Ensuring your trial is designed for all who could benefit

Trial teams need to do everything possible to make their trial relevant to the people to whom the results are intended to apply (often patients) and those expected to apply them (often healthcare professionals). The four questions below are intended to prompt trial teams to think about who should be involved as participants, and how to facilitate their involvement as much as possible. These questions should be considered by trial teams in partnership with patient and public partners, including individuals from, or representing, groups identified in Question 1. Note that:

* *‘Intervention*’ means the treatment, initiative or service being evaluated.
* ‘*Comparator*’ means the what the intervention is being compared to.
* ‘*Effective*’ means the intervention provides important benefits for people with the disease or condition that is the focus of the trial.

We recommend that trial teams use the worksheets to help them think through their answers to the four key questions.

**1.** Who should my trial results apply to?

Which groups in the community could benefit from the intervention if it was found effective, or benefit from not having it if it was found ineffective and/or harmful?

**2.** Are the groups identified in Question 1 likely to respond to the treatment in different ways?

How might the disease or cultural factors mean that some groups in the community respond to, or engage with, the treatment(s) being tested in different ways?

**3.** Will my trial intervention and/or comparator make it harder for any of the groups identified in Question 1 to engage with the intervention and/or comparator?

How might the intervention and/or comparator, including how they are provided, make it harder for some groups in the community to take part in the trial?

**4.** Will the way I have planned and designed my trial make it harder for any of the groups identified in Question 1 to consider taking part?

How might elements of trial design, such as eligibility criteria or the recruitment and consent process, make it harder for some groups in the community to take part?

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| **1. Who should my trial results apply to?** |
| **[NB. Completed by Shaun Treweek and [ ], University of Aberdeen. We were not involved in this trial,** **we did not discuss the information on the worksheets with the trial team, and the worksheets were completed retrospectively rather than at trial design, none of which is ideal.**  **The key documents we used regarding the trial were the final report sent to the funder (NIHR) and the registration document–** <https://www.journalslibrary.nihr.ac.uk/pgfar/pgfar09010#/abstract> **and** <https://www.isrctn.com/ISRCTN86234930>.  **Given the above, the information in the worksheets may not be a proper reflection of the trial because we did not have access to all the trial materials. The information is therefore intended to be illustrative, not definitive.]**  REACH-HF was a UK trial of a self-care home-based manual delivered together with a cardiac nurse or physiotherapist as rehabilitation post heart failure Participants were aged ≥ 18 years with confirmed heart failure. The trial is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment program, which means the findings are intended to be of immediate clinical relevance (i.e. the trial is pragmatic). Participants should therefore be representative of all those diagnosed with heart failure (focused on reduced ejection fraction).  Heart disease is the UK’s most common cause of death overall. The incidence of heart disease South Asians is higher than in White groups. One reason for this is suggested as the higher rate of diabetes in South Asians, which is diagnosed around 10 years earlier in South Asians than their White compatriots. In the UK Black individuals seem to be a lower risk of heart disease.  The trial population should aim to look like the UK population of women with heart disease and reduced ejection fraction. [Old (2004) data for the England](https://www.bhf.org.uk/~/media/files/research/heart-statistics/hs2010fc_ethnic_differences_in_cardiovascular_disease-full-copy.pdf) show that for the 55+ age group (mean age for the REACH-HF trial was 70) prevalence of heart disease is as below:    Clearly the absolute number involved needs to account for the numbers of each ethnic group in the population but a substantial burden of disease in men and women from India, Pakistan and Bangladesh. We were unable to find absolute numbers for cases by ethnicity but suggest that the proportion of South Asians in the trial should be not be less than 10%. There is a case for over-sampling South Asian individuals to allow greater certainty regarding conclusions drawn from their participation in the trial. |

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| **2. Are the groups identified in Question 1 likely to respond to the treatment in different ways?** [**( VIEW WORKSHEET )**](#WorksheetONE) |
| **[This question has been answered with a focus on ethnicity for the purposes of this example, though the questions have wider relevance than ethnicity.]**  There is [some evidence](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7646689/) from the US that South Asians think heart attacks and heart disease cannot be prevented. Fatalism has been mentioned as a commonly held belief among South Asians. In [one comparative study of cancer patients](https://bmjopen.bmj.com/content/3/6/e002650.long), British SAs more frequently used fatalism as a disease coping strategy than British Whites. This might have relevance for attitudes towards heart disease as well.  Perceptions from other ethnic groups are unclear.  More generally, a general distrust in research may reduce the willingness of ethnic minority individuals to take part in a trial. |

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| **3. Will my trial intervention and/or comparator make it harder for any of the groups identified in Question 1 to engage with the intervention and/or comparator?** [**( VIEW WORKSHEET )**](#WorksheetTWO) | |
| **[This question has been answered with a focus on ethnicity for the purposes of this example, though the questions have wider relevance than ethnicity.]**  The intervention is self-help home-based manual designed to be delivered by a cardiac nurse of physiotherapist facilitator. The comparator is usual care, which means no cardiac rehabilitation.  To what extent the manual had been developed together with patients from different ethnic groups is unclear. No mention of translation is mentioned, which could be a problem, particularly for older South Asian women. Moreover, the manual would need cultural tailoring, which seems unlikely to have been the case.  In principle home-based exercise ought not to be an issue although it would be good to have confirmation of this. The face-to-face visits were designed to be delivered in the participant’s home. [Work in the UK on home visits by healthcare professionals](https://onlinelibrary.wiley.com/doi/10.1111/hsc.12233) for new South Asian parents suggested that services were not always perceived to be aligned to participants’ cultural values and beliefs around, for example, sensitivity about revealing personal matters to strangers and involving men in women’s health issues. Participants were appreciative of health advice, but not parenting advice, where family advice carried more weight. It is plausible that people from different ethnic groups may have different perspectives on health professionals coming to their homes to deliver care, and whether this is an acceptable form of health care.  How acceptable, or useful such interventions might be considered to be by a wide range of ethnic groups is unclear. There is evidence from [cardiovascular disease](https://www.sciencedirect.com/science/article/pii/S0020748919301737) and [diabetes](https://www.tandfonline.com/doi/full/10.1080/13557858.2021.1881764) that cultural values need to be integrated with self-management plans for them to be effective. It would be useful to know to what degree there are differences between ethnic groups in attitudes to the components of the intervention as a way of managing heart disease. | |
| 1. **Will the way I have planned and designed my trial make it harder for any of the groups identified in Question 1 to consider taking part?** [**( VIEW WORKSHEET )**](#WorksheetTHREEA) |
| **[This question has been answered with a focus on ethnicity for the purposes of this example, though the questions have wider relevance than ethnicity.]**  It is unclear how participants became aware of the trial. The most likely route is that a clinician in one of the 5 centres in primary or secondary care invited a person to take part. Eligible patients were given a patient information sheet; it is unclear who gave the information but probably a member of the clinical team. It is unclear who took consent.  Two of the eligibility criteria (one on attending visits, the other on understanding study materials) may lead to some ethnic minority groups being disproportionately affected as they are subjective and judgement-based. Depending on the language skills of both potential participants and clinical staff, who approaches the potential participant may limit the ability of some ethnic groups (older Pakistani and Bangladeshi women for example) to participate.  Consent is written and since translation/interpretation is not mentioned, we can assume this is in English. As mentioned above, language issues (both world language and culturally-tailoring) may limit the participation of some ethnic minority individuals. The eligibility criteria highlighted above are likely to be used to explicitly exclude some individuals on language grounds linked to consent.  The trial’s outcomes largely rely on completing what sound like substantial questionnaires at least three times. This may disadvantage participants of any ethnic group with lower literacy. |

Worksheets for thinking through factors that might affect ethnic group involvement in a trial

These worksheets are intended to be used by trial teams in partnership with patient and public partners to ensure that ethnic group involvement is considered at the trial design stage.Before completing the worksheets, the trial team **should have answered Question 1** **of the INCLUDE Key Questions with regard to ethnic group involvement**.

The worksheet may cover issues that some trial teams already think about. The intention is that the worksheet will help to highlight issues consistently across trials for all trial teams, as well as raising some questions that may not be routinely considered at present.

Finally, while the worksheet asks trial teams to think about possible differences between ethnic groups, it is important to remember that there are also differences *within* ethnic groups, especially between generations and between men and women. No ethnic group is homogenous. See [Appendix 1](https://www.trialforge.org/trial-forge-centre/include/) for more on our definition of ethnicity.

**Worksheet 1**

This worksheet provides some questions **to guide your thinking about ethnic group involvement when answering Question 2** of the INCLUDE Key Questions.

