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?** |
| Completed from the trial registration document https://www.isrctn.com/ISRCTN14240288 , the lay summary on the Cancer Research UK website <https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-surgery-or-different-types-of-radiotherapy-for-rectal-cancer-star-trec#undefined> and the study website <https://www.birmingham.ac.uk/research/crctu/trials/startrec/index.aspx>. Many of the links on the study website (including to participant information sheet and the protocol are not active).  We were not involved in designing 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. Given the above, the information in the worksheet 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.]  The STAR-TREC: Can we Save the rectum by watchful waiting or TransAnal surgery following (chemo)Radiotherapy versus Total mesorectal excision for early REctal Cancer? Includes a Phase II and a Phase III study. The Phase II component randomised participants to (1) conventional TME surgery, (2) organ saving utilizing long course concurrent chemoradiation, (3) organ saving utilizing short course preoperative radiotherapy. The Phase III component randomises patients who prefer organ preservation to long course concurrent chemoradiation (CRT) vs short course radiotherapy (SCRT)  In the UK, there are 42,900 new bowel cancer cases each year. Rates of bowel cancer are lower in Asian and Black ethnic groups and in people of mixed or multiple ethnicity compared to the White ethnic group. Data from England and Wales suggests that just over a quarter of those diagnosed with bowel cancer have rectal cancer.  Ideally, the treatments should be suitable for all those at risk of the disease, and the trial population should aim to look similar to UK census data; appreciating that rates of bowel cancer are lower in some ethnic groups. |

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| **2. Are the groups identified in Question 1 likely to respond to the treatment in different ways?** [**( VIEW WORKSHEET )**](#WorksheetONE) |
| There is potential for them to respond to treatment in different ways, but there’s no clear evidence to support this. |

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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) | |
| The three treatment policies under consideration have implications for hospital stay and numbers of visits to hospital: the surgical arm involves a stay of 4-10 days in hospital; the organ saving treatment with short course radiotherapy involves high dose of radiotherapy every day for 5 days; the organ saving treatment with long course of chemoradiotherapy every weekday for 5 weeks. It is not clear from the information available as to the clinical follow-up for the surgical arm. After the organ saving treatment, there is a endoscopy and MRI after 3 months, followed by surgery to remove the rectum if the cancer has stayed the same, or second endoscopy/MRI after 1-2 months, followed by regular follow-up if there are no signs of cancer or a small operation to remove part of the bowel, or standard surgery to remove the rectum.  It is not clear if acceptability of the different treatment options will be vary by ethnicity over an above individual preferences, for example to have the cancer removed rather than treated in situ. | |
| 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) |
| All trial participants will have a diagnosis of rectal cancer – there are differences in routes of presentation for diagnosis and in stage at presentation between ethnic groups. It is not clear from the information available whether information about the trial is only available in English, and only in writing – if this is the case, this will reduce the ability of people from some ethnic groups to participate in the study. It is also not clear how potential participants will be approached about the trial, but this is likely to be by a member of the surgery/oncology team. A shared MDT decision to approach may be more inclusive than an individual decision at the discretion of the member of the team. |

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:  There are 42,900 new bowel cancer cases in the UK every year (2016-2018 data; <https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/bowel-cancer#heading-Zero>). The National Bowel Cancer Audit, covering England and Wales and the period 1 April 2017 to 31 March 2018, reports 31,676 patients diagnosed with bowel cancer, of which 8,874 were diagnosed with rectal cancer <https://www.nboca.org.uk/content/uploads/2020/01/NBOCA-2019-V2.0.pdf>. The Audit does not report on ethnicity.  Data from England 2013-2017 – bowel cancer incidence rates are lower in the Asian and Black ethnic groups and in people of mixed or multiple ethnicity compared to the White ethnic group (<https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/bowel-cancer#heading-Zero>). |
| How might the severity of the disease vary between each ethnic group? | Response: Data from Scotland suggest that uptake of bowel screening (FOB) is lower among Indian, Pakistani, Bangladeshi and other South Asian men and women than among White Scottish men and women (<https://bmjopen.bmj.com/content/10/10/e037011>). Analysis of English data confirms that stage at diagnosis is related to relative survival <https://www.nature.com/articles/bjc201549#Tab3>  Among Black Caribbean colorectal cancer patients with known stage (2012-2013), the proportion diagnosed at late stage was significantly higher than among White British colorectal cancer patients (<http://www.ncin.org.uk/view?rid=3286>). There were no other significant differences.  Data from the Thames Cancer Registry (2000-2012) including 77,057 colorectal cancer patients showed that patients from a Black Afro-Caribbean background were diagnosed at a younger age than the White British patients. Black Afro-Caribbean patients were more likely to present with Stage IV tumours than white patients, and this association persisted after adjustment for social deprivation and age. However patients with rectal cancer were less likely to be diagnosed with stage IV disease that those colon cancer (<https://www.sciencedirect.com/science/article/pii/S1877782117300152>). |
