

Participant Information Sheet Phase 1C: Consensus Conference

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

We would like to invite you to take part in our research study. Before you decide whether or not you wish to take part, we would like you to understand why the research is being done and what taking part would involve for you. We have prepared this '*Participant Information Sheet*' to tell you about the purpose of the study and what will happen to you if you decide to take part. This information sheet also tells you about the purpose of the research study and provides more detailed information about the study and how you can expect to be treated if you agree to take part.

If you wish, one of our team will go through this information sheet with you and answer any questions you have. We think this should take about 15 minutes. You are also free to talk to others about the study if you wish. Please ask us if there is anything that is not clear or if you would like more information. It is important that you take time to decide whether or not you wish to take part.

What is the purpose of the study?

Decades of research shows that African Caribbean people in the UK are more likely than any other ethnic group to be diagnosed with schizophrenia. However, their experience of mental health services is generally poor and they have worse outcomes. Fear of mental health services and stigma in the community causes African Caribbean people with schizophrenia to delay contact with services. Prolonged untreated illness is tremendously stressful and increases the 'burden of care' on families. This increases tension in the home and can cause family breakdown. This is important because we know that not having contact with their families makes patients socially isolated, keeps them in hospital longer and increases the risk having to go back into hospital. There is an urgent need to improve the care of African Caribbean people and provide better support to their families. Family Intervention (FI) is

known to be effective but patients with schizophrenia are rarely offered it. African Caribbeans are even less likely to be offered FI because of family disruption.

We therefore plan to find out if it is possible to adapt current Family Intervention to make it more suitable for African Caribbean patients and their families. We will work with patients, former service users and members of the community as well as healthcare professionals to see if it is possible to deliver our culturally-adapted Family Intervention (CaFI) on acute and rehabilitation inpatient wards and with patients in Community Mental Health Teams such as people on Community Treatment Orders (CTOs) in Manchester. 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 patients to nominate 'trusted individuals' (such as support workers, church pastors, family friends), who we will train to act as 'proxy families' where patients have no contact their own families.

Why have I been invited to take part?

We are inviting you to take part in this study because you fall into one of three groups of people:

- 1) **Current patients and former service users** who regard themselves as being from African Caribbean backgrounds (including people who see themselves as 'Black British' or of 'Mixed' heritage but who have at least 1 African Caribbean parent or grandparent).
- 2) **Carers and advocates** (including paid support workers, family and friends) who have experience of working with African Caribbeans. Unlike patients, carers and advocates need not be African Caribbean.
- 3) **Health Professionals** we would like to include a range of professions with different levels of experience/expertise including: nurses, Occupational Therapists (OT), psychologists, and psychiatrists, social workers.

What will I have to do if I take part?

The study is divided into 3 parts or 'phases'. **You have been invited to take part in a CONSENSUS CONFERENCE, which is Phase 1c of the study.** The purpose of Phase 1 is to develop 'Culturally-adapted Family Intervention' or 'CaFI' for short. This will be a new form of family therapy. 'Culturally-adapted' means making sure that the model meets the specific needs of African Caribbean people and they find it acceptable. We will begin Phase 1 of the study by reviewing previous research about culturally-adapted treatments for schizophrenia and other mental health problems (Phase 1a). In Phase 1b, we will ask patients, carers and professionals what they think about culturally-adapting Family Intervention for African Caribbean people and the kinds of things that think would important to include in this kind of therapy.

For the 'Consensus Conference' (Phase 1c), we are looking for a group of about 24 people made up of patients, carers, people from the wider community and health professionals to help us agree important things like exactly what should be included in CaFI, how many sessions and how long they should be. People who take part in the Consensus Conference will help us decide the best way of measuring whether CaFI works. They will also agree the contents, design and layout of the first draft of a manual which therapists will use to help them work with patients and families who receive CaFI in Phase 3. They will do this by using information from Phase 1a and 1b with the help of the lead researcher (Dr Dawn Edge) with support from other researchers (Amy Degnan). This phase of the research will take place in a suitable location. This is likely to be the University of Manchester or a community setting. The location will be agreed with members of our Research Advisory Group.

