Appendix 2d

Participant Information Sheet for Young People (service users under 16): CaFI-2 Randomised Controlled Trial

Study Title: Culturally-adapted Family Intervention (CaFI) for African and Caribbean people diagnosed with psychosis and their families

Part 1 – Introduction to the project

1. Invitation

We would like you to help us with our research study. Please read this information carefully and talk to your mum, dad or carer about the study. Ask us if there is anything that is not clear or if you want to know more. Take time to decide if you want to take part. It is up to you if you want to do this. If you don't then that's fine: you'll be looked after just the same.

2. Why are we doing this research?

We want to try and find out whether a new 'talking therapy' called Culturally-adapted Family Intervention (or CaFI for short) helps people with psychosis (for example, First-Episode Psychosis). We also want to know if CaFI helps family members who are not ill. CaFI is designed specifically for families with African and/or Caribbean backgrounds, including ethnicities like 'African', 'Caribbean', 'Black British', or 'Mixed heritage/ ethnicity'.

3. Why have I been asked to take part?

You have been chosen either because…

- You receive care for psychosis
- You are from Sub-Saharan African and/or Caribbean background (including 'Black British' and 'Mixed' heritage), with at least 1 Sub-Saharan African and/or Caribbean parent or grandparent
- You are at least 14-years-old

We are expecting 404 families altogether to take part.

4. Do I have to take part?

No! It is entirely up to you. If you do decide to take part:

- You will be asked to sign a form to say that you agree to take part (an assent form) this may be completed virtually, over the telephone, or in person

- You will be given this information sheet and a copy of your signed assent form to keep

You are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this will not affect the care you receive.

5. What will happen to me if I take part?

First, you will be asked to do questionnaires and interviews with a researcher this can be completed over the telephone, virtually, or in person. A computer will then randomly decide whether you will receive the CaFI therapy or not. *The way you answer the questionnaires and interviews does not affect this.*

Half of the people taking part will receive the CaFI therapy. CaFI is a talking therapy that helps families to work better together. CaFI is for the person with the diagnosis ('service user') and their families. CaFI will include 10 sessions, each lasting 1 hour. The sessions are attended by the service user and one family member/carer/another trusted person. CaFI sessions can be face-to-face or online. If you receive CaFI, you can choose where you will have your sessions.

You may be asked if you want to complete an interview after you have accessed CaFI. This will ask you about how you found it. This is optional.

All participants will be asked do questionnaires and interviews with a researcher 2 more times after the first time.

You will receive £10 for your time every time you do the questionnaires and interviews.

6. Do you need anything else?

We may record some of your therapy sessions if you receive CaFI. This is to make sure the therapists are delivering CaFI properly.

We may also ask to record some of the measures, including the PANSS interview to check the scoring is accurate.

You do not have to agree to the sessions being recorded as this is optional. You can also decide to stop the recording at any time without giving a reason.

The recording will be done using a Dictaphone if the visit takes place in person, or on Microsoft Teams if the visit is online.

The recording will be stored safely on the **[ADD SITE]** Drive, with restricted access, only available to the research team. The recording will be stored until the end of the trial, at which point the recording will be destroyed.

7. CaFI Digital

If you have virtual therapy sessions, you will be able to access this online. You can do this through a computer, tablet, or smartphone. If you do not have your own device, we will provide this. If you require training for this equipment or how to access the site, we will provide this. The content of the CaFI website will contain materials to support you through the therapy sessions with your therapists. Some of the materials/worksheets may be interactive. You can also have copies of the materials sent to you in the post.

The digital platform will comply with general data protection regulation (GDPR) and follow University of Manchester Information Governance guidelines. You will not be asked to share or input any personal identifiable information. The platform will be hosted on a secure server and will undergo regular vulnerability testing. The digital platform will be supported and maintained by the Digital Health Software team at the Centre for Health Informatics in collaboration with the central Research IT team at the University of Manchester

If you don't receive CaFI, you will carry on with your usual care. This could be medication, talking therapy that is not CaFI, or both. Your care team, like your doctor, decides what type of usual care is best for you. The CaFI team *does not* decide this.