**Disease and cultural factors that might influence the effect of treatment for some ethnic groups**

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| **Disease** | How might the prevalence of the disease vary between each ethnic group in the target population? | **Response:** The burden of cardiovascular disease is significant regardless of ethnicity. Studies have shown that 80 per cent of the global burden of CHD can be attributed to [five coronary risk factors](https://raceequalityfoundation.org.uk/wp-content/uploads/2018/03/health-brief16.pdf), all of which are relevant to the UK. Most are potentially modifiable: these are abnormal concentration of cholesterol (and other related substances found in the body), diabetes mellitus, cigarette smoking, hypertension (or high blood pressure) and lack of physical exercise. There is less evidence to explain differences in the potency of individual risk factors across distinct groups, such as individuals from different ethnic groups or younger or older adults.  South Asians living in the UK have a high rate of CVD compared to the majority population. [Work done in the UK in the 1980s](https://www.bhf.org.uk/what-we-do/our-research/research-successes/ethnicity-and-heart-disease) found that first-generation South Asians living in the UK have a higher rate of coronary heart disease (and diabetes) compared to White Europeans. [More recent data show the same pattern](https://raceequalityfoundation.org.uk/wp-content/uploads/2018/03/health-brief16.pdf) (e.g. South Asians living in Scotland have a 60-70 per cent higher incidence of acute myocardial infarction (heart attack) than the general population. Women of South Asian origin do not seem as protected from CVD as women in the general population. Further, young men of South Asian origin experience a high relative risk, at a younger age, compared to those of the majority population.  The [link between CHD and diabetes is especially strong](https://raceequalityfoundation.org.uk/wp-content/uploads/2018/03/health-brief16.pdf). The prevalence of Type 2 diabetes, for example, shows marked differences among ethnic groups. Almost one in five people of South Asian origin living in the UK develop diabetes, compared to one in twenty-five among the general population. Diabetes onset is earlier in South Asians (46 vs 57 for White individuals), and at a lower BMI than White individuals.  Although heart disease is common among people of South Asian origin, there is uncertainly as to why. [Four interrelated explanations](https://raceequalityfoundation.org.uk/wp-content/uploads/2018/03/health-brief16.pdf) emerge: people of South Asian origin are more susceptible to established CHD risk factors; they are more likely to experience established CHD risk factors; there are more specific risk factors, which are not known about; and there are fewer competing causes of death in middle-aged people of South Asian origin.  In contrast to South Asian groups, [Black groups in the UK have a significantly lower risk of heart disease compared](https://www.kingsfund.org.uk/publications/health-people-ethnic-minority-groups-england#CVD) to the majority of the population, despite having a high prevalence of hypertension and diabetes (risk factors for heart disease and stroke). Lower cholesterol levels among people of African Caribbean heritage than White Europeans may protect them against heart disease. Heart disease rates are low in sub-Saharan Africa and the Caribbean.  In summary, CHD is more prevalent in South Asians than in the majority UK population, but less prevalent in Black individuals |
| How might the severity of the disease vary between each ethnic group? | **Response:**. Mortality from CVD is decreasing in the UK but remains the leading cause of death. A closer look at data documenting the decline in CVD mortality shows that [the *rate* of decline is inconsistent across different groups within the population](https://raceequalityfoundation.org.uk/wp-content/uploads/2018/03/health-brief16.pdf). CVD mortality for men aged between twenty and sixty-nine years living in England fell by 29 per cent between 1971 and 1991. For men living in England but born in South Asia, the decline was considerably less (20 per cent). A similar trend was evident for women. See also [Kings Fund report](https://www.kingsfund.org.uk/publications/health-people-ethnic-minority-groups-england#CVD), which comes to the same conclusions.  [Data published by the UK government](https://www.gov.uk/government/publications/the-report-of-the-commission-on-race-and-ethnic-disparities-supporting-research/ethnic-disparities-in-the-major-causes-of-mortality-and-their-risk-factors-by-dr-raghib-ali-et-al) show that mortality from CHD is significantly worse for South Asians than White individuals but significantly better for Black individuals. T |
| How might the disease present in people from each ethnic group (this may include symptoms, type or pattern or rate of disease progression)? | **Response:** As mentioned above, diabetes is a risk factor for CVD and age at diabetes diagnosis is younger in South Asians by about 10 years (46 vs 57) compared to White individuals, and at lower BMI. The increased risk of diabetes may mean younger South Asians present with CVD than for other ethnic groups.  [There is evidence that CVD risk scores used in the UK do not work well for ethnic minority individuals](https://heart.bmj.com/content/100/1/60). QRISK2 under-predicted risk in South Asian and European men and women, while Framingham under-predicted risk in South Asian women and over-predicted in African Caribbeans. Classification was particularly poor in African Caribbeans. For South Asian women, QRISK2 high risk classification was also poor and would have predicted only one third of events. The study noted that future work should give particular attention to identifying high risk African Caribbeans and South Asian women. | |
