

# Family intervention for Sub Saharan African and Caribbean people with psychosis trial

<b>Submission date</b> 13/01/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 31/01/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/12/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Schizophrenia is a severe long-term mental health condition. It causes a range of different psychological symptoms. Doctors often describe schizophrenia as a type of psychosis. This means the person may not always be able to distinguish their own thoughts and ideas from reality. Around 15 people per 100,000 are diagnosed with schizophrenia in England every year. Black people are much more likely to receive this diagnosis than other ethnic groups. They have longer periods without receiving treatment. This can increase stress and family conflict. Family Intervention (FI) is a 'talking treatment' that helps reduce conflict. Service users receiving FI stay well longer. NICE recommends FI for families affected by schizophrenia. However, Black families are less likely than others to be offered talking treatments.

Previously, the researchers worked with Caribbean families, community members, and healthcare professionals to develop a culturally-appropriate FI. It was called 'Culturally-adapted FI' - 'CaFI' for short. We changed an existing FI to make it 'less White', including how things like racism and spiritual beliefs affect people's experiences of schizophrenia. People liked CaFI. Of 26 family units that started CaFI, 24 completed all 10 sessions. CaFI therapists also liked it. Service users, therapists and families all said that CaFI should become available to everyone, especially African people.

This study will test CaFI compared to usual care with people from Sub-Saharan African/Caribbean /Mixed backgrounds.

### Who can participate?

People of Sub-Saharan African and Caribbean descent, including those who self-identify as 'Black British', 'Black Caribbean', 'Black African', 'African-Caribbean', or 'Mixed' African/Caribbean', diagnosed with schizophrenia or related diagnoses.

### What does the study involve?

Each service user and their family will have a 50% chance of receiving CaFI. The other 50% will continue with their usual care. All participants will complete questionnaire assessments and interviews at four time-points in the study.

What are the possible benefits and risks of participating?

Benefits:

The feasibility pilot study of CaFI showed that service users, relatives/carers, and (service user-nominated) FSMs reported positive service user benefits, including improved symptoms (better mood, less paranoia), improved social functioning, and active planning to return to work and fulltime education. Therapeutic alliance was positively rated by all groups. Improved communication between service users, families, and health professionals was also reported. We expect participants to experience similar benefits as part of this multi-site trial, including a reduced risk of relapse.

Risk:

There is a risk that some participants may become distressed when reflecting on personal experiences of living with mental illness and its impact on family relationships.

Where is the study run from?

Greater Manchester West Mental Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

September 2017 to December 2024

Who is funding the study?

National Institute for Health Research (NIHR), UK

Who is the main contact?

1. Prof. Dawn Edge (scientific), dawn.edge@manchester.ac.uk
2. Trial Manager (public), CaFITM@gmmh.nhs.uk

**Study website**

<https://sites.manchester.ac.uk/cafi/>

## Contact information

**Type(s)**

Public

**Contact name**

Dr Trial Manager

**Contact details**

GMMH NHS Foundation Trust  
3rd Floor, Rawnsley Building  
Hathersage Road  
Manchester  
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M13 9PL

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CaFITM@gmmh.nhs.uk

**Type(s)**

Scientific

**Contact name**

Prof Dawn Edge

**Contact details**

Coupland I, University of Manchester  
Oxford Road  
Manchester  
United Kingdom  
M13 9WL  
+44 (0)161 275 2570  
dawn.edge@manchester.ac.uk

**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number**

266123

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

CPMS 44117, IRAS 266123

**Study information****Scientific Title**

The effect on relapse of Culturally-adapted Family Intervention (CaFI) compared to usual care among African and Caribbean people diagnosed with psychosis in the UK: a randomised controlled trial

**Acronym**

CaFI

**Study objectives**

The Culturally-adapted Family Intervention (CaFI) therapy is more effective than usual care (e.g. other psychological therapies) and better value for money for African and Caribbean people diagnosed with schizophrenia in the United Kingdom.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

1. Approved 27/09/2021, Health and Care Research Wales (Health Research Authority Bristol HRA Centre Level 3, Block B Whitefriars Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)2071048138; HCRW.approvals@wales.nhs.uk), ref: 266123
2. Approved 21/01/2020, South Central – Hampshire B REC (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8057; nrescommittee.southcentral-hampshireb@nhs.net), ref 19/SC/0607

**Study design**

Interventional randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Community, Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**

Schizophrenia, schizotypal and delusional disorders

**Interventions**

Current intervention as of 04/10/2021:

Design: A randomised controlled trial (RCT) with two participant groups will be used. The trial will include an internal pilot to test CaFI's feasibility with African participants. The researchers will also implement a process evaluation to find out what will make it easier/harder for CaFI to be taken up by services. The trial will be 'blind', which means that RAs collecting the data will not know which group each participant has been allocated to. This is done to avoid bias in data collection.

