



An online **P**arenting **I**ntervention to **P**revent affective disorders in high-risk **A**dolescents:
The PIPA Trial



Parent & Carer Information Sheet

An online parenting intervention to prevent affective disorders in high-risk adolescents: The PIPA Trial

Investigators: Professor Andrew Thompson, Professor Jason Madan & The PIPA Trial Team

Introduction

You are invited to take part in a research trial. Before you decide to take part, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Talk to others about deciding to take part in the trial if you wish.

Please ask the PIPA team about anything that is not clear or if you would like more information (contact details are available at the end of this document). Please take the time to decide whether or not you wish to take part.

Who is organising and funding the trial?

The trial is being coordinated by the University of Warwick, and is being led by Associate Professor Andrew Thompson and Professor Jason Madan. The trial is funded by the National Institute for Health Research. The trial is being sponsored by The University of Warwick.

What is the trial about?

Difficulties with mental wellbeing in childhood and adolescence can lead to more difficulties in young adulthood and beyond. Providing support before these difficulties occur can have an important impact on outcomes and parents/carers are an important source of support for young people. There is a large amount of evidence for interventions to prevent depression and anxiety in young people which is directly targeted towards young people; however, research into interventions targeting parents/carers is limited.

Researchers at the University of Monash in Australia have 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 educational package to support their child with their mental wellbeing. The personalised programme cover topics such as 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 educational package consists of factsheets which include information on adolescent development and wellbeing.

This leaflet presents independent research funded by the National Institute for Health Research (NIHR) under the Grants for Public Health Research [project number: 17/04/34]. The views expressed in this leaflet are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.



PIPA PIL (Parent & Carer) V4.0, 31/08/2021
ISRCTN63358736

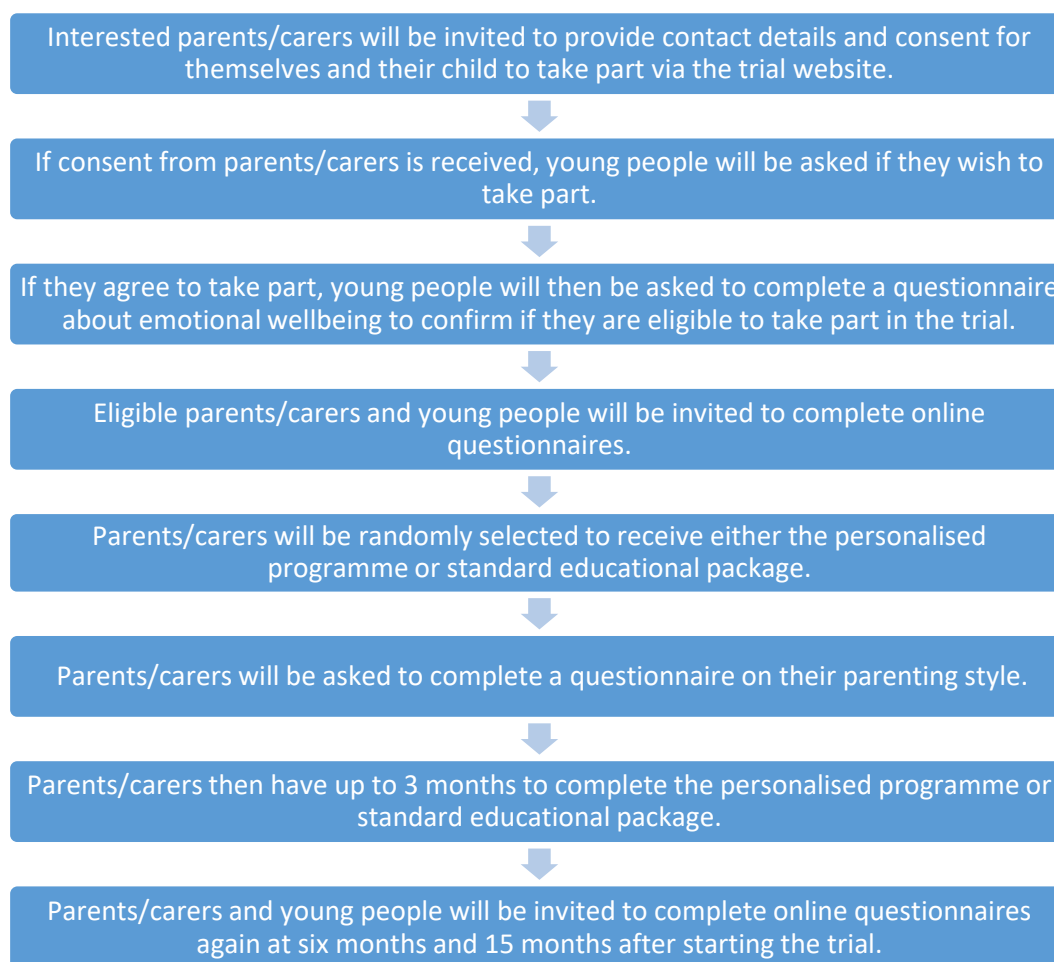
The University of Warwick has adapted the Australian Partners in Parenting website for use in the UK. This was adapted following guidance from parents/carers and teachers in the local area. The PIPA trial is exploring the effectiveness of the personalised programme and standard educational package, to see which is best at helping parents to reduce depression and anxiety in their children. The trial will involve approximately 433 families in England.

Why have I been invited?

We are inviting parents/carers of children aged 11-15 years attending secondary schools in the UK to participate in the trial. You have been contacted because your school has chosen to collaborate with us on the trial.

What would taking part involve?

The diagram below shows what taking part will involve.



Definitions

Randomisation – There will be two groups in the trial: one receiving a standard educational package and one receiving the personalised programme. Parents/carers will be randomly allocated to one of the groups by a computer. Parents/carers will know which group they were placed in once they have registered on the

Partners in Parenting website and completed some questions on their parenting style. Neither parents/carers, nor the researchers are able to choose or influence the group into which they are placed.

Partners in Parenting website– this is used to manage the standard educational package and the personalised programme. *(Please note that both the PIPA database and Partners in Parenting website do not work in Internet Explorer. If you are experiencing difficulties, please use another browser such as Chrome or Edge).*

Standard educational package – five factsheets about adolescent development and wellbeing (one released each week).

Personalised Programme – a set of modules selected for each parent/carer covering up to nine different areas of parenting and family life (one module released each week).

The Trial

- The trial is conducted online so you and your child will not be asked to attend meetings with researchers.
- Baseline and follow-up questionnaires include questions about mental wellbeing, depression and anxiety, quality of life and use of health services. Information about age, gender and ethnicity will also be collected at the start of the trial.
- More than one parent/carer per family is welcome to work through the Partners in Parenting website. However, we do ask that only one parent/carer completes the initial questionnaires and the same parent/carer will also need to complete the follow-up questionnaires. This same parent/carer would provide consent for the trial.
- All parents/carers will receive fortnightly calls from the research team to check-in and provide support (such as help with using the Partners in Parenting website) as needed. If we haven't been able to reach you after three attempts, we will leave a voicemail requesting you to call us back. In alternating weeks, parents/carers will receive a text/email message reminder to continue with their factsheets/modules. You will receive an automated email from the Partners in Parenting website when a new module/factsheet is released.
- Parents/carers and young people will be asked to complete online questionnaires again at six months and 15 months after completing the initial questionnaires (total duration of the trial for each family is 15 months).
- Each set of questionnaires (at baseline, six months and 15 months), should take on average about one hour to complete. This could take slightly longer depending on your answers to some of the questions.
- If you decide to join the trial, please can we ask that you do not discuss the online resources (the personalised programme and standard educational package) with other parents/carers who may be taking part in the trial? This is so that we can accurately measure the effectiveness of the personalised programme and the standard educational package.
- Recruitment for the PIPA trial will finish at the end of November 2021 so parents/carers who would

like to take part must register before then.

- Parents/carers may be invited to attend a focus group with other parents/carers about their experience on the trial at a later date. Around 30 parent/carers and young people may also be invited to individual interviews about their experience on the trial. These focus groups and interviews will be audio recorded, and later typed up, and will be held in accordance with the University of Warwick's data policy. If you are asked to take part in a focus group or interview and you do not want to, this is completely fine and will not affect your time on the trial. At the time of asking, we will give you more information on this so that you can make an informed decision and give consent. We will be approaching participants about this in 2021.
- University of Warwick's data policy: <https://warwick.ac.uk/services/sim/dataprotection>

Who can take part?

If you are interested in taking part, you will need to meet each of the following criteria:

- Parents/carers of young people aged 11-15 years (parent/carers include parents, carers, non-biological parents, grandparents and legal guardians).
- Parent/carer age \geq 18 years.
- Able to provide informed consent for both the parent/carer and young person.
- Sufficient understanding and knowledge to engage with content presented in English.
- Have access to the internet and a personal email account (for email communication) and mobile phone number (for phone and text messaging communication).
- Lives with the participating child.

Your child will also need to fulfil the following criteria:

- Attends one of the schools taking part in the PIPA trial (if your child's school has contacted you about the trial then they are taking part).
- Confirmed assent (agreement) to participate in the trial.
- Has a reading age of 11+ years
- Has access to a mobile phone for text messaging communication and the internet for questionnaire completion.
- Score a certain amount on some screening questions about their wellbeing.

In addition to the above, you will need to ensure that the following does not apply to you:

- Previous unsuccessful entry into this trial.
- Withdrawal from the current trial.
- Participation in an alternative parenting intervention in the last 90 days.
- A parent/carer and young person is already taking part in the trial from your household.

If you meet the criteria and you and your child are happy to take part, your eligibility will be confirmed once your child has completed the eligibility questions about wellbeing. If your child is eligible, you will both be invited to continue with the trial.

What if my child or I am not eligible?

If you are not eligible you will not be able to take part in the trial. If your child is not eligible, you will both be informed that you are ineligible for the trial.

Due to the eligibility requirements for the trial, if after you have entered some information about yourself and your child onto our database and you find out you are ineligible, we will need to keep some identifiable information on you both on our database to ensure that you are not screened for the trial twice. This identifiable data will be deleted once recruitment for the trial ends (at the end of 2021).

Do I have to take part?

No. Taking part in this trial is voluntary and choosing not to take part will not affect you or your child in any way. You can also choose to withdraw at any time, without giving a reason, by contacting one of the research team. Further details about withdrawing from the trial are provided later on in this document.

What are the possible benefits of taking part in this trial?

Taking part in this trial should help improve your knowledge of mental wellbeing in young people and assist you in picking up some tips to help support your child. By participating in this trial you will also be contributing to the evidence for research into adolescent mental health and preventive interventions. The findings of this trial may help to develop better services for young people at risk of developing mental health difficulties and provide parents/carers with skills to assist them.

What are the possible disadvantages, side effects or risks, of taking part in this trial?

Risks in taking part are minimal. It is possible that participants may find some of the topics covered in the trial upsetting. The research team will be able to monitor this through the regular phone contact and provide the necessary support and if needed let you know about where you can go to get further information and advice. If the research team becomes concerned about the welfare of a participant, we will follow approved procedures in dealing with this. This will likely involve a phone call from the team to the parent/carer/school.

Expenses and payments

Each participating family will receive £25 voucher at the end of the trial if questionnaires are completed at each time point (baseline, six months & 15 months) by both parent/carer and young person. This is as an acknowledgement of the time commitment required to complete the questionnaires (around one hour each per time point). This payment will be in the form of a voucher and the trial team will be in touch to arrange this after the completion of the last questionnaire. We will need your address to send this to you.

Will my taking part be kept confidential?

Information collected during this trial will be kept confidential and handled and stored in accordance with the Data Protection Act 2018 and the General Data Protection Regulation. Personal identifying information will be held securely at Warwick Clinical Trials Unit. This includes names and contact details which will be required for communication throughout the trial. Access to this data will be monitored throughout the trial. At the end of the trial (after the last participant has completed their last questionnaire and any interviews have been completed), names and contact details will be deleted from our records.

You and your child will be assigned participant identification numbers, which will be used during the trial by the PIPA trial team. Examples of when this will be used are when transferring data and for safety monitoring. The reason for having the identification number is to remove the need to transfer and use personal identifiable data outside of the research team. More information on data transfers can be found below.

All data will be treated in confidence and will not be disclosed or used for any unrelated purpose (except by prior agreement from the parent/carer or to address concern/risk to the participant, researcher or others).

If the research team identifies a participant deemed at risk or becomes concerned about their safety, the team will follow University of Warwick-approved procedures and inform the parents/carers, school, clinicians at Warwick Clinical Trials Unit and/or relevant authorities which could include the emergency services.

For the purpose of this trial your name and contact details may be shared with individuals from Clinical Research Networks who will be assisting with making the fortnightly phone calls to participants throughout the trial. The Clinical Research Networks fund and manage infrastructure to support high-quality health and care research in England.

Your child's school will not be made aware of any participation in the trial, except for any circumstances where we may be concerned about a participant's safety.

What will happen to the data collected about me?

As a publicly-funded organisation, the University of Warwick must ensure that it is in the public interest when we use personal identifiable information from people who have agreed to take part in research. This means that if you agree to take part in a research trial, such as this, we will use your data in the ways needed to conduct and analyse the research trial.

We will act as the data controller for the trial. We are committed to protecting the rights of individuals in line with data protection legislation. The Warwick Clinical Trials Unit will archive trial documentation and data for at least 10 years after completion of the trial. This will not include your names and contact details.

The University of Monash will be a data processor for the trial and the Partners in Parenting website (where you will enter some personal identifiable information about yourself and your child, and work through your personalised programme/standard educational package) will be managed by them and based within a Google cloud in the UK.

Parents/carers will be required to provide consent for both themselves and their child via an online form, alongside contact details for themselves and their child which will be stored securely at the Warwick Clinical Trials Unit. All other participant data will be collected online via the PIPA trial database which is subject to the University of Warwick data policy. Access to data will be restricted to authorised personnel.

Address details for participants will be collected for use in the case of an emergency where the research team may be required to contact emergency services due to concerns for a participant.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. The University of Warwick has in place policies and procedures to keep your data safe.

For further information, please refer to the University of Warwick Research Privacy Notice which is available

here: <https://warwick.ac.uk/services/sim/privacynotices/research/> or by contacting the Information and Data Compliance Team at GDPR@warwick.ac.uk.

Data Transfer

For the purpose of this trial your name, gender and contact details may be shared with individuals from Clinical Research Networks who will be assisting with making the fortnightly phone calls to participants throughout the trial. Your child's name and gender will also be shared with them.

The trial team will be using a text and email messaging service called Twilio during the course of the trial. This will help the team to send out the fortnightly text/email messages, Partners in Parenting emails and any reminders for questionnaire completion to participants. For the purpose of text messaging, yours and your child's mobile phone numbers and names will be shared with Twilio. For the purpose of sending emails, your email address and yours and your child's names will be shared with Twilio. We will ensure that this data is deleted at the end of the trial (the end of 2022). Twilio's privacy statement can be found here <https://www.twilio.com/legal/privacy>.

During the course of the trial, data will be transferred from the Partners in Parenting website site to The University of Warwick and to and from the University of Warwick and third parties (including Monash University in Australia) involved in the assessment of the questionnaires. When transferring the Partners in Parenting data and questionnaire data, your participant identification numbers will be used and the data will be anonymous.

Data Processing and Data Sharing agreements will be in place for the above purposes. Data will be transferred securely and in accordance with University of Warwick's policies.

Your anonymised data may also be used for future research, including impact activities following review and approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project.

What will happen if I don't want to carry on being part of the trial?

Taking part in this trial is entirely voluntary and you are free to withdraw from the trial at any point without providing a reason, by contacting the research team using the contact details at the end of this document. Withdrawing from the trial will not affect you or your child in any way.

The eligibility requirements for the trial state that we cannot allow previously ineligible or withdrawn participants enter the trial again and so because of this, we will also need to keep some identifiable information about you and your child on our database to ensure that you are not entered into the trial more than once. These identifiable data will be deleted once recruitment for the trial ends (at the end of 2021). If you choose to withdraw, we will use any data that you have provided us with up to that point.

To safeguard your rights, we will use the minimum personal-identifiable information possible and keep the data secure in line with the University's Information and Data Compliance policies.

If you choose to withdraw, you can either withdraw from the Partners in Parenting website (Personalised Programme or standard educational package) but still complete follow-up questionnaires, or withdraw from the trial completely at which point your child will also be withdrawn. Likewise, your child can either withdraw from completing questionnaires or withdraw completely from the trial at which point you (the

parent/carer) will also be withdrawn. If you choose to withdraw, we will use any data that you have provided us with up to that point.

What will happen to the results of the trial?

We will present the findings of the trial in a report to the funder and in relevant journals. Individual participants will not be identified in any of the publications. If you wish to find out about the results of the trial after the trial has ended, please contact the research team or go to the trial website (www.warwick.ac.uk/pipa).

Who has reviewed the trial?

This trial has been independently reviewed and given favourable opinion by the University of Warwick's Biomedical & Scientific Research Ethics Committee (BSREC): BSREC 20/19-20. This trial meets the required ethics standards.

Who should I contact if I want further information?

If you have any questions about the trial, or your involvement in it, either now or in the future, please contact the PIPA trial team using the details below:

Dr. Charlotte Connor – Senior Research Fellow
Warwick Clinical Trials Unit, Warwick Medical School
University of Warwick,
Coventry, CV4 7AL
Email: pipa@warwick.ac.uk
Tel: 02476575078

What if there is a problem?

This trial is covered by the University of Warwick's insurance and indemnity cover. If you have any concerns about this trial, please contact the trial team:

The PIPA Trial Team
Warwick Clinical Trials Unit
Warwick Medical School, University of Warwick
Coventry, CV4 7AL
Email: pipa@warwick.ac.uk

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the trial or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official, entirely independent of this trial:

Head of Research Governance
Research & Impact Services, University House
University of Warwick

Coventry, CV4 8UW
Email: researchgovernance@warwick.ac.uk
Tel: 024 76 522746

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer, Information and Data Director who will investigate the matter: DPO@warwick.ac.uk.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO): casework@ico.org.uk

Thank you for taking the time to read this Parent & Carer Information Sheet