‘Come and work here!’ Exploring the role of local community-led initiatives to improve recruitment and retention of healthcare staff in remote and rural areas

Trial Monitoring Plan – Protocol Version History

Protocol version	TMP version	Date of review	Description of change(s) made
Version 1	Version 1	28/10/2021	New protocol document developed.
Version 2	Version 2	20/12/2021	Document updated following initial review of version 1 by SERB: [Approved by SERB 23/12/2021]
Version 3	Version 3	11/3/2022	Document updated following initial research [Approved by SERB 14/3/2022]

‘Come and work here!’ Exploring the role of local community-led initiatives to improve recruitment and retention of healthcare staff in remote and rural areas V3.0 11th Mar 2022

Acknowledgement and Disclaimer:

This study is funded by the National Institute for Health Research (NIHR) (HS&DR Project: NIHR133888). The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care..

Study Protocol

Full Title:	**'Come and work here!' Exploring the role of local community-led initiatives to improve recruitment and retention of healthcare staff in remote and rural areas**
Sponsor:	**University of Aberdeen**
SERB Reference:	**SERB/2021/10/2186**
Funder:	**NIHR Health Services and Delivery Research Programme**
Chief Investigator:	**Professor Louise Locock**
Version Number and Date:	**V 3.0 – 11/32/2022**

Protocol Approval

Signatures

By signing this document I am confirming that I have read, understood and approve the protocol for the above study.

Professor Louise Locock		**11/03/2022**
Chief Investigator	Signature	Date

List of Abbreviations

CI	Chief Investigator
CSO	Chief Scientist Office
DMC	Data Monitoring Committee
GRP	Good Research Practice
PPI	Patient and Public Involvement
R&R	Remote and Rural
SERB	School Ethics Review Board

Summary

Recruitment and retention of healthcare staff in rural and remote areas is a persistent issue for health services. Much of the focus of research in this area has been on work organisation and practitioners themselves.

However, there has been less focus on the experiences of the people in remote and rural communities and what they themselves can do to attract staff. Some communities have experimented proactively with initiatives to promote their local area; to get involved in the recruitment and selection process; and to welcome and integrate new health professionals and their family members into local life. These community-led initiatives are often ad hoc and undocumented; there is potential learning about what has worked and what has been less successful that remains untapped. This project was developed with public research partners on our CSO study, as a way to capture this learning.

1.0 Introduction

1.1 Background/Rationale for study

Inequalities in health and healthcare in remote and rural areas

People living in remote and rural areas find it difficult to access quality healthcare, with negative consequences for health (Verma et al 2016; World Health Organization 2010, 2018; Wilson et al 2009). Inequitable access to appropriate healthcare professionals in remote and rural areas can compound and amplify the negative health effects of other inequalities and issues such as low income, lack of transport, social isolation, comorbidities and poor health (Strasser 2003). For example, evidence shows that people with cancer in remote and rural communities in Scotland have worse health outcomes than better connected areas (Murchie et al 2019). People with cancer living on islands or more than an hour's drive from a specialist centre on average start treatment sooner than those living within 15 minutes' drive and yet they are significantly more likely to die in the first year after treatment than those living closer by (Turner et al 2017). A study using British registry data found that people with axial spondyloarthritis (a long term inflammatory joint condition) living in rural areas reported a greater impact of their disease on their ability to work than their urban counterparts, after adjustment for age, sex and local area deprivation (Hollick et al 2020).

As Murchie et al (2019, p.1) note, "hard evidence is lacking for what causes poorer outcomes in rural populations", but lower access to services is a probable factor, which in turn influences whether people get timely referral; diagnosis; ongoing support for long term conditions; and post-discharge rehabilitation support. In addition, rural services may depend more on locum or agency staff, affecting continuity of care (Marchand et al 2017).

Recruitment and retention of the healthcare workforce is essential to maintain access to services, but is a persistent challenge for health services. Innovative approaches to healthcare delivery help with access to care (e.g. telehealth, virtual consultations, visiting support from specialty services, upskilled multi-disciplinary team members) but are insufficient: communities need doctors (Green et al 2018). When compared with their urban counterparts, doctors practising in these locations may be described as "extended generalists" (Strasser et al 2016). They carry a heavier workload and higher level of clinical responsibility across a wider range of clinical services than urban doctors, in relative professional isolation (Hogenbirk et al 2004). When a local GP retires or a small hospital cannot attract enough staff, the reduced availability of local healthcare can impact the wider sustainability of remote communities, making it harder to attract families to live and work in the area (Farmer et al 2003). Vacancies which cannot be filled may simply disappear; remaining staff 'get by' with fewer colleagues and may reduce the services they can offer.

