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Appendix 2b

Participant Information Sheet (Carers and Relatives): CaFI-2 Randomised Controlled Trial

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

We are inviting you to take part in our research study. Before you decide whether to take part, it is important you understand what the research means. It is also important to know what taking part would involve for you.

Please read through this *'Participant Information Sheet'*. It is important that you take time to decide whether or not to take part. Please feel free to discuss this with other people. Please contact us if you have any questions or would like more information.

What is the study about?

Background

Sub-Saharan African and Caribbean people in the UK are more likely than other ethnic groups to be diagnosed with schizophrenia and related psychoses.

African and/or Caribbean people diagnosed with schizophrenia/psychosis often get help later. Reasons for this include fear of mental health services, embarrassment, and shame.

Mental health difficulties can be stressful for everyone in the family. Sometimes, relationships break down. This is important because we know that not having contact with families can make people isolated and stay unwell longer.

The Problem

There is a big need to improve mental health care for African and Caribbean people. It is also important to provide better support to their families. Family Intervention is a 'talking therapy' that helps to support families living with mental health difficulties. However, Family Intervention is not usually offered to African and Caribbean service users diagnosed with schizophrenia/psychosis and their families.

Our Aim

This study aims to test a new 'talking therapy' with Black and Mixed heritage service users, their families, community members, and healthcare professionals to find out whether this treatment is helpful.

Our Plan

We first developed a talking therapy called '**Culturally-adapted Family Intervention**' (**CaFI)** to help Caribbean people with schizophrenia/psychosis and their families. We tested CaFI with a small study with Caribbean people in Manchester. People from African communities wanted to have CaFI too. So, we opened CaFI to both African and Caribbean people, including people who are Mixed heritage.

We would like to see if our CaFI therapy helps people in all parts of mental health services This includes people in psychiatric hospitals, rehab units, and Community Mental Health Teams (CMHTs). We also want to offer CaFI to people on Community Treatment Orders (CTOs) and in forensic settings.

All participants in the study will have a 50/50 chance of receiving CaFI. This means that a computer programme will choose if someone receives CaFI or their usual care. 'Usual care' might mean having talking therapy that is not CaFI, taking medication or both. 'Usual care' is different from one NHS Trust to another. What 'usual care' involves is decided by the service user's care team and what is available in their area. The CaFI research team *does not* make decisions about your relative's usual care.

Who is doing the research?

The research is carried out by researchers and health professionals at **[ADD SITE NAME].**. The same research is carried out also by Other Trusts**.** The main research site of this study is Greater Manchester Mental Health NHS Foundation Trust.

Why am I being invited to take part?

You have been invited to take part in our Culturally-adapted Family Intervention (CaFI) study to help us test whether CaFI works for Sub-Saharan African and/or Caribbean families.

We are inviting you to the study because you are:

- You are a family member, carer, support worker, or friend of a service user who meets the requirements to take part.
- You do not need to be African or Caribbean.

What ages is CaFI suitable for?

CaFI is a family therapy. We would like people of different ages to take part in the study.

Although service users must be 14 or older, there is no minimum age for other family members/carers who want to take part. However, family members/carers under 14 must be able to agree to take part ('assent'). They must also have their parent's/guardian's consent for participating in the study.

How many CaFI sessions are there?
You will be asked to attend 10 sessions. Each CaFI session is an hour long. The first few sessions may be weekly or every two weeks. However, they may come down to monthly towards the end of the therapy. The therapy will last for about 20 weeks in total. The pace of the sessions will depend on the needs of the family.

Where will the CaFI sessions take place?
CaFI sessions can take place face-to-face or via 'CaFI Digital'. CaFI Digital is an online version of the CaFI therapy that will allow us to deliver therapy sessions remotely. If you do choose to take part, you will be randomly allocated to a participant group. If the service user you are participating with is allocated to receive the CaFI therapy, they will be able to choose between face to face therapy and online therapy with a therapist.

The sessions might take place in your home, your community centre, a meeting room on the ward, or virtually through the secure "CaFI Digital" platform. This is up to you and the service user. We will try to give you as much choice as possible. If you and the service user would like a mixture of face-to-face and virtual therapy sessions with a therapist, we would be happy to accommodate this.

CaFI Digital
If you attend 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 support around 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 request copies of the materials to be 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

What will happen in the CaFI sessions?

- You will learn about schizophrenia spectrum disorder, treatments, support services, and different healthcare professionals.
- You will learn how to communicate better.
- You and the service user will learn how to cope better.

- You and the service user will be able to set goals and plan positive change.

In addition to the above, will I need to do anything else?
The researcher will visit you and the service user three times during the study. They will ask you to do interviews and questionnaires:

- *Before* you start CaFI
- *6 months* after CaFI
- *12 months* after CaFI

The interview should take an hour. You can do the interview all at once, or you can spread it across a few days. The interview will be about your mental health.

