Study Title: : AADAPT Online - Addressing young mums' and dads' low mood and their parenting

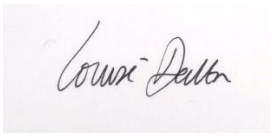
An online behavioural activation and parenting self-help package supported by peer mentors (AADAPT Online) for 16-24-year-old parents experiencing depression: a pilot randomised control trial

Internal Reference Number / Short title: AADAPT

IRAS ID: 347818

Ethics Ref: 24/WA/0366

Date and Version No: 17.04.2025 Version 1.2

Chief Investigator:	Professor Louise Dalton, louise.dalton@psych.ox.ac.uk, University of Oxford
Investigators:	Professor Elizabeth Rapa, University of Oxford
	Professor Jane Barlow, University of Oxford
	Professor Alan Stein, University of Oxford
	Professor Heather O'Mahen, University of Exeter
	Professor Fiona Alderdice, University of Oxford
	Dr Jenny McLeish, University of Oxford
Sponsor:	University of Oxford
Funder:	The Prudence Trust
Chief Investigator Signature:	

Please declare any/no potential conflicts of interest.

No conflicts of interest to declare

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, and members of the Research Ethics Committee, unless authorised to do so.

TABLE OF CONTENTS

1. KEY CONTACTS

Chief Investigator	Professor Louise Dalton, Dept of Psychiatry, University of Oxford Louise.dalton@psych.ox.ac.uk 01865 618166
Sponsor	University of Oxford Research Governance, Ethics and Assurance (RGEA) Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB
Funder(s)	The Prudence Trust
Clinical Trials Unit	N/A
Committees	Independent Oversight (for monitoring participant safety and risk management) Dr Maria Loades Clinical Psychologist (HCPC, BPS & BABCP Accredited) Reader/Clinical Tutor & NIHR Advanced Fellowship Holder Department of Psychology University of Bath mel26@bath.ac.uk

2. LAY SUMMARY

Depression is a common mental health difficulty that often starts in adolescence and is among the leading causes of illness and disability among adolescents worldwide. Becoming a parent during adolescence presents additional challenges, with young parents being at increased risk of developing depression. Not only does depression directly affect parents themselves but it has also been shown to impact on parent-child interactions, with their children having a higher risk of poorer developmental outcomes and in turn, developing mental health difficulties when they become adolescents. Importantly, the risk of postnatal depression adversely affecting child development is markedly increased in the context of socio-economic disadvantage and lack of social support. These are both common for adolescent parents. Long term solutions for adolescent depression must address early risk factors in order to disrupt the intergenerational cycle of adversity.

A therapy called Behavioural Activation (BA) has been shown to help people deal with negative thoughts and feelings and is widely used in the NHS. This study aims to see whether an Online BA package of information and activities, supported by trained volunteer parents (who were previously young parents

themselves (Parent Buddies)) is acceptable and helpful to young parents and to measure parents' level of engagement with the Online BA package. Parents in the Online BA group will also receive information and ideas of different activities to help them engage in sensitive, positive interactions with their infant. The Online BA package targets both depression *and* parenting.

3. SYNOPSIS

Study Title	An online behavioural activation and parenting self-help package supported by peer mentors (AADAPT Online) for 16-24-year-old parents experiencing depression: a pilot randomised control trial		
Internal ref. no. / short title	AADAPT		
Study registration	ISRCTN 14608187 21/11/2023		
Sponsor	University of Oxford		
Funder	The Prudence Trust		
Study Design	Pilot two arm randomised control trial		
Study Participants	Parents aged 16 – 24 years old who have low mood and a child less than 12 months old		
Study Volunteers	Parents aged 24 - 35 years at the point of supporting first parent, who also have experienced low mood and had a child when they were under the age of 25 years old to be peer mentors (Parent Buddies). Anticipated number of Parent Buddies = 20.		
Sample Size	N = 60 adolescent parents (N = approximately 20 Parent Buddies who are volunteers in the study).		
Planned Study Period	06/01/2025 until 31/12/2025		
Planned Recruitment period	Months January 2025 – Sep 2025		
	Objectives	Outcome Measures	Timepoint(s)
Co-primary	To assess feasibility of recruitment and the intervention methods	Number of young parents screened Percentage of those who were eligible at screening who were recruited Percentage of those recruited who completed the follow-up assessment	Variable
Co-primary	To measure treatment adherence and	Number of young parents completed treatment (defined as 4 out of 6 sessions)	12 weeks post randomisation

	acceptability of AADAPT Online		
Secondary	To inform the sample size of a future trial by collecting data on potential trial outcomes	Depression using the Edinburgh Postnatal Depression Scale (EPDS) Parenting Stress Index (PSI-4-SF) Multiple Dimension Scale of Perceived Social Support (MSPSS) General Health Questionnaire (GHQ-12) Parent-infant interactions assessed from simultaneous Headcam footage from parent and infant	12 weeks post randomisation
	To measure treatment adherence and engagement with AADAPT Online	Number of modules viewed in AADAPT Online Number of successful contacts attempts by Parent Buddy compared to unsuccessful contact attempts Number of times logged into AADAPT Online Total amount of time spent in AADAPT Online Number of exercises completed in AADAPT Online	12 weeks post randomisation
	To assess recruitment and retention of Parent Buddies	Numbers of Parent Buddies invited for training Percentage of those who completed training Percentage of those who actively support Mentees after training Numbers of Mentees supported by each Parent Buddy Length of time Parent Buddies remain with the programme	Various

	To assess feasibility of completion of Health Economic measures	Parent quality of life (Self-report; (EQ-5D), Recovering Quality of Life (Re-QoL) and subsections 4.1, 4.2, 4.3 and 4.4, section 5 of Client Service Receipt Inventory (CSRI)	Baseline and 12 weeks post randomisation
Exploratory	To understand Parents' and Parent Buddies' experiences of taking part in AADAPT (across both arms)	Qualitative Interviews	Invited 12 weeks post randomisation
Intervention(s)	Online psychological intervention for parents with depression supported by Parent Buddies (AADAPT Online). AADAPT Online is a behavioural activation and parenting self-help package supported by Parent Buddies		
Comparator	Waitlist control group who receive the AADAPT Online materials (but no support from Parent Buddies) via email or post after their follow-up assessment		

4. ABBREVIATIONS

AE	Adverse Event
BA	Behavioural Activation
CI	Chief Investigator
CSRI	Client Service Receipt Inventory
EDPS	Edinburgh Postnatal Depression Scale
EQ-5D-5L	European Quality of Life 5 Dimensions
GCP	Good Clinical Practice
GHQ	General Health Questionnaire
GP	General Practitioner
MSPSS	Multiple Dimension Scale of Perceived Social Support
NHS	National Health Service
Re-QoL	Recovering Quality of Life
PIS	Participant Information Sheet

PND	Postnatal depression
PSI	Parenting Stress Index
REC	Research Ethics Committee
SAE	Serious Adverse Event

5. BACKGROUND AND RATIONALE

The peak onset of psychological disorders occurs during adolescence, with depression and anxiety among the leading causes of illness and disability for adolescents. Globally, one in seven adolescents experience a mental disorder [1], and becoming a parent during adolescence presents additional mental health risks. Adolescent mothers are three times more likely to experience postnatal depression (PND) [2] than adult parents. Almost half of adolescent mothers report feeling 'often' or 'always lonely'[3] and are more likely to have a history of self-harm, suicide attempts, and substance abuse compared to adult parents [4]. Crucially, research has shown that mental health problems can also affect their children's long-term emotional, behavioural, and cognitive outcomes. For example, adolescent parental depression has been shown to predict child behaviour problems at age 2 and 3 years; when these children start school at age five, their verbal ability scores show an 11-month delay [2]. These problem behaviours and poorer academic achievement endure throughout childhood and into adolescence [4]. Research has also shown that mental health problems in adolescent parents are associated with increased use of "aggressive" parenting approaches which can negatively impact child development [4]. Importantly, the risk of PND adversely affecting parenting behaviour (and therefore child development) is markedly increased in the context of socio-economic disadvantage and lack of social support [5, 6], both of which are common for adolescent parents. Therefore, solutions for adolescent depression must address early risk factors in order to disrupt this intergenerational cycle of adversity.

