared to face-to-face (19). 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 the intervention (20). In other self-guided digital interventions for parents of children with ID, there is also some evidence that including (trained) parent support is perceived positively and may improve outcomes (21). Digital programmes for parenting/family support in families of children with intellectual disability are, therefore, likely to be optimised with an element of parent support.

2. Rationale

Children with intellectual disability and their parents face significant health inequalities and potential problems accessing appropriate support, a problem which has been exacerbated by the Covid-19 pandemic (22). Digital parenting support programmes such as those offered by Triple P, have potential to offer much needed support to families with a child with intellectual disability. Triple P online is available to families in the UK. It is currently offered to families by 52 Local Authorities in England, but is not designed to meet the needs of families with a child with intellectual disability. Triple P International has recently produced Stepping Stones Online, specifically for parents with a child with intellectual disability.

3. Theoretical framework

The theories of self-efficacy and self-regulation relating to parenting practices underpin the Stepping Stones Online programme. The full logic model for the Stepping Stones Online can be found in below (Figure 2).

Stepping Stones Triple P Online

Context and assumptions:

- Increased frequency and severity of child behavioural and emotional difficulties in children with intellectual disabilities.
- Increased stress and symptoms of mental health problems in parents of children with intellectual disabilities.
- Increased family risk factors (such as increased rates of poverty, lower rates of paid employment) can influence child developmental outcomes which in turn influences parental well-being. Families with less financial resource are also less able to pay for private services, reducing support.
- The combined presence of these child, parent and environmental factors can influence parenting practices in families of children with intellectual disabilities which can lead to increased child behaviour and emotional difficulties
- Increased demands on parent carers can reduce the accessibility of synchronous (in real time) and/or face-to-face support.
- Many families of children with behavioural difficulties may not meet eligibility criteria for support due to a lack of service resources and provision.
- Online support may be more accessible for some parent carers, can be delivered at scale, and may be more cost-effective than delivering in-person support.
- Online support may be more accessible for some families but presents additional barriers for families without internet access or access to digital devices.

Aims and mechanisms:

- Support and empower parents by increasing their confidence and skills in managing behavioural and emotional concerns and promoting positive child behaviour.
- Improvement in child behavioural and emotional concerns leads to improvement in parental wellbeing and reduction in parental stress, and in turn improves family relationships.
- Enable services to provide cost-effective, early support to parent carers and prevent the development of severe behavioural and emotional difficulties.

Inputs:

SSTP Online:

- Access to an online self-directed parenting support programme including 9 x 1-hour modules.
- Access to information on, understanding the causes of their child's behavioural and emotional difficulties, developing skills for creating a positive home environment, and enhancing their relationship with their child.
- 3 support contacts from a peer supporter who has completed SSTP Online. Contacts can be made via telephone and/or video calls.
- Peer supporter provides encouragement, motivation, and supportive accountability for self-directed engagement with SSTP Online.
- Training and supervision provided for peer supporters supporting parent carers completing the programme.
- Self-directed, online delivery enables flexible access and engagement around parent carers' availability.

Processes

- Improving understanding of causes of behavioural and emotional difficulties.
- Helping parents to develop strategies to manage behavioural and emotional difficulties, reinforce positive behaviour, and apply these skills in everyday natural environments.
- Learning alternative parenting strategies
- Equipping parents with coping skills for managing parenting stress and regulating emotions
- Parents teaching children ways to manage behavioural and emotional difficulties.
- Parents model positive behaviour.
- Improved collaboration and mutual support between parents.
- Increasing the frequency of quality time between parents and children.
- Peer supporter promotes engagement with, and adherence to, SSTP Online
- Peer supporter normalises parent carers' experiences, understands the complexities of being a parent carer, and reduces isolation.

Intended outcomes

Short-term outcomes

Child outcomes

- Reduction in child behavioural and emotional difficulties

Parent outcomes

- Improvement in parenting confidence, competence, and parenting emotional regulation.
- Reduction in less effective parenting practices
- Reduction in parental stress, anxiety, and low mood.

Longer-term outcomes

Child outcomes

- Continued reduction in child behavioural and emotional difficulties
- Continued improvement in child prosocial behaviour
- Improvement in child quality of life

Parent outcomes

- Reduction in parental stress, anxiety, and low mood.
- Continued improvement in parenting confidence, competence, and emotional regulation.
- Continued reduction in less effective parenting practices
- Reduced social isolation.
- Improvement in parental wellbeing

Family outcomes

- Improved parent-child relationship quality
- Reduced family conflict
- Improved family functioning

Services and health-economic outcomes

- Changes in families' use of Local Authority services
- Changes in use of childcare services
- Changes in parental work

Figure 2. Stepping Stones Online Logic Model

4. Research question/aims

The aim is to determine the effectiveness (including cost-effectiveness) of the Stepping Stones Online parenting programme for parents of children with intellectual disability 2-11 years of age to improve child behavioural and emotional problems.

4.1. Objectives

4.1.1. Primary Objectives

Does Stepping Stones Online and access to usual supports (US) lead to improvements in the behavioural and emotional problems of children with intellectual disabilities compared to US alone at 12 months post randomisation?

4.1.2. Secondary Objectives

Secondary objectives, are to address the following questions in relation to outcomes:

- Does Stepping Stones Online and US lead to lower levels of parental psychological distress, and other secondary outcomes compared to US alone?
- Does Stepping Stones Online and US lead to higher levels of child adaptive skills compared to US alone?
- Are the outcomes for parent carers and children moderated by the severity of the child's communication impairment?
- Are the outcomes for parents and children moderated by parent carers expectations of treatment outcome?
- Does Stepping Stones Online and US lead to a change in the use of health and social care services by the family compared to US alone?
- What is the cost-effectiveness of Stepping Stones Online and US in comparison to US alone?
- To what extent is Stepping Stones Online received and delivered as intended, and what are the key influences, including variations across context?
- How do intervention change mechanisms operate, including parent carers' experiences, and perceived value of the Stepping Stones Online intervention?

4.2. Outcome

4.2.1. Primary Outcome

Child behaviour and emotional problems at 12 months post randomisation, measured by the parent carer total behaviour problems score from the parent carer Developmental Behavior Checklist (DBC2-P) (23). The Development Behavior Checklist is a 96 item questionnaire that measures behavioural and emotional issues for young people aged between 4-18 years with intellectual disability. The total behaviour problem score comprises of items 1-95. It has been validated for use in clinical assessments and research. Each behavioural description is scored on a scale from 0 ("not true as far as you know") to 2 (“very true or often true”). The questionnaire will be completed by the parent carer at baseline, 6 months and 12 months. Parent carers will be able to complete the questionnaire online, or on paper.

4.2.2. Secondary Outcomes

The secondary outcome measures are listed below. All measures will be completed by the parents through an online survey or paper forms sent directly to the parents.

Levels of parental psychological distress will be measured using the following scales administered at **baseline, 6 months, and 12 months post randomisation** follow-ups:

a) Parent wellbeing – Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS). This is a 14 question scale that measures mental wellbeing, over the previous 6 months. Items are scored on a scale from 1 to 5 (“none of the time” to “all of the time”) (24).

b) Parenting practices - Parenting Scale Short Form (PS-SF) (25) (PS-8) is an eight item questionnaire that measures dysfunctional parenting behaviour by assessing three factors: laxness, overreactivity, and verbosity. The DAISY trial will only be using the laxness and overreactivity subscales.

Measures of parental practices and competency will be measured at **baseline and 12 months** using the following questionnaires:

c) Parent psychological distress - Kessler 6 (K6) is a six-item questionnaire that measures levels of psychological distress over the previous 30 days (26). Individuals are asked to assess the frequency and severity of distress symptoms as well as estimate the number of days they have been impacted by these symptoms and their help seeking behaviour.

d) Parent social isolation – UCLA Three-Item Loneliness Scale (UCLA-LS) (27) is a 3 item questionnaire that measures an individual’s subjective feeling of loneliness and social isolation. Items are rated 3-point scale from “I often feel this way” to “I never feel this way”.

e) Parenting emotion regulation – from the Bangor Mindful Parenting Scale (BMPS) (28), this is a 15-item questionnaire that evaluates parental interactions with their children who have an intellectual disability. Items are rated on a scale from 0 to 3 (“never true” to “always true”). The DAISY trial will use both the total score and a score for the six items relating to acting with awareness and non-reactivity (items 1, 6, 11, 2, 7, 12).

f) Parent-child relationship quality - Child Parent Relationship Scale (CPRS) (29) is a 15 item questionnaire that measures the relationship between the parent and child. Parents are asked to indicate how much each statement applies to their relationship with their child on a scale from 1-5.

g) Parental empowerment – Parenting Sense of Competence Scale Revised (PSOC-R Scale) (30) is a 16 item questionnaire that measure parental feelings of competence and satisfaction. Parents indicate how much they agree with each statement on a scale from 1-6.

