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Co-producing mental health literacy training package

Submission date
27/11/2024

Recruitment status
Recruiting

Registration date
03/02/2025

Overall study status
Ongoing

Last Edited
20/01/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Severe mental illnesses like psychosis, a mental health problem that can change how people see the world, can cause a lot of distress for a person, and have a big impact on their lives. Psychosis impacts vulnerable groups unfairly, including people from minority ethnic backgrounds, and those from social and financial hardship. In the UK, people from Black ethnic backgrounds are more likely than White British people to experience psychosis for the first time and have negative experiences accessing mental health support. The reasons for this are complex but include racism, discrimination, mental health stigma, and lack of awareness of what the symptoms and outcomes of mental illness are (mental health literacy). Mental health literacy (MHL) more broadly refers to having the right knowledge about mental illness, how to look after your mental health, and knowing where to get the right support. It can help people access the right treatments at an earlier stage to help them stay well and have a good recovery. However, interventions designed to improve MHL do not take into consideration the needs and experiences of different cultural groups. As noted in the Black community, these needs and experiences may be responsible for some of the disparities seen, which is a critical missing component in our public health approach to improving mental health. Several things promote fairer access to mental health care, incuding: 1) improving understanding within Black communities about symptoms of mental illness and where to access timely support; 2) improving education for mental health professionals around the challenges that Black people face; and, 3) ensuring everyone is treated fairly, offered a choice that respects cultural needs, and given timely access to treatments. This study aims to conduct a test run to see if a tiered MHL program is practical, acceptable, and cost-effective. This program expects to improve access to mental health care and outcomes for underserved groups.

Who can participate?
Individuals aged 18-65 years from Black ethnic backgrounds attending community settings. Staff members at Forward Thinking Birmingham (FTB) or Early Intervention Services (EIS) of NHS Trust. Participants in concept mapping workshops, including various stakeholders. Regional mental health experts who are involved in surveys and interviews. Patients, providers, and commissioners exploring the program's early impacts.

What does the study involve?
Work package 1
If participants agree to take part in work package 1, the study package they are invited to will last for a maximum of 4 months. Different community settings will be selected and split into groups, and depending on the group, participants will be asked to either participate in the MHL (MHL) Training delivered in person or learn about MHL from written leaflets and posters. The group allocation for each community setting will be randomly assigned.

All participants in the study will be asked to complete a set of questionnaires before and three weeks after the training. These questionnaires will assess the community's attitudes towards mental illness, intended and reported stigmatising behaviours, desire for social distance from someone with a mental illness, mental health knowledge, and help-seeking attitudes.

The in-person training will be delivered by young people from the Black African and Black Caribbean communities with lived experience. This training will last about 1.5 hours and will be held in person in the community, at an accessible local venue. During this meeting, a member of the research team from the University of Birmingham will also be present to observe the training and take notes.

By attending this training, participants will play an important role in helping assess the acceptability of the MHL training and in better understanding the barriers and enablers to access care, which will, in turn, support the future implementation strategy.

Participants may also be invited to participate in a focus group or one-on-one interview, during which a member of the research team will ask questions about whether the training was helpful, appropriate, and capable of improving mental health outcomes for Black people. A focus group discussion will last approximately 1.5 to 2 hours, while a one-on-one interview will last about 1 hour.

Work package 2
If participants agree to take part in work package 2, the study package they are invited to will last for a maximum of 4 months. Approximately every 4 weeks, a certified e-learning module will be implemented for a new NHS team or Trust. The timing of when each team will receive the training will be randomly allocated.

When a team is allocated, everyone in the team will be asked to complete a 20-minute certified e-learning module. This e-learning is informed by lived experience and aims to raise awareness of sociocultural diversities, cultural barriers, multicultural knowledge, and sensitivity and responsiveness to patients from Black ethno-racial backgrounds.

