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

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Short Description

Co-STARS is a training package co-developed with, and delivered by, Black youth with lived experience of mental illness to mental health professionals and underserved communities across Birmingham. It aims to improve awareness of issues faced by Black youth with mental illness and promote more equitable access to care and recovery.

Lay Summary

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 form 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, 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.

We can do several things to promote fairer access to mental health care: 1) improve understanding within Black communities about symptoms of mental illness and where to access timely support; 2) improve education for mental health professionals around the challenges that Black people face; 3) ensure everyone is treated fairly, offered choice that respects cultural needs, and given timely access to treatments.

We have developed a MHL training package called Co-Stars, that has been co-designed with young people from Black African and Black Caribbean backgrounds with experience of mental ill health. The training is delivered by these young people to our local underserved communities in places of worship and community centres. We want to see if this can encourage people from these communities to access support for their mental health (Work package 1). We have also co-designed an online training course for mental health professionals on how they can better support Black communities (Work package 2). We will gather views from people within Black communities, as well as mental health staff, on whether they think the training is helpful, appropriate, and can make a difference to improve mental health outcomes for Black people. We will test this carefully through a research trial where some community settings will receive the training, while other settings will not. This will be the same for staff training, where some mental health services will receive the training, and others will not. This is a robust way for us to see if what we are doing might work in a larger study. We also want to see how these two types of interventions can influence wider system changes that are needed to improve outcomes (Work package 3), by assessing the potential cost savings through reducing mental health detentions, keeping people well for longer, as well as the wider societal benefits (Work package 4). Ultimately, through our work, we want to lessen mental health inequalities for Black ethnic groups.

Technical Summary

Psychoses are among the most disabling illnesses worldwide and disproportionately affect minoritized ethnic groups and those in socioeconomic disadvantage. Within the UK, people from Black ethnic backgrounds are 3-5 times more likely to experience a first episode of psychosis (FEP), five times more likely to be detained, and are more likely to be subjected to the Mental Health Act than White British people. Factors contributing to these disparities are complex and influenced by wider inequities within and beyond health systems, including discrimination, cultural insensitivities, racism, stigma, and lack of recognition of the symptoms of mental illness within Black communities. There is a clear need for services to improve cultural awareness and understanding of the broader social needs of minoritized groups, as well as improve mental health literacy (MHL) within Black communities to empower individuals to seek timely mental health support.

This study aims to assess the feasibility, acceptability, and cost-effectiveness of Co-Stars, which is a co-produced, culturally appropriate tiered MHL training package. The training will be evaluated in stages: 1) a pilot cluster randomised controlled trial will assess the feasibility and acceptability of a lived experience-led training package delivered by Black young people with experience of mental ill health, to underserved communities in Birmingham, UK, and 2) a stepped-wedge cluster randomised trial will evaluate the feasibility of an e-learning training for mental health professionals. We will embed a process evaluation to explore change mechanisms and identify barriers and enablers for future implementation. Finally, to explore the system-wide impact of the intervention, we will use participatory systems mapping and novel epidemiological analyses to explore downstream effects (i.e., improved care access for Black ethno-racial groups within the intervention areas), in addition to a cost-effectiveness evaluation.

Aims and Objectives

The overarching aim of this study is to undertake a pilot evaluation assessing the feasibility, acceptability, and cost-effectiveness of a tiered Mental Health Literacy (MHL) package designed to promote equitable mental health care access and improved outcomes for Black youth in underserved communities.

The aims of Work Package 1 are to assess the feasibility and acceptability *of the MHL intervention delivered to underserved communities* and assess the barriers and enablers of the future implementation strategy/trial. To do this, we will assess 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 barriers and enablers to intervention as identified during the interviews and focus groups.

The aims of Work Package 2 are to evaluate the feasibility and acceptability *of the e-learning* to develop methodology to inform our implementation evaluation in a future trial. We will assess feasibility process outcomes, including the percentage of training uptake across staff and service teams and the acceptability evaluation detailed above.