Children’s adaptative functioning and communication needs are measured at **baseline and 12 months post randomisation** follow-up using the following scale:

h) GO4KIDDS brief adaptive scale is an eight item questionnaire that evaluates support needs, communication, socialisation, and self-help skills in children and adolescent with intellectual disability (31). Each item is scored on a scale from 1-5. Responses are summed to give an overall adaptive behaviour score, with higher scores indicating a better ability to adapt. The DAISY trial will include an additional question on alternative communication methods as used in previous research (32).

Health and social care service use and cost effectiveness of the intervention is measured using the questionnaires listed below. They will be administered at **baseline and 12 months post randomisation follow up**.

i) Parent quality of life - EQ-5D-5L (33) is 6 item questionnaire that measures an individual's perception of their health and quality of life across five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety depression. Each dimension is scored on a 3-point scale. The questionnaire also includes an overall perception of health. Higher scores indicate better perception of health and quality of life. Parent Carers will complete this scale about their own quality of life.

j) Child quality of life (parent carer report) - EQ-5D-Y-3L (34) is a 6 item questionnaire that measures a child's perception of their health and quality of life across five dimensions: mobility, looking after myself, doing usual activities, having pain or discomfort and feeling worried, sad or unhappy. The scale is suitable for children and adolescents aged between 8-15 years old. Each dimension is scored on a 3-point scale. The questionnaire also includes an overall perception of health. Higher scores indicate better perception of health and quality of life. Parent carers will complete the proxy version to assess their children's health and quality of life.

k) Paediatric Quality of Life Inventory (PedsQL) (35) is a 23 item scale that aims to measure the core dimensions of health (as described by the World Health Organization) and school functioning in children and adolescents between ages of 2 and 18. It measures four dimensions: Physical functioning, emotional functioning, social functioning and school functioning. Parents/carers will complete the proxy version.

l) Client Service Receipt Inventory (CSRI) is a research questionnaire designed to evaluate levels of health and social care service use, income, and other cost related information with to describe levels of support required and the associated cost. The questionnaire has five sections: background information, living situation, employment history, record of services accessed, and informal carers. This will also be administered at 6 months to reduce recall bias.

Process evaluation outcomes – which related to adherence and fidelity, and described in Section 5.5.2.

Usual Support (US): The use of other services and how they impact the experiences of Stepping Stones Online will be explored through a questionnaire and the process evaluation. The questionnaire will be constructed bespoke for the study and based on our preparatory research, of Usual Support received at baseline, 6- and 12-months post randomisation follow-up. Parent carers and parent supporters experience of the intervention will be explored through the process evaluation (see section 5.5.2).

5. Design and methods of data collection and data analysis

5.1. Design

A two-arm parallel group, 1:1 randomised controlled effectiveness trial of Stepping Stones Online plus Usual Support (US) versus US alone for parent carers of children with intellectual disability, with an internal pilot with clear progression criteria. 432 parent carers of a child (aged 2-11 years) with intellectual disability where parent carers have some concerns about their child's behavioural or emotional problems will be recruited. Participants will be randomised using minimisation. The internal pilot will assess recruitment, retention, adherence and the difference between US and SSTP Online. The total trial duration is 42 months with a 17-month recruitment period. Follow up assessments will be completed at six- and 12-month post randomisation. Data collected will primarily comprise of questionnaires completed online and the trial includes health economic and a mixed method process evaluation. The end of the trial will be the date of the last follow-up data collection.

5.1.1. <u>Internal Pilot and Progression Criteria</u>

Recruitment is not based on a number of sites but one overall site base. Recruitment will be from across England via social care and community organisations (e.g. Local Authorities, third sector, special schools) and self-referral (e.g. social media campaign). Since site-based metrics are not applicable, progression criteria will focus on other recruitment, retention, and engagement (adherence) indicators to monitor the trial's progress.

The internal pilot phase is the first 8 months of recruitment, with recruitment set at 100% (see Table 1). A green signal for recruitment rate is defined as recruiting 186 families (43% of total sample size), an amber signal is defined as recruiting 112 to 185 families, a red signal would be recruitment of below 112 families within this period. This is based on the assumption that recruitment will gradually increase over the first 4 months of the pilot period to then reach a steady rate over the rest of the recruitment period as outlined in the tables below. If, any criteria are in the red or amber range, action will be taken to address the issue. The TMG, with input from the TSC if necessary, will develop strategies to address the poorest performing criteria.

Table 1: Internal pilot recruitment

								Internal pilot assessment point
Recruitment month	1	2	3	4	5	6	7	8
Recruitment for GREEN								
Numbers per month	10	16	25	27	27	27	27	27
Cumulative recruited	10	26	51	78	105	132	159	186

Table 2: Progression criteria

Progression criteria	Red	Amber	Green
Recruitment			

Recruitment within first 8 months.	<60% (n=<112)	60-99% (n=112-185)	100% (n=186)
Number of families recruited (of those expressing interest)	<20%	20-49%	≥50%
Retention			
Number of families (of recruited) completed 6-month follow-up (of those that have reached timepoint)	<50% (n=<13)	50-69% (n=13-18)	≥70% (n=19-26)
Adherence			
Completion of 6/9 Stepping Stones Online skills modules (modules 1-9) and at least one parent support session	<55%	55%-66.6%	≥66.7%
Usual Support			
Proportion of families at 6-month follow-up reporting Usual Supports alongside Stepping Stones Online that are of similar intensity and content to Stepping Stones Online (smaller proportions are desirable, indicating a clearer distinction between Stepping Stones Online and usual supports).	>35%	35-25%	<25%

5.2. Randomisation

Parent carers will be individually randomised using minimisation. Balancing will be on four variables: Parent capacity to engage with the intervention (a dichotomous variable defined by four indicators), child autism diagnosis, adaptive functioning impairment severity [severe, <50, and mild/moderate, ≥50-79], and parent English as a second language on a 1:1 basis to either the intervention or comparator arm. The parent carer capacity to engage with intervention variable will be a dichotomous variable, derived from four indicators: (a) single parent family (i.e. A family with a single male or female parent living with either dependent or non-dependent children), (b) 1 or more household caregivers unemployed, (c) more than one child in the family with special education needs, and (d) any school-aged children not in school. These will be considered barriers / challenges to engaging in the intervention, and 1 or more of these being present indicating at least one significant barrier / challenge to engaging in the intervention. Randomisation will take place online through the trial database and be available 24 hours a day.

In the event that any element of the online randomisation and data collection system (REDCap) is predicted to be down for more than 48 hours the trial will move to the randomisation procedure outlined in the randomisation protocol. The CTR senior trial statistician (or other delegated statistician) will manually allocate using an appropriate statistical software that continues the minimisation. In all other situations, the research team will wait to randomise the participant until the system is back online.

5.3. Trial Intervention: Stepping Stones Online

Stepping Stones Online is designed to support and empower parent carers of a child with intellectual disability aged 2-11 years by increasing their confidence and skills in managing behavioural and emotional problems and promoting positive child behaviour. Improvement in child behavioural and emotional problems leads to improvement in parental wellbeing and reduction in parental stress, and in turn improvements in family relationships. The programme aims to provide early support to parent carers and prevent the development of severe behavioural and emotional problems. See Figure 1 Stepping Stones Online Logic Model.

Stepping Stones Online is an online programme which consists of nine core skills training modules and a final module which emphasises maintaining progress. The modules include text, videos, and interactive activities. To access and complete the online content, parents must have access to the internet or mobile data. Parent carers complete the programme independently in their own time and at their own pace, using a computer, tablet, or smartphone, and they can complete it anywhere. Each module will take 30-60 minutes to complete. Parent carers will have online access to the programme for 12 months but they will be encouraged to complete the programme within 4 months.