8. Is there anything else to be worried about if I take part?

There is nothing else required of you. We will take some information from your medical notes about your care. This way we can find out if CaFI helps people. We will **not** look at anyone else's medical notes.

9. Will the study help me?

We cannot promise that the study will help you, but it might. It will be helpful for a lot people, like service users, family members, doctors and nurses, to find out if CaFI helps people.

10. What happens when the research study stops?

We will collect all the information together and decide if it is useful in telling us if CaFI helps families.

11. Contact for further information

If you would like any further information about this study you can contact:

[INSERT THE SITE LEAD'S NAME, EMAIL ADDRESS AND CONTACT NUMBER HERE]

[INSERT THE SITE RESEARCH ASSISTANT'S NAME, EMAIL ADDRESS AND CONTACT NUMBER HERE]

Website: https://sites.manchester.ac.uk/cafi/

@cafistudy **@cafi_study**

Thank you for reading so far - if you are still interested, please go to Part 2:

Part 2 - more detail – information you need to know if you still want to take part.

12. What if new information comes along?

Sometimes during research, new things are found out about your health that might affect your treatment. If this happens, someone from the research team will tell you all about it and discuss it with you and your parent/guardian. We can then make this known to your doctor or Care Coordinator. **If you change your mind about being in this study, it will not affect your care at all.** If you decide to continue in the study, you will be asked to sign an assent form. The form shows that you have agreed to take part. This can be completed over the telephone, virtually, or in-person

13. What if I don't want to do the research anymore?

Just tell your mum, dad, carer, doctor, nurse or Care Coordinator at any time. They will not be cross with you.

14. What if there is a problem or something goes wrong?

Tell us if there is a problem and we will try and sort it out straight away. You and your mum, dad or carer can either contact the lead researcher in your area:

[INSERT THE SITE LEAD'S NAME, EMAIL ADDRESS AND CONTACT NUMBER HERE]

or the Trial Manager who can tell about your complaint to the right people:

cafitm@gmmh.nhs.uk

If you would like to speak to someone outside the research team, you can contact your NHS Trust's Patient Advice and Liaison Service: Telephone: **[ADD CONTACT NUMBER].** If you'd like, you can ask an adult, like your mum, dad or another carer, to contact them on your behalf.

15. Will anyone else know I'm doing this?

The people in our research team will know you are taking part. The doctor and your Care Coordinator looking after you will also know.
If you agree we will also tell your family doctor (GP) that you are doing the study.

Your medical notes may also be looked at by other people who work at NHS to check that the study is being carried out correctly.
No one is allowed to tell anyone else that you are taking part.

All information that is collected about you during the research will be kept strictly confidential. You will be given a number which will be used instead of your name.

Any information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it, except for letters to your family doctor (GP). Once the study is complete all information will *be kept for 10 years* or kept in your own confidential notes.

We will ask if you agree for us to audio-record your interviews. This will help us to make sure the information we use is accurate. It would be too difficult to just take notes. The recordings will be destroyed after they have been written up, and your personal information, like your name and address, will not be shared with anyone. However, we will use direct quotes that you say from your interviews, which do not have any identifiable information about you or someone else.

16. What will happen to the results of the research study?

When the study has finished, we will present our findings to other researchers, and we will put the results in medical magazines and websites that researchers read. We would like to send you a summary of the results so that you can read them. We will also have a big event in Manchester where everyone can learn about the results. They will be anonymous, which means that you will not be able to be identified from them. This won't be until the study has ended in 2023.

17. Who is organising and funding the research?

This study is being done by researchers in these regions in England: Northwest, Midlands, London, and South England. The leader of the study is in Manchester. Some CaFI researchers work in universities and some work in NHS research departments. The sponsor of the study is Greater Manchester Mental Health NHS Foundation Trust.

The research is being paid for by National Institute for Health Research. They give money to health research.

18. Who has checked the study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. This is a group of people who make sure that the research is OK to do. This study has been looked at by Hampshire Research Ethics Committee.

Thank you for taking the time to read this – please ask any questions if you need to.