EVALUATION PROTOCOL

Building Positive Relationships with your Teen: Evaluating the Teen Triple P Programme

CEDAR, University of Warwick

Principal investigators: Professor Kylie M. Gray and Dr Paul A. Thompson

YOUTH ENDOWMENT FUND

Building Positive Relationships with your Teen: Evaluating the Teen Triple P Programme

Evaluation protocol

Evaluating institution: CEDAR, University of Warwick

Chief investigator(s): Professor Kylie M. Gray and Dr Paul A. Thompson

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Project title[1]	*Building Positive Relationships with your Teen: Evaluating the Teen Triple P Programme*
Developer (Institution)	*Triple P UK*
Evaluator (Institution)	*CEDAR, University of Warwick*
Principal investigator(s)	*Kylie M. Gray and Paul A. Thompson*
Protocol author(s)	*Kylie M. Gray, Paul A. Thompson, Samantha Flynn, Richard P. Hastings, Peter E. Langdon, and Faye Tomlinson*

[1] Please make sure the title matches that in the header and that it is identified as a randomised trial as per the CONSORT requirements (CONSORT 1a).

Trial design	*Two-armed cluster randomised controlled trial with random allocation at the family level (families as clusters)*
Trial type	Efficacy with internal pilot
Evaluation setting	Family / local authority
Target group	*Families (parents/carers) of 11 to 15 year olds at the edge of care*
Number of participants	*275 families, up to 412 parents/carers*
Primary outcome and data source	*6 months post-randomisation SDQ externalising score – Parent report*
Secondary outcome and data source	(1) Strengths and Difficulties Questionnaire (SDQ; Goodman, 1999) parent report internalising problems scale, adolescent report externalising and internalising problems scales. (2) Parenting practices: Parenting Scale Adolescent version (PSA) parent report (3) Adolescent prosocial behaviours – The Prosocial behaviour subscale of the SDQ (Goodman, 1999). Adolescent and parent report. (4) Adolescent peer relationships – The Peer Relationship Problem subscale of the SDQ (Goodman, 1999). Adolescent and parent report. (5) Interparental outcome - Dyadic Adjustment Scale (DAS-7) is a 7-item measure (Sharpley & Cross 182; Hunsley et al., 2001). Parent report. (6) Parent mental health – the Kessler 6 (Kessler et al., 2003. Parent report. (7) Parent Wellbeing - The Warwick-Edinburgh Mental Well-being Scale (SWEMWBS; Tennant et al., 2007). Parent report. (8) Conflict Behavior Questionnaire (CBQ-20) (Robin & Foster, 1989). Parent and adolescent report.

	(9) Child-parent relationship – the Closeness subscale of the Child-Parent Relationship Scale (CPRS, short form) measures (Pianta, 1995). Parent report. (10) Family functioning – the Family APGAR scale. (Adapatability, Partnership, Growth, Affection and Resolve; APGAR; Smilkstein, 1978). Parent report. (11) Parent self-regulation – the Parenting Self-Regulation Scale is a 12-item parent-completed measure of parental-regulation (Tellegen et al., 2022). (12) Out of home placement (13) Antisocial behaviours - Self Report Delinquency Measure (SRDM; Smith & McVie, 2003)

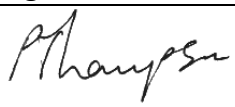
Protocol version history

Version	Date	Reason for revision
1.4	11/07/2023	*Addressed queries from Youth Endowment Fund*
1.3	20/04/2023	*Addressed queries from University of Warwick Sponsorship committee.*
1.2	15/03/2023	*Added detail to correspond with University of Warwick SOP on protocols. This provides more detail than required by YEF template.*
1.1	23/11/2023	*Revision following GeCo review. Relates to SDQ definitions.*
1.0 [*original*]		*[leave blank for the original version]*

Any changes to the design or methods need to be discussed with the YEF Evaluation Manager and the developer team prior to any change(s) being finalised. Describe in the table above any agreed changes made to the evaluation design. Please ensure that these changes are also reflected in the SAP (CONSORT 3b, 6b).

Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigators agree to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the relevant trial regulations, GCP guidelines, and CTR's SOPs.
I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

Joint Chief Investigators		
Name	**Signature**	**Date**
Professor Kylie Gray		20.04.2023
Name	**Signature**	**Date**
Dr Paul Thompson		20.04.2023

General Information This protocol describes the **Teen Triple P** trial and provides information about the procedures for entering participants into the trial. The protocol should not be used as a guide, or as an aide-memoire for the treatment of other participants. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the known Investigators in the trial. Problems relating to the trial should be referred, in the first instance, to Professor Gray / Dr Paul Thompson.

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This protocol has been developed by the Teen Triple P Trial Management Group (TMG).

For **all queries** please contact the University of Warwick Teen Triple P Trial team through the main trial email address. Any clinical queries will be directed through the Trial Manager, Atiyya Nisar, to either the Chief Investigator or a Co-Investigators.

Main Trial Email: warwickteenP@warwick.ac.uk

Randomisation

Randomisation

Stratified permuted block randomisation stratifying by local authority (1:1 randomisation by family cluster)

EMAIL CONTACT DETAILS FOR RANDOMISATION: paul.thompson.2@warwick.ac.uk

Serious Adverse Events

SAE reporting

Where the adverse event meets one of the serious categories, an SAE form should be completed and submitted to the trial team (warwickteenP@warwick.ac.uk**) within 24 hours of becoming aware of the event (See pages 47-52 for more details).**

Contact details: warwickteenP@warwick.ac.uk

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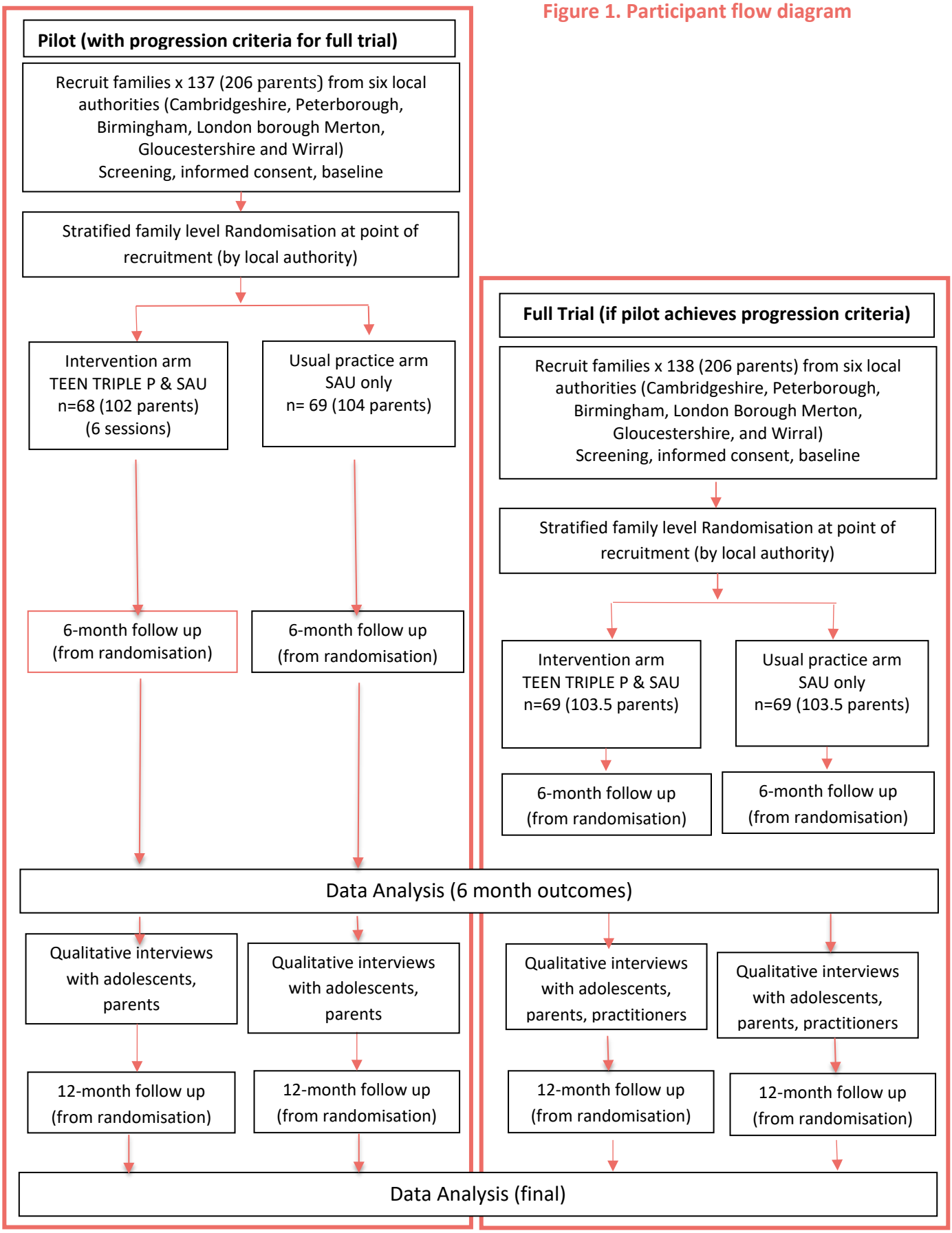
Glossary of abbreviations

AE	Adverse Event
CF	Consent Form
CI	Chief Investigator
CRF	Case Report Form
CYP	Children and Young People
GCP	Good Clinical Practice
GP	General Practitioner
HB	Health Board
HE	Health Economics
IC	Informed consent
IDMC	Independent Data Monitoring Committee
IEC	Independent Ethics Committee
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Number
LD	Learning Disability
PI	Principal Investigator
PIAG	Participant Information Advisory Group
PID	Participant Identification Number
PIS	Participant Information Sheet
R&D	Research and Development
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAU	Support as Usual
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
SSTP	Standard Teen Triple P
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

Trial summary and schema

Figure 1. Participant flow diagram



1.2 Trial lay summary

Many UK families with young people at the edge of care experience multiple and long-standing difficulties, including mental ill-health, violence, substance misuse, and relationship and behavioural difficulties. Young people are more at risk of entering the out-of-home care system when experiencing social disadvantage, maltreatment, parental substance misuse, or maternal depression. Drivers of adolescent out of home placements are associated with family stress and breakdown, and adolescent behavioural problems.

Standard Teen Triple P (Teen Triple P) is a parent skills training programme. Teen Triple P works with parents to help them find different ways to look after a young person in the family and improve family life. This can include dealing with challenges differently or taking on different positive approaches to supporting the young person.

We want to find whether this programme (Teen Triple P) works by running a clinical trial. Some families will receive Teen Triple P plus the routine support that they would normally get. Other families will only get the routine support that is currently offered. We will decide who gets the programme at random, which is like flipping a coin.

In order to work out whether Teen Triple P is helpful, our trial has two parts. In the first part, we will run what is called a 'pilot', this tests whether the trial can be run. If we find that this is the case, we will then move to do the second part, which is continuing with the main trial by inviting more parents/carers and young people to take part.

All of the parents/carers and young people who take part will be asked to complete some measures of things that may change because of taking part in Teen Triple P. We are particularly interested in whether problem behaviours change over the course of the trial. We will also ask about their background, their general well-being, relationships within the household and with peers, and any antisocial behaviours. We will also interview some of the parents/carers and young people receiving Teen Triple P, and the professionals that deliver the Teen Triple P programme. We will also ask them about their experiences of taking part in the trial.

Trial rationale and background

Many UK families with young people at the edge of care experience multiple and long-standing difficulties, including mental ill-health, violence, substance misuse, and relationship and behavioural difficulties (Ofsted, 2011). Young people are more at risk of entering the out-of-home care system when experiencing social disadvantage, maltreatment, parental substance misuse, or maternal depression (Simkiss et al, 2013; NICE Guideline, No.26. 2015). Drivers of adolescent out-of-home placements are associated with family stress and breakdown, and adolescent behavioural problems (Percy-Smith et al, 2018).