The modules cover (1) introduction to positive parenting, (2) influences on children’s behaviour, (3) helping children develop, (4) teaching new skills, (5) preventing problems and guiding children’s behaviour, (6) responding to children’s behaviour, (7) parenting routines: putting it all together, (8) planning ahead, and (9) changing challenging behaviour into positive behaviour, and (10) keeping up the good progress.

Parent carers randomised to the Stepping Stones Online group will receive an individual unique code to access the online programme. The programme platform is hosted by Triple P UK and monitors progress through the programme, including completion of modules. The study team will use these data to monitor intervention adherence. Adherence to the intervention is defined as completing at least six of the nine Stepping Stones Online skills modules (modules 1-9) and at least one parent support session .

Although the intervention will target one parent carer in the family, the participating parent carers will be able to involve a second parent carer in the online Stepping Stones Online programme if they so wish. The involvement of a second parent carer will be explored through the process evaluation.

The intervention to be tested includes access to a parent supporter to support parent carers in completing the programme. Whilst the Stepping Stones Online modules are self-directed and completed independently by parent carers, the parent supporter offers individual motivation, support, and encouragement to parents in completing the programme. Parent supporters are themselves parents of a child with intellectual disability. Parent carers will receive three parent support sessions (up to 60 minutes per session) with a parent supporter – one at the beginning of the programme, one midway through, and one at the end of the programme. Parent supporters will complete a checklist to assess fidelity of delivery of parent support for each session completed.

Training and supervision: Parent supporters will be recruited through established organisation that have processes for determining the suitability of the parent carers to act in the parent supporter role. This will be facilitated by the research team and our partner the Council for Disabled Children (CDC). Parent supporters will receive training and supervision in this role and will follow a bespoke parent supporter manual. The manual and training outline the nature of their role and interactions with programme recipients including understanding cultural difference. However, parent supporters will be taught to tailor the focus of their support to the needs of each parent carer. Discussions with a parent supporter will take place over telephone or video calls, depending on the preferences of the participating parent carer.

5.4. Comparator

US is highly variable for this population with a broad range of programmes potentially available. Fifty-one percent of Local Authorities and 35% of surveyed professionals reported offering or providing Triple P programmes. Furthermore, 24% of local offers and 23% of practitioners reported offering or providing Stepping Stones Triple P, the programme specifically developed for parent carers of children with intellectual disability.

Many Local Authorities also offer some form of self-directed, online support. Whilst around 10-13% of Local Authorities offer Triple P Online, the most frequent offered self-directed online interventions are the digital Solihull Approach programmes, including the programme ‘Understanding your child with special needs’, which is available in around 36% of Local Authorities. However, as noted earlier, Triple P Online is not designed to meet the needs of parents with a child with intellectual disability. Importantly, the Solihull Approach programmes, including ‘Understanding your child with special needs’, have not been evaluated. Despite at least 50% of local authorities offering some form of support research indicates that only a small minority are able to access that support (4).

Data on US will be collected via a survey at baseline, 6- and 12-month follow-up using a survey format bespoke for the study and based on our existing US research. To minimise contamination, parent carers enrolled at baseline in an intervention with similar content to Stepping Stones Online (for example but not limited to standard Triple P Online, any group/individual Triple P programme, Incredible Years, Solihull Approach) will not be eligible to participate.

5.5. Trial Procedures

Eligibility assessment & pre-randomisation baseline

Parent carers will complete a short interview with the research team to determine eligibility. In addition to gathering information as per eligibility criteria, Adaptive Behaviour Composite score of the Vineland Adaptive Behaviour Scales (VABS-3, Comprehensive Interview Form) will be completed.

Once parents carers have consented, but prior to randomisation, they will complete the parent carer Expectations of Treatment Outcome measure and all other baseline measures. The following measures will be required to be completed prior to randomisation: Parent Expectation of Treatment Outcome, DBC2-P, and questions related to stratification variables. Participants will be encouraged to complete the full baseline dataset. Parent carers will only be considered participants and in the trial after they have been randomised.

Randomisation.

Once the participants have completed the minimum baseline data set as outlined in the section above (eligibility assessment and pre-randomisation baseline) parent, they will randomised.

Intervention

If participants are assigned to the intervention arm, a unblinded member of the DAISY research team will enter the parent carers full name and email address into the online Triple P access management system. This will then generate an access code for Stepping Stones Online that will be sent to the parent along with brief instructions for accessing the programme. They will be encouraged to complete the programme within 4 months, but will have access to the programme for 12 months. They will also be contacted by their assigned parent supporter to schedule the first session. The first parent support session should be held within 2-4 weeks of issuing Stepping Stones Online access code.

The second parent support session should be held approximately 2 months after starting the programme and the final session will be during the final month prior (approximately 3 months after starting) to the participant finishing Stepping Stones Online programme. Participants will receive two to three reminders to engage with the intervention and in the parent supporter sessions. Intervention adherence will be collected from the bespoke Triple P DAIS dashboard.

5.5.1. Follow up

Outcome measures will be completed at baseline, and at 6- and 12-months post randomisation follow-ups. During follow-up parents will be informed about the importance of maintaining masking. If inadvertent unmasking occurs, then this will be recorded and reported.

At 6-months post randomisation a reduced dataset will be completed, consisting of the primary outcome measure (Developmental Behavior Checklist), and measures of parenting practices (Parenting Scale Short Form), parent carer wellbeing (Warwick-Edinburgh Mental Wellbeing Scale), CSRI, and usual support accessed. The full set of primary and secondary outcome assessments will be completed at 12 months post randomisation.

If parent carers do not respond to requests to complete outcome measures at 12-months follow-up, they will be invited to complete a reduced dataset consisting of the primary outcome measure, and measures of parenting practices and parent/carer wellbeing. If necessary this will then be further reduced to only the primary outcome measure to maximise data collection potential.

All measures can be completed online, hardcopy, or verbally with support from a researcher in person or via telephone or video-call within a ± 2 week window. Parents/carers will receive an email with a link that will take them directly to the questionnaires to complete at the start of the follow up window. The parent carers will receive an email reminder to complete the survey 3 days after the initial survey was emailed out. If they still haven't completed the battery of questionnaires, they will receive up to 3 more email reminder and then up to two telephone calls. If not contact has been made with the participant, a postal pack will be mailed to the participant with a freepost envelope.

5.5.2. Process Evaluation

The process evaluation will aid interpretation of the main trial findings by describing and assessing implementation of Stepping Stones Online and its mechanisms of action. Drawing on MRC methodological guidance (36). It will:

1. measure intervention adherence (parent carer completion of Stepping Stones Online modules and delivery of parent supporter sessions), and implementation fidelity;
2. identify influences on intervention recruitment/reach, adherence and implementation fidelity, and if these vary across groups/contexts; and
3. examine intervention mechanisms, including parent carers' experiences, and perceived value of, receiving Stepping Stones Online, including the role of the parent supporter sessions.

A mixed methods design will be employed. Intervention adherence (completion of 6/9 Stepping Stones Online modules and at least one parent support session) will be assessed using tracking systems which are built into the Stepping Stones Online Platform and records from parent supporters for the parent supporter sessions delivered. The Stepping Stones Online platform includes the number of modules completed (adherence outcome) and other metrics such as number of logins. Use of this information will be set out in participant information sheets, and consent sought during trial recruitment. Fidelity of implementation of parent supporter sessions will be assessed via self-complete checklists which will also capture how support is tailored to meet the needs of different parent carers. The Fidelity checklist will assess the percentage of components discussed during the parent support sessions.

To explore influences on intervention support and implementation, semi-structured qualitative interviews will be conducted with 10 parent supporters and the parent support trainer. These interviews will be used to help interpret trial data on intervention reach (levels of participation across demographic groups and geographical contexts) and recruitment and retention rates. Parent supporters will be asked to reflect on key factors shaping implementation and the role of the parent supporter. Interviews with the parent supporters and parent support trainer will also explore systems and structures that might be needed to support future implementation.