All participants will be asked to fill out a set of questionnaires before the e-learning and three weeks after the e-learning modules. These questionnaires will assess demographic characteristics such as age, gender, ethnicity, and job role, as well as the feasibility, acceptability, and fidelity of the implementation of this research. Additionally, they will evaluate mental health knowledge, attitudes, skills, and competencies when working with minoritised groups. By completing this e-learning module, participants will play an important role in helping assess the acceptability of the package and in better understanding the barriers and enablers to provide care, which will, in turn, support the future implementation strategy.

Participants may also be invited to participate in a group discussion or one-on-one interview, during which a member of the research team will ask questions about whether the training was helpful, appropriate, and capable of improving mental health outcomes for Black people. A

focus group discussion will last approximately 1.5 to 2 hours, while a one-on-one interview will last about 1 hour and will take place in the respective NHS Trust.

Please note that the group discussion or one-on-one interview will be audio-recorded using a secure encrypted recording device to help document the process and transcribed to ensure accuracy, but participants' anonymity will be protected throughout.

These audio recordings will be securely shared with a third-party transcription service for the purposes of deriving verbatim text from recorded conversations. This service will be bound by a confidentiality agreement, and the third-party transcription service will destroy all audio recordings upon verification of the accuracy of transcripts. However, the research team will retain the audio recordings and store the data safely. Participants' anonymity will be protected throughout.

What are the possible benefits and risks of participating?
While significant risks are not anticipated, participants may experience emotional distress or discomfort during the interviews, especially if sensitive topics are discussed. If this occurs, participants can request to pause or stop the interview and may seek additional support. Additionally, there are risks related to data protection, which we will mitigate by following strict confidentiality protocols and data security measures. However, it is possible that sharing accounts of lived experience or related topics may cause distress. Should it be identified during the study that participants are at risk of harm to themselves or others, local safeguarding procedures will be followed, and confidentiality may be breached by informing a member of their direct healthcare team.

Where is the study run from?
This study is run by the Institute of Mental Health at the University of Birmingham in two settings. Work Package 1 will be run in 8 community sites in Birmingham and Black Country, while Work Package 2 will be run in the Forward-Thinking Birmingham of the Birmingham Women and Children NHS Foundation Trust, Early Intervention Services of the Black Country Healthcare NHS Foundation Trust, and Birmingham and Solihull Mental Health NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
October 2023 to April 2026

Who is funding the study?
UK Research and Innovation (UKRI)

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
333999

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
RG_23-166

Study information

Scientific Title
Co-Stars: a feasibility evaluation of a co-produced mental health literacy training package to reduce mental health inequities for Black youth in underserved communities

Acronym
Co-Stars

Study objectives
A tiered Mental Health Literacy (MHL) package designed to promote equitable mental health care access and improved outcomes for Black youth in underserved communities is feasible, acceptable, and cost-effective.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/10/2024, East of Scotland Research Ethics Service (EoSRES) (Tayside Medical Science Centre Residency, Block Level 3, George Pirie Way, Ninewells Hospital and Medical School, Dundee, DD1 9SY, United Kingdom; +44 (0)1382 660111; tay.eosres@nhs.scot), ref: 24/ES/0030

Study design
A pilot open-labelled pragmatic cluster-randomised controlled trial and a pilot stepped-wedge cluster randomised trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Mental health literacy

Interventions
This is a single study with four cross-cutting work packages. The overarching aim of this feasibility study (or external pilot) is to conduct a pilot evaluation assessing the feasibility, acceptability, and cost-effectiveness of a tiered Mental Health Literacy (MHL) package. This MHL package is designed to promote equitable mental health care access and improved outcomes for Black youth in underserved communities.

All four work packages (WPs) in this study are well aligned with this overarching aim, although each employs a study design specific to its specific objective. WP 3 and WP 4 are designed to explore the system-wide impact of the intervention using realist-informed participatory systems mapping and novel epidemiological analyses to examine downstream effects of the interventions delivered in WP 1 and WP2, such as improved care access for Black ethno-racial groups within the intervention areas. WP 4 includes a cost-effectiveness evaluation of these interventions. Consequently, these packages will run simultaneously, with the same recruitment start and end dates for all packages.