An intervention is needed to address these risk factors and reduce care placements, thus changing the trajectory for young people and their families. Evidence-based parenting

intervention strategies supported by social care services can support families at the edge-of-care (Bezeczky et al 2020; National Council of Voluntary Child Care Organisations, 2007; Ofsted, 2011).

Evidence-based interventions that address a number of risk and protective factors for the development of youth behaviour and emotional problems, as well as violence and delinquency in adolescence and adulthood, can improve social, behavioural and emotional outcomes for adolescents, enhance positive parenting practices, reduce family conflict, and reduce disruptive teenager behaviour (Wetherall, 2010; Salari et al., 2014).

By improving parenting skills and the parent-child relationship, overall family functioning and adolescent emotional and behavioural adjustment improves. A key focus of all Triple P interventions is to train parents to generalise the parenting skills developed throughout the program to new problems, situations and to all relevant siblings.

Intervention

The Triple P system has long been a focus of international research, with systematic reviews and a meta-analytic study of trials of Group Triple P demonstrating improvements in child behaviour problems, parenting practices, family relationships, and parent mental health (e.g. Nogueira et al., 2022; Zarakoviti, et al., 2021). Triple P has also been shown to reduce child maltreatment and out of home placements at a population level (e.g. Prinz, 2017; Prinz et al., 2016). Triple P is effective in reducing child behaviour problems and improving parenting practices in low-income families (Nogueira et al., 2021). Triple P is a NICE recommended programme for children with conduct problems, antisocial behaviour, ADHD, children experiencing neglect and abuse, and also for special populations such as children with neurodevelopmental conditions. However, this body of research is focussed on children, rather than adolescents, and comparable research in UK populations is lacking.

Teen Triple P

A primary focus of the Triple P system of interventions is decreasing child behaviour problems through improving parenting practices, and thus improving parent-child relationships and overall family functioning and wellbeing. Triple P is widely used internationally, including in the UK, and many services in the UK offer Triple P to families engaged with social care.

Teen Triple P is a coordinated multi-level prevention/early intervention strategy that draws on social learning theory, applied behaviour analysis, research on child and adolescent development and developmental psychopathology, social information processing models and public health principles. It has many distinguishing features including its flexibility, varied delivery modalities, multi-disciplinary approach, and focus on self-regulation and generalisation of parenting skills.

Teen Triple P is an adaptation of the existing Level 4 Triple P programme (0-12 years), tailored specifically for this developmental period. This extension of the foundation Triple P programme into adolescence retains the relevant core components of the childhood programme (e.g., social and language skills, emotional self-regulation skills, independence skills, and problem-solving skills). However, Teen Triple P acknowledges the developmental shift and impending transition into adulthood, with an increased emphasis on negotiation, compromise, and shared decision-making. In addition, there is a focus on preparing adolescents to safely negotiate negative events and/or potentially risky activities that may negatively impact their health or well-being. Parenting strategies to address issues that arise in adolescence are part of Teen Triple P, and include coaching problem-solving, holding a family meeting, dealing with emotional behaviour, and using skills to manage risky behaviour (Sanders & Mazzuchelli, 2018). An overarching emphasis in Teen Triple P is on changing how parents interact in ways that acknowledge this transitional developmental period (Ralph, 2018).

Standard Teen Triple P consists of ten individual sessions delivered one-to-one between practitioner and family.

The sessions address:

- Initial interview with the parent to gather information about teenager and family background.
- Family observation and assessment to identify primary problems, describe parent-teenage, family and community/sociocultural context within which problem behaviours occur.
- Sharing of assessment findings.
- Encouraging appropriate behaviour by learning strategies to interact with their teenager.
- Observation of parent using positive parenting strategies with their teenager (Part 1).
- Strategies for managing problem behaviour.
- Observation of parent using positive parenting strategies with their teenager (Part 2).
- Introducing a routine for dealing with risky behaviour.
- Using planning ahead routines for potential risky situations.
- Strategies for promoting generalisation and maintenance of behaviour change.

A key focus of all Triple P interventions is to train parents to generalise the parenting skills developed throughout the program to new problems, situations and to all relevant siblings.

A guided participation model of information transfer (Sanders & Lawton, 1993) is used to discuss assessment information with parents and to develop a shared understanding of the

problem and possible contributing factors. This model involves providing descriptive, factual information and providing opportunities for parents to process and react to the practitioner's inferences and reasoning. The sharing of this reasoning provides a model for parents to examine causal inferences they make about their teenager's behaviour.

A self-regulation approach is used to teach parenting skills that promote parents' independence, confidence and future problem solving. Training is conducted in a way supportive of generalisation, in that parents are assisted to apply new skills to varied and novel situations rather than learning to apply specific management skills to a single discrete behaviour.

Five randomised controlled trials (RCTs) of Teen Triple P have been reported, along with a sixth quasi-experimental study. One study looked at individual delivery of Teen Triple P (Salari et al., 2014), three looked at group delivery (Arkan et al., 2020; Chu et al., 2014; Kliem et al., 2014), and one self-directed delivery (Doherty et al., 2013). Although outcomes differed across studies, the RCTs reported improvements in adolescent behaviour problems, parent-adolescent relationship (reduction in conflict), and parent mental health (Arkan et al., 2020; Chu et al., 2014; Kliem et al., 2014; Salari et al., 2014). When measured, the studies also reported improvements in parenting practices (Chu et al., 2014; Kliem et al., 2014; Salari et al., 2014). Three of the RCTs included follow-ups (3- or 6-month follow-up) reporting maintenance of improvements (Arkan et al., 2020; Chu et al., 2014; Salari et al., 2014). Sample sizes of the RCTs were similar and relatively small, ranging from totals of 46-84, with an approximately even split between Teen Triple P and control groups. The fourth study was a quasi-experimental design, matching a sample of 103 parents who had received Teen Triple (group delivery) to a community control sample of 397 parents of adolescents (10-16 years) (Steketee, et al., 2021). Similar outcomes were reported, with the Teen Triple P group reporting improvements in parenting practices, parent-adolescent conflict, and adolescent behaviour problems, with improvements maintained at 3–5-month follow-up. Only one published evaluation of Teen Triple P in the UK was identified, a RCT of web-based, parent self-directed Standard Teen Triple for adolescents with a type 1 diabetes (Doherty, et al., 2013). Compared to the usual care group (n=37), the treatment group (n=42) showed post treatment improvements in diabetes related conflict.

There have been no evaluations to date of Teen Triple P with adolescents at risk of out-of-home placement. Whilst Teen Triple P has promise as an intervention for this population on the edge of care, a rigorous RCT is needed.

Teen Triple P and young people on the edge of care

Standard Teen Triple P is an intervention established for high risk, high complexity families and is currently chosen and used in the UK by high intensity/high risk services such as Youth Justice Teams and in existing edge-of-care work. The Standard Teen Triple P programme is an intensive

one-to-one 10-week intervention for families whose teenagers have more severe behavioural difficulties and includes generalisation enhancement strategies.

Indicators for use of Standard Teen Triple P (listed below) are well matched to family presenting problems at the edge of care:

- High level of conflict and difficulties
- Dysfunctional discipline styles
- High levels of conflict over parenting
- High levels of relationship dissatisfaction
- Moderate to severe levels of parental depression or stress

Standard Teen Triple P (compared to group programmes) includes a more intensive family assessment with additional tasks of parent-child observation, gaining the teenager's perspective on the issues, and an option of gathering school information. This process recognises the need for additional information and perspectives when interventions address complexity and high risk. The development of a case formulation is followed by sharing results with parents using a guided participation model of information transfer. Practitioners discuss conclusions about the nature, extent, causes and maintaining factors for the teenagers' difficulties and establish a shared agreement on an intervention plan. This is of particular importance when families are facing very challenging home conditions as a shared understanding of the difficulties and agreement on the course of action increases parental commitment to the programme and potential for positive outcomes.

Standard Teen Triple P benefits include:

- Supports the use of adaptations and flexibility to meet specific family needs e.g. time of day, location of the delivery.
- Enables the practitioner to tailor examples to match the families' specific issues rather than generalised examples as in group programmes.
- One-to-one format enables exploration of challenging family issues which may not be disclosed in group situations.
- Greater level of confidentiality experienced compared to a group delivery.
- More extensive family assessment to explore in greater detail the issues concerning a family that includes greater involvement of the young person in the assessment process, and opportunity for practitioner observation of parent and young person.

Impact evaluation

Research questions or trial objectives

Primary objective (PO):

Determine whether there is a benefit of support as usual (SAU) plus Standard Teen Triple P (TEEN TRIPLE P) over support as usual (SAU) in improving parent/carer rated adolescent externalising behaviour problems at 6-months post-randomisation in adolescents at the edge of care.

Secondary objectives (SO):

1. Complete an Internal Pilot in the first year to inform the decision as to whether proceeding with a definitive trial is warranted and feasible.

2. Determine whether TEEN TRIPLE P + SAU, (a) reduces parent reported adolescent internalising behaviour and increases prosocial behaviours at 6 months and 12 months post-randomisation, and parent reported adolescent externalising behaviour at 12 months post-randomisation, and (b) reduces adolescent reported externalising and internalising behaviour problems and increases prosocial behaviours at 6 and 12 months post-randomisation, (c) improves parenting practices, parent self-regulation, interparental relationships, parental-adolescent relationships and parental well-being at 6 and 12 months post-randomisation, decreases adolescent reported antisocial behaviours at 12 months post-randomisation, and (d) reduces the chance of a child going into out of home placement over a 12 month period.

3. Carry out exploratory sub-group analyses of outcomes by adolescent learning disability status and whether living with foster versus biological/adoptive parents.

4. Monitor and report and adverse events related to TEEN TRIPLE P.

5. Complete a process evaluation using key indicators drawn from the logic model, including an evaluation of acceptability and the experiences of parents/carers, adolescents with a broad range of ethnic and diverse backgrounds, and other key stakeholders (e.g., practitioners, delivery team), and fidelity of delivery of TEEN TRIPLE P.

Internal pilot

The design incorporates an internal pilot in the first year with progression criteria (Avery et al., 2017) to examine whether moving on to complete a definitive trial is warranted. The proposed criteria are:

Recruitment

(i) 50% of overall final trial target (families) within first 6 months of recruitment to the trial (green=80 to 100% (n=99)); amber=60 to 79%; red=<60%);

Randomisation

(i) Proportion of recruited families randomised (green=≥90%; amber=50-89%; red=<49%).

Fidelity and adherence (first 3-4 months of those randomised to TEEN TRIPLE P who will have completed intervention by the progression decision point)

(i) Fidelity assessed according to a fidelity checklist (developed in collaboration with the delivery team, prior to the internal pilot – see later in Process Evaluation) (green=≥80 of sessions meet criteria; amber=50-79%; red=<50%);

(ii) Adherence: session attendance (green=≥ 75% of families attend at least the first 8 of the 10 sessions; amber= 50-74%; red=<50%).

Outcomes

(i) Data completeness for the Strengths and Difficulties Questionnaire (SDQ) parent reported young person externalising problems score at baseline: green=≥75%; amber=50-74%; red=<50%.

The final progression criterion will be an assessment to confirm that the support in the intervention arm is sufficiently different to the control arm. This will be an assessment based primarily on a SAU survey.

Information from the SAU survey will be examined for any overlap with the content of the TEEN TRIPLE P intervention.

Design

A two-arm cluster (with families as the clusters) randomised efficacy RCT of Standard Teen Triple P (TEEN TRIPLE P) plus SAU vs. SAU alone, running over 40 months, involving parents and foster carers of young people aged 11-15 years on the edge-of-care. There will be a 6- and 12-month follow-ups, and a process evaluation and internal pilot.

Procedure

Parents and foster carers identified by case-holding social workers and edge-of-care teams across six local authorities (Cambridgeshire, Peterborough, Birmingham, London Borough Merton, Gloucestershire, and Wirral). Participants (primary parents/carers) will be screened by case-holding social workers and edge of care teams to check initial eligibility. Those who are likely to be eligible will be invited to take part in the trial.

