PARTICIPANT INFORMATION SHEET

Psychodynamic Interpersonal Therapy for psychosis (PITp)

Please read this information before deciding whether to take part. A member of our team will go through this information sheet with you and answer any questions. **Taking part is completely your choice**, and whatever you decide will not affect your usual care.

SUMMARY

Why are we giving you this sheet?

We are inviting you to consider this study. You are invited because you experience psychosis. You **do not** have to take part **- you can withdraw at any time.** This will not affect your usual care**.**

What is the study about?

We are testing if it's practical and acceptable to offer Psychodynamic Interpersonal Therapy for people experiencing psychosis (PITp) in the NHS, to plan a larger study in future.

What would taking part involve (and how long)?

- A brief introductory contact (about **15 minutes**)
- An informed consent meeting (about **20 minutes**)
- An assessment with a Research Worker (about **1 hour**)
- You are then allocated by chance (50/50) to:
  - **PITp + usual care**
    OR
  - **Usual care only**
- A follow-up assessment about **6 months** later (about **1 hour**)

About the therapy (if you are allocated to PITp)

PITp is a talking therapy with weekly sessions for up to 6 months. Sessions give you space to talk about feelings, relationships, and experiences such as voices, visions, or distressing beliefs.

Payment and expenses

We will reimburse **£20** for each research assessment meeting (baseline and 6 months). Therapy sessions are not paid.

Potential risks

Some questions or therapy conversations may feel upsetting. You can skip questions, take breaks, or stop at any time. You may feel disappointed if you do not receive PITp and are allocated to usual care only.

Who to contact

Chief Investigator: Dr Liz Murphy, elizabeth.murphy@gmmh.nhs.uk, 0161 938 4568

What is the aim of the PITp trial?

This is an early-stage study with around 40 people with psychosis. The aim is to find out whether Psychodynamic Interpersonal Therapy for psychosis (PITp) can be delivered within NHS services in a way that is practical and acceptable, and to collect information to help plan a larger future study.

PITp is an adapted version of Psychodynamic Interpersonal Therapy (PIT) for people experiencing psychosis. In some services, PIT is also known as the Conversational Model of therapy. PITp involves an in-depth, "heart-to-heart" conversation that focuses on feelings and relationships, with space to explore experiences of psychosis if you wish. PIT has been well researched for other complex mental health difficulties, and early case studies suggest it may also be helpful for people with psychosis. This study is the first step towards planning a larger research study.

Who are we looking for?

We are looking for people who:

- are aged **18 or over**
- are currently **receiving care from NHS mental health services for psychosis**

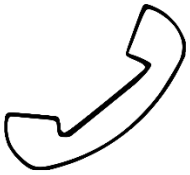
Do I have to take part?

No, you do not have to take part. You can take time to decide. If you take part, you will be asked to sign a consent form. You can still stop taking part at any time without giving a reason. This will not affect your usual care or your rights.

What will happen if you choose to take part?

First introduction (around 15 minutes)

A Research Worker will contact you to briefly explain the study and provide this information sheet. With your permission, they will check your clinical notes to see if the study may be suitable, and if so, invite you to another meeting.



Consent meeting (around 20 minutes)

You can ask questions and discuss whether the study is right for you. If you decide to take part, you will sign a consent form. The Research Worker will ask a few questions about your diagnosis and current care to confirm eligibility. If suitable, you will be invited to the baseline assessment.

Baseline assessment meeting (about 1 hour)

The Research Worker will ask questions about how you are doing (including experiences such as voices/visions, mood and day-to-day life). You will receive £20 for your time. This can happen on the same day as the consent meeting or be arranged for another day. We will try to arrange meetings at a time and place that suits you (for example, at home or where you see your care team). You can take breaks or shorten a meeting if needed.

After the baseline assessment: Study Allocation

You will be randomly allocated by computer to receive **PITp in addition to your usual care or receive usual care only**. There is a 50:50 chance, like flipping a coin.
If allocated to PITp, you will have weekly sessions for about 6 months, and the therapist will access your clinical notes as part of NHS care.

Usual care: The care you would usually receive with your care team.

Usual care plus PITp: If you are allocated to PITp, you will be offered weekly sessions with a trained therapist **for up to 6 months**. You can talk about difficult feelings, relationship problems, your past, and, if you wish, experiences such as voices, visions or distressing beliefs. The therapy aims to help you develop an understanding of your difficulties and to face and accept feelings, including feelings you would normally try to push away or avoid. **The therapist will go at your pace - you do not have to talk about anything you do not want to.**

Follow-up assessment after 6 months (about 1 hour)

All people taking part in the study will meet the Research Worker again **6 months** later and be asked the same set of questions. We will reimburse **£20** for Research Worker meetings only (not therapy sessions).

Additional options

Recording for quality

With your permission, we may audio-record some assessment or therapy sessions for quality checks. You can say no to recording and still take part.
We will also ask separately if you agree for your anonymised therapy recordings and quotes (with names and identifying details removed) to be used for teaching and training, and to help explain what we learned from the study.

