ISRCTN14608187 https://doi.org/10.1186/ISRCTN14608187

AADAPT Online – Addressing young mums' and dads' low mood and their parenting

Submission date
20/11/2023

Recruitment status
Recruiting

Registration date
22/11/2023

Overall study status
Ongoing

Last Edited
21/05/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Depression is a common mental health difficulty that often starts in adolescence. Becoming a parent during adolescence presents additional challenges and parental mental health problems can impact how parents interact with their children. Not only does depression directly effect the young parents themselves but it has also been shown to impact on parenting and parent-child interactions.
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 for different activities to help them engage in sensitive, positive interactions with their infant. The Online BA package targets both depression and parenting. Parents will be allocated to either AADAPT Online or AADAPT Self-Guided and this will be decided at random by a computer.
AADAPT Online: Parents will be given access to six online BA sessions accompanied by an initial introductory call and then six weekly conversations with a Parent Buddy. Parent Buddies can direct parents to additional content with the aim of supporting parents with the core concepts.
AADAPT Self-Guided (control arm): Parents will be given access to the BA sessions via email and or in the post, 12 weeks after being allocated to this group. They can work through these at their own pace. They will not be supported by a Parent Buddy volunteer.

Who can participate?
Parents aged 16 -24 years old with depression and low mood and a baby 12 months or younger at the start of the study.

What does the study involve?
Young Parents: When a parent agrees to take part in the study they will be asked to fill out some questionnaires about their mood, stress, perceived support and some questions about their lifestyle and family set-up. If they agree, they will also be given HeadCams to record some video footage of them playing with their baby at home. After 12 weeks all parents will be asked to complete these questionnaires again and take some more videos of them playing with their

baby if they want to. After this parents in the AADAPT Self-Guided group will be sent the AADAPT BA materials.
Parent Buddies: Will receive training from the research team about how to support parents through the BA online activities and materials. Their main role is to help parents access AADAPT online and work through the activities. They will have regular supervision sessions with the research team.
All parents and Buddies will be asked to take part in an additional interview at the end of the study to talk about their experiences of being part of AADAPT.

What are the possible benefits and risks of participating?
The results from the study will help us see if the online BA materials with peer support are helpful for young parents with low mood. All parents taking part in AADAPT will be given access to the BA support materials regardless of the group they are in. Parents will also have the option to receive images and video clips of them playing with their baby.
Some of the questionnaires and talking about being a young parent and feeling low in mood may bring up sensitive or difficult thoughts and feelings. The questionnaires have been used in previous research studies and other young parents have checked to make sure the questions are acceptable.
Parent Buddy volunteers will be able to develop their own skills to become an effective peer mentor through the training. They will also be helping us to see if the BA online materials with peer support are helpful for young parents with low mood. The study will involve talking to other young parents who are experiencing low mood. This may bring up sensitive or difficult memories, thoughts and feelings. They will receive ongoing support from the research team.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
May 2022 to December 2025

Who is funding the study?
The Prudence Trust (UK)

Who is the main contact?
Prof. Louise Dalton, louise.dalton@psych.ox.ac.uk

Contact information

Type(s)
Scientific, Principal Investigator

Contact name
Prof Louise Dalton

Contact details
Department of Psychiatry
Warneford Hospital
Oxford
United Kingdom

OX3 7JX
+44 (0)1865618330
louise.dalton@psych.ox.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
347818

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

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

Acronym
AADAPT

Study objectives
Current study hypothesis as of 19/06/2024:
The aim of the AADAPT study is to compare if an online Behavioural Activation/Parenting self-help package supported by peer mentors (referred to as Parent Buddies), is feasible and acceptable for 16-24-year-old parents experiencing low mood, and to see if it improves parental mental health and parent-child interactions.

Previous study hypothesis:
The aim of the AADAPT study is to compare if an online Behavioural Activation/Parenting self-help package supported by peer mentors (referred to as Parent Buddies), is more effective compared to waitlist control in improving parental mental health and parent-child interactions in 16-24-year-old parents experiencing low mood.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 14/11/2023, Medical Sciences Interdivisional Research Ethics Committee (MS IDREC) (Research Services, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, United Kingdom; +44 (0)1865 616575; ethics@medsci.ox.ac.uk), ref: R88863/RE001

2. Approved 19/12/2024, Wales Research Ethics Committee 3 (Health And Care Research Wales, Castlebridge, 5-19 Cowbridge Road, Cardiff, CF11 9AB, United Kingdom; +44 (0)2920 230457; HCRW.approvals@wales.nhs.uk), ref: 24/WA/0366

Study design
Interventional pilot two-arm randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Internet/virtual, Telephone

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Depression in parents aged 16-24 years

Interventions
Current interventions as of 09/01/2024:

Participants will be randomised in a 1:1 ratio to (i) AADAPT Online Intervention or (ii) AADAPT Self-Guided (waitlist control). 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 a secured web-based called Trial Deck that will automatically occur after the participating parent completes the consent and baseline measures.

