

HS & DR Full Proposal: Detailed Project Description

Full title of project

Culturally-adapted Family Intervention (CaFI) for African Caribbeans with schizophrenia and their families: A feasibility study of implementation and acceptability

Summary of Research

African Caribbeans have the highest prevalence of schizophrenia, most difficult relationships with mental health services and greatest persistent inequalities in care of all ethnic groups in the UK(1-3). The National Institute for Health and Clinical Excellence (NICE) recently updated schizophrenia guidelines(4); highlighting the lack of evidence-based psychological interventions for ethnic minorities in general and African Caribbeans in particular.

Responding to NICE recommendations(4), we propose a cultural-adaptation of an existing evidence based family intervention (FI)(5) for African Caribbeans that can be delivered at different phases of recovery and across different clinical settings. Our proposal aims to: i) culturally-adapt an existing family intervention(5), ii) test the feasibility of recruitment and implementation iii) evaluate its accessibility and acceptability among African Caribbean patients and their families. We shall test the intervention in hospital (acute and rehabilitation wards) and community settings (Community Mental Health Teams (CMHTs) – including individuals on Community Treatment Orders (CTOs)). Delivering the intervention via ‘proxy families’ (trusted individuals nominated by patients where there is little or no contact with biological families) potentially addresses an important access barrier for African Caribbeans who are especially likely to experience family disruption(6). Our approach therefore represents an innovative response to current inferior access and inequality of provision experienced by this ‘hard-to-reach’ group.

Our rationale is that:

1. Successful implementation of FI will facilitate and improve engagement in services for African Caribbean patients with schizophrenia and related disorders (ICD F20-29)(7).
2. Better and earlier engagement will improve access to a range of evidence-based interventions thus improving outcomes.
3. Successful implementation of FI in this group will pave the way to improving access to evidence-based care for other socially-excluded and ‘hard-to-reach’ groups.

Research Questions

1. How can existing evidence-based family intervention (FI) be culturally-adapted for African Caribbeans with schizophrenia and related disorders?
2. Is it feasible for culturally-adapted FI to be delivered in hospital and community settings?
3. Can ‘proxy families’ serve as acceptable alternatives where biological families are unavailable?
4. Will culturally-adapted FI be acceptable to patients, families, and health professionals?

Summary Plan of Investigation

We will use a mixed-methods approach following the Medical Research Council’s (MRC) framework for developing complex interventions (8). The study will be conducted in a number of distinct but related phases.

PHASE 1: CULTURALLY-ADAPTING THE INTERVENTION (Months 0 – 9)

PHASE 1A) LITERATURE REVIEW: Our preliminary literature review has revealed a lack of evidence for culturally-adapted psychosocial interventions for schizophrenia. We therefore shall initially widen the scope of our systematic search to include ‘mental health’ before focusing on cultural adaption of psychosocial interventions in schizophrenia.

PHASE 1B) FOCUS GROUP: We shall collect qualitative data via 3 focus groups: i) current and/or former patients ii) families, carers and advocates and iii) health professionals (n=8-10 in each group; n=24-30 in total). Patients will be of African Caribbean descent. Other participants can be from any ethnic background. A diverse sample in terms of age, profession and relationships with patients will provide a range of perspectives on how best to culturally-adapt (FI)(5) and likely training needs of family therapists who will deliver the intervention and ‘proxy families’.

PHASE 1C) CONSENSUS STUDY: In a Consensus Conference(9), key stakeholders (n=24) will culturally-adapt FI by synthesising data from Phases 1A and 1B with information on an existing evidence-based FI(5) and agreeing contents of a manual to support delivery. Stakeholders may include service user and carer agencies, voluntary sector groups, and national and local bodies such as Diverse Minds, Rethink Manchester, and the Carers Trust.

PHASE 2: TRAINING (Months 10 – 14)

We shall employ Meriden Family Programme www.meridenfamilyprogramme.com to provide cultural competency training for the Family Therapists and support workers who will deliver our culturally-adapted intervention. As NICE (4) advocate cultural competence training at both organisational and individual levels, we shall also deliver 3 ‘clinical competency’ seminars (one in each year) for staff in the participating units. Guided by outcomes from Phase 1, Meriden will train service-user peers and others identified by patients to become members of ‘proxy families’.

PHASE 3: FEASIBILITY STUDY (Months 15 – 32)

PHASE 3A: DELIVERING AND EVALUATING THE INTERVENTION

We shall test the feasibility of delivering the culturally-adapted FI in both hospital and community settings in Manchester Mental Health & Social Care NHS Trust (MHSCT); thus ensuring the intervention is tested at different levels of illness acuity and chronicity. The key objectives of this phase are a) testing the feasibility of delivering culturally-adapted FI to African Caribbean patients and families b) estimating important parameters for the design of a future randomised controlled trials (RCTs) such as i) testing recruitment strategies ii) identifying a suitable primary outcome measure for use in future research iii) examining the characteristics of outcome measures and estimating the standard deviation and intra-cluster correlation to aid in future sample size calculation iv) collecting information on follow-up response rates.

Over 12 months, 30 consenting patients and/or their families (10 in each setting) who express an interest, and are able to give informed consent, will receive 10 intensive sessions of the intervention as NICE evidence(4) suggests this number yields long term benefit. ‘Proxy families’ – trusted individuals nominated by patients (such as youth worker or community leader) will substitute for absent/estranged biological families. A similar approach has recently been undertaken in New Zealand (10) and is the subject of ongoing evaluation via RCTs by our collaborators Moxon and Ronan.

The intervention

Determining the form (session content), duration (number of sessions) and intensity (time between sessions) of the culturally-adapted FI and producing the manual will be the primary output of Phase 1. However, based on the model which we are adapting(5) and NICE guidance(4), we anticipate that the intervention will comprise approximately 10 (1-2 hour long) sessions delivered over a period of 16-20 weeks. In addition to initial patient and family assessment, core components are likely to include i) psycho-education (about the nature, course and management of schizophrenia) ii) assessment and intervention for stress management and coping with difficulties iii) problem-solving and planning for positive change.

Data collection and analysis

Quantitative: A key measure of the success of our intervention will be engagement by patients, their families and ‘proxy families’. Accordingly, we shall collect data on rates of recruitment in each of the three settings. Our primary outcome measure will be recruitment, uptake and attrition. We shall collect rates and reasons for non-completion. We shall collect demographic and outcome data as identified in Phase 1. Outcome measures may include: the modified Family Questionnaire (FQ)(11) and the Knowledge About Schizophrenia Interview (KASI (12)). The Short Form Survey (SF-12 version 2(13)) may be used to analyse disease burden and predict costs and its preference-based utility index (SF-6D) to facilitate economic evaluation and estimate quality adjusted life years (QALYs). Baseline measures will be taken pre- and post-intervention and at 3 and 12 months’ follow-up by the research assistant (RA). Data analysis will be primarily descriptive because this is a feasibility study and we do not have a powered sample size suitable for hypothesis testing (14). Data will be analysed using STATA(15).

Qualitative: Background and demographic data will be collected using a robust and systematic tool such as the Relative Assessment Interview (RAI)(5). Qualitative outcome measures which are important to patients and families will be identified in Phase 1. Qualitative data on the acceptability and accessibility of the intervention (ease of understanding, ‘user-friendliness’ of the manual) will be collected throughout using evaluation and feedback forms, interviews with up to 6 key informants identified by the research team, and semi-structured questionnaires at 12-months’ follow-up with participants who complete the intervention. We shall elicit participants’ views on the content, duration and intensity of the intervention – focusing particularly on perceptions of usefulness, cultural-appropriateness, accessibility, and facilitators/barriers to implementation. This will help us design future phase pilot studies and a multi-site RCT to test our culturally-adapted FI compared with standard FI and usual care. Qualitative data will be digitally recorded, transcribed, checked for accuracy and analysed using thematic content analysis(16). NVivo(17) will support data management and analysis.

PHASE 3B: FIDELITY STUDY (Months 30 – 32)

Adherence to the manual and delivery of the intervention will be tested by independent review of a 25% sample of recorded FI sessions. We will use a 60-item assessment checklist (18) to rate therapists’ adherence to the manual as well as knowledge and skill in delivering the intervention. Data on uptake, attrition and engagement (including number of completed sessions and reasons for non-completion) will also enable assessment of fidelity. Additionally, we will conduct

in-depth qualitative interviews with family therapists and support workers about their experience of delivering the intervention and using the manual.

Background and Rationale

Brief literature review

African Caribbeans, schizophrenia and mental health services

Increased prevalence of schizophrenia among African Caribbeans compared with other ethnic groups in the UK is consistently reported in the research literature(4, 19-21). More recently, the multi-site Aetiology and Ethnicity in Schizophrenia and Other Psychoses (AESOP) study reported that risk of schizophrenia was nine times higher in African Caribbeans than in White British people [IRR 9.1 (6.6-12.6)](2, 22). Over-representation of African Caribbeans in secondary care is also evident in Manchester where, although representing only 1.7% of the population, African Caribbeans account for 16.5% of inpatients in Manchester Mental Health & Social Care Trust's (MHSCT).

The access and utilisation of specialist services by African Caribbeans is poor (23-26). At every level of service, they are reported to have more negative experiences(24). Their pathways into care are less likely to involve their General Practitioner (GP) than White British counterparts and more often involve multiple help-seeking attempts(26). This delays access to diagnosis and treatment, which increases the duration of untreated symptoms and illness acuity on contact with services. Coercive care pathways ensue, with high rates of detention under the Mental Health Act 2007 (27) and involvement of criminal justice system in hospital admission. As inpatients, African Caribbeans experience more coercive care, such as high rates of seclusion and restraint, higher mean doses of psychotropic medication and less access to psychological therapy. They also experience worse outcomes including longer lengths of stay, higher rates of relapse and readmission(3). Regarded as 'high-risk', African Caribbeans remain hospitalised two-and-a-half times longer than White British counterparts and are disproportionately discharged on costly Community Treatment Orders (CTOs)(26, 28-29).

Against this background, it is perhaps not surprising that African Caribbeans' engagement with mental health services is characterised by fear, mistrust and avoidance (25, 30-31). This is important because delayed or non-engagement with services results in a vicious circle of negative care pathways, coercive treatment and poorer outcomes. The resultant 'circle of fear' (31) reinforces African Caribbean patients and families' negative attitudes towards and avoidance of mental health services(24, 31).

Family Intervention and African Caribbeans

Family intervention is a psychosocial treatment with a strong evidence-base of clinical effectiveness(4, 32-33). Although implementation and uptake are often sub-optimal(34-35), there is consistent evidence that engaging with schizophrenia patients and their families improves service delivery and outcomes (4, 33, 36-38). In a recent Cochrane Review, Pharaoh and colleagues (32) reported FI produced significant improvement in patients with schizophrenia. In meta-analysis (33) family intervention plus medication yielded better outcomes than medication alone. Recommended by NICE(4), family intervention in the context of schizophrenia and related disorders improves self-management and problem-solving which, in turn, reduces risk of relapse and hospital readmission(5, 39). We advocate culturally-adapting FI because NICE recommend it (4). Additionally, in community mental health conferences organised by the PI in collaboration with MHSCT, African Caribbeans expressed dissatisfaction with current provision, a strong desire for culturally-appropriate 'talking therapy', better understanding of schizophrenia, and improved relationship with mental health services. This resonates with findings from MHSCT 'In My Shoes' which found that patients and relatives felt disempowered and ill-informed <http://www.mhsc.nhs.uk/service-users/in-my-shoes.aspx>

The aim of FI is to decrease or prevent relapse, reduce burden and mental ill health amongst carers, improve social function and quality of life as well as clinical outcomes. There are a number of approaches to FI in schizophrenia. Core components of FI(32-33) include psycho-education, problem solving, cognitive appraisal, crisis management and encouraging carers to practice good self-care(40). Key FI principles common to different models include: establishing alliance with families, addressing family tension, setting reasonable and achievable expectations, focusing on maintaining gains and regarding FI as part of a total package of care. Lack of awareness or understanding of FI might partly account for reported low uptake of FI overall(34-35) and among African Caribbeans in particular. Previous work by the PI(41-42) and others suggest that African Caribbeans' models of mental illness and related attributions(43-44) means that both cognitions and behaviours will need to be addressed in culturally-adapted FI for this group. This has influenced our decision to culturally-adapt a psychologically-based model(5) developed by co-applicants Barrowclough and Tarrier (please see Research Plan for further details), which is evidence-based, widely used and the model of choice in the Trust where the study will be conducted. Although NICE recommends FI for African Caribbeans with schizophrenia(4), there is a lack of research on the feasibility of delivering FI in this or other ethnic minorities(4). It remains unclear whether the benefits of FI are generalisable to African Caribbean patients and their families (32).

Adding to the body of knowledge

Our proposed research will strengthen the existing evidence-base by: i) testing feasibility of delivering culturally-adapted FI in secondary care ii) addressing gaps in research for FI in UK ethnic minorities iii) strengthening the evidence-base for peer-engagement in developing and delivering interventions iv) testing feasibility of delivering FI via ‘proxy families’.

The study will add to emerging research into delivering psychological therapies for people with schizophrenia and related disorders (ICD F20-29) (7) at different phases of recovery and in ethnic minorities as advocated by NICE (4). In the North West, three NIHR-funded studies are underway, which involve members of our team: i) ‘HEalthy Living and Prevention of Early Relapse’ (HeLPER) Programme is testing interventions delivered in Early Intervention Services (Barrowclough & Drake); ii) family-focused interventions for acute psychosis (Baker and Barrowclough) and iii) culturally-adapting interventions for South Asians (Drake, Lovell and Husain) - the InterACT workstream. None of these studies focus on African Caribbeans. Nationally, the AESOP study of first episode psychosis strengthened the evidence on excess incidence and morbidity, inequity of access, provision and poorer outcomes for African Caribbeans (25-26) but did not develop interventions. This proposal responds to the evidence gap identified in the most recent schizophrenia guidance from NICE(4): NICE called for the development of effective interventions tailored to African Caribbeans who have the highest excess risk of schizophrenia and present the greatest challenge for services in terms of engagement, delivering effective care and risk management.