Optional extra study

If you receive PITp, we would like to invite you to an optional interview (up to 1 hour) about your experience of the therapy, even if you do not complete all sessions. We will ask you separately if you would like to take part.

These extra options are voluntary. Saying yes or no **will not affect** your care or your participation in the main PITp trial.

What are the advantages and disadvantages of taking part in the PITp trial?

Possible advantages

- Taking part will help inform future research into talking therapies for people with psychosis and may lead to better NHS care in the future.
- If you receive PITp, you may find it helpful, although this cannot be guaranteed.
- The therapy gives you space for weekly “heart-to-heart” conversations with a trained and supportive therapist. This may help you better understand your feelings, relationship patterns, and experiences such as voices, visions or distressing beliefs.
- Making sense of difficult experiences can help people feel less distressed over time and learn ways to manage their difficulties more effectively.

Possible disadvantages

- Not everyone taking part will receive PITp, and you may feel disappointed if you are not allocated to therapy. You can still access other support as part of your usual NHS care.
- Some questions in the research assessments may feel upsetting. You can skip questions, take breaks, or stop at any time.
- If you receive PITp, talking about difficult feelings may sometimes feel upsetting. Your therapist will go at your pace and support you. Some people feel more emotional at first, but this usually settles. Research into all therapies shows that therapy does not help everyone, and a small number of people may feel worse by the end. Serious lasting harm is rare. If you ever feel worse, please tell your therapist or contact your usual care team.
- In the unlikely event that something goes wrong and you are harmed by taking part, you may be able to take legal action for compensation, but you might have to pay your legal costs. The lead sponsor, GMMH NHS Foundation Trust, is responsible for any compensation for injury related to the study. The normal NHS complaints process is also available.

What if I want to withdraw from the study

You can withdraw from the study at any time, without giving a reason. This will not affect your NHS care in any way. If you would like to withdraw, or if you have any questions about the study, please contact the Chief Investigator: Dr Liz Murphy, Tel: 0161 938 4568, Email: elizabeth.murphy@gmmh.nhs.uk.

How do I complain if I am not happy with the conduct of the study?

If you have any concerns, please speak to the Research Worker or the Chief Investigator: Dr Liz Murphy. They will do their best to help.

Email: elizabeth.murphy@gmmh.nhs.uk
Phone: 0161 938 4568.

You can complain by contacting the Complaints Team at GMMH:
Email: complaints@gmmh.nhs.uk
Call: 0161 358 0600

It will be helpful to keep this sheet in case you need it for future reference.

What happens if I cannot make an informed choice to take part?

If we think you cannot make an informed choice about continuing, we will withdraw you from the study. We will keep and use the information collected up to that point.

Who will know I am taking part?

The research team and the NHS staff involved in your mental health care will know you are taking part. If you agree to join the study, we will make a note in your GMMH Health and Social Care Record (called PARIS) when we contact you, provide therapy sessions or complete an interview.

Authorised NHS staff will look at your medical records for this study (for example, Dr Liz Murphy, the Research Worker, your therapist, or named staff in GMMH Research and Innovation). We will not share what you tell us with your care team unless you say we can.

We would only share information without your permission if we were concerned that you or someone else was at serious risk of harm. If possible, we would talk to you first. We may share this with a relevant professional, such as your care co-ordinator or another member of your care team, or GP.

How will we use information about you?

We will need to use information from, you, your medical records and your care team for this research project.

This information will include your:

- First and last name
- Date of birth
- Health and Social Care Record (PARIS) ID number
- Contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

GMMH is the sponsor of this research. GMMH is responsible for looking after your information. We will not share your information related to this research project with any other organisations.

We will keep all information about you safe and secure by:

- Giving you a unique study identification number (code number) so your name does not appear on any research data
- Storing electronic copies of your information on a secure NHS drive only accessible to the research team
- Storing your written consent forms in a locked NHS cabinet in a locked NHS office.

International transfers

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will keep your study data for a maximum of 5 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- you have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- by reading this leaflet http://www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to the Chief Investigator elizabeth.murphy@gmmh.nhs.uk
- by sending an email to the Sponsor's Data Protection Officer informationgovernance@gmmh.nhs.uk
- by ringing us on 0161 938 4568.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research https://www.gmmh.nhs.uk/gdpr-in-research

What will happen to the results of the PITp trial?

The results will be presented in scientific papers and at conferences. It will not be possible to identify anyone who has taken part in the study. We will also make a summary of the results available to participants if they would like one. We hope to use the results from this study to plan a larger trial of PITp.

Who is funding the PITp trial?

The project is funded by the National Institute for Health Research (NIHR) Doctoral Clinical and Practitioner Academic Fellowship funding scheme. The results will contribute to a PhD qualification. The study is sponsored by GMMH NHS Foundation Trust and has undergone NHS Research Ethics Committee review. The Chief Investigator is Dr Liz Murphy.

What happens if you would like more information or want to get in touch?

If you would like to ask any questions or receive more information about the PITp trial then please contact:

Chief Investigator: Dr Liz Murphy
Email: elizabeth.murphy@gmmh.nhs.uk
Phone: 0161 938 4568

Thank you for reading. Please keep a copy of this information sheet.

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