All participants who agree to participate and for whom consent has been given will be screened to ensure they meet the eligibility criteria. Consent from those with parental responsibility is required, and young person assent when under 16 years of age – for research participation by young people. If the local authority has parental responsibility, then the social worker would consent to the inclusion of the young person on behalf of the local authority.

Baseline assessments will be completed prior to randomisation. Families randomised to the intervention arm will receive TEEN TRIPLE P as well as existing edge-of-care services (SAU), and those randomised to the control arm will receive SAU alone.

The primary endpoint is 6-months post-randomisation. All participants (in both trial arms) will complete assessments at baseline, 6- and 12-months post-randomisation. A number of participants (parents and adolescents), and key stakeholders will be invited to participate in semi-structured interviews to ascertain acceptability and their experience of the intervention, while we will also develop specific target indicators drawn from our logic model which will we measure during the trial.

Intervention – Standard Teen Triple P

Standard Teen Triple P is a targeted-indicated intervention for parents of an adolescent child, aged up to 16 years. The programme is indicated for parents who are concerned about their teenager's development and behaviour.

Standard Teen Triple P involves a thorough assessment of the parent-child relationship, and the application of parenting skills to a broad range of target behaviours. The programme involves parents attending 10 (1-hour) one-to-one sessions, where they learn practical strategies for how to manage their child's problematic behaviour, promote healthy development, and improve the quality of the parent-child relationship. Sessions are delivered face-to-face, either in person or via video-conferencing. All parents will be invited to attend sessions.

Practitioners use a range of learning methods, including behavioural rehearsal to teach parents new skills, guided participation to discuss assessment findings, active skills training methods to facilitate the acquisition of new parenting routines, and generalisation-enhancement strategies to promote parental autonomy.

In addition, parents are continuously provided with constructive feedback and are encouraged to set goals, practice strategies, and complete their activity workbook and homework tasks.

Sessions 1-3 are set-aside for assessment. In session 1, parents are interviewed to obtain information regarding the current problem, the teenager's developmental history and the family history. If possible, session 2 involves an interview with the teenager and an observation

of the parent-child interaction. Then, in session 3, the practitioner shares assessment findings and assists the parent(s) to set goals.

Sessions 4 – 9 are focussed on the actual intervention, whereby each session of active training (sessions 4, 6, and 8) are followed by practice sessions (sessions 5, 7, and 9). Sessions 4-5 cover promoting appropriate behaviour, sessions 6-7 are for managing problematic behaviour, and sessions 8-9 are on dealing with risky behaviour.

Session 10 the final session covers additional skills to facilitate generalisation and maintenance of treatment gains and intervention review and closure.

Parents receive a Standard Teen Triple P Family Workbook to support them in using the strategies and processes taught during the Standard Teen Programme. The Family Workbook covers each individual session including information, practice tasks, and space for taking notes/recording progress to encourage implementation of Triple P in the family. Parents retain the workbook following completion of the individual sessions.

Location: Standard Teen Triple P is delivered in the family home. There is flexibility where this is not feasible for delivery to occur in other locations, for example Local Authority or community premises where there is a private space to meet. There is also the option to deliver the programme remotely via videoconferencing where suitable.

Frequency: Standard Teen Triple P is delivered on a weekly basis over 10 weeks. There is flexibility if parents are unable to attend a session - for example due to illness or planned vacations - for practitioners to defer a session to accommodate such family life events.

Dosage: Standard Teen Triple P is a ten-session programme. Attendance at all sessions is preferable. It is practice as usual to offer alternative times/dates if a session is missed due to unforeseen circumstances.

All the parenting strategies within the Standard Teen Programme are taught by the close of Session 8 (of 10) so there is a case that completion of sessions 1-8 would be considered dose sufficient.

Implementation and practitioner training – Standard Teen Triple P

The trial will be supported by TPUK's Implementation Consultant for Research, using the Triple P Implementation Framework (McWilliam, Brown, Sanders & Jones, 2016). This framework is used to guide the implementation of Triple P through every stage, to make sure the programme is as effective as possible for families, and realistic for practitioners to deliver. This helps to sustain the programme and to get the most out of it for families in the community.

There are five phases to the Triple P Implementation Framework, corresponding to key decision-making and activity sequences in the effective implementation of Triple P. Below we have outlined key activities that apply to this trial within each phase:

1. Engagement – the 6 sites are engaged with the trial and associated commitments (2021 - 2022)

2. Commitment and Contracting – November / December 2022

3. Implementation Planning – January 2023 – March 2023

    - Each site will have a coordinator who will meet weekly with TPUK's Implementation Consultant for Research during the Implementation Planning phase.
    - Organisational structures will be set up for trial readiness (identifying the delivery team, management, mechanisms for referrals)
    - The implementation strategy is developed, and activities are identified to prepare the sites deliver Triple P for the trial.
    - Participating staff are identified and adequately prepared to participate in training. Plans are developed for:
        - Training, accreditation, and support (assign to the cohort dates, participant selection, resources).
        - Delivery with families
        - Communications
        - Reporting

4. Briefings, Training and Accreditation, clinical workshop (April – mid July 2023)

Outcomes of this phase include:

- Practitioners report being prepared prior to attending.
- Practitioners have a high-quality training experience.
- Peer Support Networks are established, and practitioners are supported to attend.
- Practitioners have time to prepare for accreditation.
- Practitioners report being prepared to deliver for the trial.
- Sufficient practitioners are trained to meet trial numbers.

5. Implementation and Maintenance (August 2023 onwards)

TPUK's Implementation Consultant for Research continues to support each site in their implementation of the programme, provides clinical support to practitioners, and regular support to the trial coordinators.

Practitioners delivering this programme can come from a range of professions (e.g. school counsellor, nurse, psychologist, social worker, or allied health professional).

Practitioners receive during training a set of Standard Teen resources including a Standard Teen Practitioners' Manual, Participant Notes for Standard Teen Triple P Provider Training, and a copy of the Teen Triple P Family Workbook. Also provided is access to a web-based information site 'The Triple P Provider Network' to access downloadable resources and updates.

Training requirements are attendance at three days of training, followed approximately a month later by a one-day Pre-Accreditation Workshop, and a half day accreditation session. All Triple P training events for the trial will be conducted remotely via zoom.

Practitioners must pass a role play based half day accreditation with a Triple P trainer and pass a Triple P multiple choice quiz to achieve accreditation in Standard Teen Triple P and be approved to deliver the programme.

Immediately following the accreditation process, practitioners will attend a half day clinical workshop (conducted via zoom and facilitated by a Triple P Trainer) entitled 'Preparing to deliver the TEEN TRIPLE P intervention' workshop. These workshops (6 in total for 20 practitioners each workshop) will be held prior to the intervention phase of the trial, covering specific trial processes, administrative preparation for their intervention delivery and a clarification / Q &A intervention content opportunity. '

During the intervention phase of the trial, practitioners will be invited at three timepoints (November 2023; March 2024 and Sept 2024) to further half-day clinical workshops (conducted via zoom and facilitated by a Triple P Trainer). Each workshop can include up to 20 participants. The specific topics of the workshops will be selected based on need from the following: Programme Fidelity and Flexibility; Cultural Diversity; Engaging Hard to Reach Families and Clinical and Implementation Support. All workshops provide an exploration of the challenges of implementing Triple P programmes with parents and practical exercises to enhance practitioner skills.

Fidelity to programme delivery: Fidelity and flexibility in delivery of Standard Teen Triple P is actively taught and discussed during practitioner training and is one of the topics for the half day workshops that practitioners will be offered during the intervention phase of the trial.

Triple P has developed its own Peer-Assisted Supervision and Support Model (PASS), whereby practitioners can provide and receive structured feedback from each other while they deliver the programme. PASS sessions are conducted in small groups of 6-8 practitioners and run for 1-2 hours every month.

Racial and Cultural Sensitivity: Triple P programmes are delivered across diverse cultural contexts in 31 countries and 22 languages. Research has shown that culturally diverse parents find Triple P strategies are highly acceptable, highly useful and parents reported being very likely to use the strategies (Morawska, et al., 2011).

Twenty-five percent of local authorities across the UK have commissioned and delivered Standard Teen Triple P. Parents are able to select from the menu of strategies taught in the programme and are thus able to decide which strategies are right for their family and culture background. Practitioners have the flexibility to tailor and provide examples that are suitable for the race and culture of the parent / carer receiving the intervention. Additionally, cultural diversity is one of the topics for the half day workshops that practitioners will be offered during the intervention phase of the trial. All University of Warwick staff complete and regularly renew mandatory equality, diversity and unconscious bias training as a condition of employment.

Primary outcome

The proposed primary outcome measure for this trial is the Strengths and Difficulties Questionnaire (SDQ) measuring parent reported externalising behaviour problems score at 6-months post-randomisation. The SDQ is a robust and well-validated measure of child and adolescent behavioural and emotional problems (Deighton et al., 2014). The SDQ externalising behaviour measure consists of the conduct problems and hyperactivity subscales.

Secondary outcomes

The logic model and theory of change document specifies outcomes and key processes of change; secondary outcomes are consistent with the logic model.

Data will be collected through multiple methods, including online, by post, in person, and over the telephone. In previous trials completed by our team, using a choice of methods for data collection has ensured that participants are able to participate in a way that best suits them and helps to addresses inequalities (Flynn et al., 2020).

All measures will be collected at baseline, 6- and 12-months post-randomisation.

Secondary outcome measures include:

(1) Adolescent behavioural and emotional problems: Strengths and Difficulties Questionnaire (SDQ; Goodman, 1999) parent report internalising problems scale, adolescent report externalising and internalising problems scales.
(2) Parenting practices: Parenting Scale Adolescent version (PSA, parent completed) is a short form of the Parenting Scale (Irvine et al., 1999) which assesses dysfunctional discipline

practices in parents. It is an adaptation of the Parenting Scale (Arnold, et al., 1993) for parents of adolescents

(3) Adolescent prosocial behaviours – The Prosocial behaviour subscale of the SDQ (Goodman, 1999) will be used to assess adolescent prosocial behaviours. This will be completed by adolescents and parents.

(4) Adolescent peer relationships – The Peer Relationship Problem subscale of the SDQ (Goodman, 1999) will be used to assess adolescent peer relationships. This will be completed by adolescents and parents.

(5) Interparental outcome - Dyadic Adjustment Scale (DAS-7) is a 7-item measure (Sharpley & Cross 182; Hunsley et al., 2001) assessing the relationship quality of couples. The DAS-7 assesses relationship satisfaction and the degree to which the couple agrees on matters of importance to the relationship.

(6) Parent mental health – the Kessler 6 is a six-item screening tool for serious mental illness in the general population (Kessler et al., 2003). It will be completed by parents.

(7) Parent Wellbeing - The Warwick-Edinburgh Mental Well-being Scale (SWEMWBS) is a measure of mental wellbeing (Tennant et al., 2007). The short (7 item) version will be completed by parents.

(8) Conflict Behavior Questionnaire (CBQ-20) (Robin & Foster, 1989) assesses adolescent-parent communication, conflict and relations. Both the adolescent and parent report versions will be completed.

(9) Child-parent relationship – the Closeness subscale of the Child-Parent Relationship Scale (CPRS, short form) measures (Pianta, 1995) will be completed by parents.

(10) Family functioning – the Family APGAR scale (Adaptability, Partnership, Growth, Affection and Resolve; APGAR) measures satisfaction with family functioning (Smilkstein, 1978). This 5-item measure will be completed by parents.

(11) Parent self-regulation – the Parenting Self-Regulation Scale is a 12-item parent-completed measure of parental-regulation (Tellegen et al., 2022).

(12) Out of home placement – all instances of out of home placement will be recorded at each follow-up time point. This will include the reason for and duration of out of home placement.

(13) Antisocial behaviours – the Self Report Delinquency Measure is a 15-item measure of antisocial behaviours (e.g., burglary, violence) and will be completed by adolescents at 12 month follow up.

Outcome measures have been selected based on psychometric properties (reliability, validity and suitability for context, including cultural context), brevity (to reduce participant burden), and affordability (with the exception of the SDQ, all measures are cost free).