WP1: A pilot cluster randomised controlled trial of lived experience-led mental health literacy training in community settings

Aims & Objectives: The aim is to assess the feasibility and acceptability of the MHL intervention delivered to underserved communities and to assess the barriers and enablers to support the future implementation strategy/trial.

Design: This is a pilot open-labelled, pragmatic, cluster-randomised controlled trial (CRT) implemented within a specific underserved community in Birmingham. The study will adhere to the CRT consort extension and procedure set out by the Birmingham Clinical Trials Unit to ensure transparency and quality of reporting. A mixed methods realist approach will be adopted for the process evaluation.

Method: Recruitment of clusters and implementation of the intervention will occur over a 6-month timeframe (months 4-9). Participants within the cluster will be consented and asked to complete pre-/post outcome measures. Structured observations assessing the fidelity of intervention delivery will be conducted, as well as two focus groups and semi-structured interviews with participants within the control and intervention arms, as well as young people delivering the training.

Setting: The target is 2 constituencies in the West region of Birmingham; a region with the highest proportion of Black African and Black Caribbean individuals in Birmingham (19% compared with 9% and 3.5% in Birmingham and the UK, respectively), with over half of the West region population living in the top 10% decile for deprivation, meaning that these communities are likely exposed to a multitude of social risk factors for development of severe mental illness.

Unit of randomisation: Community settings include places of worship (e.g., Black majority churches), youth centres, community centres, and youth residential settings. These will be randomised as clusters and allocated on a 1:1 basis to receive the intervention or control. Clusters will be stratified by setting type to prevent imbalances in treatment groups. By design, concealing treatment allocation is not possible for this study.

Population: Participants (aged 18-65 years) attending the community settings. Researchers will assess eligibility and obtain written consent before collecting the baseline measures. Individuals unable to provide informed consent due to cognitive impairment will be ineligible to take part. Participants will receive a £25 shopping voucher in respect of their time. A maximum variation sampling method will be used to identify participants for the process evaluation.

Intervention: The intervention is the lived experience-led MHL training. The training will be delivered by young people of the Black African and Black Caribbean diaspora, lasting approximately 1.5 hours and will cover: 1) symptoms and signs of mental illness (including SMI); 2) how to distinguish mental health symptoms from normal behaviours; 3) attitudes and beliefs about people with mental illness; 4) advice on how to manage wellbeing; and finally, 5) information about local services and help-seeking. The intervention will be reported using TIDIER.

Control: Written MHL material (information leaflets and posters) placed within the community setting. Before these materials are placed in the community setting, participants will be invited to complete baseline measures and then re-approached after 3-weeks to collect follow-up measures.

Sample size: The study will recruit 120 participants from approximately 8 randomised clusters. Formal power calculations are not necessary as no hypothesis testing for trial effectiveness is being evaluated. A sample of 120 (with ~60 per arm), meets sample size recommendations for pilot and feasibility studies and is sufficient to provide precision of feasibility parameters and estimates of study summary measures for a definitive trial. Twenty participants in total will be recruited for focus groups (3 groups of 5 diverse participants) and five 1:1 interviews.

Analysis: Descriptive statistics will be used to assess training fidelity and feasibility outcomes. Other data will be analysed using thematic analysis to generate important themes and patterns. For the secondary outcomes, means, confidence intervals, and intracluster correlation coefficient (ICC) of the outcome measures (both within-study and between-study clusters) will be estimated to determine which outcome(s) are most sensitive to change and provide sample size calculation for a definitive trial.

WP2: A pilot stepped wedge cluster randomised trial of e-learning for mental health professionals

Aims & Objectives: The aim is to evaluate the feasibility and acceptability of e-learning to develop a methodology to inform the implementation evaluation in a future trial (phase 3).

