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 Heidi Gardner, 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/hta/JKNZ2003#/abstract> **and** <https://www.isrctn.com/ISRCTN35358984>.  **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.]**  PROSPER was a UK trial of a physiotherapy-led exercise program for women aged ≥ 18 years who had been diagnosed with breast cancer and were at higher risk of developing shoulder problems. 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 women diagnosed with breast cancer who are at higher risk of shoulder pain.  Breast cancer is the UK’s most common cancer in women. The incidence of breast cancer is higher in White women than Asian, Black and mixed ethnic groups. The median age at diagnosis is lower in Black, Asian and Hispanic women in the UK (about 3 years younger). Ethnic minority women present with later stage cancer than White women. US data show that Black women present at younger ages, have more aggressive cancer and higher mortality.  The more aggressive cancer leads to more mastectomy in young Black compared to young White women. Ethnic minority women report less favourable clinical experiences and satisfaction than White women. Ethnic minority women report poorer long-term outcomes than White women and these differences are not fully explained by higher frequencies of later stage cancer and more aggressive tumours.  We were unable to find ethnicity data regarding shoulder pain in breast cancer and the trial team did not report it.  The trial population should aim to look like the UK population of women with breast cancer, bearing in mind that more aggressive cancers are more likely to require surgical and other intervention. Data for England 2013-2017 suggest that of all breast cancer cases:  White = 93.2%; Asian = 3.6%; Black = 2.1%; Mixed = 0.6% [and an additional 0.6% are in men].  The above proportions should be the minimum for ethnic minority participation. The proportion of minority ethnic individuals in the trial population as a whole needs to be at least 7%. Given the later stage cancer and more aggressive tumours in ethnic minority women, especially Black women, there is a case for over-sampling ethnic minority women 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.]**  As discussed in question 1, prevalence, disease severity and age of onset differs for ethnic minority women in comparison to White-British populations. Evidence for the root of these differences is limited.  There is some evidence that a cancer diagnosis carries stigma in the South Asian community where themes of *‘*shyness’, ‘modesty’ and ‘embarrassment’ about revealing intimate body parts were important. Sometimes this stigma also extended to attending screening. Data on attendance at screening by ethnic minority women is mixed, with some data suggesting lower rates, other data suggesting little difference with the majority population.  Other factors identified in systematic reviews contributing to this disparity between Black and White women including lower symptom and risk factor awareness; stigma, fear and taboo; not making time for breast awareness; fear of conventional treatment; mistrust of healthcare professionals; financial burden of healthcare and inaccessibility of services. There may be generational differences, with second generation Black women being more similar re. attitudes to breast cancer to White women than first generation Black African and Caribbean women.  More generally, a general distrust in research may reduce the willingness of ethnic minority women 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.]**  It is not clear if or how any ethnic minority patient partners were involved in the selection of the trial interventions and/or comparator, who delivers the treatments, or where they are delivered. The trial team did however, have PPI as part of their trial, it is just not clear whether ethnic minority individuals were part of this.  The intervention is physiotherapy for shoulder pain, with some treatment delivered in a hospital setting with the therapist, and some at home as self-management. How acceptable, or useful such interventions might be considered to be by a wide range of ethnic groups is unclear. It is unclear to what degree there are differences between ethnic groups in attitudes to exercise as a way of preventing or controlling shoulder (or other) problems and pain. The extent to which self-management as a treatment is seen as appropriate across ethnic groups is also unclear. For other conditions (e.g. cardiovascular), it is clear that cultural values need to be integrated with self-management plans for them to be effective.  Much of the intervention is provided as written material. There is no discussion of translation/interpretation, or to what extent these are needed by the targeted groups. Older South Asian women in particular may value translated materials. | |
| 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.]**  Patients were identified from multidisciplinary cancer team meetings and preoperative oncology and radiotherapy clinics. Screening was undertaken by a member of the clinical team (a specialist breast nurse, surgeon, research nurse or facilitator trained in PROSPER screening and recruitment procedures).  Eligible patients were given a patient information sheet while attending an oncology clinic; it is unclear who gave the information but probably a member of the clinical team. In the case of those interested and willing to participate, written informed consent was obtained by the delegated site investigator after discussion, probably a member of the clinical team.  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. Two of the eligibility criteria (one on complying with the protocol, the other on being able to provide written consent) could conceivably disproportionately disadvantage (or be used, consciously or unconsciously, to disadvantage) ethnic minority women. A 3rd criterion, BMI, may apply differently to women from different ethnic groups but is likely to be based on a criterion designed for White women.  Some of the intervention appears to be delivered as extra sessions at the hospital with a physiotherapist, which may be a problem for lower-income women (some of who are more likely to be ethnic minority), or for women who are less willing or able to demand extra time with health professionals.  The trial’s outcomes largely rely on completing what sound like substantial questionnaires at least three times. This may disadvantage women 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:** [Female breast cancer is the most commonly diagnosed cancer worldwide](https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-022-02260-0), with an estimated 2.3 million new breast cancer cases in 2020, representing nearly 12% of all cancer diagnoses and 7% of all cancer deaths. It is the [most common cancer in women in the UK](https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/breast-cancer#heading-Zero). Data from [England for 2013 – 2017](https://www.nature.com/articles/s41416-022-01718-5) shows that the incidence of breast cancer is higher in white women than Asian, Black and mixed/multiple ethnic groups classifications.  US data show that younger Black and Hispanic women have a [higher incidence of hormone receptor-negative](https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-022-02260-0) (basal-like) breast cancer than white women. |