Will my taking part be kept confidential?

Yes. If you agree to take part in the study, any information you give the researcher will be kept strictly confidential. However, we do have a responsibility to disclose information that suggests you or someone else might be harmed. If you are a current patient, we would need to inform the person responsible for your care. This is likely your key worker and/or your GP. If you are a current patient, with your permission, we would like to let your consultant or GP if you agree to take part in the study. All information about you will be kept in accordance with in the Data Protection Act of 1998. This means that your 'personal identifiable data' such as your name, address or contact number will be stored in a locked filing cabinet separate from any information you share in the focus groups. Only the lead researcher (Dr Dawn Edge) and the research team will have access the locked filing cabinet. Your name will not appear on any of the forms we use to collect information or in anything we publish about the study. Instead, we will give your information a study number or use a made up name but one that is nothing like yours so it will not be possible to identify you in anything that we publish.

You will be asked to give consent to having your conversations in groups audio-taped. This will help us to make sure the information we use is accurate as it would be difficult to do this from notes alone. The recording will be destroyed after it has been used and your personal details will never be disclosed. If you are a patient under the care of Manchester Mental Health & Social Care NHS 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. With your permission, we would also like to send information recorded from the focus groups to the UK Data Archive so that other researchers can use it in the future.

What are the possible risks of taking part?

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 assessments in the study such as KAZI are simple and unlikely to cause you any distress or harm. However, we realise that talking about experiences of mental illness and of mental health

services might be upsetting for some people. There is a risk of disclosing personal or private information during the consensus conference. We will remind you that you do not have to answer any questions you do not want to.

You can leave the focus groups at any point if you feel upset. If you do feel distressed after the focus groups, you can contact the lead researcher, Dr Dawn Edge at the University on 0161 275 2570. If you are a current patient and feeling very distressed out of office hours, we suggest you speak to your key worker or other relevant staff. We will also provide a list of organisations that are able to provide support to all participants.

Are there any possible benefits of taking part?

We cannot promise that the study will help you directly but we are doing this research because we believe that the information we collect will help us improve care and support for African Caribbean patients with schizophrenia and their families. We also believe that improving health professionals' knowledge and awareness of African Caribbean communities and African Caribbean people's knowledge about schizophrenia and understanding of health professional roles will improve relationships between staff and members of this ethnic group. Ultimately, we hope this will lead to better outcomes for patients, reduce family stress and tension, and increase staff confidence.

Do I have to take part?

No. Taking part is entirely voluntary. It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will ask you to sign a consent form. If you are a patient or carer and do not wish to take part, this will not affect the standard of care and treatment that you or the person you care for receives.

What happens if I change my mind?

You are free to withdraw at any time, without giving a reason. If you withdraw, we would like to keep any information you have given up to that point. You can still ask for information about how the study turns out. Changing your mind will not affect the standard of care and treatment 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 but we will continue to use the information we have already collected.

Expenses and payments

Reasonable travel expenses will be paid in exchange for travel receipts. 'Permitted payments' for service-users, honorarium for carers and volunteers will be paid at £10/hour (max £50 per session). 'Permitted payments' means that taking part in the study should not affect any benefits you receive.

What do I do now?

A researcher from the study will contact you in a few days. She will go through the information sheet with you and answer any questions you have. We think this should take about 15 minutes. You can let her know if you are interested in taking part. She will give you more time to think about being in the study and, if you are still interested, ask you to sign a consent form to show that you are willing to take part. She will then explain what will happen next.

What do I do if something goes wrong?

If you have a concern about any aspect of this study, please ask to speak to the lead researcher, Dr Dawn Edge (0161 275 2570), who will do her best to answer your questions. If Dr Edge and/or the remainder of the research team are unable to resolve your concern 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 and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Manchester or Manchester Mental Health & Social Care NHS Trust, but you may have to pay for your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Thank you very much for considering taking part in our research.

Please discuss this information with your family, friends or mental health team if you wish.

Please feel free to contact me should you require further information, clarification or advice on how to take part:

Dr Dawn Edge (Lead Researcher)

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Email: dawn.edge@manchester.ac.uk