Design: A pragmatic stepped wedge cluster randomised trial (SWCRT) design will be adopted with random and sequential crossover of clusters (youth mental health teams) from control to intervention (the e-learning module) until all clusters are exposed.

Methods: There will be a phased and sequential implementation of the e-learning at regular intervals across teams and trusts over 6 months (months 4-9). Staff will complete the training outcome measure before and after the e-learning. The training will be deployed in a staggered manner in line with the stepped wedge approach. Starting in the first trust (Forward Thinking Birmingham (FTB)) in month 4 and rolled out to the 4 teams in staggered intervals. The training will then be rolled out in the second trust (Black Country – Early Interventions) with staggered implementation between months 6-9. Throughout implementation, staff focus groups and semi-structured interviews will be conducted.

Setting: FTB, part of the Birmingham Women's and Children's Mental Health Trust, is a 0–25-year community and inpatient mental health service and is the primary mental health service regionally for this population. Within FTB there are 4 specialist Early Intervention Services (EIS) that offer intensive community support to young people with a first episode of psychosis. The second trust is Black Country Healthcare in which the Dudley and Walsall EIS team will be targeted, which provides community support to young people with psychosis between the ages of 14 and 65 years.

Randomisation: Cross-over of clusters (clinical team; n=6) from control to intervention will occur approximately every 4 weeks.

Population: A range of professionals (n=120) will be expected to complete the training, including psychiatrists, psychologists, community psychiatric nurses, occupational therapists, support workers and social workers. A purposive sampling method will be used to recruit staff to the focus groups and 1:1 interviews ensuring a balance of staff backgrounds, experience, and representation from across different teams and trusts. INCLUDE guidelines will be adhered to ensure diversity and inclusion in the sampling.

Intervention: The intervention is a 20-minute certified e-learning module targeted at professional systems and public organisations involved in mental health care pathways. Informed by lived experience, the e-learning seeks to raise awareness of sociocultural diversities, awareness of cultural barriers, multicultural knowledge, and sensitivity and responsiveness to patients from Black ethnoracial backgrounds.

Control: The control condition will be the unexposed observation period before sequentially crossing over to the exposed observation period (receiving the intervention).

Sample Size: Formal power calculations are not necessary as no hypothesis testing for trial effectiveness is being evaluated. A sample of 120 meets sample size recommendations for pilot and feasibility studies and is sufficient to provide precision of feasibility parameters and estimates of study summary measures for a definitive trial.

Analysis: Process outcomes will be analysed in the same manner as WP1. Parameters will be estimated for the power calculations for the secondary outcomes making adjustments for the temporal trend, ICC and number of steps.

WP3: Mixed-methods Study: Systems Mapping and Systems Change

The aim is to undertake formative research to underpin a proposed whole systems approach to evaluating the impacts of the tiered approach described in WP1/2. Specifically, this will include two key areas of work:

Systems map: A systems map will be developed in three phases: 1) Firstly, a concept mapping workshop involving key stakeholders (patients, research team, providers and policymakers) will be undertaken. This will be guided by a draft model produced by the team (who consist of mental health experts in the region) which will then be introduced and amended using an iterative consensus-building process in a face-to-face workshop. 2) This will be followed by a modified two-stage Delphi survey inviting regional mental health experts to provide their agreement or disagreement with the systems map and willingness to be involved in semi-structured interviews with the research team. 3) Those willing to take part in interviews will then be invited to share their opinions on how the tiered intervention may impact the system map and in particular their opinion on potential outcomes which should be measured at a system-wide level.

Exploring the early impacts of co-stars: To identify whether the intervention is providing tangible impacts on a system-wide level, a data-driven impact evaluation will be piloted. An interrupted time series (ITS) will be undertaken to ascertain whether the introduction of the intervention leads to a change in the relevant outcomes identified in the systems mapping process. This type of analytical approach has been advocated for use in public health evaluations and is related to structural break modelling.