Table 1: Trial design

Trial design, including number of arms		two-armed, parallel, cluster randomised controlled trial (1:1 allocation)
Unit of randomisation		random allocation at the family level (clustering)
Stratification variables (if applicable)		Local authority
Primary outcome	variable	Adolescent externalising behaviour problems
	measure (instrument, scale, source)	Parent completed Strengths and Difficulties Questionnaire (SDQ) – externalising scale (SDQ; Goodman, 1999) at 6 months
Secondary outcome(s)	variable(s)	(1) Parent and adolescent reported - Adolescent behavioural and emotional problems (2) Parenting practices (3) Parent and Adolescent reported prosocial behaviours (4) Adolescent reported peer relationships (5) Interparental outcome (6) Parent mental health (7) Parent Wellbeing (8) Conflict Behavior (9) Child-parent relationship (10) Family functioning (11) Parent self-regulation – the Parenting Self-Regulation (12) Out of home placement (13) Adolescent antisocial behaviours
	measure(s) (instrument, scale, source)	(1) Strengths and Difficulties Questionnaire (SDQ; Goodman, 1999) parent report internalising problems scale, adolescent report externalising and internalising problems scales at 6 and 12 months. (2) Parenting practices: Parenting Scale Adolescent version (PSA) parent report

		(3) Adolescent prosocial behaviours – The Prosocial behaviour subscale of the SDQ (Goodman, 1999). Adolescents and parents report at 6 and 12 months. (4) Adolescent peer relationships – The Peer Relationship Problem subscale of the SDQ (Goodman, 1999) (5) Interparental outcome - Dyadic Adjustment Scale (DAS-7) is a 7-item measure (Sharpley & Cross 182; Hunsley et al., 2001) (6) Parent mental health – the Kessler 6 (Kessler et al., 2003 (7) Parent Wellbeing - The Warwick-Edinburgh Mental Well-being Scale (SWEMWBS; Tennant et al., 2007 (8) Conflict Behavior Questionnaire (CBQ-20) (Robin & Foster, 1989) (9) Child-parent relationship – the Closeness subscale of the Child-Parent Relationship Scale (CPRS, short form) measures (Pianta, 1995) (10) Family functioning – the Family APGAR scale (Adapatability, Partnership, Growth, Affection and Resolve; APGAR; Smilkstein, 1978). (11) Parent self-regulation – the Parenting Self-Regulation Scale is a 12-item parent-completed measure of parental-regulation (Tellegen et al., 2022). (12) Out of home placement (13) Antisocial behaviours - Self Report Delinquency Measure (SRDM; Smith & McVie, 2003)
Baseline for primary outcome	variable	Adolescent externalising behaviour problems
	measure (instrument, scale, source)	Parent completed Strengths and Difficulties Questionnaire (SDQ) – externalising scale (SDQ; Goodman, 1999) at baseline
	variable	(1) Parent reported - Adolescent behavioural and emotional problems (2) Parenting practices

		(3) Parent and Adolescent reported prosocial behaviours (4) Adolescent reported peer relationships (5) Interparental outcome (6) Parent mental health (7) Parent Wellbeing (8) Conflict Behavior (9) Child-parent relationship (10) Family functioning (11) Parent self-regulation – the Parenting Self-Regulation (12) Out of home placement (13) Adolescent antisocial behaviours
Baseline for secondary outcome	measure (instrument, scale, source)	(1) Strengths and Difficulties Questionnaire (SDQ; Goodman, 1999) parent report internalising problems scale, adolescent report externalising and internalising problems scales at 6 and 12 months. (2) Parenting practices: Parenting Scale Adolescent version (PSA) parent report (3) Adolescent prosocial behaviours – The Prosocial behaviour subscale of the SDQ (Goodman, 1999). Adolescents and parents report at 6 and 12 months. (4) Adolescent peer relationships – The Peer Relationship Problem subscale of the SDQ (Goodman, 1999) (5) Interparental outcome - Dyadic Adjustment Scale (DAS-7) is a 7-item measure (Sharpley & Cross 182; Hunsley et al., 2001) (6) Parent mental health – the Kessler 6 (Kessler et al., 2003 (7) Parent Wellbeing - The Warwick-Edinburgh Mental Well-being Scale (SWEMWBS; Tennant et al., 2007 (8) Conflict Behavior Questionnaire (CBQ-20) (Robin & Foster, 1989) (9) Child-parent relationship – the Closeness subscale of the Child-Parent Relationship Scale (CPRS, short form) measures (Pianta, 1995)

		(10) Family functioning – the Family APGAR scale (Adapatability, Partnership, Growth, Affection and Resolve; APGAR; Smilkstein, 1978). (11) Parent self-regulation – the Parenting Self-Regulation Scale is a 12-item parent-completed measure of parental-regulation (Tellegen et al., 2022). (12) Out of home placement (13) Adolescent antisocial behaviours - Self Report Delinquency Measure (SRDM; Smith & McVie, 2003)

Randomisation

Following baseline assessment, families will be randomised on a 1:1 basis to either the intervention (TEEN TRIPLE P and SAU) or control arm (SAU only) using stratified permuted block randomisation, stratifying by local authority. The randomisation will allocate families as a cluster, so that parents from the same family are in the same trial arm.

The randomisation list will be produced in advance and will use a block size of 4. Outcome assessors, the research team excluding the trial manager and those undertaking the process evaluation will remain blind to allocation.

The trial statistician responsible for analysing the data will be blind. Therefore, the senior trial statistician (co-PI Thompson) will conduct the randomisation. The randomisation will be embedded within the study database.

The Trial Manager will be responsible for allocation and informing participants and intervention practitioners of a participants' allocation by phone and secure file transfer.

Randomisation will be conducted using statistical software R (version 4.2.2 -2022-10-31 ucrt), using R package 'blockRand'.

Blinding

Due to the nature of the trial, participants and practitioners will not be blind to allocation arm. In addition, the Senior Trial Statistician (PI Thompson), Trial Manager, and researchers completing qualitative interviews will not be blind to allocation. All other researchers, including the Trial Statistician responsible for analysing the data and researchers carrying out data collection, will be blind to allocation arm. If inadvertent unblinding occurs during contact with a participant, this will be recorded and reported to the Trial Manager. We do not foresee any circumstance where unblinding will be necessary.

Risk assessment

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 normal standard practice
- How the risk will be minimised/managed

This trial has been categorised as a low-risk trial, where the level of risk is comparable to the risk of standard care. 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.

Site and Investigator selection

This trial will be carried out at 6 participating sites within the UK. All sites who are interested in participating in the trial will be required to complete a registration form to confirm that they have adequate resources and experience to conduct the trial.

Before the site can begin recruitment a site /coordinator must be identified. The following documents must be in place and copies sent to the Trial email account (see contact details):

- Local Authority site approval to commence the trial
- Favourable opinion from the relevant Research Ethics Committee
- A signed Trial Agreement
- Current Curriculum Vitae and GCP training certificate of the site Principal Investigator (PI)
- Completed Site Delegation Log and Roles and Responsibilities document
- Full contact details for all personnel involved, indicating preferred contact
- A copy of the most recent approved version of the Participant Information Sheet(s) and Consent Form(s), including naming of the relevant Local Authority site
- Upon receipt of all the above documents, the Trial Manager will send written confirmation to the Principal Investigator detailing that the site is now ready to recruit participants into the trial. This letter/email must be filed in each site's Site File.

Occasionally during the trial, amendments may be made to the trial documentation listed above. The University of Warwick Trial Manager will issue the site with the latest version of the documents as soon as they become available. It is the responsibility of the University of Warwick Trial Manager to ensure that they obtain local approvals for the new documents.

Site initiation/ training will be by teleconference.

Participants

Families are eligible for the trial if they meet all the following inclusion criteria and none of the exclusion criteria apply. All queries about family eligibility should be directed to the Trial Manager before randomisation/recruitment. Figure 1 details the participant flow through the trial.

Inclusion

- Families of young people aged 11-15 years determined as being on the *edge-of-care*

Definition of *Edge-of-Care*

Edge of Care refers to children/young people who either:

- have not entered into care as they have been assessed and the LA has chosen to support them and their families through alternative provisions/services. Or
- they are being considered for care but have not entered into local authority care.

Exclusion

- Families where one or more parent has received a multi-session parenting programme covering similar content to Triple P over the previous 12-months
- Families where one or more parent is currently receiving a multi-session parenting programme covering similar content to Triple P or any multi-component manualised family intervention, such as Multi-Systemic Therapy

Sample size calculations

Parents/carers within the same family will be randomised to the same arm, making this a cluster RCT, given responses within the same family are potentially highly correlated. We might expect, based on our previous research with families, an average cluster size within families of up to a maximum of 1.5 parents and a high degree of correlation among parents/carers from the same family, so also allow for an ICC=0.5 (Davé et al., 2008). Following Teerenstra et al. (2012), we also allow for a correlation between baseline and follow-up measures of primary outcome of r=0.5 (this is a conservative estimate based on published SDQ test-retest correlations between 0.74-0.84; Nowak at al.,2008). The sample size is then inflated to account

for 20% of families being lost to follow-up at the 12-month post-randomisation follow-up time point.

Allowing for the above assumptions and an effect size to be detected of 0.35 with 90% power and a two-sided alpha of 0.05, a sample size of N=412 (N1 =206, N2=206) is required.

The choice of effect size was based on meta-analytic effects from similar parenting programmes' meta-analyses and on the basis that similar Triple P programmes report large effect sizes that are typically >0.5, some as large as 0.8. On this basis, we reduced to 0.35 given the unique nature of the population in this trial. Further evidence based on individually delivered teen parenting programmes was quite challenging to find well powered RCTs or meta-analyses, so meta-analyses that were slightly outside our age range were also considered.

An efficacy trial for standard teen Triple P report an effect of d=0.62 (Salari et al, 2014). In the other meta-analyses, it was also generally around d=0.6. Given that we are delivering this to a slightly different population, the current planned MDES 0.35 is justifiably conservative (mainly as most studies have been quite small and in a very different population). Considering the MDES from a clinically meaningful effect size, d=0.35 equates approximately to a 2-point change on our primary outcome, an effect smaller than this is unlikely to provide any meaningful change. With reference to sample size and secondary outcomes, the trial is currently powered on the basis of detecting an appropriate MDES for the primary outcome which is standard practice in all major trials (CONSORT statement; Schulz et al., 2010).

Sample size calculations were conducted using the statistical software R version 4.1.2 (2021-11-01) using the package 'pwr' version 1.3.0.

Table 2: Sample size calculations

		PARAMETER
Minimum Detectable Effect Size (MDES)		0.35
Pre-test/ post-test correlations	level 1 (participant)	0.5
Intracluster correlations (ICCs)	level 1 (participant)	-
	level 2 (cluster)	0.5

		PARAMETER
Alpha[2]		0.05
Power		0.9
One-sided or two-sided?		Two-sided
Average cluster size (if clustered)		1.5
Number of clusters[3]	Intervention	137
	Control	138
	Total	275
Number of participants	Intervention	206
	Control	206
	Total	412

Recruitment and screening

Participant identification

There will be one pathway for recruiting participants in each Local Authority (site). Practitioners in services will identify potential CYP participants in their service. Potential parents and CYP participants will be provided with trial information (either physically, online or by post/email) including an information sheet, copy of the consent/assent forms and contact information for the University of Warwick project team. If the parents are interested in taking part or would like to discuss the trial further, they can directly contact the University of Warwick research assistant/trial manager. Alternatively, with the consent of the parent, the Local Authority can

[2] Please adjust as necessary for trials with multiple primary outcomes, 3-arm trials, etc., when a Bonferroni correction is used to account for family-wise errors.

[3] Please state how the data is clustered, if there is any clustering (e.g. by delivery practitioner or setting).

provide the University of Warwick research assistant/trial manager with the parents' contact details and the research assistant will contact the family.