Many young mothers hide their mental health symptoms due to stigma and a fear that they will be judged as incapable of parenting and their child will be removed by services [7]. Young parents may also struggle with transport to appointments which may be incompatible with feeding and napping schedules [8]. An online intervention is a popular method for adolescents to access help [9] and allows parents to gain support at a time and location convenient to them. Evidence also suggests remote therapy reduces concerns about confidentiality, with a level of anonymity that helps to reduce issues related to stigma [10]. Research has found that brief internet-based BA programmes are effective in reducing depressive symptoms in mothers [11].

Increasing access to evidence-based digital interventions might provide a way to improve treatment efficiency. There is strong evidence that providing guidance via online treatments enhances treatment uptake and retention [12]. For example, attrition was reduced from 68% to 14% in an online treatment for PND when a weekly guided supportive phone call was included [13]. Other research has also found that peer support programmes are effective in reducing PND [14]. The salience of peer involvement during adolescence is well-documented [15] and organisations working with adolescent parents consistently report the need for peer support to improve parental engagement.

This project aims to address a number of important gaps in the current evidence related to treatment of postnatal mood disorders in adolescent mothers and fathers. To date, studies have predominantly been conducted with participants with a different demographic profile to young parents e.g., a systematic review of web-based interventions for perinatal mood disorders reported the mean age of study participants as 32 years [8]. Furthermore, existing research has focused on maternal PND, with a recent systematic review reiterating concerns that fathers' mental health needs are often neglected [16]. This is reflected by an absence of studies evaluating specific interventions for PND in fathers which is of particular concern given that research indicates the risk of poor developmental outcomes for infants is increased when both parents are experiencing depression [16-18].

The project team have worked in collaboration with parents, third party providers and organisations to co-design an online support package called AADAPT for both adolescent mothers and fathers aged 16-24 years old supported by Parent Buddies. The 6 sessions are supported by 15-20 minute conversations with a Parent Buddy. BA will be used to treat low mood which has been shown to be successful when delivered online and in the postnatal period. Parents will also receive information on the principles of early infant learning and attention, especially contingent responsiveness, to help depressed parents consider ways to increase opportunities for positive interactions with their infant.

Aims

The proposed research will assess the feasibility of recruitment and intervention methods. It will also measure the acceptability and adherence of the Online BA/Parenting self-help package supported by Parent Buddies. It will also inform the sample size of a future trial by collecting data on potential trial clinical outcomes. Parents' and Parent Buddies' experiences of taking part in the AADAPT study will also be explored.

6. OBJECTIVES AND OUTCOME MEASURES

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**
Coprimary Objectives		
1) To assess feasibility of recruitment and the intervention methods	Number of young parents screened Percentage of those screened who were recruited Percentage of those recruited who completed follow-up	Various
2) To measure treatment adherence and acceptability of AADAPT Online	Number of young parents completed treatment (defined as 4 out of 6 sessions completed)	12 week post randomisation

Secondary Objectives		
1) To inform the sample size of a future trial by collecting data on potential trial outcomes	Depression using the Edinburgh Postnatal Depression Scale (EPDS) Parenting Stress Index (PSI-4-SF) General Health Questionnaire (GHQ-12) Multiple Dimension Scale of Perceived Social Support (MSPSS) Parent-infant interactions assessed from simultaneous Headcam footage from parent and infant	12 weeks post randomisation
2) To measure treatment adherence and engagement with AADAPT Online	Number of modules viewed in AADAPT Online Number of successful contacts with Parent Buddies compared to unsuccessful contact attempts Number of times logged into AADAPT Online Total amount of time spent in AADAPT Online Number of exercises completed in AADAPT Online	12 weeks post randomisation
3) To assess feasibility of completion of Health Economic measures.	Numbers of measures completed of the following: Parent quality of life (Self-report; (EQ-5D), Recovering Quality of Life (Re-QoL) and subsections 4.1, 4.2, 4.3 and 4.4, section 5 of Client Service Receipt Inventory (CSRI)	12 weeks post randomisation
Exploratory Objectives To understand Parents' and Parent Buddies' experiences of taking part in AADAPT (in both arms)	Qualitative Interviews	12 weeks post randomisation

7. STUDY DESIGN

A pilot two-arm randomised controlled trial to measure the acceptability and adherence of the Online BA/Parenting self-help package supported by Parent Buddies.

8. PARTICIPANT IDENTIFICATION

8.1. Study Participants

Parents aged 16 – 24 years old with low mood who have a child under the age of 12 months at the time of recruitment to the study.

Study Volunteers (Parent Buddies): Parents aged 24 - 35 years old at the point of supporting their first Mentee, who also have experienced low mood and had a child when they were under the age of 25 years old.

8.2. Inclusion Criteria

Parent participants:

1. Aged 16 to 24 years of age
2. A parent of a child born within 12 months at time of recruitment to the study
3. Score of 10 or above on Edinburgh Postnatal Depression Scale (EPDS)
4. Lives in the UK
5. Able to provide free and informed consent to participate
6. Sufficient understanding of English (secondary school, age 11) level reading ability (the self-help package requires participants to read and understand the documents and suggested activities)

Parent Volunteers (Parent Buddy):

1. Aged 24 at point of supporting first Mentee to 35 years of age
2. Had first baby when they were under 25 years old
3. Have had experience of low mood (defined as feeling low, down, depressed or stressed most days for 2 or more weeks; does not need to have been formally diagnosed by a healthcare professional)
4. Lives in the UK
5. Able to provide free and informed consent to participate
6. Sufficient understanding of English (secondary school (age 11) level reading ability as Parent Buddies will be helping parents navigate the self-help package.

8.3. Exclusion Criteria

The participant may not enter the study if ANY of the following apply:

Parent Participant:

1. Co-habiting partner already randomised into the study
2. Active suicidality
3. Active symptoms of psychosis or mania
4. Currently receiving psychological treatment (i.e 'talking therapy' including counselling)

Parent Volunteer (Parent Buddy):

1. Current mental health or emotional difficulties that preclude capacity to be an appropriate Parent Buddy to another person who has mental health difficulties
2. Unable to obtain a clear DBS certificate

9. PROTOCOL PROCEDURES

9.1. Recruitment

Adolescent Parents:

Potential participants will be introduced to the study by their Family Nurse Partnership (FNP) Nurse, Health Visitor (or other similar support staff working alongside them) during their routine contact with these clinicians. These clinical care teams will share the study advert and brief study information leaflet with parents who are within the age range (16-24 years) during parents' routine clinical appointment.

The clinical staff (FNP nurses and health visitors) will ask parents for permission to pass their contact details (name, phone number, email address) to the study team.

If parents give permission for their contact details to be passed to the research team, they would then be sent an introductory text message with a link to the study information on Trial Deck, a secure online platform hosted by software developers, to ensure they have access to all the information about the study. If these parents have not completed the online screening questions for the study within 7 days of being sent the online link to the full study information, the research team will follow-up with a text and then a phone call to check they received the link and ensure that they have had the opportunity to ask questions.

