



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



Young Person 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 The PIPA Trial. Before you decide, you need to understand why this research trial is being done and what you would have to do. Please take the time to read this information carefully and talk to others about deciding to take part in the trial if you would like.

Please ask us about anything that is not clear or you would like more information and take time to decide whether or not you would like to take part.

Who is organising and funding the trial?

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

What is the trial about?

Mental health in young people is a problem all over the world. The PIPA Trial will be looking at anxiety (feeling worried and scared) and depression (feeling sad). These kinds of difficulties can start when people are quite young and so it's important for young people to understand them and get help if they need it.

Parents/carers can help their children feel better if they are feeling depressed or anxious. Most young people live with their parents/carers so they are often the first to notice if their child is feeling worried, scared or sad. We hope that if we can help parents/carers learn more about mental health, they will be able to help support their children.



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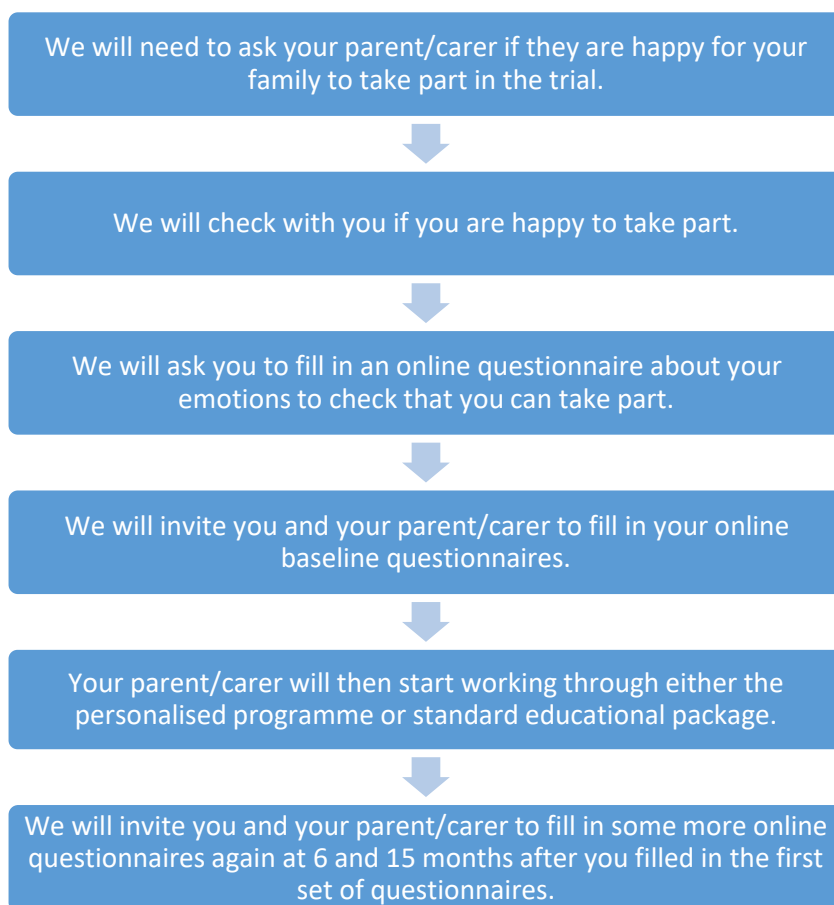
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We think the internet is a good way to teach people how to deal with things like mental health. We have been working with researchers in Australia (at Monash University) on the 'Partners in Parenting' website to help parents/carers and young people with their mental health. We are trying to find out whether a personalised programme or standard educational package is a good way to help families learn about mental health. About 433 families in England will take part in the trial.



What would taking part involve?

We are inviting families of young people aged 11-15 years attending schools in the UK to be involved. The chart below shows what you will have to do if you agree to take part.



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- The trial is completed online so you won't be asked to go to meetings with researchers.
- The online questionnaires will ask about your emotions and mental health and we will also ask about your age and gender. *(Our online questionnaires won't work in Internet Explorer. If you have any problems, you might need to try a different browser like Chrome or Edge).*
- Your parent/carer will work through either the personalised programme, which has up to 9 modules about different areas of parenting and family life, or a standard educational package, which has 5 factsheets about teenage development.
- We will ask you and your parent/carer to fill in some online questionnaires again at 6 and 15 months after the first set of questionnaires (so the total time spent on the trial will be about 15 months).
- Each set of questionnaires should take about one hour to fill in (so about three hours in total for the trial), although this could take a little longer depending on your answers. We will text you the links to these with your parent/carer's permission.
- Recruitment for the trial will finish at towards the end of 2021 so families that would like to take part must register before then.
- Around 30 parents/carers and young people will also be invited to do an interview about what it was like to take part in the trial. These interviews will be recorded, and kept according to the University of Warwick's rules on managing personal information. If you and your family are asked to take part in an interview but you don't want to, this is completely fine and won't affect you taking part in the trial. We will be asking parents/carers and young people about this in 2021.
- University of Warwick's rules about managing information: <https://warwick.ac.uk/services/sim/dataprotection>

Who can take part?

If you are interested in taking part in the trial, you must be able to say yes to all of these questions:

- Are you between 11 and 15 years old?
- Is your school taking part in the PIPA trial?
- Has your parent/carer said that they are happy for your family to take part?
- Are *you* happy to take part?
- Do you understand what the trial is about and what you would have to do?
- Do you have a mobile phone so we can text you?
- Do you have access to the internet to fill in the questionnaires?



You will also need to score a certain amount on an online questionnaire about your emotions.

What if I can't take part in the trial?

If you have answered NO to any of the above questions, or score a certain amount on the online questionnaire about your emotions, then, unfortunately, you won't be able to take part in the trial and we will let you and your parent/carer know.

