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

Therapist Information Sheet V1.2, 13/01/2023

STUDY SUMMARY

- People with learning disabilities in secure care are more likely to stay there longer than people without a learning disability.
- Records show that people in secure care hurt either themselves or others more often than in other mental health hospitals.
- People who struggle with reading information and communication can find creative approaches a helpful way to understand and manage their own mental health needs.
- Art psychotherapy is a therapy where people work with a therapist and make artwork to help them to communicate about any difficulties they are having. It can be helpful for people who find it hard to talk about what they are thinking about, feeling, or struggling with.

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

- Before you decide to take part it is important you know why the research is being done and what it will involve.
- You can discuss with the management team at your trust before making a decision.
- You are free to decide whether you would like to take part.
- If you choose to take part and then decide you no longer want to be involved you can stop taking part without giving a reason.
- Please let us know if there is anything in this leaflet that is not clear or if you would like more information. A member of our team will answer your questions.
- If you decide to take part, we will offer 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 the purpose of the study and what will happen to you if you take part

Section 2: Gives you more detailed information about the conduct of the study

PART 1. PURPOSE OF THE STUDY AND WHAT WILL HAPPEN

WHY ARE WE DOING THIS STUDY?

We want to find out if a manualised interpersonal art psychotherapy approach reduces aggression in people with learning disabilities who are in secure care. We will be testing if interpersonal art psychotherapy is more effective and cost efficient compared to usual care.

As part of the trial, we also want to understand the experiences of therapists who deliver art therapy. We would like to invite you to take part in an interview to discuss your experiences.

WHY HAVE I BEEN INVITED TO TAKE PART?

You have been invited to take part because you are part of the therapy team delivering the interpersonal art therapy.

DO I HAVE TO TAKE PART?

No. It is up to you if you decide to take part in this study. Participation is entirely voluntary. If you decide to take part, you will be given the information sheet to keep and you will be asked to sign a consent form. Please feel free to ask any questions before you decide whether to take part.

WHAT WILL HAPPEN TO ME DURING THE STUDY?

A researcher will contact you to ask if you would be happy to participate in the interview, which will last up to 1 hour. The interviews will explore your experience of delivering the intervention and supervision, examples of 'in-therapy' responses from participants, and implications for clinical practice. The interview can take place face to face, over the phone or over web-conferencing software (Zoom or teams for example). If you agree to take part, the interview will be arranged at a time convenient for you. We would like to record the interview and request your consent to do so. The audio recording of the interview will be transcribed (typed up).

WHAT ARE THE POSSIBLE BENEFITS AND DISADVANTAGES OF TAKING PART?

It's unlikely you will see any direct benefits, but you will be helping to improve care for those with mental health difficulties in secure care. The main disadvantage is you will need to give up some of your time to take part in the study.

WILL I BE PAID FOR TAKING PART IN THE STUDY?

You will not be paid for taking part in the study.

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?

Taking part in the study is entirely voluntary. You can decide to stop the interview at any time.

Even if you stop taking part in the study, the information we already recorded about you might still be used. You can ask for these to be destroyed but we ask that you talk to your care team about how helpful the information is to our research.

Sometimes, we can't destroy your data. That might happen if we have written about the research already.

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

If you are concerned about any aspect of this study, you should discuss with the researchers who will do their best to help you schema@cardiff.ac.uk and CNTWSponsormanagement@cntw.nhs.uk or your manager if appropriate. If you are still concerned you can tell the 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]

WILL MY TAKING PART BE KEPT CONFIDENTIAL?

Yes. We may use quotes from your interview in reports, presentations, publications or training. However, if we do this you will not be identified and we would change all names or places that you mention so that it is not possible for someone to identify you. What we talk about will be kept confidential, unless you tell us something that indicates that you or someone else is at risk of harm. Any information you tell that indicates you or someone else is at risk will be reported to the PI and managed according to your local trust's policies. All information that you give to us as part of this study will be stored securely in locked cabinets or on secure computers at the hospital site and Cardiff University. 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

WHAT ARE THE DATA PROTECTION ARRANGEMENTS?

We are responsible for looking after your information and using it properly. As part of that, a data protection impact assessment has been done.

We will use your name and your contact details to contact you about the research study and to oversee the quality of the study. Individuals from Cardiff University, and Cumbria,

Northumberland, Tyne and Wear NHS Foundation Trust may look at your research records to check the accuracy of the research study. The only people in Cardiff University who will have access to information that identifies you will be people who need to contact you to collect data or audit the data collection process, or send you results of the study. The people who analyse the information will not be able to identify you and will not be able to find out your name or your contact details.

Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust and Cardiff University will keep the research data from this study for 5 years after the study has finished. After this time, they will destroy all the information they have saved.

The research data collected during the trial may be shared with other researchers here in the UK, or abroad, including other academic institutions or commercial companies. We will not share any of your personal data with these researchers.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you stop taking part in the study, we will keep the information about you that we have already obtained. To protect your identity, we will only collect personal information that is absolutely necessary.

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

-at www.hra.nhs.uk/information-about-patients/ and
www.hra.nhs.uk/patientdataandresearch
-by asking one of the research team at your hospital
-by contacting the study sponsor's Data Protection Officer in writing:

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

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

WHO IS ORGANISING AND FUNDING THE RESEARCH?

This study is sponsored by Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust and is being organised and monitored by the Centre for Trials Research at Cardiff University. Funding for the study has been provided by the National Institute for Health Research.

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.

<LOCAL SITE CONTACT DETAILS>

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