Existing evidence on recruitment and retention interventions

Considerable research has been undertaken internationally on factors affecting rural recruitment and potential interventions, and it is a long-standing WHO priority (World Health Organization 2010; 2018; 2020, 2021). A title and abstract search

on Medline including the search terms 'rural/remote', 'recruitment/retention', 'community' and 'workforce' yielded 203 results over the last 10 years, including several recent systematic reviews (e.g. Marchand et al 2017; Holloway et al 2020; Koebisch et al 2020) and a review of reviews (Esu et al 2021). This body of research has focused mainly on health service organisation and practitioners themselves (especially doctors and to a lesser extent nurses): what attracts or deters them from applying for rural jobs, what professional support and development they need, and whether exposure to rural practice during training improves recruitment and retention. Much of the work in this field has been led by Australia, Canada and the US; considerably less has been rooted in the context of the UK health system. This is an issue because context matters (World Health Organization, 2021). A Nuffield Trust working paper on acute care in remote areas concludes that solutions from other countries may not always work in a UK context, and that multiple strategies across organisations are likely to be needed (Nuffield Trust 2017).

Systematic reviews of the international literature on remote and rural healthcare workforce solutions indicate that many recruitment and retention strategies are based on little definitive evidence. Being born or brought up in a rural area remains the strongest predictor of career intention, and extensive rural placements during training may also help, but combining several strategies is most likely to be effective (Hays 2017).

The evidence for financial incentives and coercive strategies from systematic reviews (for example offering 'golden hellos' and requiring people to spend some time post-qualification in rural placements) is also mixed. The most recent research result in our search (Esu et al 2021 p. i54), a review of reviews of recruitment and retention interventions, concludes:

"There was a paucity of evidence for the effectiveness of the various interventions. Regulatory measures were able to attract health workers to rural and underserved areas, particularly when obligations were attached to incentives. However, health workers were likely to relocate from these areas once their obligations were completed. Recruiting rural students and rural placements improved attraction and retention although most studies were without control groups, which made conclusions on effectiveness difficult."

A recent updated review from WHO, looking specifically at retention, also concludes the strength of evidence in most studies was low or very low (World Health Organization 2020; see also Nuffield Trust (2017) for a similar conclusion for UK-based evidence). Thus there remain many gaps in knowledge internationally about how best to attract new people from diverse backgrounds to remote and rural areas - and how to keep them there.

Previous studies in the UK context (including by co-applicants Cleland, Watson and Skåtun) have also highlighted themes raised in the international literature, such as the importance of rural birthplace, and concerns about professional and/or personal (social) isolation (Cleland et al 2012, Cleland et al 2013, Richards et al 2005). The issues may be different for doctors at various life and career stages. A

study of GPs and hospital doctors aged over 50 years led by co-applicant Cleland (2020) indicates the importance of sustainable workload and support to keeping people in post. At the same time, early findings from our current CSO- funded study suggest doctors late in their career may seek out new challenges in rural and remote areas, and relish the opportunity to practise more generalist medicine, at a time when they are less tied for family reasons to a particular place. Much of the focus of existing recruitment research has focused on attracting newly qualified staff; understanding what may draw or keep experienced late-career clinicians to remote areas has received less research attention. In short, there remain many gaps in knowledge about how best to attract new people from diverse backgrounds to remote and rural areas - and how to keep them there.

Members of the research team for this proposal are currently collaborating on a study funded by the Scottish Chief Scientist Office (CSO) examining the motivations and preferences of doctors in relation to remote and rural working in Scotland. This research is 8 months into a 2-year project; after a qualitative interview phase, year 2 will focus on a discrete choice experiment across Scotland, to inform the development of potential interventions for future testing in the NHS. The idea for this complementary proposal, looking at how local communities can supplement NHS interventions, was suggested by public partners on our advisory panel.