| How might the disease present in people from each ethnic group (this may include symptoms, type or pattern or rate of disease progression)? | Response: In a survey of 1013 adults aged 60 years and older, symptom awareness for bowel cancer was significantly lower among all non-white ethnic groups compared to white British/Irish <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7967942/#!po=42.3077>. Symptom awareness was also lower among those whose first language was not English compared to those whose first language was English. In the same survey, awareness of national screening for bowel cancer was lower among Afro-Caribbean and Somali adults compared with White British/Irish adults.  There are differences in route to diagnosis of cancer by ethic group but the patterns are not clear <https://www.nature.com/articles/s41416-022-01847-x#MOESM4>  See also above section for comments on stage at presentation. | |
| 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 study is being run at a number of UK sites where the population are more ethnically diverse than the UK as whole including Birmingham and Manchester (<https://populationdata.org.uk/>)   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | White | Asian/Asian British | Black/Black British | Mixed | Other | | UK | 87.2 | 6.9 | 3.0 | 2.0 | 1.0 | | Birmingham | 57.9 | 26.6 | 9.0 | 4.4 | 2.0 | | Manchester | 66.7 | 17.1 | 8.6 | 4.7 | 3.1 |   There are also recruitment sites in the Netherlands and Denmark. | |
| 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:  In interviews of 1916 adults in England in 2016, levels of cancer stigma were low, but individuals from a Black, Asian and Minority Ethnic background had higher stigma scores (on the Cancer Stigma Scale) than those from a White background <https://bmccancer.biomedcentral.com/articles/10.1186/s12885-019-5787-x>. In the same study, higher cancer stigma was associated with not being screened as recommended for colorectal cancer.  <https://news.cancerresearchuk.org/2022/09/23/health-inequalities-breaking-down-barriers-to-cancer-screening/>  In a systematic review which included 15 studies (6 from the UK) identified a number of themes in relation to **interactions with healthcare services** (discrimination, lack of autonomy, language barrier, embarrassment, preference or/use of “traditional medicine”), **emotional reactions to cancer** (fatalism, God’s will, punishment from god, superstition, cancer is deadly, fear delaying help seeking, fear motivating help seeking, secrecy, avoidance, stigma, taboo) and **knowledge and beliefs** (low health literacy abut cancer, causes of cancer, cancer treatment and prognosis, and cancer signs and symptoms) in minority ethnic groups <https://onlinelibrary.wiley.com/doi/10.1111/ecc.12556>  Patients from Black or Asian ethnic groups report more negative experiences of cancer care than patients from white ethnic groups (smaller proportions report that care was excellent, that they always understood the clinical nurse specialist, and that they trusted and had confidence in hospital doctors and ward nurse (<http://raceequalityfoundation.org.uk/wp-content/uploads/2018/07/REF-Better-Health-471-1.pdf>). | |
| How might ways of describing the disease be different for each ethnic group? | Response:  The systematic review <https://onlinelibrary.wiley.com/doi/10.1111/ecc.12556> described above includes some quotes from the original research articles:   * we don’t even talk loudly about cancer: we whisper when cancer is mentioned or discussed. * People feel that if they don’t talk or think about it, it won’t happen.   Many minority ethnic languages do not have a word for the disease. <https://www.bmj.com/content/314/7080/535.9> | |
| How might cultural practices, beliefs and traditions influence the acceptability of, and adherence to, the treatment(s) for each ethnic group? | Response:  Qualitative research involving 55 cancer patients from an ethnic minority background or their carers identified inequalities faced by ethnic minority patients, including deciding the best treatment and a dismissive attitude towards incorporating alternative forms of medicine as part of their treatment. <https://northerncanceralliance.nhs.uk/wp-content/uploads/2021/09/NHSE-Qualitative-report-Experiences-of-ethnic-minority-patients-in-England-2020-1.pdf> | |
| How or when might people in each ethnic group access healthcare for this disease differently? | Response:  See comments above in relation to screening, stage of presentation and route to diagnosis. | |
| 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\***

|  |  |  |
| --- | --- | --- |
| **What** | How might the intervention(s) and comparator limit participation of people from each ethnic group in the target population? | Response:  The Phase II component randomised participants to (1) conventional TME surgery, (2) organ saving utilizing long course concurrent chemoradiation, (3) organ saving utilizing short course preoperative radiotherapy. The Phase III component randomises patients who prefer organ preservation to long course concurrent chemoradiation (CRT) vs short course radiotherapy (SCRT).  A recent systematic review <https://www.sciencedirect.com/science/article/pii/S093665552200156X> concludes that it is difficult to draw conclusions on ethnicity and risk of radiotherapy toxicity.  The long course concurrent chemoradiation involves daily treatment for 5 weeks; the short course radiotherapy involves daily treatment for 5 days. From the information available, it is not clear if these treatment sessions are as out-patient/day case or in-patient. If out-patient/day case, 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.  It is not clear what terminology was used to describe the two arms with organ preservation – the trial acronym refers to “watchful waiting”. In a study of clinically-localised prostate cancer, the terminology was changed to “active monitoring” <https://www.journalslibrary.nihr.ac.uk/hta/hta24370/#/abstract>. As noted above, people from ethnic minority groups often have lower engagement with screening, and may also have lower levels of engagement with a policy of watchful waiting/active monitoring. |
