Research Protocol

The effect on relapse of Culturally-adapted Family Intervention (CaFI) compared to usual care among African & Caribbean people diagnosed with psychosis in the UK: Phase 1 Qualitative Study

(CaFI) Study

IRAS number: 254857

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Signature: Date: ……/……/……

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Name (please print):

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Position:

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Chief Investigator:

Signature:  Date: .26./.06./.19.

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Name: (please print): Dawn Edge

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Table of Contents

SIGNATURE PAGE 2
Study Protocol 6
Our study has three main aims: 7
Research questions (RCT) 7
Background and Rationale 7
Brief literature review 7
Implications for current NHS policy and practice 8
Why this research is needed now 8
Previous Related Research 9
Concise statement of the research 10
Study Aims 10
Research Plan & Methods 11
Phase 1: Qualitative Study 11
Phases 2 & 3: Internal Pilot and RCT 12
Study design 12
Internal pilot 12
Health service setting and context 13
Summary Plan of Investigation (Internal pilot & RCT) 13
Population 13
The intervention 13
Primary outcome 13
Secondary outcomes 14
Sample Size 14
Inclusion criteria (service users) 14
Family members 15
Exclusion criteria (service users) 15
Recruitment 15
Data collection and analysis 15
Quantitative 16
Qualitative- Internal pilot 16
Main trial 16
Timetable (months) 17

Project management 17
Approval by ethics committees 18
Patient and Public Involvement 18
Team Members & Expertise 18

Date	Version number	Changes
7th March 2019	**1**	
26th June 2019	**2**	1. The protocol refers to the entire study – i.e. Phases 1, 2 & 3. For clarification about the age limit in relation to Phase 1 (Qualitative Study), we have added the following under 'Focus group samples' (p.6) to clarify the age requirements in Phase 1: "*The minimum age for service users and relatives/carers/advocates taking part in focus groups is 16. The minimum age for healthcare professionals is 18. There is no upper age limit.*" 2. We thank the panel for their helpful recommendation regarding the potential for younger people to be intimidated when participating in focus groups with older people. Accordingly, we will undertake a focus group comprising younger people but will widen the age range, making it 16-25 to facilitate recruitment. Members of this younger group will be invited to participate in the later 'mixed' focus group. As this will essentially involve a process of self-selection, we anticipate that participants are unlikely to be intimidated by participating in the forum. However, the age and other demographics will be considered by the experienced researcher who will facilitate the 'mixed' focus group. We have clarified this on p. 6 of the Protocol. 3. The document does not refer to forensic settings in the Phase 1 part of the protocol. The protocol discusses forensic settings only in relation to the subsequent phases, specifically, the clinical trial (to

		which this IRAS application does not extend). Thus, we are happy to confirm that the original document does not have a reference to the forensic settings in Phase 1. Reference in relation to Phases 2 & 3 is necessary as we shall recruit participants into the trial from forensic settings. 4. The document does not contain a reference to direct debit payment. 5. For consistency, we have changed 'digital recordings' to 'audio recordings' on p.6, 11 & 12. 6. Updated NHS Trust acronym on p.10 from MHSCT to GMMH.

The effect on relapse of Culturally-adapted Family Intervention (CaFI) compared to usual care among Black African & Caribbean people diagnosed with psychosis in the UK: A Randomised Controlled Trial.

Plain English Summary

Schizophrenia and other forms of psychosis are serious mental illnesses that cost the UK around 9 billion pounds per year. Treatment is expensive, and many people with these illnesses cannot work. Moreover, families and friends often give 'informal care', so the actual cost of treatment is probably much higher than we think. In addition, there are significant emotional and social costs; supporting people with schizophrenia and psychosis is stressful. There is often conflict in families, and they can easily get 'burnt out'.

Black people in the UK are diagnosed with psychoses, including schizophrenia, at much higher rates than any other ethnic group. Moreover, Black people tend to get into services later than others, and they tend to have longer periods at home without receiving any treatment. This can increase family conflict. Oftentimes, families end up calling the police to help the individual get the treatment they need.

For the individual with schizophrenia, police involvement and being 'sectioned' under the Mental Health Act is part of a 'negative care pathway' that many Black people experience. Once in psychiatric services Black people receive higher doses of medication and are more often treated in seclusion. They also stay longer in hospital than White British people and get more Community Treatment Orders (compulsory treatment in the community). This makes their treatment both more expensive and less satisfactory.

Getting families to understand service users' experiences and supporting service users in understanding the impact of their behaviour on their families can reduce stress and conflict. Family Intervention (FI) is a form of 'talking treatment' that helps with this. It is a form of therapy for service users and their families and carers that can help them to talk about their feelings and to listen to each other. Service users who receive FI are more likely to take their medication and look after themselves better. This stops them from becoming unwell again and going back into hospital as often.