Implications for current NHS policy and practice

Inequality of access has serious public health implications in terms of the cost- and clinical-effectiveness of schizophrenia care: under-utilisation of clinically and cost effective existing interventions reduces efficiency and increases the cost of service provision (45). Potential costs related to inequitable access and poor outcomes for African Caribbeans are likely to be high, but remain unquantified. Collection of QALY data will assist us in design of future RCTs to assess cost-effectiveness. However, our primary focus is addressing inequity of access experienced by African Caribbeans by culturally-adapting a clinically-effective schizophrenia intervention to promote engagement in evidence-based care. This is in line with Government policy to foster equity and access to NHS care(46).

An intervention that improves access is also likely to improve patients’ quality of life and wellbeing by reducing: duration of untreated illness, lengths of hospitalisation and risk of relapse and readmission. In a group with prevalence rates 9 times higher than the general population and inpatient stay two-and-a-half times the mean, this could yield significant improvements in quality of life and cost savings for services locally and across the NHS – particularly in other cities with substantial numbers of African Caribbeans such as London, Bristol and Nottingham. These are centres in which a significant amount of research into African Caribbeans with schizophrenia has been conducted – including the MRC-funded AESOP study (22). However, these studies have tended to focus on observational epidemiology and, more recently, on understanding care pathways (25-26) .

Feasibility data and the development of patient and family-centred outcomes will be used in future studies to examine whether effective engagement in FI improves quality of life for patients and families as well as clinical- and cost-effectiveness in this ‘hard-to-reach’ group. Effective implementation in this ethnic group may also pave the way for FI in other ‘high risk’, marginalised groups such as prisoners and refugees. Improving engagement, access and care of minority groups will enable services to fulfil their statutory Equality Duties and meet Care Quality Commission (CQC) Essential Standards. This especially important with the reduction of patient beds, long waiting lists and the emergence of CTO’s and CRHT teams where the burden of the care is placed in community settings.

Collaboration between clinicians, patients, carers and commissioners to develop effective, sustainable interventions promotes new ways of working, maximises engagement, and optimises outcomes(46-47). Our patient-centred approach will be of interest to patients and providers as well as commissioners, policy-makers and health service researchers. Partnership between established NHS and academic centres in Manchester and London guarantees the clinical and academic quality of our research. Dissemination through stakeholder/user-researcher and academic networks such as HealthTALKOnline; Mental Health Research Network, NHS Trusts’ User and Carer networks, and Manchester Academic Health Sciences Centre (MAHSC) will maximise knowledge transfer across the NHS, NIHR and wider research communities.

Why this research is needed now*Timeliness of the research*

Despite decades of research and five years of major Department of Health investment aimed at ‘*Delivering Race Equality*’ in mental health (30), recent NICE review concluded that the care and treatment of African Caribbeans with schizophrenia remains in crisis (4). Service responses are inconsistent and mostly ineffective (4). African Caribbeans remain more likely than other groups to receive high doses of psychotropic medication and less likely to receive psychological therapy (24) NICE highlights the urgent need to develop culturally-appropriate, evidence-based interventions for African Caribbeans because, compared with other groups, they experience significantly higher levels of morbidity, inferior access to care and worse outcomes (4). Delayed access to diagnosis and treatment negatively affects families’ perceptions of the burden of care (48-49). This increases the risk of family breakdown, patients’ isolation and social exclusion, factors which are known to increase relapse and readmission rates. Proactive, recovery-based, family-

centred approaches improve risk management by identifying early warning signs and strategies to address them (50). However, a recent 12-month audit of FI in MHSCOT revealed that of 118 patients recorded as having ‘high/moderate’ contact with their families; just 3 were offered FI of whom 2 had accepted [Haddock, Personal Communication]. There were no data on the ethnicity of recipients. This contrary to NICE guidance and reflects more than a decade of concerns about how little progress has been made in integrating this FI into service delivery (34-35).

Relevance of the research

NICE specifically advocates research to determine whether culturally-adapting family intervention (FI) for schizophrenia would facilitate engagement; thereby improving clinical care and reducing relapse/readmission rates and lengths of stay for African Caribbeans(4). Recent systematic review confirmed the clinical effectiveness of FI(32). However, organisational and professional barriers, such as the unavailability of Family Therapists in some areas and perceptions that their input is time- and labour-intensive, often prevent FI being offered to schizophrenia patients(34-35). African Caribbeans with schizophrenia are doubly-disadvantaged (in terms of accessing FI) due to high levels of estrangement from their families (26, 28). Furthermore, discussions with former service users and carers in preparing this proposal confirm previously-reported social model of mental illness (42, 44), which is associated with dissatisfaction with services and non-compliance (51). Assessing the feasibility of engaging with African Caribbeans to culturally-adapt, deliver and evaluate FI has important implications for how to improve their engagement and access to other evidence-based interventions. From our initial review of the evidence, we believe that, in the NHS, our proposal to develop ‘proxy families’ to facilitate African Caribbeans’ participation in FI is a novel approach to tackling the problem of working with patients who are estranged from their families and would therefore not ordinarily be perceived as being eligible for FI. We also plan to deliver cultural competence training to FI therapists and to raise awareness of culturally-appropriate care in the workforce as NICE states that cultural competence at both individual and organisational are important aspects of facilitating culturally-competent care(4). Such approaches are needed to tackle patient, service user, staff and organisational barriers to accessing family intervention (34-35, 52).

Aims and objectives

Concise statement of proposed research

With key stakeholders, we shall culturally-adapt an existing evidence-based family intervention (5) for African Caribbean families with schizophrenia across in- and out-patient clinical settings in Manchester. To optimise access to our intervention in this group, we shall create ‘proxy families’ where biological families are absent or estranged. We shall examine feasibility of its implementation, develop patient and family-centred outcomes, evaluate its acceptability and pilot the collection of cost and quality of life measures.

Key Aims

1. Assess feasibility of culturally-adapting, implementing and evaluating an innovative approach to FI among African Caribbean patients with schizophrenia and their families across a range of clinical settings.
2. Test feasibility and acceptability of delivering FI via ‘proxy families’ where biological families are not available.

Study objectives

- i) Involve key stakeholders (patients, families and clinicians) in culturally-adapting an existing family intervention for African Caribbeans with schizophrenia.
- ii) Produce a manual to support delivery of the intervention.
- iii) Identify client and family centred outcomes and quality of life outcomes
- iv) To identify and address the training needs of therapists and ‘proxy families’.
- v) Test feasibility of delivering culturally-adapted FI among African Caribbeans in hospital and community settings.
- vi) Test feasibility of recruiting biological and ‘proxy families’ and delivering the intervention via both.
- vii) Test the feasibility of recruiting participants in hospital and community settings
- viii) Compare recruitment and retention in different clinical settings
- ix) Identify outcome measures for future randomised studies and assess the feasibility of collecting them.
- x) Assess acceptability of the intervention with key stakeholders – patients, their families and mental health professionals.