Alternatively, parents can contact the study team directly themselves or scan the QR code that will take them to Trial Deck, where they will be able to watch a video about the study and read the information about the study (Participant Information Sheet).

The study will also be advertised using a video and flyer on Department of Psychiatry website and through the study team's Instagram account and X (formerly twitter account). Posters and flyers will be sent to the team's contacts and relevant online and in-person community noticeboards e.g. Kooth Digital Health or children's centres (where permission has been given). The study advert will also be placed in free parent magazines (e.g. Families Magazine).

Parent Buddies:

Organisations that run Parent Buddy support schemes will help us to specifically recruit participants for the Parent Buddy roles. The study will also be advertised using a video and flyer on social media and other print media. Posters and flyers will be sent to the team's contacts and their professional networks.

Individuals who express an interest in becoming a Parent Buddy will be able to scan a QR code/click a link that will take them to an online PIS hosted by Qualtrics.

Potential Parent participants and potential Parent Buddy volunteers will be allowed as much time as they wish to consider the information, and the opportunity to question the research team, or other independent parties, to decide whether they will participate in the study.

9.2. Screening and Eligibility Assessment

Adolescent parents who express an interest in taking part in the study will be able to scan a QR code/click a link that will take them to Trial Deck a secure online platform. They will be able to read the PIS and if they wish to proceed, they will create an account on Trial Deck to complete initial screening questions. The questions will focus on the basic inclusion criteria (1. age 2. parent of a baby under 12 months 3. feeling low 4. living in UK 5. their live-in partner in the AADAPT study 6. having active talking therapy). Those who answer *Yes to Q1-Q4 and No to Q5-Q6* will be presented with a consent form (part 1) and then asked to provide their GP details, contact information and complete The Edinburgh Postnatal Depression Scale (EPDS) which is a screening tool for depression. Those who score 10 or more on the EPDS will be told that AADAPT may be suitable for them and that to check this they will receive a phone call from the Clinical Psychologist within the research team. The Clinical Psychologist will use their clinical judgement to ensure the AADAPT trial is suitable; this contact will specifically explore whether the participant is actively suicidal or experiencing current symptoms of psychosis or mania as part of a bi-polar disorder. If these symptoms are identified, individuals will be signposted to services, helplines and resources rather than continuing their participation in AADAPT. The research team will follow safeguarding procedures as specified below. Those who are eligible to take part will be asked to access Trial Deck again, be presented with another consent form (part 2) and asked to complete the demographic information and additional baseline measures.

We will allow parents 4 weeks to complete baseline measures or until their baby is 12 months and 28 days (whichever comes first). Parents may be asked to repeat certain measures if there is greater than 4 weeks between the time of the first and last measure being completed.

Parents interested in taking part as a Parent Buddy can scan a QR code to read the PIS online and if they wish to proceed will ask individuals to complete basic screening criteria online. Potential participants will then be presented with a consent form (part 1). They will then be asked for their contact details and demographic information. Once consented the Clinical Psychologist in the research team will then call these potential participants to talk through the role of the Parent Buddy in more detail and what would be involved. They will also make a clinical judgement about whether the individual is able to support other young parents i.e. their mental health or emotional difficulties preclude their capacity to be an appropriate Parent Buddy to another person who has mental health difficulties (if so, the individual would not be eligible to take part). If the participant is eligible, after the call the research team will email a link to complete the consent form (part 2) via Qualtrics.

9.3. Informed Consent

Participant information will be presented to the potential participants detailing: the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; the known side effects and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason and with no obligation to give the reason for withdrawal. Each potential participant will be given sufficient time to read through the PIS and ask questions to the research team, before deciding whether to take part.

Adolescent parents who are eligible to take part following the screening process (part 1, detailed above) will be asked to access Trial Deck again, be presented with another consent form (part 2). Participants

must name and date the latest approved version of the Informed Consent form before any further study specific procedures are performed. A copy of the completed consent forms will be sent to parents.

Parent Buddies who are eligible to take part following the screening process (part 1, detailed above) will be emailed a link to complete another consent form (part 2) via Qualtrics. A copy of both part 1 and part 2 signed Informed Consent will be emailed to the participant. The original signed form will be retained at the study site.

9.4. Randomisation

Participants will be randomised in a 1:1 ratio to (i) AADAPT Online Intervention or (ii) waitlist control (AADAPT Self-Guided). Stratified and blocked randomisation procedure will be implemented. Randomisation will be minimised by severity of depression (EPDS scores <=12; >=13 and the age of the parent (<=20; >=21). Participants will be randomised using Trial Deck that will be triggered automatically after the participating parent completes the consent and baseline measures. The group allocation will be communicated to parents immediately on the Trial Deck system.

9.5. Blinding and code-breaking

Due to the nature of the trial, blinding is not possible to the trial participants of the allocated psychological therapy nor to the research team.

9.6. Description of study intervention(s), comparators and study procedures (clinical)

9.6.1. Description of study intervention(s)

AADAPT Online is an online adaption of Behavioural Activation (BA) which is an evidence-based treatment for low mood. It also includes a parenting component that helps parents consider ways to increase opportunities for positive interactions with their infant. AADAPT Online comprises a parent website and accompanying Parent Buddy system. The 6 core sessions are supported by weekly conversations with a Parent Buddy. These are conducted as 15-20 minute Teams calls or an online messaging exchange on Trial Deck. Parent Buddies will receive a manual and a training programme delivered by the Clinical Psychologist in the study team. Parent Buddies will also attend weekly group supervision sessions for the first five weeks they are in the study progressing to bi-weekly sessions thereafter.

9.6.2. Description of comparator(s)

The waitlist control group will receive the AADAPT Online materials (but no support from Parent Buddies) via email or post after their follow-up assessment called AADAPT Self-Guided.

9.6.3. Description of study procedure(s)

When Parent Buddies have completed part 1 and part 2 consent forms they will be invited to the online training session with the study team which will comprise a total of 10 hours, plus 7 hours of independently-completed homework tasks. The training will include short talks, practice role-plays, group discussion and homework review delivered by the team's Clinical Psychologist. They will learn about Parent Buddy expectations, goals and competencies, especially around safeguarding and setting boundaries with their Mentee, and not sharing information or contacting Mentees outside of the study remit and hours. At the end of the training sessions, the research team will assess competency levels and decide if the trainee has

developed the necessary skills to become a Parent Buddy. This will include 1) attendance at training sessions 2) active involvement and demonstration of skills in training session activities 3) self-reflection about their new skills and training experience and demonstration of skills through a practice conversation (role play) in a 30-minute online assessment with the study team 4) self-reflection and 5) availability for supporting parents and attending supervision sessions. They will also need to complete a DBS Check and for the result to be clear. Parents will not be allocated to any Mentees until the research team have checked the DBS result and the Parent Buddies have successfully attended and completed the training. Successful Parent Buddies will be allocated a parent to support through AADAPT Online. Parent Buddies will only be allocated a maximum of two Mentees at any one time. Parent Buddies will record information on contact attempts with their Mentees.

Once adolescent parent participants have consented (part 1 and 2) to take part and are confirmed as eligible, they will then have 4 weeks to complete the online baseline measures prior to randomisation. Due to copyright restrictions, participants will have the choice to complete the PSI-SF questionnaire over the phone with the research team or have this posted to them with a pre-paid return envelope.

If participants indicate they would be interested in recording video footage, Headcams will be posted to participants using the University of Oxford mail service courier with a postage-paid return envelope and instructions about how to return the headcams via the courier service (unless within 20 miles of the University of Oxford and then the research team will arrange to collect these). Headcam footage will be reviewed by the research team once received, unless the parent participant requests that the research team delete the data before it is viewed or transferred to the secure university system. Video footage and/or still images will be shared with any participants who recorded video footage after the post-treatment assessment timepoint via email link.