Semi-structured qualitative interviews will be conducted with 30 parent carers who are trial participants in the Stepping Stones Online arm. These interviews will explore their experiences of receiving the intervention, including factors affecting adherence, patterns of engagement with SSOL modules, the acceptability and perceived value of online delivery, and the role of parent support. Parent carers will also be asked about their use of other services, and how Stepping Stones Online is perceived in relation to these, including whether its content and delivery methods are viewed as distinctive.

The interviews will further explore whether other parent carers in the family (who are not trial participants) have accessed Stepping Stones Online. Where relevant, participants will be asked if they are willing to share information sheets about interview participation with these family members. Up to 10 additional interviews will then be conducted with “second parent carers” who have accessed Stepping Stones Online but are not trial participants.

Purposive sampling will be used to include parents recruited via contrasting pathways (i.e. agency vs self-referral) different carer roles (e.g. mothers, fathers, non-biological parents, and diversity of parent/family characteristics, including the age of the identified child with intellectual disability.

Alongside quantitative assessment of primary and secondary outcomes (main trial participant measures), data from qualitative interviews will examine operation of intervention mechanisms (e.g. how parent support reinforces self-guided programme content) and interrogate patterns in the quantitative data.

Qualitative interviews will be subjected to thematic analysis (37). In line with Centre for Trials Research good practice, a Qualitative Analysis Plan will be developed prior to data collection, which includes agreed processes for defining and refining codes and double coding. Triangulation of qualitative and quantitative data will be guided by Palinkas et al’s (38) taxonomy of mixed methods designs, including clarifying how qualitative and quantitative methods will inform each other, and the process through which they are integrated. Quantitative analysis of process evaluation data will be included in the primary trial statistical and Health Economic Analysis Plan (SHEAP).

5.6. Data Management

Source Data is defined as *“All information in original records and certified copies of original records of clinical findings, observations or other activities in a clinical trial necessary for the reconstruction and* *evaluation of the trial. Source data are contained in source documents."* There is only one set of source data at any time for any data element, as defined in the table below.

Trial data	*Source Data*					
	CRF	*Electronic System*	*trial master file*	*Questionnaire**	*interview*	*Process Evaluation*
Eligibility assessment					X	
VABS-3					X	
Informed consent				X		
Parent expectation of treatment survey				X		
Randomisation		X				
Demographics				X		
Delivery of intervention		X				
Compliance		X				
Development Behaviour Checklist				X		
Warwick Edinburgh Mental Wellbeing Scale				X		
Kessler 6				X		
Parenting Scale Short Form				X		
UCLA Three-Item Loneliness Scale				X		
Bangor Mindful Parenting Scale				X		
Parenting Sense of Competence Scale				X		
GO4KIDDS				X		
EQ-5D-5L				X		

EQ-5D-Y-3L				*X*		
PedsQL				*X*		
CSRI				*X*		
US survey				*X*		
Withdrawal form				*X*		

***Paper or electronic CRF as indicated in database upon data entry**

5.6.1. Data Collection

The preferred method of data collection will be online but in the event that, participants are not able to, participants can have an in person visit and complete with a member of the research team. Alternatively, participants can complete over the phone with a member of the research team or receive a hardcopy to complete on paper. Data will then need to be entered into the database by a member of the trial team. The method of data collection will be confirmed with the participant during the full screening assessment. If participants choose hardcopy they will be sent the questionnaire booklet and a prepaid envelope to return the questionnaire by mail to the trial team in Birmingham. All hardcopy data collection and data entry will be primarily completed by the research team in Birmingham.

Data received by the team in Birmingham will be checked for missing, illegible or unusual values (range checks) and consistency over time. These will be monitored to ensure that no changes are required to forms or validations to facilitate data entry. Electronic data will be checked at point of data entry through inbuilt validations. All hardcopy data will be scanned, verified for accuracy, and then saved electronically. At the end of the trial, after all analysis has been completed, hardcopy data will be destroyed.

The CTR will send reminders for any overdue assessments. The reminders will be sent directly to participants for all online data collection and for situations where hardcopy data collection is being used, the CTR will liaise with the Birmingham research team. This will be managed in accordance with the follow up windows outlined in section 5.5.1 or by contacting research staff responsible for data collection.

It is intended to develop data recording for this trial as a web-based system. This is a secure encrypted system accessed by an institutional password, and complies with the General Data Protection Regulation 2016. Participants are sent a link that will take them directly to the relevant questionnaires and will not require a password. The system will assign unique ID codes (PIDs) to each participant, and the questionnaire links will be unique to each participant. The system can be accessed on:

<Insert Web address for CRFs Here>

As the majority of outcome data is participant reported, changes to the data and queries will be limited. The full procedure for monitoring data quality will be outlined in a study specific data management plan.

5.7. Main Analysis

5.7.1. Blinding

The statistician carrying out the main statistical analyses will remain blind to allocation up until the point the analysis is performed. In addition, outcome data will be collected by researchers who will also remain blind to allocation and will be trained to minimise the risk of participants revealing allocation in follow-up assessments. Researchers (i.e. blinded researchers) collecting follow-up data will differ from the researcher (i.e. unblinded researcher) who informed the parent carer of their allocation. If the blinded researcher is accidently made aware of the allocation of the participant, this will be recorded.

5.7.2. Missing, Unused & Spurious Data

The impact of missing data on trial outcomes will be investigated according to missing data mechanisms and re-fit the primary analysis within a multiple imputation framework. The impact of different levels of intervention receipt on outcomes will be evaluated using two-stage least squares instrumental variables regression.

Full detail provided in the SHEAP.

5.7.3. Procedures for Reporting Deviations from the Original SHEAP

These will be submitted as substantial amendments where applicable and recorded in subsequent versions of the protocol and SHEAP.

5.7.4. Inclusion in Analysis

All randomised participants' data will be included in analysis, if consent has been obtained to use their data and have not withdrawn from the trial.

5.7.5. Statistical Analysis

Statistical analysis for internal pilot outcomes will be primarily descriptive, estimated as frequencies and percentages, means and standard deviations, or medians and interquartile ranges as appropriate. Internal pilot outcomes will be assessed against the pre-specified progression criteria (see earlier).

Our primary analysis will include one primary caregiver from each randomised family who provide outcome data (i.e., intention to treat basis) and overall effect of the intervention on post-randomisation DBC total score measures using a partially-nested general linear mixed model (39), adjusting for baseline DBC total score and randomisation prognostic factors: parent capacity to engage with the intervention, child autism diagnosis, adaptive functioning impairment severity, and parent English as a second language. We will consider the role of parent supporters as a source of clustering. As parent supporters will support the intervention for several parent carers allocated to the intervention arm only, this will be a form of partial nesting and may lead to an underestimation of standard errors (and thus inflated Type-I error) if not appropriately accounted for. We will also report intra-cluster correlation coefficients, the number of clusters, and cluster sizes. The model will have a three-level structure, level 1 (time), level 2 (individual) and level 3 (parent supporter).

Secondary outcomes will also follow the same analysis framework with appropriate adjustment to generalised linear mixed models where necessary. Moderation analyses by inclusion of interactions between each of the moderators, parent/carer expectations of treatment outcome, and severity of the child's communication impairment (GO4KIDDS), and trial arm.

Distributional assumptions for the primary linear mixed model will be checked as follows:

i) Linearity – plotting residuals vs predictor(s). If a structure is present, then transformation or an alternate model specification is required (i.e. GLMM);

ii) Homogeneity of variance – variance of the residuals across groups is the same. There is scope to fit models allowing for heterogeneous groups, but the setup is different (Generalized linear mixed model - GLMM);

iii) Residuals are approximately normally distributed – plotting QQ plot. If distributional assumptions are not satisfied, as appropriate, a generalized linear model with alternate link function will be used.

Three types of sensitivity analysis will be conducted:

1. Exploring the impact of missing data on trial outcomes by investigating likely missing data mechanisms and re-fitting the primary outcome within a multiple imputation framework (including exploring MAR and MNAR mechanisms via delta-based controlled multiple imputation). Imputation variables for the model will include all covariates and the outcome appearing in the analysis as per recommendation by White et al. (40). In addition, variables that are predictive of missingness are included on the basis of strength of association with response variables. Also, any variables that explain response or non-response (41).

