## Appendix 2c

# Participant Information Sheet (Family Support Members): 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*

People from Sub-Saharan African and Caribbean backgrounds 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, stigma, and shame.

Mental health difficulties can be stressful for everyone in a family. Sometimes, relationships break down. This is important because we know that not having contact with families can make people isolated. People not in regular contact with other tend to become unwell more often and to stay unwell longer.

### *The Problem*

There is a big need to improve mental health care for Black people in the UK. 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)** with help from Caribbean people diagnosed with schizophrenia/psychosis and their families. We tested CaFI in a small study with Caribbean people in Manchester. African people wanted to have CaFI too. So, this study is for both African and Caribbean people, including people of Mixed heritage.

We want to know 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 or 'secure' 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' differs from one NHS Trust to another. What 'usual care' involves for the service user is decided by their care team and what is available in their area. The CaFI research team *does not* make decisions about the service user'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 being 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 expressed interest in supporting a service user diagnosed with schizophrenia/psychosis in therapy
- You are *at least* 18-years-old or older
- You do *not* have to be African or Caribbean

## Volunteering as a Family Support Member

### *What is a Family Support Member?*

Where family members (FM) are not available, service users can participate with Family Support Members (FSMs) who can be:

- **Nominated Family Support Members (nFSM)** – 'trusted individuals' (e.g. friends, care coordinators, faith/community leaders) designated by service users to enable them to participate in CaFI.

- **Allocated Family Support Member (aFSM)** – a person allocated to the service user by the study team to enable them to participate in CaFI. The pool of aFSMs will include former service users as 'befrienders' or 'peer support workers' whom we shall recruit, deploying them where service users without families are unable to nominate anyone. Service users will be provided with demographic and other information about aFSM, to help them choose from those available.

FSMs would support the service user in each CaFI session throughout their therapy, for example, assisting the service user with therapy exercises. This can increase the service user's confidence in using the new skills that they have learned in CaFI.

Family Support Members will *not* deliver the CaFI therapy itself. CaFI will be delivered by a qualified therapist and a co-therapist.

Family Support Members will *not* receive CaFI therapy for themselves. The therapy is for service users and their families.

### *What is asked of Family Support Members?*

Family Support Members are asked to make a commitment to supporting at least one service user over all 10 CaFI sessions. FSMs are also asked to follow data protection and information governance guidelines. This means that they would not tell anyone outside the CaFI team about what was said in CaFI sessions or meetings. They would also be asked not to reveal personal information, like the name or address of the service user.

If you are taking part as a **nominated Family Support Member (nFSM)**, like family members, you will be asked to complete questionnaires and interviews *before* you start taking part in CaFI, and again at *6 months* and *12 months* after CaFI sessions end.

If you are taking part as an **allocated Family Support Member (aFSM)** you will not be asked to complete questionnaires and interviews as part of CaFI. You will only be asked to complete a demographics questionnaire at the beginning of the study.

FSMs do *not* need to have personal experience of mental health difficulties. However, we welcome people from different backgrounds to take part. This includes people who have lived experience of mental health difficulties.

### *Do Family Support Members receive support?*

Yes. All Family Support Members will receive training on data protection and information governance (confidentiality), schizophrenia and psychosis awareness, and cultural awareness. FSMs will have regular group supervision to talk about their experiences with a CaFI team member.

## CaFI therapy

### *What ages is CaFI suitable for?*

CaFI is a family therapy. We would like people of different ages to take part in the study. The service user you will be working with could be any age above 14 years. Family Support Members must be *at least* 18 years or older.

### *How many CaFI sessions are there?*

Each service user receives 10 sessions of CaFI. The first few sessions may be weekly or every two weeks. The therapy will last for about 20 weeks in total. The pace of the sessions will depend on the needs of the service user.

### *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 CaFI therapy remotely. Service users who choose to take part and have been allocated an intervention group, will be able to choose between face-to-face therapy and online therapy.

