



## SECURE CARE HOSPITAL EVALUATION OF MANUALISED (INTERPERSONAL) ART- PSYCHOTHERAPY: A RANDOMISED CONTROLLED TRIAL

### Participant Information Sheet V1.3, 13/01/2023

#### STUDY SUMMARY

- Art Therapy (Art Psychotherapy) can be helpful for people who find it hard to talk about how they are feeling or thinking.
- We want to see if art therapy is helpful for people like you.
- Everyone who takes part in this research will be able to have art therapy at some point.
- Some people will have to wait a bit longer to get art therapy.
- During the study you will be asked to complete some questionnaires about your mental and physical health. You will be asked questions at the start, after four months, and after nine months.
- We are a research team from Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust and Cardiff University.

#### WE WOULD LIKE TO INVITE YOU TO TAKE PART IN A RESEARCH STUDY

- Before you choose to take part in the research it is important that you know why the research is being done and what will happen.
- You can speak with staff, family, and friends before choosing to take part or not.
- You are free to choose if you would like to take part and can say 'YES' or 'NO'.
- If you choose to take part and then change your mind you can ask to stop. You do not have to say why. The care and support you get will not change.
- If you have any questions about the research do ask us.
- If you choose to take part in this research, we will give you a copy of this information sheet and ask you to sign a consent form.

There are two sections to this information sheet:

**Section 1:** Tells you about the research and what will happen to you if you take part.

**Section 2:** Gives you more information about the research.

## PART 1. PURPOSE OF THE STUDY AND WHAT WILL HAPPEN

### WHY ARE WE DOING THIS STUDY?

We want to find out if Art Therapy (interpersonal art psychotherapy) is helpful and 'value for money' for people who are in secure care. We will find this out by checking how helpful it was for people who had art therapy first against people who wait a bit longer to get it.

To do this we will need to recruit 200 people. If you agree to take part in the research, you will either get to start art therapy or you will have to wait nine months before you start it. Everyone taking part in the research will get art therapy at some point.

Whether you are doing art therapy or not a member of the research team will meet with you to ask you questions about your mental and physical health. They will then meet with you after four months and again after nine months.

### WHY HAVE I BEEN INVITED TO TAKE PART?

You have been invited to take part because you are in secure care.

### DO I HAVE TO TAKE PART?

'No' you do not have to take part. It is your choice.

A member of the research team will tell you about the study and this information sheet. You can ask questions before you choose to take part.

If you want to take part, you will be given the information sheet to keep and you will be asked to sign a consent form.

You are free to stop taking part in the research at any time, you do not have to say why. If you change your mind, your hospital care team will continue to provide you care and support.

### WHAT WILL HAPPEN TO ME DURING THE STUDY?

When you start the research	In the research	After 4 months (19 weeks)	After 9 months (38 weeks)
<ul style="list-style-type: none"> <li>your case notes are reviewed</li> <li>you complete questionnaires about your health and mood</li> </ul>	<ul style="list-style-type: none"> <li><b>You could get</b></li> <li>Art Therapy at the start, <b>OR</b></li> <li>Art Therapy at the end</li> </ul>	<ul style="list-style-type: none"> <li>your case notes are reviewed</li> <li>you complete questionnaires about your health and mood</li> </ul>	<ul style="list-style-type: none"> <li>your case notes are reviewed</li> <li>you complete questionnaires about your health and mood</li> </ul>

## Getting art therapy at the start or waiting for it

A computer will decide which people in the research get art therapy straight away and which people wait a bit longer. This means it is decided by chance. The process is called randomisation.

We do it this way so that the results of the research are fair, and we can check the results properly.

## Art Therapy

The art therapy lasts for 12 weeks. You will go once a week for one hour, with more sessions if you need them. You will get to work with the therapist by yourself. You will be asked to draw and make artwork in the sessions and speak to the therapist. You do not need to be good at art to do art therapy. Doing art in therapy can help people to think clearly and make it easier for you to communicate.

## Research Questions

You will be asked to complete some questionnaires about your mental and physical health.

Your care team will be asked to share some information from your case notes. Your case notes will tell us about the treatments and activities you do and any events that are recorded during the research.

The questionnaires take about 40 mins to complete. Someone from your care team or research team can help you to answer the questions or you can choose to do them on your own.

In this research you will be asked to complete the same questionnaires 3 times. Once at the start, once after four months, and then one last time nine months after you started.

## Recordings

If you say yes, the therapist will record your therapy sessions (only the words you say, not pictures or video). Only people in the research team will listen to the recordings. Written notes will be taken from the recordings. The recordings will then be deleted.

Your name and personal information will not be on the notes. We will use the notes in our research to see how the therapists worked with you and what was helpful to people in the therapy.