| How, and in what way, were people from each ethnic group involved in selecting or designing the trial intervention/comparator? | Response:  In the information available (ISCRTN registration <https://www.isrctn.com/ISRCTN14240288>; and the study website <https://www.birmingham.ac.uk/research/crctu/trials/startrec/index.aspx> it is not clear whether people from different ethnic groups were involved in selecting or designing the trial intervention/comparator. |
| 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: It is not clear who will deliver the interventions/comparator but it is assumed that it will be delivered by the normal surgical/oncology teams within the treating hospital.  The ethnic profile of doctors in the NHS is more diverse than the wider population, with around 40% coming from ethnic minority backgrounds. Asians represent almost 30% of NHS medical staff. This may help with recruitment of some ethnic groups, although racism and prejudice among some members of the majority population could have the opposite effect.  Ethnic minority patients report lower satisfaction and less positive experiences of care overall and ethnic minority patients remained less positive than those in the White British group, after statistical adjustment. Ethnic minority patients also reported lower confidence in, and less understanding of, healthcare professionals, including clinical nurse specialists, doctors and ward nurses  It is unclear what impact these factors will have in the trial. Clear, culturally sensitive communication between doctor, patient and family will, as always, be helpful for both care delivery and the trial. |
| 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:  It is not clear from the information available how the outcome data is collected. Much of it may be available through the routine follow-up of this patient group, but it is not clear from the information available if additional study visits would be required. In the Phase II study, there are participant questionnaires at 12 and 24 months; in the Phase III study, there are questionnaires at 3, 12, 24 and 36 months. It is not clear if these are completed by post or at face-to-face visits, or if they are available in languages other than English.  If the study follow-up involves additional visits to hospital, 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:  All participants will be in hospital and have had a diagnosis of rectal cancer. |
| 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:  As noted above, it is not clear whether there are additional study visits over and above the routine follow-up that this patient group would receive.  The treatments under consideration within the study involve different numbers and length of treatment sessions:   * Surgery: hospital stay of 4-10 days * Organ saving treatment with high dose radiotherapy: radiotherapy every day for five days; MRI at 3 months followed by surgery to remove rectum or second endoscopy and MRI at 1-2 months; then regular follow-up, a small operation to remove the part of the bowel where the cancer is, or standard surgery to remove the rectum. * Organ saving treatment with long course of chemoradiotherapy – radiotherapy every weekday for 5 weeks, with a chemotherapy drug on the same days. MRI at 3 months followed by surgery to remove rectum or second endoscopy and MRI at 1-2 months; then regular follow-up, a small operation to remove the part of the bowel where the cancer is, or standard surgery to remove the rectum.   As noted above, there are patient completed questionnaires over a period up to 36 months |
| 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 inclusion criteria are primarily clinical. There is a criteria “able and willing to provide written informed consent for the study” but it is not clear from the information available if the PIL/ICF is available in languages other than English. There are contraceptive requirements (for women and men) within the organ preservation arms (not clear if this is just in the Phase III study, or in the relevant arms in the Phase II study). |
| 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:  From the information available (registration documents, trial website), it is not clear how participants are approached or made aware of the study. |
| How might the information that tells potential participants about the trial (e.g. participant information leaflet) limit the participation of each ethnic group? | Response:  From the information available, it is not clear what information potential participants receive, or whether the information is available in languages other than English, or whether it is available in a non-written form.  The lay summary on the cancer research website <https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-surgery-or-different-types-of-radiotherapy-for-rectal-cancer-star-trec#undefined> and the information on the study website <https://www.birmingham.ac.uk/research/crctu/trials/startrec/index.aspx> are written in English. |
| How might cultural practices, beliefs and traditions change the way each ethnic group perceives the information they are given? | Response:  The information that is available does not detail the information that potential participants receive about the study. It is not clear whether members of the public from any ethnic group were involved in preparing the information that potential participants receive about the study (either in writing or orally). Differences in attitudes to health research are likely to limit participation of people from different ethnic groups unless this are considered as part of the information they receive. |
| 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:  The protocol for this trial is not publicly available, and the registration documents do not detail how consent is sought or recorded, or who will receive consent. It is also not clear whether any members of the public from any ethnic group were involved in preparing the consent materials and this may limit the ability of some ethnic groups to participate. |