The short questionnaires will be about:

- Your quality of life
- Your beliefs about schizophrenia and psychosis
- Your relationships with family and staff

The researcher will only look at your family member's (the service user) medical notes. The researchers will **not** look at your own medical notes.

If you opt for CaFI Digital, a researcher can arrange to complete any questionnaires and interviews virtually with you.

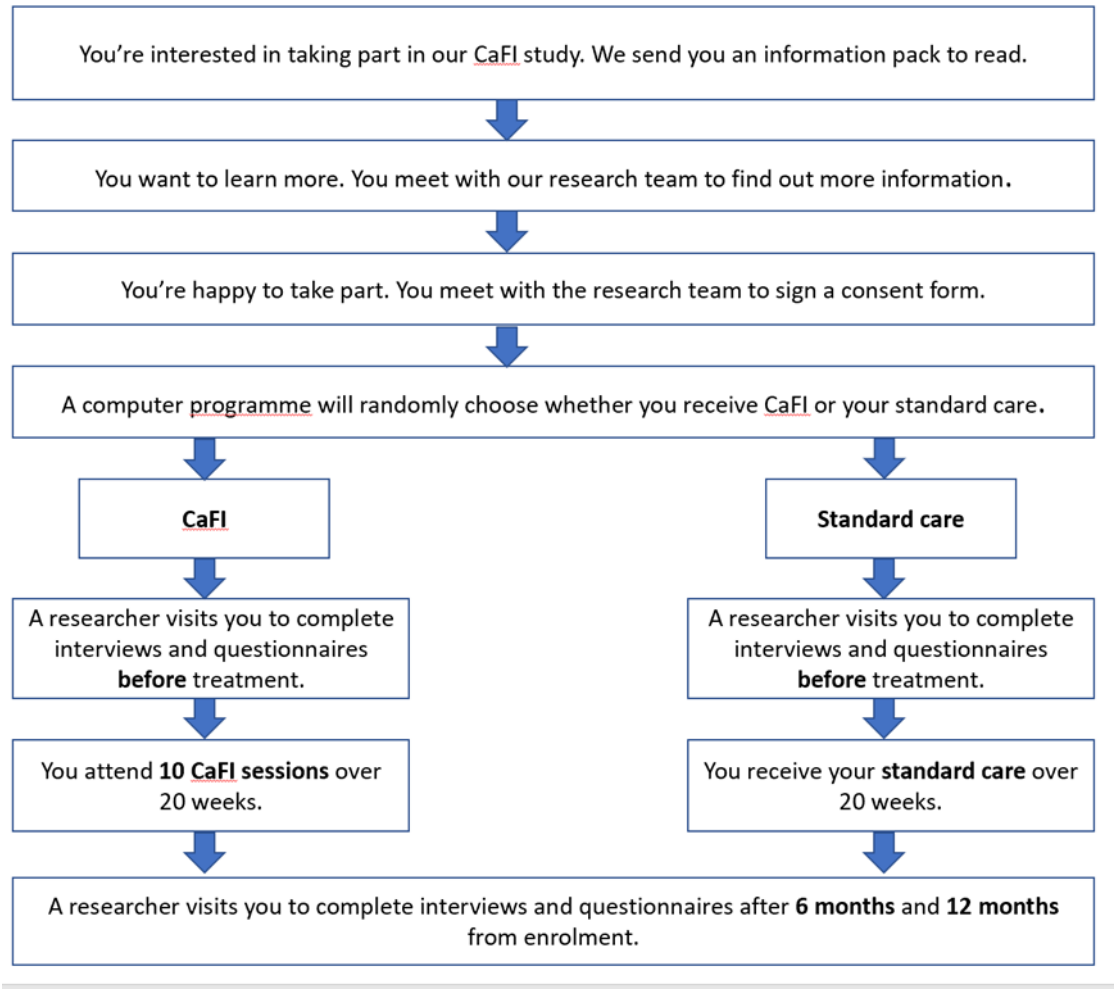
Recording
We will request your permission to record some of the CaFI therapy sessions if you are randomised to receive the trial intervention. This is to assess whether researchers are delivering CaFI as per the manual.

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.

What will taking part involve from me?



Do I have to take part?

- No. You do not have to take part.
- It is up to you to decide whether or not to take part.
- If you agree to take part, a researcher will ask you to sign a consent form.
- If you do not want to take part, this **will not affect the care and treatment that you or the person that you are caring for receives.**

Will I get paid for taking part?