However, many people with schizophrenia and psychoses are not in contact with their families. For them to still benefit from FI, we realised that we needed to do things differently. We have worked with Black Caribbean service users and their families and developed Culturally-adapted FI (CaFI). CaFI is similar to FI, although its content is 'less White' and more culturally acceptable. For example, it takes into consideration things like racism and spirituality and how they affect Black people's experiences of mental illness. It also makes it possible for service users who are not in regular contact with their families to benefit from the treatment. We did this by asking service users to choose 'trusted individuals' such as their Care Coordinators to work with them. If service users were unable to think of anyone who could do this, we invited community members to 'come alongside'

them as 'Family Support Members' (FSMs)to support them through the therapy. Half the people who received CaFI did so with FSMs, showing a clear need for them.

People who tried CaFI really liked it: 24 out of 26 families completed all ten sessions. CaFI therapists and other health workers also liked it. Everyone who took part thought that it should be available to other ethnic groups as well. We now plan to test CaFI with Black Africans, Caribbeans and people of 'Mixed' African/Caribbean heritage. Although there are differences between these groups, we think that being Black or of Mixed heritage means that some of their experiences are similar and that developing a therapy around these similarities makes sense. As Black people are more likely to be in forensic care (compulsory treatment after committing a crime), we also plan to test CaFI in these settings. FSMs may be especially needed here because people in forensic care are especially likely to lose contact with their families.

Our study has three main aims:

1. See if CaFI works at least as well as usual care and is good value for money
2. Understand what will make it easier/harder for CaFI to be taken up by services
3. Find out what can be done to make it more likely CaFI will be taken up and how best to overcome barriers

The study will run for 54 months in Manchester, Merseyside, London, Midlands, and Southampton. Sites in Bristol and Nottingham may be included later if required. This enables us to look at different services in different parts of the country. We will also talk to people about their experiences and views of CaFI.

Research questions (RCT)

1. Compared with usual care, will Culturally-adapted Family Intervention (CaFI) prove more cost and clinically-effective for African and Caribbean populations in the UK?
2. What are the main barriers and facilitators to CaFI becoming part of routine care?
3. How can facilitators be maximised and barriers overcome?

Background and Rationale

Brief literature review

The incidence of psychotic disorders was once believed to be similar across all populations, but Kirkbride et al[1] confirmed previous findings[2-7] of higher rates among Black populations. The Aetiology and Epidemiology of Schizophrenia and Other Psychoses (AESOP) study[8] reported that, compared with White British people, rates of schizophrenia are around 6 and 9 times greater in Black African and Caribbean groups, respectively.

Although there has been a rapid rise in the number of psychological interventions aimed at meeting the culturally-specific needs of ethnic minorities, they have been mostly among South Asian[9], Latina[10], and Chinese[11 12] people. Studies in Black populations have been predominantly conducted in

the United States[13]. We undertook a systematic review[59] and found no trials of culturally-specific psychological therapies, such as FI, for Black populations.

Implications for current NHS policy and practice

Schizophrenia and related psychoses are serious mental illnesses (SMI) that are associated with considerable economic, societal, and personal burden[14 15]. In the UK, the estimated yearly cost of schizophrenia is £8.8bn[1]. Forty percent of this cost (£3.5bn) is attributable to service provision. Lost employment accounts for an additional 47% (£4.1bn), and informal care provided by family and friends accounts for 13% (£1.2bn). The burden of caring for someone with schizophrenia can adversely affect carers' physical and mental health[15], resulting in family conflict. This conflict can, in turn, increase rates of relapse and hospital readmission[16].

Over the past 50 years, UK research has consistently reported that people of Black African and Caribbean origin are more likely to be diagnosed with schizophrenia than other ethnic group[8 17-19]. Despite initiatives to tackle race-based inequalities in mental health[20 21], Black people continue to experience worse care and outcomes. They have longer inpatient stays and receive higher doses of psychotropic medication. They are also more likely to be discharged on Community Treatment Orders, whereby they receive continued supervised treatment, making their care more coercive and costly[22].

People with SMI become more isolated as their social networks shrink over time, which is detrimental to their mental health[23]. Conversely, social support improves mental health and wellbeing and access to care [24]. Black people diagnosed with SMI are more likely to lose contact with their families and communities[25], reducing their access to FI. Our study will enable such service users to receive CaFI by working with FSMs.

Previous research has highlighted the barriers to implementing FI as part of routine care[26 27]. Implementation science in mental health has been described as 'embryonic'[28]. The intersections of cultural adaptation and implementation science might be particularly helpful for bridging the 'translational gap' and facilitating uptake of interventions[29]. The proposed study includes process evaluation to identify and address the facilitators and barriers to implementation to improve the likelihood of CaFI becoming part of routine practice.

