TITLE: BE SURE - Building an understanding of Ethnic minority people's Service Use Relating to Emergency care for injuries

PROTOCOL VERSION NUMBER AND DATE

Document	Version number	Date	Submission/ approval	Comments
BE SURE study protocol	1.1	28-02-2022		Ready for submission to IRAS
BE SURE study protocol	1.2	31/03/2022		Including REC Feedback
BE SURE study protocol	1.3	07/12/2022		WP3 inc. 6 months outcome details Specific dates removed and replaced with time periods Updated study design flowchart Added Third Sector Organisations
BE SURE study protocol	1.4	13/02/2024		Changed table 2 and related details on page 15 and page 16
BE SURE study protocol	1.5	03/06/2024		Changed Scottish sites for Nottingham/EMAS - Taken out mention of UKSeRP and just left SAIL
BE SURE study protocol	1.6	27/08/2024		Removed table on page 13

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Document version control

NHS Yorkshire Ambulance Service NHS Trust
Scottish Ambulance Service *Taking Care to the Patient*
NHS East Midlands Ambulance Service NHS Trust
NHS South East Coast Ambulance Service NHS Foundation Trust

SIGNATURE PAGE

UNIVERSITY OF LINCOLN

The undersigned confirm that the following protocol has been agreed and accepted and that the Joint Chief Investigators agree to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirements as amended.

We agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the conduct of the study without the prior written consent of the Sponsor.

We also confirm that we will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: P Griffiths .... Date: ..28..../.02...../.22

Name (please print): Paola Griffiths

....

Position: Research Governance Manager

....

Chief Investigator:

Signature: A Khanom .... Date: ..28..../.02../...22

Name: (please print): Ashra Khanom

....

Co-Chief Investigator:

Signature: H Snooks .... Date: ...28../..02../..22

Name: (please print): Helen Snooks

....

Contents

KEY STUDY CONTACTS

Chief Investigators	Dr Ashra Khanom, Swansea University Medical School, Singleton Park Campus, Swansea, SA2 8PP 07955503377 a.khanom@swansea.ac.uk Professor Helen Snooks, Swansea University Medical School Singleton Park Campus, Swansea, SA2 8PP 07432622246 h.a.snooks@swansea.ac.uk
Study Manager	Dr Fadi Baghdadi, Swansea University Medical School, Singleton Park Campus, Swansea, SA2 8PP Fadi.baghdadi@swansea.ac.uk
Sponsor	Mr Ceri Jones, Director of REIS & Head of Research Development (Research, Engagement and Innovation Services), Swansea University, Singleton Park Campus, Swansea, SA2 8PP researchgovernance@swansea.ac.uk
Joint-sponsor(s)/co-sponsors(s)	N/A
Funder	NIHR HS&DR
Study Co-investigators	Dr Bridie Angela Evans, Research Officer, Swansea University and Public and Patient Involvement Lead, PRIME Centre Wales, Swansea University Medical School, Singleton Park Campus, Swansea, SA2 8PP b.a.evans@swansea.ac.uk Professor Steve Goodacre, Professor of Emergency Medicine, University of Sheffield, School of Health and Related Research (ScHARR), Regent Street, Sheffield, S1 4DA, and Emergency Department, Northern General Hospital Herries Road, Sheffield, S5 7AU s.goodacre@sheffield.ac.uk Mrs Thanuja Hettiarachchi, Public Contributor, c/o Swansea University Medical School, Swansea University, Swansea, SA2 8PP thanuh@gmail.com Professor Ann John, Professor of Public Health and Psychiatry, Swansea University Medical School, Singleton Park Campus, Swansea, SA2 8PP

	a.john@swansea.ac.uk Professor Ronan Lyons, Clinical Professor of Public Health, Swansea University Medical School, Data Science Building, Singleton Park, Swansea, SA2 8PP r.a.lyons@swansea.ac.uk Dr Alison Porter, Associate Professor, Swansea University Medical School, Singleton Park Campus, Swansea, SA2 8PP A.M.Porter@swansea.ac.uk Professor Ian Russell, Emeritus Professor of e-Trials Research, Swansea University Medical School, 5 Fitzallan Place (main home since pandemic), Wester Inch Village, Bathgate, West Lothian, EH48 2UN i.t.russell@swansea.ac.uk Mrs Solmaz Safari, Public Contributor, c/o Swansea University Medical School, Swansea University, Swansea SA2 8PP Solmaz.Safari@Swansea.ac.uk Professor Niroshan Siriwardena, Professor of Primary & Pre-Hospital Health Care, School of Health and Social Care, University of Lincoln, Brayford Pool, Lincoln, LN6 7TS nsiriwardena@lincoln.ac.uk Professor Alan Watkins, Professor of e-Trials Research Swansea University Medical School, Singleton Park Campus, Swansea SA2 8PP a.watkins@swansea.ac.uk Professor Julia Williams, Head of Research, South East Coast Ambulance Service NHS Foundation Trust, Nexus House, 4 Gatwick Rd, Crawley RH10 9BG julia.williams@secamb.nhs.uk
Collaborators	MS Fiona Bell, Head of Research Yorkshire ambulance service NHS Trust, Springhill 2, Brindley Way, Wakefield 41 Industrial Estate, Wakefield, WF2 0XQ Mr Paul Gowens, Associate Director, Research Development and Innovation, Scottish Ambulance Service Scottish Ambulance Service, Gyle Square, 1 South Gyle Crescent, Edinburgh, EH12 9EB

ROLE OF STUDY SPONSOR AND FUNDER

The study sponsor is Swansea University. The sponsor is ultimately responsible for study delivery to the commissioner. The Chief Investigators are operationally responsible for delivery of study findings, its design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results on behalf of the sponsor.

PROTOCOL CONTRIBUTORS

The Joint Chief Investigators and all co-investigators are responsible for study design and all elements of the study protocol.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT GROUPS AND INDIVIDUALS

We will set up an independent Study Steering Group (SSG) to ensure that the study is delivered rigorously, ethically and to time. This group will provide advice about any proposed amendments to the study design or methods e.g. recruitment strategy, sampling.

Study management will be overseen by the BE SURE Research Management Group (RMG), comprising all co-applicants and nominated collaborators. This group will meet at approximately three monthly intervals throughout the study and will report to the SSG and sponsor.

We will set up a Core Research Group (CRG) to manage day to day delivery of the study (e.g. Permissions; Data management; Patient and Public Involvement (PPI)), and Task and Finish groups as necessary to complete the study by Work Package. These groups will meet regularly and report to the RMG. We will set up site meetings with clinical and Third Sector organisations to ensure co-ordination and delivery of the study.

At all stages two public contributors (co-applicants) who are members of the RMG will be invited to contribute. There will also be two public contributors on the Study Steering Group. Public contributors will be supported by a PPI facilitator (BAE, PPI lead for PRIME Centre Wales) to ensure that public and patient perspectives (e.g. on data collection, interpretation and dissemination of findings) inform all stages of this research.

TIMELINE

Start Date: 01/10/2022
End Date: 31/03/2025

ABBREVIATIONS

ALF	Anonymised Linkage Field
AS&Rs	Asylum Seekers and Refugees
CAD	Computer Aided Dispatch
CAG	Confidential Advisory Group
CCG	Clinical Commissioning Group
DARS	Data Access Request Service
DMAP	Data Management and Access Plan
ED	Emergency Department
ECDS	Emergency Care Data Set
EMAS	East Midlands Ambulance Service
ID	Identity
HES	Hospital Episode Statistics
NARSG	National Ambulance Research Steering Group
NHS	National Health Service
ONS	Office of National Statistics
PIS	Participant Information Sheet
PCR	Patient Clinical Record
QR code	Quick Response code
REC	Research Ethics Committee
R&D	Research and Development
SAIL	Secure Anonymised Information Linkage
SECAMB	South East Coast Ambulance Service
STROBE	STrengthening the Reporting of OBservational studies in Epidemiology
YAS	Yorkshire Ambulance Service

BACKGROUND

Injuries cause 5 million deaths worldwide each year and many more people are left with disability [1]. About 86 million people in the European Union receive injury-related medical treatment each year, with more than 12 million admitted to hospital [1]. In the United Kingdom (UK) around six million ED visits result from accidental injuries [2]. In 2019, the NHS in Wales (with a population of around 3 million) recorded 1068 deaths, 39,055 hospital admissions and 316,820 ED attendances due to injury [3].

A literature search in MEDLINE and CINAHL using the terms ('ethnic*' or race or culture or Black or Hispanic or Asian or 'ethnic minority' or 'migrant' or 'immigrant') AND (‘emergency service*' or EMS or ED or ‘Emergency Department’ or ambulance or ‘patient transport’) AND (injury or injuries or accident* or trauma*), narrowed by date (2010-2020), English Language, high-income countries and subject headings (triage, crime victims, healthcare disparities) returned over 900 papers. Following title and abstract search we identified 166 relevant papers. Another 40 papers were identified from Google Scholar and citation search. The majority of papers were from the United States (US) [4-29] with a smaller proportion from the UK [30-41], other countries of Europe [42-43, 29, 37, 44-46], Canada [47-50], Australia [51] and New Zealand [52-53].

Most of the reported studies were carried out in EDs or on ED data, with only a small minority in the prehospital setting [15-16]. Systematic, scoping and narrative reviews identified disparities in emergency care in terms of pain management [15], length of hospital stay [17], quality of care [18-19], disability [5, 20], repeat attendance [5, 21], and mortality [21-22] between ethnic minority groups and White populations following injury presentation. Several papers identified an elevated risk of certain injury presentations among ethnic minority groups such as gunshot injuries [23], long bone fractures [6], head injuries [24], alcohol related injury [25], workplace injury [54], assaults [26, 41], self-harm and attempted suicide [7, 31] and FGM [40]. However, there was a lower prevalence for certain injuries among ethnic minority groups such as falls among the elderly [30], road traffic injuries [30], fire injuries [39] and partner violence [27] compared to the White population.

There were reported variations within ethnic minority groups in terms of injury presentation, for example, there were higher rates of unintentional injury among refugees [49] and higher rates of assault in Somali groups [48] in Canada. There was an increased risk of partner violence among Australian indigenous groups [51]; self-harm and attempted suicide among asylum seekers and refugees in Europe [45, 54]; and suicide risk among young women of South Asian and Black African origin in the UK [46].

The literature review highlighted a paucity of UK data reporting injury and mortality by ethnic groups [42, 28], which may mask underlying inequalities in injury presentation and differences in emergency care. Evidence from other countries such as the US may not be appropriate or relevant for the UK setting as health systems and patterns of migration are dissimilar. There is considerable scope for taking a more analytical approach to studying injury presentation and differences in emergency care among ethnic minority groups in the UK that will inform policy and practice and help to reduce future disparities and burden of injury, mortality and disability.

A founding and sustained principle of the NHS is that there should be equity of access and treatment for all [55]. However, death and morbidity rates due to injury are found to be higher in some ethnic minority populations [5, 56, 7, 26]. Systemic structural, cultural, language and socio-economic factors disproportionately affect ethnic minorities in their use and outcomes of public services, including healthcare [55]. There are concerns that ethnic minority people are more likely to make greater use of emergency healthcare, probably reflecting difficulties in accessing primary care [57-59]. Also people from ethnic minority groups including AS&Rs and Gypsy, Roma and Travellers are disadvantaged in terms of their knowledge, ability to access services, quality of care provided, and outcomes [58, 60-61]. There is also insufficient detailed understanding of comparative epidemiology, processes of care, including investigations provided and - crucially – outcomes. This gap in evidence is partly due to weaknesses in routine information systems [57], where the recording of ethnicity data tends to be poorly recorded, particularly in emergency prehospital care [57] settings and a lack of focus or priority on this area of inequality until recently. The COVID-19 pandemic has highlighted the differential risk of infection and death among ethnic minority groups and the importance of improving routine data collection by ethnicity, occupation and faith [62] in order to tackle issues of disparity.

Moreover, future changes in the delivery of NHS care as proposed in the NHS Long Term Plan [63] may deepen inequalities as people with urgent care needs including minor injuries will be redirected towards NHS 111 (telephone service) and GP led Urgent Treatment Centres. Following COVID-19, further initiatives have been trialled to control immediate access to emergency care. In some areas, patients are required to book ahead for ED appointments [64]. However, vulnerable and marginalised ethnic minorities are less likely to be aware of these alternative services or have the financial or practical means to access them in this way [55, 58]. In our Health Experiences of Asylum Seekers and Refugees (HEAR) study [58], we found 77% of survey respondents knew about the 999 service, but only 28% were aware of the Out of Hours GP service. Research across Europe [59] reports a rise in migrants' and asylum seekers' use of emergency services in some countries. High use has been associated with language barriers, social deprivation, poor access to primary care [57-59], delayed or restricted access to secondary healthcare [55, 58], or people falling through gaps between other services (such as community mental health services) [31, 55, 58].

We will make use of and analyse existing UK health care data on injury, patient reported experience measures and qualitative data to address the evidence gap and to inform policy to address disparities in injury presentation and outcomes that exist between and among groups including their extent and nature.

1. AIMS AND OBJECTIVES

1.1 RESEARCH AIM

To investigate disparities in how ethnic minorities present to emergency ambulance services and Emergency Departments (ED) with injuries, the care they receive and what happens to them, compared to the White British population, to inform policy to address differences in care, morbidity and mortality.

1.2 RESEARCH OBJECTIVES

To:

- Describe what is already known about ethnic minority populations' use of emergency health services for injury, the care they receive, patient experience and outcomes (Work Package (WP1)
- Describe the quality (completeness, consistency) of ethnicity data in routine emergency care datasets and identify gaps (WP2)

- Compare between people in ethnic minority groups and White British people: injury type, severity, care delivered, outcomes, beliefs and experiences when they make contact with emergency services for injuries (WP2, WP3)

- Explore with people from ethnic minority groups: knowledge of service availability, factors which deter or encourage them to seek help, experiences of emergency healthcare for injuries (WP4)

- Explore emergency healthcare providers' experiences of delivering care to people from ethnic minority groups presenting with injury (WP4)

- Synthesise quantitative and qualitative findings (WP5) to:

    - help policy makers and care providers to develop and implement interventions to promote accessibility of services for injury in ethnic minority populations

    - enable ambulance service and EDs to improve care and outcomes for people in these populations with injuries

    - inform injury surveillance resources where they exist, to include ethnicity dimension in their reporting of injury (WP5) [3]

2. STUDY DESIGN AND METHODS

2.1 OVERALL STUDY DESIGN – THEORETICAL/CONCEPTUAL FRAMEWORK

The study will be conducted over 24 months – 01/10/2021 to 30/09/2023. We will use a mixed methods sequential explanatory design. Our theoretical framework combines pragmatism (viewed through post-positivist and constructivist lenses) [65] and the ethics of principlism [66]. Methods will begin with a scoping review followed by cross sectional analysis of routine linked data to investigate differences comparing minority ethnic groups with White British people in injury presentation, investigations and treatments provided and outcomes. We will also conduct a patient survey together with qualitative data from interviews of patients and staff to explore possible explanations for any differences found. Findings from quantitative and qualitative data will be synthesised to generate implications for policy and service delivery.

2.2 ETHICS AND APPROVALS

We will seek Research Ethics Committee (REC) favourable opinion for the study protocol, consent forms and other relevant documents, and will complete all necessary research permissions through the Health Research Authority. In addition, information governance approvals (including CAG) will be sought to carry out data linkage and retrieval of outcomes for analysis from NHS Digital in England via its Data Access Request Service (DARS. Ethical issues which may arise in the BE SURE study, for consideration are as follows:

2.2.1 Assessment and management of risk

This study is observational in nature, and does not carry any identified risk to patients, staff or researchers. We will carry out a postal survey and semi-structured interviews and focus groups with patients to understand their experiences of accessing and receiving care following injury. We will also seek the views of NHS emergency care staff (clinical and managerial) and Third Sector organisations about their experiences of providing care to people from an ethnic minority background presenting with injury.

2.2.2 Consent

We will not seek consent to participate from patients identified for anonymised follow up using routine data. Our study posters will include a privacy notice and reference to how people can opt out from having their data linked. These posters will be displayed on participating NHS Trust websites and in EDs, and Third Sector organisations. Also, we will include a question on the questionnaire to allow respondents to opt out of linking their responses to routine data. Clinical members of staff at each ambulance service and ED will have access to identifiable data but Swansea University staff will only have access to anonymised patient data for analysis through the Sail Databank.

The Participant Information Sheet (PIS) provided to interview and focus group participants will explain their involvement in the study and how their information will be used, including consent, anonymisation and confidentiality. These will be prepared in careful consultation with our PPI members. Participants will have the opportunity to contact their clinical care team or Third Sector organisation to discuss the questionnaire and interviews, and to ask questions about how their survey data will be anonymised and linked to their health data. All participants will be advised that they can withdraw from the study at any point without this decision affecting their care.

Participants taking part in qualitative interviews and focus groups will be consented to participate according to current qualitative research recruitment processes. Qualitative interviews and focus groups would not involve adults lacking mental capacity and an assessment of capacity will be made before commencing the interview/focus group to ensure participants have the mental capacity to consent. We will use interpreters where requested to ensure we obtain informed consent from participants for whom language is a barrier. In cases where a participant lacks the capability to complete the questionnaire on their own due to language barriers or poor literacy skills or other incapacities of a more practical nature, we will ask carers or family members to read the study information and to support or complete the study questionnaire on behalf of the participant. There will be a space on the questionnaire to indicate whether the questionnaire has been completed by the respondent or by a carer or relative, so that outcome data can still be collected for people who lack capacity to consent or have language difficulties.

We recognise that our target population group may be vulnerable due to not being aware of the notion of what it means to be involved in a research study, have distrust of authorities or because of language barriers. Third Sector organisations and community peer researchers will be on hand to assist people with the questionnaire and answer questions. We will take care to ensure that where available appropriately trained researchers at each site carry out all interviews sensitively. Training and procedures will be guided by our PPI members (SS and TH) and AK and FB who have extensive experience of conducting research with people from vulnerable groups [58]. Where site researchers are not available to conduct the interviews then the research team at Swansea will undertake these interviews. Focus group and interview participants will receive a translated participant information leaflet where required and will provide written consent prior to their involvement. Participation will be voluntary, and participants will be free to withdraw at any time. Interviews will be audio-recorded, with permission of participants, and the audio-recordings will be transcribed with all identifiers removed.

2.2.3 Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigators, site Principal Investigators or designee will ensure that appropriate approvals from participating organisations are in place and comply with the relevant guidance

2.2.4 Amendments

Substantial amendments that require review by REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.

For any amendment to the study, the Chief Investigators or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigators or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

If applicable, other specialist review bodies (e.g. Confidentiality Advisory Group (CAG)) will be notified about substantial amendments in case the amendment affects their opinion of the study.

The Chief investigators will be responsible for the decision to amend the protocol and will request advice from the REC about whether an amendment is substantial or non-substantial. The Study Manager will communicate all substantive changes to relevant stakeholders (e.g., REC, R&D, regulatory agencies), with all amendments tracked to identify the most recent protocol version.

2.2.5 Peer review

This study has been funded through an open competition, peer reviewed process, by the NIHR HS&DR through its 19/165 HS&DR Injuries, accidents and urgent and emergency care themed Call.

2.2.6 Patient & Public Involvement

We are firmly committed to the involvement of patient or public representatives at all stages of our research project. We follow guidance for good practice as published by INVOLVE [67].

Dr Bridie Evans, co-investigator is leading on PPI in this study. We have recruited two public members Mrs Thanuja Hettiarachchi and Mrs Solmaz Safari, to our Research Management Group. They have been involved from proposal development stages and named as research team members. We have recruited two additional public members to the independent Study Steering Group. Public members of these groups will, as full committee members, consider and contribute to all discussion on:

- Acceptability of the research
- Rigour and design of the research study
- Approach to data analysis and interpretation of findings
- Study progress

2.3 SETTING

We will carry out this study in the catchment areas of one receiving hospital ED within four ambulance services. We selected sites whose catchment areas included a population of significant ethnic diversity and where an established electronic patient data capture system was in place in the ambulance service. The sites could provide linkable electronic datasets and ethnicity coding which is available in approximately 70% of patient records [68]. We asked each selected service to nominate an ED within its catchment area, where the resident population is ethnically diverse and we hope to retrieve 80% of ED records where ethnicity is available [69]. Third Sector organisations at each site will help to provide access to the local population. They will promote the study across their networks and community groups to encourage people to respond to postal survey questionnaires and provide support with recruiting and managing peer researchers to administer the questionnaires.

2.4 METHODS

The study design and recruitment flowchart below provides an overview of the study design and recruitment of study participants across Work Packages 2 – 4 (Figure 1. Recruitment flowchart p.14).

2.4.1 WP 1 – Scoping Review

We will undertake a systematic scoping review of literature using the methodological framework proposed by Arksey and O'Malley [70] and further refined by the Joanna Briggs Institute [71], to identify and synthesise the available quantitative, qualitative and mixed or multimethod evidence on injury presentation by people from ethnic minority groups; emergency service response (999 ambulance service and ED) and health outcomes. We will build on our initial search strategy, which we will refine to answer the following research questions:

- What does the national and international evidence say about emergency service injury presentation, experience of care and outcomes for people in ethnic minority groups, including disparities between ethnic minority and White British populations?

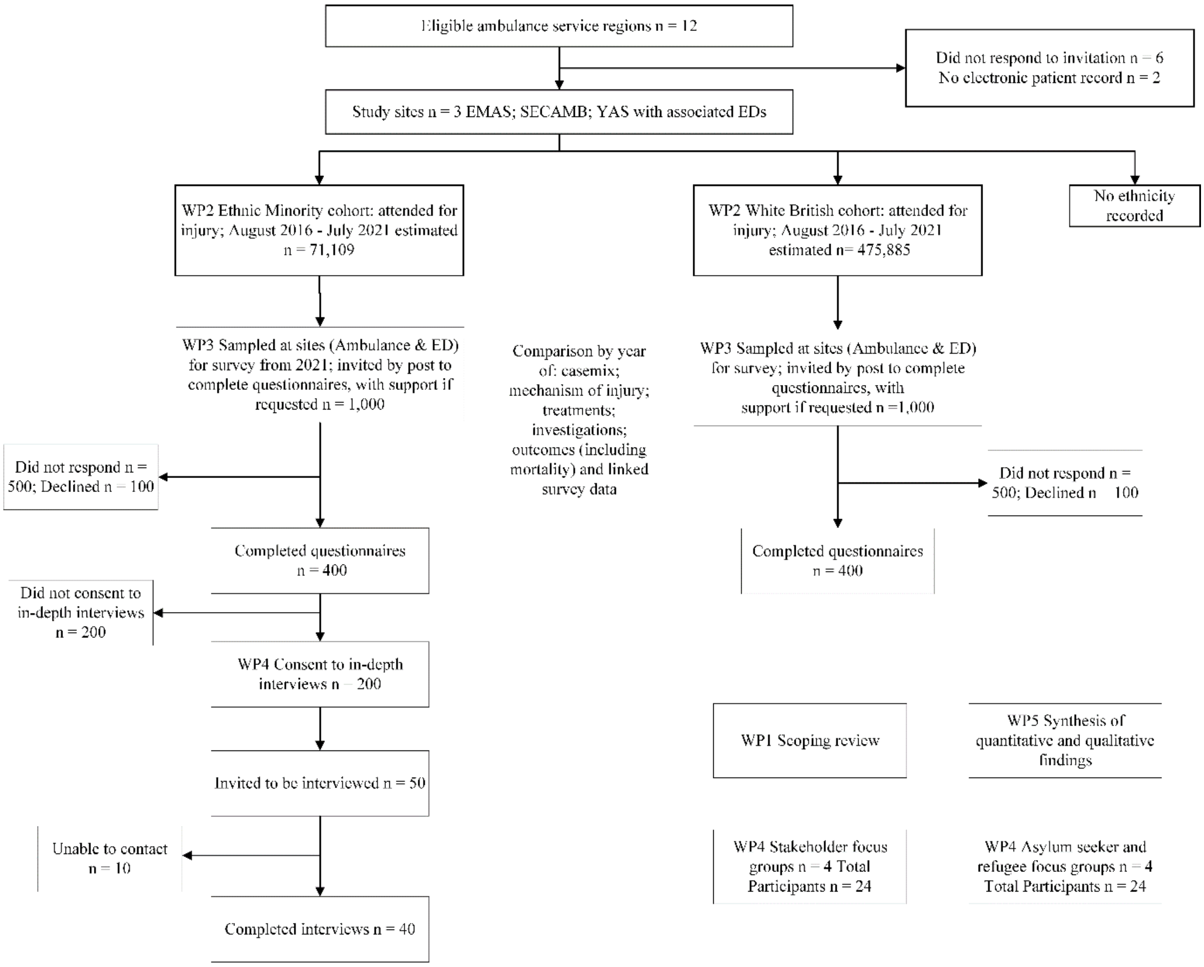

Figure 1. Recruitment flowchart

- What methodological approaches have been used in previous research on this topic?
- What outcomes should be included in research on emergency care for injuries in ethnic minority populations?
- What is known about the quality of ethnicity data in routine emergency care datasets?
- What are the gaps in the evidence base for future research?

Co-investigators and collaborators will act as an expert reference group and contribute to papers for inclusion in the review based on their expertise. Included papers in the review will be thematically analysed, reporting on injury presentation, provider response (treatment and decision-making), and experience of care and health outcomes.

2.4.2 WP2 – Routine linked data epidemiology of injury presentation, care delivery and outcomes

Routine ambulance service data for five years related to patients presenting with injury within the ambulance service catchment area of the participating ED will be linked to existing Emergency Department, inpatient, outpatient and Office of National Statistics (ONS) datasets (using NHS Digital [72]. Individual-level prehospital data on attendances for injury will be retrieved by each ambulance service from its Computer Aided Dispatch (CAD) and Patient Clinical Record (PCR) systems; these data are currently unavailable in NHS Digital. Clinical data will include ethnicity; condition code; job cycle time (from first 999 call for the incident to time ambulance reported free to respond to next 999 call); medications given and disposition (conveyed to hospital, left at scene or referred). These data will be linked using a study-specific Identity (ID) to patient identifiable data held in separate files – the “split file” method [73] – and uploaded to NHS Digital by each site. Patient identifiable data will be used within NHS Digital to create Anonymised Linkage Fields (ALFs), which will then be used to retrieve routinely recorded outcomes for these patients.

We will also retrieve routine data on ED attendances for injury for participating EDs for the same period from NHS Digital. We will then retrieve anonymised linked routine health outcomes (via NHS Digital) for six months after index presentation with injury to ambulance services and EDs, to assess outcomes unless the person has specifically opted out [74]. We expect a 0.17% opt out rate as reported elsewhere [69]. We will request data related to: diagnoses; disposition from ambulance service and ED; length of stay at index episode in hospital; treatments received and discharge code; ICU admissions and length of stay; further ED attendances and emergency admissions; and deaths up to six months.

The nature, scope and size of the study cohorts make it infeasible to seek patient consent to access their data; we therefore propose to seek the necessary research, ethical and information governance permissions to allow the study team to access patient identifiable data without prior consent. All activities related to data collection, transmission and processing, data storage, retention and destruction, and output disclosure and dissemination will comply with the appropriate information governance policies and procedures.

The aggregated data will be partitioned into cohorts of ethnic minority patients, patients from the White British population and those for whom no ethnicity is recorded; with appropriate sub-groups identified using 2011 Census ethnicity categories [75]. Patients with multiple presentations or attendances will be included with the first (index) presentation or attendance as baseline, and data from subsequent presentations or attendances contributing to outcomes. As this is an under researched area, we plan to hold a Stakeholder Consultation workshop to help clearly define our study outcome measures.

We will compare patterns of presentation, attendance and outcomes through cross-sectional analyses to investigate differences in:

- Patterns of injury presentation including demographics; geography and deprivation; mechanism of injury; severity; injury type (accidental, non-accidental, assault, self-harm); casemix; route to care (direct, via 111 telephone advice service or via general practice)
- Treatments and investigations
- Potential safety incidents (e.g. hospital admission or death within 72 hours of discharge from 999 or ED care) following injury
- Immediate outcomes including ambulance attendance, transportation to hospital, hospital admission, length of stay in hospital and ICU, death following injury
- 6 month outcomes (further ED attendances, hospital admissions and deaths) following injury

2.4.3 WP 3 – Questionnaire survey

We will survey people from ethnic minority and white British backgrounds who were attended for injury in England by one of our four ambulance services or presented with an injury to our nominated ED in the preceding 6 months. Each of the four study sites will search through their routine ED records and ambulance service records (within the ambulance service catchment area of the nominated ED) to identify patients presenting with injury and coded as belonging to an ethnic minority group, including those patients who were attended to by the ambulance service but were not conveyed to hospital. They will also identify a similar sized cohort of patients identified as White British. We will also review 6 months outcome data (NHS digital) from the incident date for all patients included the questionnaire sample.

Each study site will send out 500 postal questionnaires (n=2000 in total, 4 sites) to 250 patients in the ethnic minority cohort, and 250 patients in the White British cohort. Before sending out questionnaires, the clinical care team will check death records to ensure that the person has not died, to avoid causing distress to their family. All recipients will be asked to return completed questionnaires in a prepaid envelope to Swansea University. A reminder letter will be sent after two weeks. Recipients will also have the option to complete the questionnaire online (via a secure approved platform) using a QR code, reducing the potential burden of having to return the questionnaire by post. Where patient contact numbers are available, the clinical care team will contact the patient by telephone after one week of posting the questionnaire, to complete the questionnaire over the telephone. This will ensure we reach our predicted 40% response rate and receive n=800 analysable questionnaires. We will give all respondents a £10 voucher for completing the questionnaire [76]. Previous studies in the emergency care setting [77] and in hospital [78] have found postal questionnaires yielded a response rate of around 30%. However, when patients were surveyed over the telephone [78] the response rate increased to 92%.

To ensure we do not exclude under-served groups in our study sample, we will raise awareness of our study across sites using a range of media with support from NHS and Third Sector partners. Our proposed public engagement will make use of social media supported by use of Infographics, which has been suggested by our PPI members, along with face to face interaction (COVID-19 restrictions permitting).

We will base our survey questions on those used successfully in the HEAR survey [58], focusing on knowledge of services, beliefs, experiences of injury, expectations and health-seeking behaviour. The questionnaire will also include standardised questionnaires to measure satisfaction with care (Quality of Care Monitor) [79], experience of care (Patient Reported Experience Measure) [80, 81] and current health status (SF-12) [82]. The questionnaire will be translated into several languages and translated versions will be made available on request.

We will recruit and train twelve community peer researchers from the ethnic minority community from different groups bringing diverse cultural awareness and a range of language skills [58, 83-84], and plan their training to collect questionnaire data through telephone, WhatsApp/Zoom/TEAMS, or face to face (as COVID-19 restrictions allow at the time of data collection). The peer researchers will work closely with the clinical care team in their localities who will refer respondents who request language support to the appropriate peer researcher with the patient's consent to help complete the questionnaire. We will link questionnaire responses to routine NHS data as described in WP2 for comparison of routine outcomes and experience of care between ethnic minorities and the White British population.

Questionnaires will be returned to Swansea University via pre-paid envelopes included with questionnaires and responses will be uploaded into an approved secure data platform. The identifiable patient data and survey responses will be saved into separate “split” files and uploaded into NHS Digital. Patient identifiable data will be used to generate respondents’ ALFs, and, using their study-specific ID, survey responses will be linked to clinical records from ED (HES and ECDS)and prehospital, inpatient and ONS datasets without breaking confidentiality [73]. We know that the ambulance service data systems include appropriate patient-level identifiers and believe that the completeness of these (NHS numbers supported by core demographics) will be sufficiently high to obtain excellent linking rates, with relatively low attrition due to non-matching or dissenting numbers. We have tried and tested this methodology in emergency and primary care trials e.g. the NIHR HTA funded SAFER 2 trial [85]. As this is a new study with new sites, we will pilot our data collection and linkage processes as soon as permissions are in place.

2.4.4 WP 4 – Qualitative interviews and focus groups

We will collect qualitative data at each of the four study sites. We will conduct a total of n=40 interviews with patients (10 in each site, identified from survey respondents who provide their contact details) and four focus groups with Asylum Seekers and Refugees (n=6 participants, per site, identified by Third Sector organisations) to give people an opportunity to provide their own narrative about their circumstances, routes to seeking care, injury experiences (personal or family), views regarding their need, service use, care received, and post injury impact on physical and mental health including terminology (labels) used.

Focus group participants who have experienced an injury in the previous 12 months and survey respondents will be selected by age, gender, postcode, ethnic group and location to hospital. Where language is a barrier, an interpreter will be present. Those who participate will be provided with contact numbers for support groups should they experience any distress during their participation and would like additional support. All participants in patient interviews and focus groups will receive a £20 voucher in recognition of their contributions [71]. Focus groups will be undertaken at the premises of local Third Sector Organisations.

We will also conduct four focus groups with stakeholders (one in each site with six participants, supplemented with telephone interviews as required to include people not able to take part in the focus group). We will recruit stakeholders from a range of professional groups: ambulance call takers, paramedics, and operational managers; ED clinicians; GPs and other primary care staff; social services staff; and Third Sector support workers. We will explore participants’ experiences and practicalities of delivering care to ethnic minority patients who present with injury, including their resource and training needs. Questions will cover care management, delivery processes, treatment pathways, perceived impact on patients, issues around diversity and terminology, and wider organisational impact across health economies, such as information sharing, communication and continuity of care. All stakeholders will receive a £20 voucher to compensate for the time taken to contribute to the study [86].

We anticipate that COVID-19 restrictions will have eased to allow face-to-face, socially distanced interviews and focus groups. If restrictions remain, then researchers will conduct telephone or online interviews. With participants' consent, we will audio record and transcribe all interviews and focus groups.

2.5 INCLUSION AND EXCLUSION CRITERIA

Our inclusion and exclusion criteria will ensure that participants can provide information to meet study objectives. Stakeholder focus group inclusion criteria include clinical staff, operational managers and Third Sector organisation staff involved in providing care or support for people who are injured. Inclusion and exclusion criteria applied to patients is shown below.

Table 1. Inclusion and exclusion criteria

Inclusion criteria				
CHARACTERISTICS	**WP2:** ROUTINE LINKED DATA EPIDEMIOLOGY	**WP3:** QUESTIONNAIRE SURVEY	**WP4:** QUALITATIVE INTERVIEWS	**WP4:** INTERVIEWS QUALITATIVE FOCUS GROUPS (AS&RS)
Population	People of all ages	Any adult (18 plus)	Any adult (18 plus)	Any adult (18 plus)
Emergency service contacts	Contacted emergency ambulance or attended ED	Attended on scene by ambulance or attended ED	Indicated willingness to be interviewed on returned questionnaire	Contacted emergency ambulance or attended ED
Injury	Coded with injury	Coded with injury	Coded with injury	Experience of injury (personal, family, friend)
Dates	Preceding 5 years	Preceding 6 months	Preceding 6 months	Preceding 12 months
Ethnicity status	All people recorded with an ethnicity and those for whom no ethnicity is recorded	Classified as belonging to ethnic minority including White minority Gypsy, Roma and Traveller groups (2011 ONS census classification) or as White British	Classified as belonging to ethnic minority including White minority Gypsy, Roma and Traveller groups (2011 ONS census classification)	Asylum seeker or refugee
Location	Nominated ED catchment area within participating ambulance service	Nominated ED catchment area within participating ambulance service	Nominated ED catchment area within participating ambulance service	Nominated ED catchment area within participating ambulance service
Exclusion Criteria				
Population		Children, adults lacking mental capacity	Children, adults lacking mental capacity	Children

Injury coding	Coded with no reference to an injury	Coded with no reference to an injury	Coded with no reference to an injury	No experience of injury (personal, family, friend)
Ethnic group			Classified as White British (2011 ONS census)	Classified as not asylum seeker or refugee
Location	Outside the nominated ED catchment area	Outside the nominated ED catchment area	Outside the nominated ED catchment area	Outside the nominated ED catchment area

2.6 DATA ANALYSIS

2.6.1 WP 1 – Scoping Review

We will take a systematic approach to the scoping review. Papers and documents identified from database searches will be screened independently by title, abstract and full paper following a protocol which includes inclusion and exclusion criteria by at least two reviewers from the research team (AK, FB, BAE). All discrepancies between reviewers will be resolved by a single arbitrator (HS). Data will be charted [70] reporting on aims or research questions, participant characteristics, study design, relevant findings on injury presentation, inequity in care, provider response (treatment and decision-making), experience of care and health outcomes including any implications for policy, practice or research. All results will be discussed by the research team as the analysis progresses [71]. We will describe but not appraise included papers for methodological quality or risk of bias, which is consistent with guidance on conducting scoping reviews [70-71].

2.6.2 WP 2 – Routine linked data epidemiology of injury presentation, care delivery and outcomes

Our Statistical Analysis Plan (SAP) will characterise and allow for differences in population between study sites. We will interpret results in the light of these differences to maximise generalisability across the UK population. Methods and findings will be reported following STROBE guidance for reporting observational studies [87]. The study DMAP will detail conventions on comparison of processes and outcomes (including inclusion and exclusion rules for covariates and factors), management of missing data, selection of confounders and the reporting of outcomes. To ensure we are able to report on outcomes by ethnicity (and ethnic subgroups, where appropriate), we will cross-reference and validate key variables across data sources (e.g. Hospital Episode Statistics (HES), ONS and CCG)). We will adjust our comparisons between cohorts (ethnic minority and White British) and subgroups using pre-specified factors and covariates (e.g. age; gender; socio-economic status) obtainable from routine data. We will request deprivation measures associated with patient residence. These ecological data will comprise an Index of Multiple Deprivation and component domains, and we will include appropriate summaries as confounders in our statistical models.

Analysis of routine data will be both descriptive and comparative, summarising the epidemiology of injury by ethnicity (including patterns of presentation; injury type, severity and case-mix; processes and outcomes of care) based on those presenting to the emergency services within and between ethnic minority groups and White British people. We will include analysis by (ethnic) subgroups where numbers allow. Across the four study sites, we expect to identify approximately 70,000 people from ethnic minority groups and 480,000 people from White British background who have presented or attended for injury. This will give ample power to undertake meaningful comparisons across aspects of presentation (e.g. proportion presenting with a specific condition), disposition (e.g. proportion admitted to hospital; length of stay) and further outcomes (e.g. re-attendance rates, mortality) over time and between cohorts and pre-specified subgroups.

Limitations in routine data will define a third study cohort, comprised of people presenting with injury but for whom no useable data on ethnicity was recorded or available. We will describe the characteristics and outcomes (e.g. age, sex, injury type and severity; and healthcare outcomes) for this cohort and compare them with the ethnic minority and White British cohorts. This will address our objectives related to the quality of ethnicity data in emergency care settings.

2.6.3 WP 3 –Questionnaire survey

The questionnaire data will be collated using a secure platform and then prepared for further analyses, covering both direct analysis of responses (using standard descriptive statistical methods, including tabulated counts and percentages), and those analyses which will combine questionnaire responses with other study outcomes. The expected (n=800) volume of analysable questionnaire responses will (using 90% power, 5% significance) enable us to detect differences in outcomes equivalent to a standardised statistical effect of ~0.23; this, in turn, corresponds to some clinically meaningful differences in study outcomes (e.g. Self-reported Quality of Life).

2.6.4 WP 4 – Qualitative interviews and focus groups

We will use framework analysis [88] to analyse qualitative interview and focus group data. We will identify themes from the literature and initial analysis of the survey data to develop our framework. We will code transcripts according to themes laid out in our framework, which will be refined as analysis progresses. AP will lead analysis of interview and focus group transcripts with input from at least two members of the research team (FB and AK) and two PPI contributors (SS and TH) with support from BAE. The PPI members will help to validate the analysis process, supporting key stages of coding, refining themes, interpretation and encouraging a critical stance to test and confirm findings [89]. The team will meet at regular intervals to discuss, make comparisons and observe synergy between datasets. Analysis of the large volume of data generated by the interviews and focus groups will be supported by use of NVivo 11, computer assisted qualitative data analysis software to help organise and interrogate the data. We will remove all identifiable data from interview and focus groups transcripts and assign a participant number for identification. Where appropriate, anonymous coded excerpts or quotes will be included in reports to funder and peer reviewed papers.

2.6.5 WP 5 – Synthesis of quantitative and qualitative findings

Synthesis and reporting of quantitative and qualitative findings will be informed by identifying meta-themes that cut across each component of the study [90], which will assist us in understanding the aims of our research and research questions. We will interpret the results and consider similarities and differences, including recurring themes and issues that emerge from the scoping review, routine data, survey responses and people’s views and experiences of injury and care received. We will use this evidence to inform the need and appropriateness of our policy recommendations for improving injury care for ethnic minorities, including direction of future research.

3. DISSEMINATION, OUTPUTS AND ANTICIPATED IMPACT

Our dissemination approach will seek to maximise stakeholder interest and understanding of the study to describe the quality of data, to highlight service use, need and to address any gaps in surveillance of injury by ethnicity.

Our communication, publication and dissemination plan will include engagement with patient and professional groups, NHS managers, commissioners and policy makers and Third Sector organisations. The plan will include assessment of stakeholder needs and communication activities and milestones. We will use the plan to guide our Stakeholder Event, which will take place once the study data collection and analysis are complete. The Stakeholder Event will be designed to be inclusive allowing patients, PPI, Third Sector organisations, service providers and policy makers the space to share their views. At the event, we will discuss and further refine our findings to ensure our results are representative and are widely shared with the community and service providers. Our PPI members will provide support to patient contributors during the event and we will seek advice from delegates who attend the event on how to build on this study to take this work forward.

Given the implications for practice, policy and research, we will publish our results in scientific journals and scientific conferences, in the UK and worldwide. The annual 999 EMS Research Forum Conference http://www.999emsresearch.co.uk/en/, which is hosted each year by a UK ambulance service and is administered by Swansea University PRIME Research Centre Wales for Unscheduled Care brings together academics and practitioners. In addition to a full final study report, we will produce a summary version to be disseminated through the PRIME network (http://www.primecentre.wales) and NHS and Third Sector organisation newsletters and social media pages. We will also present findings at other appropriate national and international events, such as the Health Services Research Network annual conference, the International Forum for Quality in Healthcare and the European Society for Emergency Medicine.

Outputs of the research will include:

1) A final comprehensive research report detailing all the work undertaken together with supporting technical appendices, abstract and executive summary. The plain English executive summary will focus on results/findings and be suitable for use separately from the report as a briefing for NHS managers, emergency care practitioners and the public.
2) Interim reports at intervals agreed with the funder (HS&DR programme)
3) A set of PowerPoint slides which present the main findings from the research for use by the research team or others in disseminating research findings to the NHS and other stakeholders.
4) Exemplar patient stories to raise awareness and enhance understanding of the problem under research.
5) Papers for academic peer reviewed journals such as the Annals of Emergency Medicine, Emergency Medical Journal and BMC Emergency Medicine to ensure the research forms part of the scientific literature and is available to other researchers. We support an open access model of research dissemination.
6) Articles for professional journals which are read by the NHS management community and which will be helpful in raising wider awareness of the research findings e.g. Ambulance UK, Health Service Journal.

7) Seminars, workshops, conferences at regional, national and international level or other interactive events at which the research team will present and discuss the research and its findings with NHS managers and Third Sector organisations.

8) User-friendly materials for the public, service managers, commissioners and policy makers using infographics to maximise accessibility and reach.

4. STUDY MILESTONES

Stage 1	Begin applications to: ▪ Health Research Authority (study sponsorship, IRAS, REC favourable opinion, CAG approval), ▪ DARs (NHS Digital) approval ▪ Information Governance Permissions (SAIL Databank - data haven) ▪ Study set up (collaboration agreements) ▪ Prepare patient facing documents with PPI input
Stage 2	▪ Complete ethics, research and governance permissions ▪ Stakeholder Consultation workshop
Stage 3	▪ Site capacity and capability ▪ Recruitment of study research staff (administrator and clinical care team) ▪ Recruit and train peer researchers ▪ Undertake scoping review
Stage 4	▪ Identify patients and send out questionnaires (n= 2000) ▪ Collate and prepare prehospital routine injury presentation data to link anonymously to existing datasets: HES/SMR, HES/ECDS/A&E Datamart and ONS - held by NHS Digital - retrieve 6 month outcomes ▪ Pilot our routine data collection and linkage processes
Stage 5	▪ Conduct qualitative interviews (n=40) ▪ AS&R (n=6) and stakeholder focus groups (n=6) ▪ Data entry into secure platform (n =800) questionnaires
Stage 6	▪ Link survey responses - anonymise and prepare split files to upload into NHS Digital ▪ Qualitative framework analysis ▪ Quantitative analysis ▪ Synthesise quantitative and qualitative data ▪ Stakeholder Event to discuss results
Stage 7	▪ Finalise and submit report to funder ▪ Prepare papers and other materials for post-funding dissemination

5. PATIENT AND PUBLIC INVOLVEMENT

Our research team is committed to actively involving public contributors, for their invaluable insights which strengthen rigour, relevance and accountability of our research [67, 86]. In keeping with the principles of co-production [91] our public contributors will actively contribute to all aspects of the study. We have strong relationships with individuals from ethnic minority communities, who have contributed experience-based expertise throughout the process of planning this proposal. SS and TH are integral members of our co-applicant team, involved in planning, discussing and agreeing the details of our research proposal. Their expertise has helped make our research as ethical, safe, relevant and efficient as possible for participants. They have advised on using peer researchers, social media and offering incentives to increase response rates and data quality and to thank participants. Both have completed the asylum process and now have refugee status. Both have been community peer researchers. They will be equal members of our RMG, involved in all decisions about study implementation and dissemination. They will support the peer researchers and also diverse public contributors taking part in our Stakeholder Event, which they will co-plan. We will recruit two more public contributors to our Study Steering Group, alongside academic and clinical experts, to provide independent advice and scrutiny to our study team.

We will facilitate and support our public contributors to be effectively involved throughout the research, using the UK Standards for Public Involvement [96] to guide us. We have named and budgeted co-applicant BAE as their contact person. She will provide support and identify training needs. We have a realistic budget, calculated in accordance with INVOLVE guidelines [67], which allows us to offer honorariums and reimburse expenses to enable their active involvement [86].

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