If the CYP (and parent/guardian if appropriate) are interested in taking part, an appointment will be arranged with a research assistant (via telephone or teleconference) and the following will be carried out:

- The trial will be explained in detail, including the randomisation and consent process. Research assistants will ensure that the participant has had sufficient time to consider the information in the information pack.
- Eligibility will be assessed.
- Consent to participate will be obtained from either:
- CYP parent/guardian alongside assent from CYP if CYP is under 16 years-of-age

The appointment with the research assistant can be made in two ways, the research assistant can contact the participant/parent or guardian to arrange the appointment (using contact details from the screening log), or the participants/parent or guardian can get in touch directly with the research assistant to request the appointment. Alternatively, consent can be obtained directly using an online form, prior to baseline data collection if the participant preferred.

The local Authority will be advised of the outcome of the eligibility assessment.

Contact logs

A contact log of all ineligible and eligible but not consented/not approached will be held in a secure online database that can be accessed by the trial team and the research department so that any biases from differential recruitment will be detected. The log will be completed by Local Authority staff. When at site, identifiable information should only be entered on these for those CYP who say that they want to take part, for those who do not want to take part only no-identifiable information (e.g. ID) will be held on the screening log. Contact log data will be monitored and a TMG/TSC report will be produced for each meeting containing summaries of screened, recruited, refusal of participants. Plots of the actual vs predicted recruitment will also feature in each report.

Recruitment rates

A total of 412 participants (parent/guardians) will be recruited at an expected rate of 34-35 per month, across six authorities (approximately 6 per Local Authority site, per month), over 12 months. 206 participants will be recruited in the pilot phase, and 206 in the main trial phase.

Informed consent

The parent/guardian and CYP participants will have been sent a Participant Information Sheet and copy of the consent/assent form prior to the first appointment taking place and given sufficient time to read the information. There will be two versions of the Participant

Information Sheet for CYP who take part in the main trial, one for 11 to 15-year-olds, and one for 16-year-olds if they turn 16 during the trial. Trial information will be appropriately adapted for use by younger CYP. We will provide trial information in alternative formats (e.g., audio file, video) and make these available to all participants.

The trial manager/research assistants, who have been fully trained in trial procedures, will explain the trial in detail, including randomisation and consent for long-term follow-up using routinely collected data and appropriate data linkage. If happy to take part, informed consent will be obtained from parental/guardian consent and CYP assent obtained from CYP. Verbal consent will be obtained (either via telephone, video conferencing or face-to-face meeting). Research assistants will 'sign' an online consent form on behalf of the participant is they choose to join the trial, evidence of this will be sent to the participant in the form of a PDF document showing the online form on screen. If a participant turns 16 during the course of the trial, they will be re-consented (i.e. asked to complete a consent form for age 16+), before the next data collection/follow-up stage.

A contacts form will be completed for participants including multiple methods of contact (address, telephone, email address) to minimise loss to follow-up. Preferences for follow-up data collection (face-to-face, telephone, online, videoconferencing, or postal) will be obtained to ensure that participants are being contacted in the way that suits them best. They can change their mind at any stage.

Consent will be sought for data (including personal data and special category) to be archived at the end of the trial via the ONS Secure Research Service. This is a condition of taking part in the trial and a requirement of the funder. We have drawn on the YEF template wording for this. Furthermore, data sharing plans will be explicitly included in the participant information sheets.

The right of the participant to refuse to participate in the trial without giving reasons must be respected and participants will remain free to withdraw at any time from the trial without giving reasons and without prejudicing their further treatment. Additionally, parents/guardians will have the right to withdraw their child from the trial at any point if the child is under 16.

Contact details will be securely transferred from the site to the trial team, who will conduct baseline data collection and randomisation. Only when informed consent has been obtained from the participant AND they have been randomised/enrolled into the trial will they be considered a trial participant.

Informed consent will be taken by research assistants prior to the qualitative interviews. The parent/guardian, CYP participant, and practitioner will have been sent a Participant Information Sheet and copy of the consent/assent form prior to the interview taking place and given sufficient time to read the information. There will be two versions of the Participant Information Sheet for CYP who take part in the qualitative interviews, one for 11 to 15-year-olds, and one for 16-year-olds if they turn 16 during the trial. Trial information will be

appropriately adapted for use by younger CYP. Research assistants, who have been fully trained in trial procedures, will explain the qualitative component in detail. If happy to take part, informed consent will be obtained from CYP 16+ years of age and parental/guardian consent and CYP assent obtained from CYPs under 16 years of age. Informed consent will also be obtained from parents/guardians and practitioners who choose to take part. Verbal consent will be obtained (either via telephone, video conferencing or face-to-face meeting). Research assistants will 'sign' a consent form on behalf of the participant if they choose to take part.

Outcome measures

Baseline measures

Participants will be screened at site or online or via the telephone and eligibility will be assessed. Potential participant details will be passed from the trial site to the trial team in Warwick. The trial team will contact the participant as per their preferred choice of data collection to take consent and complete the baseline data:

- Baseline demographic CRF including:
    - DOB (dd.mm.yyyy)
    - Sex/gender (including inclusive language and 'prefer not to say' option)
    - Who they live with and any changes in living arrangements between baseline and follow-up,
    - Ethnicity
    - If English is their first language
    - SEND (learning disability and/or autism spectrum disorder)
    - long term physical or mental health conditions / illnesses
- Baseline outcome measures completed

The trial evaluation team (Warwick) will also collect contact details including name, address including postcode, telephone number and email address for the purpose of completing baseline and follow-ups. These will be kept separate from trial data. The trial team will make use of text messages, email, and post to maintain contact with participants and remind them of upcoming appointments for data collection. Full DOB will also be collected as it is required for determining trial eligibility, and funder archiving (including data linkage).

After completion of the baseline measures, participant details will be passed to the senior trial statistician at the University of Warwick to be randomised.

Participants will be followed-up, as described above, at 6 months post-randomisation and 12 months post-randomisation.

Primary outcome

The proposed primary outcome measure for this trial is the Strengths and Difficulties Questionnaire Measure parent reported externalising behaviour problems score at 6-months post-randomisation. The SDQ is a robust and well-validated measure of behavioural and emotional problems (Deighton et al., 2014).

Secondary outcomes

Secondary outcome measures include:

(1) Adolescent behavioural and emotional problems: Strengths and Difficulties Questionnaire (SDQ; Goodman, 1999) parent report internalising problems scale, adolescent report externalising and internalising problems scales.
(2) Parenting practices: Parenting Scale Adolescent version (PSA, parent completed) is a short form of the Parenting Scale (Irvine et al., 1999) which assesses dysfunctional discipline practices in parents. It is an adaptation of the Parenting Scale (Arnold, et al., 1993) for parents of adolescents.
(3) Adolescent prosocial behaviours – The Prosocial behaviour subscale of the SDQ (Goodman, 1999) will be used to assess adolescent prosocial behaviours. This will be completed by adolescents and parents.
(4) Adolescent peer relationships – The Peer Relationship Problem subscale of the SDQ (Goodman, 1999) will be used to assess adolescent peer relationships. This will be completed by adolescents and parents.
(5) Interparental outcome - Dyadic Adjustment Scale (DAS-7) is a 7-item measure (Sharpley & Cross 182; Hunsley et al., 2001) assessing the relationship quality of couples. The DAS-7 assesses relationship satisfaction and the degree to which the couple agrees on matters of importance to the relationship.
(6) Parent mental health – the Kessler 6 is a six-item screening tool for serious mental illness in the general population (Kessler et al., 2003). It will be completed by parents.
(7) Parent Wellbeing - The Warwick-Edinburgh Mental Well-being Scale (SWEMWBS) is a measure of mental wellbeing (Tennant et al., 2007). The short (7 item) version will be completed by parents.
(8) Conflict Behavior Questionnaire (CBQ-20) (Robin & Foster, 1989) assesses adolescent-parent communication, conflict and relations. Both the adolescent and parent report versions will be completed.
(9) Child-parent relationship – the Closeness subscale of the Child-Parent Relationship Scale (CPRS, short form) measures (Pianta, 1995) will be completed by parents.

(10) Family functioning – the Family APGAR scale (Adaptability, Partnership, Growth, Affection and Resolve; APGAR) measures satisfaction with family functioning (Smilkstein, 1978). This 5-item measure will be completed by parents.
(11) Parent self-regulation – the Parenting Self-Regulation Scale is a 12-item parent-completed measure of parental-regulation (Tellegen et al., 2022).
(12) Out of home placement – all instances of out of home placement will be recorded at each follow-up time point. This will include the reason for and duration of out of home placement. This measure directly informs a longer term impact from our logic model as this can be used to evaluate whether a reduction in the number of people entering care is improved post-intervention.
(13) Adolescent antisocial behaviours - the Self Report Delinquency Measure is a 15 item measure of antisocial behaviours (e.g., burglary, violence) and will be completed by adolescents at 12 month follow up.

Outcome measures have been selected based on psychometric properties (reliability, validity and suitability for context, including cultural context), brevity (to reduce participant burden), and affordability (with the exception of the SDQ, all measures are cost free).

Procedures	**Data collection timepoints**				
	Screening	**Baseline**	**Treatment Phase**	**6 month follow-up**	**12 month follow-up**
Screening logs	X				
Eligibility	X				
Informed consent and assent	X				
Contacts form	X				
Demographics		X			
Randomisation		X			

Delivery of intervention			X		
Fidelity/adherence in treatment delivery (practitioner completed)			X		
Outcome measures:					
Adolescent wellbeing self-report: self-report version of the Strengths and Difficulties Questionnaire		X		X	X
Adolescent wellbeing parent/guardian-report: parent-report version of the Strengths and Difficulties Questionnaire		X		X	X
Parenting Scale Adolescent version (PSA, parent completed)		X		X	X
Dyadic Adjustment Scale (DAS-7)		X		X	X
Kessler 6		X		X	X

Warwick-Edinburgh Mental Well-being Scale (SWEMWBS)		X		X	X
Conflict Behavior Questionnaire (CBQ-20)		X		X	X
Closeness subscale of the Child-Parent Relationship Scale (CPRS, short form)		X		X	X
Family APGAR scale		X		X	X
Parenting Self-Regulation Scale		X		X	X
Out of home placement		X		X	X
Self Report Delinquency Measure		X			X
Fidelity measures: Attendance/ engagement logs Session summary forms			 X X		
Qualitative interviews (post 6 month follow-up): • Adolescents • Parents/guardians • Practitioners				 X X X	
Withdrawal forms		X	X	X	X

Compliance / adherence

Parent TEEN TRIPLE P attendance/engagement data will be recorded in logs by practitioners, including: start date of family engagement with the intervention; number of sessions offered and number of sessions completed. The number of sessions delivered will be recorded by practitioners in Session Summary forms and any implementation challenges recorded.

Standard Teen Triple P is a ten-session programme. Attendance at all sessions is preferable. All the parenting strategies within the Standard Teen Programme are taught by the close of Session 8 (of 10) so there is a case that completion of sessions 1-8 would be considered dose sufficient. Thus, adherence/compliance will be defined as at least one parent carer from the family completing up to and including session 8 of the programme.

To measure fidelity (quality) of delivery of TEEN TRIPLE P, each practitioner will be required to complete a fidelity checklist at the end of each session completed. Triple P have treatment fidelity checklists for each session, which practitioners are encouraged to use. These will be revised by the trial team in collaboration with the delivery team and an overall fidelity score will be generated for each family's receipt of TEEN TRIPLE P

Analysis

A final Statistical Analysis Plan will be produced prior to any analysis being undertaken. All statistical analyses will be conducted using R version 4.1.2 (2021-11-01).

Missing, unused & spurious data

A final Statistical Analysis Plan will be produced prior to any analysis being undertaken and will provide detail of handling missing data. We will explore 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).

Procedures for reporting deviation(s) from the original SAP

Any deviations from the original SAP will be submitted as substantial amendments where applicable and recorded in subsequent versions of the protocol and SAP.

Termination of the trial

Beyond the internal pilot, there will be no formal 'stopping rules' or 'discontinuation criteria' for individual participants, parts of trial and entire trial. Any concerns with participant well-being will cross reference this section with those for the TSC as this group is likely to be involved with this decision-making process.

