EQUITy in Black Adult health (EQUITA) - a randomised feasibility trial of a co-produced and faith-placed intervention to increase uptake of breast, cervical, bowel, and AAA screening in the North East of England, Leeds and Scotland

Version Control Table

Amendment Number	Date	Changes Made	Rationale
1	30.09.2025	Updated Table 2. Progression Criteria	Requested
2	30.09.2025	Trial registration detail included	Required
3	10.11.2025	Updated inclusion criteria for male participants: changed age range from 50–74 years to "men aged 50 and over" to align with national Abdominal Aortic Aneurysm (AAA) screening eligibility.	Requested by study team to align with NHS AAA screening age criteria.

Abstract

Background
Breast, bowel, cervical, and Abdominal aortic aneurysm (AAA) screening saves lives. However, stark inequities in uptake of screening exist for people from ethnic minority groups. This trend is particularly alarming within the Black community, where lower screening rates put them at higher risk of death for lack of early diagnosis and provision of effective early treatment. These inequities need tackling urgently. Culturally tailored, community-centred and participatory approaches show promise in tackling health inequities. This 24-month study aims to examine feasibility and acceptability of a co-produced, faith-placed intervention to increase uptake of breast, bowel, cervical, and AAA screening among Black communities.

Intervention
In previous research, we worked with Muslim women to co-produce a faith-based intervention to improve uptake of breast, bowel and cervical cancer screening. This approach was subsequently tailored for early detection of prostate cancer among Black men, resulting in a peer-led, two-hour workshop. The workshop included 1) discussions on barriers to early diagnosis, 2) health education by a Black GP, 3) video testimonials from community members, 4) discussions on accessing care and asking the GP questions, 5) videos featuring Black women health for the family, 6) perspectives from religious leaders, 7) a social component with food and music. We will adapt this intervention in partnership with the Black community to encourage uptake of breast, cervical, bowel, AAA screening.

Methods
Underpinned by the Integrated Screening Action Model, we will conduct a mixed-methods, multicentre two-arm randomised feasibility trial with 300 Black people (female aged 25-74, male aged 50 and over in churches in Glasgow, North East of England, and Leeds, who are not or partially up to date with screening they are eligible for, allocated to one of two arms, per site: 1) intervention, 2) control. A process evaluation through focus groups with participants (6x n=8), PICE/Peer-facilitators (n=12), and stakeholder interviews (n=10), will allow us to identify opportunities for modification in

the feasibility trial and intervention.

Expected results

An assessment of suitability of the trial's parameters will inform development of a large-scale trial using pre-specified progression criteria and a traffic light system for evaluation of STOP-AMEND-GO criteria. To gain a preliminary indication of intervention effectiveness we will capture knowledge, attitudinal change to screening (e.g., intentions to screen at baseline and 3-month follow-up), and behavioural outcomes (e.g., NHS screening attendance at 6 months).

Anticipated impact and dissemination

Our vision is to tackle current inequities by testing the feasibility and acceptability of a co-produced, peer-led intervention to improve engagement with breast, bowel, cervical and AAA screening among Black people in the UK. We will conduct a rigorous feasibility and process evaluation of the first theory-driven and co-produced intervention for Black people using culturally appropriate messages that support screening for early diagnosis in this underserved group. To maximise study impact, engagement and collaborative working with members of the community and key stakeholders provides an essential route to dissemination. A Knowledge Mobilisation plan will be developed. If warranted, we will seek further funding to test intervention effectiveness in a powered randomised controlled trial.

Registration Details

ClinicalTrials.gov ID: NCT06981182

1 Introduction

Population screening in the UK aims to reduce morbidity and mortality from cancer and Abdominal Aortic Aneurysm (AAA) (1). The UK offers four population screening programmes for asymptomatic adults (breast cancer, cervical cancer, bowel cancer, AAA). Targeted screening for specific groups is also offered (diabetic eye screening, pregnancy and newborn, lung health checks). The success of screening programmes largely depends on uptake of screening among the invited populations. However, stark inequalities in the uptake of screening exist for people from ethnic minority groups and across the life course (2–11).

There are more than 2.4 million Black, Black British, Black Caribbean or African people in the UK (12,13). For simplicity, we will refer to this group as 'Black', although it is important to acknowledge the heterogeneity within this population. Black people are the most likely out of all ethnic groups to live in the most deprived neighbourhoods, with 20.2% of Black African, 18.2% of Black Caribbean, and 21.6% of people identified as 'Black Other' living in the most income-deprived decile of neighbourhoods compared to 8.7% White British and 17.4% Asian people, according to the 2019 English indices of deprivation (14). The uptake of screening is significantly lower in more deprived areas (15,16). This trend is particularly alarming within the Black community, where lower screening rates put them at higher risk of death for lack of early diagnosis and provision of effective early treatment.

Advanced-stage cancers may reflect multiple factors, including tumour biology, the existence of co-morbidities, as well as uptake of screening and timeliness of medical help-seeking (17). In a large population-based study linking primary care data to hospital and cancer registry data for 243,825

patients, ethnic differences were found in the diagnosis of cancer through screening, particularly for breast and bowel cancer. Fewer Black patients (5.1%) were diagnosed via screening compared to White (8.3%), Asian (10.9%), or Mixed (9.5%) cancer patients (17). Screening programmes save lives, improve health, and offer informed choice (1).

1.1 Breast screening

Breast cancer is the most common cancer in the UK, accounting for 15% of all cases (18). In the UK, breast cancer age-standardised mortality rates decreased by 37% between 1971- 1973 and 2017-2019, from 52 to 33 per 100,000 (18). This significant reduction in mortality rates has largely been attributed to the NHS Breast Screening Programme, cancer prevention efforts, as well as the efforts by UK charities in raising awareness and promoting the uptake of breast screening (19). However, despite breast cancer incidence rates being lower for Black women than for White women in the UK, Black women face a younger age at diagnosis, later stage at diagnosis, and have worse outcomes than White women (10). This suggests Black women have not equally benefitted from advancements in the UK in early detection and diagnosis (10). The breast screening programme is one of the most well-taken-up NHS screening programmes; however, screening attendance has fallen to its lowest level in the past decade, with people from Black, Asian and Minority ethnic backgrounds having disproportionately lower participation rates (9,20,21). Limited data are available; however, in a population-based cohort study (n = 655,516), White British women were most likely to attend their first breast screening call (67%) and routine recall (78%) invitation. Black Caribbean women were more likely than Black African women to attend first call (63% vs. 49%) as well as routine recall (74% vs. 64%) appointments (11).

1.2 Bowel screening

Bowel cancer is the fourth most common cancer in the UK, accounting for 11% of all new cancer

cases. In the past decade, bowel cancer incidence rates have declined in the UK by approximately 6% (4% for women; 9% for men) when comparing 2016-2018 to 2006-2008 (22). Age-standardised mortality rates for bowel cancer reduced from 21.6 per 100,000 in 1993-1995 to 13.1 in 2016-2018 (19). While incidence rates are lower for Black people (22), late-stage diagnoses have been found for colon cancer for Black African and Caribbean women and Caribbean men (23). Lower uptake of bowel screening among ethnic minority groups has been reported since the implementation of the UK screening programmes (24,25), specifically for Black people (5,7). In a population-based study in England including 86,850 eligible adults aged 60–74 years, there was evidence that Black people were more likely to not have taken up bowel screening compared with white people (aOR 1.36 [95% CI 1.09, 1.70]) (26). While limited data exist for the UK, in the US ethnic disparities have been found in bowel cancer survival, and Black men and women have the worst outcomes (27– 29).

1.3 Cervical screening

Cervical cancer can be prevented by the detection and removal of precancerous lesions or cured if diagnosed and treated at an early stage of disease, and global elimination has been set as a target by the WHO by 2030 (30). Again, significant advances have been made in the detection and treatment of cervical cancer. The age-standardised incidence rate of cervical cancer for women in the UK between the ages of 35-69 years, reduced from 17.8 per 100,000 in 1993-1995 to 12.9 in 2016-2018. Age-standardised mortality rates also reduced significantly from 7.0 to 3.2 per 100,000 (19). Organised screening programmes, like the UK's, are thought to play a key role in this success (31). There is strong evidence of a relationship between deprivation and incidence of cervical cancer and ethnic minority groups are less likely to attend cervical screening than White British people (4,8,32). In a study with 3113 women, Black women were significantly more likely to be unaware of (OR 8.63 (5.48-13.58)) or unengaged with cervical

screening (OR 4.34 (1.25-15.06)) than White women (32). Suboptimal participation in cervical screening is particularly concerning, as some studies indicate lower rates of Human Papilloma Virus (HPV) vaccination among Black people, and HPV is the principal risk factor for cervical cancer (33).

Cervical cancer incidence rates for Black and ethnic minority groups have been reported to be lower than for their White counterparts in the UK (34), but Black women aged 65 years and over have been reported to be at higher risk than other ethnic groups (35). There is a lack of cervical cancer epidemiological data by ethnicity in the UK; however, in different contexts, and again despite lower incidence rates, later-stage diagnosis and poorer outcomes have been reported for Black compared to White women (36–39). Cervical cancer mortality rates are projected to continue to decline; however, action is needed to ensure that Black women benefit from advances equally (39).

1.4 Abdominal aortic aneurysm (AAA) screening

AAA screening follows a similar pattern to the major national cancer screening programmes. White men are thought to be at the highest risk of AAA, followed by Black/Black British men, whilst Asian/Asian British are at the lowest risk (3). Deprivation is negatively associated with the uptake of AAA screening. A study in England reported an uptake of 62.1% in the most deprived Index of Multiple Deprivation (IMD) decile vs. 84.1% in the least deprived decile (15). Although ethnicity data are often missing from AAA screening uptake data (15), and Black people are the most likely out of all ethnic groups to live in the most deprived neighbourhoods, uptake of AAA screening is likely lower amongst Black men in the UK. In a 2021 study in the US using electronic health records (n=6,682), the odds of receiving AAA screening within 1 year of becoming eligible were 27% lower for Black patients compared to White patients [OR = 0.73, 95% CI (0.58,0.93) (40). Despite prevalence being lower in Black men in the US, similarly to the UK, worse outcomes

have been reported for Black men following AAA repair, including higher rates of complications, renal failure, and reoperation (41,42).

1.5 Opportunities to influence screening uptake

Barriers and facilitators to screening uptake show a complex interplay of individual, social, environmental, and economic factors and can vary depending on specific programmes; however, there are common themes and substantial overlap. For example, racial bias and discrimination have been reported as barriers to accessing healthcare (43), with a 2022 survey of 2051 Black people finding that 65% experienced discrimination from healthcare professionals (44). The NHS Race and Health Observatory (NHSRHO, 2023) emphasised the urgent need to address unjust racial disparities, particularly experienced in health and healthcare by Black communities. NHSRHO highlights institutional racism and cultural insensitivity as factors discouraging attendance by Black people (45,46). A history of unethical medical experiments, mistreatment, and poor experiences has led to a deep-seated mistrust of society, governments, and healthcare institutions among Black communities, demonstrated in the COVID-19 pandemic (47,48). In a survey with 100 Black women with breast cancer, 96% stated that they do not see women of colour represented enough in the media talking about breast cancer, despite their higher mortality (49). The NHS is said to represent Black people insufficiently in health promotion and health education materials discussing cancer, despite known health inequities (10). Cultural factors, including social stigma, language, and health literacy factors (50), and communication with healthcare providers (51), also act as core barriers. Ethnic minority groups are disproportionately affected by deprivation, a key determinant of health (49) and therefore screening is particularly vital to this group. Additionally, living with long-term illnesses and disabilities can heighten common barriers to screening (e.g., prior negative experiences of health care) and add additional barriers (e.g., competing demands of illness self-management).

Multimorbidity is more prevalent, and at a younger age, among people living in the most disadvantaged communities and from minority ethnic groups, including Black people (52). The inequities in health experienced by the Black community are shocking, unjust, preventable, and contravene the Equality Act 2010. Yet, no specific interventions or policies to tackle these inequities for Black people have been reported in the UK.

1.6 Review of existing evidence

We conducted a systematic search across major databases, including PubMed, Medline, PsycINFO, Scopus, and Web of Science. Searches on different types of screening were assigned to different members of the research team, and results were subsequently collated. The searches were tailored to address the focus on health screening among Black populations, using both specific and broad search terms. These included "Black community health", "screening inequalities", "racial health disparities", "Black patient outcomes", "ethnic screening uptake", "racial bias in healthcare" and “community participation”. Specific screening types were also included in these search terms. Our inclusion criteria required that peer-reviewed articles were published within the last ten years, excluding non-English language publications. Upon an initial screening of titles and abstracts, a review of the full texts of selected articles was undertaken to extract relevant data.

Interventions targeted at specific communities work significantly better than interventions to improve population-level screening uptake and cultural tailoring can produce health promotion messages consistent with one’s belief system (53). There is international evidence that community engagement interventions are effective at improving health behaviours (54). Such interventions include involving ethnic minority groups in the design, development, and delivery of interventions. Evidence that this approach is effective and cost-effective in the UK is lacking

(55), despite Medical Research Council (MRC) guidance highlighting that interventions need to be supported by the communities whose health we aim to improve. Co-production with people from Black ethnic groups, currently underrepresented in targeted interventions, is recommended (51,56). Community-centred health initiatives empowering people through participatory approaches are needed to improve screening uptake and tackle health inequities (57). Living in disadvantaged neighbourhoods or experiencing discrimination as a group may lead to collective feelings of powerlessness. Conversely, empowerment processes can mitigate these health risks (58) and promote healthy communities (59). Community knowledge can lead to more effective health solutions. Participating in collective activities can enhance social cohesion, individual self-efficacy (60), and can boost critical health literacy (61).

1.7 Rationale for the Study

The uptake of population health screening in Black communities in the UK is an under-researched area. There are few studies focused on Black people and national screening programmes. We aim to fill this gap and address health inequities for Black communities across the adult life course by using a participatory and community-centred approach to increase the uptake of screening programmes that target healthy populations, i.e., breast, bowel, cervical and AAA screening. Taking a life course and asset-based approach leverages the community's collective nature to collaboratively tackle shared barriers across generations. The life-course perspective recognises that health is shaped by various factors and events across a person's lifespan, highlighting a complex interplay of biological, behavioural, psychological, and social factors (62). It emphasises how social determinants influence health across different life stages (63). Risk factors and adverse exposures can be identified across various domains and frequently cluster in socially determined patterns, collectively exerting a synergistic impact on both immediate and enduring outcomes. As screening programmes can affect people both directly

and indirectly through significant others, our intervention will harness the collective influence of community members participating in the same place, at the same time.

Updated Medical Research Council (MRC) guidance on the development and evaluation of complex interventions emphasises the need for a bold approach, advocating the use of different methods than have previously been used, especially in areas where experience remains limited but where there is a recognised urgent need for progress (64). Therefore, this study will address all screening programmes aimed at generally healthy populations, i.e., AAA, breast, cervical and bowel cancer screening, rather than a single programme.

There are five key drivers for taking this multi-screening approach, which has the potential to be more effective and cost-effective. It is inefficient and less feasible for research to develop and for people to engage with multiple individual interventions, especially given that (2) key barriers, such as lack of trust and experiences of discrimination, overlap between programmes. People facing barriers to one type of screening may also encounter them for other types of screening (65). Moreover, (3) addressing screening programmes collectively allows working with the whole community, helping to build trust and shared understanding of screening, which can help foster peer and intergenerational social support for screening uptake (66). (4) A life course approach facilitates a focus on addressing pre-existing health conditions as risk factors for developing other illnesses and barriers to screening participation. For example, Black people experience higher rates of diabetes, which increases bowel and breast cancer risk, but public knowledge of this increased risk is low, and cancer screening uptake is lower among people with diabetes (67). (5) Most importantly, Black people who have worked with the research team to develop this proposal have told us they would prefer and value an intervention informing the whole community about screening programmes together.

In determining the focus of the project, screening programmes have been selected that are

universally relevant to the healthy general population and have demonstrable potential for early intervention to significantly improve health outcomes. Specifically, the project will prioritise AAA, breast, bowel, and cervical screening as standard preventive measures critical for early detection of conditions that can be asymptomatic for prolonged periods. The selection rationale is not only rooted in evidence indicating pronounced barriers to the uptake of these screenings among Black communities but also in the potential impact on health disparities. For instance, Black men are less likely to attend AAA screenings, and Black people, in general, participate less in cancer screening—our focused approach directly addresses these discrepancies.

While other NHS screening programmes, such as diabetic eye screening and pregnancy-associated screening, are important, evidence suggests that Black populations participate in diabetic eye screening at similar rates to other groups (66). Additionally, low uptake of antenatal screening does not appear to be the primary factor contributing to disparities in maternal health outcomes (45). Therefore, these screening programmes are not the focus of the present study. However, experiences, barriers, and facilitators related to these types of care will be explored qualitatively as part of the process evaluation. This will provide further insights into healthcare access within Black communities and may inform the development of future interventions targeting these specific areas. By focusing on screening programmes with the greatest potential for reducing health inequities, this study aims to generate robust, targeted, and impactful findings, contributing to the optimisation of preventative health strategies within Black communities.

1.8 The underpinning work

The current research builds on the research team's extensive experience in developing and evaluating community-centred and participatory approaches to improve screening uptake among underrepresented groups. Faith-based health promotion consistent with principles underpinning one's

faith, alongside psychological, social, and environmental factors that improve screening uptake, offers a culturally acceptable and effective method of addressing screening barriers (68-72). The EQUITA intervention is directly informed by two studies—IMCAN (Improving Muslim Women's CANcer Screening Uptake) (73-75) and PROCAN-B (Early diagnosis of PROstate CANcer for Black men (76-79), which provide the foundation for adapting this approach to multiple screening programmes targeting Black communities in the UK.

The IMCAN study, funded by Cancer Research UK, is a non-randomised, two-arm feasibility trial design, and investigates the feasibility, acceptability, and preliminary effectiveness of a co-produced, peer-led faith-based intervention to increase breast, bowel, and cervical cancer screening among Muslim women. The intervention was initially developed in 2021 in a pilot study through a participatory co-design process involving community members and an Alimah, a female religious scholar (73-74). The intervention is a structured, peer-led two-hour workshop, which incorporates facilitated peer-led discussions on screening barriers, health education delivered by a general practitioner, video testimonials from Muslim women sharing cancer screening experiences and survivors, and a faith-based perspectives on cancer screening delivered by the Alimah (73-75). In 2024, the intervention was delivered 16 times with 177 Muslim women who were not up to date with their screening in the North East of England and Glasgow, with ongoing quantitative evaluation assessing its impact on knowledge, attitudes, and screening behaviour. The study also includes a qualitative process evaluation with focus groups and interviews (n=36) for incorporation of wide ranging perspectives into the intervention and trial (80). Preliminary findings indicate that the co-produced, peer-led faith-based intervention is acceptable to participants and effective in increasing screening engagement within this population.

The PROCAN-B study, funded by Prostate Cancer Research, translated this community-centred, participatory approach by partnering with Christian Black men to adapt the IMCAN intervention in order to increase awareness of prostate cancer risk, and encourage early diagnosis among Black men

(76-79). Through a co-design process, another peer-led, two-hour workshop was developed in partnership with Black community members. The workshop also included peer-led discussions on barriers to accessing healthcare for early diagnosis of prostate cancer, health education delivered by a Black general practitioner, video testimonials from Black prostate cancer survivors, activities to facilitate navigating healthcare interactions, and religious leaders' perspectives on proactive health behaviours (75). A unique feature of the intervention, shaped by community input, was the inclusion of a segment in which Black women emphasised the importance of men engaging in health-seeking behaviours for the benefit of their families. The intervention was delivered in 2023-2024 in Glasgow and the North East of England (n=62), with follow-up qualitative evaluation through focus groups in 2024 (n=40). Findings suggest that participants responded positively, reporting increased awareness of prostate cancer risks, significantly increased intention to engage with prostate cancer health checks, and greater confidence in engaging with healthcare services.

The IMCAN and the PROCAN-B studies are truly participatory in their approach. Community members are employed by the projects as part-time Community Recruitment Leads, one in each region. Their role is to facilitate community engagement and recruitment. As valued members of the research team, the Recruitment Leads are present at every team meeting. This always ensures community presence. The studies also have committed Public Involvement and Community Engagement (PICE) groups, with whom the co-production was conducted. In addition, both studies trained members of the community to become peer-facilitators, to support intervention deliver.

The EQUITA study builds on these studies by using the same community-centred and participatory approach to apply a whole-community, multi-screening strategy to encourage uptake of breast, bowel, cervical, and abdominal aortic aneurysm screening among Black communities. The intervention will retain the core elements of the participatory approach, including the Community Recruitment Leads on the research team, PICE group for co-production, trained peer-facilitators, and faith-based engagement while expanding its scope to multiple screening programmes and a broader population.

The structured workshop format, which has demonstrated feasibility and acceptability in previous studies, will be tailored in collaboration with Black communities to ensure cultural relevance.

1.9 Aims and research questions

EQUITA's primary aim is to examine feasibility and acceptability of a co-produced and faith-placed intervention to increase uptake of breast, cervical, bowel, and AAA screening among Black communities in the North East of England, Leeds and Scotland.

Research questions:

1. Can the existing intervention be adapted in partnership with a Public Involvement and Community Engagement (PICE) group to improve engagement with breast, cervical, bowel, and AAA screening programmes in the Black community?
2. Can a two-arm cluster-randomised feasibility trial of the peer-led intervention be delivered in three sites: Leeds, North East and Glasgow?
3. What are the perspectives of participants, peer facilitators, and key stakeholders on intervention and trial methodology, acceptability, and intervention implementation?
4. What is the feasibility trial's performance on key parameters and predefined progression criteria?
5. Is it feasible to conduct an economic evaluation to assess the cost-effectiveness of the intervention?
6. What are effective data dissemination strategies, and can the next phase be prepared by designing a study protocol for a definitive trial and logic model for implementation?

2 Methods and Analysis

2.1 Theoretical framework

This research is underpinned by the Integrated Screening Action Model (I-SAM) (81). The I-SAM

integrates: 1) the stages of behaviour change of the Precaution Adoption Process Model (82), 2) targets for behaviour change of the Capability, Opportunity, Motivation, and Behaviour (COM-B) model (83), and 3) the interrelationship between individual, social, and environmental factors reflected in the socio-ecological model (81).

The I-SAM model recognises seven stages that govern people's screening behaviour; these are: 1) unaware of screening, 2) unengaged with screening, 3) undecided about participation, 4) decided to act and take up screening, 5) acting and taking up screening, 6) repeat participation in screening, and 7) decided not to act and not take up screening. This staging allows tailoring of interventions based on people's specific stage of screening behaviour. An interaction between participant and environmental factors can influence the screening behaviour process; people's ability and willingness to engage in the screening process and how and where the screening is offered would collectively lead people to be at different stages of the screening process. The I-SAM also recognises sources of behaviour that interventions can target; these are derived from the COM-B model, which suggests that behaviours can be understood in terms of capability, opportunity and motivation. One or more constructs of the COM-B model need to be improved to support screening behaviours. For this project, we recognise that people will be at different stages of the screening behaviour process. For instance, some people might be unaware of AAA, breast, cervical, and/or bowel screening being offered by the NHS or might be aware but are currently not acting/engaging with screening due to personal or environmental barriers. Therefore, the intervention will first start by talking about cancer and AAA screening and explaining its benefits, while the influences that might cause Black people not to engage or decide not to obtain screening will also be tackled. Further, we will also assess each participant's stage of the screening process according to the I-SAM at the beginning of the study using questionnaires and their progress in the screening process at 3 months follow-up.

2.2 Setting

The EQUITA study will be conducted in three socioeconomically deprived areas that are under-represented in UK research: Leeds, the North East of England, and Glasgow. In the North East, recruitment will take place across Newcastle, Durham, Sunderland, North and South Tyneside, and the Middlesbrough area. Ensuring the inclusion of Black populations in areas with lower ethnic diversity is critical to capturing a broad range of experiences and ensuring representation in research. Additionally, the inclusion of both England and Scotland allows for the consideration of two distinct healthcare systems, which is important for informing future scalability and implementation. Previous studies have been conducted in the North East of England and Scotland, providing a foundation for recruitment and intervention delivery. As part of the feasibility assessment, the study will introduce Leeds as a third site, allowing for the evaluation of intervention feasibility in a new location. Findings from this multi-site approach will inform the design and feasibility of a future full-scale trial.

Christian church settings will be used, as Black majority churches have been growing in the UK (84). In Black communities, churches serve as a community hub and often hold a position of trust and credibility. This trust can be leveraged to disseminate health information and promote health behaviours (85). The substantial presence of Black Christians within the target regions supports the research approach and recruitment strategy. In the North East of England, approximately 41,000 individuals identify as Black, including those of mixed White and Black African/Caribbean backgrounds, according to 2021 census data (86). Leeds has a similar demographic profile, with around 60,000 individuals identifying in these categories (86). Additionally, Glasgow reports approximately 9,000 Christians born in Africa, the Caribbean, or the Americas, as per the 2011 census data (87). The decision to specifically engage with Christian groups is informed by the proportionally higher number of individuals who identify as such

within these communities compared to their White counterparts. Data from the 2011 census indicates that out of 1.9 million people identifying as Black/African/Caribbean/Black British across England and Wales, 1.3 million reported being Christian (compared to around 30 million Christians among 48 million people identifying as White) (88). This observation suggests that churches are not only prevalent and influential in these communities but also serve as crucial access points for engagement and communication. The substantial presence of Black Christians in the targeted regions means that churches in these areas offer viable and practical venues for participant recruitment.

2.3 Research design

This study is a mixed-methods, clustered two-arm randomised feasibility trial using the Integrated Screening Action Model (I-SAM) (81). The study's primary aim is to examine the feasibility of the intervention delivered in person across three sites. Feasibility studies are an important step in developing complex interventions (89). A qualitative process evaluation will be included, using focus groups and interviews. A mixed-methods approach will help identify and anticipate problems that might undermine intervention delivery, implementation, or evaluation in a subsequent definitive trial (90). The study will follow the reporting standards of the SPIRIT (Standardised Protocol Items: Recommendations for Intervention Trials) statement (91) and the CONSORT (Consolidated Standards of Reporting Trials statement) CONSORT extension for feasibility studies (92).

The research includes six work packages, as presented in Figure 1.

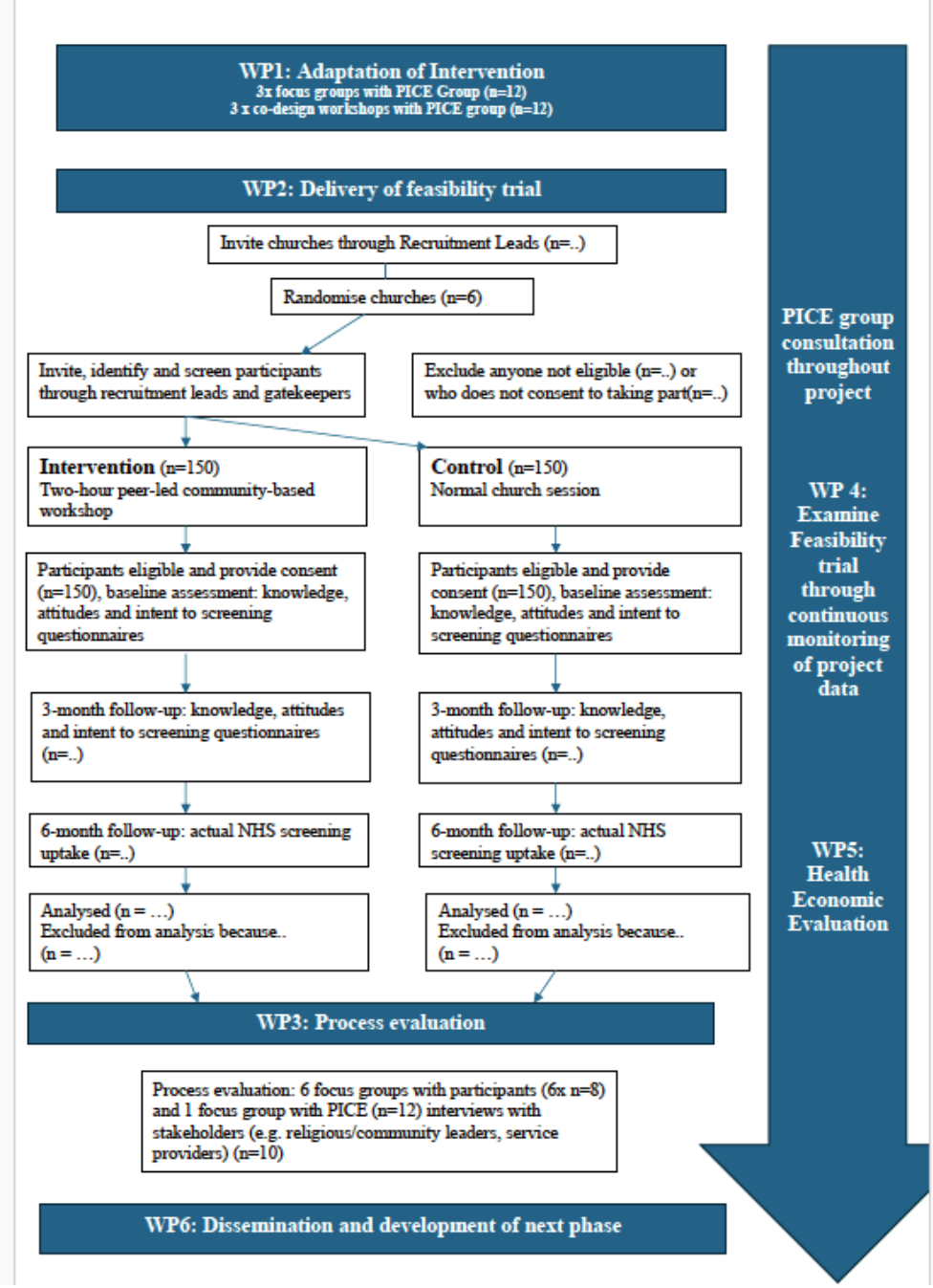

Figure 1 Flow diagram EQUITA Work packages 1

2.4 Work Package 1 (WP1)-Adaptation of intervention

Objective 1: To adapt the existing intervention in partnership with a Public Involvement and Community Engagement (PICE) group to improve engagement with breast, cervical, bowel, and AAA screening programmes.

Through the Recruitment Leads we will recruit a Public Involvement and Community Engagement (PICE) group of at least twelve men and women from Black communities, aiming for

at least four individuals from each region. To obtain wide-ranging perspectives, we will use purposive sampling to target participants (aged 25+) and aim for balance and diversity regarding characteristics such as a) age, b) gender, c) ethnic background within the Black community, and d) location.

Barriers and facilitators to breast, cervical, bowel, and AAA screening for Black people will be explored in three online focus groups with PICE members. The online format is suitable, as members will be located in the North East of England, Leeds and Glasgow. Online focus groups and meetings were successfully utilised in the pilot study, IMCAN, and PROCAN-B, demonstrating their feasibility for participant engagement and data collection. Recruitment Leads provided technical support where required, ensuring accessibility for all participants. Topic guides from previous research will be adapted to structure discussions and ensure consistency across sessions. To maximise the collective engagement of the community, focus groups will be conducted as a single group rather than being divided by gender. However, input from the PICE group will be sought to determine whether any modifications to this approach are necessary to ensure cultural appropriateness and participant comfort.

Findings from the initial focus groups will provide a foundation for the iterative process of intervention adaptation in three co-design workshops. This co-design phase uses a participatory approach with three online workshops with the PICE group based on the World Café method to adapt the intervention. The World Café method is a research method that focuses on fostering collaborative dialogue and conversation between participants in a group setting and is based on providing a comfortable informal setting which facilitates the inclusion and exchange of diverse views on a topic (93). This method enables researchers to engage more deeply with the communities they study, generating richer insights. It is particularly useful for exploring complex topics and developing creative solutions to challenging problems. The World Café method has been used successfully with marginalised groups and provides a structured yet flexible way to

engage participants in meaningful dialogue and generate valuable insights and ideas (94). This method has been employed in the pilot study, as well as in the IMCAN and PROCAN-B studies. Participants will be organised into small online groups to encourage open and interactive discussions. Each session will begin with the presentation of a topic or question, followed by a brief period for individual reflection. Participants will then engage in an initial round of discussions, sharing their ideas and perspectives. The existing intervention and its components will serve as the starting point for these conversations. Groups will then be reshuffled, allowing participants to continue the discussion with different individuals. This process will be repeated several times, enabling conversations to develop further and allowing for deeper exploration of key themes. At the end of the session, all participants will reconvene as a whole group to share the insights and ideas that emerged from their discussions. In doing so, we will use peer learning insights, focusing on social network influences and empowerment (95).

The focus groups and workshops will be digitally audio-recorded, and transcription will be outsourced. Thematic analysis will be used to analyse and map data from the focus groups and co-design workshops to the I-SAM. Data analysis will be continuous and will feed into the next focus group or workshop. A draft intervention strategy will be developed from the Behaviour Change Wheel's hubs of sources of behaviour (capability, opportunity and motivation), intervention functions, and policy categories. Intervention content and mode of delivery will be based on the Behaviour Change Techniques (BCTs) (83). The BCT-Ontology will be drawn upon so that relevant domains are linked to BCTs, and the draft intervention strategy will include a focus on the intervention's mode of delivery (96).

The intervention will be a peer-led, multidimensional community workshop. It will incorporate multiple components that tackle barriers to screening and that are present in the existing IMCAN and PROCAN-B interventions, if the PICE group believe these are helpful, such as health

education about breast, cervical, bowel and AAA screening delivered by a healthcare provider with an opportunity to ask questions, personal testimonials through survivors' stories, as well as members of the community discussing experiences of screening, and utilising community and peer support and religious leaders. These components will be delivered in culturally appropriate ways. However, this initial prototype of the intervention will be informed by further discussions with the PICE group. APEASE criteria (Affordability, Practicability, Effectiveness and cost-effectiveness, Acceptability, Side-effects/safety, Equity) will be applied when deciding on the intervention strategy (83). As part of WP1, we will also train our peer facilitators as trusted sources for delivering the intervention. They will play a crucial role in sustainable implementation and in enhancing community capacity for research (58).

2.5 Work Package 2-Delivery of the feasibility trial

Objective 2: To deliver a two-arm cluster-randomised feasibility trial of the peer-led intervention in three sites: Leeds, North East England, and Glasgow.

Control/comparator group

The EQUITA study will invite six churches, two in each location, to participate. The Recruitment Leads, all community members themselves with strong networks in the community, will facilitate the identification and recruitment of these churches. Cluster randomisation, with the church as unit of randomisation, will be undertaken. Thus, three churches will be randomised to the intervention group, and three to the control group. To minimise the risk of contamination, we will invite churches that are not in close proximity. We will aim to match-pair churches, for example by Index of Multiple Deprivation (IMD) profile, to ensure that conditions are similar. The goal is to deliver the intervention twice in each location. The control group will have regular church sessions; however, they will receive the intervention after data collection is complete.

2.6 Study population

Participants are eligible if they are:

- Members of participating churches,
- Self-identify as Black,
- Female aged 25-74,
- Male aged 50 and over,
- Not up to date with all screening tests for which they are eligible, e.g., women who are up to date with one form of screening (e.g., breast) will be eligible for recruitment if they are not up to date with others (e.g., cervical or bowel).

Since this study assesses outcomes across four specific screening programmes—breast, cervical, bowel, and AAA screening—the targeted age groups and genders align with the eligibility criteria for these programmes. Currently, eligibility for bowel screening differs between England (60+) and Scotland (50+); however, as England is in the process of aligning its age criteria with Scotland's, participants aged 50 and above will be included. The male age criterion has been amended to "50 and over" to reflect the NHS AAA screening programme's eligibility threshold. To ensure recruitment focuses on individuals who would benefit most from the intervention and who may not already have positive attitudes toward screening, the strategy will prioritise those who are not up to date with the screening for which they are eligible, following the approach used in the IMCAN study.

2.7 Sample and recruitment

To obtain wide-ranging perspectives and ensure a diverse sample, purposive sampling will be used to target participants of various age groups as well as different backgrounds. Snowball sampling, through participants and the recruitment leads' networks, will also be applied to ensure sample sizes are achieved. This approach has been successfully implemented in both the PROCAN-B and IMCAN studies.

A formal sample size calculation is not required for a feasibility study (97), where recommended sample sizes typically range between 24 and 50 participants (98). For this study, we aim to recruit 150 participants per arm, with 100 per site (total n = 300) (Table 1). This sample size will enable the generation of robust estimates for recruitment and retention rates, as well as the distribution of potential outcomes, which will inform future sample size calculations (99). This approach is consistent with feasibility studies registered with the United Kingdom Clinical Research Network.

Table 1. Sample sizes for the feasibility trial

North East of England		Leeds		Glasgow	
Intervention (n=50)	Control (n=50)	Intervention (n=50)	Control (n=50)	Intervention (n=50)	Control (n=50)

2.8 Intervention delivery

As cluster sampling is used, the church is the unit of randomisation. We will therefore deliver the intervention to the entire congregation but only seek to include effectiveness data (i.e., surveys and screening uptake) from those who meet the study's eligibility criteria. This method of delivery supports the notion of the collective characteristic of the community, in which building trust and united support for screening is essential. This approach will initially be explored with the PICE group. As part of the process evaluation, we will qualitatively explore if this method of intervention delivery and using the collective characteristic of the community, is feasible, and acceptable.

To provide context regarding the proportion of study participants relative to the overall congregation, the attendance of all individuals present at each session will be recorded, noting those who are not eligible for inclusion in the effectiveness data. This will enable the assessment of the broader reach of the intervention within the community to non-eligible attendees such as younger individuals, who may contribute to intervention impact via family and social encouragement for screening adherence and who may derive benefits themselves in the future

as they reach screening-eligible ages.

2.9 Work Package 3-Qualitative Process Evaluation

Objective 3: To explore perspectives of participants, peer facilitators, and key stakeholders on intervention and trial methodology, acceptability, and intervention implementation.

According to MRC guidance, process evaluation is essential in designing and testing complex interventions (64). Qualitative process evaluation in this study will involve focus groups with participants (6x n=8) (face-to-face if possible), PICE/peer facilitators (1x n=12) (online), and stakeholder interviews (face-to-face or online, depending on participant preference) with professionals, such as public health practitioners, representatives from local councils who play key roles in implementing health policies and programmes at the community level, as well as community leaders from local organisations (n=10) (100). Focus groups with intervention participants will examine the acceptability of intervention content and delivery, explore barriers and facilitators to the delivery of the intervention and consider possible adaptations to improve participant experiences and potential behaviour change. We will also explore participants' perspectives on factors influencing their screening behaviour that are not addressed by the intervention (e.g., barriers related to pre-existing illnesses and disabilities). PICE group members, peer facilitators, and other stakeholders, such as healthcare providers or religious/community leaders involved in the delivery of the intervention, will also be asked about their perspectives of how the delivery went and what could be improved. Questions will draw on the Theoretical Framework of Acceptability (TFA) and focus on how the intervention components and delivery processes work in the real world, including recruitment of participants and the actual delivery of the intervention (101). Interviews and focus groups will be audio-recorded and transcribed. Thematic analysis will examine themes and patterns in people's perspectives (102). This work package, led by LN, will provide a detailed qualitative analysis of participants', stakeholders', and

peer facilitators' perspectives regarding what worked and suggestions for modification of the feasibility trial and the intervention.

2.10 Work Package 4- Examine feasibility of a definitive trial

Objective 4: To examine the feasibility of a definitive trial by assessing the feasibility trial's performance on key parameters and predefined progression criteria.

Primary Research Question:

How did the trial perform on key parameters:

- Participant eligibility/recruitment/retention to follow-up
- Peer-facilitator recruitment/retention/training
- Randomisation
- Completion of secondary outcome measures
- Data collection tools/processes
- Potential effect size for full trial
- Intervention content and delivery (fidelity, modality)
- Protocol adherence
- Feasibility and acceptability of the intervention

Secondary Research Questions:

- Did knowledge of and attitudes toward screening programmes change?
- What proportion of people self-report uptake of screening they are eligible for within 3 months of baseline?
- What proportion of participants undertake NHS screening within 6 months of baseline?

2.11 Methods for data collection

Primary outcome:

Process data, including time, costs, recruitment, training, delivery, and any challenges encountered, will be logged for implementation insights. STOP-AMEND-GO progression criteria and a traffic light system, following CONSORT recommendations (103), will indicate whether or how to proceed to a definitive trial. Preliminary progression criteria are presented in Table 2. Findings will be reviewed within context, including qualitative process evaluation data, to make continuation decisions. If all categories are green, this does not necessarily mean guaranteed continuation and trial progression. Likewise, if most categories are green but some categories fall into the amber or red zone, this would not necessarily indicate that a definitive trial is not feasible. The reasons for the amber/red indicators need to be carefully understood and analysed and strategies to overcome any challenges need to be carefully reviewed and implemented (104). The Steering Committee, with an independent view, will be consulted regarding conclusions about progression.

Table 2. Preliminary progression criteria

Progression Criterion	Indicator Green	Indicator Amber	Indicator Red	Method of assessment	Rationale (including for target where appropriate)
1. Was recruitment of churches feasible?	Recruitment of a sufficient number and size of churches within 3 months to support the recruitment of approximately 100 participants per site	Church recruitment is delayed, or the number/size of churches raises concerns about ability to meet participant targets, but is still likely to support recruitment	Recruitment target not achieved Church recruitment takes longer than 6 months or the number/size of churches is clearly insufficient to support participant recruitment targets.	Descriptive project monitoring data Qualitative data-process evaluation	Assessing recruitment of churches is essential for progression to a definitive trial. Adhering to the project's timeline as much as possible, we will aim to continue recruitment past 3 months until a sufficient number of churches has been recruited to support participant recruitment, and viability and fidelity of the trial. Similar research has had a church recruitment period range between 1 months to 9 months, with an average of 3.5-3 months (1), therefore our target of 3 months to reach the desired number of churches seems justified.
2. Were churches willing to be randomised?	All churches willing to be randomised.	Randomisation was achieved but was a barrier to some churches	Randomisation was a key barrier which prevented participation.	Descriptive project monitoring data, qualitative assessment	Willingness of churches to accept randomisation is essential for the validity and scalability of a potential definitive trial. If randomisation is not acceptable, recruitment will be biased and progression to a definitive trial may not be feasible. Qualitative process evaluation data should support understanding in challenges or non-acceptance of randomisation.
3. Was participant recruitment feasible?	In each location and for each arm, at least 60% of participant recruitment is achieved within 5 months from the time of confirmed church recruitment.	In each location and for each arm, 40–59% of participant recruitment is achieved within 7 months.	Recruitment target less than 40%	Quantitative descriptive baseline data Qualitative data: process evaluation	Assessing participant recruitment is essential for progression to a definitive trial. Based on our previous work, we consider a target of 60% of participant recruitment within 5 months, from the time of confirmed church recruitment. This target, within this timespan, seems feasible based on our experience (2,3), and on the literature (4–7). Not surpassing 7 months, adhering to the project's timeline as much as possible, we will aim to continue recruitment past 5

					months until a sufficient sample size and minimum of 100 participants per site is reached to ensure viability and fidelity of the trial. Rather than setting a sample size as progression criterion, the literature suggests to track the recruitment rate per site per month as the preferred method of evaluating feasibility (8). Therefore, careful tracking of recruitment, time period and rate of recruitment per site, is part of the feasibility trial. Local context is important (8), which will be explored in the process evaluation.
4. Was participant recruitment sufficient across all age groups to allow feasibility assessment for each of the four screening programmes?	Participant recruitment of all age groups aligned with each programme, was achieved.	Participant recruitment for one screening programme was lower than expected in a specific age group, but still sufficient to permit feasibility assessment.	Participant recruitment for at least one screening programme was insufficient (e.g., Black men 65+ was not achieved)	Quantitative descriptive baseline data Qualitative data: process evaluation	Recruitment across all age groups is needed to assess feasibility in each of the four screening programmes. If one programme has lower recruitment, feasibility can still be assessed but with caution. If recruitment is insufficient for a programme, feasibility may be challenging for that group, or for that programme.
5. What proportion of participants could be followed up at 3 months?	In each church and for each arm, at least 60% of participants could be followed up at 3 months	In each location and for each arm, between 40% and 59% of participant follow-up is achieved between 3-5 months	Follow up target was <40%	Quantitative descriptive follow-up data Qualitative data: process evaluation	Assessing participant follow-up is essential for progression to a definitive trial. We consider a target of 60% follow-up reasonable considering our experience in previous research and the average rate of follow-up questionnaire completion in randomised trials is 40% (9). Qualitative process evaluation data will aim to understand what worked well regarding follow-up procedures, and what did not.
6. Were consent procedures acceptable to participants?	Consent procedures were acceptable to all participants	Consent procedures were acceptable to most participants, although some issues were raised	Procedures were not acceptable to participants	Qualitative data: process evaluation	Assessing acceptability of consent procedures is essential for progression to a definitive trial. If participants find consent procedures burdensome, confusing or difficult, this could impact on participation. Understanding participants' views and experiences, will help shape appropriate consent procedures for a potential definitive trial.

7. Were data collection tools suitable?	Participant response rate >70% at baseline, participants express acceptability	Participant response rate >60%, participants mostly express tools to be acceptable	Response rate<50% and participants shared concern about data collection tools	Quantitative descriptive data and qualitative data	Understanding acceptability of data collection measures through measuring response rate and exploring this qualitatively, is essential before progressing to a definitive trial. Based on our team's experience in previous work and existing literature (9), we consider a response rate of 70% at baseline, sufficient to undertake analysis for feasibility and acceptability.
8. Was obtaining actual NHS screening data acceptable to participants?	>50% of participants provide consent to obtaining NHS screening data	>40% of participants provide consent to obtaining NHS screening data	<40% of participants provide consent to obtaining NHS screening data	Quantitative descriptive follow-up data Qualitative data: process evaluation	We will aim to collect NHS screening attendance as efficacy outcome as this will be required to measure impact in a definitive trial. However, based on our team's experience in previous work, some participants may be reluctant to give consent. We have therefore set a pragmatic threshold of >50%, which would indicate sufficient acceptability to proceed, while allowing us to to explore reasons for non-consent qualitatively.
9. Was obtaining actual NHS screening data feasible?	Actual screening data obtained from all 4 screening programmes, in both countries	Issues with obtaining actual screening data arise in at least 1 screening programme, in one location	Issues with obtaining actual screening data arise in more than 2 screening programmes	Descriptive project monitoring data Qualitative data: process evaluation	We will aim to collect NHS screening attendance as efficacy outcome as this will be required to measure impact in a definitive trial. However, based on our team's experience in previous work, obtaining these data can be problematic. If data cannot be obtained from one or more programmes, it may limit the ability to evaluate the intervention's impact comprehensively. This criterion therefore assesses the practicality of working with screening data services, including approvals and timelines, to determine whether this element would be deliverable in a definitive trial.
10. Was the intervention feasible and acceptable?	Intervention content and delivery were predominantly feasible and acceptable to all participants	Intervention content and delivery mostly feasible and acceptable to participants but some issues were raised.	Major concerns about intervention delivery or content	Qualitative data: process evaluation	Understanding participants' and stakeholders' views on the feasibility and acceptability of the intervention, is essential for a definitive trial and potential implementation and scalability. Qualitative data will provide in-depth understanding regarding what worked well and what did not work well from all perspectives

					involved in the project. These data are key to both improving the trial, and the intervention.
11. How many become peer facilitators, how many were trained within 4-5 months and retained at 3-month follow-up?	>80% of peer facilitators are recruited and trained within 4-5 months and retained at 3- months follow up (68,99).	Between 60% and <80% of the peers are recruited and trained within 4-5 months and retained at 3-month follow-up.	Amber target not achieved	Descriptive project monitoring data Qualitative data: process evaluation	Peer-facilitators are central to the delivery and acceptability of this intervention. We consider a target of 80% within 4-5 months and retained at 3-months, reasonable considering our experience in previous research, and the amount of time and effort involved for peer-facilitators (2,3,10). This target allows for some shortfall, due to availability or drop-out, while still ensuring sufficient coverage to assess whether the peer-facilitator model is working for a definitive trial and future implementation.

Secondary outcome:

Measures of screening-related knowledge, attitudinal change, intention, preparedness, likelihood of screening uptake, self-reported screening uptake, and actual NHS screening attendance will capture secondary outcomes.

In the IMCAN study, we adapted scales from Cancer Research UK's Cervical, Breast, and Bowel Cancer Awareness Measures (CAM) (108). The CAM is a validated questionnaire that has been used by Cancer Research UK since 2008 to assess public awareness of cancer symptoms, risk factors, and barriers to seeking medical assistance. While only the 2008 version underwent formal validation, the survey has been regularly updated. For this study, we will use the most recent 2023 version, which remains freely available for use. The CAM includes knowledge of symptoms and risk factors of breast, cervical, and bowel cancer, awareness of the NHS screening programmes including age of invitation and frequency, a question including 22 barriers to screening ranging from emotional to practical barriers, attitudinal change to screening, self-reported screening uptake, intention, preparedness, and sociodemographic descriptors. The CAM captures participants' socioeconomic status by measuring level of education, living arrangements (owning outright, mortgage, renting from local authority/privately, squatting, other), and their postcode. Socioeconomic status will be included as a variable to examine both primary and secondary outcome measures. This analysis will assess whether socioeconomic status influences study participation, retention, follow-up, as well as knowledge, attitudes, and screening uptake.

The CAM includes separate sections for each cancer type, resulting in a lengthy survey when

incorporating breast, bowel, and cervical cancer awareness measures. To ensure feasibility and reduce participant burden in the IMCAN study, we streamlined the survey by removing some knowledge-based questions that require in-depth understanding. Additionally, recognising that barriers to screening often overlap across different cancer types, we adopted a pragmatic approach by consolidating relevant questions where appropriate. Rather than asking participants about barriers to breast, bowel, and cervical cancer screening separately, certain items were combined. For example, instead of presenting three separate questions, participants are asked to respond on a 4-point Likert scale to the statement, 'I am too busy for cancer screening.' However, where it is essential to assess cancer-specific barriers, questions remain distinct. For instance, cervical cancer screening may be perceived as painful, while bowel cancer screening may be viewed as messy. These differences necessitate separate items to capture the nuances of participant concerns. For AAA screening, questions assessing knowledge and awareness will be adapted from existing literature (109). These survey items, previously trialled in the UK and informed by other studies, include multiple-choice questions with single-choice responses on AAA definition, risk factors, detection methods, and the screening process.

Living with long-term illnesses or disabilities can heighten and add barriers to screening (52). Alongside other participant characteristics (e.g., sex, age, socioeconomic status), self-reported long-term conditions and disabilities will be captured and examined as potential moderators of intervention reach and effectiveness. To avoid widening inequalities, it is important to consider if interventions are equally accessible and effective for people living with long-term conditions and disabilities – if not, this is crucial to reflect on and address in future iterations and ahead of a trial. A pre-existing self-

report measure will be selected based on recent recommendations for measurement selection and in consultation with the PICE group. This process will ensure that the chosen measure provides comprehensive information on the type and number of conditions while adequately capturing both mental and physical health conditions (110).

Participants will complete secondary measures at baseline, post-workshop, and 3-month follow-up. The survey will be administered via the Qualtrics platform. Participants who prefer a paper-based format will be accommodated. To minimise bias, self-completion will be encouraged; however, based on previous experience, some individuals may require assistance from peer facilitators. Providing options for in-person and telephone survey completion is expected to enhance participation rates and reduce missing data. Peer facilitators will receive training to support participants in survey completion where needed. To further promote inclusivity, survey instruments will be translated into participants' preferred languages to facilitate administration. Peer facilitators and Recruitment Leads will assess whether and which translations are required. Translations will be outsourced to professional translators. An open-ended question will be included at the end of the survey to allow participants to provide any additional insights, ensuring that their perspectives are fully captured. The feasibility of using these measures will be assessed through data monitoring, identifying determinants of missing data to inform the full trial design.

2.12 Screening uptake

Self-reported screening uptake is valuable for assessing retention to follow-up as a feasibility aspect. Assessing actual screening uptake in a future trial would require a

longer follow-up period to yield meaningful results. However, as part of the feasibility assessment, and with participants' consent, including the collection of NHS numbers, we will collaborate with clinical colleagues to measure actual NHS screening attendance, uptake, or requests for appointments and screening kits at the six-month follow-up. This process will generate essential data to inform the design of a definitive trial, where the primary outcome will be actual screening uptake.

The following measures will be implemented to ensure the privacy of the participants' NHS screening data:

1. Approval will be obtained from the NHS screening programmes/hubs.
2. The research team will share NHS numbers, study IDs, dates of birth, names, and addresses with the NHS screening programmes/hubs.
3. The data linkage will solely be conducted by the NHS. Data will be analysed and transferred directly from the screening programme/hubs to the Robertson Centre for Biostatistics, University of Glasgow. The screening programmes will share participant IDs and information about their screening attendance with the Robertson Centre.

2.13 Data and statistical analysis

Qualitative and quantitative analysis methods (the former led by LN, the latter led by KW and AMcC) will be used as appropriate. Recruitment and retention rates will be reported with 90% confidence intervals, summarised according to baseline characteristics. Differences in retention rates will be assessed using logistic regression methods. Participants' scores on outcome scales, and changes over time, will be reported using descriptive methods. Paired t-tests, or non- parametric alternatives, will estimate changes over time, with 90% confidence intervals. Correlations between baseline and follow-up

measures will be reported with 90% confidence intervals. Feasibility studies with wide confidence intervals can lead to unreliable decisions about larger trials. A 95% confidence level might be too stringent and misrepresent effect sizes. Using a lower confidence level offers a more balanced approach by providing narrower intervals while maintaining sufficient precision (111). We will present data descriptively and analyse changes within groups over time. Mixed-effects regressions will help us understand outcome distributions and temporal patterns, adjusting for baseline values and random cluster effects to provide intervention effect estimates and confidence intervals. These will guide our sample size considerations, though we anticipate relying more on clinically important effect sizes for robust planning, as initial estimates may be imprecise.

We will estimate ICCs at different levels for all measures, in line with CONSORT guidelines for cluster-randomised trials. However, we are aware that there may be considerable uncertainty in these estimates. Non-response to follow-up will also be assessed, and its likely impact on all estimated parameters considered. The qualitative analysis has been described in WP3.

Outcomes for WP4:

1. Indication of the feasibility, recruitment, and follow-up within a randomised trial
2. Information about the distribution of potential outcomes for such a trial
3. Sample size calculation for a definitive randomised trial.

2.14 Work-package 5- Health economic evaluation

Objective 5: To evaluate the feasibility of a future health economic evaluation of the intervention, generating evidence to inform a full trial.

The feasibility of using resource use logs to identify and capture the cost of delivering the intervention will be tested, by refining and adapting the data collection instruments developed in the IMCAN study to the EQUITA population and intervention. We will capture the full range of resources involved in the delivery of the intervention (e.g., cost of venue, time and opportunity cost of peer educators, transport costs, and opportunity cost of travel for participants and staff). Suitable reference costs will be also identified (112). A rapid, non-systematic scoping review will identify suitable frameworks to project the effect of increased screening uptake on lifetime costs and outcomes (113). A pre-trial economic model (i.e., a probabilistic decision analytic model) will be developed to evaluate the potential cost-effectiveness effectiveness of the EQUITA intervention compared to the control, thus informing the economic evaluation of a future, full-scale trial. Separate models will be created for breast, bowel, cervical, and AAA screening to capture the impact of increased screening uptake generated by the intervention on cost savings and improvements in survival rates and QALYs over the long term. The models will be populated using the evidence generated in the EQUITA feasibility study (i.e., rates of screening uptake) and secondary literature parameters. The NHS personal social service perspective will be used in the base-case analysis; in line with NICE update guidance, the inclusion of broader, societal cost and outcomes in a broader, societal perspective will also be explored (114). An expected value of perfect information (EVPI) analysis will also be also carried out to explore the value of removing all decision uncertainty in the cost-effectiveness results, thus informing whether conducting a full-scale trial of the intervention versus control is worthwhile (115). If UK – based estimates are not available, we will use estimates from systematic reviews or meta-analyses (116,

117). If estimates of cancer or AAA incidence are not available for the EQUITA target population, average population statistics will be used, and sensitivity analyses will test the sensitivity of results to changes in the incidence parameter. The model assumptions, including the identification of plausible scenarios for sensitivity analyses will be discussed with the clinical team. WP5 is led by MD.

Outcome for WP5: Evidence-based insights into the economic feasibility of implementation of a definitive trial and the intervention.

2.15 Work package 6- Data dissemination and development of the next phase

Objective 6: To develop effective knowledge mobilisation and dissemination strategies and prepare the next phase by designing a study protocol for a definitive trial and logic model for implementation, if this feasibility trial finds this is warranted.

Dissemination, outputs, and anticipated impact

The EQUITA project aims to tackle inequities in breast, cervical, bowel, and AAA screening outcomes by working in partnership with the community to co-design and deliver a culturally tailored intervention. In the short term, we aim to increase knowledge and awareness of breast, cervical, bowel, and AAA screening among members of Black communities taking part in this study, offering them informed choice, encouraging uptake of screening, and improving help-seeking behaviours. Leveraging this approach may also lead to indirect benefits when our participants raise awareness among other members in their social environment by telling them about the intervention. In the long term, we plan

to conduct a randomised controlled trial (RCT) study to assess the effectiveness and cost-effectiveness of the intervention if EQUITA findings indicate this is feasible. Establishing feasibility is a vital first step to informing a definitive trial. Testing the intervention in a subsequent trial has scope for national and international implementation, which will ensure that as many Black people as possible, in the UK and beyond, benefit from the intervention and ultimately increase early diagnosis and breast, cervical, bowel cancer and AAA survival rates.

To maximise study impact, for objective 6, engagement with the PICE group, peer facilitators, participants, and stakeholders provides an essential route to dissemination and support for ongoing mobilisation, and implementation of the research findings with Black communities, service providers, policymakers, and the general public. Continuous engagement with these stakeholders throughout the research process will ensure that emerging findings and research outputs will be fed back to study participants in a timely manner and accessible format. Community involvement has been integral to the development of this study. During the planning phase, members of the community contributed through PPI meetings, with a PPI co-applicant actively participating in protocol development discussions. Throughout the study, community members will be engaged at each study site and involved across all work packages to ensure meaningful participation and alignment with community needs.

The research team, including Recruitment Leads and with input from the Steering Committee and PICE group (led by PvdG), will develop a Knowledge Mobilisation (KM) plan throughout the project using the KTM toolkit (2023) (118). Strategies include

disseminating findings through peer facilitators, community organisations and events, partner organisations (councils, and NHS entities), a project website, media, and academic journals and conferences. Outputs include a study report, images and visual abstracts, and toolkits, academic papers, and conference presentations. The peer facilitators also play a key role in mobilising emerging findings with their organisations/sites by acting as local champions. Additionally, they will be central to developing accessible outputs as part of the guidance documents and dissemination activity.

We will organise dissemination events in each location to launch the work to participants, the PICE group, local community groups, local authorities, service providers, academics, and policymakers. Drawing from insights gained from the PROCAN-B study, which highlighted the prominent role of community events within the Black community, dissemination efforts will be aligned with existing community events. Dissemination of findings may include a concise and accessible presentation, accompanied by a display stand featuring a banner and study results presented in an easily understandable format, such as the previously mentioned infographic. This approach is intended to foster trust within the community, thereby enhancing the study's impact by promoting informed decision-making and encouraging screening uptake.

A project website will be established to support recruitment and dissemination throughout the study and for one year following its completion. Website engagement metrics will be monitored to assess reach and impact.

A report summarising the study findings will be produced, including plain English summaries for participants, developed in collaboration with the PICE group. Building on our approach in

the IMCAN and PROCAN-B studies, we will also develop manuals detailing the intervention delivery and peer facilitator training for the EQUITA study. These manuals will serve as toolkits and will be disseminated to researchers, service providers, and community organisations, as well as made available on the project website. To maximise public and stakeholder engagement, we will coordinate regular press releases and collaborate with university communication teams to engage with local media. This will ensure that the study and its progress are communicated effectively to the public, service providers, and policymakers.

The study findings will also be disseminated through publications in international peer-reviewed journals and presentations at relevant national and international conferences. We aim to publish four key components of the study, in collaboration with peer facilitators and PICE group members: the study protocol (*PLOS ONE*), barriers and facilitators to screening (*Public Health*), feasibility findings (*Pilot and Feasibility Studies*), and the process evaluation (*Social Science & Medicine*). In addition, the study will be presented at two national conferences—the Society for Social Medicine & Population Health (protocol, November 2025) and the UK Public Health Science Conference (preliminary findings, November 2026)—as well as one international conference, the European Public Health Conference (November 2026).

To promote open research and data sharing, anonymised data from interviews, focus groups, workshops, feasibility assessments, and health economic analyses from all work packages will be made available via the University of Sunderland's data repository.

Establishing links with policymakers within the Department of Health and Social Care and the Home Office will be essential to ensuring that the study findings are disseminated at the highest governmental levels. Engagement with Select Committees will further support the integration of findings into policy discussions. Our well-connected co-investigators and collaborators will play a key role in facilitating the dissemination of EQUITA's findings to policymakers and national commissioning bodies. Additionally, NIHR evidence-sharing mechanisms, including press releases and targeted publicity, will enhance dissemination efforts and promote the adoption of findings into practice.

Possible barriers to further research, development, adoption, and implementation

Following the completion of this project, governmental budget constraints may limit the implementation of recommendations related to screening programmes for Black communities. Additionally, a change in government during the project's duration could result in modifications to existing screening policies. To ensure adaptability, ongoing engagement with stakeholders, including policymakers, will be maintained throughout the study. This will enable the research team to respond promptly to policy changes and ensure that the study's findings remain relevant and actionable within the evolving healthcare landscape.

Outcome for WP6: Co-produced KM plans and strategies to deliver timely, relevant and tailored outputs for different knowledge users, including Black communities, service providers, policymakers, and the general public during and beyond the study period. An RCT trial protocol and logic model to inform a future funding application, supported by a

strong network of stakeholders.

3 Project management

EQUITA will be jointly managed day-to-day by FC and JE. Weekly meetings will be conducted with research staff. Monthly online meetings will involve the wider research team to discuss project progress and challenges. EQUITA's full project team, including Steering Committee Collaborators (SCC), will meet twice a year, once online and once in person, to ensure the extensive expertise of the SSC is ingrained at each stage of the project. There will be six meetings with the PICE group per year. All meetings will be minuted to ensure action points are recorded, and project management tools will be used, such as Trello, to efficiently monitor the progression of the project and ensure deliverables within the allocated timeline.

Timescale and milestones

24 months: 01/03/25 – 28/2/27.

Key milestones are summarised in Figure 2.

Milestones																								
Project Month	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**
Calendar Month	Mar-25	###	May-25	Jun-25	####	Aug-25	Sep-25	Oct-25	Nov-25	Dec-25	Jan-26	Feb-26	Mar-26	Apr-26	May-26	Jun-26	Jul-26	Aug-26	Sep-26	Oct-26	Nov-26	Dec-26	Jan-27	Feb-27
Ethics approval University of Sunderland	x	x	x																					
Ethics approval HRA	x	x	x	x	x	x	x	x	x	x														
RIDAC approval	x	x	x	x	x	x	x	x	x	x														
Recruitment of PICE group	x	x	x																					
Work with Recruitment Leads to recruit churches	x	x	x	x	x	x																		
Work Package 1: adaptation of intervention with PICE group	x	x	x	x	x	x																		
PICE peer facilitator group training				x	x	x	x	x	x															
Write up feasibility trial protocol	x	x	x																					
Preparation for data collection	x	x	x	x	x	x																		
Recruitment of intervention participants				x	x	x	x	x	x	x	x	x												
Work Package 2: Delivery of the feasibility trial							x	x	x	x	x	x	x	x	x	x	x							
Monitoring of project data	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Data collection follow-up 3 months										x	x	x	x	x	x									
Obtaining NHS screening data follow-up 6 months													x	x	x	x	x	x						
Work Package 3: Qualitative process evaluation										x	x	x	x	x	x	x	x	x						
Qualitative data analysis														x	x	x	x	x	x					
Work Package 4: Examine feasibility	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Quantitative data analysis													x	x	x	x	x	x	x	x	x			
Work Package 5: Health economics evaluation	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Work Package 6: Data interpretation, dissemination and development of next steps																x	x	x	x	x	x	x	x	x
NIHR report																							x	x	x
Review modifications, development of logic model, and randomised trial protocol (if warranted)																			x	x	x	x	x	x
Writing publications and funding applications to build on the work																			x	x	x	x	x	x
Consultation of Steering Committee Collaborators and service providers, throughout the project as required and at regular intervals (2x per year)					x					x						x							x	

Figure 2. Key milestones and timeline

4 Research governance and ethical approval

We will obtain ethical approval from Sunderland University's Research Ethics Committee, following the UK Research Integrity Office Code of Practice. As we will be using NHS data regarding actual attendance, we will also need to obtain NHS Research Ethics Committee approval , and we need approval from all screening programmes that hold the data. We will comply with the UK Research Integrity Office Code of practice for research throughout the project. Non-coercive recruitment methods will be used, including advertisement through community organisations' platforms. Gatekeepers may explain EQUITA but will not actively recruit. Written informed consent will be obtained, emphasising voluntary participation and data sharing.

4.1. Data management

Data will be stored electronically using secure (University of Sunderland, Teesside University and University of Glasgow) networks, servers and storage systems. Contact details and signed informed consent forms will be encrypted and stored separately and destroyed when the project is completed. Audio recordings will be removed from the digital recording device, stored on the networks and destroyed when the project is completed. Access to the full dataset will be restricted to the research team. However anonymised data will be shared with others upon reasonable request.

All data will be treated and stored in accordance with the Data Protection Act (2018). We will only collect personal data we need for this study, which will include demographics including age, employment, marital status, ethnicity and cancer screening status. Ethnicity data are sensitive personal data, however data will be anonymised (removing personal identifiers and

applying unique codes) and the identity of participants will remain confidential in all analyses and outputs.

Funding acknowledgment & disclaimer

This study is funded by the National Institute for Health and Social Care (NIHR) (Project reference 164073). The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

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