Once adolescent parents have been randomised, the research team will inform their GP of their participation in the study and which group they have been allocated to. Parent participants allocated to the intervention arm will then access AADAPT Online and be allocated an available Parent Buddy who will support them through the online treatment sessions. There are 6 core treatment sessions (with 2 optional sessions for adolescent parents who are struggling to complete sessions 4-6) which are hosted on the Trial Deck platform. Adolescent parents will be given access to each session (taking approximately 20-30 minutes each) one at a time and encouraged to complete a session each week for total of seven weeks (with some flexibility for parents to maximise engagement). They will also receive weekly contact from a Parent Buddy to check progress and provide support. Participants can decide if the Parent Buddy interacts with them using messenger on Trial Deck or via Teams call. Adolescent parent participants will receive support until they finish the six sessions or 10 weeks of contact support has been provided by the Parent Buddy (whichever occurs first). During the 10 weeks the Adolescent Parent is working through AADPAPT Online, the research team will monitor their engagement with Trial Deck. If the research team notice that the parent has not logged in for over a week, they will send a text to check they are not having difficulties logging onto the platform and remind them AADAPT Online is available for them to access.

Participating parents in both arms (AADAPT Online and AADAPT Self-Guided) will be asked to complete post-treatment measures (questionnaires and record Headcam footage) 12 weeks after randomisation.

Qualitative interviews will be conducted with Parent Buddies and adolescent parents in both arms of the study. All participants will be invited to take part. If the research team do not receive a response to the invitation they will follow-up with a text and phone call. They will be asked to provide feedback about the study procedures, acceptability and useability of the treatment.

9.7. Assessments

Assessments will be completed via a mixture of online and paper copy self-report questionnaires and an optional headcam video footage of parent-child interactions. These will be administered at baseline and 12 weeks after randomisation. The research team will monitor assessment completion. Trial Deck will notify participants if measures have not been completed and the research team will contact participants (by phone) if measures have not been completed within 3-5 days of the invitation to complete measures (at both timepoints).

All measures will be collected at both time points with the following exception - demographic information is only collected at baseline.

9.7.1 Demographics

Participating parent demographics will be collected based on parent report. The data will include (i) parent and child date of birth, (ii) parenting role (e.g. mother, father), (iii) parental ethnicity, (iv) parental education, (v), parental employment status, (vi) household circumstances. This information will be used to describe the sample, and parental age will inform randomisation minimisation.

In order to describe the Parent Buddies who will be supporting the parents in the study, the Parent Buddies will provide information on (i) their age, (ii) parenting role, (iii) ethnicity, (iv) education and (v) employment status.

9.7.2 Symptoms of depression

Edinburgh Postnatal Depression Scale (EDPS) is a widely used self-report questionnaire that measures symptoms of depression with 10 items on a scale from 0-3 [19, 20]. Scores of 10 or greater indicate possible depression.

General Health Questionnaire (GHQ-12) is a self-report questionnaire of common mental health symptoms [21] It comprises of 12 items on a 4-point scale from better than usual to much less than usual. The GHQ-12 has shown to be reliable with adolescents in the UK [22].

9.7.3 Parental Stress

Parenting Stress Index (PSI-4-SF) is a parent self-report and consists of 36 items that assesses 3 domains of parental distress, parent-child interactions and child characteristics [23]. The short form PSI has demonstrated good psychometric properties in infants as young as 12 months [24].

9.7.4 Parental Support

The Multidimensional Scale of Perceived Social Support (MSPSS) will be used to assess parent's perceived social support [25]. It is a 12-item questionnaire with three subscales assessing perceived support from significant other, family and friends. Responders rate how strongly they agree with each item from 1 (very strongly disagree) to 7 (very strongly agree). The MSPSS has been found to have good internal reliability in adolescent populations [26].

9.7.5 Parenting and Child Outcomes

Wearable HeadCam video footage of interactions between participants and their babies will be analysed to look at parenting and child outcomes. The headcams are attached to head-bands which parents and children can put on their head, allowing capture of first-perspective video data of parents and children. Parents will record two 5-minute videos of themselves interacting with their baby at each assessment timepoint. The variables coded will be: *Parent*: emotional tone (mood), responsivity, verbal encouragement, intrusiveness; *Parent-Child*: emotional attunement (synchronicity); *Child*: emotional tone (mood), visual attention. These will be assessed by the research team using the coding developed by Pearson and colleagues [27]. These measures of the quality of interactions are associated with lower symptoms of later child psychopathology [28].

9.7.6 Treatment Adherence and Engagement

The number of sessions viewed on AADAPT Online and number of sessions completed will be recorded. Completed treatment will be defined as completing four out of the six sessions. The number of successful and unsuccessful contact attempts as recorded by the Parent Buddy will also be recorded. To describe the use of the intervention, the frequency of logins to Trial Deck, the time spent on this platform and number of exercises completed will also be assessed.

9.7.7 Economic Measures

Parent quality of life (Self-report; (EQ-5D-5L) assesses overall wellbeing including anxiety and depression and each dimension is answered on a 5-point scale. Respondents also indicate on a 0-100 visual analogue scale how they perceive their overall health that day with 100 being the best health imagined. [29]. The EQ-5D-5L has previously been used in depression studies and demonstrates excellent psychometric properties [30].

Parents will also complete the Recovering Quality of Life (Re-QoL) which will assess quality of life for those with mental health disorders [31].

Client Service Receipt Inventory (CSR) has been extensively used in health research and allows respondents to indicate the services they have accessed [32]. To minimise burden on parents and only include relevant items, only subsections 4.1, 4.2, 4.3 and 4.4, section 5 of CSRI will be used in this study.

9.7.7 Qualitative interviews with parents and Parent Buddies

Qualitative interviews with Parent Buddies and parent participants allocated to both arms will be conducted to explore Parent Buddies' and parents' experiences of taking part in the study. Qualitative interviews will take place approximately 12 weeks after randomisation. A topic guide that has previously been created and implemented to explore parents' experiences of online interventions [33] will be used.

Participants will be invited to take part in the interview by email and then followed up with a telephone/text message (up to three times). Interviews will be conducted either via Microsoft Teams (Teams) or over the telephone, depending on participant preferences. Interviews will last approximately 30 – 60 minutes and will be either audio recorded on Teams or through a digital recorder, depending on how the interview is being conducted. Recordings on a digital recorder will be uploaded within 24 hours to the secure university network. Recordings will be transcribed by the research team (manually or using the Teams transcript), or by a third-party provider who is a University registered supplier and will be required to adhere to recommendations from an Oxford University Third Party Security Assessment (TPSA). The transcriber will be required to delete all audio files after verbatim transcriptions have been

checked by the research team. Information that could reveal the identity of a participant to other people will not be included in transcriptions. Transcripts will then be analysed using thematic analysis [34, 35].

9.8. Sample Handling

No samples will be taken as part of this study.

9.9. Early Discontinuation/Withdrawal of Participants

During the course of the study a participant may choose to withdraw early from the study at any time. This may happen for several reasons, including but not limited to:

- The occurrence of what the participant perceives as an intolerable adverse event (AE)
- Inability to comply with study procedures
- Participant decision

In the case of participant withdrawal, data collected will only be retained until that point unless the participant requests otherwise or agrees to take part in the further assessments.

The number of withdrawals from treatment and/or follow-up measures will be logged with a summary of the reasons provided (if offered by the participant).

Participants may choose to stop treatment but remain in the study data collection follow-ups unless they inform the research team otherwise.