Intervention(s):
Online psychological intervention for parents with depression supported by peer mentors (AADAPT Online). AADAPT Online is a behavioural activation and parenting self-help package supported by peer mentor volunteers (referred to as Parent Buddies). The six modules are completed by the adolescent parent over six weeks. Parent Buddies will conduct an initial introductory call with the parent followed by weekly 15-20 minute conversations (either via messaging or audio/video call) to provide support to the adolescent parent.

Comparator:
Waitlist control group who receive the AADAPT Online materials (but no support from peer mentor volunteers) via email or post after their follow-up assessment.

For both arms (intervention and wait list), there is a follow-up assessment 12 weeks after randomisation.

Study information will be available online. After eligibility screening which involves questions online and a brief phone call with the research team, participants will be automatically randomised to receive either AADAPT Online or to the wait-list control after consenting online and completing some baseline measures. Treatment allocation will be communicated to participants online.

_____

Previous interventions:

Participants will be randomised in a 1:1 ratio to (i) AADAPT Online Intervention or (ii) AADAPT Self-Guided (waitlist control). Randomisation will be minimised by severity of depression (EPDS scores <=13; >=14) and the age of the parent (<=20; >=21). Participants will be randomised using a secured web-based called Trial Deck that will automatically occur after the participating parent completes the consent and baseline measures.

Intervention(s):
Online psychological intervention for parents with depression supported by peer mentors (AADAPT Online). AADAPT Online is a behavioural activation and parenting self-help package supported by peer mentors (referred to as Parent Buddies). The seven modules are completed by the parent over 7 weeks supported by weekly 15-20 minute conversations (either via messaging or audio/video call) between the adolescent parent and the Parent Buddy.

Comparator:
Waitlist control group who receive the AADAPT Online materials (but no support from peer mentors) via email or post after their follow-up assessment.

For both arms (intervention and wait list), there is a follow-up assessment 12 weeks after randomisation.

Study information will be available online. After eligibility screening which involves questions online and a brief phone call with the research team, participants will be automatically randomised to receive either AADAPT Online or to the wait-list control after consenting online and completing some baseline measures. Treatment allocation will be communicated to participants online.

Intervention Type
Behavioural

Primary outcome measure
Current co-primary outcome measures as of 19/06/2024:
1. To assess the feasibility of recruitment and intervention methods, including the number of young parents screened, the percentage of those who were eligible at screening who were recruited, and the percentage of those recruited who completed the follow-up assessment – measure using data collected by the AADAPT online throughout the study
2. Measure treatment adherence and acceptability of AADAPT Online, including the number of young parents who completed treatment (defined as 4 out of 6 sessions) measure using data collected by the AADAPT online throughout the study

Previous primary outcome measure:
Parental depression is measured using parent self-report questionnaire (Edinburgh Postnatal Depression Scale, EPDS) at baseline and 12 weeks post randomisation

Secondary outcome measures

Current secondary outcome measures as of 19/06/2024:
1. Parental depression measured using a parent self-report questionnaire (Edinburgh Postnatal Depression Scale, EPDS) at baseline and 12 weeks post-randomisation
2. Parent-infant interactions measured using simultaneous Headcam footage from parent and infant collected at baseline and 12 weeks post-randomisation
3. Parental stress measured using a parent self-report questionnaire (Parenting Stress Index, PSI-4-SF) at baseline and 12 weeks post-randomisation
4. Parental mental health measured using a self-reported General Health Questionnaire (GHQ-12) at baseline and 12 weeks post-randomisation
5. Perceived social support measured using parent self-report (Multiple Dimension Scale of Perceived Social Support, MSPSS) at baseline and 12 weeks post-randomisation
6. Health economic outcome measured using self-report European Quality of Life 5 Dimensions (EQ-5D-5L), 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) at baseline and 12 weeks post-randomisation
7. Treatment adherence and engagement with AADAPT Online, including the number of modules viewed, the number of successful contact attempts by Parent Buddy compared to unsuccessful contact attempts, the number of times logged in, the total amount of time spent in AADAPT Online and the number of exercises completed in AADAPT Online measured using data collected by AADAPT online and study records throughout the study
8. Assessment of recruitment and retention of Parent Buddies, including the number of Parent Buddies invited for training, percentage of those who completed training, percentage of those who actively support Mentees after training, the number of Mentees supported by each Parent Buddy, length of time Parent Buddies remain with the programme measured using study records throughout the study
9. Qualitative outcomes of the AADAPT intervention, measured using data collected from semi-structured interviews after 12 weeks post-randomisation

