[Insert logos of local NHS Trust and University]

Participant Information Sheet

Improving Social Recovery in Psychosis: a definitive randomised controlled trial and process evaluation of Social Recovery Therapy compared to treatment as usual for people with psychosis and severe social disability

This project is funded by the National Institute for Health Research Health Technology Assessment Programme (project number: NIHR169529).



Hello. I'm Jo Hodgekins, a Clinical Psychologist and Associate Professor at the University of East Anglia, and I lead the Improving Social Recovery in Psychosis research study. For over 15 years I've been doing research to support people who have experienced psychosis reconnect with activities they find meaningful, to understand why this can be difficult, and to come up with new treatments that might help. This study tests a talking therapy we've developed, called Social Recovery Therapy, or SRT for short. SRT is an approach that combines practical strategies and psychological support to help people improve their confidence and independence after psychosis and spend more time doing the things they enjoy.

We would like to invite you to take part in a research study called the Improving Social Recovery in Psychosis study. Before you decide to take part, we would like you to understand why this research is being done and what it will involve for you. Taking part is completely your choice and your decision will not affect your care. This information sheet will tell you about why the project is being done and what will happen if you decide to take part. Please take as much time as you need to read this information sheet. It includes a lot of information so please feel free to read one section at a time, taking breaks if you need to. A researcher will also go through it with you and will be happy to answer any questions.

What is this study about?

- Those who have experienced psychosis sometimes struggle with activities e.g. work, school or leisure
- We put you in contact with a therapist for “social recovery therapy” (A talking therapy)
- It is our hope that this therapy will lead to a better social recovery

This study is for people who are:

- Aged 18+
- Who are receiving support from NHS mental health services in East Anglia, Sussex, Pennine and Northeast of England, and
- Have experienced psychosis, and
- Are not spending much time doing structured activities e.g. work, education, housework, leisure activities etc

If you are interested in taking part in the project, we will ask you some questions about how you are spending your time to help us decide whether this project is right for you.

Do I have to take part?
No, it is up to you to decide whether or not you want to take part. If you do decide to take part, you will be given this information sheet to keep and will also be asked to sign a consent form. Even if you decide to take part, you can change your mind at any time without having to give a reason. If you decide not to take part, or to stop taking part at any point, will not affect any usual support you may be receiving or your medical or legal rights in any way.

What is the therapy being tested?
The therapy is called **Social Recovery Therapy (SRT)**. It's a talking therapy aimed to help people who have experienced psychosis spend more time doing activities that are meaningful to them.

You'll work with a therapist to choose activities you'd like to do and explore what might be making them difficult. Together, you'll find ways to overcome these challenges. The therapy also aims to help you understand your experiences and feel less worried about trying new things.

Sessions are usually weekly for up to 9 months, lasting about an hour. Some sessions involve talking and others may include going out and trying new things. Timing and location are flexible and agreed between you and your therapist.

Why is the study called a 'randomised controlled trial'?
SRT is a relatively new therapy, so we need to find out if it's helpful. To do this, we will put people into two groups:

- One group receives SRT alongside usual care.
- The other group receives usual care only (this is the 'control' group, which allows us to make comparisons).

A computer will randomly assign participants to one of these two groups. It ensures both groups have an equal spread of level of social difficulties but doesn't use any other personal information. This process is called 'randomisation'.

Randomisation helps to make the study fair. It can feel disappointing not to receive the therapy. However, the decision is not a judgement about you or anything to do with your health, background, personality, or anything you did or didn't do.

Because we have two groups—one with SRT and one without—the study is 'controlled.' Each group will be the same size, so everyone has a 50/50 chance of receiving SRT in addition to usual care.

What will happen if I decide to take part?

Here is an overview of what will happen if you take part in the study.

Eligibility Meeting and Assessment

If you decide to take part, you'll meet with an independent research assistant at a time that suits you and in a confidential space of your choice – either at home or in an NHS clinic. Some meetings may be able to take place online or over the phone. During this meeting, you'll be asked to complete some questionnaires about your current difficulties and social situation. You will complete these with the research assistant, either electronically or on paper, depending on your preference. The assessment takes around two hours in total, spread over two or more sessions to make it as comfortable as possible. You're welcome to have a friend, relative, or worker with you if you'd like. If you wish, we can also provide a brief written summary of the assessment for you to keep and share with your care team.

Random Allocation

After the assessment, you will be **randomly** placed into one of two groups: either the group offered SRT alongside your usual care, or the group that continues with usual care without SRT. A member of the research team will let you know which group you have been placed in, and we will also inform your current care team.

The therapy group

If you are in the therapy group, in addition to your usual care you will be offered weekly or fortnightly meetings with a therapist for up to 9 months. The therapy sessions will take place at a time that suits you and in a confidential space of your choice – either at home or in an NHS clinic.

The control group

If you are in the control group, you will still receive your usual care but without the additional SRT.

Assessments

You will be invited to meet with the research assistant again to repeat the first assessment at two further points—9 months and 15 months after your initial assessment. You and a family member may also be invited to take part in an additional interview to share your experiences of the study and any treatment you received, but you can choose not to take part in this interview if you prefer. We would not ask your family member to take part if you did not consent for us to do so.

Follow Up

Your face-to-face contact with the research team will finish after 15 months, but we would still like to understand the longer-term effects of SRT. To do this, we will look at information from your health records to see how you are doing two years after your first assessment. We won't need to meet with you for this, but we will send you a short text message or email—whichever you prefer—to ask a few quick questions about how you've been spending your time since your 15-month assessment.