Research Plan / Methods

Research design and theoretical/conceptual framework

We will use the Medical Research Council’s (MRC) framework for developing complex interventions, which incrementally guides researchers from theory building to long-term implementation and evaluation(8). Whilst acknowledging this is not a linear process, MRC recommends a carefully-phased approach by addressing key uncertainties prior to exploratory and definitive trials. Our intervention is ‘complex’ because of difficulties identifying

key elements required for delivery, uncertainty both in relation to its feasibility and acceptability in a 'hard-to-reach' community and the specificity and variability of outcomes⁽⁸⁾.

We plan to review the literature at study commencement for new and emerging evidence thus building on existing evidence and previous theory-building, development work on FI such as: current NICE schizophrenia guidance⁴; a recent systematic review which confirmed that FI reduces relapse and hospital readmissions, increases compliance with medication and improves family environments and general social function⁽⁴⁸⁾; and the work of Barrowclough and Tarrier whose FI model will be culturally adapted in our study. Collaborators Moxon and Ronan are currently evaluating FI in community settings in New Zealand⁽¹⁰⁾. Evidence from this work (particularly on uptake and retention) will contribute to future refinement of our intervention.

Health service setting and context

The study will take place in Manchester Mental Health and Social Care NHS Trust (MHSCCT). Covering the inner-city areas where the majority of the city's African Caribbean population live⁽⁵³⁾, MHSCCT provides mental health and community services to an ethnically diverse urban population. As with national statistics, Black patients (African, African Caribbean, or 'Mixed' ethnicity of African or Caribbean descent) are over-represented in both in- and outpatient schizophrenia services. African Caribbeans account for 16.5% of the Trust's in-patients secondary care but only 1.7% of the population.

Methods

PHASE 1: CULTURALLY-ADAPTING THE INTERVENTION (Months 0 – 9)

Phase 1 Research Question (RQ)

RQ 1: How can family intervention (FI) be culturally-adapted for African Caribbeans with schizophrenia and related disorders?

Phase 1 Study Objectives

- i) Involve key stakeholders (patients, families and clinicians) in culturally-adapting an existing family intervention (FI) for African Caribbeans with schizophrenia.
- ii) Produce a manual to support delivery of the intervention.

1A –LITERATURE REVIEW.

We will conduct a broad scoping review⁽⁵⁴⁻⁵⁵⁾ of existing literature to establish key issues and identify gaps in knowledge concerning cultural adaptation of psychological interventions. Broad search terms will provide an overview, maximising the coverage of the subject area and minimising potential bias from excluding pertinent information. This has proved useful to 'map' the breath of research in relation to the size and scope of existing primary and secondary studies where evidence is limited⁽⁵⁶⁾. Citations will be exported into a bibliographical software programme (Endnote) and categorised according to the subject area and methodological design. Data will be extracted using a charting method⁽⁵⁷⁾ into NVivo⁽¹⁷⁾ before thematic analysis (16) is undertaken to provide a narrative review⁽⁵⁸⁾ of potential issues or solutions for cultural adaptation of psychological interventions. From this phase, a summary of key issues will inform Phases 1B and 1C.

1B – FOCUS GROUPS. As access and engagement are crucial aspects of this study, we shall collect qualitative data on how to create the optimal intervention that both engages potential participants and produces beneficial outcomes. Focus groups will be our primary method of collecting these data. However, to maximising inclusion, patients and carers who wish to take part in the study but feel unable to participate in focus groups will be offered the alternative of one-to-one interviews. In focus group discussions, we shall elicit participants' perspectives on how best to culturally-adapt the intervention to meet the particular needs of this ethnic group and ways to facilitate potential participants' engagement, uptake and completion. In this context, although NICE recommends 10 sessions⁽⁴⁾, this might be perceived as onerous and hinder participation in a community where engagement is known to be problematic. Focus group work will enable us to explore relevant issues such as recruitment, retention, engagement and the form (content of sessions), duration (number of sessions) and intensity (length of time between sessions) of the programme. In preparatory work, discussions with members of the African Caribbean community suggests that the term '*family intervention*' might itself be a barrier to recruitment and uptake as it may be seen as synonymous with surveillance by external agencies and interference in family life. Focus groups will enable us to explore such issues and develop effective communication strategies both for recruitment into the study and development of the manual to support delivery of our intervention. We shall also ask focus group participants to suggest an alternative to the term 'proxy families', which we currently use to describe patient-nominated others and/or trained community and peer support workers who will substitute where patients wish to participate but biological families are not available. Finally, we shall collect data on the likely training needs of 'proxy families', family therapists, and the support workers who will assist therapists in delivering the intervention.

Inclusion/exclusion criteria

Patients (n=8): Current or former male and female patients, age 18 or older, who self-identify as being of 'African Caribbean origin' – including 'Black-British' and 'Mixed' African Caribbean. Participating patients might include those receiving treatment from Community Mental Health Teams (CHMTs) or on Community Treatment Orders (CTOs) who are considered well enough to participate by clinical teams. Although not on active treatment, former patients might be subject to periodic review by mental health teams and/or in receipt of support from voluntary sector agencies such as African Caribbean Mental Health Services (ACMHS) which currently provide 'drop-in' facilities for such individuals.

Carers and advocates (n=8): Carers (including paid support workers, family and friends) and advocates (such as ACMHS) who have experience of working with African Caribbeans. They need not be African Caribbean.

Clinical staff (n=8): We shall include a range of professions with different levels of experience/expertise including: nurses, Occupational Therapists (OT), psychologists, and psychiatrists, social workers.

Data collection: We will hold 4 focus groups – one for each group of stakeholders and a 'mixed' group comprising purposely selected participants. The purpose of the fourth group is to validate preliminary findings and to enable us to resolve through discussion any differences between groups. Focus groups will last approximately 60-90 minutes – including time for setting up, establishing ground rules and addressing participants' queries. To facilitate data collection (led by Edge and Baker with input from the Research Management Group (RMG)), we shall produce a topic guide. Content will be based on key themes identified from the literature review (Phase 1A) and information gathered from preliminary discussions with former service users and carers. Likely issues may include: nature of African Caribbean families and impact of schizophrenia; cultural models and attributions of mental illness in general and schizophrenia in particular; perceptions of psychological therapy and potential modification to enhance cultural sensitivity; 'traditional' methods of family interventions ('what works and what doesn't'); barriers to accessing and engaging in family intervention; and preferences with regard to recruitment and retention. An important aspect of this phase of the study will be asking participants to identify outcome measures they regard as relevant and important to them as it will inform data collection and help us to refine the delivery phase of the study (Phase 3). Focus groups and/or individual interviews will be facilitated by an experienced qualitative researcher (Edge) with support from the Research Assistant (RA). Data will be digitally recorded.