Continuation of the trial from internal pilot to main trial will be decided by the Trial Steering Committee and funder at month 12 (see Internal Pilot Section).

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, and they have not withdrawn consent to use their data.

Internal Pilot analysis

Statistical analysis for internal pilot feasibility outcomes will be primarily descriptive. Feasibility outcomes will be estimated as frequencies and percentages, means and standard deviations, or medians and interquartile ranges as appropriate. Feasibility outcomes will be assessed against the pre-specified progression criteria. Percentage of missing data will also be reported descriptively.

Analysis of primary and secondary outcomes

Our primary analysis will include all randomised participants who provide outcome data (i.e., a modified intention to treat analysis set) and compare mean scores between arms on the parental SDQ total problems score at 6-months post-randomisation (including both parents' ratings where available) using multilevel models to account for clustering (parents in families), and adjusting for baseline SDQ score, adolescent factors (age, sex, parents in household), and local authority.

We will also consider in a sensitivity analysis the role of Triple P practitioner as an additional source of clustering. As practitioners will deliver the intervention to several families 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. To account for any clustering, we will fit a heteroscedastic partially nested mixed-effects model. We will also report intra-cluster correlation coefficients, the number of clusters, and cluster sizes.

Secondary outcomes will be analysed similarly. However, secondary outcomes that are adolescent self-report will use linear regression to compare mean scores between trial arms, controlling for baseline scores, age, sex, and local authority. No random effects are included when analysing these outcomes as we do not need to adjust for parent clustering of responses, i.e. there is no dependency of responses from within the same household as we only anticipate one adolescent per household to respond.

We will explore the extent to which there were differential intervention effects by local authority by extending our primary analysis model to include sub-group by trial arm interaction

terms. Similarly, potential moderators, young person learning disability status, ethnicity, and in-care vs in family home status, will be explored by inclusion of an interaction of moderator and treatment allocation variables into the primary analysis model. In addition to interpreting the magnitude and statistical significance of interactions, plots of the interactions will also be examined. These analyses will be hypothesis generating in nature only (i.e., will not be confirmatory and only indicate whether further research targeting the intervention may be warranted).

We will conduct two further sensitivity analyses:

• 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);

• Exploring the impact of different levels of intervention receipt (adherence) and fidelity of intervention delivery on outcomes. We will use either two-stage least squares instrumental variables regression or inverse probability of treatment weighting methods to examine the effect of the intervention in those who receive varying levels of it.

All analyses will be checked subject to satisfying required assumptions. These checks include:

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

2. 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).

3. 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. Alternatively, data transformation could be used but use of the GLM is preferable.

Longitudinal follow-ups (12 months post-randomisation)

We will fit linear mixed models, accounting for repeated post-randomisation measures (6- and 12-months post-randomisation) within participants, adjusting for baseline measures, adolescent factors (age, gender, parents in household), local authority and practitioners to investigate the overall effect of the intervention on post-randomisation measures.

Exploratory mediation analyses may also be carried out to examine variables at 6 months that may mediate intervention effects between baseline and 12-month follow-up. Any such analyses will be specified once a final Logic Model is confirmed. We would, however, anticipate

a theoretically derived set of questions relating to changes in parenting practices to mediate the impact of intervention on SDQ outcomes.

Analyses described in this section will be reported in the 12-month post-randomisation report only.

Withdrawal & participant retention

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 because they will still receive support services as usual. If a participant initially consents but subsequently withdraws from the trial, clear distinction will be made as to what aspect of the trial the participant is withdrawing from. These aspects will be:

- Withdrawal from intervention (TEEN TRIPLE P only).
- Partial withdrawal from future follow-up data collection (e.g., some questionnaires, interviews).
- Withdrawal from previously collected data, prior to data analysis.

Participants who consent and subsequently withdraw should complete the trial withdrawal form or the withdrawal form should be completed on the participant's behalf by the site staff/ trial team based on information provided by the participant. This withdrawal form should be sent to the Trial email address. Any queries relating to potential withdrawal of a participant should be forwarded to the Trial Manager, Atiyya Nisar.

Participant retention

Participants who do not complete the 6-month follow-up data collection will be considered lost to follow-up. The trial team will monitor retention throughout the trial. To minimise loss to follow-up participants (both CYP and parent/guardian) will be (i) offered shopping vouchers for taking part in this trial, contingent upon questionnaire completion at each time-point, which will be stepped to encourage completion at the follow-up timepoints (baseline=£10, 6-months=£20, 12-months=£25). CYP and parent/guardian will also be offered £20 shopping vouchers for participating in an interview, and (ii) sending CYP and their families 'thank you' cards following each contact.

Some participants may have difficulties with reading and writing. We will make materials (including trial materials such as PIS where possible) available in alternative formats (e.g., audio file, video) and provide a choice of data completion methods (see earlier). The materials will be written in easy to read, lay language. Participants will be given the choice of how to complete the follow-up questionnaires (with a Research Assistant face-to face, over the telephone, or via videoconferencing, or directly in the secure bespoke online database).

Participants will be sent email or text message reminders that their next assessment is due, and a reminder if the assessment has not been completed in a certain number of days. A plan will be followed, and a fixed number of reminders will be sent as not to burden participants with reminders. Considering that nature of the difficulties that many of these families face, multiple reminders may be required. We will send up to four prompts.

Implementation and process evaluation

Research questions

Recruitment and reach

1. What are the most effective approaches for recruiting parents/carers and adolescents to take part in this trial of TEEN TRIPLE P?
2. What are the retention rates of parents/carers? What are the reasons for attrition?
3. To what extent were parents/carers from diverse backgrounds recruited to the trial?

Intervention fidelity, adherence and dosage

4. How well was TEEN TRIPLE P implemented? Did practitioners deliver the intervention as intended, with high fidelity to the manual?
5. What is the usual dosage/average number of sessions attended by parents/carers?

Intervention mechanisms

6. What are the barriers and facilitators for good implementation?
7. How does TEEN TRIPLE P differ from support as usual (SAU)?
8. What are parents'/carers' and adolescents' experiences of, attitudes towards, and perceptions of TEEN TRIPLE P, as well as its impact?

Research methods

Recruitment and reach

Demographic and baseline data will be used to describe the numbers of parents/carers and adolescent approached to participate in the trial, and the proportion who agree to do so. In addition, we will also collect participant demographic information on ethnicity and sex.

We will develop a recruitment and retention log of how many parents/carers and adolescent were approached, recruited, retained at all stages, and reasons for attrition (if given).

Implementation fidelity, adherence and dosage

In collaboration with the delivery team, we will review and adapt if needed Triple P's fidelity processes and existing practitioner-completed implementation fidelity rating scale for the delivery of TEEN TRIPLE P to parents/carers in this context. This scale will also include any

features bespoke to the current TEEN TRIPLE P approach as specified in the Logic Model. Quantitative data on adherence and fidelity will be used for analysis of key trial outcomes, to investigate relationships between intervention outcomes and intervention receipt, and fidelity.

TEEN TRIPLE P attendance data will be recorded by practitioners, including start date of parents/carers and adolescent engagement with the intervention; number of sessions completed. TEEN TRIPLE P attendance data will be recorded by practitioners, as well as if the session took place as planned, and any implementation challenges.

Intervention mechanisms

Interviews with up to 20 parents/carers in the intervention group will establish their experiences of the trial (e.g., randomisation, questionnaire completion), of TEEN TRIPLE P, and factors impacting adherence. Interviews with up to 15 parents/carers in the control group will establish their experiences of being in the trial, this will be balanced across local authorities where possible. All interviews will explore retention to the trial, and factors affecting this. We will sample parents/carers from different local authorities, with a broad range of ethnic and diverse backgrounds. During the pilot phase, we will conduct a further 10 short interviews from each arm of the trial to inform progression criteria only.

Interviews with up to 10 adolescents with families from both trial arms with the majority intervention arm will explore their experiences of the research and intervention and reflect on what they have noticed in relation to their parent attending the intervention.

Qualitative interviews with adolescents and parents will explore perceived benefits and mechanisms of the interventions. Interviews with practitioners will explore unintended effects and key components of TEEN TRIPLE P. These data will enable us to explore the extent to which key intervention mechanisms appear to be working as intended, variation across context e.g., by practitioner, local authority, family context), and any unintended mechanisms or barriers to participation. Together with quantitative data on hypothesised short, medium, and long-term impacts, this data will be used to refine the intervention's logic model and to examine ways in which TEEN TRIPLE P adds to and/or strengthens potential impacts of SAU.

Interviews with up to 15 practitioners will explore their experience of delivering TEEN TRIPLE P, and the potential systems and structures which would be needed for future implementation of TEEN TRIPLE P. Interviews with practitioners will also explore factors impacting adherence and fidelity, which will help us to understand the mechanisms that might contribute to/explain the outcomes of the trial.

The process evaluation interviews will also explore questions around how wider structural factors (e.g. racism, discrimination, poverty, other stressors) may influence the experiences and needs of the participants in the trial. The process evaluation will therefore specifically recruit participants across as wide a variety of experience as possible, as informed by the Project Advisory Groups and in collaboration with the relevant advisory and support groups within the

LAs. A suitable sampling frame will be agreed with the advisory groups to ensure diversity in the IPE sample that reflects the families recruited into the trial.

We will collect information about SAU to explore the provision of existing services (usual practice) and how TEEN TRIPLE P is distinct from this provision.

Analysis

Framework Thematic Analysis will be used to analyse qualitative interview data, with the framework informed by a combination of the MRC Process Evaluation guidance (Dieppe et al, 2008; Skivington et al, 2021) and the logic model. Quantitative data on recruitment, adherence and fidelity will be analysed descriptively. Triangulation will be conducted, combining the qualitative and quantitative data on recruitment, adherence, fidelity and intervention mechanisms. Qualitative data will be used to interpret patterning in recruitment, adherence and fidelity data, with analysis of quantitative data in turn highlighting areas which should be further explored in qualitative interviews and analysis.

Table 3: IPE methods overview

Research methods	Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Research questions addressed	Implementation/ logic model relevance
Quantitative	Recruitment and retention logs	Data collected by delivery team and local authorities, as well as research team	Descriptive	RQ1, 2 and 3	Useful information to understand recruitment approaches for future implementation of TEEN TRIPLE P
Quantitative	TEEN TRIPLE P session checklists	Practitioners delivering TEEN TRIPLE P rating every delivered session	Descriptive	RQ4	Fidelity critical to success of underpinning theoretical mechanisms
Quantitative	Practitioner records	Attendance data collected by practitioners delivering TEEN TRIPLE P	Descriptive	RQ5	Dosage / adherence critical to success of underpinning theoretical mechanisms

Qualitative	Interviews (semi-structured)	At least 35 parents/carers, at least 10 adolescents, and at least 15 practitioners, in both the TEEN TRIPLE P trial arms	Framework thematic analysis	RQ6 and 8	Perceptions of stakeholders are a key component to assess change processes

Safety reporting

Serious adverse events and adverse events will be assessed by the Trial Steering Committee and reported to the Research Ethics Committee for consideration as required.

The site Principal Investigator (PI) is responsible for ensuring that all site staff involved in this trial are familiar with the content of this section.

All SAEs must be reported immediately (and within 24 hours of knowledge of the event) by the PI at the participating site to the Trial team unless the SAE is specified as not requiring immediate reporting. The University of Warwick SOP will be followed and all SAEs/AEs will be reviewed by the PI at site. The safeguarding policy of each Local Authority site will be followed.

Definitions

This trial will collect GCP SAEs and trial-specific SAEs and AEs.
SAEs and AEs need to be reported for all trial participants, therefore parent(s) and the young person participating in the trial.