Methodology & procedure: In the implementation phase, process evaluation data will be collected through the trial. The researchers will conduct semi-structured interviews at two different time points (3 and 9 months) with 30 members of staff (therapists, care coordinators, NHS senior leaders and service managers, commissioners) purposively sampled. People over time will enable us to tap into their perceptions and experiences of the intervention, and what factors affect CaFI's implementation in services. Interviews will be audio-recorded, transcribed verbatim, anonymised and analysed using Normalisation Process Theory (May & Finch, 2009).

Trained Clinical Study Officers (CSOs) and RAs will take informed consent and complete baseline assessments from participants in an initial meeting. An additional meeting will be arranged if this is not feasible. Parents/guardians of participants under the age of 16 will be present at consent taking. However, the assessments will be conducted confidentially 1-to-1 with all service users to eliminate the possibility of bias caused by parental/guardian presence during data collection.

Following baseline data collection, participants will be randomised into one of the two conditions: the intervention group (who will receive CaFI) or the control group (usual care). Intervention group participants will be asked to nominate relatives, carers, or Key Workers (or equivalent) to attend the CaFI sessions with them. Where this is not possible and participants

cannot suggest alternatives, the researchers shall provide details of Family Support Members (FSMs) from whom they can choose someone to support them during therapy. Participants will attend 10 x 1h sessions within a 26-week window. Participants will be able to choose whether they wish to receive the CaFI intervention face-to-face or online, via the CaFI:Digital platform. Control participants will continue with usual care, and they will not have access to CaFI.

Post-intervention data will be collected within a month after each intervention participant has completed their 10th session. Control participants will be invited to complete data collection at the 26-week time-point from enrolling in the study (the therapy window). Follow-up data will be collected at 6 months and 12 months for both intervention and control participants. Thus, data will be collected at four time-points per participant.

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Post-intervention data will be collected within a month after each intervention participant has completed their 10th session. Control participants will be invited to complete data collection at the 20-week time-point from enrolling in the study (the therapy window). Follow-up data will be collected at 6 months and 12 months for both intervention and control participants. Thus, data will be collected at four time-points per participant.

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## **Intervention Type**

Behavioural

## **Primary outcome measure**

Relapse (as defined by a worsening of symptoms lasting over two weeks, a Cochrane recommended measure) assessed using case-notes/medical records (service users only) throughout the study

## **Secondary outcome measures**

Current secondary outcome measures as of 04/10/2021:

At baseline, after 10th session (intervention) or 26 weeks (control), 6 months, and 12 months:

1. Number of psychiatric and compulsory admissions (service users) measured using patient records
  2. Length of inpatient stays (service users) measured using patient records
  3. Positive, negative, and general symptoms measured using the Positive and Negative Syndrome Scale (PANSS) (service users)
  4. Social functioning measured using the Personal and Social Performance Scale (PSP) (service users)
  5. Illness perceptions measured using the Brief Illness Perception Questionnaire (Brief-IPQ) (service users and family members/FSMs)
  6. Knowledge about psychosis measured using the Culturally-adapted Knowledge about Psychosis Questionnaire
  7. Emotional distress measured using the General Health Questionnaire (GHQ-12) (family members/FSMs)
  8. Health status and quality of life measured using the EQ5D-5L (service users and family members/FSMs)
  9. Quality of staff-service user relationships measured using the Working Alliance Inventory (WAI) (service users and therapists/key workers)
  10. Service engagement of service users measured using the Service Engagement Scale (SES)
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Previous secondary outcome measures:

At baseline, after 10th session (intervention) or 20-weeks (control), 6 months, and 12 months:

1. Number of psychiatric and compulsory admissions (service users) measured using patient records
2. Length of inpatient stays (service users) measured using patient records
3. Perceived coercion (service users) measured using
4. Positive, negative, and general symptoms measured using the Positive and Negative Syndrome Scale (PANSS) (service users)
5. Social functioning measured using the Personal and Social Performance Scale (PSP) (service users)
6. Illness perceptions measured using the Brief Illness Perception Questionnaire (Brief-IPQ) (service users and family members/FSMs)
7. Knowledge about psychosis measured using the Knowledge about Psychosis Interview (KAPI) (family members/FSMs)
8. Knowledge about psychosis measured using the Culturally-adapted Knowledge about Psychosis Questionnaire
9. Emotional distress measured using the General Health Questionnaire (GHQ-12) (family members/FSMs)
10. Health status and quality of life measured using the EQ5D-5L (service users and family members/FSMs)
11. Quality of staff-service user relationships measured using the Working Alliance Inventory (WAI) (service users and therapists/key workers)
12. Service engagement of service users measured using the Service Engagement Scale (SES)

**Overall study start date**

01/09/2017

**Completion date**

30/12/2024

**Eligibility**

## Key inclusion criteria

Current inclusion criteria as of 04/10/2021:

Service users:

1. People of Sub-Saharan African and Caribbean descent, including those who self-identify as 'Black British', 'Black Caribbean', 'Black African', 'African-Caribbean' or 'Mixed' African/Caribbean
2. At least one parent/grandparent born in a sub-Saharan African/Caribbean country
3. Diagnosis of schizophrenia or related psychoses (ICD F20-29/ DSM-V) (American Psychiatric Association, 2013; World Health Organization, 1992)
4. Receiving treatment via psychiatric inpatient services (acute or rehabilitation), forensic or within community services within a participating NHS Trust
5. 14 years or older in keeping with the age groups served by Early Intervention Services and adult services
6. Assessed by researchers as having the capacity to provide informed consent
7. Assessed by care teams as being well enough to participate in therapy
8. Sufficient understanding of the English language to complete measures
9. No significant cognitive impairment implicated in aetiology (e.g. organic disorder)
10. Does not present a high short-term risk to themselves or others as assessed by care teams

Family members and nominated Family Support Members (FSMs):

Family members and nominated family support members do not have to be of African or Caribbean origin.

All participants:

1. Assessed by researchers as having the capacity to provide informed consent
2. Family members and nominated FSMs must be aged 14 years or older
3. Sufficient proficiency in English to enable completion of measures

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Previous inclusion criteria as of 05/02/2021:

1. People of Sub-Saharan African and Caribbean descent, including those who self-identify as 'Black British', 'Black Caribbean', 'Black African', 'African-Caribbean' or 'Mixed' African/Caribbean
  2. At least one parent/grandparent born in a Sub Saharan Africa/Caribbean country
  3. Diagnosis of schizophrenia or related psychoses (ICD F20-29/ DSM-V) (American Psychiatric Association, 2013; World Health Organization, 1992)
  4. Receiving treatment via psychiatric inpatient services (acute or rehabilitation), forensic or within community services within a participating NHS Trust
  5. Aged 14 years or older in keeping with the age groups served by early intervention services and adult services
  6. Assessed by researchers as having the capacity to provide informed consent
  7. Assessed by care teams as being well enough to participate in therapy
  8. Sufficient understanding of the English language to complete measures. We anticipate that the majority of participants will meet this criterion. However, we shall evaluate it during the acceptability work and early in recruitment and modify if necessary to ensure we do not exclude groups with some of the highest need e.g. people seeking asylum.
  9. No significant cognitive impairment implicated in aetiology (e.g. organic disorder)
  10. Do not present a high short-term risk to themselves or others as assessed by care teams.
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Previous inclusion criteria:

1. Ethnicity: People of Sub-Saharan African and Caribbean descent, including those who self-identify as 'Black British', 'Black Caribbean', 'Black African', 'African-Caribbean', or 'Mixed' African/Caribbean'
2. Diagnosis: Schizophrenia or related diagnoses (ICD F20-29/ DSM-IV). We shall exclude to those with non-psychotic or organic brain disorder or cognitive impairment
3. Capacity: Assessed by Care Coordinators/key workers as having the capacity to provide informed consent and to participate in therapy.
4. Assessed by Care Coordinators/key workers as not presenting a high, short-term risk to self or others

**Participant type(s)**

Patient

**Age group**

Mixed

**Lower age limit**

14 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 404; UK Sample Size: 404

**Total final enrolment**

154

**Key exclusion criteria**

Current exclusion criteria as of 04/10/2021:

Service users:

1. Organic brain disorder
2. Cognitive impairment sufficient to impact completion of assessment measures
3. Substance use as primary diagnosis
4. Currently receiving any form of family intervention

Family members and nominated Family Support Members (FSMs):

1. Service user does not meet ethnicity or diagnostic criteria
2. Cognitive impairment sufficient to impact completion of assessment measures
3. Inability to understand study information or to give informed consent and complete measures

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Previous exclusion criteria as of 05/02/2021:

1. Organic brain disorder
2. Cognitive impairment sufficient to impact completion of assessment measures
3. Substance use as primary diagnosis.
4. Currently receiving any form of family intervention

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Previous exclusion criteria:

1. As substance use often co-occurs with psychoses, this will not be an exclusion criterion unless it is the primary diagnosis
2. Under the age of 14. However, family members under 14 (e.g. siblings) can participate if they are able to give assent, depending on parental/guardian consent
3. Family members, and FSMs do not have to be of Caribbean or Sub-Saharan background

**Date of first enrolment**

01/11/2021

**Date of final enrolment**

30/11/2023

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Prestwich Hospital**

Greater Manchester Mental Health NHS Foundation Trust

Harrop House

Bury New Road

Prestwich

Manchester

United Kingdom

M25 3BL

**Study participating centre**

**University of Manchester**

Oxford Road

Manchester

United Kingdom

M13 9PL

**Study participating centre**

**Healthy Minds Bury**

Pennine Care NHS Foundation Trust

225 Old Street

Ashton-under-Lyne  
United Kingdom  
OL6 7SR

**Study participating centre**  
**Queen Elizabeth Hospital Birmingham**  
University Hospitals Birmingham NHS Foundation Trust  
Mindelsohn Way  
Birmingham  
United Kingdom  
B15 2TH

**Study participating centre**  
**Coventry And Warwickshire Partnership NHS Trust**  
Wayside House  
Coventry  
United Kingdom  
CV6 6NY

**Study participating centre**  
**University of Warwick**  
Kirby Corner Rd  
Coventry  
United Kingdom  
CV4 7AL

**Study participating centre**  
**Tatchbury Mount Hospital**  
Calmore  
Southampton  
United Kingdom  
SO40 2RZ

**Study participating centre**  
**King's College London**  
Health Service & Population Research  
De Crespigny Park  
London  
United Kingdom  
SE5 8AF

**Study participating centre****Maudsley Hospital**

South London and Maudsley NHS Foundation Trust  
Denmark Hill  
London  
United Kingdom  
SE5 8AZ

## Sponsor information

**Organisation**

Greater Manchester West Mental Health NHS Foundation Trust

**Sponsor details**

Prestwich Hospital  
Bury New Road  
Prestwich  
Manchester  
England  
United Kingdom  
M25 3BL  
+44 (0)161 2710076  
sarah.leo@gmmh.nhs.uk

**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.gmw.nhs.uk/>

## Funder(s)

**Funder type**

Government

**Funder Name**

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: HTA 16/167/76

**Funder Name**

National Institute for Health Research (NIHR) (UK)

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

01/06/2025

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository.

Repository: UK Data Archive/University of Manchester

When data will be made available: 6 to 12 months after study conclusion.

What criteria for data to be shared, with whom: Future researchers.

Whether consent from participants is needed: Participants will have consented to the participant information sheet, which specifies that data will be freely available to the public on the UK Data Archive for ten years. It is stated that future researchers will be able to use their data.

Comments on data anonymisation: Participants will be allocated a study number. Personal identifiable data and participant study numbers will not be stored in the same location.

Ethical or legal restrictions: No patient identifiable data will be available.

**IPD sharing plan summary**

Stored in non-publicly available repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version 3	15/06/2021	26/08/2021	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No