Participants may also withdraw their consent, meaning that they wish to withdraw from the study completely.

In addition, the Investigator may discontinue a participant from the study treatment at any time if the Investigator considers it necessary for any reason including, but not limited to:

- Parent's mood deteriorates or parent develops symptoms of mania, psychosis or becomes actively suicidal.
- Sustained period (at least 3 weeks) when Parent has no contact with child due to disagreement between parents about visitation or safeguarding concerns.
- Parent Buddy's mood deteriorates or Parent Buddy develops symptoms of mania, psychosis or becomes actively suicidal.
- Parent or Parent Buddy does not respect the boundaries of their relationship (as set out in AADAPT materials (for parents) or AADAPT training and Parent Buddy manual (Parent Buddy)).
- Parent Buddy does not maintain requirements regarding:

a) Supervision attendance
b) Adequate demonstration of Buddy competencies and skills (as observed and assessed through ongoing supervision or through concerns raised by Parent participants)

If a Parent Buddy is no longer able to continue participating in the study for any reason, the parent will be reallocated another available Parent Buddy.

Wherever possible the data of randomised participants will be analysed. If a participant withdraws from the study treatment but has completed 3 treatment sessions their data will still be analysed. Withdrawn participants will be replaced if they withdraw 13 weeks before the study end date. The type of withdrawal and reason for withdrawal will be recorded.

If the participant is withdrawn due to an adverse event, the CI will contact local agencies (e.g. GP, social care, local authority) to ensure safety and support is in place.

9.10. Definition of End of Study

The end of study is the point at which study data from the last participant assessment or qualitative interview has been collected.

10. SAFETY REPORTING

Safety reporting window will begin from the time of consent and end when then participant completes the study.

10.1. Definition of Serious Adverse Events

A serious adverse event is any untoward medical occurrence that:

- results in death
- is life-threatening
- requires inpatient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity

Other 'important medical events' may also be considered a serious adverse event when, based upon appropriate medical judgement, it may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

There is a low risk of SAEs in the current trial; however the following details a non-exhaustive list of potential SAEs and Adverse Events (AE):

Potential Serious Adverse Events (SAEs) (to Parent participant or Parent Buddy volunteer):

1. Admission to psychiatric hospital
2. Sectioned under the Mental Health Act
3. Significant and sustained deterioration of pre-existing mental health condition that requires immediate intervention: a) for parent participants that cannot be accommodated within the treatment protocol (as determined in clinical supervision) b) for Parent Buddies that means they are unable to perform their role in supporting parent participants
4. Diagnosis of new serious psychiatric condition
5. Suicidal thoughts with intention and means

6. Identification of a safeguarding issue that reaches the threshold for referral to MASH (Multi Agency Safeguarding Hub)

Adverse Events (AEs):

1. One or more aspect of the therapy or assessment procedure induces unacceptable levels of distress for either the parent, or the Parent Buddy
2. A sustained and significant increase in detrimental behaviours (e.g. increased severity self-harm, increased and sustained anxiety, social isolation or rumination) as determined by the session recordings of parents' interactions with Parent Buddies collected throughout the study
3. Drop-out of treatment / request to change Parent Buddy (all routinely monitored for presence of AEs)
4. A participant (parent or Parent Buddy) reports an actual or perceived AE as defined above to the study team (e.g. distress triggered by completing study measures or session content)

Parent Buddies will be asked to report any concerns to the Clinical Psychologist in the team. Further investigation will be made by the clinical team and the CI and the SAE/AE procedures will be followed where applicable. The team, the CI and Independent Oversight clinician will assess the frequency and severity of the adverse event(s) and determine whether the participant should be withdrawn from the trial. The decision of the clinical team will be taken in the event that consensus is not reached.

10.2. Reporting Procedures for Serious Adverse Events

All AEs and SAEs (both those relating to the trial and not directly relating to the trial) will be recorded, logged and monitored by the CI, wider research team and the Independent Oversight clinician. If an AE is reported more than once for a participant, or more than three times during the study, it will be treated as an SAE.

A serious adverse event (SAE) occurring to a participant should be reported to the REC that gave a favourable opinion of the study where in the opinion of the CI the event was 'related' (resulted from administration of any of the research procedures) and 'unexpected' in relation to those procedures. Reports of related and unexpected SAEs should be submitted within 15 working days of the Chief Investigator becoming aware of the event. The Independent Oversight clinician will also review the actions and response of the team.

In the event that a complaint is received from a participating parent or Parent Buddies the CI will attempt to resolve the issue as far as is possible. If this is not possible, and the issue remains unacceptable to participants, formal complaints will be logged and dealt with by the sponsor's representative in liaison with the CI. Those indicating an AE or SAE will be logged accordingly.

11. STATISTICS AND ANALYSIS

11.1. Statistical Analysis Plan (SAP)

The plan for the statistical analysis of the study are outlined below. There is not a separate SAP document in use for the trial.

11.2. Description of the Statistical Methods

In accordance with CONSORT guidelines, participant flow will be recorded and reported. Descriptive statistics will be provided with regard to recruitment, drop-out, and intervention completion. Baseline variables will be presented by randomised group using frequencies (with percentages) for binary and categorical variables and means (and standard deviations) or medians (with lower and upper quartiles) for continuous variables. There will be no tests of statistical significance nor confidence intervals for differences between groups on any baseline variables.

For measuring intervention acceptability and adherence, key measures by arm and for all participants will be summarised.

Acceptability of health economic measures will be assessed by percentages of health economic measures completed. Where data is completed descriptive statistics will be generated to inform potential trial outcomes.

A summary of the clinical outcomes using mean scores by arm and for all participants combined will also be produced. For the EPDS the % of those scoring above the clinical cut-off will be reported. The data will inform the planning of a full trial. Loss to follow-up together with reasons will be reported by arm.

Due to the nature of the intervention neither the parents nor the research group can be blinded to treatment group.

11.2.1 Qualitative analysis

Interviews will be audio-recorded and transcribed verbatim. Transcribed interviews will be analysed using an inductive thematic analytic approach [34, 35]. Rather than relying on a pre-existing coding or theoretical framework, codes and themes will be data-driven. Transcripts will be read and reread to gain a sense of each experience. The data will be manually coded detailing inductive descriptive codes by marking similar phrases or words from the narratives. Reflexive thematic analysis will be used as it enables team members to reflect and engage with the data, generating themes from the codes using mind mapping techniques.

11.3. Sample Size Determination

Randomising 60 adolescent parents for this study was decided in accordance with Whitehead *et al*. [36], where 30 participants in each arm is considered acceptable for a pilot RCT. Furthermore, taking into account O'Mahen *et al.* [11] which used a depressed maternal parent population (but not specifically depressed adolescent parents), the **Intervention** pre-treatment mean (SD) 20.24 (3.28), post randomisation mean (SD) 11.05 (4.71); **Control** pre-treatment (mean (SD) 21.07 (4.0); post-randomisation mean (SD), 14.24 (5.11), yields a value of -0.87 Cohen's effect size. Assumption of a similar distribution for this study's sample means a two-sided *t*-test at 5% significance level would yield a power >90% for n=30 in each group.

Twenty participants will take the role of Parent Buddies which is needed in order for each Parent Buddy to have no more than 2 Mentees at one time and to ensure adequate numbers of Parent Buddies if some are not deemed suitable after completion of the Parent Buddy training programme.

11.4. Analysis populations

The primary analysis population is defined as all participants for whom data are available analysed according to the groups they were randomly allocated to, regardless of treatment compliance.

11.5. Decision points

Due to the rapid nature of the trial there will be no interim analyses.

11.6. Stopping rules

As this study is a pilot there are no formal stopping criteria.