Data analysis: These data will subsequently be transcribed, checked for accuracy and analysed using thematic content analysis within a qualitative methodological framework (Framework Analysis)(59) by Edge and the RA. Two other experienced qualitative researchers (Baker and an independent methods' specialist) will rigorously review the research process. This is a recognised method of ensuring 'trustworthiness' of the data and subsequent findings(60-61). NVivo (17) will support data management and analysis.

1C – CONSENSUS CONFERENCE. Consensus methods are often used in health service research where there is complexity and little previous work⁴¹. We shall therefore adopt this methodology to produce a culturally-adapted psychosocial intervention for African Caribbean patients and their families. In a one-day consensus conference, key stakeholders (n=24) will synthesise data from Phases 1A and 1B to identify essential elements for culturally-adapting an existing model of FI, which has been rigorously tested in RCT(62-63). The current model(5) comprises 3 key components: i) psycho-education, ii) stress management and coping responses and iii) problem-solving and goal planning. Participants will also identify areas of disagreement to enable further modification of the intervention(64-65). It is important to note that 'consensus' does not necessarily denote full agreement. Rather, consensus will be arrived at through a process of facilitated open discussion and debate to fully explore areas of agreement/disagreement in terms of the extent to which respondents agree with a) the issue under consideration and b) with each other. It is particularly important that dissenting and less dominant voices are enabled to contribute as they may highlight important issues that have not previously been considered. This will be facilitated by via the chair of the group (DE). We propose an approach of 'near unanimous' agreement (threshold to be determined by RMG) to connote consensus (66). Accordingly, we do not anticipate residual areas of disagreement. However, should these remain; the Research Management Group (RMG) will make the final decision in consultation with expert-non participants.

The representativeness of the groups' views and ratings will be verified by posting findings to a larger but similarly comprised group of expert non-participants who will be identified by the Research Management Group (RMG).

Sample and Recruitment

Stakeholders (n=24) will include patients, former patients, families, and clinicians. Participants will be recruited via Mental Health Research Network (MHRN), African Caribbean Mental Health Services (ACMHS), Manchester Mental Health & Social Care NHS Trust website and carer support groups. We will also recruit via advertisement in community settings such as 'Black-Majority' churches.

The intervention: Participants in the consensus conference will agree the specific topics to be included in our culturally-adapted FI based on the literature review and findings from the focus group. However, the focus of our intervention will

be on changing attributions in order to effect behaviour change thereby creating more supportive family relationships. In light of African Caribbeans' reported experience of services(67), we anticipate that the *psycho-education component* of our culturally-adapted FI will include information about the causes, nature, course and treatment of schizophrenia with a particular focus on medication (dose, mode of delivery, effects and side-effects), the Mental Health Act and pathways to care (the role of key individuals such as the police and Approved Mental Health Professionals (AMPs)). The *stress management and coping component* will provide information about the relationship between Expressed Emotion (EE), perceptions of stress and the burden of care and strategies for creating more benign family environments. *Problem-solving* will focus on motivational intensity and practical strategies for crisis management and self-care. However, it may be that findings from the literature review and focus group (Phases 1A & 1B) reject some of these elements in favour of others which stakeholders regard as more culturally-appropriate for this ethnic group. These may include – shame and stigma; facilitating reintegration of people with schizophrenia into the community; illicit drug use and schizophrenia; and the relationship between spirituality and mental illness.

Supporting manual: Consensus conference participants will also determine contents, design and layout of the first draft of a manual which we will develop to support delivery with patients and families. The manual that supports the current intervention is in the form of a pamphlet. Whilst we might retain this format to provide concise, relevant, easy-to-read information for patients and families, Drake and Baker will lead production of a more detailed draft manual. Our Research Advisory Group (RAG) – comprising patients, carers and community members – will assist us in further refining the manual which therapists will use to guide delivery of session content. This will facilitate consistency of approach, which is an important outcome of our feasibility study. In addition to an overall timetable and outline session plan, the manual will contain detailed information and relevant materials for each session broken down into 'bite size' portions (each around 10 minutes long) with time for questions/clarification after each portion. For example, if the topic for Session 3 is 'Medication' – sub-topics might include: types of medication and how they work, 'depot' injections, side-effects and how to counter them; all of which would be further explored before moving to the next topic.

PHASE 2: TRAINING (Months 10 – 14)

Phase 2 Study Objective

- iii) To identify and address the training needs of therapists and 'proxy families'.

1) *Therapists' training needs:* As recommended by NICE (4), we will provide cultural competency training for the family therapists and support workers who will deliver our intervention. To do so, we will employ Meriden Family Programme to build on findings from Phase 1 of our study and provide appropriate training. Meriden Family Programme is 'a training and organisational development programme, which trains clinical staff, service users, and carers in the skills needed to work with families and to ensure that workers are able to deliver quality, evidence-based family interventions' www.meridenfamilyprogramme.com. Meriden works with psychiatry tutors to deliver mandatory requirements for the inclusion of service users and carers in psychiatric training. Their work has received national recognition – including the Health Service Journal (HSJ) 'Innovation in Mental Health Award' in 2008. In addition to cultural competence training for the Family Therapists and support workers, we shall deliver 3 'clinical competency' workshop seminars (one in each year of the study) for the staff in participating units in the Trust. This will afford opportunities to share preliminary findings from the study with and receive feedback from MHSCT staff. Providing cultural competence training for staff is in line with NICE guidance(4) to address cultural competence at both individual and organisational levels.

2) *'Proxy Families' training needs:* For several years, Meriden has delivered well-evaluated, modular training for carers – including modules that address the particular needs of Black and Minority Ethnic (BME) carers. We shall employ Meriden to train service-user peers and volunteers in their role as members of 'proxy families'. Service user peer workers will be identified via MHSCT's Recovery College (see below). Key components of the training will be identified in Phase 1 but are likely to include psycho-education and governance issues such as confidentiality, data protection, and Health and Safety. Additionally, as 'proxy family' members are essentially volunteers (who might include former patients); it is important that they are provided with strategies for accessing support whilst retaining appropriate boundaries.

PHASE 3: FEASIBILITY STUDY (Months 15 – 32)

Phase 3 Research Questions:

- RQ 2. Is it feasible for culturally-adapted FI to be delivered in hospital and community settings?
- RQ 3. Can 'proxy families' serve as acceptable alternatives where biological families are unavailable?
- RQ 4. Will culturally-adapted FI be acceptable to patients, families, and health professionals?

Phase 3 Study Objectives

- v) To test the feasibility of delivering culturally-adapted FI among African Caribbeans in hospital and community settings.
- vi) To test the feasibility of recruiting biological and 'proxy families' and delivering the intervention via both.
- vii) Test the feasibility of recruiting participants in hospital and community settings
- viii) Compare recruitment and retention in different clinical settings

- ix) To identify outcome measures for future randomised studies and assess the feasibility of collecting them.
- x) To assess the acceptability of the intervention to key stakeholders – including patients, their families and mental health professionals.