The aims of Work Package 3 are to identify whether the MHL intervention is providing tangible impacts on a system-wide level. To this end, we will develop a systems map and pilot a data-driven impact evaluation.

The aims of Work Package 4 are to examine the cost-effectiveness and social return on investment of the MHL intervention. We will assess cost-effectiveness based on the costs and health outcomes collected in Work Packages 1 and 2. Our PPI panel will help us determine which items 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).

Keywords

Mental Health; Prevention; Health Inequities; Mental Health Literacy; Feasibility evaluation; Cultural Psychiatry; Ethnic minorities; Community Psychology; social determinants

Introduction

1. Vision

Stark Mental Health Inequalities

Severe mental illnesses (SMI) such as psychotic disorders are amongst the most disabling illnesses worldwide [1]. They are accompanied by enormous personal, healthcare, and societal costs, and disproportionately affect minoritised ethnic groups and those in socioeconomic disadvantage [2, 3]. Within the UK, people from Black ethnic backgrounds (African, Caribbean, British) are 3-5 times more likely to experience a first episode of psychosis (FEP), five times more likely to be detained, and more likely to be subjected to the Mental Health Act than White British people [4-7].

Factors contributing to these disparities are complex and influenced by wider inequities within and beyond health systems, including bias, discrimination, and racism towards Black individuals, as well as stigma and lack of recognition of the symptoms of mental illness [8-10]. Through our own work on ethnicity and pathways to care in Birmingham, we identified further barriers to accessing timely care, which included internalised and externalised stigma, differing illness attributions, and a disinclination to access mental health services and primary care, with preference instead to seek help from faith-based or community organisations [11-13]. This lack of trust and disengagement in services is thought to stem from feelings of disempowerment within the system, perpetuated by negative experiences and relationships with health professionals including experiences of racism, cultural insensitivity, less autonomous care, and inequitable offer of resources [14-18]. Black individuals with psychosis are less likely to be offered NICE-recommended treatments such as clozapine for treatment-resistant schizophrenia [19-21], or Cognitive Behavioural Therapy (CBT) [22], but more likely to be prescribed depot/injectable antipsychotics, to be re-admitted to hospital, and to have longer inpatient stays [19, 23]. The consequences of these experiences are likely to be far-reaching; our recent work from NIHR SUPEREDEN showed poorer five-year clinical and social outcomes for those from Black backgrounds with FEP [24].

The Mental Health Act review and subsequent Government White Paper, in line with the NHS Long Term Plan, were clear that alongside proposed legislative reform, there is a need to ensure that individuals can always access the right mental health treatment at the right time to ensure that they are supported to stay well and are less likely to be subject to the Mental Health Act [25-27]. **There**

is a clear need for improved mental health knowledge to reduce stigma within Black communities as well as empower individuals from these communities to advocate for their own mental health and seek timely support. Enabling Black groups to identify gaps in provision will be a critical step in improving care access and outcomes. Educating health professionals is needed to improve cultural competence and understanding of the broader social needs of minoritised groups, as well as the eradication of racial bias and discrimination from health services. Finally, alerting commissioners to the persistent nature of these inequalities, as well as possible solutions to address them, is also urgently needed.

Mental Health Literacy to improve place-based health inequities and equitable care access

Health literacy refers to an individual's ability to understand and utilise information to make decisions about their health and navigate health services [28, 29]. It is described by the World Health Organization (WHO) as the cornerstone of a healthy society, with **health literate individuals being able to actively participate in societal economic prosperity, community activities, and enjoy better health and well-being [29].** Conversely, low levels of health literacy (commonly seen in those from low socio-economic backgrounds, minority ethnic groups or those affected by mental health conditions; groups which often experience the greatest inequities in health outcomes [28, 30]), are deemed the **most potent social determinant of health by WHO**, with far-reaching consequences [28, 29, 31, 32]. **With the widening poverty gap in the UK, coupled with an increased prevalence of mental health difficulties, particularly among young people [15, 33], addressing these issues has never been more pertinent.**