2. Exploring the impact of different levels of intervention receipt on outcomes. We will use two-stage least squares instrumental variables (IV) regression to examine the effect of the intervention in those who receive varying levels of it. The completion of 6/9 Stepping Stones Online skills modules (core modules 1-9) and at least one parent support session will be used in the instrumental variable analysis. The control group attendance will be set to one and those in intervention group will be assigned the number of sessions attended for the IV regression analysis.

5.7.5.1. Subgroup Analysis

Parent carers expectations of treatment outcome will be explored by inclusion of an interaction of moderator and treatment allocation variables into the primary analysis model.

5.7.6. Qualitative Analysis

Qualitative data will be analysed using thematic analysis informed by the research objectives and the intervention Logic Model (see Figure 2). A data integration process will combine findings from statistical and qualitative analyses. Full details of the analysis plan can be found in the QAP and SHEAP.

5.7.7. Health Economic Evaluation

The economic evaluation will assess the cost-effectiveness of the intervention versus the comparator. The time horizon will be a 12-month within trial analysis and, if the results suggest it would be relevant, a model extrapolating this to lifetime.

The general approach will follow current guidance for evaluating social care and digital health technology (42, 43). As there is a lack of outcome and methods guidance for economic evaluations of interventions for people with ID, we will also follow published suggestions for this population (44, 45).

The perspective will be societal, and we will collect data relating to both the child and parent carers. Resource use will include National Health Service, Personal Social Services, Local Authority plus family out-of-pocket expenses. Relevant resources were identified in consultation with the parent carer advisory group and from the team's previous research.

We will conduct a cost-utility analysis with an outcome of quality adjusted life-years (QALYs); data to inform the calculation of QALYs will be collected using the EQ-5D-5L for parent carers (33), and the EQ-5D-Y-3L proxy (34) and PedsQL health related quality of life (35) for children. The EQ-5D-5L will be valued using the recommended method at time of analysis (46). The EQ-5D-Y-3L has previously been used to assess quality-of-life in this population, however currently there is no UK value set for the EQ-5D-Y-3L, therefore EQ-5D-Y-3L results will be valued using best practise recommendations at the time that data collection is complete (15, 47). The PedsQL will be valued using a mapping algorithm (48, 49). We will also conduct a cost-effectiveness analysis using the primary outcome of the study; the DBC. Resource use and economic outcomes will be collected at baseline, 6- and 12-months follow-up.

Analyses will be conducted using intention-to-treat principles and any missing data will be handled using established recommended methods (50). Mean costs and QALYs per adult, child and family group will be presented and adjusted for relevant baseline characteristics. For both the cost-utility and cost-effectiveness analyses an incremental cost per outcome will be calculated and will be presented with 95% confidence intervals estimated using non-parametric bootstrapping, to assess uncertainty. Uncertainty will be further explored with two sensitivity analyses: 1) using a healthcare payer and personal social services perspective, and 2) assessing the impact of missing data by presenting complete case results. Finally, an exploratory analysis will convert the WEMWBS outcome to Mental Wellbeing Adjusted Life Years (MWALYs) for parent carers, this has the potential to provide a better understanding of quality of life estimates with respect to the sensitivity of instruments. This exploratory analysis is especially timely due to recent developments in this field, particularly if MWALYs become more widely adopted in other similar studies (51, 52)

6. Project setting

As the intervention is digital and able to be directly accessed anywhere via the Triple P UK online intervention platform, we will not restrict recruitment to individual Local Authorities. Recruitment will be from across England via social care and community organisations (e.g. Local Authorities, third sector, special schools) and self-referral (e.g. social media campaign).

7. Participant recruitment

7.1. Eligibility criteria

7.1.1. <u>Inclusion criteria</u>

Participants are eligibility if they meet the following criteria

1. Family has child aged 2-11 years with an intellectual disability
2. The identified child with intellectual disability meets the following:

   a. has a diagnosis or is in the process of exploring a diagnosis or the child's presentation is related to intellectual and/or severe developmental disabilities – including but not restricted to 'Learning Disability', Global Developmental Delay, Pervasive Developmental Delay or Special Educational Needs

   AND

   b. Has an Adaptive Behavior Composite score on the Vineland Adaptive Behaviour Scales (VABS-3, Comprehensive Interview Form) of <80

3. A biological, step, adoptive, foster parent carer available to complete the intervention and study measures;
4. Parent carer English language ability sufficient to engage with the Stepping Stones Online programme;
5. Parent carer aged ≥18 years old;
6. Parent carer(s) concerned about the child with ID's behavioural and /or emotional problems;
7. Parent carer lives in England;
8. Parent carer able to provide informed consent.

7.1.2. <u>Exclusion criteria</u>

Participants are not eligible if they meet any of the following criteria:

1. Child with intellectual disability is in 24-hour residential placement;
2. Child with intellectual disability is in a foster placement due to end before the 12-month post-randomisation follow-up data collection point;
3. There are current child protection concerns relating to the child with ID that have been indicated to research team at the point of recruitment;
4. The family is not in a position to engage with the intervention (for example family is in crisis);
5. Another parent carer in the family has already been recruited into the trial;
6. Parent carer is unable to access the internet, despite supports provided;
7. Families where one or more parent has received a multi-session parenting programme covering similar content to Stepping Stones Online over the previous 12 months;
8. Families where one or more parent is currently receiving a multi-session parenting programme covering similar content to Stepping Stones Online or any multi-component manualised family intervention, such as for example Multi-Systemic Therapy, Stepping Stones Triple P;
9. Primary residence outside of England.

7.2. Sampling

7.2.1. <u>Size of sample</u>

Sample size calculations were conducted using R version 4.4.1 (2024-06-14), and the 'pwr' R package.

Parent carers will be randomised to either Usual Support (US) only or Stepping Stones Online plus US. Only one parent carer per family will provide responses to the outcome measures and will be the same parent carer at each time points, so no family level clustering is necessary within the analysis framework nor in estimating the required sample size. The decision on what parent carer is recruited if both are interested will be left up to them. Following Teerenstra et al. (53) for partially nested designs, we allow for a conservative correlation estimate between baseline and follow-up measures of primary outcome of r = 0.64 (53); based on previous research r = 0.74 (54) and r = 0.86 (39); assume a parent supporter cluster size of 10; an intra-class correlation coefficient, ICC=0.01 given that we anticipate a small amount of parent supporter random effect variation (56); and up to 30% of families being lost to follow-up at 12-months post randomisation.

Allowing for the above assumptions and an effect size to be detected of 0.3 with 90% power and a two-sided alpha of 0.05, a sample size of 432 parent carers (per arm N1 = 216, N2 = 216) is required. A minimum detectable effect size (MDES) of 0.3 corresponds to a 7 point change on the DBC which would be considered meaningful in practice for this population.

7.3. Recruitment

Organisations will disseminate information about the research study through posters, together with a professional social media campaign. Parent carers will be required to register their interested in the study by directly contacting the research team via email, telephone, or by completing the expression of interest form on the study website. Parent carers will be able to access information about the study, including the Participant Information Sheet (PIS), and will be able to discuss the study with a member of the research team. Parent carers will complete a interview with the research team to confirm eligibility and confirm there are no questions about the trial. During the screening process the Vineland Adaptive Behaviour Scales (VABS-3 Comprehensive Interview Form) will be completed. Once participants are deemed eligible, they will receive a link to a consent form to complete prior to the baseline assessment and randomisation.

A record of all ineligible and eligible but not consented or randomised individuals will be kept on the online research database so that any biases from differential recruitment can be detected. The study will also keep a record of the referral source.

A total of 432 participants will be recruited at an expected rate of 25 per month.

Routine monitoring of recruitment and retention will take place during the trial. A traffic light system will be implemented to assess key criteria. Monitoring information will be reviewed at the Trial Management Group (TMG).

7.3.1. Consent

The participant's informed consent must be obtained using the trial Consent Form (CF), which follows the PIS. The participant should be given sufficient time after the initial invitation to participate before being asked to sign the CF. Informed consent must be obtained prior to the participant undergoing procedures that are specifically for the purposes of the trial. Consent will be sought from the participant after they are deemed eligible by a member of the research team. The information sheet will be electronically sent to the participant at least 24 hours in advance of the screening call. Prior to taking consent, a member of the research team will ensure that the individual does not have any questions about the study. Consent will be recorded electronically via link sent directly to the individual, on hard copy by posting the CF or in person, or via a recording the telephone videoconferencing call. When taking consent verbally the researcher will read each consent statement and ask the participant to confirm their agreement. Only one method of recording consent will used per participant and the method will be logged on the database. In the situation where consent is recorded on a paper form, or a recording is used, consent details and method of collection will be entered onto the database by a member of the research team. Electronic or hard copy consent forms will be reviewed by a member of the research team prior to initiating any further trial activity. In the event that, there is an issue with the electronic or hard copy CF, a member of the research team will contact the individual twice to try and address the issue.