11.7. Procedures for Reporting any Deviation(s) from the Original Statistical Plan

Any deviations from the statistical section of the protocol or the statistical analysis plan will be fully described in the final analysis report.

12. DATA MANAGEMENT

The plan for the data management of the study are outlined below. There is not a separate Data Management document in use for the study.

12.1. Source Data

Source documents are where data are first recorded, and from which participants' data are obtained. These include, but are not limited to,

- Parent reported questionnaires
- Parent Buddy questionnaires
- Parent/Child video footage
- Parent and Parent Buddy interviews

All documents will be stored safely in confidential conditions. On all study-specific documents, other than the signed consent, the participant will be referred to by the study participant number/code, not by name.

12.2. Access to Data

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

Access to personally identifiable data will be restricted to a need-to-know basis. This will include the PI, co-investigators, research staff involved in data collection. Parent Buddies will only be told the first name of their parent Mentee.

Agreements will also be in place with external organisations (AADAPT Online hosting provider and software developer) who will be data processors and will require access to personal data collected in this study. Oxford University Third Party Security Assessments (TPSA) will be conducted for the organisation and they will be required to comply with the TPSA recommendation. The data held by Global Initiative is only for the use of this study. The AADAPT participants are excluded from any marketing communication,

re- or cross-invitation to this or other studies. The role of Global Initiative is to collect, store, and process data on behalf of AADAPT via its platform Trial Deck.

12.3. Data Recording and Record Keeping

All those taking part (adolescent parents and Parent Buddy volunteers) will be assigned a unique ID. A document that links the participant's personally identifiable data with the participant ID will be stored separately from all other research data. Trial Deck is an online secure data entry system developed by Global Initiative. It is designed to collect sensitive data, such as participant contact details, and securely retain them separate from a trial's clinical data. Trial Deck is accessed via a secure HTTPS connection and all stored sensitive data is encrypted at rest to AES-256 standards.

The main study data will be entered directly into an electronic format by the participant or trial team. Data will be hosted on network servers/drives which are maintained by University of Oxford MSD and are backed up every 24 hours and firewalls and authentication are in place to block any inappropriate access.

While most main trial data will be directly entered electronically, due to copyright restrictions paper versions will be provided for PSI-4-SF, and if access to the online measures is not possible. In these cases, the original copy will be returned to the study team. All measures (electronic or paper) will be date stamped upon receipt. Data will be labelled with the participant ID (no names or other identifiable information) locked in secure cabinets, in lockable offices and only the researchers will have access to the files. A separate database will be used to securely store all identifiable participant information required to contact participants and permit follow up. Access to this information will be strictly on a need-to-know basis and databases will be password protected on a secure server.

Sessional treatment data will be captured within Trial Deck and this will be available to the research team. As noted above, Global Initiative (the company who supports Trial Deck) will be subject to a University of Oxford TPSA and will be required to comply with recommendations.

Qualitative interviews will be audio recorded using a digital audio recorder or Teams. Recordings will be held temporarily on these audio-recording devices for no more than 24 hours before being securely transferred to a restricted access folder on the University of Oxford IT Network where they will be stored separately from all other research data in a restricted access OneDrive folder. The audio recording will be either i) transcribed by a member of the research team (manually or using Teams), or ii) sent securely via OneDrive to a transcriber with a contract with the university (and who has been subject to and found to comply with recommendations from a TPSA). The transcriber will be required to delete all audio files after returning the verbatim transcription to the research team.

Where Teams is used to transcribe (option i), the audio recording will be used to create a Teams transcript which will be automatically generated by Teams in Nexus 365 STREAM. The transcript will then be formatted, checked against the original audio, names removed and saved to a secure restricted access OneDrive folder. The recording on MS STREAM will then be deleted. Transcripts will be de-identified.

Participants' identifiable information will be kept in order for the research team to inform them of the study results. This is anticipated to be at least 3 years, which is when the study funding is due to finish. Any research documents with personal information, such as consent forms, will be held securely at the University of Oxford for 3 years after the end of the study. Qualitative interview transcripts will be retained securely to support publications of findings from the study until they are no longer required. The linkage

information will be permanently destroyed at the end of the study. Audio-recordings will be stored until recordings have been transcribed verbatim, and transcriptions thoroughly checked. This means that audio files will be destroyed by the end of the study. At the end of the study, Global Initiative are under instruction to delete all participant data held on their production server, after a manual backup allowing a 30 day grace period.

13. QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

13.1. Risk assessment

No formal risk assessment will be undertaken as this is a small pilot RCT study.

13.2. Study monitoring

Regular monitoring will be performed where data will be evaluated for compliance with the protocol and accuracy in relation to source documents. Following written standard operating procedures, the trial manager will verify that the study is conducted and data are generated, documented and reported in compliance with the protocol, GCP and the applicable regulatory requirements.

13.3. Study Committees

Monitoring participant safety and risk management

A clinician, independent from the research team and research institution, has agreed to provide independent oversight to safeguard the interests of participants and maintain the integrity of the study. They will review safety data, including adverse events and serious adverse events, to assess the risks and benefits of the intervention. They will consider these adverse events occurring during the trial, including their frequency, severity, and relationship to the intervention, and assesses whether any observed adverse events are within acceptable limits or if they warrant further investigation or action. If needed as a result of safety concerns, they may be involved in interim analyses of efficacy, safety, and futility. They can provide recommendations to the trial sponsors regarding the continuation, modification, or termination of the trial. In cases where unexpected safety concerns or serious adverse events arise, they will advise on risk management strategies and protocols to address these issues. This may involve implementing additional safety measures, modifying the study protocol, or recommending the suspension or termination of the trial if necessary.

14. PROTOCOL DEVIATIONS

A study related deviation is a departure from the ethically approved study protocol or other study document or process (e.g. consent process or administration of study intervention) or from Good Clinical Practice (GCP) or any applicable regulatory requirements. Additionally, if it becomes apparent that one of more of the exclusion criteria is met (or inclusion criteria not met) by the participant. [NB. This will be logged but the participant remains in treatment as long as clinically appropriate].

Any deviations from the protocol will be documented in a protocol deviation form and filed in the study master file.

15. SERIOUS BREACHES

A "serious breach" is a breach of the protocol or of the conditions or principles of Good Clinical Practice which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the trial subjects; or

(b) the scientific value of the research.

In the event that a serious breach is suspected the Sponsor must be contacted within 1 working day. In collaboration with the CI, the serious breach will be reviewed by the Sponsor and, if appropriate, the Sponsor will report it to the approving REC committee.

16. ETHICAL AND REGULATORY CONSIDERATIONS

16.1. Declaration of Helsinki

The CI will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

16.2. Guidelines for Good Clinical Practice

The CI will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

16.3. Approvals

Informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC).

The CI will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

16.4. Other Ethical Considerations

This study involves collection of online questionnaire data from people aged 16 -18 years who are considered "competent youth". Both parents and Parent Buddies will be provided with study information and will have the opportunity to discuss the study and have questions answered prior to taking part.

Participation in the study also introduces burden on participants from completion of questionnaires for research purposes. Participants will be reimbursed for their time participating in research specific elements of the study. The questionnaires that are administered are commonly used in clinical practice and research, however there is a possibility that some of the questions may cause some distress. Participants will be encouraged to raise these concerns with the research team and participants will be provided with contact details for further discussion if required.

Completing the pre- and post-treatment assessments may involve reflecting on distressing thoughts and feelings. These assessments are similar to those used in routine clinical practice, however for some parents they may cause a degree of distress or discomfort. The acceptability of all measures has been carefully considered with PPI representatives and these measures have been used in other similar studies. The voluntary nature of all assessments will be emphasised throughout, and study team will be vigilant for families who appear unduly distressed or upset, and will notify senior members of the study team immediately.