This pilot evaluation will be undertaken in three phases:

Identification of suitable data sources: Guided by health data science expertise in the research team (JSC/FC), expert opinion from the systems mapping process and through open source searching, a directory of suitable datasets and outcomes which could inform the systems-wide impact of the intervention will be compiled (e.g. the use of West Midlands Police Data to assess the rate of s136 interventions in Black males).

Trial of ITS model: Using available datasets (those open access or those already accessible by the research team), a pilot ITS will be undertaken. The study period will be set between 2022-2024. Incidence rates (calculated by the number of new cases divided by the denominator given by the at-risk population) will be analysed monthly (weekly where possible) throughout the study period and these trends will be depicted graphically. The primary breakpoint to be examined is the introduction of the intervention; therefore, for the ITS modelling, monthly data one year prior and one year following this timepoint will be included. The sensitivity of the analysis around this breakpoint will be examined.

Stakeholder engagement: Three focus groups (consisting of 6-8 people) with key stakeholders (patients, providers and commissioners) will be undertaken to demonstrate the findings from the trial to unpick the possible mechanisms for these changes as a result of the impact of the intervention of the systems map. The secondary aim of these focus groups will be to optimise the strategy to undertake such systems change evaluation on a broader scale when the intervention is rolled out for a full trial.

WP4: Economic evaluation to examine cost-effectiveness and social return on investment

This tiered approach is likely to reduce direct health costs (admission and healthcare usage), but it could also have important cost implications for the healthcare sector, public sector and society more broadly. For example, if it is effective at improving mental wellbeing, there are likely to be important cost implications for the healthcare sector, public sector and society more broadly. The primary base case analysis will adopt a public sector perspective in line with NICE guidelines, with a wider societal perspective explored as a secondary analysis.

Data collection: Firstly, and most relevant to WP1/2, resource use data will be used to estimate the costs associated with each of the intervention and control arms.

This will include i) intervention costs; ii) healthcare resource use; iii) wider public sector resource use; and iv) private costs. Information on unit costs or prices will be sourced to attach to each resource use item, to enable an overall cost to be calculated (e.g. PSSRU Unit Costs of Health and Social Care).

Cost-effectiveness: To compare intervention arms with the control, a within-study analysis and a model-based economic analysis will be undertaken. This will primarily use the data collected within the trial and from the quasi-experimental study. Initially, the base case analysis will be framed in terms of a cost-consequences analysis, and data will be reported in a disaggregated manner on the incremental cost and important consequences assessed in WP1/2. The main economic analysis will assess cost-effectiveness based on the costs and health outcomes collected in WP1/2. The economic evaluation will be conducted and reported in accordance with relevant guidelines (e.g., CHEERS checklist) and recommended methodologies.

Social return on investment: As not all costs are quantifiable, an SROI will also be explored. The PPI panel (and work undertaken during the QR-funded period) will help determine which items (including ones where costs are intangible) matter and discuss how they should be quantified. This is particularly relevant when considering the impacts of how the wider system changes in response to this intervention (for example, the impacts of improved community connectedness).

Patient and Public Involvement & Engagement (PPIE): This programme of work from conception through to delivery has been informed by PPIE, including young people with lived experience and charitable partners who have provided advice on study management, training and support for PPIE, as well as inputting into the lay summary. Good practice in line with UK Standards for Involvement has been ensured. A diverse PPI advisory group will be appointed to advise on the ethical and delivery aspects of the project. Individuals from the Youth Advisory Group at the Institute for Mental Health, the West Midlands School for Public Health Consortium (PHRESH) and NIHR applied research collaboration (ARC) as well as the partnership with Catalyst4Change CIC – a grassroots charity supporting the mental health needs of Black African and Black Caribbean communities across Birmingham – will be identified.

Intervention Type
Mixed

Primary outcome(s)
WP1 Outcome: Feasibility outcomes include the proportion of consenting clusters, percentage of training uptake and completion of pre- and post-outcome measures, as well as the acceptability of the intervention and assessment of the barriers and enablers.

