

Participant Information Sheet : CaFI Phase 3 Feasibility Study

IRAS Ref: 135146

REC Ref: 13/NW/0571

Study Title: Culturally-adapted Family Intervention (CaFI) for African Caribbean people diagnosed with schizophrenia 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 is about and what taking part would involve for you. Please read through this *'Participant Information Sheet'* carefully. It is important that you take time to decide whether or not to take part. Feel free to discuss this with other people. Please contact us if you have any questions or would like further information.

What is the study about?

Background

African Caribbean people in the UK are more likely than any other ethnic group to be diagnosed with schizophrenia. Fear of mental health services and stigma in the community mean that Caribbean-descended people diagnosed with schizophrenia often delay contact with services. Long periods of untreated symptoms can be very stressful and increase the 'burden of care' on families. This can increase tension in the family and can cause breakdown in relationships. This is important because we know that not having contact with families can make people socially isolated, keep them in hospital longer and increase the risk of having to go back into hospital.

The Problem

There is an urgent need to improve the mental health care of African Caribbean people and provide better support to their families. Family Intervention is a 'talking therapy' known to be effective but patients/service users diagnosed with schizophrenia and their families are rarely offered it. African Caribbean people are even less likely to be offered Family Intervention.

Our Aim

This research aims to work with service users, their families, members of the community and healthcare professionals to adapt a current model of Family Intervention to make it more suitable for African Caribbean patients/service users and their families.

Our Plan

We have named our culturally appropriate therapy, 'Culturally-adapted Family Intervention' or CaFI for short. CaFI will be delivered to 30 service users diagnosed with schizophrenia or psychosis who are receiving mental health care in Manchester. We would like to test whether it is possible to deliver our Culturally-adapted Family Intervention (CaFI)

to service users on acute and rehabilitation inpatient wards, and with patients/service users in Community Mental Health Teams (CMHTs), including people on Community Treatment Orders (CTOs).

Who is carrying out the research?

This research is being carried out by researchers and clinicians at The University of Manchester and Manchester Mental Health and Social Care Trust (MHSCT).

Why am I being invited to take part?

You have been invited to take part in our Culturally-adapted Family Intervention (CaFI). You will help us test CaFI to see if it is appropriate for African Caribbean families.

We are inviting you to be a part of this study because you are:

1. A current patient/ service user

- You are African Caribbean background (including 'Black British' and 'Mixed' heritage) with at least 1 African Caribbean parent or grandparent
- You are receiving care at Manchester Mental Health and Social Care Trust OR Greater Manchester West Mental Health NHS Foundations Trust
- You have received a diagnosis of schizophrenia or psychoses

2. A family member, carer or 'advocate'

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

What if I cannot take part with relatives?

We realise that some people may have lost contact or have difficult relationships with their families. To make it possible for them to take part, we will ask service users to either nominate 'trusted individuals' (such as support workers, church pastors or close friends) to work alongside them. If service users are unable to nominate someone, they will be able to work with 'Family Support Members' who have been recruited to support them through the sessions. Family Support Members have been trained in 'cultural competence' (to improve understanding of African Caribbean communities) and 'research governance' (principles and practice of confidentiality in research).

How many CaFI sessions will there be?

You will attend 10 sessions of CaFI which will each be 1 hour long. The first few sessions may be weekly or fortnightly, but they may be reduced to monthly toward the end of the intervention. The intervention should be delivered in about 20 weeks. The pace of the sessions within this time period will depend on the needs of the service user and their families.

Where will the CaFI sessions take place?

The therapy sessions will take place in a suitable location. This might be in your home, in a community centre, or a meeting room on the ward. We will try and give you as much choice as possible but it will depend on where you are staying.

What will the CaFI sessions do?

We expect the sessions to:

- Share information about schizophrenia and psychosis, treatment and support services, and the roles of different healthcare professionals
- Encourage positive communication with services and between family members
- Teach skills to reduce stress, solve problems and cope better within the family
- Support the service user and family to set goals and plan for positive change

Will I have to complete interviews or questionnaires?

- The researcher will ask to visit you at three specific times during the study – just before starting CaFI, immediately after the final session, and 3 months after CaFI.
- *Patients/service users* will be asked to complete an interview about their mental health and short questionnaires about their quality of life, beliefs about schizophrenia/psychosis, and relationships with family and staff.
- *Family members or Family Support Members* will be asked to complete an interview about their knowledge of schizophrenia/psychosis and short questionnaires about their quality of life and general health.
- The interviews will take around 1 hour. The interviews can be carried out in one go or over several meetings. We will try to make appointments at times which suit you.
- At the 3 month meeting, you will also be given the option of taking part in an interview about your experiences of the research and taking part in the CaFI sessions. These interviews will last no longer than 45 minutes.