Table 4. SAE definitions

Term	Definition
Serious Adverse Event (SAE) (GCP)	Any adverse event that - • Results in death • Is life-threatening* • Required hospitalisation or prolongation of existing hospitalisation** • Other medically important condition***

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

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

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

Trial specific SAE reporting requirements

In addition to the SAE reporting requirements above, for the purposes of this trial the following events will also be considered SAEs and must be captured on the SAE form and reported to the University of Warwick CI(s) and Trial manager with 24 hours of knowledge of the event:

- Detention within hospital using the Mental Health Act
- Increasing suicidal ideation and/or plans or actual attempts to harm oneself with associated suicidal intent. Practitioners will report any incidence of this occurring.

The following will be considered AEs:

- Deliberate self-harm which is not life-threatening nor associated with suicidality as judged by the practitioner.
- A deterioration in mental state defined as increased anxiety, low mood, aggression, or new evidence of thought disorder and/or perceptual disturbances as judged by the practitioner.
- Disclosure of a history of physical and/or sexual abuse and/or criminal exploitation.
- Imprisonment.
- Removal from the family home.
- Safeguarding risk to the young person has increased during their participation in the trial to such an extent that the LA have had to initiate care proceedings.

Causality

Causal relationship will be assessed for the Teen Triple P parenting intervention. The Principal Investigator (or another delegated qualified person from the trial team) will assess each SAE to determine the causal relationship and the Chief Investigator (or another appropriately

qualified member of the Trial Management Group) can also provide this assessment where necessary:

Table 5 Causality in SAEs

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

The causality assessment given by the Principal Investigator at Local Authority site (or delegate) cannot be downgraded by the Chief Investigators (or delegate), and in the case of disagreement both opinions will be provided.

Expectedness

The Chief Investigator (or another delegated appropriately qualified individual) will assess each SAE to perform the assessment of expectedness.

Expected events (AE) will be listed here:

Increased expression of emotion (e.g., crying) during sessions with a practitioner.

This event does not need to be reported as an AE.

Reporting procedures

Participating Site Responsibilities

The Local Authority site PI should sign and date the SAE CRF to acknowledge that he/she has performed the seriousness and causality assessments. Investigators should also locally report SAEs in accordance with local practice.

A completed SAE form for all events requiring immediate reporting should be submitted via email to the University of Warwick Chief Investigators and Trial Manager within 24 hours of knowledge of the event. A separate form must be used to report each event, irrespective of whether or not the events had the same date of onset.

The participant will be identified only by Participant identification number, partial date of birth (mm/yy) and initials. The participant's name should not be used on any correspondence.

It is also required that sites respond to and clarify any queries raised on any reported SAEs and report any additional information as and when it becomes available through to the resolution of the event. Additionally, the University of Warwick evaluation team may request additional information relating to any SAEs and the site should provide as much information as is available to them in order to resolve these queries.

Serious Adverse Event (SAE) email address

warwickteenP@warwick.ac.uk

Serious adverse events should be reported throughout the treatment period up to 28 days after the participant receives the intervention.

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

• Full participant trial number

• An Adverse Event

• A completed assessment of the seriousness, and causality as performed by the PI (or another appropriately qualified person registered on the delegation log).

If any of these details are missing, the site will be contacted and the information must be provided by the site to the University of Warwick team within 24 hours.

All other AEs should be reported on the CRF.

Expected adverse events will be assessed by the Trial Steering Committee and reported to the Research Ethics Committee for consideration as required.

The University of Warwick evaluation team responsibilities

Following the initial report, all SAEs should be followed up to resolution wherever possible, and further information may be requested. Follow up information must be provided on a new SAE form.

The University of Warwick evaluation team should continue reporting SAEs until 28 days after the participant receives the last part of the intervention. Once an SAE is received by the University of Warwick evaluation team, it will be evaluated by the Chief Investigator(s) (or their delegate) for an assessment of expectedness.

Related and unexpected Serious Adverse Events (SAEs) will be submitted to the Sponsor and the Research Ethics Committee. These should be sent within 15 days of the CI becoming aware of the event.

Urgent Safety Measures (USMs)

An urgent safety measure is an action that the Sponsor, Chief Investigator or site Principal Investigator may carry out in order to protect the subjects of a trial against any immediate hazard to their health or safety.

Any urgent safety measure relating to this trial must be notified to the Research Ethics Committee immediately by telephone, and in any event within 3 days in writing, that such a measure has been taken. USMs reported to the University of Warwick evaluation team will be reported to the Research Ethics Committee

Cost data reporting and collecting

We propose to collect data to enable us to estimate the delivery costs of TEEN TRIPLE P, as follows:

1) Personnel for the implementation of the programme. Collected from the delivery team including the number of TEEN TRIPLE P sessions delivered per parent and the number of person days per parent.

2) Programme costs. Collected by the delivery team including costs of travel per family.

3) Facilities, equipment and materials. Collected from the delivery team and LAs, including costs to local authority delivery teams of any support materials needed for the intervention.

4) Other programme inputs. Local authority delivery teams will keep note of any other costs arising as a result of intervention delivery. These data will be used to estimate the intervention costs, which will be reported with appropriate confidence limits.

Ethics and registration

The University of Warwick's strict research Code of Practice will be adhered to at all times. Ahead of ethical review, we will finalise our procedures and develop the trial materials. Parents/carers and adolescents will not and cannot participate in the project or the evaluation until we receive ethical approval. An application will be submitted to the University of Warwick Sponsorship Committee. On successful approval from the University of Warwick, we will submit an application to the NHS Social Care Research Ethics Committee. We will submit all related participant facing documents including participant information leaflet (PIL), questionnaires, interview schedules, data collection form, and consent forms for review.

The trial will be registered at *www.controlled-trials.com* and we will include the ISRCTN (International Standard Randomised Controlled Trial Number) in the protocol as soon as it becomes available.

We will establish two Project Advisory Groups (PAGs) of parents of adolescents at the edge of care, adolescents, and community members, with a broad range of ethnic and diverse backgrounds. This group will not have a formal governance role but will work closely with the project team on matters including: advice on information sheets and other ethics matters, measures, co-production of dissemination outputs for parents, acting as ambassadors for the research project, and creating communication pathways with parents of adolescents at the edge of care.

Data management

Source data will be paper or online versions of the CRFs/questionnaires. If CRFs/questionnaires are completed by the Research Assistant face-to face, over the telephone, or via videoconferencing the research assistant will complete the questionnaire on a laptop directly onto a secure bespoke online database. The research assistant will also be able to complete a paper copy of the CRF as a 'backup' in case of technical difficulties. If CRFs/questionnaires are posted to the participants, they will be returned in free-post envelopes to the University premises where the data can be inputted by trial team staff. CRFs/questionnaires will only contain a unique identifier (PID) per participant, initials and date of birth (partial so not identifiable – month and year only). No other identifiable information will be recorded on the CRFs/questionnaires. Participants will also be able to complete the CRF/questionnaire directly in the secure bespoke online database.

The trial team at the University of Warwick will enter paper CRF/questionnaire data on to the secure bespoke online database. Access to the database will be via username and password and restricted to appropriately-trained personnel only. The database will be housed on local servers managed by the University of Warwick staff in accordance with all appropriate legislation.

Identifiable data will be encrypted and stored separately from non-identifiable data.

Wherever possible data will be validated at point of entry, thereby reducing the opportunity for missing or unexpected data. All changes made to the data will be recorded and visible via an audit log within the database.

Copies of CRFs/questionnaires will be returned to the Trial Manager by courier or scanned and sent via a secure data file transfer method such as OneDrive. Qualitative interview recordings will be recorded on encrypted audio-recorders/video-recorders and stored on password protected computers at the University of Warwick. All files will be encrypted. Any transcripts will be fully pseudonymised.

A data management plan will be developed to outline the details of how data will be collected, transferred, stored and accessed by the team.

Data collection

Data will be collected through multiple methods, including online, by post, in person, using videoconferencing, and over the telephone. In previous trials completed by our team, using a choice of methods for data collection has ensured that participants are able to participate in a way that best suits them (Flynn et al., 2020). Offering choice also helps to address inequalities affecting participants. For example, participants who are concerned about their reading ability can opt to complete measures by telephone with a researcher, without having to explain that this is because they cannot read.

Completion of CRFs

Paper CRFs

The hard-copies of CRFs/questionnaires will be completed by the trial team at the University of Warwick and data checking/ querying within approximately four weeks of completion. CRF pages and data received by the University of Warwick will be checked for missing, illegible or unusual values (range checks) and consistency over time. If missing or questionable data are identified, a data query will be raised on a data clarification form. The data clarification form will be sent to the researcher collecting the data and shall be requested to respond to the data query on the data clarification form. The original CRF pages should not be altered.

Electronic CRFs

Participants will be given the option of completing CRF and questionnaire data using an online system. The system will be developed by the University of Warwick and tested prior to going live (Qualtrics).

Participants will be provided with a unique Participant Identification (PID) number and will access the online CRF using this number, initials, and DOB.

Database

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.

A user password will be supplied to investigators upon completion of all processes required prior to opening. All data on the online database will be subject to data check for data quality, as per the data management plan. Due to the low-risk of this trial and based on participant numbers, this QC check is set as 10%. A full Data Management plan will be written.

Protocol/GCP non-compliance

All trial team staff, including the Principal Investigator at site, should report any non-compliance to the trial protocol or the conditions and principles of Good Clinical Practice to the Chief Investigators in writing as soon as they become aware of it.

Data protection

We will abide by the data protection principles set out in GDPR (2018). Our legal basis for processing personal data will be public task (Article 6(1)(e)), and our ethical basis will be informed consent. Information sheets will include our intention on behalf of YEF to transfer

identifiable data to the Department for Education (DfE) for anonymisation, and for the YEF to subsequently become data controllers for the pseudonymised data in their archive, enabling future research with this trial cohort.

We will store digital trial data in a secure folder, accessible only to the research team, on a secure server. Paper-based trial data will be stored in locked cabinets and offices for the duration of the trial. Qualitative data will be recorded on encrypted audio-recorders and stored on password protected computers, on secure servers, at site and securely transferred to the University of Warwick. Qualitative recordings will be transcribed fully and pseudonymised for analysis using NVivo computer software. All full data management plan and statistical and qualitative analysis plan will be developed. Pseudonymised, digital data will be stored for 10 years. All data will be confidential, and it will not be possible to identify a child or any member of their family within any publication arising from this work.

We are a team who are experienced with working within social care settings using sensitive and protected data.

A single participant level dataset will be prepared at the end of the trial and supplied to DfE for indefinite archiving within the ONS SRS. The data will be controlled by YEF who will review their retention intentions every 5 years.

End of Trial definition

The end of the trial is defined as the date of final data capture to meet the trial endpoints. In this case end of trial is defined as the date of the last follow-up data collection.
We will notify the Sponsor and the Ethics Committee of the end of the trial within 90 days of its completion or within 15 days if the trial is terminated early.

Indemnity

The University of Warwick will provide legal liability for damages in respect of accidental personal injury to third parties and accidental loss of or damage to third party property in relation to this research.

Trial sponsorship

The University of Warwick will act as Sponsor for trial. The Sponsor shall be responsible for ensuring that the trial is performed in accordance with the following:

- Conditions and principles of Good Clinical Practice.
- Declaration of Helsinki (1996)

- UK Policy Framework for Health and Social Care Research.
- The General Data Protection Regulation (2016)
- Other regulatory requirements as appropriate.

The Sponsor will be delegating certain responsibilities to the Chief Investigators, and sites as appropriate in accordance with the relevant agreement.

Funding

The trial is funded by the Youth Endowment Fund (YEF). Sites will meet the costs of programme delivery through funding from YEF.

Trial management

TMG (Trial Management Group)

The TMG will normally meet bimonthly during the trial. TMG members will consist of all Co-investigators, collaborators and the trial team and will oversee all aspects of the trial. The role of the TMG will be to help set up the trial by providing specialist advice, input to and comment on trial procedures and documents (information sheets, Protocol, etc.). They will also advise on the promotion and running of the trial and deal with any issues that arise. TMG members will be required to sign up to the remit and conditions as set out in the TMG Charter.