Please note, only when informed consent has been obtained from the participant and they have been randomised/enrolled/registered into the trial can they be considered a trial participant.

Participants should always be asked to complete a CF. One copy should be given to the participant but and the original should be kept in the Trial Master File (TMF). If consent is recorded electronically or through a recording, an electronic copy will be sent to the participant. Where consent is captured on paper, a copy will be made and returned to the participants. All trial procedures that are mandatory vs optional will be clearly outlined in the trial consent form, including taking part in a qualitative interview as part of the process evaluation and the possibility of data being shared for future research

The right of the participant to refuse to participate in the trial without giving reason must be respected. After the participant has entered the trial, they must remain free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing his/her further treatment or access to services.

7.4. Withdrawal

Participants have the right to withdraw consent for participation in any aspect of the trial at any time. The participants care will not be affected at any time by declining to participate or withdrawing from the trial.

If a participant initially consents but subsequently withdraws from the trial, clear distinction must be made as to what aspect of the trial the participant is withdrawing from.. These aspects could be:

- Withdrawal from intervention
- Partial withdrawal from further data collection (e.g., questionnaires, clinical assessments)
- Complete withdrawal from further data collection

The withdrawal of participant consent shall not affect the trial activities already carried out and the use of data collected prior to participant withdrawal. The use of the data collected prior to withdrawal of consent is based on informed consent before its withdrawal.

Furthermore, it is important to collect safety data ongoing at the time of withdrawal, especially if the participant withdraws because of a safety event.

In all instances participants who consent and subsequently withdraw, a withdrawal form should be completed on the participant’s behalf by the researcher/PI based on information provided by the participant. This withdrawal form should be completed on the online trial database. Any queries relating to potential withdrawal of a participant should be forwarded to DAISYCardiff@cardiff.ac.uk

7.5. Lost to Follow up

To minimise lost to follow up, participants will be given vouchers in recognition of their contribution to the study. They will receive a total of £80 divided into set amounts per assessment timepoint. Participants will receive £15 for completing the baseline assessment, £25 at 6-month and £50 at 12-

month. Participants will also receive a £40 voucher for taking part in the process evaluation interview. Participants will also receive newsletters to keep them engaged with the trial progress. Regardless of protocol adherence participants will complete all assessments. Two reduced data sets have been identified to reduce participant burden and drop out due to the number of questionnaires. The first data set is the primary outcome measure and parent/carer wellbeing measures. The second data set is just the primary outcome measure.

Follow up windows, and processes for contacting participants to complete outcome assessments are outlined in section 5.5.1. Participant will be classed as lost to follow up in the following two scenarios 1) they don't complete the 6-month and 12-month data collection time points or 2) they complete the 6 month follow up time point but they don't complete the 12 month follow up assessments.

8. Safety reporting

There are no expected adverse events related to the intervention or research procedures, therefore formal monitoring of adverse events will not take place.

However, should any member of the research team become concerned at any point about the well-being or safety of a participant or their child, study staff will follow a study-specific Standard Operating Procedure for dealing with harm which will be explained to participants during the consent process and highlighted explicitly in participant information sheets. This could result in the events being reported to the safeguarding officer in the participant's local authority or escalated to the police if anyone is deemed to be at immediate risk of harm.

9. Ethical and regulatory considerations

9.1. Assessment and management of risk

A Trial Risk Assessment has been completed to identify the potential hazards associated with the trial and to assess the likelihood of those hazards occurring and resulting in harm. This risk assessment includes:

- The known and potential risks and benefits to human subjects
- How high the risk is compared to standard practice
- How the risk will be minimised/managed

This trial has been categorised as a TYPE A, low risk. A copy of the trial risk assessment may be requested from the Trial Manager. The trial risk assessment is used to determine the intensity and focus of monitoring activity.

9.2. Research ethics committee (REC) and other regulatory review & reports

9.2.1. Regulatory review & compliance

Ethical approval will be sought from the Health Research Authority. This research will be conducted according to Centre for Trials Research (CTR) Standard Operating Procedures, which are compliant with regulatory requirements for clinical research, including Good Clinical Practice and data processing and storage. It is possible that carers could become distressed during assessments and interviews, given the nature of measures and interviews topics included, relating to mental well-being and quality of life. Researchers will receive study-specific training in dealing with distress should this arise, and parent carers will be signposted to local sources of help and support if indicated. It is unlikely ethical issues will arise directly for children because participation is for parent carers. All children and parent carers in the trial will continue to receive usual supports. All research staff and parent supporters will receive training on safeguarding procedures. Parent carer advisory group (PCAG) will advise on any ethical issues during the life of the trial.

9.2.2. <u>Amendments</u>

All amendments to the protocol will be reviewed by the TMG, Sponsor, and the relevant ethics committee. Changes will be recorded on the amendment history log contained in this protocol.

9.3. Peer review

The trial has undergone peer review during the grant application stage. The protocol, participant documents and other relevant trial management documents have undergone review by the CTR Quality Assurance team.

9.4. Patient & public involvement

Two parent carer co-investigators are included in the research team, including one from a global majority background. They have been involved with the project planning and will jointly lead PPI activities including advising on diversity and inclusion aspects throughout the trial.

A parent carer advisory group inputted into the design of this study. This group consisted of 6 parents of children with ID. A series of 7 co-production workshops were held covering topics such as review and impressions of SSTP Online, how to best support parents to engage with and complete SSTP Online, which families might benefit from SSTP Online, pathways to accessing the programme (and recruitment pathways), primary outcome measure, secondary outcome measures, health economics measures, mitigating digital access barriers, how to describe/present the programme to parent carers, randomisation in a trial and how to communicate this information, review and revision of the Stepping Stones Online Logic Model, and accessing Stepping Stones Online at the completion of the study.

A parent carer advisory group (PCAG) will continue throughout the trial. Parent carer members of this group will be supported to attend via the provision of support for childcare, flexible meeting options (e.g. online, evening meeting times), pre meeting individual preparation sessions, and opportunities to debrief after meetings. We will also offer a mix of group and individual meeting options, as some parent carers feel more comfortable participating one-to-one than in a group. Members who need to withdraw from the advisory will be supported to do so. There will be clear processes for recruiting replacement members to maintain diverse representation.

Parent carer members of the advisory group will receive meeting materials and regular project updates in between meetings in accessible formats according to their preferences.

With the Council for Disabled Children we have also consulted professionals, consisting of social care commissioners and senior managers. A professional advisory group (PAG) will also be included in the trial advising and contributing throughout, with a specific focus on dissemination and development of future implementation in social care services. This group will be chaired by co-investigator Hudson, who has expertise in the commissioning of social care services for people with intellectual disabilities. Parent carers will have also have representation on the TSC.

9.5. Protocol compliance

The trial risk assessment has been used to determine the intensity and focus of central monitoring activity in the DAISY trial. Low monitoring levels will be employed and are fully documented in the trial monitoring plan. All protocol deviations will be recorded on the trial specific deviation log and reviewed regularly by the TMG and TSC.

Investigators should agree to allow trial related monitoring, including audits and regulatory inspections, by providing direct access to source data/documents as required. Participant consent for this will be obtained.

The CI and investigator’s organisations/institution(s) will permit trial-related monitoring, audits, REC/ IRB review, and regulatory inspection(s), providing direct access to source data / documents.

9.6. Data protection and confidentiality

The CTR 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. A limited amount of personal data will be collected including name and contact details for the purposes of trial follow up activities. Data will be stored in a secure manner and will be registered in accordance with the General Data Protection Regulation 2016. The data custodian for this trial is the University of Birmingham.

9.7. Indemnity

The University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage

9.8. End of study and archiving

The end of study will be defined as the date of the last follow-up data collection.