| How might the severity of the disease vary between each ethnic group? | **Response:** [UK data show](https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-022-02260-0) the median age at diagnosis for breast cancer is lower in the Black, Hispanic, and Asian groups (Black = 56 years, Hispanic = 55 years, South Asian = 56 years) compared to white non-Hispanic women (59 years). Ethnic minority women present with later stage cancer than white women. [Data from the US](https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-022-02260-0) highlight that Black women have more aggressive cancers diagnosed at a younger age; mortality is also higher. These data show that an estimated 3.1% of all Black women will ultimately die from breast cancer compared to 2.6% of white women despite lower incidence.  These more aggressive cancers lead to increased treatment with mastectomy in young Black compared to young White women. This may partially explain why [ethnic minority patients report less favourable](https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-022-02260-0) clinical experiences and lower satisfaction levels pertaining to their cancer treatment.  A [number of studies](https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-022-02260-0) have reported poorer long-term breast cancer outcomes in ethnic minorities compared to white women which are not fully explained by the higher frequencies of higher stage and biologically aggressive tumours in these patient groups. Data from the POSH study indicated a [significantly lower 5-year overall survival](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3887284/) of 71.1% in Black women, compared to 82.4% in white women (W vs. B: *p* = 0.0160) with a 5-year distant relapse-free survival 14.2% lower in Black women than in white women (W vs. B: *p* = 0.0053). After adjustments ethnicity remained an independent factor for poor outcomes. |
| 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, age at diagnosis is younger in ethnic minority women and the cancer stage at presentation is higher. [Uptake of breast screening by ethnic minority women seems unclear](https://pubmed.ncbi.nlm.nih.gov/34452771/) with some reports saying uptake is lower, others higher.  [Black women have a higher frequency of grade 3 tumours](https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-022-02260-0) than White and Asian women, and higher proportions of oestrogen negative/progesterone negative/ HER2-negative tumours than other ethnic groups.  It is uncertain whether ethnic minority women experience shoulder pain after breast cancer treatment more or less often, or have more or less severe pain etc than ethnic majority women. [A 2014 systematic review on post-treatment shoulder pain](https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0096748&type=printable) made no mention of ethnicity or race in its finding. | |
| 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 is being led by Warwick University and is being run across 17 breast cancer centres across England. These sites include London, Birmingham, Blackburn and Coventry and these sites are likely to serve diverse patient populations.  It would be sensible to check local site populations against the overall disease burden, but the national spread of the trial should mean that substantial populations of all ethnic groups are in the recruitment areas of at least some participating sites. | |
| 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://bmjopen.bmj.com/content/8/7/e020892) that a cancer diagnosis carries stigma in the South Asian community where themes of *‘*shyness’, ‘modesty’ and ‘embarrassment’ about revealing intimate body parts were important. Sometimes this stigma also extended to attending screening.  A [systematic review](https://bmjopen.bmj.com/content/4/2/e004076) (18 studies: 11 quantitative, 6 qualitative and 1 mixed method) identified factors contributing to this disparity between Black and white women including lower symptom and risk factor awareness; stigma, fear and taboo; not making time for breast awareness; fear of conventional treatment; mistrust of healthcare professionals; financial burden of healthcare and inaccessibility of services. There may [be generational differences](https://bmjopen.bmj.com/content/5/3/e006944.long), with second generation Black women being more similar re. attitudes to breast cancer to white women than first generation Black African and Caribbean women.  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 ‘breast cancer’ 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 physiotherapy-led exercise programme incorporating behavioural strategies. 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 exercise as a way of preventing or controlling shoulder (or other) problems and pain. It is also unclear to what degree self-management is a concept that works equally across different ethnic groups. There is evidence from other conditions such as [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 PROSPER NIHR report shows that 92% of trial participants were white, with 5% Indian, Pakistani or Bangladeshi, which may suggest that this sort of intervention is less appealing to ethnic minority individuals (especially Black), or reflect wider problems with trial recruitment and ethnic minority involvement.  More generally many [South Asian people are unwilling to participate](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2571097/) in trials because they accept their illness as an unalterable punishment from God, or have a fear of what research entails. | |
| How or when might people in each ethnic group access healthcare for this disease differently? | **Response:** [UK data suggest](https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-022-02260-0) that the median age at diagnosis for breast cancer is lower in the Black, Hispanic, and Asian groups (Black = 56 years, Hispanic = 55 years, South Asian = 56 years) compared to white non-Hispanic women (59 years). Ethnic minority women present with later stage cancer than white women.  [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 physiotherapist-led exercise program with a mixture of face-to-face and home-based delivery. The comparator is a leaflet in English produced by a charity. All participants, including the intervention group, received this leaflet. To what extent this leaflet 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, leaflets would need cultural tailoring, which seems unlikely to have been the case.  The intervention itself also uses written material in English, which will present the same challenges as mentioned above. 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 exercise as a way of preventing or controlling shoulder (or other) problems and pain. |
| 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 but there is no information regarding the ethnicity of these individuals. |
| 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 physiotherapist. Screening was done by a member of the oncology team (a specialist breast nurse, surgeon, research nurse or facilitator trained in PROSPER screening and recruitment procedures). Leaflets were handed out by the surgical oncology team.  It is therefore likely that the participants will meet with a clinician or research nurse based at one of the 17 trial 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 interventions/comparator is done as a mixture of face-to-face (comparator and part of intervention) and home-based (both groups again).  In principle home-based exercise ought not to be an issue although it would be good to have confirmation of this. Attending research visits may well be. 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: | |
| **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 three recommended face-to-face visits with up to more if needed depending on physiotherapist capacity, plus home-based exercise. Trial follow-up was 6 weeks, 6 months and 12-months. The first intervention session was 1-hour, with the others set at 30 minutes. It is not clear when these were delivered but likely to be during hospital working hours. It is unclear how the intensity of the intervention/comparator delivery may impact specific ethnic 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 eligibility criteria are mostly clinically focussed but not all. Two criteria:   * Willing and able to comply with the protocol * Written informed consent   ..are likely to disproportionality affect ethnic minority women. 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.  Clinicians with expertise in breast cancer care will be able to shed more light on whether any specific clinical criterion may disproportionately impact certain ethnic groups. BMI threshold do vary by ethnic groups (South Asians certainly) and the BMI cut-off of 30 may be inappropriate for some 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:** Patients were identified from multidisciplinary cancer team meetings and preoperative oncology and radiotherapy clinics. Screening was undertaken by a member of the clinical team (a specialist breast nurse, surgeon, research nurse or facilitator trained in PROSPER screening and recruitment procedures).  Eligible patients were given a patient information sheet while attending an oncology clinic; it is unclear who gave the information but probably a member of the clinical team. In the case of those interested and willing to participate, written informed consent was obtained by the delegated site investigator after discussion, probably a member of the clinical team.  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.  Issues of trust are likely to be particularly important for Black women, who are an important group for this trial based on disease prevalence and outcomes. |
| 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). |
| 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 women 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. Family is also important to people with Black heritage. Potential participants are given time to consider their involvement so this should be possible in all or many cases in principle. | |
| 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 but it is not clear if they were involved in outcome choice, or whether there was ethnically diverse membership of PPI groups. |
| 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:** The vast majority of trial outcomes are scales of one sort of another with trial participants providing data via postal questionnaires. It is unclear whether and how the outcomes may limit participation beyond language issues because of using what are likely to be substantial questionnaires. Whether the outcomes match what patients of any ethnic group consider important is unclear.  Descriptive background data included age, height, weight, marital status, education level, employment, handedness, ethnicity and self-reported comorbidity. |
| Other factors to consider: | |
| **Who** | How might the people who collect data limit the participation of each ethnic group in the target population? | **Response:** Data are collected by self-report through questionnaires. This in itself might limit the participation of some ethnic groups (and some women in all ethnic groups) because of literacy and language limitations. |
| 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:** See above. |
| 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**

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| **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 pain and quality of life could conceivably have a cultural element although this is uncertain. Given the different disease presentation for white and some ethnic minority women (e.g. Black women), 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 presentation and severity of breast cancer for people with Asian and Black heritage.  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**

|  |  |  |
| --- | --- | --- |
| **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:** A dissemination event was planned for participants but was delayed due to COVID. This is scheduled to be held in the future.  Otherwise dissemination looks like scientific publications. 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. The full NIHR publication is open access though. |
| 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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