Previous secondary outcome measures as of 09/01/2024:

1. Parent-infant interactions assessed from simultaneous Headcam footage from parent and infant collected at baseline and 12 weeks post-randomisation
2. Parental stress measured using parent self-report questionnaire (Parenting Stress Index, PSI-4-SF) at baseline and 12 weeks post-randomisation
3. Parental mental health will be assessed using self-reported General Health Questionnaire (GHQ-12) at baseline and 12 weeks post-randomisation
3. Perceived social support measured using parent self-report (Multiple Dimension Scale of Perceived Social Support, MSPSS) at baseline and 12 weeks post-randomisation
4. Health economic outcome measures using self-report European Quality of Life 5 Dimensions (EQ-5D-5L), 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) at baseline and 12 weeks post-randomisation
5. Qualitative outcomes of the AADAPT intervention, collected in the format of semi-structured interviews after 12 weeks post-randomisation

---

Previous secondary outcome measures:

1. Parent-infant interactions assessed from simultaneous Headcam footage from parent and infant collected at baseline and 12 weeks post-randomisation
2. Parental stress measured using parent self-report questionnaire (Parenting Stress Index, PSI-4-

SF) at baseline and 12 weeks post-randomisation
3. Perceived social support measured using parent self-report (Multiple Dimension Scale of Perceived Social Support, MSPSS) at baseline and 12 weeks post-randomisation
4. Health economic outcome measures using self-report European Quality of Life 5 Dimensions (EQ-5D-5L), 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) at baseline and 12 weeks post-randomisation
5. Qualitative outcomes of the AADAPT intervention, collected in the format of semi-structured interviews after 12 weeks post-randomisation

Overall study start date
01/05/2022

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 09/01/2024:

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

---

Previous inclusion criteria:

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

Peer Mentors (Parent Buddies):
1. Aged 25-35 years
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)
4. Lives in the UK
5. Able to provide free informed consent to participate

6. Sufficient understanding of English (secondary school level, age 11) reading ability as they will be helping parents navigate the self-help package

Participant type(s)
Patient

Age group
Mixed

Lower age limit
16 Years

Upper age limit
24 Years

Sex
Both

Target number of participants
60 adolescent parents (30 in each arm)

Key exclusion criteria
Current exclusion criteria as of 09/01/2024:

Adolescent parents:
1. Aged under 16 or over 25 years
2. Not a parent
3. Child older than 12 months at time of recruitment
4. Co-habiting partner already randomised into the study
5. Score of less than 10 on EPDS
6. Active suicidality
7. Active symptoms of psychosis or mania as part of bi-polar disorder
8. Currently receiving psychological treatment
9. Lives outside the UK
10. Unable to consent to participate
11. Insufficient understanding of English

———

Previous exclusion criteria:

Adolescent parents:
1. Aged under 16 or over 25 years
2. Not a parent
3. Child older than 12 months at time of recruitment
4. Co-habiting partner already randomised into the study
5. Score of less than 10 on EPDS
6. Active suicidality
7. Active symptoms of psychosis or mania as part of bi-polar disorder
8. Currently receiving psychological treatment
9. Lives outside the UK

10. Unable to consent to participate
11. Insufficient understanding of English

Peer Mentors:
1. Aged under 25 years or over 35 years
2. Not a parent
3. Had first baby when they were aged 25 years or older
4. No experience of low mood (defined as feeling low, down, depressed or stressed most days for 2 or more weeks)
5. Lives outside of UK
6. Current mental health or emotional difficulties that preclude capacity to be an appropriate peer mentor to another person who has mental health difficulties
7. Unable to consent to participate
8. Insufficient understanding of English

Date of first enrolment
01/06/2024

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Department of Psychiatry
Warneford Hospital
Oxford
United Kingdom
OX3 7JX

Sponsor information

Organisation
University of Oxford

Sponsor details
Research Services
Boundary Brook House
Churchill Drive
Headington

Oxford
England
United Kingdom
OX3 7GB
+44 (0)1865 61675
ethics@medsci.ox.ac.uk

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
The Prudence Trust

Alternative Name(s)
Prudence Trust

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results will be published in peer-reviewed scientific journals with open access.
A summary of the findings will be circulated at the end of the study to all participants.

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	06/06/2024	04/07/2024	No	No
Protocol file	version 1.1	18/12/2024	10/01/2025	No	No
Protocol file	version 1.2	17/04/2025	25/04/2025	No	No