Mental health literacy (MHL) is an extension of health literacy that refers specifically to having the necessary skills, knowledge, and agency to aid in the recognition, management, and prevention of mental illness [34]. **MHL is essential for promoting early detection and early treatment of mental health problems to improve longer-term outcomes [35-37]**. In large-scale programmes that seek specifically to reduce mental health stigma, interventions were most effective when people with lived experience of mental health conditions informed the development and delivery of the programmes [38, 39]. Thus, there are calls for MHL interventions to be contextually developed and applied so that they fit the context in which they are to be deployed, and that high priority groups are engaged through co-design principles [29, 40]. Empowering minority and marginalised communities, who are often excluded from these processes, will enable the development (and delivery) of a sustainable, culturally relevant and trusted intervention, drawing on local knowledge and trusting relationships [41]**. To date, there is no evidence of effective MHL interventions delivered by (and for) high priority, marginalised groups, with research in this area limited to low-quality studies and lack of rigour to establish efficacy [27, 38, 42-44].**

But there also needs to be wider systems change, driven top-down from healthcare attitudes, knowledge and skills of working with minoritised groups. Through our own work within Early Intervention in Psychosis (EIP), we demonstrate A Learning Healthcare System (LHS) describes an iterative data-driven approach that leverages data from routine practice, to learn and provide real-time actionable insights to improve the timely offer of treatments, tailored to the individual. Utilizing cutting-edge digital technology such as machine learning, smartphone applications, and high-speed computing, there is enormous potential for a modern LHS to transform patient care and outcomes. Whilst there is good evidence of LHSs improving care in other disease areas such as stroke, there is underutilization of clinical data from electronic health records within early psychosis. Further, the way in which data is collected, in systems that are often fragmented or uninterpretable, poses a challenge for unlocking the full potential of routine data. Most of our existing evidence base is therefore drawn from one-off cohorts, but these data do not offer real-time interoperability, and our 'gold standard' randomised controlled trials are often based on small, underrepresented samples that might not reflect the caseloads of our early intervention services. This means that little is understood about the real-world effectiveness of such treatments, particularly for underserved groupsed a mismatch between service providers' reported cultural competencies and service users' perceptions of staff applying these competencies, potentially impeding service engagement [45, 46].

Utilising digital technologies is one possible solution for rapid scaling of interventions to public health dissemination levels to remove structural and systemic barriers inherent with health and social care systems. Through our scoping work, we were unable to identify any evaluated co-designed e-learning packages designed to improve health literacy pertaining to health equity among marginalised groups in the UK [27, 47]. Although lived experience-led e-learning and training/education programs have been developed to address a range of mental health topics (e.g., police discrimination towards people experiencing mental distress; use of coercive measures in psychiatry [48-50]), **to our knowledge, no MHL intervention has simultaneously addressed and robustly evaluated a rigorously co-designed, place-based, multi-modal intervention, incorporating e-learning and lived experience-led delivery to improve MHL and outcomes for minoritized groups [27, 38, 47].**

Building on our ongoing work, we aim to co-develop a pilot evaluation of a co-produced, culturally appropriate, placed-based, tiered mental health literacy training package (Co-Stars; QR funded) delivered within underserved communities across **Birmingham, UK**, and via an e-learning package implemented within mental health trusts across the region. **Given the limitations of the current evidence base as noted above, our package is highly novel, and much needed to tackle mental health inequalities perpetuated within the system.**

Place

Birmingham is a large multi-cultural city with numerous risk factors indicative of low levels of health literacy. Fifty one percent of the population consists of individuals from ethnic minority backgrounds, with 9% from Black African and Black Caribbean heritage (compared to 3.5% as national average) [51]. Fifty percent of Birmingham wards rank in the top 10% of need in England [51]. The multiple impact of deprivation and minority status is evident in the high incidence rates of psychosis (431.2 young people are predicted to develop psychosis over 12-months, of which, 74.8% are ethnic minorities) [52, 53]. Birmingham is also one of the most vulnerable areas to literacy challenges in the entire country [54]. These highlight the importance of addressing MHL in settings such as Birmingham to address place-based health inequities.