PHASE 3A: DELIVERING AND EVALUATING THE INTERVENTION

The purpose of a feasibility study is to identify and estimate key parameters to facilitate designing the main study (subsequent RCT) (68). Research in a ‘hard-to-reach’ population will pose significant challenges requiring alternative approaches. However, our team includes members with considerable experience of undertaking research in ‘hard-to-reach’ ethnic minority groups (Abel, Drake, Lewis, Lovell) and African Caribbeans in particular (Edge, Bhugra). Edge has successfully undertaken studies in the locality and has developed a range of outreach and engagement strategies to facilitate recruitment of African Caribbeans such as making presentations in churches and community centres(41). Additionally, the work undertaken in Phase 1 will help us to identify and address potential barriers. For example, we have been alerted that the term ‘*family intervention*’ might be a barrier to recruitment. We will use the focus groups to help us develop effective strategies to overcome such potential barriers to recruitment, engagement and retention. This allows us to take a normative approach to customising our intervention for this particular group. In this context, it will be particularly important to focus on patient- and family-centred outcomes such as reducing family tensions, improving communication and understanding between patients and families, and facilitating patients’ reintegration into their families and communities.

Anecdotal evidence from clinical practice suggests that an important difference between undertaking family work with African Caribbeans and other ethnic groups is the extent to which trust must first be established. Phase 2 training will enhance therapists’ engagement skills in terms of establishing and maintaining effective working relationship with African Caribbean participants. Our preparatory work also indicates that focusing on the extent to which the intervention will empower families by equipping them with knowledge and basic skills will be important for engaging with African Caribbean families. For ‘proxy families’, it may also be necessary to highlight potential personal benefits of participating. For example, cultural competence training could facilitate entry into long-term volunteering and/or accredited training, which is important as unemployment rates are high among potential service-user participants and African Caribbeans.

Sample and Recruitment

Over 12 months, 30 consenting patients and/or their families (10 in each setting – acute wards, rehabilitation wards and community) will be recruited into the study. This will allow us to include patients at differing levels of acuity and chronicity and consider the feasibility of delivering family intervention across different clinical environments. There are currently 213 patients of African Caribbean descent in MHSCT. Excluding those who are too unwell to participate, we anticipate Trust staff will approach 150 of these to join our study, of whom 100 will be eligible. We conservatively estimate that 1 in 3 will consent to participation in the research. A sample of 30 patients is sufficient to look at the feasibility of delivery across a range of patient and family-types (14).

Patients identified as suitable with the support of MHRN and MHSCT staff during the ‘setting-up’ phase of the project will, if agreeable, be approached by research liaison staff and further informed about the study. Those who meet inclusion criteria (please see below) and are assessed by researchers as having capacity to consent; will be given at least 48 hours to read information about the study, question researchers and decide whether or not to take part. Once written, informed consent has been given patients will be contacted by the PI or RA to set up an initial meeting with the family therapist.

Biological family members will be recruited with the support of MHRN and liaison staff who will distribute information to them. Additionally, we will place posters in appropriate locations in participating settings such as visiting/relatives’ rooms. Where patients are recruited first, we will also seek their permission to write to their families informing them about the study and inviting them to participate. Our correspondence will include the research contact number for the PI and indicate willingness to meet with potential participants to address any queries or reservations they might have about participating the study.

We will create ‘*proxy families*’ where patients wish to participate but are either estranged from their families or have no close family. Our collaborators in New Zealand (Moxon and Ronan) have successfully delivered a brief (2-session) family intervention community in settings with a sample that included a small number of substitute family members (3 out of 28 family members)(69). Like our New Zealand colleagues, we intend to ask patients to nominate individuals they consider important/influential in their lives, people who they trust, or anyone who provides emotional support. This may include ‘trusted individuals’ such as support, youth or community workers. Additionally, we will test the feasibility of recruiting ‘proxy family’ members via local media (community radio, newspaper) and posters in locations likely to be frequented by large numbers of African Caribbeans such as ‘Black-Majority Churches’ with whom the PI has collaborated to deliver community-level mental health conferences. We will also advertise for committed individuals who are well enough and might wish to volunteer become ‘proxy family’ members via ‘Service User Forums’. The Trust currently collaborates with African and Caribbean Mental Health Service (ACMHS) to run a service user peer-befriending scheme. ‘Befrienders’ who meet inclusion criteria could also apply to become members of ‘proxy families’.

To avoid recruiting individuals who are likely to drop-out at an early stage, the level of commitment entailed by participation will be made clear from the outset and explored during the recruitment process. We shall also emphasise flexibility in delivery of the intervention. This will be important both for unrelated patient-selected others and peer support workers currently referred to as “*proxy families*”.

We recognise the relative heterogeneity of potential ‘proxy family’ members in terms of their personal and emotional resources and of their social and emotional commitment. This will inevitably cause variations in the type of bond unrelated others may have with patient participants compared to relatives. However, as evidence shows that psychiatric staff display similar responses to relatives (although less likely to be ‘over-involved’ and hostile) (70); this may also be the case for ‘proxy families’. We will address this by encouraging good behavioural management and goal setting and by incorporating the interactions of non-relatives into our analyses. This will be facilitated by skilled professional delivery in much the same way as standard FI. Previous research also indicates that FI is sufficiently flexible to deal with the vast range of interactions manifested in high Expressed Emotion (EE) relatives. Although we can find no previous evidence of delivery via ‘non-kin dyads’, we are aware that retention in FI studies can be poor. Given the range of individuals likely to be involved, we are hopeful that the retention rate for this group of trained volunteers as suggested by comments from the public reviewer. Based on previous work by our New Zealand partners, we conservatively estimate it will be at least 50%. However, even if attrition is higher, we anticipate that the impact will be limited by the relatively small numbers of non-kin expected to take part. Our study will enable us to test whether this novel approach is feasible thus potentially facilitating more equitable delivery of psychological therapy.

MHSCT is also setting up a “Recovery College” to train peer-support workers from within and outside Black and Minority Ethnic (BME) communities, as part of its commitment to the national ImROC recovery programme(71). Already trained in their role supporting service users with severe mental illness, ‘befrienders’ and peer-support workers will be further trained by Meriden to ensure sufficient cultural competence and in preparation for their specific role as ‘proxy family’ members (Phase 2). Peer-support workers have been used successfully to engage “hard-to-reach” substance misusers in the US, a role in which their credibility is critical. They have also taken on supporting schizophrenia sufferers in US services (72) and delivering educational interventions for schizophrenia sufferers in group and family interventions and in Germany(73) (74). Their use in Scottish mental health services has been evaluated, highlighting relevant strengths (credibility, personal experience, distinct from other staff members) and limitations (defining boundaries and expectations, limited training, dealing with their own difficulties and experiences). Didactic or training interventions requiring them to function as authority figures nullify their advantages(72). Well defined roles and relatively structured, time limited interventions reduce demands on them. Membership of ‘proxy families’ would play to their strengths.