Why this research is needed now

Service users from Black African and Caribbean backgrounds (including those who regard themselves as 'Black British' and 'Mixed) are more likely than other ethnic groups to be diagnosed with schizophrenia[30]. Explanations for this include migration[31], living in cities ('urbanicity')[32 33], and socio-economic disadvantage[34]. Lower rates of diagnosis in Africa and the Caribbean[35 36], as opposed to in the UK, suggest that personal and institutional discrimination are also important contributory factors[37 38].

Alongside higher rates of diagnosis, Black people also have poorer access to mental healthcare, more negative experiences of services, and worse outcomes[20 21]. They are more likely than other groups to

be admitted to hospital with police involvement under the Mental Health Act[30 39]. Once hospitalised, they experience higher rates of seclusion and other forms of coercive care[40 41]. These experiences make Black people fear and mistrust mental health services[42]. Together with high rates of shame and stigma in these communities[43], it is not surprising that Black people tend to avoid contact with mental health services. Research also shows that even when they try to get help, it is not forthcoming[44 45]. The net result is that African and Caribbean people tend to enter into services later in the illness process[45] and are sicker by the time they do so[44]. Long periods with untreated psychosis place great strain on family relationships and may partly explain why people diagnosed with SMI from these communities are especially likely to lose contact with their families[46]. This reduces their access to evidence based therapies such as Family Intervention (FI).

NICE recommend FI for schizophrenia[47]. Although there are different models of FI, they share common core components such as psycho-education, problem solving, and stress and crisis management[48 49]. There is strong evidence that FI is both cost- and clinically-effective[48 49]. For example, FI has been shown to improve medication compliance, self-care and problem-solving, and to reduce the risk and frequency of relapse[48]. As well as improving service users' social functioning and quality of life, FI has been found to reduce carer burden and associated ill-health[50]. However, the viewpoint that FI is time intensive and costly means that it is greatly underused in the NHS[51]. As Black service users are less likely to be in contact with their families (NICE recommends FI is offered only to people in regular contact with their families), they are even less likely to receive FI[47]. This is important, as FI offers advantages over individual therapies, such as Cognitive Behavioural Therapy (CBT), due to family member involvement[52]. We therefore propose the opportunity to offer FI to people without family contact via Family Support Members (FSMs). This might be an important step in helping them to reengage with families and communities members.

In summary, although FI is recommended by NICE for the treatment of schizophrenia, it remains currently underused in the NHS[26]. NICE have recommended developing culturally-appropriate psychological therapies to improve Black people's access to evidence-based care. Without alternative measures of delivering FI, such as involving FSMs, NICE recommendations could inadvertently worsen the inequalities in accessing psychological therapy currently experienced by Black service users and their families. This is especially pertinent for the forensic population, among whom Black service users without family contact are over-represented[20].

Previous Related Research

Given the lack of research into FI among minority ethnic groups[53], we undertook an NIHR-funded feasibility pilot[54] to determine if it was possible to culturally-adapt, implement, and evaluate FI for African-Caribbeans. Our findings demonstrated the feasibility of successfully:

1) recruiting service users and families from this 'hard-to-reach' population
2) recruiting Family Support Members (FSMs) to enable service users not in contact with their families to receive the CaFI intervention
3) delivering CaFI in the NHS in acute, rehabilitation and community settings
4) retaining family units in therapy: 24 of 26 (92%) of those who commenced our Culturally-adapted Family Intervention (CaFI) completed all 10 sessions

CaFI also received high acceptability ratings (above 80%) from service users, family members and health professionals. All groups reported positive benefits, including improved symptoms (as evidenced by better mood and less paranoia) and improvement in social functioning (as evidenced by engaging in volunteering and active planning to return to work and full-time education). Therapeutic alliance was positively rated by all groups. Improved communication between service users, families and health professionals was also reported. Service users' health utility index improved, especially among individuals who were not in contact with their families and who participated with FSMs.

The HTA-funded systematic review[55] highlighted the importance of therapeutic communication and alliance between Black and minority ethnic groups and mental health professionals. Our feasibility pilot achieved therapeutic alliance scores (WAI[56]) comparable or higher to findings from a systematic review of therapeutic alliance in psychological therapies for psychosis[57], underscoring CaFI's acceptability.

In light of the long history of negative relationships between Black people and mainstream mental health services, these are important findings. Although the study was not powered to test hypotheses, the results suggest that engaging Black families in psychological therapy has the potential to a) reduce inequalities in accessing evidence-based, NICE-recommended care and b) deliver significant cost savings. Demonstrating the effectiveness of the intervention might also have implications beyond African and Caribbean people. For example, the role of FSMs might be an important means of enabling access to psychological care for others without families in the UK such as refugees.

Concise statement of the research

The HS&DR-funded study on which this application is based was a feasibility pilot to develop and evaluate the implementation of Culturally-adapted Family Intervention (CaFI) for African-Caribbean people diagnosed with schizophrenia and psychoses, and their families [54]. The proposed study differs in important ways – specifically, it will:

1. Be randomised: In the feasibility pilot this was not the case, and results are therefore not generalizable: we cannot be certain that the findings were not due merely to chance.
2. Be fully powered: This will enable assessment of clinical effectiveness of the intervention compared with usual care.
3. Determine cost-effectiveness: Although in the pilot we proved the feasibility of collecting health utility data as the basis for health economic evaluation, the feasibility study was not designed to determine cost-effectiveness.
4. Include Black Africans: The study population of the feasibility pilot was limited to people from the Caribbean of African descent (including those who self-identified as Black British or 'Mixed', but who had parents/grandparents who migrated from the Caribbean).
5. Include the forensic population among whom Black Africans and Caribbeans are disproportionately represented[58]

Study Aims

Our study has three main aims:

i) Test CaFI's clinical and cost-effectiveness in African and Caribbeans compared with usual care

ii) Identify barriers and facilitators to successful implementation
iii) Determine how to maximise facilitators and overcome barriers

Research Plan & Methods

Phase 1: Qualitative Study

Qualitative data via focus groups and consensus methods will be collected and analysed to ensure the intervention is suitable for a Black population comprising Caribbeans and Sub-Saharan Africans. Semi-structured interview schedules and supporting materials (e.g. PowerPoint presentation) used in the feasibility study will be adapted for this proposal based on PPI input and emergent research evidence. Focus groups will be audio-recorded, transcribed verbatim, and analysed using Framework Analysis[81]. This approach is well-suited to our study as it allows both a priori and emergent themes to be identified. A priori themes will include: perceptions of the intervention's cultural relevance, content and structure of the intervention, and the training needs of therapists and Family Support Members. Consensus health service research methods are usually used where there is complexity and little previous work providing a mechanism for improving group decisions[80]. There are a number of approaches to building consensus. The most common being: i) Delphi studies[77,79]; ii) Nominal group technique (NGT)[78] and iii) Consensus development conferences or panels[80]. In this study, we shall use NGT to arrive at consensus on findings from interviews and focus groups via discussion and voting with experts by experience (service users and carers) and by profession (experts in the fields of transcultural mental health, psychosis, development and/or delivery of psychological interventions). In this context, 'consensus' will equate to 'near-unanimous agreement' achieved by, for example, 80% rating of items as 'high priority'[79].

Focus group samples

We shall conduct separate focus groups with the following stakeholders: i) service users of Sub-Saharan African and Caribbean origin diagnosed with schizophrenia or related diagnoses; ii) relatives/carers/advocates of service users of Sub-Saharan African and Caribbean origin; and iii) healthcare professionals with experience of working with service users of Sub-Saharan African and Caribbean origin and/or their families. Each focus group will have 8-10 participants, based on literature[81] and our previous experiences of conducting focus groups with these stakeholder groups as part of the feasibility study. The minimum age for service users and relatives/carers/advocates taking part in focus groups is 16. The minimum age for healthcare professionals is 18. There is no upper age limit.

We shall conduct separate focus groups with young participants (aged 16-25) to lower potential age-related barriers to participation. However, respecting participants' right to choose, we will not exclude any participants in this age bracket from taking part in the other focus groups, if they wish to do so. We shall also conduct a fourth 'mixed' focus group with a sub-set of participants from the previous three groups to explore consensus on topics and issues discussed in the separate focus groups. These 'mixed' groups will be open to anyone from the previous focus groups if they are comfortable to participate in a group comprising people of mixed ages.

Data collection will be facilitated by Chief Investigator or local Site Principal Investigators, with support from Site Research Assistants.

Each of the following localities shall conduct all four focus groups, totalling up to (30 x 4 =) 120 unique participants:

North West: Greater Manchester Mental Health NHS Foundation Trust (research site)
Pennine Care NHS Foundation Trust (research site)
The University of Manchester (research site)
Mersey Care NHS Foundation Trust (Participant Identification Centre)

Midlands: Coventry & Warwickshire Partnership NHS Trust (research site)
Birmingham & Solihull Mental Health NHS Trust (research site)
The University of Warwick (research site)

London: King's College London (research site)
South London & Maudsley NHS Foundation Trust (research site)

Southampton: Southern Health NHS Foundation Trust (research site)

Focus group findings will inform the cultural-adaptation for Sub-Saharan African service users and their families, and further refinement of the intervention content, delivery and therapist training.

Phases 2 & 3: Internal Pilot and RCT

Study design

This is a mixed-method study comprising a qualitative intervention development phase, multi-site Randomised Controlled Trial (RCT) with an internal pilot, and a process evaluation. The main trial will involve testing Culturally-adapted Family Intervention (CaFI) in four geographical locations (6 NHS Trusts + 2 contingency Trusts) across England. This will be done with a Caribbean sample, among whom feasibility and acceptability have been established (HS&DR Feasibility Pilot)[59] and people of Sub-Saharan African origin.

Internal pilot

As CaFI was not established with African people, neither its acceptability nor the feasibility of recruitment and retention have been tested in this population. In preparing this application, we consulted with members of the Sub-Saharan African community and relevant agencies, such as African & Caribbean Mental Health Services (ACMHS), Manchester. These consultations suggested that CaFI is desired by this population and that there are sufficient similarities between African and Caribbean populations to justify further refinement of the intervention to ensure that it meets the needs of both African and Caribbean people. Specifically, the individuals we consulted felt that it was not the intervention itself that would require adaptation. Rather, the therapy manual and supporting resources would need to include African-specific material and that this would need to be reflected in therapists' cultural competence training. We shall therefore undertake work alongside setting up the main trial to culturally-adapt the intervention with a Sub-Saharan African sample, using the processes and procedures used to develop CaFI[59]. We shall then test the feasibility of recruitment, retention, and data collection in this population by running an internal pilot. Depending on the outcome, we shall either continue with a Caribbean only sample at this stage or incorporate Sub-Saharan Africans into the main study.

Rehabilitation, community and forensic setting in eight NHS Mental Health Trusts:

Table 1: Number of potentially eligible service users across sites

Sites	N
Northwest	
Greater Manchester Mental Health (GMMH) NHS Foundation Trust (host Trust)	1,520
Pennine Care NHS Foundation Trust	375
Mersey Care NHS Foundation Trust	690
Midlands	
Birmingham & Solihull NHS Foundation Trust	3100
Nottinghamshire Health NHS Foundation Trust	1045
London	
South London & Maudsley (SLAM) NHS Foundation Trust	4140
South	
Avon and Wiltshire Mental Health Partnership NHS Trust (Bristol)	325
Southern Healthcare NH	250
Total	**11,425**

Summary Plan of Investigation (Internal pilot & RCT)

Population

The target population will be African- and Caribbean-origin service users (including people who regard themselves as 'Black British' and of 'Mixed' heritage) in rehabilitation, community and forensic settings, and their families. Where biological family members are not available, service users will be able to participate by involving Family Support Members (FSMs). FSMs will can be trusted individuals (such as friends or care coordinators/key workers) nominated by service users. Alternatively, they may be community volunteers, 'befrienders' or former service users (peer support) specifically recruited into this role.

The intervention

10x1-hour sessions of Culturally-adapted Family Intervention (CaFI) will be delivered within a 20-week 'therapy window'. The control group will receive usual care, which typically consists of medication and support from nurses. Given previous reports of lack of availability of FI and our experience of CaFI, we do not anticipate that this 'usual care' will involve forms of FI or similar psychological interventions. To ensure this, this will be one of our exclusion criteria.

Primary outcome

The primary outcome is reduction in relapse, as rated from service user records (case-notes) using a well-established definition of a two-week exacerbation of symptoms leading to a change in management [60]. Past studies[60] have demonstrated the ability to predict rating of relapse via case-notes in 98% of participants.

Secondary outcomes

The secondary outcome is the Positive and Negative Syndrome Scale (PANSS)[61], Personal and Social Performance Scale (PSP)[62], Perceived Criticism Scale (PCS)[63], Brief Illness Perception Questionnaire (Brief-IPQ)[64], Knowledge about Psychosis Interview (KAPI)[65], General Health Questionnaire (GHQ-12)[66], EQ-5D-5L[67], Working Alliance Inventory (WAI)[68] and Service Engagement Scale (SES)[69].

Sample Size

An existing meta-analysis indicates a relative risk of 0.55 for relapse after family intervention without cultural adaptation[48]; 40% of controls relapsed. Our feasibility study to develop and evaluate CaFI's implementation in Manchester provided outcome data to confirm these findings. A reduction in risk of relapse from 40% during follow-up to 24% (i.e. a risk ratio of 0.6) would equate to a clinically-significant difference sufficiently convincing to inform commissioning and facilitate change in practice. In the control arm, we assume 70% of participants will relapse by 6 months based on previous meta-analyses[48].

Using Stata's 'power logrank' command and assuming a hazard ratio of 0.60 (i.e. the intervention is expected to lower the hazard of relapse over time), 260 participants recruited across four locations (130 in each arm) will provide 80% power, allowing for 20% withdrawal (using Schoenfeld's formula).

Based on our feasibility pilot and recruitment into a previous multi-site study, we are confident that we can recruit the numbers required. In our study, we recruited to target. The Aetiology and Ethnicity in Schizophrenia and Other Psychoses (AESOP) study[8] recruited n=447 eligible Black African and Caribbean participants and n=207 controls from three of our proposed sites - South-east London, Nottingham and Bristol over 18 months in total (Bristol last 9 months only).

Table 1 shows that, nationally, there are approximately 11,500 mental health service users who meet the ethnicity criteria. From our feasibility pilot, we anticipate that there will be missing data and errors in ethnic labelling. Whereas incorrectly labelling Africans as Caribbeans was problematic in the feasibility study, it should have limited impact on recruitment into the proposed trial, as both Africans AND Caribbeans will be recruited. Furthermore, even if half the data were either missing or flawed, that would still leave a pool of 5,750 potential participants.

Randomisation will be stratified by location (NW; Midlands; South; London) and ethnic background (AC; BA). Within each stratum, participants will be randomly allocated (1:1) to either the intervention or control arms in blocks of size 4, 6 or 8: block size will also be chosen at random.

Inclusion criteria (service users)

- African and Caribbean descent (including those who self-identified as 'Black-British', 'Black Caribbean', 'Black African', 'African-Caribbean' or 'mixed' African/Caribbean, but who had at least one parent or grandparent who was born in Sub-Saharan Africa or the Caribbean).
- Diagnosis of schizophrenia or related diagnoses (ICD F20-29/ DSM-IV) [70 71]
- Receiving treatment through psychiatric (acute or rehabilitation) inpatient services or community services within the eight participating NHS Trusts.
- 14 years or older

- Assessed by key workers as having the capacity to consent and participate
- Sufficient understanding of the English language to complete measures.
- No significant cognitive impairment implicated in aetiology (e.g. organic disorder)
- No high risk to self or others as assessed by care teams.

Family members

Family members do not have to be of African or Caribbean origin. They are generally required to be at least 16 years old, but exceptions can be made if a nominated family member (e.g. a sibling or a child) is under 16 and able to assent, with consent from a guardian. They must have sufficient understanding of the English language to be able to give written, informed consent and complete measures.

Exclusion criteria (service users)

- Other ethnic groups
- Not diagnosed with a schizophrenia spectrum disorder or related non-affective psychoses
- Cognitive impairment
- Substance use as primary diagnosis

Recruitment

Based on our sample size calculation, we will need to recruit 14 participants per month across all 8 NHS Trusts. Data will be collected by RAs blind to delivery of the intervention at 4 time-points: baseline, post-intervention and at 6 and 12 months follow-up.

As recruitment will be within communities previously labelled 'hard-to-reach', we shall adopt engagement and recruitment strategies informed by our PPI work and previous HS&DR (CaFI) study. These may include but are not limited to using local media, working with Faith-Based Organisations (FBOs), voluntary sector agencies and community groups.

Within services, we shall place advertisement posters and flyers in GMMH sites accessible to service users, carers and advocates. We anticipate that the study will be adopted onto the NIHR portfolio. Accordingly, NIHR Clinical Research Network (CRN) Clinical Studies Officers (CSOs) will support recruitment, helping to identify and recruit suitable participants. CSOs and RAs will work collaboratively to publicise the study and inform clinical staff about the inclusion criteria. Recruitment packs, including the study Participant Information Sheet (PIS), will be provided for service users who are deemed well enough to participate by their clinical teams, who have the capacity to consent and who gave permission to be contacted by the research team. Service users who remain interested will be invited to meet with the RA to receive further information about the study and ask any questions before being consented into the study. Consenting participants will be asked to complete baseline assessments during the initial meeting. An additional meeting will be arranged if this is not feasible.

Data collection and analysis

Quantitative

In our HS&DR pilot trial, we have demonstrated the feasibility of delivering CaFI using the following parameters:

- Recruitment (number approached versus number consented)
- Attendance (number of sessions attended)
- Attrition (number of drop-outs at each time point)
- Retention (the proportion of participants who complete therapy sessions)
- Completeness of outcome measurement

In keeping with our protocol, this has informed our choice of outcomes for the proposed trial. Specifically, we have decided against using hospital admission as a primary outcome measure because changes in practice and service delivery (e.g. fewer inpatient beds, greater emphasis on community care) mean this is no longer a meaningful measure. Instead, we focus on relapse. We have demonstrated the feasibility of collecting relapse data (paper in preparation) and this is a Cochrane-recommended measure[48]. We have also demonstrated the feasibility of collecting all proposed secondary outcomes[59].

Statistical analyses will be performed on an intention-to-treat basis. The log-rank test will be used to compare the survival distributions of the two arms. If its assumptions are met, Cox's proportional hazards model will be fitted, allowing adjustment for covariates.

Economic analysis: An economic evaluation comparing the cost-effectiveness of CaFI with usual care will be performed and reported according to the CHEERS statement. Alongside the cost of delivering CaFI, use of other healthcare resources, informal care and employment status will also be captured and considered (societal perspective).

Qualitative- Internal pilot

Qualitative work (focus groups, individual interviews with 'key informants', expert consensus conference) will be undertaken to ensure the intervention is culturally-adapted for a Black population, which includes both Caribbeans and Sub-Saharan Africans. This work will adopt the methods and procedures used to co-develop CaFI in the feasibility pilot.

Main trial

To explore potential barriers and facilitators to implementing CaFI, semi-structured interviews will be undertaken with approximately 30 service users and family members (biological and FSM); purposively sampled across all sites. The final sample will be informed by findings from the quantitative study and by iterative data collection processes. It is intended to collect data face-to-face. Where this is not possible, telephone/Skype or similar will be used to ensure maximum variation within the sample. Interviews will be audio-recorded, transcribed verbatim, and analysed using thematic analysis[69].

Understanding why effective interventions such as CaFI are successfully implemented in some settings but not others is a key issue for wider uptake and spread. Process evaluation is an essential part of designing and testing a complex intervention and is required to understand how and under what conditions implementation is effective[70]. There are a large number of theoretical frameworks available to understand the implementation processes[71]. We will draw upon a theoretical approach known as Normalisation Process Theory (NPT) which facilitates understanding of the extent to which

new processes become part of routine practice[72]. NPT is comprised of four main constructs that represent individual and collective levels of work involved in the implementation of new practice namely, coherence, cognitive participation collective action and reflexive monitoring.

We will conduct semi-structured interviews with around 30 staff (therapists, care coordinators, NHS senior leaders and service managers, commissioners) purposively sampled across all sites. Interview schedules will be informed by NPT and will focus on understanding:

- Sense making: how CaFI is understood and compared with existing practices
- Implementation: how CaFI is developed and translated into practice
- Embedding: how CaFI becomes or does not become routinely incorporated into the everyday work of professionals
- Integration: how CaFI is sustained as part of normal practice

Interviews will be audio-recorded, transcribed verbatim, and analysis will occur blind to trial outcomes to avoid biased interpretation of the findings. Anonymised transcripts will be analysed using Framework Analysis, allowing for both inductive and deductive coding. Deductive coding will be informed by NPT.

Timetable (months)

Total duration: 54
Setting up main trial (Caribbean) & cultural-adaptation (African): 12
Trial Recruitment: 24
Duration of intervention/participant: 10 weeks within 20 week window
Duration of follow-up: 12
Trial duration/participant: 17 (including follow-up)
Close-out (analyses, write up, initial dissemination): 3

Project management

The project will be managed by a Project & Trial Manager in collaboration with CTU. A Research Management Group (RMG) comprising all applicants plus representative from the host Trust's Research and Innovation department will be established. Via regular monthly meeting, they will provide study management and oversight.

A Study Steering Committee (SSC), at least 75% of whom will be independent of the study (including an independent chair and lay members), will be established. They will provide independent scrutiny and notify funders of any concerns regarding conduct of the study, including falling behind with recruitment or unexpectedly high rates of adverse events.

A Data Monitoring Committee (DMC), a 100% independent four-member panel of Experts by Profession will provide independent assessment of the study conduct. They will assess the progress of the project and determine on whether the RCT will be continue based on the Stop/Go internal pilot.

As with the CaFI Feasibility Pilot, a Research Advisor Group (RAG) comprising service users and carers will be established. RAG will advise on matters such as cultural-validity of and accessibility of study materials. They will contribute to therapists' cultural competence training. At least one member of RAG will be a member of RMG.

Approval by ethics committees

NHS, HRA and site-specific approvals for each participating NHS Trust will be sought.

Patient and Public Involvement

We have consulted with community members, service users and carers in developing this proposal. Specifically, the RDS bursary award has enabled us to consult about the desirability of CaFI for Sub-Saharan Africans. There is overwhelming support for further refining the intervention with PPI and trialling it with a 'Black' versus Caribbean population.

The study is an example of Community-partnered Participatory Research (CPPR) pioneered in the US[72]. For our feasibility study, we adopted NIHR principles for meaningfully engaging with service users and communities to develop research with versus either for or about them[73]. Our experience indicates that partnering with service users, community members and other key stakeholders to develop interventions has a positive effect on uptake, retention and satisfaction. This is particularly important when developing interventions for so called 'hard-to-reach' communities who are known to mistrust mental health services.

As with our feasibility study, we plan to provide PPIE research training and support. Specifically, we shall deliver sessions on research methods and governance as well as awarding honorary contracts to interested individuals to enable them to undertake further study, thus building capacity. Group and individual supervision will be provided for all involved in testing the intervention.

Team Members & Expertise

Principal Investigator

Dr Dawn Edge: Senior Lecturer, Division of Psychology & Mental Health, at the University of Manchester. Dr Edge will lead the project, overseeing all aspects, including setting up, data collection and analysis, dissemination, ethics and governance. She will supervise the trial manager and RAs and oversee coordination across all sites.

Co-applicants

1. Professor Kathryn Abel: Professor of Psychiatry & Director of Centre for Women's Mental Health, School of Health Science, at the University of Manchester and Hon Consultant Psychiatrist (GMMH). Prof Abel will provide expertise in schizophrenia, trial design and senior oversight of the trial.

2. Dr Lesley-Anne Carter: Research Fellow, Centre for Biostatistics, School of Health Sciences, at the University of Manchester. Dr Carter will provide expertise in trial design and statistics.

3. Dr Katherine Berry: Senior Clinical Lecture, in the Division of Psychology & Mental Health, School of Health Science, at the University of Manchester and Consultant Clinical Psychologist (GMMH). Dr Berry will contribute to trial design and therapists' training. She will lead on clinical supervision of therapists.

4. Professor Linda Davies: Professor of Health Economics Research based in the Division of Population Health, Health Services Research & Primary Care, at the University of Manchester. Prof Davies will provide expertise in health economics.

5. Professor Anthony Morrison: Professor of Clinical Psychology, in the Division of Psychology & Mental Health, at the University of Manchester. Director of Research, Development & Innovation, Greater Manchester Mental Health (GMMH) NHS Foundation Trust (the host Trust). In addition to expertise in trial design, Prof Morrison will facilitate service access and provide expertise in trialling psychological interventions.

6. Reverend Paul Grey: Independent Service User Consultant and 'expert by experience'. As chair of the RAG and member of RMG and TSC in our feasibility, Rev Grey will provide invaluable insight from the service user perspective.

7. Ms Sonia Lindsay: Carer Consultant. A member of the RAG in our CaFI feasibility study, Ms Lindsay will provide expertise from the carer perspective.

8. Mrs Michelle Ayavoro: Community Member and activist. A member of the RAG in our CaFI feasibility study, Mrs Ayavoro will be a community-focused Independent Consultant on this project.

9. Dr Shanaya Rathod: Consultant Psychiatrist & Director of Research, Department of Research & Development, at the Southern Health and Social Care Trust. Dr Rathod's role in this project is to provide expertise in cultural adaptation.

10. Dr Shublade Smith: Consultant Psychiatrist, in the Department of Psychiatry, at the Kings College London. Dr Smith's role in this project is providing expertise in transcultural and forensic psychiatry.

11. Dr Claire Henderson: Consultant Psychiatrist, Department of Psychiatry, at Kings College of London. Dr Henderson's role in this project is to provide expertise in trial design and transcultural psychiatry. She will be the site lead in London.

12. Dr Louisa Codjoe: Psychologist, Department of Psychology, at Kings College of London. Dr Codjoe's role in this project is to provide expertise in transcultural psychology.

13. Professor Swaran Singh: Head of Mental Health and Wellbeing, Warwick Medical School, at the University of Warwick. Prof Singh's expertise is in transcultural psychiatry. Professor Singh will be site lead for Coventry and Warwickshire Partnership NHS Trust.

14. Dr Richard Drake: Consultant Psychiatrist, Division of Psychology & Mental Health, at the University of Manchester. Dr Drake's role will be trial design, liaison with clinical services, and providing expertise in culturally-adapted and other psychosocial intervention trials in schizophrenia.

15. Professor Gillian Doody: Dean of Medical Education, Professor in General Adult Psychiatry and Medical Education, Faculty of Medicine & Health Sciences, at the University of Nottingham. Prof Doody will contribute expertise in trial design. Her experience as member of the AESOP team will be invaluable. She will be site lead for Nottingham.

16. Dr Jonathan Evans: Consultant Senior Lecturer, Centre for Academic Mental Health, School of Population Health Sciences, Bristol Medical School, at the University of Bristol. As site lead in Bristol, Dr Evans will provide expertise in psychosis and liaison with clinical services.

17. Dr Nicholas Kennedy: Consultant Psychiatrist, Birmingham and Solihull Mental Health NHS Foundation Trust. With expertise in transcultural psychiatry, Dr Kennedy's role in this project will be to support participant identification in the trust.

Collaborators

Dr Judith Richardson, NICE: Expertise in Health Service Policy and service implementation.

Professor Peter Bower: Chair in Health Sciences, Health Services Research & Primary Care, Division of Population Health, at the University of Manchester. Prof Bower's role in the project includes providing expertise in clinical trials and population health.

Voluntary sector collaborators

African & Caribbean Mental Health Services, Manchester

Rethink, Manchester

More collaborators will be sought during the project.

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