If you have already given us some information about yourself and then find out that you can't take part, we will need to keep some information about you and your parent/carer. This is to make sure that you are not entered into the trial more than once. We will delete all this information once we stop inviting people to take part in the trial (at the end of 2021).

Do I have to take part?

No, you don't have to take part in the trial if you don't want to and this won't affect you or your family in any way. If you do decide to take part in the trial but change your mind later on, this is also completely fine. You just need to let the research team know and you don't have to give a reason. More information about this is given later on in this sheet.

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

Taking part in this trial will help you and your family find out more about mental health and emotions. The results of this trial could help create better ways of helping young people and their families with mental health.



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

We don't think that there are many disadvantages to taking part in this trial, however, there is a small chance that you may find some topics upsetting. If this happens you should speak to your parent/carer. The research team will also be able to support you and your family. If the research team becomes concerned about you, we will follow guidelines on how to deal with this. This will likely involve a phone call from the team to your parent/carer/school.

Expenses and payments

Each family that takes part in the trial will get a £25 voucher at the end of the trial if both parent/carer and young person fill out questionnaires at the start and after 6 and 15 months. This is to say thank you for taking part.

Will my taking part be kept private?

Information we collect about you and your parent/carer will be kept private and we will follow rules to keep this safe. This will only be used to help us run the trial and we won't use this information for anything else without your permission.

Details about your gender, name, address and mobile phone number will be stored at Warwick Clinical Trials

Unit. We need mobile phone numbers so that we can text you during the trial and phone your parent/carer. There will be also be some people helping us to make phone calls to parents/carers during the trial and your name and gender will be shared with them. When we've finished texting and phoning all families at the end of the trial (around the end of 2022), we will safely delete your name and contact details.

We need your contact details and address in case the trial team is worried about you and/or your parent/carer and is only collected in the unlikely event that we need to contact you or let other people know. This could include your parent/carer, school, doctors at Warwick Clinical Trials Unit and/or the emergency services.

You and your parent/carer will be given a code, made up of letters and numbers, which we will use as much as we can during the trial, instead of using your names. For example, there will be some times on the trial where other teams of people need to check that the information we are collecting is ok. We will use this code, instead of your name, so that they won't know who you are. These teams are used to checking this sort of information and this happens on other trials too.

Your school will not be told if you and your parent/carer decide to join the trial, except if we are worried about you, as mentioned above.

What will happen to the information collected about me?

The University of Warwick needs to make sure that it is in the public interest when we collect the personal information of people who take part in research. We will only use your information to help us run the trial and not for any other reason.

The University of Warwick will act as the 'data controller'. This means that we are responsible for your information and will follow rules to help us make sure it is kept safe. Warwick Clinical Trials Unit will keep all documents and participant information for at least 10 years after the trial is finished. All trials need to keep such information for a while after trials have finished. This won't include your names and contact details.



Monash University (in Australia) will be a 'data processor' for the trial and the 'Partners in Parenting' website (where your parent/carer will enter information about themselves and you) will be managed by them and kept safe in a Google cloud in the UK.

All other information we collect about you and your parent/carer will be collected via the PIPA Trial database. Only people working on the PIPA Trial will be able to log into this database.

If you give us some information and then ask us to change it, we might not be able to. This is because we need to follow rules on managing information and manage it in specific ways to keep it reliable and correct.

For further information, please follow the link 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.

Sharing information

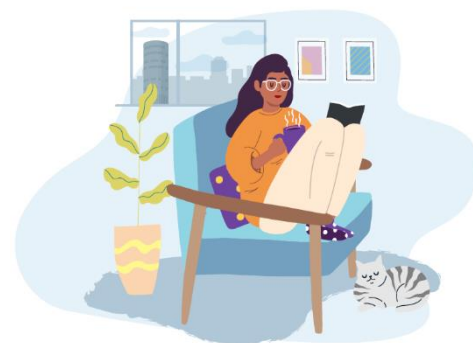
We will be using a text messaging service called 'Twilio' during the trial to help send out reminders to you to complete questionnaires. Your name and mobile phone number will be shared with 'Twilio' but this information will be deleted at the end of the trial (2022). Twilio's privacy statement can be found here <https://www.twilio.com/legal/privacy>.

If information is shared between the University of Warwick and other companies about the online questionnaires you fill in we will use your code and NOT your name, and the information will be kept anonymous. The only time your name and gender will be shared is with the people helping us to make the phone calls/texts during the trial and if we are ever worried about you.

We have data sharing agreements for all these reasons and information will be shared according to University of Warwick rules. We may use your anonymised information (not your name) for future research projects if your parent/carer lets us know at the start of the trial that this is okay.

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

Taking part in this trial is entirely up to you and you can stop taking part at any point without giving a reason and this won't affect you in any way. If you choose to withdraw, we will use any data that you have given us up to that point. Your parents/carers, however, can carry on working through the online resources if they want to. If you would like your parent/carer to stop completing the questionnaires about you, you can contact us and we will let them know that they will have to stop taking part.



What will happen to the results of the trial?

We will write up the findings of this trial in a report and in some educational journals. You and your parent/carer will not be named in any of the publications. If you would like to find out about the results of the trial after it has ended, please contact the research team.

Who has reviewed the trial?

This trial has been reviewed and approved by the University of Warwick's Biomedical & Scientific Research Ethics Committee (BSREC): BSREC 20/19-20.

Who should I contact if I want more information?

If, at any point during the trial, you have any questions, 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 worries 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 want to make a complaint?

Any complaint about the way you have been dealt with during this 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 would like to raise a complaint on how we have handled your personal information, 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 information 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 Young Person Information Sheet

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