Methods

This study is the **second phase** of an ongoing project (Figure 1), developed in line with the Medical Research Council (MRC) framework for developing and evaluating complex intervention [55]. **Phase 1** of Co-Stars is ongoing through our institutional QR-funded project, which involves a robust, co-produced, tiered MHL package aiming to raise awareness of intersectional issues that Black ethnoracial groups face, including racism, stigma, trauma, and barriers to accessing timely mental health support. Using a modified Delphi approach, the package has been co-developed with young people from Black African and Black Caribbean backgrounds with lived experience of mental ill health. A Training Needs Analysis (TNA) [56] is also being conducted with professionals to evaluate existing knowledge and identify areas where training interventions are necessary. By May 2024, we will have a multi-modal training package that is certified, user-needs assessed, manualised, and ready for deployment and testing:

Tier 1: Certified *lived experience-led* training package;
Tier 2: Certified *e-learning course* for mental health and social care professionals.

Within this bid, we aim to pilot the feasibility of the tiered training outputs from our funded Phase 1 work in a series of evaluations (Figure 2), which will form the basis for our **Phase 2** activities (Figure 1). If we demonstrate acceptability and feasibility of the training package, we will seek funding to progress to Phase 3, which is a multi-site (across all four nations in the UK) large scale cluster randomised controlled trial.

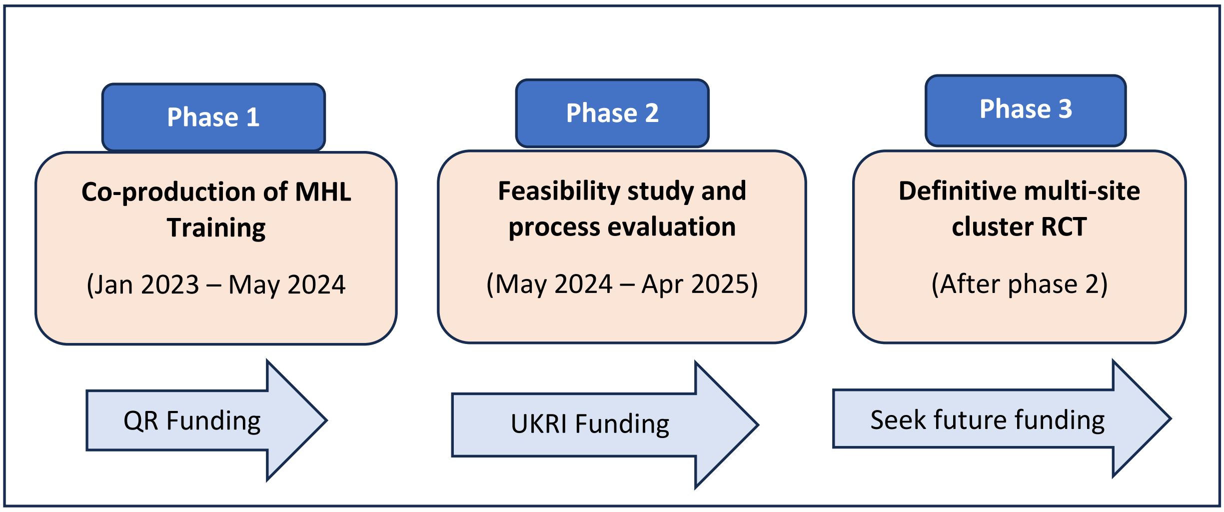
2. Approach

Aims: We aim to undertake a pilot evaluation assessing the feasibility, acceptability, and cost effectiveness of a tiered MHL package designed to promote equitable mental health care access and improve outcomes for underserved groups. We will co-design and co-develop the following work packages (WP; Figure 2) based on close engagement with stakeholders and PPIE:

- **WP1:** Pilot Cluster Randomised Controlled Trial (CRT) of lived experience-led mental health literacy training in community settings
- **WP2:** Pilot Stepped Wedge Cluster Randomised Trial (SWCRT) of e-learning for mental health professionals
- **WP3:** Mixed-methods Study: Systems mapping and systems change evaluation
- **WP4**: Economic evaluation of WP1-3 to examine cost-effectiveness and social return on investment

In addition to assessing impact, we will embed a process evaluation to explore the mechanisms of change and resources required to support intervention reach and impact in the continued rollout. The process evaluation will be critical to understand how the implementation is achieved, how each of the interventions produce change, and how might context affect implementation and outcomes, including impact on mental health inequalities.

Figure 1. Phased approach to Co-Stars Evaluation.



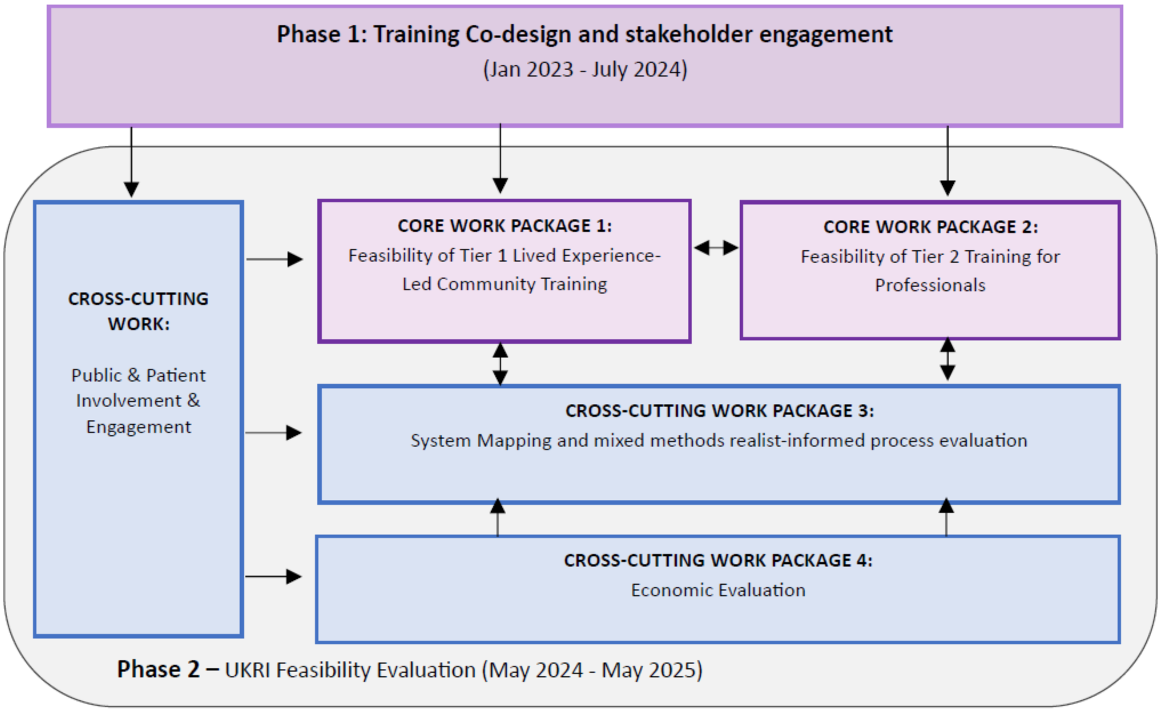


Figure 2: Overview of work packages for Phase 2 feasibility evaluation development

WP1: Pilot cluster randomised controlled trial of lived experience-led mental health literacy training in community settings
Aims & Objectives: To assess the feasibility and acceptability of the MHL intervention delivered to underserved communities and assess the barriers and enablers to support the future implementation strategy/trial.
Design: A pilot open-labelled, pragmatic, cluster randomised controlled trial (CRT) implemented within a specific underserved community in Birmingham. We will adhere to CRT consort extension [57] and procedure set out by 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. We will also conduct structured observations assessing the fidelity of intervention delivery, 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: We will target 2 constituencies in the West region of Birmingham; region with the highest proportion of Black African and Black Caribbean individuals in Birmingham (19% compared with 9% and 3.5% in Birmingham and UK, respectively), with over half of the West 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[51].
Unit of randomisation: Community settings includes places of worship (e.g., Black majority churches), youth centres, community centres, youth residential settings) 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 prior to 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 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 TIDER [58].

Control: Written MHL material (information leaflets and posters) placed within the community setting. Prior to these materials being 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.

Outcome: Feasibility outcomes include 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. Our secondary outcome is the assessment of key training outcomes: *1. Knowledge* - The Mental Health Knowledge Scale (MAKS) [59, 60]; *2. Illness attributions and stigma* - 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 [61]; Community Attitudes towards Mental Illness (CAMI) scale [62]; and *3. Help-seeking attitudes and efficacy* - General Help-Seeking Questionnaire [63, 64].

Sample size: We 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 [65]. 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 [66]. 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 [67, 68]. For the secondary outcomes, means, confidence intervals, 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 definitive trial.

WP2: A Pilot Stepped Wedge Cluster Randomised Trial of e-learning for Mental Health Professionals

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

Design: We will adopt a pragmatic stepped wedge cluster randomised trial (SWCRT)[69] design with random and sequential crossover of clusters (youth mental health teams) from control to intervention (our 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 a 6-month period (months 4-9; Appendix A, GANTT Chart). 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. Through the course of implementation, we will conduct staff focus groups and semi-structured interviews.

Setting: FTB, part of the Birmingham Women's and Children's Mental Health Trust, is a 0–25 years 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 offers intensive community support to young people with a first episode of psychosis. The second trust is

Black Country Healthcare in which we will target the Dudley and Walsall EIS team, 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 interview ensuring a balance of staff backgrounds, experience, and representation from across different teams and trusts. We will also adhere to INCLUDE guidelines to ensure diversity and inclusion in our sampling[70].

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 seek 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).

Outcome: Feasibility process outcomes will include percentage of training uptake across staff and service teams in addition to the acceptability evaluation (detailed in WP1). Secondary outcome is the assessment of the training outcome the California Brief Multicultural Competence Scale [71, 72], which assesses mental health staff knowledge, attitudes, skills, and competencies when working with minoritised groups.

Sample Size: Formal power calculations are not necessary as no hypothesis testing for trial effectiveness is being evaluated [65]. 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 [66].

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

We are aiming 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[73] will be developed in three phases: 1) Firstly, we will undertake a concept mapping workshop involving key stakeholders (patients, research team, providers and policymakers). 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 modified 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, we are proposing to pilot a data-driven impact evaluation. We are planning to undertake an interrupted time series (ITS) 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[74].

This pilot evaluation will be undertaken in three phases: 1) 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 we aim to compile a directory of suitable datasets and outcomes which could inform the systems wide impact of the intervention (e.g. the use of West Midlands Police Data to assess the rate of s136 interventions in Black males). 2) Trial of ITS model: Using available datasets (those open access or those already accessible by the research team), we will undertake a pilot ITS. 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 on a monthly basis (weekly where possible) throughout the study period and these trends will be depicted graphically. The primary break point 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. We will examine the sensitivity of the analysis around this break point. 3) Stakeholder engagement: We plan to undertake three focus groups (consisting of 6-8 people) with key stakeholders (patients, providers and commissioners) to demonstrate our 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 of 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; 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 [75, 76].

Social return on investment: As not all costs are quantifiable and so we will also explore a SROI [77]. Our PPI panel (and work undertaken during the QR funded period) will help us 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 deliver has been informed by PPIE, including young people with lived experience and our charitable partners who have provided advice on study management, training and support for PPIE, as well as inputting into the lay summary. We have ensured good practice in line with UK Standards for Involvement [70, 78]. We will appoint a diverse PPI advisory group who will advise of ethical and delivery aspects of the project. We will identify individuals from our 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 our partnership with Catalyst4Change CIC –

a grassroots charity supporting the mental health needs of Black African and Black Caribbean communities across Birmingham.