16.5. Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the host organisation, Sponsor and funder (where required). In addition, an End of Study notification and final report will be submitted to the host organisation, REC, HRA, Sponsor and funder (where required). Reports to the funder will be sent every 6 months or on request.

16.6. Transparency in Research

Prior to the recruitment of the first participant, the trial will have been registered on ISCRTN and the trial information will be kept up-to-date during the trial. The CI or their delegate will upload results to all those public registries within 12 months of the end of the trial declaration.

16.7. Participant Confidentiality

The study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database(s). All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

16.8. Expenses and Benefits

No additional funding will be provided to participants for travel expenses as all research activities will take place independently online or by participants' in their own homes.

Adolescent Parent participants: will receive £25 for completing the baseline assessment, and £25 for completing all of the items in the follow-up assessment and £25 for the qualitative interview.

Parent Buddies: for training they will receive a total of £140 (rounded from £12.50 x 8 hours online sessions + 3 hours of homework). For supporting 1 mentee through the programme they will receive a maximum of £275 (£25 per session of support for the mentee (each mentee receiving up to a maximum of 8 support sessions) plus £25 per hour of supervision; average of 3 hours of supervision per mentee). A 'session' of support for the mentee includes time spent directly engaging with mentee (through Teams call or Messenger function), preparation before the call, field notes/administration after the call and preparation for supervision). Supervision will be more frequent for the first mentee supported (weekly for first 5 sessions) but will be less frequent for subsequent mentees as Parent Buddies gain in experience and

skill (hence average 3 hours of supervision per mentee). They will also receive £25 for taking part in the qualitative interview.

All individuals will be reimbursed in vouchers unless an individual specifically requests a bank transfer.

17. FINANCE AND INSURANCE

17.1. Funding

This study has been funded by The Prudence Trust.

17.2. Insurance

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London). NHS indemnity operates in respect of the clinical treatment that is provided. Appropriate contractual arrangements will be put in place with all third parties.

18. PUBLICATION POLICY

The Investigators and research team will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by The Prudence Trust. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged. A summary of the study findings will be circulated at the end of the study to all participating parents.

19. DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

Ownership of IP generated by employees of the University vests in the University. The University will ensure appropriate arrangements are in place as regards any new IP arising from the trial.

20. ARCHIVING

All anonymised research data and consent forms will be stored on the University of Oxford secure servers for 3 years after the study has been published.

21. REFERENCES

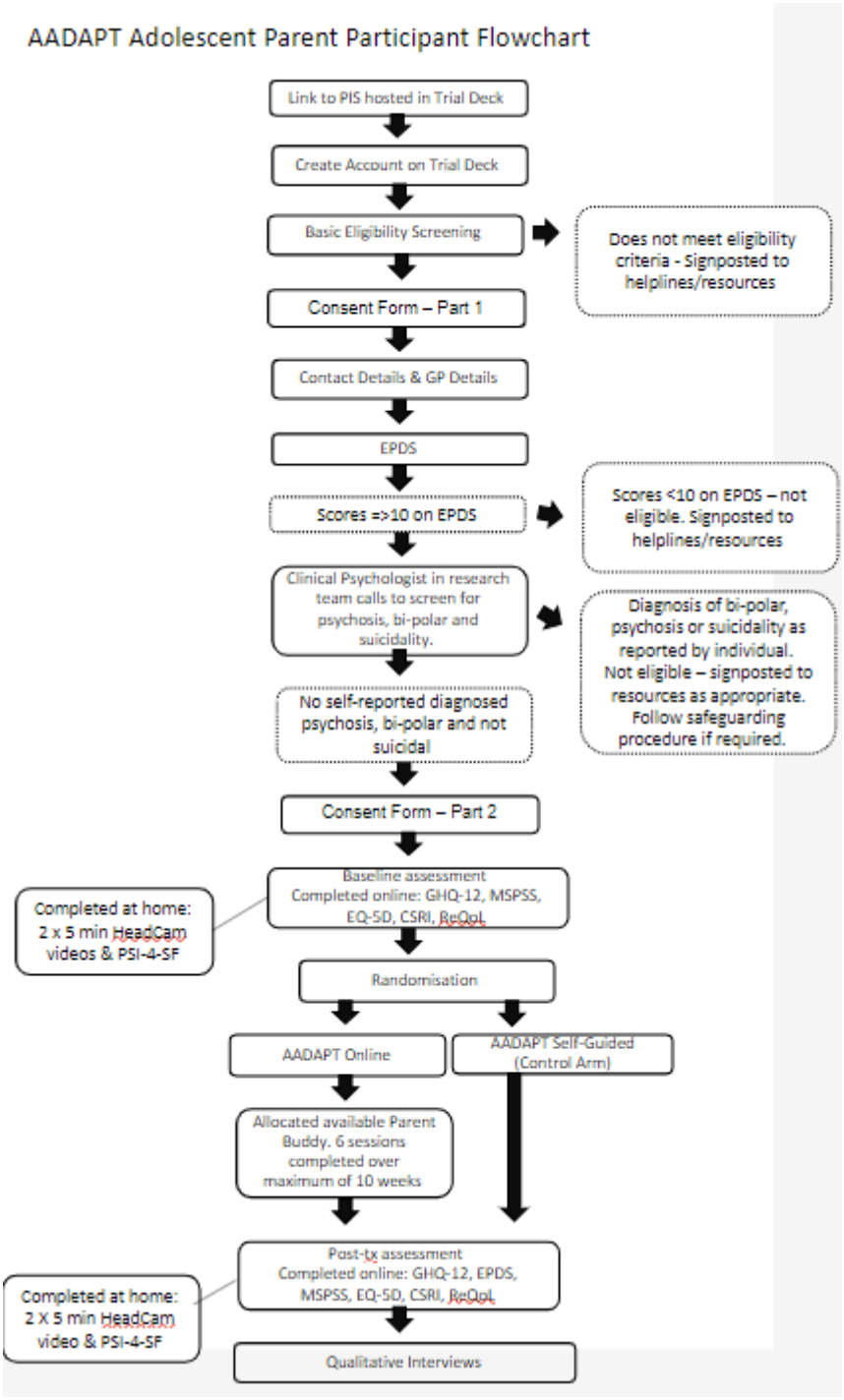
1. UNICEF.,*The state of the world's children 2021 On my mind: Promoting, protecting and caring for children's mental health*. 2021

2. Public Health England., *A framework for supporting teenage mothers and young fathers*. 2016.
3. Cross, T.B.R. *Escaping the bubble: Working together to tackle loneliness and social isolation across the UK*; Available from: https://assets.ctfassets.net/5ywmq66472jr/24YdkN5sa8oYYQSGkOmuke/e5e66fb7d529ab26e9864bd5e59bc1fd/Coop_trapped_in_a_ bubble_Summary_report_BRC__1_.pdf.

