**Parenting Intervention for Parents with Psychosis**

**in Adult mental health services**

**PARTICIPANT INFORMATION SHEET (PIS)**

**Invitation to take part in a research study**

You are being invited to take part in a research study to **use a self-directed parenting programme**.

Before you decide whether to take part, it is important for you to understand **what the study is about** and **why it is being done.**

Please read the following information carefully and take at least **48 hours to consider it**. Ask us if anything is **not clear** or if you would like **more information.**

**Who will conduct the study?**

Greater Manchester Mental Health (GMMH) NHS Foundation Trust and the University of Manchester will run the study.

It will be led by Lynsey Gregg (lynsey.gregg@manchester.ac.uk), a researcher from the University of Manchester.

The study manager is Holly Reid. Contact Holly if you have any questions about the study at pippa@gmmh.nhs.uk or on **07825 680 284.**

**What is the purpose of the study?**

The study aims to find out if using a parenting programme is helpful to parents with psychosis, and whether they find it easy to use.

The parenting programme is called the **Triple P positive parenting programme.**

It is a **10-week programme** that parents work through at their **own pace at home** using either a **workbook** to guide them, or an **online** programme on a computer, tablet or mobile phone.

We want **75 parents with psychosis** to take part.

**Why have I been invited to take part?**

You have been invited to take part because:

You are a **parent of a child aged 2-12**

You have experienced at least one episode of **psychosis** after the **age of 18**

You are under the care of **a care coordinator** who works at Greater Manchester Mental Health NHS Foundation Trust or Pennine Care NHS Foundation Trust

**What will I have to do if I take part?**

* You will meet a research worker to find out if you are eligible to take part.
* If you are not eligible, or do not want to take part, a researcher will ask you a few questions about **your background** (e.g., your age, children’s age, etc.) and your **reason for not taking part**. Answering these questions is **optional.** If you choose to give us this information, it will be **used for research**. It will not be linked to your personal data. This also means you will **not be able to withdraw** this data after you have given it.
* If you are eligible and you would like to take part, we will ask you to **sign a consent form.**
* We will ask for your consent to access your medical records and add a copy of your consent form. This means your clinical team will be able to see that you are taking part in this study but will not access your study data.
* Next you will fill in some **questionnaires** about your family, your children’s behaviour and your experiences of being a parent. You will also be asked to take part in an **interview** about your well-being and mental health. These assessments will take around **1.5 hours.**
* After this you will be placed in one of two groups:
**Group 1:**

You will receive your **usual care** from adult mental health services
(25 parents will be placed in this group).

**Group 2:**
You will receive your usual care and **in addition**, you will be given access to the **Triple P** **positive parenting programme** which you will be asked to complete within 15 weeks of starting it (50 parents will be placed in this group)

**Group 1:
Usual care only**

If you are placed in this group nothing will change in your usual care, you will take part in **study assessments only**.

At the end of the study, you will be given a copy of the Triple P workbook to keep and to use.

**Group 2:
Self-directed Triple P + Usual Care**

If you are placed in this group you will:

1. **choose** whether to access the Triple P parenting programme online (via a computer or mobile phone) or by using a workbook.
2. be asked to work through the **workbook** or **online programme** within **15 weeks**
3. **complete study assessments**

There will be no changes to your usual care except that your care coordinator might check on your progress with the parenting programme during their visits. They may ask how you are getting on with it, and whether you need any help. It will be up to you and your care coordinator to decide how much **support** you need to use Triple P, and how much to discuss it when you meet. We will ask your care coordinator to tell us how often they discuss it with you, by filling in brief questionnaires.

**How are the groups decided?**

Sometimes we don’t know which way of helping people is best. To find out, we need to compare different approaches.

To do this, we put people into groups and give each group a different treatment. The results are compared to see which approach is better.

To try to make sure the groups are the same to start with, each person who takes part is put into a group by chance (randomly). This is done after you have agreed to take part, by a computer which has no information about you. You cannot choose which of the groups you will be placed in.

You have a **1 in 3** chance of being placed in the usual care group, and a **2 in 3** chance of being placed in the self-directed Triple P plus usual care group.

