

An online parenting intervention to prevent affective disorders in high-risk adolescents

Submission date 30/01/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 18/09/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/01/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Problems with mental wellbeing in childhood and adolescence can lead to difficulties in young adulthood and beyond. Giving support before these problems occur can have an important impact on the young people and parents/carers are an important support for young people. There is a lot of information about ways to stop depression and anxiety in young people which is directly targeted towards young people; however, research into guidance for parents/carers is limited.

Researchers at the University of Monash in Australia successfully developed an online, parent-focused programme (Partners in Parenting) which provides families with either a personalised programme in the form of nine modules or a standard education package to support their child with their mental wellbeing. The personalised programme includes how to create a positive and nurturing family environment and help families develop a range of skills and knowledge to support their child's mental wellbeing. The standard education package is factsheets which include information on adolescent development and wellbeing.

The University of Warwick has adapted the Australian Partners in Parenting website for use in the UK. The PIPA trial is looking to see which works best to help parents/carers reduce depression and anxiety in their children, the personalised programme or the standard educational package. The trial will involve approximately 433 families.

Who can participate?

The study is open to parents/carers of young people aged 11-15 years (parent/carers include parents, carers, non-biological parents, grandparents and legal guardians) who have access to the internet and an email account and are living with the young person who also agrees to take part. And young people who are attending one of the schools taking part in the PIPA Trial and have access to a mobile phone.

What does the study involve?

The PIPA Trial team will be asking schools in Birmingham and Coventry to send out an invitation letter to all parents/carers of young people aged 11-15. The parents/carers and young people would then agree to take part in the trial. Young people will then be asked to answer some

questions on wellbeing to see if they are able to take part in the trial. Parents/carers and young people who are able to take part in the study will then be asked to answer some more questions and will then be randomised (like tossing a coin) to either work through the personalised programme or the standard education package. Parents/carers and young people will be asked to complete some more questions again at six and 15 months after starting the trial.

What are the possible benefits and risks of participating?

The benefits of taking part in this trial could be to help know more about mental wellbeing in young people and help in picking up some tips to help offer support. By taking part in this trial parents/carers and young people will be giving information to help get information about adolescent mental health and ways to stop young people becoming depressed.

Risks in taking part are minimal. It is possible that parents/carers may find some of the topics covered in the trial upsetting. The research team will be in regular contact to give support if necessary and advice on services available.

Where is the study run from?

The Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick (UK)

When is the study starting and how long is it expected to run for?

March 2019 to August 2024

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Andrew Thompson, Andrew.D.Thompson@warwick.ac.uk

Study website

<http://www.warwick.ac.uk/pipa>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

PIPA

Study information

Scientific Title

An online parenting intervention to prevent affective disorders in high-risk adolescents: a randomised controlled trial

Acronym

PIPA

Study objectives

This project aims to investigate whether the online parenting resources developed in Australia can be adapted for a UK context and assess whether the personalised programme reduces the risk of affective disorders in young people at high risk, using a randomised controlled trial methodology. We hypothesise that there will be reduced levels of depression in those young people whose parents receive the tailored online intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/11/2019, Warwick Biomedical & Scientific Research Ethics Committee (BSREC) (University House, University of Warwick, Kirby Corner Road, Coventry, CV4 8UW; +44 (0)24 7657 5732; BSREC@Warwick.ac.uk), ref: BSREC 20/19-20

Study design

Single-blind prospective parallel-group intention-to-treat RCT with families randomised to the intervention or control group in a 1:1 ratio.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Affective Disorders in high-risk adolescents

Interventions

Active Intervention: The Partners in Parenting Personalised Programme

The personalised programme assesses each parent in nine modifiable parental domains that have been endorsed by research evidence and international experts as important risk or protective factors, in order to identify the areas of parenting requiring improvement. The programme is then automatically personalised to each parent, ensuring that all areas for improvement (i.e. all risk and protective factors relevant to that parent) are targeted. The personalised programme comprises two individually tailored components:

1. An automated feedback report highlighting areas of strength and how parents can improve, which is provided immediately after parents complete an online measure assessing their current parenting practices; and
2. An interactive programme comprising up to nine modules, with a different combination of modules specifically recommended for each parent based on identified areas for improvement.

When parents first see their recommended modules, they can further personalise their programme by deselecting recommended modules and/or selecting additional modules. They then confirm their selection and commence their personalised programme.

The nine modules cover the nine parenting domains developed by our Australian collaborators, titled How to prevent depression and anxiety in your teenager: Strategies for parents. When parents log in to their personalised dashboard on the Partners in Parenting website, they see

their modules and any goals they have set, as well as their progress. Modules include illustrations, audio clips, vignettes, goal-setting exercises, and an end-of-module quiz with immediate feedback to consolidate learning. Each module takes 15-20 minutes to complete, and one module per week is unlocked for parents, in a set order.

Control group: The Partners in Parenting Standard Educational Package

Parents in the control arm will be provided with a standardised package of online educational materials about development of young people and wellbeing. Each week for five weeks, parents receive an automated email inviting them to access their factsheet for that week (to match the expected mean number of modules received by the intervention group). To mirror the experience of intervention group parents accessing each module on the trial website, control group parents will access each factsheet by logging in to their personalised dashboard. The factsheets provide general information to parents (without tailored, actionable strategies) and are designed to represent a selection of resources that are available to parents as part of the current UK health promotion approach for wellbeing of young people. The materials will be adapted from highly credible existing resources such as that provided on the Raising Children Network website. Minor adaptations will be made to the language (e.g. idioms) following consultations with focus group parents. The topics of the five factsheets are as follows:

1. Teen development: An overview.
2. The teenager's developing brain.
3. The teenager's changing body.
4. Resilience.
5. Happy teenagers and teenage wellbeing. We have chosen to use an active control in order to engage parents and to aid retention in their allocated group for the duration of the trial.

Both the personalised programme and standard educational package will be delivered automatically by the Partners in Parenting website.

Intervention Type

Behavioural

Primary outcome measure

Feelings and actions are measured using the Short Mood and Feelings Questionnaire (SMFQ) at baseline, 6 months and 15 months.

Secondary outcome measures

1. Number of cases of adolescent depression or anxiety disorders is measured using the Development and Well-Being Assessment (computer-administered parent and child interviews) at baseline and 15-months.
2. Adolescent anxiety symptoms (parent- and self-report) are measured using the Spence Children's Anxiety Scale at baseline, 6 months and 15 months.
3. Adolescent wellbeing/resilience is measured using the SDQ and Warwick Edinburgh Mental Wellbeing Scale (parent- and child-report) and the Resilience Scale for Adolescents (child-report) at baseline, 6 months and 15 months.
4. Parenting (parent- and child-report) is measured using the following measures at baseline, 6 months and 15 months.
 - 4.1. Parenting to Reduce Adolescent Depression and Anxiety Scale (PRADAS).
 - 4.2. Parenting Self-Efficacy Scale (PSES).
5. Parent mental wellbeing is measured using the Short Warwick Edinburgh Mental Wellbeing Scale at baseline, 6 months and 15 months.
6. Attachment is measured using the Inventory of Parent and Peer Attachment at baseline, 6

months and 15 months.

7. Health economic outcome is measured using the Childhood Health Utility at baseline, 6 months and 15 months.

8. Quality of life is measured using the EQ5D-5L and EQ5D-5L-Y questionnaires at baseline, 6 months and 15 months.

9. The services and supports used by participants are measured using the Client service receipt inventory at baseline, 6 months and 15 months.

10. Satisfaction with the intervention is measured using the intervention satisfaction survey at 6 months and 15 months.

Overall study start date

01/03/2019

Completion date

31/08/2024

Eligibility

Key inclusion criteria

1. Provision of written informed consent
2. The target population is parents of young adolescents (aged 11-15 years). Parents include all primary caregivers, including non-biological parents, grandparents, and legal guardians.
3. Sufficient literacy levels to understand and engage with content delivered aurally or visually in English, and has regular access to the Internet and a personal email account (for email communication) or cell phone number (text messaging communication). Early adolescence represents the highest risk period for developing depression.
4. Adolescents scoring 5 above on the SDQ Emotional Problems subscale, indicating a higher-than-average risk for emotional problems.

Participant type(s)

Carer

Age group

Adult

Sex

Both

Target number of participants

433

Total final enrolment

512

Key exclusion criteria

1. Unable to complete the online parenting intervention
2. Previous entry or randomisation in the present trial.
3. Participation in a clinical trial of a parenting intervention in the last 90 days.

Date of first enrolment

09/02/2021

Date of final enrolment

30/04/2023

Locations

Countries of recruitment

United Kingdom

Study participating centre

Secondary State and Independant Schools in Coventry and Birmingham yet to be approached

United Kingdom

unknown

Sponsor information

Organisation

University of Warwick

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Sponsor type

University/education

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ROR

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Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

28/02/2025

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 article		15/08/2022	16/08/2022	Yes	No