| How close is the match between each ethnic group living with the disease and the ethnic groups living in the areas where the trial is to be run? | **Response:** The trial was led by Exeter University and the main trial was run in four centres (Birmingham, Cornwall, Gwent and York) with a substudy being run in Dundee. [Birmingham is ethnically diverse](https://en.wikipedia.org/wiki/List_of_English_districts_by_ethnicity) (58% White) but York (94% White), Wales ([93% White](https://www.ethnicity-facts-figures.service.gov.uk/uk-population-by-ethnicity/national-and-regional-populations/regional-ethnic-diversity/latest)), South West England ([92% White](https://www.ethnicity-facts-figures.service.gov.uk/uk-population-by-ethnicity/national-and-regional-populations/regional-ethnic-diversity/latest)) and Dundee ([94% White](https://www.scotlandscensus.gov.uk/search-the-census#/explore/snapshot)) are much less diverse.  It would be sensible to check local site populations against the overall disease burden, but given the importance of South Asians in a CVD trial, these sites may not all be a good match between the ethnic groups needed and where the trial is recruiting. | |
| Other factors to consider: | | |
| **Cultural** | How might perceptions of the disease and social stigma around it be different for each ethnic group in the target population? | **Response:** There is [some evidence](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7646689/) from the US that South Asians think heart attacks and heart disease cannot be prevented. Fatalism has been mentioned as a commonly held belief among South Asians. In [one comparative study of cancer patients](https://bmjopen.bmj.com/content/3/6/e002650.long), British SAs more frequently used fatalism as a disease coping strategy than British Whites. This might have relevance for attitudes towards heart disease as well.  Perceptions from other ethnic groups are unclear.  In terms of trial participation, generally, trials are known to lack diversity – much of this may be down to lack of trust in the medical and research systems due to historical abuse and exploitation of Black and minority ethnic populations. [Research](https://www.diabetes.org.uk/resources-s3/2017-11/south_asian_report.pdf) has shown that South Asians are often explicitly excluded from research due to perceived cultural and communication difficulties. It has also been shown that many [South Asian people are unwilling to participate](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2571097/) because they accept their illness as an unalterable punishment from God, or have a fear of what research entails. | |
| How might ways of describing the disease be different for each ethnic group? | **Response:** It is uncertain whether terms than ‘heart disease’ may be used by some ethnic groups. | |
| How might cultural practices, beliefs and traditions influence the acceptability of, and adherence to, the treatment(s) for each ethnic group? | **Response:** The intervention is a self-help home-based written manual designed to be delivered by a trained facilitator (a cardiac nurse or physiotherapist) to support rehabilitation after heart failure. The intervention content covers exercise, managing stress, managing hydration and monitoring signs and symptoms.  How acceptable, or useful such interventions might be considered to be by a wide range of ethnic groups is unclear. It would be useful to know to what degree there are differences between ethnic groups in attitudes to this sort of intervention to preventing or managing heart disease (or other) problems. It is also unclear to what degree self-management is a concept that works equally across different ethnic groups. There is evidence from [cardiovascular disease](https://www.sciencedirect.com/science/article/pii/S0020748919301737) and [diabetes](https://www.tandfonline.com/doi/full/10.1080/13557858.2021.1881764) that cultural values need to be integrated with self-management plans for them to be effective.  The REACH-HF NIHR report shows that the study only recruited 7 individuals with ethnic minority backgrounds. It is unclear if this is of the 216 recruited to the main trial, or to all components of the study. Either way, it is a small proportion of all participants. This may suggest that this sort of intervention is less appealing to ethnic minority individuals, or reflect wider problems with trial recruitment and ethnic minority involvement. | |
| How or when might people in each ethnic group access healthcare for this disease differently? | **Response:** [Recent evidence](https://www.kingsfund.org.uk/publications/health-people-ethnic-minority-groups-england#CVD) suggests that greater awareness among health care providers of the CVD risk in South Asian populations, earlier diagnosis and improved management of diabetes and CVD, together with second-generation adopting healthier lifestyles than first-generation migrants, have reduced CVD mortality risks relative to white Europeans. Research also indicates that South Asian groups have equitable access to care for heart disease and better survival rates from it. In contrast, Black groups have lower than expected rates of access to and use of cardiovascular care.  [Cultural and social norms](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3588185/) strongly influence health-seeking behaviours – research has shown that health promotion activities tend to be based on assumptions of individualism and self-investment, which may need to be re-thought for South Asian groups in particular where community is often more important. [South Asians](ghttps://www.diabetes.org.uk/resources-s3/2017-11/south_asian_report.pdf) are often explicitly excluded due to perceived cultural and communication difficulties. Language and cultural differences are barriers that impact all minority groups – with people from non-White-European populations seeking healthcare at later stages of their disease than their White counterparts. [Language and literacy factors](https://www.pcdsociety.org/resources/details/living-with-diabetes-a-qualitative-review-of-minority-ethnic-groups-in-a-deprived-london-borough) are also known factors that impact on overall health literacy. Study participants have reported that both the spoken and written health information provided were sometimes meaningless, even when translated into their own language. Their inability to transform information into action was either due to limited health knowledge or limited linguistic proficiency in either their native language or English and they also felt they were unable to maximise their consultation with their healthcare professional. | |
| Other factors to consider: | | |

**Worksheet 2**

This this worksheet provides some questions **to guide your thinking about ethnic group involvement when answering Question 3** of the INCLUDE Key Questions.

**Intervention and comparator factors that might affect how some groups engage with the intervention and/or comparator\***

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| **What** | How might the intervention(s) and comparator limit participation of people from each ethnic group in the target population? | **Response:** The intervention is self-help home-based manual designed to be delivered by a cardiac nurse of physiotherapist facilitator. The comparator is usual care, which means no cardiac rehabilitation.  To what extent the manual had been developed together with patients from different ethnic groups is unclear. No mention of translation is mentioned, which could be a problem, particularly for older South Asian women. Moreover, the manual would need cultural tailoring, which seems unlikely to have been the case.  Material targeting the individual is a strategy that works from a White ethnic group perspective but may be less effective in South Asians (who tend to have more of a sense of community, so appeals to community may be useful) and Black individuals, where appeals to family may be more useful.  How acceptable, or useful such interventions might be considered to be by a wide range of ethnic groups is unclear. It would be useful to know to what degree there are differences between ethnic groups in attitudes to the components of the intervention as a way of managing heart disease. |
| How, and in what way, were people from each ethnic group involved in selecting or designing the trial intervention/comparator? | **Response:** The trial did involve patient and public partners (there was a PPI group of six individuals) and these individuals contributed to much of the trial work. There is no information regarding the ethnicity of these individuals. Without special efforts, it is reasonable to assume that the PPI will have been from a predominantly White perspective, as it is for most UK trials. |
| Other factors to consider: | |
| **Who** | How might the person delivering the intervention/comparator limit participation of people from each ethnic group in the target population? | **Response:** The intervention is delivered by an NHS cardiac nurse or physiotherapist. Recruitment was from both primary and secondary care but it is unclear who did this.  It is likely that the participants will meet with a clinician or research nurse based at one of the 5 sites. Black and ethnic minority populations are known to distrust the medical and research systems due to historical abuse and exploitation, and may remain unconvinced that research participation is something for them.  That said, [NHS staff are a more diverse group](https://www.ethnicity-facts-figures.service.gov.uk/workforce-and-business/workforce-diversity/nhs-workforce/latest) than the wider UK population – of NHS staff whose ethnicity is known, 79.2% are White (including White minorities), and 20.7% are from all other ethnic groups. This contrasts to the wider population – the [2011 Census](https://www.ethnicity-facts-figures.service.gov.uk/uk-population-by-ethnicity/national-and-regional-populations/population-of-england-and-wales/latest) showed that 86.0% of the population of England and Wales was White. If the staff conducting research visits with participants are of the same ethnicity, or share a common language, distrust may be reduced.  In general, those tasked with screening and recruitment will need cultural competence training to ensure that people from ethnic groups different to their own are approached, and that both recruiter and potential recruit feel comfortable about the discussion. Depending on the language requirements of target ethnic groups, this may require interpretation and/or translation. |
| Other factors to consider: | |
| **How** | How might the mode of delivery (e.g. telephone, video-call, face-to-face, in groups) limit participation of people from each of the ethnic groups in the target population? | **Response:** The mode of delivery of the intervention is done as a mixture of face-to-face (minimum of three face-to-face contacts with a facilitator (plus telephone contacts)) and home-based. The comparison group participants had no contact about usual care.  In principle home-based exercise ought not to be an issue although it would be good to have confirmation of this. The face-to-face visits were designed to be delivered in the participant’s home.  [Work in the UK on home visits by healthcare professionals](https://onlinelibrary.wiley.com/doi/10.1111/hsc.12233) for new South Asian parents suggested that services were not always perceived to be aligned to participants’ cultural values and beliefs around, for example, sensitivity about revealing personal matters to strangers and involving men in women’s health issues. Participants were appreciative of health advice, but not parenting advice, where family advice carried more weight. It is plausible that people from different ethnic groups may have different perspectives on health professionals coming to their homes to deliver care, and whether this is an acceptable form of health care. |
| Other factors to consider: | |
| **Where** | How might where the intervention/comparator is delivered (e.g. hospital, general practice, local library) limit the participation of people from each ethnic group in the target population? | **Response:** As above. |
| Other factors to consider: | |
| **When & Intensity** | How might when the intervention/comparator is delivered (e.g. during working hours) or the intensity (e.g. number of times it is delivered, over what period, time commitment for each session and overall) limit participation of people from each ethnic group in the target population? | **Response:** The total intervention time commitment was a minimum of three face-to-face visits with more if needed, plus home-based exercise and telephone contact. The total intervention time was 12 weeks. It is unclear how long face-to-face visits were or when they were delivered but it seems reasonable to assume that these were done during working hours for the nurse/physiotherapist.  Trial follow-up was at 4, 6 and 12-months and these were clinic visits. Getting to hospital can be an issue for a variety of reasons including – poor transport links, the timing and length of research visits (i.e. clashing with working hours, childcare or caring responsibilities), financial reasons (time away from work, cost of travel, parking charges). Many of these factors disproportionately impact people from poor socioeconomic backgrounds, which often includes ethnic minority groups.  Clearly explaining to participants in a culturally appropriate way why attending all visits is important will be key for all ethnic groups. |
| Other factors to consider: | |

\*These factors are taken from TIDieR ([http://www.equator-network.org/reporting-guidelines/tidier/](about:blank)).

**Worksheet 3a**

This worksheet provides some questions **to guide your thinking about ethnic group involvement when answering Question 4** of the INCLUDE Key Questions.

**Trial eligibility and participation factors that might affect how some groups engage with the trial**

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| **Eligibility** | How might eligibility criteria exclude members of each ethnic group in the target population for reasons other than their clinical eligibility for the trial (e.g. availability of medical history, must speak English, location, gender, age, discussing pregnancy, internet/mobile telephone access)? | **Response:** The list of eligibility criteria is long are mostly clinically focussed but not all. These criteria:   * ..unable to travel to research assessments or accommodate home visits * Patients who are unable to understand the study information or unable to complete the outcome questionnaires   ..are likely to disproportionality affect ethnic minority individuals and those on low incomes (and there is likely to be overlap across these two groups). It is also unclear how these judgements are made, although the judgement itself is likely to be made by the recruiter. No mention is made of translation so an ability to understand written English (for intervention, comparator and consent) seems central. This would be expected to disadvantage ethnic minority women. As prevalence data suggest that South Asians are a key group for this trial, the language issue is important because English-language skills are less good in older South Asian women in the UK.  Clinicians with expertise in cardiovascular care will be able to shed more light on whether any specific clinical criterion may disproportionately impact certain ethnic groups. |
| Other factors to consider: | |
| **Opportunity to participate** | How might the way(s) (and by whom) potential participants are made aware of the trial (e.g. posters in clinic, written letter from a doctor, asked by a nurse) limit the participation of each ethnic group in the target population? | **Response:** It is unclear how participants became aware of the trial. The most likely route is that a clinician in one of the 5 centres in primary or secondary care invited a person to take part.  Eligible patients were given a patient information sheet; it is unclear who gave the information but probably a member of the clinical team. It is unclear who took consent.  The criteria mentioned above may lead to some ethnic minority groups being disproportionately affected as they are subjective and judgement-based. Depending on the language skills of both potential participants and clinical staff, who approaches the potential participant may limit the ability of some ethnic groups (older Pakistani and Bangladeshi women for example) to participate.  It is unclear if the trial team explored who should make the initial approach with an ethnically diverse group of patient and public contributors. |
| How might the information that tells potential participants about the trial (e.g. participant information leaflet) limit the participation of each ethnic group? | **Response:** As some ethnic groups including individuals for whom English may not be their first language are a key required group within the trial (e.g. South Asians, Indian subcontinent) then translation of written and oral material into some languages other than English is likely to be essential (see above). [Other cultural barriers for South Asians](https://onlinelibrary.wiley.com/doi/epdf/10.1111/dme.13895) (e.g. preference for traditional remedies, see earlier) may be as important, or more important, than linguistic barriers so should not be forgotten. [These beliefs, and linguistic issues, are likely to be more relevant among older generations](https://onlinelibrary.wiley.com/doi/epdf/10.1111/dme.13895).  It does not look likely that any material was translated into other languages, or culturally modified. |
| How might cultural practices, beliefs and traditions change the way each ethnic group perceives the information they are given? | **Response:** See earlier comments about self-management and appeals to individualism rather than community and family. |
| Other factors to consider: | |
| **Consent procedures** | How might the way consent is sought (i.e. where, by whom, written vs verbal, verbal translations/multiple languages, access to interpreters) limit the participation of each ethnic group in the target population? | **Response:** Consent is written and since translation/interpretation is not mentioned, we can assume this is in English. As mentioned above, language issues (both world language and culturally-tailoring) may limit the participation of some ethnic minority individuals. The eligibility criteria highlighted above are likely to be used to explicitly exclude some individuals on language grounds linked to consent. | |
| How might the way people would like to discuss participation with family before providing consent differ for each ethnic group? | **Response:** [South Asian women](https://www.researchgate.net/publication/7480322_The_Influence_of_Family_on_Immigrant_South_Asian_Women%27s_Health), particularly older women, are known to make decisions about their healthcare in consultation with members of their community and family. Involvement of family members in the consent process should therefore be considered, including for other genders. Family is also important to people with Black heritage.  Caregivers were invited to be involved in this trial, which strongly suggests that decision making together with family members/friend was encouraged. | |
| How might the way the research team can check how well consent information is understood differ for each ethnic group? | **Response:** There is no information about how understanding is confirmed. | |
| Other factors to consider: | | |

**Worksheet 3b**

This worksheet provides some questions **to guide your thinking about ethnic group involvement when answering Question 4** of the INCLUDE Key Questions.

**Trial data collection factors that might affect how some groups engage with the trial**

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| --- | --- | --- |
| **What** | How, and in what way, were people from each ethnic group in the target population involved in selecting the trial outcomes? | **Response:** Public contributors have been involved and they did explicitly contribute to discussions about patient-reported outcomes. It is unclear if the PPI Advisory Group was ethnically diverse. |
| How might the trial outcomes themselves, or other data being collected (e.g. a patient’s background information) limit the participation of each ethnic group? | **Response:** Most trial outcomes are scales of one sort of another although there are other measures including accelerometery and mortality. Data were collected from trial participants at three clinic visits.  It is unclear whether and how the outcomes may limit participation beyond language issues because of using what are likely to be substantial questionnaires.  [Demographic data](https://academic.oup.com/eurjpc/article/26/3/262/5925627) were collected and included age, sex, ethnicity and employment status. |
| Other factors to consider: | |
| **Who** | How might the people who collect data limit the participation of each ethnic group in the target population? | **Response:** This is unclear because it is unclear who collects data from participants at clinic visits. |
| Other factors to consider: | |
| **How** | How might data collection methods limit the participation of each ethnic group in the target population? | **Response:** See above. |
| Other factors to consider: | |
| **Where** | How might where data are collected limit the participation of each ethnic group in the target population? | **Response:** Getting to hospital can be an issue for a variety of reasons including – poor transport links, the timing and length of research visits (i.e. clashing with working hours, childcare or caring responsibilities), financial reasons (time away from work, cost of travel, parking charges). Many of these factors disproportionately impact people from poor socioeconomic backgrounds, which often includes ethnic minority groups. |
| Other factors to consider: | |

**Worksheet 3c**

This worksheet provides some questions **to guide your thinking about ethnic group involvement when answering Question 4** of the INCLUDE Key Questions.

**Factors that might affect the planned analysis of trial results**

|  |  |  |
| --- | --- | --- |
| **Retention** | How might the trial data available for participants differ between each ethnic group in the target population? | **Response:** See Worksheet 3b. |
| Other factors to consider: | |
| **Benefits** | How might the benefits of the trial intervention(s) differ between each ethnic group in the target population? | **Response:** Some outcomes, most noticeably quality of life, depression and well-being could conceivably have a cultural element although this is uncertain. Given the different disease presentation for White and some ethnic minority individuals, especially South Asians it would be reasonable to assume that there could be potential differences due to that, or to acceptance of a self-help intervention such as the used in this trial. |
| Other factors to consider: | |
| **Harms** | How might the possible harms of the trial intervention(s) differ between each ethnic group in the target population? | **Response:** As above. |
| Other factors to consider: | |
| **Subgroup analyses** | How should variation between ethnic groups in the target population be explored– should there be planned subgroup analyses? | **Response:** An exploration of benefits and harms by ethnic group should be pre-planned, especially given the different prevalence for South Asian heritage individuals.  The need for this pre-planned subgroup analysis suggests that over-sampling by ethnicity might be useful. This is unlikely to affect the applicability of the evidence to the majority population but will improve the certainty of conclusions coming from the subgroup analysis. The overall sample size does not need to be changed and it is unlikely to be feasible to fully power any subgroup analyses. |
| Other factors to consider: | |
| **Interim analyses** | How should any interim analysis handle variation between ethnic groups in the target population? | **Response:** Any planned interim analysis should look for signals suggesting that benefits or harms were importantly different in one or more ethnic groups. The certainty available for this will be less than for the majority population, although oversampling may help. |
| Other factors to consider: | |
| **Stopping triggers** | How should any rules to stop the trial early on safety or benefit grounds handle variation between ethnic groups in the target population? | **Response:** Any stopping rules should consider the benefits or harms by ethnic group. The certainty available for this will be less than for the majority population, although oversampling may help. |
| Other factors to consider: | |

**Worksheet 3d**

This this worksheet provides some questions **to guide your thinking about ethnic group involvement when answering Question 4** of the INCLUDE Key Questions.

**Factors that might affect the planned reporting and dissemination of trial results**

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| --- | --- | --- |
| **What** | How, and in what way, were people from each ethnic group in the target population involved in planning the reporting and dissemination of the trial results? | **Response:** Public contributors were part of the trial but it is not clear if or how they were involved in planning the reporting and dissemination of the trial results. There is no suggestion that the PPI was ethnically diverse. |
| Other factors to consider: | |
| **How** | How might planned reporting and dissemination methods limit engagement with each ethnic group in the target population? | **Response:** There are range of dissemination approaches planned for REACH-HF, mostly targeted at the NHS. Scientific publications are part of the and the NIHR report mention events aimed at patients without giving further details. |
| Other factors to consider: | |
| **Where** | How might where trial results are planned to be reported and disseminated limit engagement of each ethnic group in the target population? | **Response:** The [NIHR journal library](https://www.journalslibrary.nihr.ac.uk/hta/JKNZ2003#/abstract) provides the bulk of what is likely to be publicly available on this trial.  Using publications as the only form of dissemination is not conducive to engaging any ethnic group, or member of the public with the results of this trial. At the very least the publication(s) that come from this trial should be open access.  Dissemination materials intended for the public should consider the health beliefs, health literacy and languages of the ethnic groups in the community and use channels appropriate for the ethnic group. For example, community radio can be a useful tool for some ethnic groups (e.g. Sikhs), as can social media. |
| Other factors to consider: | |

Worksheet for thinking through measures to address factors that might prevent full community involvement

Use this worksheet to list key factors that might affect the involvement of some ethnic groups in the target population of your trial, along with measures to mitigate the effect of those factors and their cost. Add extra rows as needed.

Please remember that there are also differences *within* ethnic groups, especially between generations and between men and women. No ethnic group is homogenous.

|  |  |  |
| --- | --- | --- |
| **Factors that may prevent full community involvement** | **Proposed measures (several options may be needed)\*** | **Cost of measures** |
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\*See https://centreforbmehealth.org.uk/resources/toolkits/ for suggestions for how to address factors that affect community-wide involvement.

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