If you are in the therapy group, we may audio record some of the sessions you have with your therapist with your permission. This is because we want to check that the therapy is being carried out in the way that we expect. All recordings will be stored securely on computer systems on University or NHS sites and anyone listening to the recordings will sign a declaration of confidentiality. All recordings will be deleted after they have been checked.

We would also audio record any interviews you take part in about your experiences of the therapy or taking part in the study. This is so that we can remember what you've said accurately, but we will store the recording in an anonymous way so that you cannot be identified and will erase it once we have used the information you have given us.

What are the possible risks of taking part?
If people feel pressurised into undertaking new activities, they can sometimes find that certain psychological difficulties get worse or come back. However, the aim of SRT is to help people explore new activities they want to do while taking care to minimise the risk of any psychological difficulties.

What are the possible benefits of taking part?
If you wish to take part you will:

- Meet with a researcher to see what activities would be meaningful to you
- Have regular meetings with a therapist to help with this
- Get offered three x £20 payments (in vouchers)

What happens when the research stops?
When the research project finishes, all participants will receive standard care from their usual team.

What happens if something goes wrong?
If you are harmed by taking part in a research project, there are no special compensation arrangements. If you are harmed by someone's negligence you may have grounds for legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the study, the normal National Health Service complaints mechanisms will be available to you.

Will my taking part in this project be kept confidential?
If you consent to participate in the study, we will inform the team responsible for your care that you are taking part in the research project. If we believe that there is any risk to your safety or the safety of anyone else, we will have to pass this information on to your current care team.

With your permission, we may also share other information you give us during your assessments with your current care team, for example, information about your mental health and social situation which might be important for your care. The study team and individuals from authorities responsible for making sure the research is done properly may look at relevant sections of your medical records.

How will we use information about you?
We will need to use information from you and your medical records for this research project. This information will include your initials, NHS number, name and 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.

Sussex Partnership NHS Trust and the University of East Anglia are Sponsors of this research and are responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- NHS England so that we can collect information about how you are getting on in 2 years' time.

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

- Storing paper copies of consent forms and questionnaire in locked filing cabinet
- Keeping electronic data (e.g. typed up notes of interviews, audio recordings) on secure computer systems on University or NHS sites
- Ensuring that data is transferred between sites securely to ensure no-one outside the research team is able to access it.

Your data will not be shared outside of the UK.

How will we use information about you when 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 10 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, and without it having any impact on any other care you receive. We will keep information about you that we already have..

If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS record. If you do not want this to happen, tell us and we will stop.

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, and you can decide if you want to continue being involved in the project or not.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. Your anonymised research data may be shared with other researchers to help learn more about social recovery following psychosis. The data would be stored securely, and you would not be able to be identified.

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

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

- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking someone from the research team
- by sending an email to dataprotection@uea.ac.uk

What will happen to the results of the research?

The results of the study will be written up for publication in health professional journals and will be presented at conferences in the UK and abroad. When we report the results of the research we may quote some of your words, however your anonymity will be preserved at all times. You can choose to be kept informed of any publications resulting from the study.

Who is organising and paying for the research?
The research is being paid for by the National Institute of Health Research (NIHR) Health Technology Assessment Programme. It is sponsored by Sussex Partnership NHS Foundation Trust and the University of East Anglia. The research is being carried out by researchers from Sussex Partnership NHS Foundation Trust, Norfolk and Suffolk NHS Foundation Trust, Cambridgeshire and Peterborough NHS Foundation Trust, Pennine Care Foundation Trust, Cumbria Northumberland Tyne and Wear NHS Foundation Trust, the University of Sussex, University of East Anglia and the University of Manchester.

How have patients and the public been involved in this study?
Service users with lived experience of mental health difficulties helped develop the research topic and what research questions should be asked and one of them is a co-applicant who will continue to be involved in the study.

In designing this study, we have listened to the opinions of people with lived experience on the frequency of participant visits and the questionnaires that we will use. People with lived experience have also reviewed all study materials, including this Participant Information Sheet.

Who has approved the research?
Research projects like this one can't go ahead without being approved by an NHS Research Ethics Committee. The Ethics Committee checks that the risks associated with the study have been reduced to a minimum and balanced against potential benefits. They also check you have been given enough information to make an informed choice about whether to take part. This study has been considered and approved by the London Bloomsbury Research Ethics Committee (26/LO/0203).

Where can I get more information?
For general information about taking part in research you can contact your local NHS trusts' research and development department:

[Insert as appropriate for local site]

If you need further information about this specific project, please contact a member of the study team. You can contact the team at any time using the following email address:

isrip.study@uea.ac.uk

If you would prefer to contact the team by phone, the names and telephone numbers of some team members are given below. They can be reached during office hours, Monday to Friday.

Dr Jo Hodgekins	Chief Investigator	J.Hodgekins@uea.ac.uk
Lauren Ooi	Trial Manager	L.Ooi@uea.ac.uk
Xxx	Local Principal Investigator for site	[insert contact details]

If you would like to speak to someone independent of the study team, for more information or if something goes wrong or you would like to make a complaint, you can speak to your local PALS (Patient Advice and Liaison Service).

[Insert as appropriate for local site]

Thank you for reading this!
Thank you for taking the time to read this information sheet. If you decide to take part in the project you will be given a copy of this sheet, together with a copy of your consent form, to keep.