In addition to recruitment via local media and community publicity, we shall host 2 community events in areas of high population density of African Caribbeans within the Trust footprint – Moss Side/Hulme and Longsight/Levenshulme to launch the study. During these events, we shall i) outline study aims and objectives ii) explain the role, level of involvement and inclusion/exclusion criteria of potential ‘proxy family’ members and iii) gauge the level of interest and willingness among eligible individuals. We shall provide collaborating Community Mental Health Teams (CMHT’s) with information about these events and the study more generally for distribution to African Caribbean patients and families. We shall monitor and report sources of recruitment as these will be important indicators for future RCTs. To test the feasibility of our recruitment strategy, we shall regularly review progress against strict milestones. From previous work, we anticipate that recruitment might be slow initially but will speed up as publicity via community radio, churches etc take effect.

Inclusion/exclusion criteria

Patients must be of African Caribbean descent (including those who self-identify as ‘Black-British’, ‘African Caribbean’ or ‘Mixed’ African Caribbean). Both biological and ‘proxy family’ members can be from other ethnic groups. All participants will be aged 18 or older able to give written, informed consent and commit to participating FI.

Delivering the intervention

Content, duration and intensity of the intervention

The ultimate form (content of sessions), duration (number of sessions) and intensity (length of time between sessions) of this brief intervention will be a key outcome of Phase 1 study. Although NICE⁽⁵⁾ recommends 10 intensive sessions, we know that uptake and retention in FI is often poor(35) (63) and that an important strategy for overcoming reluctance to participate is ensuring that time commitment does not appear too onerous(69). We will therefore address this in Phase 1. Based on current evidence(5, 10), we anticipate that the programme will consist of sessions (1- 2 hours long; including setting up and debriefing) – these may be weekly initially (to cover assessments, education and stress management) but subsequently may be fortnightly or monthly. Should participants leave the intervention early, we will seek their consent

to administer KASI(12) at that point and at 3 and 12 month follow up. We will also seek to collect qualitative data about why they left early and what could have been done differently to facilitate retention. Allowing for cancellation or postponing sessions due to sickness, holidays etceteras and flexibility of approach, we anticipate that the intervention will be delivered within 20 weeks. The intervention will be delivered by 2 experienced FI therapists (Agenda for Change Band 7) as recommended by NICE(4)) using the manual developed in Phase 1. We will also employ 2 support workers to act as 'co-therapists' – this is considered good practice and will be especially important when working with large family groups or where there is a lot of hostility. Co-therapists will also support data collection, for example, making 'fieldnotes' and observations during sessions.

Outline of process of delivering FI and related data collection

1) Assessment of needs and strengths

Data will be collected by the RA who will not be involved in delivering the intervention. Initial session(s) will focus on assessing the needs of patients and families and tailoring the intervention to meet their particular needs. Where both patients and family members are participants, it is recommended that they are first seen together to outline and agree the purpose of subsequent family work. At this stage, the potential role of the family in the patient's rehabilitation and recovery and that of the therapist in delivering FI will also be outlined.

Family assessment will take the form of an individual interview using the Relative Assessment Interview (RAI)(5) to collect information including: basic demographic data; chronology of the patient's illness; perceptions of the nature and severity of symptoms; social functioning (including patient's self-care and engagement in household tasks); perceptions of the cognitive; emotional and physical impact of the patient's illness on the interviewee; and their relationship with the patient. As part of the RAI, we will administer the KASI(5, 12) to elicit what participants already know about schizophrenia. Findings will be used to inform the psycho-education component of the intervention as well as gauging progress as a function of the intervention. We will also ask relatives to complete the modified Family Questionnaire(11) – a checklist of patient-focused problems. This scale allows relatives to rate (on a 5-point scale) the frequency of patients' behaviours, the amount of personal distress such behaviours generate and ability to cope with these difficulties. The checklist will be a useful means of validating interview data. It will also be used to evaluate progress and outcome at follow-up. Finally, we shall use the 12-item Short Form Survey (SF-12 version 2(13)) to analyse disease burden and predict costs. A preference-based utility index (SF-6D) has been developed from the SF-12 to facilitate economic evaluation and estimate quality adjusted life years (QALYs). This will be important for future studies. However, as our focus is on feasibility in this study, we shall examine scores before and after the intervention. Our Health Economist collaborator (Harrison) will provide advice on collection and analysis of these and cost data to maximise their usefulness for preparing future studies.

Patient assessment: As with relatives, the aim of patient assessment is to identify problems and strengths so that the intervention can be tailored to address areas of particular concern. We will elicit data in 3 broad areas: i) psychopathology – current and past episodes of illness – and interventions to date (including perceptions of effectiveness); ii) perceived level of functioning (including behavioural excess currently and over the course of illness) and iii) patient's strengths – interests, abilities, personal resources and access to other support. We know that perceptions of relatives' attitudes towards them and their attitudes towards relatives can predict important patient outcomes such as relapse rates. Patients who perceive their family environment positively have significantly better survival rates without symptom exacerbation(75). We will therefore assess the feasibility of using the Perceived Criticism Scale (PCS)(76), 'a simple and useful tool for clinical and research purposes'(75) p173, with participating patients in addition to collecting data outlined above and basic demographic information.

2) Psycho-education component

Session 1: As previously stated, the exact content of the intervention will be determined in Phase 1. However, in line with the FI model that we are culturally-adapting, we will begin by presenting information and facilitating discussion about schizophrenia such as about 'helpful' and 'unhelpful' beliefs. We will also explore explanatory illness models (51) and participants' understanding/explanations of symptoms such as hallucinations, unusual beliefs (delusions) and experiencing distressing perceptions such as 'hearing voices'. Frequent reference to relatives' beliefs (as assessed with KASI and RAI) will enable us to take a personalised approach to delivering the intervention as assessment data will help us identify areas that are particularly problematic, for example: the concepts of medication as prophylaxis (vs cure) and 'self-medication' with illicit drugs; controllability (the extent to which symptoms are under patients' control); the roles of mental health professionals and other key agencies (such as social workers and the police) and community available support. Assessment interview is conducted individually. Psycho-education sessions may be delivered collectively if so determined in Phase 1.

Session 2 - N: We recognise that Phase 1 participants may determine that we require more time to deliver the information outlined in Session 1. Session numbers would therefore change to reflect the empirically-derived will of the focus groups. Subsequent to information-giving session(s), therapists will actively encourage relatives to consider any misconceptions or difficulties experienced in assimilating information about the illness, prepare the environment for change, identify strengths, and work on problem areas identified by the patient and family members. The manual developed in Phase 1 (providing information on goals, tasks, strategies, and homework for each session) will be used to guide therapists

through the intervention. Post-test KASI(12) will be conducted following delivery of this component of the intervention and again at 3 and 12 months' follow-up.

3) *Assessment and intervention for stress and coping with problems*

If Phase 1 results indicate that this component should be retained, they will also determine the exact content based on the current model where 'Session 1' defines and provides information about stress and stress management, introduces participants to self-monitoring of stressors, elicits resources available to family members and highlights strengths. 'Session 2' reviews self-monitoring, identifies 1 or 2 specific areas/situations for in-depth analysis as a basis for commencing intervention. Subsequent sessions would evaluate the outcome of planned interventions, modify as appropriate, generalise strategies to other situations and target new areas for intervention.

4) *Problem-solving and planning for positive change*

The aim of these components of the intervention will be to teach families a constructive approach to problem-solving by constructing 'problems' as 'needs' that can be addressed through positive behavioural change, including capitalising on patient and family members' strengths. As with other FI, we will begin assessment using a patients' 'strengths/needs' list. Similar lists might also be constructed for family members if deemed helpful. Key steps in the process of 'Goal Setting and Planning for Positive Change' include(5): i) identifying difficulties/problems/issues ii) translating problems into needs iii) identifying strengths (abilities, interests, resources) iv) selecting a need to work on v) using the approaches to generalise ways of meeting need vi) setting realistic goals and breaking down into manageable steps vii) making a plan for each step viii) reviewing goals and steps ix) planning for maintenance, generalisation and extension of goals x) identifying a new goal and recommencing the process.

Data collection

Quantitative: Our primary outcome measure will be recruitment, uptake and attrition rates. We will collect recruitment data on rates in each of the three settings and demographic data from all participants. For example, we shall collect and analyse recruitment and retention data in relation to i) the number of patients available in each of the 3 clinical settings, ii) the number who were approached iii) the number who agreed to participate and iv) number who subsequently withdrew consent. This will enable us to analyse comparative recruitment rates from the different sources: clinician referral, public advert and community organisations. We shall also collect information on non-completers. Using the quantitative outcomes indicated above (KASI, FQ, PCS and SF-12) baseline measures will be taken pre- and post-intervention and at 3 and 12 months' follow-up. In cases where participants leave the intervention early, we will attempt to gather the outcome measure at the time of exit and also achieve follow-up post intervention and at 3 and 12 months. Although these are individual-level measures, it is intended that they will form the basis of later trial and economic evaluation. Assessing the feasibility of collecting these data and exploring the feasibility of developing instruments to do so where none currently exist will therefore be important at this stage.

Additionally, in Phase 1 we will identify meaningful patient-, family- and service-centred outcomes and the most appropriate means of measuring them. Patient- and family-centred outcomes might include: improved access to care (better GP access, less police involvement); better engagement with mental health staff (such as ability to engage in care planning and risk management); and reduction in relapse and re-admission rates. Service-centred outcomes might include improved perception of cultural competence and confidence dealing with African Caribbean patients and families in staff satisfaction survey.

Qualitative: Relative Assessment Interview (RAI)(5) will be used to collect data prior to delivery of the intervention (please see Family Assessment above). Qualitative data collection during delivery of the intervention will focus on perceptions and experience of the process of participation as well as content, length and delivery of sessions. Acceptability of the intervention will be further tested by exploring the views of all participants (patients, families and 'proxy families') who complete the intervention at 12-months' follow-up. For this component of the research, we plan to use semi-structured questionnaires (to be developed by Edge and Baker with input from the RMG) to facilitate data collection. Questionnaire items will be identified during the course of the study – particularly in Phase 1 and from preliminary qualitative data analysis. We shall also seek to elicit participants' views on the content, duration and intensity of the intervention. We will focus particularly on perceptions of usefulness, cultural-appropriateness, and accessibility (including ability to read and understand information provided). Inclusion of open questions will enable us to explore aspects of the intervention that participants particularly liked/disliked and areas which they think should have been included. Perceptions of facilitators/barriers to implementation will also be explored. This information will be used to help design future pilot studies to develop a multi-site RCT to test our culturally-adapted FI compared with standard FI and usual care. We will also collect qualitative data after each session (evaluation/feedback forms will be designed by the research team) and from in-depth interviews with participants identified by the qualitative leads (Edge and Baker) and verified by external methods experts as 'key informants'.

Data analysis

Quantitative analyses will be primarily descriptive as this is a feasibility study and we do not have a powered sample size suitable for hypothesis testing (14). We shall present statistics on recruitment, consent and attrition. We shall examine the characteristics of the various outcome measures and consider what statistical methods might be most appropriate in a future trial; adding to what we already know about these measures. KASI subscales scores make non-parametric tests such as Wilcoxon matched-pairs suitable to compare pre- and post-test data. Physical and Mental Health Composite Scores (PCS & MCS) for SF-12 will be computed using the scores for the twelve questions – each ranging from 0 to 100, where a zero score indicates the lowest and 100 the highest level of health. PCS & MCS summary scores are unlikely to be meaningful due to the sample's size and heterogeneity, but we will examine the sources of variation within our data (such as basic demographic variables, proxy/biological family co-participants) and estimate effect sizes to inform sample size calculation for further RCTs.

Although our focus will be on piloting the use of the study outcome measures, demographic information and quantitative elements of the semi-structured questionnaire will be analysed using descriptive statistics. We will calculate standard deviations and confidence intervals for the outcome variables to inform the sample size estimate of a future trial. Our primary analysis for a future trial would be by intention to treat. However, we are aware of the problem of loss to follow up in mental health trials, and we will also plan in any future trial for additional analysis to take account of this: in this study we will prepare for this by examining the outcomes at point of departure from the trial. Significance (α) will be set at 5% (0.05) with a 95% CI. Data will be analysed using (15). Qualitative data analysis will be as in Phase 1B.

PHASE 3B: FIDELITY STUDY (Months 30 – 32)

Study objectives

- ii) To produce a manual to support delivery of the intervention.
- iii) To identify the training needs of therapists and 'proxy families'.
- iv) To test the feasibility of delivering culturally-adapted FI among African Caribbeans in hospital and community settings.

Adherence to the manual and delivery of the intervention will be tested by independent review of a 25% sample of recorded sessions using an assessment checklist. Adapted from the Cognitive Therapy Scale for Psychosis (CTSPsy)(18), the Cognitive Therapy Scale for Family Intervention (CTS-FI) is a 60-item checklist used to rate therapists' performance in delivering family intervention. It rates areas such as: agenda setting and adherence; checking understanding and providing feedback; interpersonal effectiveness (including ability to demonstrate warmth, caring and concern); working collaboratively with patients and families and the level of skill demonstrated in delivering the intervention (ability to select and facilitate appropriate techniques). Data from Phase 3A about uptake and attrition rates and engagement with the intervention will also provide means of assessing fidelity. Additionally, to assess the acceptability of the intervention to health professionals, we will conduct in-depth qualitative interviews both with family therapists and support workers. The level of any additional support required by 'proxy family' members will be assessed by administering structured questionnaires to support staff and will form an important aspect of assessing the feasibility of the study.