The TMF and TSF containing essential documents will be archived at an approved external storage facility for a minimum of 10 years. The CTR will archive the TMF and TSFs on behalf of the Sponsor. Essential documents pertaining to the trial shall not be destroyed without permission from the Sponsor.

9.9. Access to the final dataset

Participants will be asked to consent for their data to be shared with researchers in the UK and abroad in recognition of the importance of open and transparent research. Researchers can access the final data set by contacting the CTR. The CTR and CI will review all data requests to ensure they adhere to all trial data protection and ethical requirements and follow the process outlined in the standard operating procedure.

10. Dissemination policy

10.1. Dissemination policy

All publications and presentations relating to the trial will be authorised by the TMG.

Results will be made available via peer-reviewed open-access journals and academic conference presentations, and in more accessible formats including lay summaries (distributed via social media, relevant websites and networks). We will tailor methods to stakeholders as appropriate including an online animation video co-produced with our PPI advisory group. All outputs will be shared with Local Authorities, carers, organisations involved in advertising the study, and the public.

Led by co-investigators Griffin and Minhas (both of whom are family carers), we will work with the study parent carer advisory group to co-produce outputs suitable for families of intellectual disability children; e.g. trial results, fact sheets about Stepping Stones Online from a parent experience perspective, an understanding of the evidence base, and how to get access to and get the most out of Stepping Stones Online. The parent carer advisory group will guide co-production of materials that will be of most use to families.

Led by co-investigator Hudson, we will work with the professional advisory group to develop study outputs for commissioners and social care managers.

We will hold a dissemination event for stakeholders including policy representatives, and present findings at least one conference. We will also hold a dissemination event for parent carers.

Potential barriers, implementation, and impact: The trial-specific protocol and project outputs will constitute novel IP. The findings from the current trial will inform best practice regarding the use of Stepping Stones Online for children and families. Should the results indicate Stepping Stones Online is both effective and cost-effective, uptake into usual support would be dependent on feasibility and cost of the intervention. Dissemination to, and collaboration with service commissioners and policy makers, would therefore be critical in influencing uptake. The professional advisory group will be key in supporting this component.

There may be challenges associated with acceptability and accessibility of the intervention and associated trial procedures, and feasibility of wider implementation. We will explicitly examine these challenges within the current trial and undertake remedial action as needed following discussion with PPI advisory and independent steering groups. Short-term impacts and outputs associated with the proposed study include a detailed trial protocol, logic model, delivery protocol (parent supporter manual and training materials). Longer-term impacts could include for example improved child and parent-carer well-being, quality of life, and family functioning (see Figure 1 Logic Model).

Future wider scale implementation of the intervention relies on an available infrastructure to support a digital intervention. This infrastructure is already available – Triple P UK have an online platform used to deliver their currently available online parent support programmes. As outlined in our research on usual supports, Triple P UK currently provide online parent support programmes in social care settings, specifically Local Authorities. In addition, Local Authorities also provide a range of parent support programmes.

10.2. Authorship eligibility guidelines and any intended use of professional writers

All authorship eligibility guidelines will be outlined in the trial's publication policy and will meet the guidelines of the target journals.

11. References

1. Buckley N, Glasson EJ, Chen W, Epstein A, Leonard H, Skoss R, et al. Prevalence estimates of mental health problems in children and adolescents with intellectual disability: A systematic review and meta-analysis. Australian & New Zealand Journal of Psychiatry. 2020;54(10):970-84.

2. Totsika V, Hastings RP, Emerson E, Berridge DM, Lancaster GA. Behavior problems at 5 years of age and maternal mental health in autism and intellectual disability. Journal of Abnormal Child Psychology. 2011;39(8):1137-47.

3. Totsika V, Hastings RP, Emerson E, Hatton C. Early years parenting mediates early adversity effects on problem behaviors in intellectual disability. Child Development. 2020;91(3):e649-e64.

4. Sapiets SJ, Hastings RP, Stanford C, Totsika V. Families' access to early intervention and supports for children with developmental disabilities. Journal of Early Intervention. 2023;45(2):103-21.

5. National Collaborating Centre for Mental Health. Challenging behaviour and learning disabilities: Prevention and interventions for people with learning disabilities whose behaviour challenges 2015 [Available from: https://www.nice.org.uk/guidance/ng11.

6. National Institute for Health Care Excellence. Learning disabilities and behaviour that challenges: service design and delivery 2018 [16.02.2026]. Available from: https://www.nice.org.uk/guidance/ng93.

7. National Institute for Health Care Excellence. Mental health problems in people with learning disabilities: prevention, assessment and management 2016 [16.02.2026]. Available from: https://www.nice.org.uk/guidance/ng54.

8. Mazzucchelli TG, Sanders MR. Stepping Stones Triple P: a population approach to the promotion of competent parenting of children with disability. Parenting Research and Practice Monograph. 2012;2(2).

9. Sanders MR, Baker S, Turner KM. A randomized controlled trial evaluating the efficacy of Triple P Online with parents of children with early-onset conduct problems. Behaviour Research and Therapy. 2012;50(11):675-84.

10. Florean IS, Dobrean A, Păsărelu CR, Georgescu RD, Milea I. The efficacy of internet-based parenting programs for children and adolescents with behavior problems: A meta-analysis of randomized clinical trials. Clinical Child and Family Psychology Review. 2020;23(4):510-28.

11. Prinz RJ, Metzler CW, Sanders MR, Rusby JC, Cai C. Online-delivered parenting intervention for young children with disruptive behavior problems: a noninferiority trial focused on child and parent outcomes. Journal of Child Psychology and Psychiatry. 2022;63(2):199-209.

12. Ingels JB, Corso PS, Prinz RJ, Metzler CW, Sanders MR. Online-delivered over staff-delivered parenting intervention for young children with disruptive behavior problems: Cost-minimization analysis. JMIR Pediatrics and Parenting. 2022;5(1):e30795.

13. Ruane A, Carr A. Systematic review and meta-analysis of Stepping Stones Triple P for parents of children with disabilities. Family Process. 2019;58(1):232-46.

14. Hodgetts S, Savage A, McConnell D. Experience and outcomes of stepping stones triple P for families of children with autism. Research in Developmental Disabilities. 2013;34(9):2572-85.

15. Ondruskova T, Royston R, Absoud M, Ambler G, Qu C, Barnes J, et al. Clinical and cost-effectiveness of an adapted intervention for preschoolers with moderate to severe intellectual disabilities displaying behaviours that challenge: the EPICC-ID RCT. Health Technology Assessment (Winchester, England). 2024;28(6):1.

16. Ruane A, Carr A, Moffat V, Finn T, Murphy A, O'Brien O, et al. A randomised controlled trial of the Group Stepping Stones Triple P training programme for parents of children with developmental disabilities. Clinical Child Psychology and Psychiatry. 2019;24(4):728-53.

17. Whittingham K, Sofronoff K, Sheffield J, Sanders MR. Stepping Stones Triple P: An RCT of a parenting program with parents of a child diagnosed with an autism spectrum disorder. Journal of Abnormal Child Psychology. 2009;37(4):469-80.

18. Day JJ, Baker S, Dittman CK, Franke N, Hinton S, Love S, et al. Predicting positive outcomes and successful completion in an online parenting program for parents of children with disruptive behavior: An integrated data analysis. Behaviour Research and Therapy. 2021;146:103951.

19. Papakonstantinou Rodi L, Hastings RP, Gray KM, Wolstencroft J. Practitioners' experiences of delivering parenting interventions remotely: A mixed-methods study. Journal of Policy and Practice in Intellectual Disabilities. 2024;21(2):e12482.

20. Day JJ, Sanders MR. Do parents benefit from help when completing a self-guided parenting program online? A randomized controlled trial comparing Triple P Online with and without telephone support. Behavior therapy. 2018;49(6):1020-38.

21. Flynn S, Hastings RP, Burke C, Howes S, Lunsky Y, Weiss JA, et al. Online mindfulness stress intervention for family carers of children and adults with intellectual disabilities: Feasibility randomized controlled trial. Mindfulness. 2020;11(9):2161-75.

22. Creswell C. Editorial Perspective: Rapid responses to understand and address children and young people's mental health in the context of COVID-19. Wiley Online Library; 2023. p. 209-11.

23. Gray K, Tonge B, Einfeld S, Gruber C, Klein A. Developmental behavior checklist 2. Torrance, CA: WPS. 2018.

24. Tennant R, Hiller L, Fishwick R, Platt S, Joseph S, Weich S, et al. The Warwick-Edinburgh mental well-being scale (WEMWBS): development and UK validation. Health and Quality of life Outcomes. 2007;5(1):63.

25. Kliem S, Lohmann A, Mößle T, Foran HM, Hahlweg K, Zenger M, et al. Development and validation of a parenting scale short form (PS-8) in a representative population sample. Journal of Child and Family Studies. 2019;28(1):30-41.

26. Kessler RC, Andrews G, Colpe LJ, Hiripi E, Mroczek DK, Normand S-L, et al. Short screening scales to monitor population prevalences and trends in non-specific psychological distress. Psychological Medicine. 2002;32(6):959-76.

27. Hughes ME, Waite LJ, Hawkley LC, Cacioppo JT. A short scale for measuring loneliness in large surveys: Results from two population-based studies. Research on Aging. 2004;26(6):655-72.

28. Griffith GM, Hastings RP. Bangor mindful parenting scale (BMPS). Handbook of Assessment in Mindfulness Research: Springer; 2022. p. 1-9.

29. Driscoll K, Pianta RC. Mothers' and Fathers' Perceptions of Conflict and Closeness in Parent-Child Relationships during Early Childhood. Journal of Early Childhood & Infant Psychology. 2011(7).

30. Johnston C, Mash EJ. A measure of parenting satisfaction and efficacy. Journal of Clinical Child Psychology. 1989;18(2):167-75.

31. Perry A, Taheri A, Ting V, Weiss J. The GO4KIDDS brief adaptive scale. Journal of Applied Research in Intellectual Disabilities. 2015;28(6):594-7.

32. Hastings RP, Totsika V, Hayden NK, Murray CA, Jess M, Langley E, et al. 1000 Families Study, a UK multiwave cohort investigating the well-being of families of children with intellectual disabilities: cohort profile. BMJ open. 2020;10(2):e032919.

33. EUROQOL. EQ-5D-5L 2005 [16.02.2026]. Available from: https://euroqol.org/information-and-support/euroqol-instruments/eq-5d-5l/.

34. EUROQOL. EQ-5D-Y-3L 2025 [16.02.2026]. Available from: https://euroqol.org/information-and-support/euroqol-instruments/eq-5d-y-3l/.

35. Varni JW, Sherman SA, Burwinkle TM, Dickinson PE, Dixon P. The PedsQL™ family impact module: preliminary reliability and validity. Health and Quality of Life Outcomes. 2004;2(1):55.

36. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. BMJ. 2015;350.

37. Braun V, Clarke V. Thematic analysis: A practical guide. New York: Sage; 2021.

38. Palinkas LA, Aarons GA, Horwitz S, Chamberlain P, Hurlburt M, Landsverk J. Mixed method designs in implementation research. Administration and Policy in Mental Health and Mental Health Services Research. 2011;38(1):44-53.

39. Candlish J, Teare MD, Dimairo M, Flight L, Mandefield L, Walters SJ. Appropriate statistical methods for analysing partially nested randomised controlled trials with continuous outcomes: a simulation study. BMC medical research methodology. 2018;18(1):105.

40. White IR, Royston P, Wood AM. Multiple imputation using chained equations: issues and guidance for practice. Statistics in Medicine. 2011;30(4):377-99.

41. Van Buuren S, Boshuizen HC, Knook DL. Multiple imputation of missing blood pressure covariates in survival analysis. Statistics in medicine. 1999;18(6):681-94.

42. National Institute for Health and Care Excellence. Evidence standards framework for digital health technology 2019 [16.02.2026]. Available from: https://www.nice.org.uk/what-nice-does/digital-health/evidence-standards-framework-esf-for-digital-health-technologies.

43. National Institute for Health and Care Excellence. Incorporating economic evaluation 2024 [16.02.2026]. Available from: https://www.nice.org.uk/process/pmg20/chapter/incorporating-economic-evaluation.

44. Benedetto V, Filipe L, Harris C, Tahir N, Doherty A, Clegg A. Outcome measures for economic evaluations and cost-effectiveness analyses of interventions for people with intellectual disabilities: a methodological systematic review. Journal of Applied Research in Intellectual Disabilities. 2023;36(2):230-40.

45. Lamsal R, Zwicker JD. Economic evaluation of interventions for children with neurodevelopmental disorders: opportunities and challenges. Applied Health Economics and Health Policy. 2017;15(6):763-72.

46. Hernández Alava M, Pudney S, Wailoo A. Estimating the relationship between EQ-5D-5L and EQ-5D-3L: results from a UK population study. Pharmacoeconomics. 2023;41(2):199-207.

47. Kreimeier S, Greiner W. EQ-5D-Y as a health-related quality of life instrument for children and adolescents: the instrument's characteristics, development, current use, and challenges of developing its value set. Value in Health. 2019;22(1):31-7.

48. Khan KA, Petrou S, Rivero-Arias O, Walters SJ, Boyle SE. Mapping EQ-5D utility scores from the PedsQL™ generic core scales. Pharmacoeconomics. 2014;32(7):693-706.

49. Viecili MA, Weiss JA. Reliability and validity of the pediatric quality of life inventory with individuals with intellectual and developmental disabilities. American Journal on Intellectual and Developmental Disabilities. 2015;120(4):289-301.

50. Faria R, Gomes M, Epstein D, White IR. A guide to handling missing data in cost-effectiveness analysis conducted within randomised controlled trials. Pharmacoeconomics. 2014;32(12):1157-70.

51. Johnson R, Jenkinson D, Stinton C, Taylor-Phillips S, Madan J, Stewart-Brown S, et al. Where's WALY?: A proof of concept study of the 'wellbeing adjusted life year'using secondary analysis of cross-sectional survey data. Health and Quality of Life Outcomes. 2016;14(1):126.

52. Yiu HHE, Buckell J, Petrou S, Stewart-Brown S, Madan J. Derivation of a UK preference-based value set for the Short Warwick-Edinburgh Mental Well-being Scale (SWEMWBS) to allow estimation of Mental Well-being Adjusted Life Years (MWALYs). Social Science & Medicine. 2023;327:115928.

53. Teerenstra S, Kasza J, Leontjevas R, Forbes AB. Sample size for partially nested designs and other nested or crossed designs with a continuous outcome when adjusted for baseline. Statistics in Medicine. 2023;42(19):3568-92.

54. Sanders M, Hoang N-PT, Hodges J, Sofronoff K, Einfeld S, Tonge B, et al. Predictors of change in stepping stones triple interventions: The relationship between parental adjustment, parenting behaviors and child outcomes. International Journal of Environmental Research and Public Health. 2022;19(20):13200.

12. Appendices

12.1. Appendix 2 – schedule of procedures

Procedures	**Visits (insert visit numbers as appropriate)**					
	Screening	**Baseline**	**Treatment Phase**	**6M Follow up**	**12M follow up**	**Ad hoc**
Eligibility assessment	X					
VABS-3	X					
Informed consent		X				
Parent expectation of treatment survey		X				
Randomisation		X				
Demographics		X				
Delivery of intervention			X			
Intervention adherence				X	X	
Parent supporter Fidelity Checklist			X			
Development Behaviour Checklist		X		X	X	
Warwick Edinburgh Mental Wellbeing Scale		X		X	X	
Kessler 6		X			X	
Parenting Scale Short Form		X		X	X	
UCLA Three-item Loneliness Scale		X			X	
Bangor Mindful Parenting Scale		X			X	
Child Parent Relationship Scale		X			X	
Parenting Sense of Competence Scale		X			X	
GO4KIDDS		X			X	
EQ-5D-3L		X			X	

EQ-5D-Y		X			X	
PedsQL		X			X	
CSRI		X		X	X	
US survey		X		X	X	
Safeguarding events						X
Withdrawal form						X

12.2. Appendix 3 – amendment history

<table>
<tr><td colspan="5">The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version</td></tr>
<tr><th>Amendment number</th><th>Date of amendment</th><th>Protocol version number</th><th>Type of amendment</th><th>Summary of amendment</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table>