## You can choose to tell us what you thought about taking part in this research

If you would like to you can tell us what you thought about taking part in the research. You can choose to be interviewed by a member of the research team and you can tell them about what being in the research was like for you.

### WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

Art therapy may help you feel better. When we know the results at the end it could help other people to make choices about their therapy. This could help their mental health and mood.

### WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

You will need to give up some of your free time to take part in the study.

Sometimes people can feel emotional during and after art therapy, but your art therapist or staff will help you with this.

### WILL I BE PAID FOR TAKING PART IN THE STUDY?

You will not be paid for taking part, but you will receive a total of £50 in 'love to shop' vouchers for questions you complete during the study. This will be a £15 voucher at the start, £15 after four months, and £20 after nine months.

## This completes Part 1 of the Information Sheet

If the information in Part 1 has interested you and you are considering taking part, please continue to read the additional information in part 2 before making any decision.

## PART 2. DETAILED INFORMATION ON STUDY CONDUCT

### WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON TAKING PART IN THE STUDY?

You can choose to stop taking part in this research at any time. You do not have to complete all the questionnaires. You can speak to your care team or a member of the research team about this.

If you choose to stop taking part in the research, the information we have already collected about you could still be used. You can ask for this information to be destroyed. You can speak to your care team or a member of the research team about this unless we have written about the research already. When we do write about the research your name will not be used and nobody will be able to know who you are.

### WHAT IF NEW INFORMATION BECOMES AVAILABLE?

If there is important new information about art therapy when we are doing this research your study doctor, or a member of your care team will tell you about it. They will help you choose if you want to continue taking part in the research and you can tell us what you would like to do.

### WHAT IF THERE IS A PROBLEM AND I WISH TO COMPLAIN?

If you are unhappy about any part of this research, you can tell the research team who will do their best to help you. You can email us or ask a member of your care team to get in touch with us, using the email address [schema@cardiff.ac.uk](mailto:schema@cardiff.ac.uk) or [CNTWSponsormangement@cntw.nhs.uk](mailto:CNTWSponsormangement@cntw.nhs.uk)

If you still feel upset you can tell a team in the NHS, the NHS complaints advocate:  
<https://www.nhs.uk/using-the-nhs/about-the-nhs/how-to-complain-to-the-nhs/>

[INSERT LOCAL PALS CONTACT DETAILS]

If something does go wrong, and you are harmed during the research and this is due to someone's mistake then you may have grounds for a legal action for compensation against Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints system will still be available to you to use (if appropriate).

### WILL MY INFORMATION BE KEPT SAFE (CONFIDENTIAL)?

All information collected about you will be kept secret (confidential) and safe (secure) and the research team will follow Data Protection laws.

If you choose to take part in the research, we will give you an ID number when we collect your questionnaire answers. We will not use your name. The information we collect will be about the treatment you get and your mental and physical health.

All study data will be kept securely by people in the research team (this means it has 'restricted access').

## WHAT ARE THE DATA PROTECTION ARRANGEMENTS?

Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust are the 'sponsor' of this research, this means they are responsible for managing it. They are being helped by researchers at Cardiff University and have money for the study from the National Institute for Health Research.

We will only collect information that is really needed. The research will use information from you and your case notes. We will look after it safely and use it properly.

We will not share your name or personal details.

The information collected during the study may be shared with other researchers in the UK, or abroad, for example other universities or companies. After the study is over, we will keep the information for 5 years in a safe place.

To make sure the research is reliable, you will not be able to see or change the information we have collected about you. If you want to stop being in the study your information could still be used. You can ask for this information to be destroyed but we might not be able to destroy it.

You can find out more about how we use your information by asking one of the researchers or looking at these websites:

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

Or you can write to the study sponsor's Data Protection Officer at:

Data Protection Officer

Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust

St Nicholas Hospital

Jubilee Road

Gosforth

NE3 3XT

by phone: 0191 246 6896 or by email: [DPO@cntw.nhs.uk](mailto:DPO@cntw.nhs.uk)

-or at <https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection> and

## WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH?

At the end of the study the results will be written in reports. The results and reports will be shared with other researchers and the public. We may use things you have said in our reports but you will not be identified in any reports or presentations about the study. At the end of the study, you will be able to see a summary of the results here:

<https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/schema>.

## WHO HAS REVIEWED THE TRIAL?

All research is looked at by an independent group of people, called a Research Ethics Committee to protect your interests. This trial has been reviewed and approved by  
XXXXXXXX

## CONTACT FOR FURTHER INFORMATION

If you have any questions or would like further information about the trial please contact  
[schema@Cardiff.ac.uk](mailto:schema@Cardiff.ac.uk) or your hospital trial team.

<LOCAL SITE CONTACT DETAILS>

**Thank you for reading this information and considering taking part in this trial.**