4. Siegel, R.S. and A.R. Brandon, *Adolescents, pregnancy, and mental health.* J Pediatr Adolesc Gynecol, 2014. **27**(3): p. 138-50.
5. Lovejoy, M.C., et al., *Maternal depression and parenting behavior: a meta-analytic review.* Clin Psychol Rev, 2000. **20**(5): p. 561-92.
6. Stein, A., et al., *Effects of perinatal mental disorders on the fetus and child.* Lancet, 2014. **384**(9956): p. 1800-19.
7. Maternal Mental Health Alliance. *The maternal mental health experiences of young mums*. 2023. Availablefrom: https://maternalmentalhealthalliance.org/media/filer_public/2b/c1/2bc1d7f4-b64e-40bc-96e3-ccf773c33ad0/final_-_the_maternal_mental_health_experiences_of_young_mums.pdf.
8. Lee, E.W., et al., *Web-based interventions for prevention and treatment of perinatal mood disorders: a systematic review.* BMC Pregnancy Childbirth, 2016. **16**: p. 38.
9. Moltrecht, B., et al., *Young parents' experiences of pregnancy and parenting during the COVID-19 pandemic: a qualitative study in the United Kingdom.* BMC Public Health, 2022. **22**(1): p. 523.
10. Dennis, C.L. and L. Chung-Lee, *Postpartum depression help-seeking barriers and maternal treatment preferences: a qualitative systematic review.* Birth, 2006. **33**(4): p. 323-31.
11. O'Mahen, H.A., et al., *Netmums: a phase II randomized controlled trial of a guided Internet behavioural activation treatment for postpartum depression.* Psychol Med, 2014. **44**(8): p. 1675-89.
12. Cuijpers, P., et al., *Is guided self-help as effective as face-to-face psychotherapy for depression and anxiety disorders? A systematic review and meta-analysis of comparative outcome studies.* Psychol Med, 2010. **40**(12): p. 1943-57.
13. O'Mahen, H.A., et al., *Internet-based behavioral activation--treatment for postnatal depression (Netmums): a randomized controlled trial.* J Affect Disord, 2013. **150**(3): p. 814-22.
14. Shorey, S., et al., *Evaluation of a Technology-Based Peer-Support Intervention Program for Preventing Postnatal Depression (Part 1): Randomized Controlled Trial.* J Med Internet Res, 2019. **21**(8): p. e12410.
15. Blakemore, S.J. and K.L. Mills, *Is adolescence a sensitive period for sociocultural processing?* Annu Rev Psychol, 2014. **65**: p. 187-207.
16. Goldstein, Z., et al., *Interventions for paternal perinatal depression: A systematic review.* J Affect Disord, 2020. **265**: p. 505-510.
17. Sweeney, S. and A. MacBeth, *The effects of paternal depression on child and adolescent outcomes: A systematic review.* J Affect Disord, 2016. **205**: p. 44-59.
18. Ramchandani, P.G., et al., *The effects of pre- and postnatal depression in fathers: a natural experiment comparing the effects of exposure to depression on offspring.* J Child Psychol Psychiatry, 2008. **49**(10): p. 1069-78.
19. Cox, J.L., J.M. Holden, and R. Sagovsky, *Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale.* Br J Psychiatry, 1987. **150**: p. 782-6.
20. Wisner KL, P.B., Piontek CM, *Clinical Practice. Postpartum Depression.* N Engl J Med, 2022. **347**(3): p. 194-9.
21. Goldberg, D., Williams, P, *A user's guide to the General Heath Questionnaire*. 1988, NFER-Nelson: Windsor.
22. Tait, R., G. Hulse, and S. Robertson, *A Review of the Validity of the General Health Questionnaire in Adolescent Populations.* The Australian and New Zealand journal of psychiatry, 2002. **36**: p. 550-7.
23. Abidin, R.R., *Parenting Stress Index Fourth Edition (PSI-4)*. 2012, PAR: Odessa, FL, USA.
24. Barroso, N.E., et al., *Psychometric properties of the Parenting Stress Index-Short Form (PSI-SF) in a high-risk sample of mothers and their infants.* Psychol Assess, 2016. **28**(10): p. 1331-1335.
25. Zimet GD, D.N., Zimet SG, Farley GK, *The Multidimensional Scale of Perceived Social Support.* Journal of Personality Assessment, 1988. **52**: p. 30-41.
26. Zimet, G., et al., *Psychometric Characteristics of the Multidimensional Scale of Perceived Social Support.* Journal of Personality Assessment, 1990. **55**(3-4): p. 610-617.

27. Costantini I, V.M., Campbell A, Burgess R, Glen K, Moraitopoulou G, Paul E, Bornstein MH, Culpin I, & Pearson RM, *Mental Health Intergenerational Transmission (MHINT) Process Manual.* 2021.
28. Compas, B.E., et al., *Coping, emotion regulation, and psychopathology in childhood and adolescence: A meta-analysis and narrative review.* Psychol Bull, 2017. **143**(9): p. 939-991.
29. Herdman, M., et al., *Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L).* Qual Life Res, 2011. **20**(10): p. 1727-36.
30. Feng, Y.S., et al., *Psychometric properties of the EQ-5D-5L: a systematic review of the literature.* Qual Life Res, 2021. **30**(3): p. 647-673.
31. Keetharuth, A.D., et al., *Recovering Quality of Life (ReQoL): a new generic self-reported outcome measure for use with people experiencing mental health difficulties.* Br J Psychiatry, 2018. **212**(1): p. 42-49.
32. Beecham, J.K., M, ed. *Costing psychiatric interventions*. 2nd ed. Measuring Mental Health Needs, ed. G. Thornicroft. 2001: Gaskell. 200-224.
33. Creswell, C., et al., *Digitally augmented, parent-led CBT versus treatment as usual for child anxiety problems in child mental health services in England and Northern Ireland: a pragmatic, non-inferiority, clinical effectiveness and cost-effectiveness randomised controlled trial.* Lancet Psychiatry, 2024. **11**(3): p. 193-209.
34. Braun, V. and V. Clarke, *Using thematic analysis in psychology.* Qualitative Research in Psychology, 2006. **3**(2): p. 77-101.
35. Braun, V. and V. Clarke, *Reflecting on reflexive thematic analysis.* Qualitative Research in Sport, Exercise and Health, 2019. **11**(4): p. 589-597.
36. Whitehead, A.L., et al., *Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable.* Stat Methods Med Res, 2016. **25**(3): p. 1057-73.

22. APPENDIX A: STUDY FLOW CHART



23. APPENDIX B: SCHEDULE OF STUDY PROCEDURES – Adolescent Parent

		Screening	Baseline (after full informed consent)	Randomisation (after competition of online baseline measures)	Intervention Arm (6 sessions to complete with support from Parent for up to 10 weeks)	Post-Treatment (12 weeks after randomisation)	Close-Out (after post-treatment)
Enrolment	Basic Eligibility Screen	X					
	First Informed Consent Procedure	X					
	Contact Information & GP Details	X					
	EPDS	X				X	
	Screening phone call	X					
	Full Informed Consent to study	X					
	Demographics		X				
Allocation	Randomisation			X			
Intervention	AADAPT Online (intervention arm)				X		
	AADAPT Self Guided (control group)						X
Assessments – Parent Report	GHQ-12		X			X	
	MSPSS		X			X	
	Re-QoL		X			X	
	EQ-5D		X			X	
	CSRI		X			X	
	PSI-4-SF		X			X	
Assessment	Headcam Recordings (optional)		X			X	
Close-out	Qualitative Interview						X (invited at point of post-treatment assessments, 12 weeks after randomisation)

24. APPENDIX C: SCHEDULE OF STUDY PROCEDURES – Parent Buddies

		Screening	Pre-Training	Training (4 weeks)	Supporting a Parent (up to 10 weeks)	Prior to Study Ending or Involvement in Study
Enrolment	Basic Eligibility Screen	X				
	Demographics	X				
	First Informed Consent Procedure	X				
	Screening phone call	X				
	Full Informed Consent to study	X				
	DBS		X			
Training	AADAPT Online Training			X		
Post-Training	20min Conversations with Parent				X	
	Parent Buddy Logs				X	
	Supervision sessions				X	
Close-Out	Qualitative Interviews					X

25. APPENDIX D: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made

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