Do I have to take part?

- No. Taking part is entirely voluntary.
- It is up to you to decide whether or not to take part.
- If you agree to take part, you will be asked to sign a consent form.
- If you do not want to take part, this will not affect the standard of care and treatment that you or the person you care for receives.

Will I get paid for taking part?

- You will be refunded for reasonable travel expenses, but you must keep your travel receipts and give them to the research team.
- You will be paid £10 per hour of your time meeting with the researcher to complete interviews and questionnaires. This will not affect any benefits you receive.
- You will not be paid to take part in the therapy sessions.

Will my taking part be kept confidential?

Yes. If you agree to take part in the study, and information which is collected during the course of the study will be strictly confidential, although we do have a responsibility to inform your key worker if you tell us information that suggests you or someone else might be harmed. All information you give to the researcher will be kept in accordance with in the Data Protection Act of 1998. This means that information which could be used to identify you, such as your name and address, will be stored safely in a locked filing cabinet separate from any questionnaire data. Your name will not appear on any of the forms, we will give you a study number instead. With your permission, we would like to inform your key worker if you agree to take part in the study.

If you are a service user under the care of Manchester Mental Health & Social Care NHS Trust or Greater Manchester West NHS Foundation Trust, a copy of your consent form will be placed in your usual medical notes and this copy may be reviewed by the Trust Clinical Audit Department to confirm that you have given written informed consent to taking part in the study. Responsible individuals from the University of Manchester may also look at the research records to audit the conduct of the research.

You will be asked to give consent for the CaFI sessions and interviews to be digitally recorded. This is so that the research team can check the sessions and research meetings are being delivered as they should be. The audio-recordings will be destroyed after they have been used and your personal details will never be disclosed.

If you are a patient/service user, the CAFI research team and therapists may look at relevant sections of your medical notes to confirm information relating to your mental health care, such as diagnosis, care plan, service use/ hospital admission and risk assessment information. We will ask for your consent to do this on the consent form.

What will happen to my data?

Your anonymised data will be held securely by the research team at The University of Manchester for 5 years after the last publication of the study or for 10 years, after which point it will be destroyed. Personal information (e.g. name, contact details) will be destroyed as soon as it is no longer needed.

What happens if I change my mind?

You are free to withdraw from the study at any time without giving a reason. Changing your mind will not affect the standard of care that you or the person you care for receives. In the unlikely event that you lose the capacity to consent during the course of this study, you will be withdrawn from the study. If you withdraw, we would like to keep any information you have given up to that point.

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 and is recommended by the National Institute for Health & Care Excellence or 'NICE'.

The interviews and questionnaires are unlikely to cause you significant distress or harm. However, talking about personal experiences relating to mental health or social relationships may be upsetting for some people. There is a risk of disclosing personal or private information during the interviews. You do not have to answer any questions that you don't 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 lead researcher, Dr Dawn Edge, via telephone 0161 275 2570 or email dawn.edge@manchester.ac.uk.

If you are a current service user and feeling distressed, we can support you to contact the person in charge of your care (key worker/ care coordinator). If it is out of hours, you can contact your local crisis team. The researcher will give you this phone number.

We can also provide a list of organisations that are able to provide support to all participants. These include the Samaritans (08457 909090), Rethink National Advice Service (020 8974 6814) and SaneLine (0845 767 8000).

Benefits

We cannot promise that the study will help you directly in the short term, but we believe that this research can lead to improvements in the care and supported offered to African Caribbean people diagnosed with schizophrenia and psychosis and their families.

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

What do I do if something goes wrong?

If you have any concerns, please contact the lead researcher, Dr Dawn Edge, who will answer any questions you have. If Dr Edge and/or the other research team members cannot resolve your concern and/or you wish to make a complaint regarding the study, please contact a University Research Practice and Governance Coordinator on 0161 275 7583 or 0161 275 8093 or by email to research.complaints@manchester.ac.uk.

In the event that something does go wrong and you are harmed during the research at the

fault In the event that something does go wrong and you are harmed during the research at the fault of somebody else, then you may have the grounds to take legal action for compensation against the University of Manchester, Manchester Mental Health & Social Care NHS Trust or Greater Manchester West NHS Foundation Trust, but you may have to pay for your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

What do I do now?

You will have the option to meet with the researcher to go through this information booklet and answer any questions you may have. You will be given time to think about taking part in the study. If you are interested, you will be asked to meet with the researcher 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:

Amy Degnan (Research Project Manager)

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Thank you for considering taking part in our research study.