TSC (Trial Steering Committee)

A Trial Steering Committee (TSC), consisting of an independent chair with relevant expertise, and at least two other independent members including a lay representative and Statistician, will meet at least annually and will oversee all aspects of the trial. Non-independent members will include the joint CI. The joint CI, statistician, Trial Manager and other members of the trial management team may attend in an observer capacity at the request of the Chair.
The first meeting will be as soon as possible, to review the Protocol and arrange the timelines for the subsequent meetings. If necessary, additional/more frequent meetings may occur. The TSC will provide overall supervision for the trial and provide advice through its independent chair. The ultimate decision for the continuation of the trial lies with the TSC and funder. TSC members will be required to sign up to the remit and conditions as set out in the TSC Charter which will be filed in the TMF.

DMC (Data Monitoring Committee)

The Trial Steering Committee will be responsible for determining if a DMC is required for this trial. There are no plans for a separate DMC and it is expected that the TSC will take on this

role. If a DMC is deemed necessary, DMC members will be required to sign up to the remit and conditions as set out in the DMC Charter.

PAG

The Participant Advisory Groups (2) will be responsible for providing advice on all trial aspects from the perspective of young people in similar circumstances. The Local Authority sites will assist in finding appropriate members for these groups.

Quality Control and Assurance

Monitoring

The clinical trial risk assessment has been used to determine the intensity and focus of central and on-site monitoring activity in the trial. Low monitoring levels will be employed and are fully documented in the trial monitoring plan.

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.

Findings generated from on-site and central monitoring will be shared with the Sponsor, CI, PI & local R&D.

Audits & inspections

The trial is participant to inspection by regulatory bodies. The trial may also be participant to inspection and audit by the University of Warwick under their remit as Sponsor.

Publication policy

Outputs from the trial will include open access peer reviewed journal articles in international academic journals, at national and international academic conferences and at University public engagement events. A publications plan and policy will be written for the trial and approved by the TMG. All publications and presentations relating to the trial will be authorised by the TMG. The first report published about the impact of the intervention will be the evaluation report to the funder.

Stakeholders and interests

Intervention delivery team

Mr Matt Buttery – Chief Executive Officer, Triple P UK & Ireland

Ms Jo Andreini – Operations Manager, Triple P UK

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Evaluation team

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The project delivery team will be responsible training practitioners and providing intervention support. The local authorities will be responsible for recruiting parents/carers and adolescents. They will then pass the details of the adolescent and their parents/carers to the evaluation team. The evaluation team will check eligibility, consent and complete baseline data collection before parents/carers are randomised by the trial statistician. The evaluation team will complete data collection again at 6- and 12-months post-randomisation.

Risks

A full risk assessment will be completed before trial start. The main areas of risk currently identified are as follows:

Accrual

The delivery team/local authorities may not recruit sufficient numbers of participants. We would work with the delivery team to: (i) ensure that our accrual rate increases over time as the trial gains momentum, and is not set at a rate that is likely to unachievable, (ii) use a time period for accrual that is realistic, and (iii) consider including additional sites should they be needed.

Adolescent | parent/carer attrition

We may lose participants from the trial (i.e., non-completion of measures over time). We will: (i) offer participants shopping vouchers for taking part in this trial, contingent upon questionnaire completion at each timepoint, and stepping this to encourage completion at the follow-up timepoints (baseline=£10, 6-months=£20, 12-months=£25). Adolescents and family carers will also be offered £20 shopping vouchers for participating in an interview, and (ii) send adolescents and their families thank-you cards following each contact.

Difficulties with literacy/other social inequalities

Some participants may have difficulties with reading and writing. We will make materials available in alternative formats (e.g., telephone completion, audio file, video, EasyRead) and provide a choice of data completion methods (see earlier).

Contamination

There may be a risk of contamination in this trial, if the same practitioners will be supporting parents/ carers and adolescents in both trial arms. However, the delivery team have assured us that this will not be the case. Different practitioners will be allocated to each condition, dependant on their training in TEEN TRIPLE P. Other parenting interventions may also be delivered to the SAU only group following recruitment. The internal pilot will provide data to check on these issues.

COVID-19

In the event of continued pandemic-related disruption, research processes can be moved entirely to non-contact methods (and we already plan to use a variety of data collection methods – see earlier). Thus, if intervention delivery can continue, the trial could continue in a situation where restrictions are re-introduced. The statistical analysis plan will also include strategies to evaluate any effects of pre- vs. during/post-pandemic restriction data collection.

Timeline

Start Date	End date	Activity	Staff responsible/ leading
		Project and Evaluation Set Up and Mobilisation stage - Pilot	

03/01/23	31/01/23	Recruitment of local site coordinators. Implementation Planning (Consultant weekly meetings with each of the sites coordinators, preparing for the trial) & Managers briefings	Project Team
01/02/2023	28/02/2023	Evaluator completes protocol	Evaluator
01/03/2023	15/03/2023	YEF to review protocol and provide feedback. In some cases an external peer reviewer will also provide feedback. (including reviewing progression criteria)	YEF, Project team, Evaluator
15/03/2023	15/04/2023	Evaluator incorporates feedback and submits final protocol	Evaluator
01/02/2023	30/04/2023	Evaluator drafts information sheets and privacy notices	Evaluator
01/02/2023	30/04/2023	Evaluator incorporates feedback and submits final information sheets and privacy notices	Evaluator
01/02/2023	30/04/2023	Evaluator prepares ethical application and obtains approval /provides confirmation to YEF	Evaluator
01/02/2023	15/04/2023	Project team agree Information Sharing Agreements (ISAs) and referral mechanism with partners/stakeholders	Project team, Evaluator
01/02/2023	30/04/2023	Recruitment of evaluation team (Research Fellow)	Evaluator
17/04/2023	17/06/2023	Recruitment of evaluation team (Research Assistant)	Evaluator
16/01/2023	15/03/2023	Recruitment, vetting and DBS checks of practitioners (LAs responsibility) for project intervention delivery and site management	Project team
01/05/2023	01/07/2023	Research staff training	Evaluator
17/04/2023	17/07/2023	Practitioner briefings, Practitioner training, accreditation and 1/2 day clinical workshops = 120 practitioners across 6 sites	Project team
01/02/2023	30/04/2023	Recruit PAG members	Evaluator, Project team

01/02/2023	31/03/2023	Finalise information sharing agreements	Evaluator, Project team, YEF
01/04/2023	30/06/2023	Building and testing database	Evaluator
19/06/2023	31/07/2023	Site initiation visits	Evaluator
01/04/2023	31/07/2023	Statistical analysis plan	Evaluator
		Project and Evaluation Delivery - Pilot	
01/08/2023	28/02/2024	Start recruitment and eligibility assessments	Project team, Evaluator
21/08/2023	23/03/2024	Delivery of intervention	Project team
01/11/2023	30/11/2023	Trainer Facilitated Clinical support workshops (1 per site over the pilot)	Project Team
01/06/2023	31/08/2023	Survey of SAU	Evaluator
01/08/2023	28/02/2024	Baseline data collection	Evaluator
01/08/2023	28/02/2024	Randomisation	Evaluator
01/02/2024	31/08/2024	6 month Follow up data collection	Evaluator
01/08/2024	28/02/2025	12 month Follow up data collection	Evaluator
01/03/2024	30/04/2024	Submission of draft pilot report	Project team, Evaluator
01/04/2024	30/04/2024	YEF make decision whether to progress to efficacy trial	YEF
15/04/2024	15/07/2024	Submission of final peer-reviewed pilot report	Project team, Evaluator

01/01/2024	01/02/2024	Pilot phase review - lessons learned	Evaluator, Project team, YEF
		Project and Evaluation Delivery - Efficacy	
01/03/2024	30/09/2024	Continue recruitment and eligibility assessments	Project team
23/03/2024	20/01/2025	Continue delivery of intervention and implementation and clinical support days (2 per site)	Project team
01/03/2024	30/09/2024	Baseline data collection	Evaluator
01/03/2024	30/09/2024	Randomisation	Evaluator
01/09/2024	31/03/2025	6 month Follow up data collection	Evaluator
01/03/2025	30/09/2025	12 month Follow up data collection	Evaluator
01/04/2025	31/05/2025	Process evaluation interviews (therapists)	Evaluator
01/08/2024	31/08/2025	Process evaluation interviews (Parents & Adolescents)	Evaluator
01/08/2024	30/09/2025	Transcription	Evaluator
01/08/2023	30/09/2025	Data entry and cleaning	Evaluator
01/10/2025	01/11/2025	Data QC	Evaluator
01/11/2025	31/01/2026	Analysis	Evaluator
13/01/2025	14/02/2025	Submission of end of phase report	Project team
01/06/2025	31/07/2025	Submission of draft final evaluation report (6 MONTHS)	Evaluator
01/08/2025	30/010/2025	Submission of final, peer reviewed evaluation report (6 MONTHS)	Evaluator

01/02/2026	31/03/2026	Submission of draft final evaluation report (12 MONTH OUTCOMES)	Evaluator
01/04/2026	31/06/2026	Submission of final, peer reviewed evaluation report (12 MONTH OUTCOMES)	Evaluator
01/05/2026	31/07/2026	Evaluator supports with YEF publication process	Evaluator
01/02/2026	31/10/2026	Data archived	Evaluator
		Project Performance / Monitoring	
01/08/2023	30/09/2025	Quarterly Monitoring	Project team
01/05/2026	31/05/2026	Submission of 'End of project report and project budgets'	Project team

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Appendix: Lone working policy

Lone Working

Lone workers should ensure that their team/line manager have their personal contact number, their In Case of Emergency (ICE) details, and details of their car make/model and registration number (if applicable) or other travel details. It is the lone worker's responsibility to ensure that all contact details are maintained and updated.

All lone workers that are issued with mobile phones are expected to keep them charged and turned on whilst at work. Lone workers should consider putting the phone number for their team office/buddy in the phone so that they have quick access if required. There are a number of personal safety mobile apps which could also be considered: https://www.suzylamplugh.org/Pages/Category/app-directory

Protocol for attending a home visit alone

Before a home visit, the RA who is completing the visit shares information with their buddy about which participant (Participant ID) they are going to visit and where they are meeting them, whether this is in a public place or at a family home, the date and time of the meeting, and how long they anticipate that this will last.

On the day of the home visit, the RA who is completing the visit calls their buddy to confirm that they have arrived at the meeting location. If possible, the RA completing the visit can share their location with their buddy on their mobile phone. The RA and buddy agree a time to call after the visit and if the RA completing the visit does not call at the agreed time then the buddy will call them to confirm that they are OK. If necessary, this can be completed when the RA completing the visit arrives home after the visit.

If the RA who is completing the visit answers the phone, then the buddy will ask if they are OK and if they need to arrange for another call to take place (if the visit has overrun). The process above is then completed at the newly arranged time.

If the RA who is completing the visit does not answer the phone after a couple of attempts, then the buddy can try to call the person/place they were visiting to establish if they are there or when they left. If no contact can be made, then the buddy must report this to their line manager or a senior member of staff who will then escalate the procedure. If there is concern then the police should be contacted by the buddy.

University security should also be informed of the situation by calling 02476 522222. University security will then respond to the incident and will liaise with emergency services as required.

If the RA completing the visit feels unsafe but cannot leave the situation, a phrase must be agreed which will be used and understood by the buddy. This phrase means that they are in difficulty and requires help, for example, "I need the red folder". This should prompt the buddy to consider phoning the police.

Principles of Lone Working from the Warwick Clinical Trials Unit:

When lone working, staff should:

- Be alert to warning signs (body language, tone of voice)
- Carry out a '10 second risk assessment', if staff feel unsafe they should leave
- Check for evidence of pets
- On arrival assess the layout and quickest/safest exit route
- Be aware of entrances and exits
- Place themselves near an exit
- Be aware of the positioning of items which could be potential weapons
- In multi-storey buildings consider safety when choosing lifts or staircases
- Remain calm and focussed under no circumstances put themselves at risk
- Consider the distance that they are travelling each day. Staff should liaise with their line managers about reasonable distances to travel in a day.

Remember that if they are in any doubt about their safety, to leave the situation

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