- You will be refunded for reasonable travel expenses. However, you must keep your travel receipts and give them to the research team.
- You will be paid £10 for the completion of study outcome measures, at three time points (baseline, 6 months, 12 months). This will not affect any benefits you receive.
- You will *not* be paid to take part in the therapy sessions.

Who is the sponsor for this research study?
Greater Manchester Mental Health NHS Foundation Trust (GMMH) is the sponsor for this study. GMMH is based in Manchester, England, UK. GMMH will act as the custodian of the data for this study.

How will we use information about you?
We are legally able to use your sensitive information for a "public interest task" and for "research purposes". This is based on the Data Protection Act of 2018.

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.

Your name will not be shown on any of the forms we use to collect information. Your name will also not be in anything that we publish about the study. Instead, we will give your information a study number or use a made-up name that is nothing like yours. It will not be possible to identify you in anything that we publish. We may use quotes from you.

We will ask for your consent to having your interviews audio-recorded. This will help us to make sure the information we use is accurate. It would be too difficult to just take notes. The recording will be destroyed after it has been written up, and your personal details will never be shared with anyone. However, we will use direct quotes that you say from your interviews.

We will keep all information about you safe and secure. Your 'personal identifiable information' will be stored securely in a locked filing cabinet. This will be separate from any information that you share in any sessions with researchers. The site lead researcher, **[ADD NAME]**, and the research team for the study will only have access to this locked filing cabinet.

However, we will share information if we think you or someone else might be harmed. If this happens, we will share information with someone who can help.

Once we have finished the study, we will keep some of the data so we can check the results. This data will be saved for 10 years after the study has finished. We will write our reports in a way that no-one can work out that you took part in the study.

With your permission, we would also like to send written information from the focus groups to the UK Data Archive. This is so that other researchers can use it in the future.

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.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to cafitm@gmmh.nhs.uk

What happens if I change my mind?
You are free to withdraw from the study at any time without telling us why. If you change your mind, this will not affect the quality of care that you or anyone you know receives.

If you lose the ability to consent, you will be withdrawn from the study. If you withdraw, we would like to keep information that you have given us so far.

What are the risks and benefits of taking part?
Risks
Family Intervention has been widely used in the UK and other countries. It is safe and effective. It is recommended by the National Institute for Health & Care Excellence or 'NICE'.

The interviews and questionnaires will most likely **not** cause you great distress or harm. However, you might become upset if you talk about personal experiences with mental health or social relationships. Remember – you do not have to answer any questions that you do not want to answer. You can leave the interviews at any point if you feel upset.

What to do if you feel distressed
You can contact the site lead researcher, **[ADD NAME],** via telephone **[ADD CONTACT NUMBER]** or email **[ADD EMAIL].**

We can help you to contact the person in charge of your care if you are a service user and feel distressed.

You can also contact your local crisis team if it is out of hours. The researcher will give you this phone number.

We can also give you a list of organisations that are able to provide support to all participants:

- **Samaritans**: 116 123
- **SaneLine:** 0300 304 7000 (4:30 to 10:30 PM, Everyday)

- **Mind:** 0300 123 3393 (9:00 AM to 6:00PM)

Benefits

We cannot promise that the study will help you or your family directly. We believe that this research can lead to better care and support offered to African and Caribbean people diagnosed with schizophrenia and psychosis and their families.

We also aim to improve the relationships between service users, families, and staff members. This could lead to benefits for service users and their families. This could reduce family stress, and increase staff confidence in working with African and Caribbean people.

What do I do if something goes wrong?

Please speak to the site lead researcher if you have any concerns, **[SITE LEAD NAME]**:

- **[ADD CONTACT NUMBER]**
- **[ADD EMAIL]**

They will do their best to answer your questions.

If **[ADD SITE LEAD NAME]** is unable to solve your concern, please contact the Trial Manager who will contact the research team in your area or your Mental Health Trust:

- cafitm@gmmh.nhs.uk

You can also contact cafitm@gmmh.nhs.uk if would like to make a complaint.

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]**
Email: **[ADD EMAIL]**

If something goes wrong and you are harmed during the research at the fault of somebody else, then you have the right to take action against the Greater Manchester Mental Health NHS Foundation Trust. However**,** you might have to pay for your legal costs. The normal National Health Service complaints system will still be available to you. You can find further information about how to complain on the NHS website:

- https://www.nhs.uk/using-the-nhs/about-the-nhs/how-to-complain-to-the-nhs/.

What do I do now?

You can choose to meet with the researcher to go through this information virtually, via the telephone, or in person and ask questions. You will have time to think about taking part. If you are interested, you will meet with the researcher virtually, via the telephone, or in person

to sign a consent form to show that you want to take part. The researcher will explain what will happen next.

How to contact us

If you are interested in taking part or have any questions about the study, please 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]

Thank you for considering taking part in our research study.