The impact of place and community action

A number of studies have measured 'community attractiveness' or features of the community that are associated with better or worse recruitment/retention. These place-based differences may or may not be amenable to change or intervention. The Community Apgar Questionnaire (Schmitz et al 2011) was developed in rural Idaho to measure the assets and capabilities of rural communities related to physician recruitment and retention and identify which factors are most important for a community with limited available resources to address. The scoring system features 50 items across five domains (geographic; economic; scope of practice; medical support; hospital and community support). The geographic domain in particular includes place-related features such as recreational opportunities, spousal satisfaction, schools, shopping, housing, social networks and general perception of the community.

The influence of the community in attracting and integrating a healthcare worker and their family is regularly identified as important across a range of settings (Holloway et al 2020; Koebisch et al 2020; Malatzky et al 2020; McGrail 2017; Paladine et al 2020; Terry et al 2018; Reed et al 2017). Hollick et al (2019) note how interactions with both patients and place shape staff experience of providing care in remote areas – sometimes positively, but sometimes also generating negative feelings. This research, however, has focussed more on the perspectives and preferences of healthcare workers themselves than on the experiences of communities, and what they have done, or could do, to help attract and integrate those workers. Some communities have experimented proactively with various initiatives to:

- promote their local area (e.g. https://www.ullapool.com/visit/moving-to-ullapool.html);
- get involved in the recruitment/selection process (e.g. a successful Facebook campaign by residents on Jura to find a GP (https://www.facebook.com/PerfectPracticeJura);
- scout dual career move opportunities
- welcome and integrate new health professionals and their family members into local life, for example inviting them to join societies and clubs.

Our public partners tell us these initiatives are often ad hoc and undocumented, so potential learning about what has worked or been less successful remains untapped.

The importance of an 'engaged community' is noted in the WHO review on retention (World Health Organization 2020, 2021). Indeed, the WHO's (2021) most recent report highlights the need for a 'whole of society' approach to the issue of recruitment and retention.
Community and stakeholder engagement are key to this whole of society approach. Rural communities are socially, culturally and economically distinct and thus solutions will need to be interconnected, bundled and tailored to the local context. But knowledge of what has worked with relation to communities is less well known. There is some limited international research that has considered community activism (Barnett & Barnett 2003), including the development of community-led action plans (Veitch et al 2002; Veitch & Grant 2004) and community education and support (Shannon 2008) in relation to recruitment and retention. Our research will build on this and consider a range of communities in remote and rural parts of the UK in order to develop a holistic understanding of what has been more or less successful for these communities in recruiting doctors and other health professionals.

The research will also expand our understanding by including family members, particularly spouses/partners but also older teenagers where appropriate. Spouses/partners, as other new members of the community who could contribute to the community, may be as much the target of community recruitment initiatives as practitioners themselves (Farmer et al 2003; Farmer & Kilpatrick 2009; Green et al 2018), ultimately contributing to a community's social capital (Prior et al. 2010) and potentially furthering community sustainability (Curran et al 2004; Kanakis et al 2019). By expanding on the limited international work on spousal perspectives (Cameron et al 2012; Kazanjian & Pagliccia 1996; Mayo 2004; Myroniuk et al 2016), we hope to break new ground in the UK by considering rural recruitment and retention from multiple perspectives.

This project aims to capture this learning and develop an online repository of initiatives for other local communities and the NHS to use. It complements existing ongoing work by this co-applicant team.

2.0 Study Aims, Objectives & Research Questions

1. To explore the experiences of remote and rural community members and organisations of trying to attract healthcare staff and their families to their area
2. To map local context and describe initiatives they have undertaken to improve recruitment
3. To understand how community initiatives have been received by staff and families who have been attracted as a result
4. To assess which initiatives seem to have been most successful (or not) and why
5. To provide resources for other communities and the NHS based on this learning

Research questions

- What community-led initiatives have been tried to attract and retain healthcare staff and their families in remote and rural areas?
- How far are these initiatives judged to have been successful and why?
- What community-based resources and assets can help explain differences between communities?
- What can other remote and rural communities and the NHS learn from these initiatives?

Establishing clear causal links in this field is likely to be very difficult, given the complexity of factors at play in any individual's decision. However, in depth qualitative methods will provide rich insights into what has been tried; by whom; whether and why it was felt by the community, staff and their families to be worthwhile; how they define 'success'; and what resources and people skills different communities are able to draw on (or not).

The findings will complement our existing study of motivations and preferences of doctors working in remote and rural areas, which aims to develop recommended interventions for further testing in the NHS. We recognise that community-led initiatives cannot be a 'magic bullet' and should not substitute for NHS action, even if they can be part of a wider solution. However, our public partners tell us that in small remote communities, the boundaries between NHS and community action may be blurred – for example in terms of publicising vacancies through multiple formal and informal routes. Moreover, the NHS may not always be aware of community initiatives that they could link up with (such as local council drives to attract workers across all sectors of the economy).

3.0 Study Design

3.1 Study Description

This is a qualitative case study design with three components:

1) Mapping: we will identify 6 diverse remote and rural communities as case study sites, 3 in Scotland (including Highlands and at least one island community) and 3 in England. Sites will be identified drawing on our existing network of PPI, professional contacts, supplemented by a public-facing blog to invite communities to send in examples of initiatives. In each site we will conduct an initial site visit (if possible) and focus group to identify, describe and categorise different types of community-led recruitment and retention initiatives which have been tried. Participants may include

local councillors/council officials and representatives of other local community organisations (e.g. Chambers of Commerce, Tourist Boards, schools).
2) Interview study: we will conduct in-depth interviews with up to 30 people who have been involved in designing and/or delivering recruitment and retention initiatives in these areas, and professionals (including nurses and allied health professionals) and family members who have been attracted as a result of such initiatives.
3) Job advert/recruitment campaign analysis: as part of our existing workforce grant, we are already collecting examples of job adverts for doctors. We will extend this to include adverts for other professionals, identified both by interview and focus group participants, and by wider searching of publicly available sources.

4.0 Study Population

4.1 Sampling and Number of Participants

We will identify 6 local communities as case studies, 3 in Scotland (including Highlands and at least one island community, e.g. Ullapool and Orkney) and 3 in England (e.g. Yorkshire Dales and a coastal community). Scotland has one third of the UK's land mass but around 8% of its population; around 70% of that 8% are concentrated in the 'central belt' from Glasgow to Edinburgh. Thus Scotland offers comparatively much greater variation in degree and nature of remoteness to study than other parts of the UK.

The 6 local communities will be identified drawing on intelligence from our existing network of PPI and professional contacts, data from co-applicants' current studies of doctors' experiences of remote and rural working and variation in care provision in rural areas, desk based research and an online blog to garner further examples. We will purposively sample areas which a) have a long track-record of successfully recruiting and retaining healthcare staff, b) have previously had a history of vacancies but have overcome the problem, to help identify possible success factors, and c) continue to struggle with recruitment.

Measuring and classifying rurality is complex and challenging; methodologies differ slightly even within the UK. Scotland measures remoteness in terms of drive time to a settlement of 10,000 people or more (Scottish Government 2018), while in England measures include how sparsely or densely populated an area is (Office for National Statistics 2011). Mindful of this, aspects of variation we will consider in selecting our sample areas include:

- population size, composition and density;
- economy, affluence and employment/unemployment;
- internet and phone connectivity;
- degree of remoteness and transport links (for example being able to fly to Orkney makes it more accessible than isolated communities in the mainland such as Caithness);
- degree of tourism and attractiveness of natural environment (for example the Yorkshire Dales and the Western Highlands are popular tourist destinations, unlike some coastal communities in both North East and North West England and North East Scotland);

- cultural resources, societies and activities (for example Cromarty has a new 36-seat community enterprise cinema; Wick, with a population around ten times that of Cromarty, has no cinema).

For the mapping phase, an initial focus group will be held in each area chosen to understand the local context and identify, describe and categorise different types of community-led recruitment and retention initiatives which have been tried locally. Participants may include local councillors/council officials and representatives of other local community organisations (e.g. Chambers of Commerce, Tourist Boards, schools) who have been involved in recruitment initiatives. Participants will be invited to describe the context of their local economy and social life. We have allowed for a sample up to **6 participants per focus group**, but this will remain flexible. Our PPI partners advise us that the reality in some communities is that only a small number of people may have been involved in designing and supporting such initiatives or be aware of the range of initiatives undertaken. We will identify these participants through our existing networks e.g. PPI partners, advisory panel members, and local contacts who have expressed an interest in being involved in future research from our existing CSO study as well as through advertising (see Flyer) in/through local community groups whose details are freely open online.

We will then recruit a **purposive sample of approximately 30 interview participants across the same 6 areas**. The exact composition of the interview sample in each case study will vary depending on local context and who in each community is best placed to provide relevant information (Malterud et al 2016). Interviewees may include some participants from the mapping phase who wish to share experiences and reflections on a one-to-one basis; other community members who have been involved in local initiatives; and professionals (including doctors, nurses and allied health professionals) and family members who have been the intended audience of such initiatives and have been attracted to the area. Teenage children over the age of 16 may also be interviewed where relevant. We will identify these participants in a similar manner to our focus groups: using existing networks e.g. PPI partners, advisory panel members, and local contacts who have expressed an interest in being involved in future research from our existing CSO study as well as through advertising (see flyer) in/through local community groups whose details are freely open online. Further, we will also ask focus group participants to mention the research to relevant individuals as a form of snowball sampling. Potential participants, however, will have the free choice of whether to be a part of the research or not.

Our sample of job adverts and recruitment campaign materials will be inclusive of all examples we find during the course of the study. As part of an existing CSO grant, we are already collecting examples of job adverts for doctors. We will extend this to include generic healthcare recruitment campaign materials and job adverts (past and present) for other professionals, which will be identified both by interview and focus group participants, and by wider searching of publicly available sources over a six-month period. Where possible we will identify the outcome of adverts for individual posts.

4.2 Inclusion Criteria

Members, or former members, of the community in the 6 case study areas who have been, or were, involved in any way in planning or implementing community-led activities to help recruit or retain healthcare staff; staff and family members of staff (aged 16 or over) in those areas (See sampling for more detail)

4.3 Exclusion Criteria

- not speaking English or Gaelic (we have funding for interpreter and translator should an interviewee wish to talk in Gaelic)
- Inability to consent

5.0 Participant Selection and Enrolment

5.1 Identifying Participants

The 6 local communities will be identified drawing on intelligence from our existing network of PPI and professional contacts, data from co-applicants' current studies of doctors' experiences of remote and rural working and variation in care provision in rural areas and our online Blog. We will purposively sample areas which a) have a long track-record of successfully recruiting and retaining healthcare staff, b) have previously had a history of vacancies but have overcome the problem, to help identify possible success factors, and c) continue to struggle with recruitment.

In order to identify participants in our research site we will use multiple approaches including word of mouth, snowball sampling, whereby existing participants pass on details to other friends or relatives they think may be interested, as well as advertisements in local community groups (see: Flyer).

5.2 Consenting Participants

Focus Groups: Before the focus group, participants will have been sent an information sheet explaining the study and a copy of the consent form. If we are able to hold the focus groups in person, signed consent forms will be collected on the day. If they are held online the researcher will send each participant the information sheet and consent form at least 24 hours in advance to consider if they would like to participate in the research. The researcher will have a brief online conversation with each of the participants individually before a main focus group meeting, to test the equipment and get consent. We will attempt to do it as close to the event as possible. This is likely to be either on the day or the day before, depending on the availability and convenience of the participant. Consent will be recorded, transcribed, and the recording deleted. At the beginning of the focus group we will re-confirm with the participants that they still give consent to participate at the focus group.

Interviews: Before the interview, participants will have been sent an information sheet, at least 24 hours before any interview, explaining the study and a copy of the consent form and given an opportunity to ask any questions about the study. If we are able to hold the interview in person, signed consent forms will be collected on the day.. At the beginning of the interview we will read out each statement on the

consent form and ask the participant to confirm verbally they agree with each statement. This will be recorded as part of the audio recording and be included in the transcript.

6.0 Study and Safety Assessment

This is a desk based, focus group and interview study to explore community-led initiatives have been tried to attract and retain healthcare staff and their families in remote and rural areas. It does not raise any substantial safety issues.

7.0 Data Collection and Management

7.1 Data Collection

Interviews and focus groups will be recorded using a digital recorder or Microsoft Teams. In accordance with the standards of good qualitative research we will keep electronic versions of interview/focus group notes and a research diary. Recordings will be transcribed verbatim by a third party (Approved by the University) and checked for accuracy.

7.2 Data Management System

Participants will be assigned a unique identifier. All electronic resources will be stored on the University of Aberdeen server, with access restricted to the study team. Interviews and focus groups will be transcribed into MS Word documents which will be stored securely on the University of Aberdeen server, with access restricted to the study team. Any notes will be anonymised and not shared outside the research team.
Participants are free to withdraw at any time. However, data collected up until the point of withdrawal may still be used in analysis.

We will not be accessing medical records or medical data for the participants. Identifiable material from all participants (e.g., names, demographic details) will be stored separately to any transcripts on a spread sheet or log and used for linking to anonymised data. This spread sheet or log will be restricted and only accessible by the researchers. Anonymised data will be stored and subsequently archived on the secure networked PCs of the University of Aberdeen according to its Research Governance Guidelines. It will be stored on password protected University of Aberdeen devices and systems.

8.0 Data Analysis

8.1 Proposed Analysis

We will adopt a modified grounded theory approach (Charmaz 2014), analysing interview and focus group findings thematically (Braun and Clarke 2006) and iteratively. To facilitate cross-case comparison we will develop detailed case descriptions for each site. For job adverts we will analyse both visual and text data, and develop a taxonomy of types of initiatives. Data collection and analysis will be

informed by 'asset-based community development' (Kretzmann and McKnight 1993).

8.2 Transfer of data

To transfer data securely between colleagues both inside and outside the University, researchers will use the University Approved File Transfer Services, either ZendTo (which is available at https://zendto.abdn.ac.uk/), or via Office 365s Sharepoint system.

9.0 Inspection of Records

The PI, CO-Is and all institutions involved in the study shall permit study related monitoring, audits, and REC review. The CI agrees to allow the Sponsor or, representatives of the Sponsor, direct access to all study records and source documentation.

10 Good research practice

10.1 Ethical Conduct of the Study

The study will be conducted in accordance with the principles of good research practice (GRP).
A favorable ethical opinion will be obtained from the appropriate university ethics committee prior to commencement of the study.

10.1.1 Confidentiality

Participants will be assigned a unique ID number. Any field notes will use the ID number and this will not be shared out with the study team. All audio-recordings and transcripts will be anonymised to ensure confidentiality. In any presentations/publications, we will be careful to avoid providing details of specific local communities that might identify individuals in R&R communities. If required to maintain confidentiality, places and people will be given pseudonyms.

All forms, documents, audio files, reports, and other records will be identified in a manner designed to maintain participant confidentiality. All records will be kept in a secure storage area with limited access to study staff only, except as necessary for monitoring and auditing by the Sponsor or its designee. The PI and study staff involved with this study will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the Sponsor or its designee will be obtained for the disclosure of any said confidential information to other parties.

10.1.2 Data Protection

The study team involved with this project will comply with the requirements of the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. The

HRA recommended wording to fulfil transparency requirements under the GDPR for health and care research has been included in the PIS.
The study team will also adhere, if appropriate, to the current version of the NHS Scotland Code of Practice on Protecting Patient Confidentiality. Access to collated participant data will be restricted to the study team.
Computers used to collate the data will have limited access measures via user names and passwords.
Published results will not contain any personal data that could allow identification of individual participants.

10.1.3

The University of Aberdeen is sponsoring the study.

Insurance –

- The University of Aberdeen will obtain and hold a policy of Public Liability Insurance for legal liabilities arising from the study.

Indemnity: The Sponsor does not provide study participants with indemnity in relation to participation in the Study but has insurance for legal liability as described above**.**

11. Study Responsibilities

11.1 Protocol Amendments, Deviations and Breaches

The study team will seek approval for any amendments to the Protocol or other study documents from the Sponsor and SERB. Amendments to the protocol or other study docs will not be implemented without these approvals.
In the event that there is a need to deviate from the protocol, the nature of and reasons for the deviation will be documented and submitted to the Sponsor. If this necessitates a subsequent protocol amendment, this will be submitted to the Sponsor for approval and then to the appropriate REC for review and approval.
In the event that a serious breach of GRP is suspected, this will be reported to the Sponsor immediately using the form "Breach Report Form".

11.2 Study Record Retention

Raw data such as paper field notes, electronic scans of the field notes, and typed notes will be retained for 6 years after study end date. However, audio recordings/video recordings will be destroyed at the end of the project, i.e., 15 months.

11.3 End of Study

The end of study is defined as the last day of funding. However, our analysis of data will continue beyond this date to support the development of further publication and synergies with other related grants and research. The Sponsor, CI and/or the SC have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the Sponsor and REC within 90 days, or 15 days if the study is terminated prematurely. The CI will ensure that any appropriate follow up is arranged for all participants.
A summary report of the study will be provided to the Sponsor and REC within one year of the end of the study.

12. Reporting, Publication and Notification of Results

12.1 Authorship Policy

Ownership of the data arising from this study resides with the study team and their respective employers. On completion of the study, the study data will be analysed, and a study report will be prepared.

12.2 Publication

The study report will be used for publication, teaching purposes and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study.

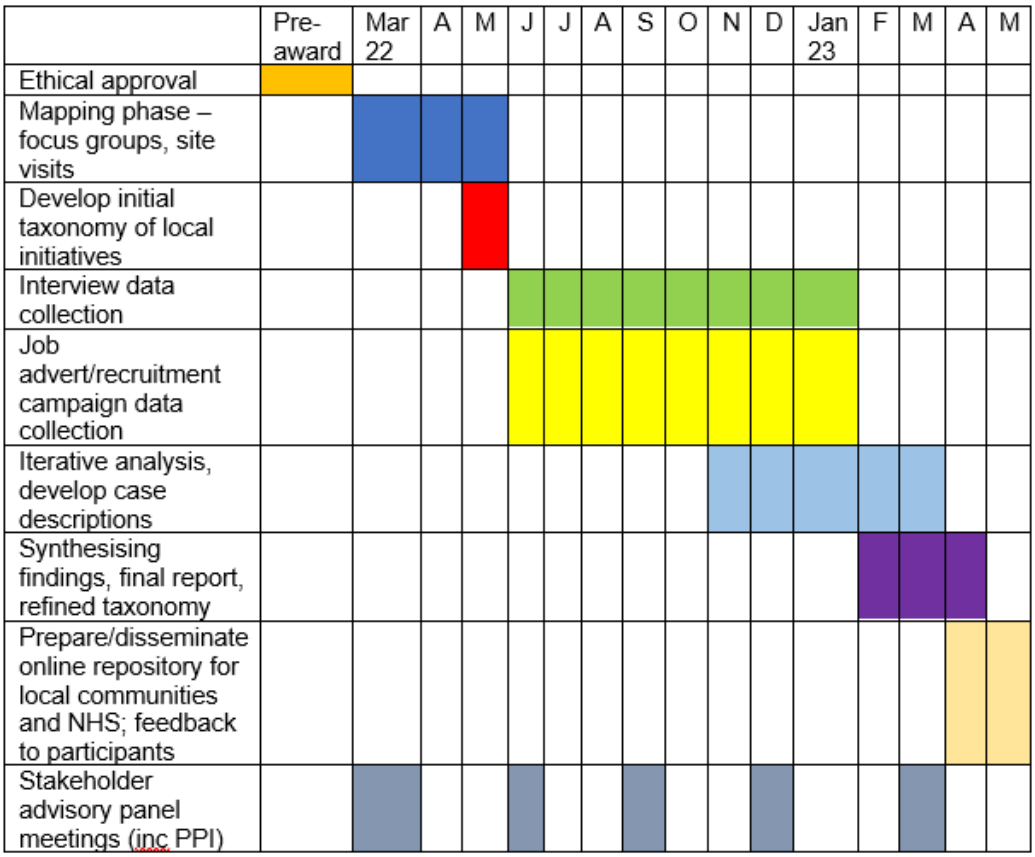
12.3 Peer Review

We will not seek an additional internal review prior to submitting for SERB approval. This study has already been internally peer reviewed prior to funding application and externally peer reviewed over two rounds as part of the NIHR funding process and this documentation will be submitted as part of the SERB application.

12.4 Reporting to Participants

All participants will have the opportunity to receive a summary of the study results and a thank you for participating. This will be an optional statement on the informed consent form for interviews.

Appendix 1: Timeline



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