WP2 Outcome: Feasibility process outcomes will include the percentage of training uptake across staff and service teams in addition to the acceptability evaluation (detailed in WP1). The secondary outcome is the assessment of the training outcome of the California Brief Multicultural Competence Scale, which assesses mental health staff knowledge, attitudes, skills, and competencies when working with minoritised groups.

Key secondary outcome(s))
The secondary outcome is the assessment of key training outcomes:
1. Knowledge measured using the Mental Health Knowledge Scale (MAKS)
2. Illness attributions and stigma measured using the Reported and Intended Behaviour Scale (RIBS) – Intended Behaviour Subscale to assess intended and reported stigmatising behaviours and desire for social distance from someone with a mental illness and the Community Attitudes towards Mental Illness (CAMI) scale
3. Help-seeking attitudes and efficacy - General Help-Seeking Questionnaire

Completion date
30/04/2026

Eligibility

Key inclusion criteria
WP1:
1. Participants attending the community settings (e.g. Black majority churches, youth centres, community centres, youth residential settings) and
2. Black Ethnicity
3. Aged 18-65 years

WP2:
1. All staff who have the potential for direct encounter with patients and working in either Forward Thinking Birmingham (FTB) or Early Intervention Services (EIS)
2. This would include, but is not confined to, psychiatrists, psychologists, community psychiatric nurses, occupational therapists, support workers, paramedics, and social workers.

WP3:
1. Concept mapping workshop: Patients, research team, mental health service providers, and policymakers.
2. Modified Delphi survey and semi-structured interviews: Regional mental health experts
3. Exploring the early impacts of co-stars: Patients, providers, and commissioners.
4. All participants in WP3, who did not take part in WP1 or WP2, will be 18 years or older and capable of giving consent in accordance with the Mental Capacity Act 2005.

WP4:
This package will include the participants of WP1 and WP2.

Participant type(s)

Health professional, Population

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Unable to understand verbal explanations or written information given in English or to demonstrate capacity to consent.

Date of first enrolment
10/03/2025

Date of final enrolment
20/04/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Birmingham Women's and Children's NHS Foundation Trust
Steelhouse Lane
Birmingham
England
B4 6NH

Study participating centre
Black Country Healthcare NHS Foundation Trust
Trafalgar House

47-49 King Street
Dudley
England
DY2 8PS

Study participating centre
Edgbaston Community Centre
40 Woodview Dr
Birmingham
England
B15 2HU

Study participating centre
Birmingham and Solihull Mental Health NHS Foundation Trust
The Uffculme Centre
52 Queensbridge Road
Moseley
Birmingham
England
B13 8QY

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
All information collected for this study will be subject to the General Data Protection Regulation and Data Protection Act 2018. We will ensure your confidentiality by storing your personal data electronically on a secure network at the University of Birmingham using encrypted files. Data will only be accessed by authorised members of the research team via password-protected University of Birmingham-issued computers. Paper copies of study documents will be stored in a locked filing cabinet in a locked room at the University of Birmingham, accessible only to authorized research personnel. Any information that could identify you (e.g., name, address, etc.) will be removed from your study data, and your study data will be linked by a unique code. The document which links your unique code with your identifiable personal information will be stored separately allowing the research team to identify your data. Audio recordings will be destroyed as soon as transcripts have been generated and checked for accuracy. Any personally identifying data will be removed from interview transcripts and workshop observation notes at the earliest possible opportunity, and pseudonyms will be used instead of real names. The third-party transcription service will be bound by a confidentiality agreement. Any demographic information reported in publications (e.g., age, sex, ethnicity) will be summarized for the group as a whole to prevent identification of individuals. We may share the data with third parties if they request raw data for their review or systematic review. In such cases, we will ensure that any data which could identify you individually will not be shared.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	27/09/2024	24/01/2025	No	Yes
Participant information sheet	version 1	27/09/2024	24/01/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			24/01/2025	No	No
Statistical Analysis Plan			24/01/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes