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Inclusivity Checklist for Clinical Research

	Checklist item	Yes	No	NA
Setting research priority and research question				
1	Describe the diversity of the target population.			
2	Engage with under-represented communities relevant to the target condition.			
3	Include members of the community as research partners.			
4	Evidence activities that raise awareness of and promote interest in the study amongst under-represented communities.			
Research Inclusion considerations				
5	Describe the Research Inclusion Plan in the study protocol.			
6	Budget for the Research Inclusion Plan in the funding application.			
7	Designate individual(s) responsible for delivering the Research Inclusion Plan.			
8	Document diversity of the research team.			
9	Embed an evaluation of the Research Inclusion Plan in the study. *(optional)*			
Study design				
10	Describe how inclusion and exclusion criteria mitigate discriminatory bias.			
11	Document how protocol flexibility accommodates the needs of under-represented groups.			
12	Pre-specify representative recruitment targets, ensuring these are reviewed throughout the research.			
13	Document the use of decentralised trial methods (move research delivery into communities) or non-traditional trial designs. *(optional)*			
14	Include options for partial participation, assent, and permission for future study contact in the consent form. *(optional)*			
Study delivery				
Recruitment and retention strategies				
15	Document how recruitment strategies are multiple, diverse, and flexible to address inclusivity.			

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	Checklist item	Yes	No	NA
16	Specify mechanisms of feedback about recruitment and retention with recruiting sites and under-represented groups.			
17	Document plan for inclusion of research sites from geographically under-represented areas.			
18	Document that research staff have received training in cultural competence, implicit bias, and inclusive communication.			
19	Document how people with lived experience of the target condition, clinicians, and healthcare professionals have helped with recruitment of under-represented groups.			
20	Document strategies used to increase accessibility for participants from under-represented communities (e.g. compensation, logistics, and travel arrangements).			
Communication Strategy				
21	Document steps to ensure study materials such as Patient Information Leaflets and Consent Forms are short, simple, and written in easy-to-read language.			
22	Document the strategies available throughout all stages of the research for people with communication difficulties (e.g. do not speak English, sight or hearing impairments).			
23	Document how communication strategies reflect participant preference.			
Data Collection and Reporting				
24	Collect comprehensive demographic data on participants.			
25	Report results stratified by under-represented characteristics or sub-groups.			
Impact, dissemination and engagement				
26	Document dissemination of research results to participants and wider relevant communities.			

We would like to acknowledge everyone who has contributed their expertise and time in the production of the Inclusivity Checklist.
We would especially like to thank our patient, community and public partners who have steered and shaped this project.

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Glossary of terms

Term	Other terms used in literature	Definition
Under-represented	Under-served	These terms are often used interchangeably in health research. However, under-served generally refers to groups of people that don't have equal access to healthcare and research-based treatments and consequently experience poorer health outcomes. Under-represented refers to groups of people that are less represented or included in research that one would expect from population estimates.
Research inclusion	Equality, Diversity, and Inclusion (EDI) in research	The practice of including and accommodating people who may face discrimination and exclusion, either directly or indirectly, due to characteristics such as the protected characteristics under The Equality Act 2010. Research inclusion ensures fair opportunity for all to participate in research.
Community Researcher	Community officers Community brokers Community liaison Research link workers Citizen scientist	A Community Researcher is a paid employment role as part of the research team. They are members from under-represented communities, and provide linkage of the research project to the communities. They may be employed on per project basis, although their role may be more effective in a long-term collaboration. Examples include Health Research Ambassadors that work with NIHR ARC West and Caafi Health.
Community Engagement Officer	Lay navigators Research champions Health ambassadors Community champions	More commonly found in organisations such as the NIHR, Community Engagement Officers represent the organisation and establish linkage with local communities. They may or may not be a member of under-represented communities. This is a paid employment role as part of the organisation.
Research Champions	Community engagement officer Public engagement coordinator	Research champions are individuals who undertake a role to promote and advocate research *generally* to other patients and members of the public; this is often done by individuals with the lived experience on a voluntary basis (with PPIE payment) and examples include NIHR Research Champions.
Study / Trial Management Group	Research team	Group responsible for research (from design, delivery to dissemination); ideally consist of stakeholders including researchers, clinical experts, patient and public representatives, and a Research Inclusion Lead.
Research Inclusion Lead	Diversity officer Research inclusion specialist	A member of the Study / Management Group who will have a primary role in drafting the Research Inclusion Plan, engaging with communities, keeping a log of activities, presenting research inclusion on agenda items in regular research meetings, monitoring inclusion progress, and providing feedback and updates to the communities.
Representative		In the context of research participation, the characteristics of interest in the research population is proportional to what one would expect from population estimates.

Guidance on the Inclusivity Checklist

	Checklist item	How
	Setting research priority and research question	
1	Describe the diversity of the target population. *Demographic characteristics may include age, gender, ethnicity, socioeconomic status, disability, and other under-represented characteristics*	• Check published literature, including clinical trials data, cardiovascular audits / registries, and data collected as part of routine care. • Speak with healthcare professionals treating the conditions about the characteristics of the people they treat. • Undertake preliminary scoping analyses of disease epidemiology where these have not been performed.
2	Engage with under-represented communities relevant to the target condition.	• Ideally, establish the research questions *with* the communities. What are important questions that the communities want answered? • Explore existing community partnerships, patient advocacy groups, patient support groups, charities, and PPI networks at local, regional or national level. See Appendix 1 for a list of existing PPI groups within cardiovascular research. • Link with other researchers involved in community engagement activities and use their links to partner with community groups. • Case Study 1: NIHR Leicester BRC Dance & Health Project • If no known community partnerships exist, identify community leaders and begin building partnerships. This may involve speaking with local religious leaders, organisers of regular community meet-ups, public relations officers at charitable organisations, or patient and community engagement officers within institutions or organisations.
3	Include members of the community as research partners. *This may be either as a patient or public representative on the trial/study management group or a "Community Researcher" involved with the local research team.*	• Highlight to the community the significance of their involvement in health research and invite them to take part in steering the research. Resources such as a spoken word film 'INVISIBLE' may be useful to share. • Ensure clearly defined Terms of Reference for Patient and Public Involvement (PPI), or job specification for Community Researchers. See Appendix 2 for examples. • Provide adequate training to research partners. This includes training for PPI or research delivery such as facilitation skills. • Payment should be provided for PPIE as per NIHR guidelines; Community Researchers as per institutional employment policy. • Case Study 2: Deep End Research Alliance (DERA) and Community Research Link Workers. DERA also provides a useful Community Researcher Toolkit for consideration. • Diversify existing PPIE groups or establish new PPIE group.

	Checklist item	How
		• Ensure mechanisms are in place to allow feedback to the community regarding priority setting and milestones throughout the research cycle, using principles of Community Based Participatory Research (CBPR).[1,2] CBPR is an equitable and collaborative research approach involving community members, researchers, and stakeholders.
4	Evidence activities that raise awareness of and promote interest in the study amongst under-represented communities.	• Undertake community outreach and educational events to build relationship and promote trust. • Engage with local communities by attending local events or festivals and celebrations. For example, having a 'market stall' to share health-related knowledge and promote research study at monthly events within the local community centre. • Implement marketing strategies involving promotion and branding. For example, using a study-specific logo on all participant facing material.
	Research Inclusion considerations	
5	Describe the Research Inclusion Plan in the study protocol.	*This is now mandatory for all NIHR submissions.* • Present the study to community groups and relevant PPI to identify barriers to participation and potential solutions. For example, mobile apps may be challenging for people who are older with lower digital literacy; paper version alternatives should be provided instead. • Refer to existing guidance on EDI plan. Some resources are included here: ○ NIHR INCLUDE. The NIHR-INCLUDE Project and Trial Forge have multiple frameworks including ethnicity, impaired capacity to consent, and socioeconomic disadvantage. ○ Leicester Centre for Ethnic Health Equality Impact Assessment ○ Leicester Centre for Ethnic Health Toolkit for Increasing the Participation of Rural and Coastal Communities in Health and Social Care Research ○ FOR Equity web-based tools and resources to reduce social and health inequalities ○ HRA/MHRA Inclusion and Diversity Guidance [currently under consultation] ○ NIHR Research Inclusion Toolkits Hub • Case study 3: Research Inclusion Plan from the CORAL study (NIHR152257)
6	Budget for the Research Inclusion Plan in the funding application.	• Contact your funding body to see if they offer a dedicated consultation on enhancing community engagement and inclusion in research. • Consider including costs for a Research Inclusion Lead (see 7 below). • Budget for Community Researchers, training resources and upskilling of research team, interpreting & translation services, alternative communication resources including visual aids, videos and animations.

	Checklist item	How
		• Consult your wider department and institutions locally or nationally to identify established resources to improve inclusion. • See Appendix 3 for further considerations in costing inclusive research.
7	Designate individual(s) responsible for delivering the Research Inclusion Plan.	• Appoint a Research Inclusion Lead if resources permit. • Alternatively, designate a member of the Study/Trial Management Group with knowledge and interest on research inclusion and diversity. • If not possible, have the Research Inclusion Plan as a permanent review item on the agenda of research meetings to ensure its implementation.
8	Document diversity of the research team.	• Consider 'positive action' measures when hiring new researchers. • Extend the research team to include Community Researchers. • If possible, principal investigators (PI) at recruitment sites should reflect under-represented characteristics (e.g. women, people from an ethnic minority)
9	Embed an evaluation of the Research Inclusion Plan in the study. *(optional)*	Methods of evaluation include: • Keeping a log of activities related to the Research Inclusion Plan (who implements each component and how) • Collecting information on use of specific components of the research plan (e.g. how often are interpreting services and translated study materials used, how many participants are recruited through Community Researchers or social media campaigns) • Questionnaires to recruiters and participants about acceptability and usability of specific components of the inclusion plan
	Study design	
10	Describe how inclusion and exclusion criteria mitigate discriminatory bias.	• Consider whether the proposed criteria directly or indirectly discriminate against groups of individuals. For example, specifying that people should be "able to read and understand English" excludes people who do not speak English well or at all. Participant use of digital technology (e.g. mobile phone app) excludes those without phone or internet access or have lower digital literacy. • Use validated measures in inclusion and exclusion criteria rather than proxy measures. For example, the Frailty Index should be used instead of an age cut-off in frailty-related studies.
11	Document how protocol flexibility accommodates the needs of under-represented groups.	• Consider preference-based randomisation to allow inclusion of more under-represented participants (if appropriate). • Consider elements of the protocol which could be optional, to allow for partial trial participation (if appropriate).

	Checklist item	How
		• Consider making secondary or exploratory objectives optional (if appropriate). • Consider offering research procedures as both individual and group options, depending on participant preferences. • Consider reasonable adjustments that may be required for a participant to complete a study (e.g. having carer or family support to attend appointments, budgeting double time for trial activities where interpreter is required). • Establish referrals to support services for participants who experience social inequalities.
12	Pre-specify representative recruitment targets, ensuring these are reviewed throughout the research.	• Recruitment targets should be set through discussions between the research team, under-represented communities, and other relevant stakeholders. • Targets should be reviewed regularly throughout and after the research, and the results shared with all stakeholders including funders providing an EDI budget.
13	Document the use of decentralised trial methods (move research delivery into communities) or non-traditional trial designs. *(optional)*	• Consider conducting trial-related activities digitally, at homes of trial participants or at a healthcare facilities local to trial participants where possible. • Provide the option of remote or telemedicine research visits and procedures • NIHR provides further guidance and case studies on decentralised trials here • HRA also provides links to key resources here (see section on Links to key resources) • Consider non-traditional trial designs, if appropriate, such as the hub and spoke model or a nested trial design • Case study 4: BCIS4, an RCT utilising the hub and spoke model for delivery • Case study 5 ROMA-WOMEN, a nested trial dedicated to women
14	Include options for partial participation, assent, and permission for future study contact in the consent form. *(optional)*	• Assent options, such as questionnaire completion with help from others, should be considered in scenarios of impaired capacity during trial participation. • If appropriate, include options for partial participation. For example, if collecting multiple tissue samples such as blood, saliva, and urine, allow participants the choice of samples to donate. • Include other optional clauses around contact about other research studies in the future. For example, “I agree to being contacted with details of future relevant research and to my contact details being stored at [location] for this purpose.”
	Study delivery	
	Recruitment and retention strategies	
15	Document how recruitment strategies are multiple, diverse, and flexible to address inclusivity.	• Depending on the context of the study, utilise any of the following:

	Checklist item	How
		○ Advertise the research study as widely as possible using patient or research registries, health service directories, direct mail letters using GP lists, word of mouth referrals, local community groups, NIHR Patient Recruitment Centres. and external vendors. A small list of known external vendors is available in Appendix 4. ○ Implement offline recruitment strategies in locations relevant to populations of interest. For examples, places of worship, supermarkets, pharmacies, public libraries, local events, barber shops, and community centres. Other methods may include public transport advertisement, media advertisement such as specific radio stations, or billboards in areas where the target population lives. ○ Implement online recruitment through digital platforms such as social media, NHS app, online forums, and media sources which is accepted by the populations of interest. • Consider the QuinteT Recruitment Intervention (QRI) or similar qualitative research embedded within trials to optimise recruitment.
16	Specify mechanisms of feedback about recruitment and retention with recruiting sites and under-represented groups.	• This should detail mechanisms for discussion around recruitment and retention with: ○ Recruiting sites; regular communication to identify barriers to recruitment ○ Under-represented communities involved with study; to continue engagement and optimise recruitment and retention. This discussion should start as early as possible, ideally at the study design stage. ○ Study participants; see item 23. • Provide and discuss recruitment progress by under-represented characteristics at Trial / Study Management Group meetings.
17	Document plan for inclusion of research sites from geographically under-represented areas.	• Identify neighbourhoods or postcodes with high socioeconomic deprivation using Indices of Multiple Deprivation/ Lower-layer Super Output Area Level and target recruitment of sites at these areas. • Use UK Census data to identify population demographics (e.g. health, religion, ethnic group, economic activity, household deprivation, etc.) in different areas of the UK. • Consider embedding sub-studies in specific geographical areas to target under-represented populations.
18	Document that research staff have received training in cultural competence, implicit bias, and inclusive communication.	• Mandate inclusion training, similar to mandated Good Clinical Practice (GCP), for all members of the research team. • Available training modules: ○ *NIHR Learn modules* (free), including:

	Checklist item	How
		○ Introduction to cultural sensitivity in research ○ Inclusive language and communications guide ○ Increasing participation of ethnic minorities in health and social care research ○ EDI in Health and Social Care Research ○ Research involving participants lacking mental capacity ○ *Leicester Centre for Ethnic Health* *Cultural Competency Training* (£400; 50% discount for public sector organisations) • Use the above resources and your community partnerships / patient advisory groups to create a bespoke training plan that meets the needs of your study • Dedicate time during all Site Initiative Visits (SIV), if applicable, to research inclusion. This should at the minimum address the Research Inclusion Plan of the specific study, training on importance of diversity, resources dedicated to the specific study such as translation, interpretation, and budget for longer visits.
19	Document how people with lived experience of the target condition, clinicians, and healthcare professionals have helped with recruitment of under-represented groups.	• Ask recruiters (for example, clinicians and healthcare professionals) to target recruitment of study participants with under-represented characteristics. • Provide endorsement by patients with lived experience, such as weblinks to patient experience videos on the participant recruitment flyer or participant information leaflet; or by clinicians demonstrating support for research participation during clinical consultations or via letters of support.
20	Document strategies used to increase accessibility for participants from under-represented communities (eg. compensation, logistics, and travel arrangements).	Consider providing: • Compensation for time and expenses (reimbursement may be monetary or vouchers). • Reimbursement for care (e.g. childcare or other care responsibilities). • Provide snacks or meals if research visits are prolonged. • Accessible and flexible study locations, such as home visits, local clinics, GPs, or community venues • Transport options, including free parking, transport (e.g. taxi) or reimbursement of transport cost. • Extended office hours and or ensure contact is available out of hours. • Align study protocol with clinical visits to increase efficiency and fewer study visits.
	Communication Strategy	
21	Document steps to ensure study materials such as Patient Information Leaflets and Consent Forms are short, simple, and written in easy-to-read language.	• Use health literacy guidelines and plain English to write participant facing materials. • Use readability tools such as FOG index to assess participant facing materials. • Remove *all* jargon from participant facing materials.

	Checklist item	How
		• Provide a top-page concise overview of the research study on the Participant Information Leaflet (PIL). • Co-produce study material with individuals from under-represented communities. • Include visuals and text-enhancing images. The images used should reflect the population of interest (e.g. ethnic diversity, disability) if possible. • Include pilot or feasibility study result in PIL where available. • Culturally adapt the materials where possible. This may include tailoring study materials using accepted terminology or exploring feelings of relevant communities and addressing these in the materials. • Case study 6: the ADAPTABLE study, an example of culturally tailored recruitment material • Incorporate multimedia use such as animations and videos for people with low literacy. • User language to appeal to people's motivation, e.g. use phrases such as "Can you help?" to appeal to a potential participant's altruistic motives. • For complex materials, layer information starting with the most important message. • Consider design aesthetics of materials, including images, colour, font style, size, and branding. • See Appendix 5 for additional resources for creating participant facing material including readability checkers.
22	Document the strategies available throughout all stages of the research for people with communication difficulties (e.g. do not speak English, sight or hearing impairments).	• Budget for translation (forward and backward translation) of participant facing materials and interpreting services including but not limited to commonly spoken languages, British Sign Language, and braille. • If materials are translated, ensure post-translation review is undertaken by both professional agency as well as individuals from the communities. A post-translation review will check for errors and ensure the translation reads correctly especially after formatting; this is particularly important for languages that are not written left-to-right like English. • Explore the use of digital translation platforms (e.g. Pocketalk, DeepL, Google Translate) to introduce a study to potential participants who do not speak English. • Case study 7: Pocketalk • Employ multilingual staff or identify staff who can communicate in the native language with the population of interest. • With permission from study participants, include family members as much as possible throughout the research process.

	Checklist item	How
23	Document how communication strategies reflect participant preference.	• Make available multiple modes of communication such as email, telephone, video call, or post. • Capture the preferred communication method for each participant. • Have a dedicated study helpline or central email account that all participants can use. • Provide reminder calls or postcards for study visits and ensure vigorous follow-up for missed appointments • Provide regular study updates and frequent check-ins with participants (e.g. weekly or monthly follow-up calls or sessions) • Establish rapport with study participants using a personalised approach. Examples include: ○ Showing gratitude to participants ○ Staff introduction using first name ○ Allowing participants the option to choose how they would like to be addressed ○ Staff self-disclosure (where applicable) to build relationship ○ Dedicated time and space for participants to ask questions ○ Birthday and thank-you cards
	Data Collection and Report	
24	Collect comprehensive demographic data on participants.	• Collect demographics as part of study data with ethical approval. This may require explicitly asking participants their ethnicity or other characteristics as these are often poorly documented in medical records. It is also important to ensure and reiterate transparency to participants as to why specific demographic data is being collected. • Utilise Diversity and Inclusion Survey (DAISY) questions as part of diversity monitoring in research. • Collect anonymised demographic data on eligible population who refuse participation or are not being approached. • Collect data on reasons for participant drop out. • Allow for proxy completion of data where possible (family members, friends, care workers or clinicians).
25	Report results stratified by under-represented characteristics or sub-groups.	• Describe study outcomes by under-represented characteristics. • Consider conducting sub-group analysis by under-represented characteristics (pre-specify analysis by under-represented characteristics in the statistical analysis plan)
	Impact, dissemination and engagement	

	Checklist item	How
26	Document dissemination of research results to participants and wider relevant communities.	• Utilise mailing lists, social media platforms e.g. X (Twitter), and/or study-specific website to provide regular updates to participants. • Upon study completion, confirm whether the participant would like to receive a copy of the study result and provide an approximate time frame as to when it may become available. • Create easy-read flyers or short educational videos of the research results in relevant languages and disseminate widely to research participants, relevant patient population, communities, charity groups and more. • Hold a 'celebration event' to share the research results and thank the wider patient and public contributions, including communities which have provided input into the research process.

Case Studies

The following case studies provide select examples of inclusive practices in cardiovascular research.

Case study 1: NIHR Leicester BRC Dance & Health Project, an innovative way of community engagement within existing research infrastructure
Case study 2: Deep End Research Alliance (DERA) and a model of community engagement through Community Research Link Workers (CRLWs)
Case study 3: Research Inclusion Plan from the CORAL study
Case study 4: BCIS-4, a multi-centre RCT using a hub and spoke delivery model
Case study 5: ROMA:WOMEN, an international RCT dedicated to women to improve coronary bypass outcomes
Case study 6: ADAPTABLE, an example of culturally tailored research recruitment materials
Case study 7: Using Artificial Intelligence (AI)-enabled pathway to increase participation of people who don't speak English into research studies

Case Study 1: NIHR Leicester BRC Dance & Health Project, an innovative way of community engagement within existing research infrastructure

Summary

The Dance and Health Project was established by the National Institute for Health Research (NIHR) Leicester Biomedical Research Centre (BRC) to promote public and community involvement in health research. It uses an innovative method of engagement – a weekly 60-min dance class to promote physical health, followed by 30 minutes of researcher-led discussion.

The Dance and Health Project was designed to reach participants from low-socioeconomic backgrounds and ethnic minority groups who are especially under-represented in cardiovascular research. Researchers can discuss research with communities in a safe space and fun environment.

The project's commitment to inclusivity and cultural relevance has received overwhelming positive feedback from both community members and researchers and is an exemplar of effective community engagement in research. Community engagement facilitated through a pre-existing programme means that researchers do not necessarily need to establish new partnerships, which may be time and resource intensive.

Key points

- Innovative and creative methods can promote research engagement with under-represented communities.
- Community engagement facilitated through pre-existing partnerships where these are available saves time and money and should be used whenever possible.
- Community engagement needs to be long-term, instead of a tokenistic one-off activity.

Additional information

- Website https://leicesterbrc.nihr.ac.uk/get-involved/

- Publication Pritchard, R., Darko, N. & Stevenson, E. Enhancing community engagement, public involvement, and social capital through researchers' participation in community dance projects: unexpected outcomes in ` communities. Res Involv Engagem **10**, 79 (2024). https://doi.org/10.1186/s40900-024-00616-9

- Contact detail NIHRLeicesterPPIE@uhl-tr.nhs.uk

Case Study 2: Deep End Research Alliance (DERA) and a model of community engagement through Community Research Link Workers (CRLWs)

Written by Dr Kate Fryer, Co-Lead and Project Manager of DERA

Summary

The Deep End Research Alliance (DERA) is a three-way partnership of patients, clinicians and academics. DERA aims to tackle health inequalities by designing and carrying out research in partnership with under-served communities, working at the intersection of ethnicity and socio-economic deprivation. Since 2021, DERA has been building partnerships with local communities and developed a model of community engagement that centres around Community Research Link Workers (CRLWs). The model works as follows:

1. Identify key people and organisations representing local ethnic minority communities.
2. Build relationships and establish trust.
3. Identify and train CRLWs: generic and project-specific.
4. Support CRLWs throughout study.
6. Evaluate and co-produce next steps.
7. Share outcomes of the study with the community.

We have shown that the CRLW model of engagement increases participation of people from ethnic minority communities in research when compared with other methods of engagement we have used in DERA. Community leaders and CRLWs said that sharing resources and power in the research process builds trust and interest in research participation in their communities.

DERA recommends a CRLW model which builds capacity and embeds reflective practice, mutual respect, and power sharing across the research team.

Key points

- Health research is often 'exclusive by design'.
- CRLWs are critical in ensuring culturally appropriate research while providing a balanced voice to research projects.
- CRLWs should be involved across all stages of research, from priority setting to disseminating outputs.

Additional information

- Website https://sites.google.com/sheffield.ac.uk/dera/research-within-communities/community-researcher-toolkit?authuser=0

- Contact detail DERA@Sheffield.ac.uk

Case Study 3: Example of Research Inclusion Plan from the CORAL study (COenzyme Q10 in heaRt fAiLure with reduced ejection fraction (CORAL, NIHR152257)

Summary

The CORAL study is a pragmatic randomised controlled trial (RCT) testing the effectiveness of co-enzyme Q10 in patients with heart failure. Participants are being recruited from General Practices across England. The CORAL researchers have developed and embedded an inclusivity intervention to increase participation of people from under-represented groups.

Intervention components include:

- targeted site selection in socioeconomically deprived areas
- recruitment and employment of Community Champions to engage minority populations
- cultural competency training for recruiting staff
- co-produced easy-read study materials
- interpreting and translation services, and
- financial incentives for all participants

Key points

- The inclusivity intervention was embedded and budgeted for at the design stage of the study.
- We will conduct an evaluation to collect data on the use, acceptability and cost of each intervention component.
- This evaluation will provide data to guide decisions about which inclusivity intervention components work best and should be incorporated in future studies.

Additional information

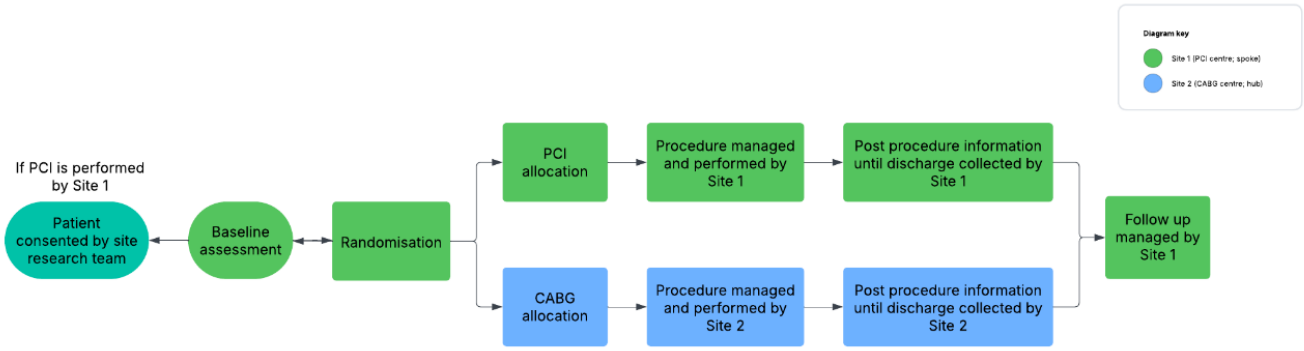
- Website	https://coral-study.bristol.ac.uk/
- ISRCTN Registration	https://doi.org/10.1186/ISRCTN26946710
- Contact detail	Dr Barbara Warnes, CORAL Trial Manager, coral-study@bristol.ac.uk Dr Rachel Johnson, CORAL co-Chief Investigator, rachel.johnson@bristol.ac.uk Dr Maria Pufulete, CORAL co-Chief Investigator, maria.pufulete@bristol.ac.uk

Case Study 4: BCIS-4, a multi-centre RCT using a hub and spoke delivery model

Summary
The BCIS4 trial compares the effectiveness of percutaneous coronary intervention (PCI, cardiac stents) and coronary artery bypass grafting (CABG, bypass surgery) for people with heart failure. It uses a hub and spoke study delivery model.

The hub and spoke model already exists in clinical care delivery and pathways – District General Hospitals (DGHs; spoke) offer angiography and PCI services, and may refer patients onwards to a regional tertiary hospital which offers CABG (hub). By utilising a hub and spoke model, more participants can be identified from geographically wider areas whilst reducing the need to travel long distances for research procedures. Similarly, smaller district hospitals are involved in research that would otherwise be delivered only in tertiary centres.

In BCIS4, participants may be identified at a PCI centre (site 1; spoke). If they were randomised to CABG, participants would attend the tertiary hospital for surgery (site 2; hub) and all research activities until the time of discharge would be conducted at the tertiary hospital. Subsequent research follow-up, however, would return to site 1 which is geographically closer to the participant's home location. See image below for schematic summary.



There are logistical and research governance complexities which needs to be managed often on a bespoke basis. As an example, in order to provide informed consent, eligible participants at the spoke site would need to have the opportunity to discuss the risks and benefits with a surgeon at the hub site. If there is no pre-existing agreement at the service level, additional hurdles including financial agreements and research capacity will all need to be addressed.

The HRA provides a template Hub and Spoke Agreements for consideration.

Key points

- The hub and spoke model includes more local hospitals that may not otherwise participate in research.
- This may yield additional eligible participants as well as improved retention rate.
- This model of delivery can be complex and participant pathways need to be carefully considered along with research governance and logistical challenges.

Additional information

- ISRCTN Registration https://doi.org/10.1186/ISRCTN29654606

- Contact detail bcis-4@leicester.ac.uk

Case Study 5: ROMA:WOMEN, an international RCT dedicated to women to improve coronary bypass outcomes

Summary
ROMA:Women is the first cardiac surgery trial enrolling only women. This approach is necessary as women are under-represented in cardiovascular research and specifically in research on the use of multiple arterial grafting (MAG) in coronary artery bypass grafting (CABG). Enrolling only women in the ROMA:Women trial addresses this evidence gap and ensures an adequate sample size to definitively answer whether MAG is best for women CABG patients.

There are several strategies which have proved successful in trial design and increasing recruitment of women:

1. Having women in the majority of Steering Committee positions (>75%)
2. Having patient representatives on the Steering Committee and participating in oversight
3. Strongly encouraging identification of women as principal investigators and study personnel
4. Interviewing women who declined to participate in ROMA or ROMA:Women, to obtain qualitative perspectives on why they chose not to participate
5. Nested trial design (or RCT within RCT). This makes use of the existing ROMA trial infrastructure and allows incorporation of all women patients from the main ROMA trial (n=690)
6. Actively promoting the ROMA:Women trial in the cardiovascular community through presentation at meetings, newsletters, social media, and email outreach.

UK enrolment is currently ahead of target and this approach is an example for cardiovascular trialists to consider when designing trials for women or other under-represented groups.

Key points
- Women are under-represented in cardiac surgery trials.
- ROMA:Women is the first cardiac surgery trial dedicated to women and will inform sex-specific CABG guidelines regarding the use of multiple arterial grafts in women.
- Designing trials specific for under-represented groups is feasible and can be used to address evidence gaps.

Additional information

- Website https://www.theromatrialwomen.com/

- Publications Gaudino M, Bairey Merz CN, Sandner S, et al. Randomized Comparison of the Outcome of Single Versus Multiple Arterial Grafts trial (ROMA):Women-a trial dedicated to women to improve coronary bypass outcomes. *J Thorac Cardiovasc Surg*. 2024;167(4):1316-1321. doi:10.1016/j.jtcvs.2023.06.006

Gaudino M, Fremes SE, Mehran R, Bairey Merz CN; ROMA:Women Steering Committee and Investigators. ROMA:Women: Innovative Approaches for the First Cardiac Surgery Trial in Women. *Circulation*. 2023;148(17):1289-1291. doi:10.1161/CIRCULATIONAHA.123.064033

- Contact detail roma@le.ac.uk

Case Study 6: ADAPTABLE, an example of culturally tailored research recruitment materials

Summary
Cultural tailoring of recruitment materials is often suggested as a strategy to promote the enrolment of under-represented groups in clinical trials. However, there is a lack of guidance for research teams to create such materials. In this study, the authors described the development of guidelines for cultural tailoring of recruitment material for African Americans and Latinos. The developed guideline was pilot tested in the ADAPTABLE study, a large pragmatic trial on the optimal dose of aspirin for secondary prevention in patients with atherosclerotic cardiovascular disease.

Specific considerations for images and language used in recruitment material were suggested depending on the population of interest:

- Use of visuals recognised by the population (e.g. image of research participants)
- Use of preferred terminology by the population (e.g. avoid using 'disease' which has a negative connotation, or use inviting words such as 'learn' instead of 'join')
- Address informational needs specific to the population (e.g. emphasis on confidentiality)
- Specify incentives for study participation (e.g. health risks and benefits)

Tailored vs non-tailored recruitment banner for Facebook campaign in the ADAPTABLE study is presented below. In the pilot study, the authors reported significantly higher clicks per impression ratio and enrolled a greater percentage of African American using tailored compared to non-tailored ads (13% vs 8%, respectively).

	Original	Tailored
Ad		
Image(s)	Multicultural group sitting at a table smiling for the camera	Multigenerational Black families actively engaged
Messaging	Focus on study and researchers	Appeal to altruism ("we need you!") Value of participating
Language	Uses the word "disease", which may have negative connotation Focuses on being "eligible" Uses the term "cardiologists," which may be unfamiliar	Focuses on learning about the study Avoids using the word "disease" Includes a call to action Uses the term "heart doctor" instead of "cardiologist"
Readability	Flesch Reading Ease: 63.2 Flesch-Kincaid Grade Level: 7 Passive Sentences: 25%	Flesch Reading Ease: 80.3 Flesch-Kincaid Grade Level: 5.4 Passive Sentences: 0%

Key points

- Cultural tailoring of recruitment material can and should be done, starting with a focus on language and images.
- Participant facing materials, including recruitment material and participant information leaflet, should be co-produced with the population of interest.

Additional Information

- Publication Cunningham-Erves, J., Kusnoor, S.V., Villalta-Gil, V. *et al.* Development and pilot implementation of guidelines for culturally tailored research recruitment materials for African Americans and Latinos. *BMC Med Res Methodol* **22**, 248 (2022). https://doi.org/10.1186/s12874-022-01724-4

Case Study 7: Using Artificial Intelligence (AI)-enabled pathways to increase participation of people who don't speak English into research studies

Summary
People who do not speak English well or at all are often excluded from research studies because it can be difficult to organise an interpreter and translate patient information material quickly enough to introduce the study in their language.

For example, people who have urgent heart surgery (about half of the heart surgery population) are transferred from their local hospital to the heart surgery centre at short notice and often on the day before their operation. Research nurses therefore only have a narrow window in which to introduce a research study to them.

We designed an AI translation pathway making use of a hand-held device called the Pocketalk to translate the first conversations that researchers have with people about a study and online translators to rapidly translate the patient information leaflet.

In preliminary testing within our team, we found that simple and concise English language avoiding jargon and colloquialisms, short sentences, subject-verb-object sentence structure, using the same verb tenses throughout resulted in good translations in all languages tested (Romanian, Italian, Portuguese, Spanish, Arabic, German, Malayalam)

We have applied for funding (NIHR research for Patient Benefit) to conduct a proof-of-principle study to test this AI translation pathway.

Key points

- Using online translators allows recruiting staff to introduce a study to a potential participant quickly in their language.
- This can be followed up with standard NHS interpreting / translation service.
- We are conducting a study to test the usability and acceptability of the AI translation pathway with patients and recruiters.

Additional information

- Website *https://www.pocketalk.com/en_gb/*

- Contact Emma Hopkins (Cardiac Research Sister, Bristol Heart Institute): emma.hopkins@uhbw.nhs.uk
Maria Pufulete (Bristol Medical School): maria.pufulete@bristol.ac.uk

Appendices

The following appendices provide additional resources; however, they are not intended to be exhaustive. If you are aware of additional resources and would like them added to the appendices please contact heartsurgerypsp@leicester.ac.uk.

Appendix 1. Existing PPI Groups in Cardiovascular Research
Appendix 2. Examples of terms of Reference for Patient and Public Involvement; Job specification for Community Researchers
Appendix 3. Template for costing research inclusion
Appendix 4. External vendors for research recruitment
Appendix 5. Additional resources to consider when creating participant-facing material

Appendix 1. Existing PPI Groups in Cardiovascular Research

Group	Brief Description	Contact
National Cardiac Surgery PPI Group	Established as part of the National Cardiac Surgery Cardiac Trials Initiative, the National Cardiac PPI Group is a collection of committed individuals who have lived experience of heart disease in one form or another. They work alongside clinicians and researchers to develop research trials that mean something to patients.	https://le.ac.uk/cardiovascular-sciences/about/heart-surgery/national-ppi-group Email: heartsurgerypsp@leicester.ac.uk Phone: +44(0)116 252 2188
Heart Research UK Patient and Public Network	Patient and public members living in the UK with experience of living with or caring for someone with a heart condition. The group's purpose is to help form HRUK's strategy, inform and guide their charity activities and the research they fund.	https://heartresearch.org.uk/patient-and-public-network/ Email: info@heartresearch.org.uk Phone: +44(0) 113 234 7474
BHF Heart Voices	Community of people with lived experience with a heart or circulatory condition who help shape the work at British Heart Foundation.	https://www.bhf.org.uk/for-professionals/information-for-researchers/how-to-apply/patient-and-public-involvement Email: heartvoices@bhf.org.uk
Heart Valve Voices	UK's dedicated heart valve disease charity who works with patients and clinicians to help increase awareness of heart valve disease.	https://heartvalvevoice.com/ Email: info@heartvalvevoice.com
The Aortic Dissection Charitable Trust	UK & Ireland charity uniting patients, families and the medical community in a shared goal of improving diagnosis, increasing survival and reducing disability due to aortic dissection.	https://aorticdissectioncharitabletrust.org/ Email: heretohelp@tadct.org
Take Heart Leicester	Local patient support group for adult cardiac patients, based at the University Hospitals of Leicester.	https://takeheartleicester.co.uk/ Email: thl@takeheartleicester.co.uk Phone: +44(0) 7970075039
Cardiovascular Care Partnership UK (CCPUK)	National cardiovascular charity, affiliated to the British Cardiovascular Society (BCS) which supports patients with cardiovascular disease and associated conditions, their carers and also other cardiovascular support groups. The group's overall purpose is to be the patient & carer voice for the BCS.	https://www.ccpuk.org.uk/ Email: ccp@bcs.com
International Heart Spasms Alliance	International Heart Spasms Alliance (IHSA) is dedicated to supporting those affected by unseen heart issues.	https://www.internationalheartspasmsalliance.org/ Email: ihsacontact@gmail.com

	IHSA serves both the patient and medical communities by educating, informing, and enlightening them to help achieve earlier diagnoses, better treatments, and support research into these conditions.	
UK Vascular Research PPI Registry	A list of volunteers with personal experience of, or an interest in, vascular conditions such as PAD and Abdominal Aortic Aneurysm (AAA). Members on the Registry are contacted when new vascular research studies are being discussed by health professionals, to ensure that patient and public opinions and experience are included within the design.	Email: PPIVasc@leicester.ac.uk
Pumping Marvellous	The UK's patient led heart failure charity. The Foundation's goal is to deliver HOPE to its recipients through the facilitation of better outcomes by cross-working and advocating at a local, regional, national, and international level. Working hand-in-hand with all stakeholders to deliver better pathways and be the patient voice of progression.	https://pumpingmarvellous.org/ Email: hearts@pumpingmarvellous.org Phone: +44(0) 177 279 6542
Somerville Heart Foundation	The only UK-wide charity dedicated to supporting young people and adults born with all forms of Congenital Heart Disease. They provide support, advocacy, communication, and a community for those we are here to help. They also campaign for their rights to receive excellent medical care to enable them to lead happy, healthy, and longer lives.	https://sfhearts.org.uk/ Email: info@sfhearts.org.uk Phone: +44(0) 1473 252007

Appendix 2. Examples of Terms of Reference for Patient and Public Involvement; and Job Specification for Community Researchers

The roles of patient, community, or public members as research partners need to be clearly defined. Below we provide the Terms of Reference of a National PPI group and an exemplar job specification for a patient as researcher, which can be applied to the role of a community researcher.

- National Cardiac Surgery PPI Group Terms of Reference
- Job specification for a patient researcher, which can be applied to community researcher.

Appendix 3. Costing for research inclusion

No standardised costing template exists for costing Research Inclusion. The NIHR, which mandates an inclusive research design as a condition of funding, provides the following advice:

NIHR Finance guidance for applicants, see "Research inclusion" under Costing assumptions

Include any costs related to ensuring your research is designed, recruited, delivered, and mobilised inclusively. This may be (but is not limited to) costs associated with:

- upskilling research teams with additional expertise relevant to equality, diversity and inclusion. For example, training in understanding how to work with specific groups relevant to the research, health inequalities, reasonable adjustments etc.
- inclusive recruitment materials or strategies to attract and retain diverse participants, or those from under-served communities and places
- adjustments to research materials, protocols, methods, or events. This ensures participation and retention of diverse groups
- purchasing specialist software or services
- additional or alternative data collection. This is to ensure data collected from the relevant population is robust, or that findings can be fully applied to different populations
- additional sites or locations to carry out your research
- inclusively mobilising research findings

Clearly detail staff costs associated with research inclusion should be clearly indicated and included in the 'Staff costs' section. NIHR acknowledges that research delivered inclusively may take longer, and this may result in increased staff costs.

Costings for reasonable adjustments that you, or any co-applicants may require, should not be included under the research inclusion costing. Please attribute these costs under 'Other direct costs'.

The following items may be helpful to consider when costing for research inclusion. They are by no means exhaustive, and the exact items will depend on the study proposed and its Research Inclusion Plan.

Budget Item
Staff cost
Community researcher(s)
Community Engagement Officers
Research Inclusion lead
Patient, public, and community involvement
Community engagement (consider venue, travel, catering, access to facilities, and any consumables)
PPI contributor payment if members of the community are part of study / trial steering group (consider the number of meetings involved throughout the whole research process)
Donation or financial support for community / patient group
Direct costs in research design and delivery
Non-conventional trial design (costing will be considered in SoECAT)
Advertisement cost (e.g. online and offline, printing, advert fees)
External vendor for recruitment assistance
Participant incentives
Financial reimbursement (consider food, travel, accommodation, childcare, carer costs)
Staff travel to participants
Communication & accessibility cost
Staff training on research inclusion

Development of communication resources (visual aids, videos, and/or animations)
Translation and back-translation costs for all recruitment material
Interpreter cost
Braille and audio material
Assistive technology hire
Any other reasonable adjustments required for research participation (e.g. increased visit time)
Participant testimonial videos
Administrative costs (e.g. study-specific website, telephone costs, postal stamps, and stationary)
Dissemination
Outreach and education events (consider venue, travel, catering, access to facilities, and any consumables) to disseminate result to relevant communities
Celebration event

Appendix 4. External vendors for research recruitment.

Group	Website
COUCH Health	https://couch.health/
Egality Health	https://egality.health/
Health Watch	https://www.healthwatch.co.uk/
Caafi Health	https://www.caafihealth.org.uk/

* Disclaimer: the authors of this checklist have no experience or affiliation with external vendors for inclusive research recruitment.

Appendix 5. Additional resources to consider when creating participant-facing material

Resource	Website	Description
Guidance on creating and designing recruitment materials		
NHS Health Research Authority (HRA)	https://www.hra-decisiontools.org.uk/consent/examples.html https://www.hra.nhs.uk/planning-and-improving-research/research-planning/participant-information-design-and-review-principles/	Examples and templates of participant information sheets from the Health Research Authority's Consent and Participant Information Guidance
NIHR Good Practice Guide: Inclusive Language and Communications	https://learn.nihr.ac.uk/course/view.php?id=1181 (NIHR login required)	This outlines and provides context to the five key principles for NIHR affiliated researchers to communicate inclusively.
University of Florida, Clinical and Translational Science Institute	https://www.ctsi.ufl.edu/research/participant-recruitment/recruitment-flyers/best-practices-for-recruitment-flyers/	Example patient information sheet with highlighted best practices on creating participant facing recruitment materials
University of North Carolina, Translational and Clinical Sciences Institute	https://tracs.unc.edu/docs/recruitment/Recruitment_Designing_Effective_Recruitment_Materials_20211006.pdf	Training presentation on designing effective participant facing recruitment materials
The Plain English Campaign	https://www.plainenglish.co.uk/free-guides.html	Series of guides to aid the use of plain English in written materials.
Readability checkers		
Flesch-Kincaid Grade Level test and Flesch Reading Ease test within Microsoft Office	https://support.microsoft.com/en-gb/office/get-your-document-s-readability-and-level-statistics-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2	A function which is available within Microsoft Words. Free online calculators also available from web searches.
Gunning Fog Index	http://gunning-fog-index.com	A readability checker that generates an index score by reading level.
Hemmingway Editor	https://hemingwayapp.com/	Hemmingway text editor, including readability checker.
Creating accessible documents		
Leeds Beckett University	https://teachlearn.leedsbeckett.ac.uk/-/media/files/clt/guide-to-alternative-and-accessible-formats.pdf	Leeds Beckett guide on providing materials in accessible and alternative formats.
Accessibility checker within Microsoft Office	https://support.microsoft.com/en-gb/office/improve-accessibility-with-the-accessibility-checker-a16f6de0-2f39-4a2b-8bd8-5ad801426c7f#PickTab=Windows	Guidance on using in-built accessibility checker, currently only available on Microsoft Word but soon to be available for other office desktop apps.

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