**Study Assessments**

* You will be asked to **fill in questionnaires** and take part in an **interview** with the research worker at the start of the study and again **after 4 months**, and after **9 months**. This is to check whether things change over time and whether there is any benefit from using self-directed Triple P.
* At these appointments the research worker will ask about how you have been feeling: for example, how your mood has been, and about stress you have felt in relation to parenting as well as your child’s behaviour.
* You can choose to meet with the researcher **online** (on Zoom or MS Teams) or **in your home,** depending on which you prefer. We will make **appointments to suit you.** These questionnaires and interview will take around **1.5 hours.** They can be spread over more than one visit if you prefer.
* You will also be asked to complete two questionnaires over the telephone or online
**6 months** after starting the study.
* You will be involved in the research for **9 months in total** (the study overall will last for over 2 years).
* You will be asked **not to tell the research worker** whether you were placed in the Triple P group. This is so the research worker remains “blind” to which group you are in and is not biased in carrying out any assessments with you.
* We will ask you for permission to audio or video record some assessments. You can say no to us recording assessments and still take part in the study.

**Optional End of Study Interview**

* Some participants will be invited to take part in an **additional research interview** towards the end of the study to find out what they liked and disliked about the study. **This is optional**. You can say no to taking part in this interview and still take part in the overall study.

**Will I be paid to take part?**

We cannot pay you, but you will be given a **high street voucher** after completing each set of assessments as a thank you for taking part, as follows:

1. A £20 voucher at the start of study after the first assessments are completed
2. A £20 voucher after the assessments at 4 months
3. A £5 voucher after the questionnaires at 6 months
4. A £20 voucher after the final assessments at 9 months

If you agree to take part in the interview with a researcher about your experiences of the study will receive an additional £20 voucher after completing it.

* We will ask you to sign a separate consent form later if you are interested in taking part in this additional interview.
* Like the assessments, these interviews can be conducted online (Zoom, MS Teams) telephone, or in your home. This will take around 1 hour. This interview will be recorded and transcribed (typed out in full). You can ask us to stop recording at any time.
* We may use a University of Manchester approved external service to transcribe (type out) your interview. Anyone who transcribes your interview will have a duty of confidentiality to you.
* We will only interview **12-15** of the 75 parents that take part in the overall study. Due to small numbers, we might not be able to interview you, even if you express interest. If this is the case, we will inform you via telephone or email.
* Recordings of interviews will be protected by a password and will be destroyed after they have been transcribed. Any identifying information will be removed from the transcripts so that you cannot be recognised. Once your transcripts are de-identified, we will not be able to withdraw this data.

**What happens if I decide not to take part or change my mind?**
It is **up to you** to decide whether to take part. If you decide to take part, you will be given this information sheet to keep and will be asked to sign a **consent form**.

If you take part, you can **stop the study at any time**. This will not affect your usual care. We will use the data we have collected already in our research unless you tell us not to.

To stop, you should contact the study manager or your care coordinator and let us know. If you decide to withdraw, we will ask you to take part in an **optional withdrawal interview**, where we ask about your background, experience of taking part, and reason for withdrawing.

**This is optional.** You can choose to withdraw without giving us any further information. If you choose to answer these questions, the information will be used for research. You will not be identified.

**What happens if I become unwell?**
If you become too unwell to take part at any point during the study you would not be expected to continue, and we would stop all contact with you. If you become well again before your participation in the study was originally due to end, you may rejoin the study if your care coordinator confirms to us that you are well enough to do so, and that you are able to consent again.

**Who is organising and funding the study?**

The study is sponsored by **the University of Manchester** and organised in collaboration with **Greater Manchester Mental Health (GMMH) Foundation Trust.** It is funded by the **National Institute for Health and Care Research** **(NIHR)** as part of their Research for Patient Benefit programme.

All research in the NHS is looked at by an independent group of people, called a **Research Ethics Committee** to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by the Cambridgeshire and Hertfordshire Research Ethics Committee.

**Will my taking part in the study be kept confidential?**

Any **information** (name, address, telephone number, date of birth, audio recordings) that could **identify you** will be kept **confidential** and **stored securely** at the University of Manchester or in Greater Manchester Mental Health Trust in locked filing cabinets (paper copies) or on password protected secure servers (electronic copies) and will be destroyed as soon as possible.

