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

Submission date
13/01/2020

Recruitment status
No longer recruiting

Registration date
31/01/2020

Overall study status
Completed

Last Edited
19/12/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Contact information

Type(s)
Public

Contact name
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Scientific

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M13 9WL
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
266123

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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 wing 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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Previous intervention as of 27/08/2021:
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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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Previous intervention:
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.

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Intervention Type
Behavioural

Primary outcome(s)
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

Key secondary outcome(s))
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)

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.

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
14 years

Sex
All

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

United Kingdom

England

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

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically 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?

HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet version 3	11/11/2025	11/11/2025	No	Yes
Protocol file		15/06/2021	26/08/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes