Appendix 1: Research Protocol

Study Title: Co-production and evaluation of an e-learning resource to improve African Caribbean families’ knowledge about schizophrenia and engagement with services

Background
Inequality of access to appropriate, evidence-based interventions for schizophrenia in African Caribbeans has persisted despite decades of national and local policy and practice initiatives. For African Caribbeans, delayed engagement with services is associated with greater illness acuity and severity on initial and subsequent service contacts compared with other ethnic groups. Delay in engaging with services partly results from negative attitudes related to misinformation, stigma and discrimination in African Caribbean communities coupled with a deep-seated fear and mistrust of mental health services. This is important because we know that non-engagement creates a vicious cycle of delayed admission, formal detention, poor experiences and outcomes, increased fear and mistrust of mental health service and further avoidance of contact.

Untreated, symptoms of schizophrenia exacerbate family tensions and worsen perceptions of the burden of care. Escalating family hostility, often resulting in police involvement, increases patients’ risk of estrangement from their families, relapse and social isolation. Available evidence suggests that community-based, education programmes could be effective in improving access and engagement in this high risk, ‘hard-to-reach’ African Caribbean population. This is because evidence indicates that improving families’ attitudes and knowledge about schizophrenia positively affects carers’ perceptions, reduces family tension, facilitates engagement with services, and improves patient and carer experiences and outcomes.

However, these findings relate to White families. There is little evidence about family educational interventions in ethnic minorities in the UK. Moreover, there are currently no culturally-appropriate resources specifically aimed at African Caribbean families with schizophrenia. This is an important omission because African Caribbeans in the UK not only have far higher rates of diagnosis with schizophrenia than other groups; they also have worse outcomes. NICE guidance acknowledges deficiencies in provision and the need to work with African Caribbean stakeholders to develop culturally-appropriate interventions.

Rationale
Improving family members’ attitudes and knowledge about schizophrenia has been shown to reduce family tensions and hostility thus creating more sympathetic home environments, which in turn reduces risk of relapse and rehospitalisation. NICE guidance suggests family-focused interventions for African Caribbean families with schizophrenia are urgently needed. As there are currently no culturally-appropriate, psychological education resources for this group, we plan to work with families and service users to develop and test such a resource in this ethnic group.

Aims
1. To co-produce, with African Caribbean community members, a culturally-appropriate e-learning resource to improve attitudes and knowledge about schizophrenia and engagement with services.
2. To assess feasibility and acceptability of the intervention in this high risk community.
3. To pilot data collection methods for outcomes to support development of a future RCT.

Objectives:
1. Recruit African Caribbean community-based stakeholders (service users, carers and family members)
2. Co-produce with them a culturally-appropriate e-learning resource to educate families about schizophrenia and its management
3. Test the feasibility of delivering the intervention in African Caribbean families
4. Identify family and patient-centred outcomes and pilot data collection
5. Evaluate accessibility and acceptability of the intervention
6. Evaluate the effect of the intervention on families’ attitudes and knowledge about schizophrenia
7. Evaluate the intervention’s effect on family tension, carer burden and engagement with services

Research Questions
(1) Can an e-learning resource (co-produced with African Caribbean community members) improve attitudes and knowledge in families of African Caribbean people diagnosed with schizophrenia?
(2) Can this e-learning resource positively impact African Caribbean service users’ engagement and perceived experiences of schizophrenia services?
(3) Will the resource be acceptable to the families of African Caribbean people diagnosed with schizophrenia?

Hypothesis
Effective delivery of a culturally-appropriate, education resource about schizophrenia will yield patient, carer, and service benefits by facilitating more wellness-promoting family environments and improving engagement with and experiences of services.

Plan of investigation
Research design
A mixed-methods design adopting Medical Research Council’s (MRC’s) Framework, which advocates a systematic approach to developing, implementing and evaluating complex interventions. MRC recommend a carefully phased approach to address key uncertainties before exploratory and definitive trials. Our intervention is ‘complex’ because of difficulties identifying elements required for delivery, uncertainty about its acceptability in a ‘hard-to-reach’ community, and the specificity and variability of outcomes.

Phase 1: Realist Literature Review
As there is little information about psychological education for African Caribbeans, we shall undertake a realist literature review of relevant literature to inform focus groups and the form and content of our intervention.

Method
The realist literature process involves the following overlapping and iterative stages:

(i) **Clarify the scope of the review** and agree review questions with stakeholders and research management group input.

(ii) **Undertake relevant data base searches** such as MEDLINE, EMBASE, and PSYCHLIT, for peer reviewed publications, policy documents and grey literature using key terms such as: schizophrenia, psychosis, education/psycho-education, African Caribbean and references lists to guide hand-searches. Only publications in English will be included as we do not have resources for translation. Searching will be an iterative, interactive process requiring multiple search strategies depending on the quality and availability of evidence. To facilitate data management, articles will be incorporated into an EndNote database.

(iii) **Appraise evidence and extract data**. Together with the Research Assistant (RA), DE & RD will initially review abstracts to judge publications’ relevance to our study before reading potential articles. Decision on inclusion/exclusion recorded and quality of evidence rated in 4 key domains: methodological quality, participants, outcomes and results/conclusions (total scores 0-14). Scores of 7 or above indicate ‘good’ quality and less than 5 ‘poor’ quality. Disagreements will be resolved by discussion and the Research Management Group (RMG) if necessary.
(iv) **Synthesise and refine the evidence.** Data will be extracted independently by the RA and recorded on data extraction sheets. A matrix will be developed to summarise narrative analyses and facilitate qualitative appraisal of methodological quality and relevance by DE & RD. Preliminary findings will be refined by discussion with the remainder of the team and a set of key themes agreed.

(v) **Produce and disseminate findings.** The synthesis will inform subsequent phases of the research and submitted for peer-review publication.

**Phase 2: Focus Groups**

To identify culturally-salient issues for resource-development, we shall conduct six focus groups with African Caribbean stakeholders: current service users, former service users, carers and families, young carers and relatives, community members and mixed group (6-10 in each group, 36 – 60 in total). In preparing for this proposal, carers and former service users expressed a preference for a ‘bespoke’, interactive, multi-media intervention. In the focus groups, we shall explore this further. We shall also elicit participants’ views about the scope, content and mode of delivery and identify culturally-salient issues for developing an e-learning resource that will be acceptable to people from this ethnic group.

**Recruitment & Participants**

Via Clinical Research Network (CRN), voluntary sector agencies such as African & Caribbean Mental Health Services (ACMHS) and local media, we shall recruit key stakeholders as follows: (i) people diagnosed with schizophrenia but not currently in services, (ii) young current service users diagnosed with schizophrenia or psychosis (16-29 yrs), (iii) family members and carers, (iv) young family members and carers (16-29yrs), (v) community members and (vi) mixed group (6-10 in each group; 36 -60 in total). To ensure the widest possible range of views, our community sample will include community leaders and other key opinion-makers with the capacity to tackle stigma.

**Inclusion/exclusion criteria**

Service user participants and community members will be of African Caribbean origin (including those who self-identify as Black-British/African Caribbean or ‘Mixed’ African Caribbean). People from other ethnic groups will be excluded. Family members and carers need not be of African Caribbean origin but should be related to someone who has been diagnosed with schizophrenia who regards themselves as being of ‘African Caribbean origin’. All participants must be aged 16 or older; able to give written, informed consent. Preparatory work suggests that professionals in the focus groups would undermine the intervention’s credibility as a ‘community-generated’ resource. Consequently, health professionals will also be excluded.

**Method**

We will hold six focus groups – one for each group of stakeholders (i. former service users with a diagnosis of schizophrenia ii. young current service users with a diagnosis of schizophrenia or psychosis) iii. family members and carers iv. young (16 – 29 yrs) family members and carers v. community volunteers) and a ‘mixed’ group comprising purposely selected participants (from the five groups above) to validate preliminary findings and resolve any differences between groups. The resource will be co-produced with African Caribbean stakeholders. We will ask participants to provide feedback on the design, accessibility and content of the resource. Groups will last approximately 60-90 minutes – including time for setting up, establishing ground rules etc. The groups will predominantly be facilitated by an experienced researcher (DE) using a topic guide based on key findings from the realist review (Phase 1) and our preparatory work. The final ‘mixed’ focus group will be co-facilitated by informatics expert (GM). Likely issues include: perceptions of schizophrenia, impact on the family, care pathways, medication, stigma and sources of help and support. Data will be digitally-recorded, transcribed verbatim and checked for accuracy.
Data analysis

Using thematic analysis, preliminary codes and categories will be assigned to the transcribed text\(^1\) and emergent themes subject to constant comparison and examined for goodness of fit until a final set of key themes are identified\(^2\). We will use latent-level analysis, using interpretative analytical techniques\(^3\). Adopting an inductive, iterative approach; data analysis will commence with the first focus groups. Subsequent data collection will be informed by previous analyses thus ensuring emergent, participant-generated themes are fully explored. DE and JO will lead data analysis. To ensure trustworthiness, participants will be asked to verify findings. Independent academic peers will review processes and findings to ensure rigour. NVivo\(^4\) will support data management and analysis.

Phase 3: Producing the e-learning resource

The e-learning resource will be based on the key issues agreed in focus groups. Working with 6-10 African Caribbean participants drawn from the focus groups and our e-health partners at University of Manchester, we will co-produce the resource via 4 one-day digital storytelling workshops. We shall work with ‘Patient Voices’ [http://www.patientvoices.org.uk/index.htm] – a social enterprise group who use carefully-developed, award-winning methodology to facilitate telling and sharing of ordinary people’s reflective stories to improve and inform health and social care. We will begin with an introductory session to outline the process and share examples of digital stories and e-learning resources with participants who will then be supported to map out their stories and identify preferred media (creative writing, drama, art, photographs) for telling their stories. In subsequent sessions, participants will create their ‘digital stories’; working individually and in groups with support from workshop facilitators.

Completed digital stories (6-8) – typically 2-3 minutes long – will form the core of our interactive e-learning resource combined with factual information about schizophrenia and short before-and-after, multiple-choice self-assessment of identified learning-objective covered by each story (e.g. hearing voices, medication). We shall also include a reflective element to enable participants to record their feelings about the stories and impact on their views. We may also include role play about difficulties people encounter when coming into contact with health professionals and how to manage them. Additionally, an important feature of the resource will be signposting participants to key sites/useful links such as NICE pages on medication and treatment and Care Quality Commission (CQC) standards for patients and carers.

Before final editing, members of the original focus group and the African Caribbean opinion makers/leaders will view and comment on the resource. Length of the finished programme will be determined with stakeholders. Perhaps, 60 minutes-long, it will be sub-divided into sections around each story to facilitate completion. Final format will be determined by stakeholders but we anticipate the intervention being web-based, requiring basic computer skills. We will produce DVDs and workbooks for people without internet access/computer literacy and develop a manual about how to use the resource. This will also enable us to test the feasibility and acceptability of alternative methods of delivery.

Phase 4: Piloting the use of the resource

This phase of the research is a randomised, mixed methods study to test feasibility and acceptability of the e-learning resource among African Caribbean families with schizophrenia. We shall also pilot the collection of e-monitoring data (such as frequency of use) and collect focus-group informed patient, family and carer outcomes and pilot collection of service-centred and cost outcomes for future evaluation of the resource in an RCT.
Participants & Recruitment
Based on samples in similar research, we shall recruit 40 African Caribbean community participants with family members who have been diagnosed with schizophrenia. Recruitment will be via local media and support from organisations such as ACMHS, CRN, and Black Majority churches (BMCs) in Manchester. The study will be advertised on local social media pages with support from the aforementioned organisations. For example, these organisations may advertise the study by uploading and sharing one of the study adverts on their profiles (e.g. Facebook, Twitter). Informed consent will be taken by our RA prior to randomisation. Participants will be informed that they have a 50/50 chance of being allocated to intervention or control groups. They will be advised about the significance of randomisation for enabling the team to determine the extent to which the intervention can be said to be responsible for any changes in knowledge and attitudes. All participants will be advised that, if assigned to the intervention group they will have immediate access to the e-learning resource and if assigned to the control group, they will have access to it at the end of the data collection period.

Randomisation
Participants will be randomly assigned to either an intervention or control group of equal size (20 in each arm), using the web-based randomisation service, http://www.sealedenvelope.com. Group assignment will be recorded in a database, and the result of each randomisation emailed to the trial administrator. We will not use stratification in this small pilot study, but we will examine baseline data to inform us on the distribution of potential stratification variables for a future trial. As the resource is free for simple randomisation, there are no cost implications.

Inclusion criteria
As in Phase 1, participants must be aged 16 or older. Participants must also have family members who are of African Caribbean origin (including ‘Black British’ and ‘Mixed’ Caribbean) who have been diagnosed with schizophrenia.

Outcome Measures
Patient and Family-Centred Outcomes
An important component of this study will be working with participants to identify meaningful outcomes and how to measure/evaluate them. These may include: improvements in family environment, carer burden, feeling more in control of situations, perceptions of stigma and police involvement. We shall develop a topic guide to capture participants’ views in qualitative interviews.

Quantitative Measures
We shall test the feasibility of collecting quantitative data and comparing them across the two arms of the study, using participant-identified outcomes. Potentially, we may also use the following validated measures:

1. Knowledge About Schizophrenia Interview (KASI) (Modified Version): KASI items were designed to assess both presence/absence of knowledge about schizophrenia but also the impact of that knowledge on attitudes and actions. Requiring mostly ‘Yes/No/Don’t Know’ responses, KASI is quick to administer (maximum 30 minutes). Scoring is via 4-point system, ‘1’ relating to negative and potentially harmful views and ‘4’ knowledge over and above correct information. KASI has been widely used in hospital and community; with professional and lay people. However, it was developed in the 1980s so some elements may be outdated. More importantly, it has not been formally tested with members of this ethnic group.
Working with participants and one of the originators (co-applicant CB), we will therefore produce a modified, culturally-adapted version.

2. Opinions about Mental Illness (OMI) Scale:\textsuperscript{22,23}: The 51-item OMI measures attitudes to mentally-ill people using a 6-point Likert scale where ‘1’=’strongly agree’ and ‘6’=’strongly disagree’. Five sub-scales measure ‘Authoritarianism’, ‘Ideology’, ‘Restrictiveness’, ‘Benevolence’ and ‘Interpersonal Ideology’ and the factors associated with these constructs. High Authoritarian and Restrictiveness scores together with low scores for Benevolence indicate negative attitudes to mental illness. The OMI has been successfully used in research with African Caribbean people in Jamaican\textsuperscript{24}.

3. The Modified Illness Perception Questionnaire (IPQ-SCV)\textsuperscript{25} will be used to measure families’ perceptions of the extent to which patients’ ability to control symptoms affects sympathy and tolerance levels. Designed by Barrowclough and colleagues\textsuperscript{25} the IPQ-SCV assesses illness beliefs about consequences, cure-control and timeline of schizophrenia from the caregiver’s perspective using a 5-point Likert scale. There is no overall score. The 3 subscales have scores ranging from 1-5.

4. SF-12 version 2\textsuperscript{26}. Adopted from SF-36\textsuperscript{27}, SF-12 v2 is a practical, reliable and valid self-reported measure of functional health 12 questions to and well-being. It is widely used to monitor population health, analyse disease burden and predict costs and is particularly useful at the community-level as it can be completed in 2-3 minutes. 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, in this study, we shall examine scores before-and-after and at 6-month follow-up.

5. We shall pilot collection of quantitative data on use of the e-resource, electronically captured through the resource itself (and via a workbook for the DVD version), in collaboration with Manchester e-health sciences applicant (GM), service–centred outcomes (such as readmission rates), and cost outcomes developed with our health economist collaborator.

Procedure
Participants’ attitudes to and knowledge about schizophrenia will be assessed at 3 time-points i) prior to using the e-learning resource and at ii) 2 weeks and iii) 6 months afterwards. Mutually-convenient times and venues for completing outcome measures will be agreed with consenting participants. The control group will also be tested at the same time points but will not receive the intervention until after research data collection has ended.

Time-point 1 (Baseline Assessment): Basic demographic details and quantitative outcome measures will be completed by the RA. Participants in the intervention arm will select whether to access the resource via online e-learning or DVD/paper-based blended learning. In either case, they will also receive a manual/study guide on its use. We shall review the manual and a test example with participants to ensure comprehension and offer additional telephone advice and support. The nature, frequency and resolution (or not) of difficulties and queries will be recorded for later analysis. We shall also record and subsequently analyse any comments made by control group participants.

Time-point 2 (Acceptability): Two weeks after receiving the intervention-resource, participants will be asked to attend a feedback session on the intervention using acceptability outcomes developed with them in groups in Phase 1 – for example, how ‘user-friendly’ and comprehensible they found it and any perceived
effects on them. We shall collect these data using semi-structured questionnaires. Outcome measures (listed above) will also be assessed in both intervention and control groups. Data collection related to participants’ pattern of use of the resource and their scores on the e-learning programme online will be embedded in the resource. Participants who used the DVD/paper-based/blended solution will be asked to return the workbook and their scores recorded by the RA. They will also be asked to record perceptions (likes/dislikes) and experiences of using the DVD and workbook using a semi-structured questionnaire contained in the workbook. In similar studies with other groups, 1-2 weeks was the optimum timeframe as this enabled participants to complete the programme and to absorb content without adversely affecting attrition.

Time-point 3 (Outcome): This will be divided into 2 parts. First, participants in both intervention and control groups will be retested on outcome measures 6 months after delivery of the intervention. We shall then undertake qualitative work with a purposively-selected sample of approximately 15 participants (10 from the intervention and 5 from control groups). With the intervention group (n=10), we shall explore in detail their views about the resource’s accessibility, perceived usefulness and impact on attitudes and beliefs about schizophrenia. We shall also explore their views about the outcome measures, the feasibility of data collection and participation in the study more generally. In-depth, qualitative interviews with members of the control group (n=5) will enable us to gather data on their perceptions and experience of recruitment and randomisation and their views on factors that influence recruitment and retention among control group members. Selection criteria will include age, prior knowledge of schizophrenia and gender. We shall develop a topic guide to facilitate this element of the study based on emergent issues that emerge at time-points 1 & 2.

**Data analysis**

Quantitative data analysis
Demographic information will be analysed using simple descriptive statistics. We shall also calculate and compare recruitment and retention rates into intervention and control arms of the study. Because KASI sub-scales are ordinal and distances between variables unequal, a non-parametric test such as Wilcoxon matched-pairs will be used to compare pre- and post-test data (Z-scores). We shall use linear regression to examine the relationship between illness belief (IPQ-SCV) and other key outcome variables such as gender. As the OMI is being used for the first time with an African Caribbean group in the UK, principal components analysis with varimax rotation will be undertaken. Items with eigenvalues greater than 1 will be retained for further analysis of factors and related sub-scales. 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. With such wide possible variations, PCS and MCS scores have little meaning. In practice, age-specific mean difference scores are usually calculated. However, due to the sample size, we are unlikely to have sufficient power to examine differences within the sample on this and other measures by demographic information such as age, gender and socio-economic status (SES). Instead, our focus will be on piloting the use of these measures and ‘intra-family correlation’ (the extent to which responses ‘within families’ may be correlated). Significance (α) will be set at 5% (0.05) with a 95% CI. Data will be analysed using SPSS Version 19.

Qualitative data analysis
All interviews will be digitally-recorded with participants’ consent. Data will be analysed by DE and the RA using thematic content analysis as detailed in Phase 2 methods.
Ethical Considerations

Ethics approval will be obtained from the University of Manchester’s and NHS Research Ethics Committees. R & D approval will be obtained from Manchester Mental Health & Social Care NHS Trust who will host the study.

Sponsor
The University of Manchester the sponsors of the study.

Likely benefits of the proposed research

Our intervention is likely to benefit service users, carers and families and services.

Service users

Improving African Caribbean families’ knowledge about schizophrenia will benefit patients in a number of ways. In the short term, we anticipate: i) Better understanding of the disorder and patients’ experience within their families thus: reducing hostility and tendency to blame patients for symptoms; creating less stressful, more sympathetic home environments and potentially reducing the risk of relapse ii) Facilitating more timely access to care via more positive care pathways (e.g. via GP versus police) iii) Better and earlier engagement with specialist schizophrenia services thereby reducing patients’ likelihood of developing secondary co-morbidity such as substance misuse, which is particularly problematic among African Caribbean patients with long duration of untreated illness.

Carers and families

Our intervention will benefit the carers and families of African Caribbean patients by: (a) improving their understanding of the condition, thus enabling them better to advocate for family members with schizophrenia (b) reducing family tension and facilitating healthier, wellness-promoting, family relationships (c) reducing likelihood of accessing care via negative pathways such as potentially damaging police involvement in admissions, which increases shame, stigma and alienation from services.

Services

An intervention that improve access to cost- and clinically-effective care for African Caribbeans and other ‘hard-to-reach’ groups would improve patients’ quality of life and wellbeing. 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 cost savings for services locally and the wider NHS from reduced relapse and rehospitalisation and Commissioning for Quality and Innovation (CQUIN) payments linked to early intervention as well as improving patient, carer and staff experiences. Improving patient outcomes would also yield benefits for the wider health and social care community by improving efficiency of service delivery. Finally, 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.

NICE recommends novel, family-focused interventions for African Caribbeans. This proposal will co-produce a culturally-acceptable, family-focussed, e-learning resource and pilot the feasibility and acceptability of its implementation among African Caribbean families with schizophrenia to improve attitudes and knowledge about the illness and its treatment. Future research will include longitudinal studies examining clinical and cost effectiveness for service-users, carers, families and services.

Dissemination

To disseminate our findings to service users and carers, we shall enlist African Caribbean Mental Health Services (ACMHS) and other influential bodies such as MIND and Rethink. We shall share our findings via Patient and User and Carer forums and prepare plain English summaries for the Clinical Research Network.
(CRN). We shall actively involve African Caribbean communities in disseminating findings such as presentations and seminars in Black Majority churches, community groups and conferences to counter misinformation and challenge stigmatising attitudes and beliefs.

We shall use Manchester Mental Health & Social Care Trust’s (MMHSCT) Research & Development communications to maximise impact on practitioners and service managers. Collaboration with Greater Manchester Public Health Unit will facilitate dissemination to health planners such as Clinical Commissioning Groups (CCGs). Subject to University of Manchester Intellectual Property (UMIP), our e-learning resource will be freely-available to service users, carers and community members, NHS and other public bodies and voluntary sector. With UMIP, we will develop a strategy for independent sector access.

In addition to CRN and Manchester Academic Health Science Centre (MAHSC), we shall disseminate findings via conference presentations and academic and professional journals. We shall present key findings at national and international conferences for service users, non-governmental organisations (NGOs), policy makers and those responsible for design services.

**Expected outputs of research**

We aim to produce a practical, evidence-based intervention that directly improves lay knowledge about schizophrenia in a high-risk group which experiences poor outcomes. If the feasibility and acceptability of our intervention can be demonstrated, this will enable us to prepare randomised controlled trials (RCT) (firstly an exploratory trial and then a large multi-centre study) to demonstrate the extent to which the intervention improves African Caribbean families’ knowledge about schizophrenia, affects their attitudes to people with the condition, and perceptions/experience of engaging with services. Information from this study about recruitment, attrition and outcome measures will assist us in designing future research. We anticipate results within five years of the end of the proposed study.

**References**

26. Ware J, Kosinski M, Keller S. A 12-Item Short-Form Health Survey: Construction of scales and preliminary tests of reliability and validity