Your name will not be on study documents (except consent form), you will be identified **by a study number** only.

Only **authorised people** will be able to see your personal information. This includes members of the **study team**, as well as **regulatory authorities** from the NHS and the University of Manchester.

Your **clinical team** (including your GP and your care coordinator) will be **informed that you are taking part** in this study but will not be able to see any data we collect.

If you tell us anything that suggests **you or someone else is at risk of harm**, we may have to **inform authorities**, such as your **GP or the police**. We will involve you in this decision as much as possible.

We may pass on your contact details to our Admin Team so they can send you shopping vouchers as a thank you for taking part. If you give us consent, we will keep your contact details for up to 5 years.

**What will happen to the results of this study?**

* We will publish the results of this study in an **academic journal**
* The results may also be presented in **conferences**
* We may publish **anonymised direct quotes** from your interview
* Anonymised data may be made available to other researchers
* You will **not be identified** in any of these uses

We can **send you a summary** of the results if you allow us to keep your contact details. If you give us consent, we will store your contact details for 5 years after publication.

**What are my rights regarding the data you collect about me?**

You have a of rights number of rights under data protection law regarding your personal data, for example, you can request a copy of the information we hold about you. If you would like more about your rights or how researchers use data about patients,

please visit: [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)

You can also ask a member of the research team for more information.

**What are the benefits of taking part?**

We hope that having access to Triple P will help you, but we cannot promise this. The information we get from this study may help us to **improve the care** of parents with psychosis in in the future.

**What are the risks of taking part?**

The assessments involve talking about your children and how you are feeling which you may find upsetting. You can **pause or stop** the study at any time. You are **free to withdraw** from the study at any time.

**What if I need more information or there is a problem?**

If you need any further information, or have any concerns about the study please contact the Study Manager, **Holly Reid** on **07825 680 284** or at **pippa@gmmh.nhs.uk**

If you would like to make a **formal complaint** to someone **outside the research team,** for example, if the research team has been **unable to address your concerns**, please contact:

The Research Ethics Manager, Research Office, Christie Building,
The University of Manchester, Oxford Road, Manchester, M13 9PL
Email: research.complaints@manchester.ac.uk
Telephone: **0161 306 8089.**

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner’s Office](https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Flinks.uk.defend.egress.com%2FWarning%3FcrId%3D654d2d828a45ba069068ccf4%26Domain%3Dgmmh.nhs.uk%26Lang%3Den%26Base64Url%3DeNrLKCkpKLbS189MztfLL0rXK83WT87PS04tyisGAIpgChU%253D&data=05%7C01%7Caansha.priyam%40gmmh.nhs.uk%7Cc75fc028378f4eec083c08dbe156dcea%7C0a8053324f1b4f7e9fc9d4b8f03d6174%7C0%7C0%7C638351535435520996%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=PPAr5lgR523tzja%2BbVvp5v%2FdElafFZIUSlrjEkIZEDI%3D&reserved=0) about complaints relating to your personal identifiable information Tel 0303 123 1113

**Thank you for reading about our study!**

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**DATA PRIVACY STATEMENT**

The law says that we must have a **legal basis** to collect your data. This means we need to have a particular **reason** for collecting your data. We can collect your data under two legal bases:

1. A task carried out in the public interest
2. A process necessary for scientific research purposes

The University of Manchester and Greater Manchester Mental Health NHS Foundation Trust are the **data controllers** for this research.

This means that they are **responsible** for making sure your data is:

1. Kept securely and confidentially
2. Only used in the way the researchers tell you it will be used
* Your name and any other personal data we collect will not be stored with your research data. A computer-generated ID code will be used will be used to link the two.
* Research data will be kept for **5 years after the study has been published.**
* Your contact details will be kept for **5 years after the study has ended.**
* Your anonymised data may be used by other researchers after the study has ended.

You can learn more about your data privacy by reading The University of Manchester privacy notice: https://documents.manchester.ac.uk/display.aspx?DocID=37095