The sessions might take place in the service user's home or other suitable place such as community centre, or a meeting room on the ward or online through CaFI:Digital. We will try to give service users as much choice as possible. For example, if they would like a mixture of face-to-face and online therapy sessions, we would do our best to make this happen as smoothly as possible. Family Support Members will support service users in the space where the sessions take place (whether face-to-face or online).

We will ask the service user you support whether they are happy to have some of their sessions recorded. This is to assess whether researchers are delivering CaFI as per the manual. If the service user agrees to this, you will be asked to provide your consent.

## CaFI Digital

If the service user chooses to have online therapy sessions, they can do this through a computer, tablet, or smartphone. If they do not have their own device, we will provide this. If you do not have a device to participate, we will also provide support around this. If you require training on how to access the CaFI website, we will provide this. The content of the CaFI website will contain materials to support the service user through the therapy sessions. Some of the materials/worksheets are interactive. We will provide paper copies of key materials (e.g. workbooks). Others can be sent in the post if needed.

The CaFI: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?

- Learning about schizophrenia spectrum disorder, treatments, support services, and different healthcare professionals.
- Learning to communicate better in difficult situations.
- Learning how to cope better with schizophrenia/psychosis.
- Learning to set goals and plan for positive change.

## In addition to the above, will I need to do anything else?

If you are taking part as a **nominated Family Support Member (nFSM),** the researcher will visit you three times during the study. They will ask you to complete interviews and questionnaires before you start CaFI, and again at 6 months and 12 months after CaFI ends.

The interview should take about an hour. You can do the interview all at once, but you can complete on more than one visit if necessary. The interview will be about you views on the CaFI therapy and taking part in the study.

The short questionnaires will be about:

- Your beliefs about schizophrenia and psychosis.
- Your relationship with the service user

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

If you are taking part as an **allocated Family Support Member (aFSM)** we will only ask you to complete a demographics questionnaire at the beginning of the study. You will not be asked to complete the other interviews and questionnaires mentioned above.

## 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 anyone you know 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. This will not affect any benefits you receive.

***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 (e.g. name, age) 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 if you are taking part in interviews, as a nominated Family Support Member (nFSM).

We will ask for your consent to having your interviews digitally-recorded if you are taking part as a nominated FSM. This will help us to make sure the information we use is accurate. It would be difficult to just take notes without the risk of missing important information. Any recordings will be destroyed after it has been written up, and your personal details will never be shared with anyone. Although we will use direct quotes that you say from your interviews, your identity will not be revealed.

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, **[SITE LEAD 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 will be able to help but will discuss this with you.

Once we have finished the study, we will keep some of the data (information) so we can check the results. 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 (group interviews) to the UK Data Archive. This is so 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 you already gave.

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 once we begin analysing it.

### *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 Lauren Manderson, Trial Manager, lauren.manderson@gmmh.nhs.uk
- by ringing us on 07826415698

### *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 that you complete as a nominated Family Support Member (nFSM) 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 and start again if you feel able to do so.

It might be upsetting to hear about service users' experiences in the CaFI sessions.

### *What to do if you feel distressed*

You can contact the site lead researcher, **[NAME]**, via telephone **[NUMBER]** or email **[EMAIL].**

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

- **Samaritans**: 116 123
- **SaneLine:** 0300 304 7000 (4:30 to 10:30 PM, Everyday)
- **Mind:** 0300 123 3393 (9:00 AM to 6:00PM)

Researchers will also provide details of local services/organisations – especially those who specialise in supporting Black people's mental health.

***Benefits***

We cannot promise that the study will help the service user or you personally. 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. Reducing stress in families, and increasing staff confidence in working with African and Caribbean people could lead to benefits for both service users and mental health services.

**What do I do if something goes wrong?**

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

- **[PHONE]**
- **[EMAIL ADDRESS]**

They will do their best to answer your questions.

If Dr Josanne Holloway 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, Lauren Manderson:

- 07826415698
- lauren.manderson@gmmh.nhs.uk

You can also contact Lauren 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 (PALS):

**[CONTACT INFORMATION HERE].**

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 online, 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 online, 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 PHONE NUMBER HERE]**

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

Thank you for considering taking part in the CaFI research study.