| How might the way people would like to discuss participation with family before providing consent differ for each ethnic group? | Response:  It is not clear if PIL/ICF are available in languages other than English, or if provision has been made to use translators.  If written material is a key part of the information provision for the trial this is likely to limit participation of individuals from any ethnic group with low literacy levels. If recruiting staff can speak the same language as the potential participant, this problem may be mitigated. Even with translation, older people from some ethnic groups do not read the language they speak.  It is also unclear if the written information has been developed together with people from a range of ethnic groups. It is possible that even for non-White British who read English well, the text may inadvertently limit participation |
| How might the way the research team can check how well consent information is understood differ for each ethnic group? | Response:  From the information available, it is not clear how the research team will check how well consent information is understood.  The challenge for the research team to understand how well consent information has been understood is around language ability and cultural competence (i.e. an awareness of issues that maybe be important to some ethnic groups but not others, or more to some groups than others). If the research team member is White-British it is unlikely that he/she/they will have this for any ethnic group other than White-British unless he/she/they has received training. |
| 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:  The protocol for this trial is not publicly available – it is not clear from the information available who was involved in the selection of outcomes. The primary outcome for the Phase II study is recruitment rate; and for the Phase III study, the proportion of patients who prefer organ preservation with successful organ preservation (in situ rectum, no defunctioning stoma and an absence of active loco-regional cancer failure at 30 months). Secondary outcomes include mortality, morbidity and quality of life. |
| 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:  After radiotherapy or chemoradiotherapy participants see the trial team every 3 months for a year, then every 6 months for the next 3 years, with a CT scan after 2 years. After surgery participants see the trial team after a month and then at regular intervals for up to 3 years, with a scan after 2 years. It is not clear from the information available all of these are part of routine follow-up for this patient group or whether any are additional study-specific visits. Many of the secondary outcomes are clinical and therefore may be available as part of routine follow-up for this patient group.  The questionnaires used (EORTC QLQ-C30, EORTC QLQ29, EQ-5D-3L, ICIQ-MLUTS, ICIQ-FLUTS) are validated and may have had PPI input during their development. Some of these questionnaires include questions about topics that people of any ethnic group may feel uncomfortable about answering (sexual disfunction, urine/stool leakage). There is also a question about depression, which carries stigma in some Black, Asian and ethnic minority groups <https://www.mentalhealth.org.uk/explore-mental-health/a-z-topics/black-asian-and-minority-ethnic-bame-communities> |
| Other factors to consider: | |
| **Who** | How might the people who collect data limit the participation of each ethnic group in the target population? | Response:  From the information available, it is not clear who the people collecting the data are – likely to be NHS staff. There are also participant questionnaires but it is not clear how these are delivered (for example by post or at a face-to-face follow-up visit). |
| Other factors to consider: | |
| **How** | How might data collection methods limit the participation of each ethnic group in the target population? | Response:  If the clinical outcomes are extracted from medical notes after routine follow-up appointments, the data extraction process itself is unlikely to limit participation of any ethnic group.  It is not clear whether the questionnaires are available in languages other than English – if they are not, this is likely to impact on participation. |
| Other factors to consider: | |
| **Where** | How might where data are collected limit the participation of each ethnic group in the target population? | Response:  If the clinical outcomes are extracted from medical notes after routine follow-up appointments, the data extraction process itself is unlikely to limit participation of any ethnic group.  If the data collection involves additional visits to hospital, the issues described previously (transport links, timing/length of visit) are likely to have an impact.  As noted above, it is not clear where the participant questionnaires are completed (by post or at follow-up visits). |
| 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:  As noted previously, it is not clear whether the outcome data is collected as part of routine follow-up or research visits to the hospital – this may impact on retention.  Again, as noted previously, it is not clear how the questionnaire data is collected, but if questionnaires are only available in England, this has potential to impact on retention. | |
| Other factors to consider: | | |
| **Benefits** | How might the benefits of the trial intervention(s) differ between each ethnic group in the target population? | Response:  It is not clear whether the benefits of each of the trial interventions are likely to differ between each ethnic group. Sample sizes are small (Phase II study n=120; Phase III study n=300) – although an exploration of benefits by ethnic group may be possible, the sample sizes may be insufficient. | |
| 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:  It is not clear whether the harms of each of the trial interventions are likely to differ between each ethnic group. Sample sizes are small but an exploration of harms may be possible. | |
| 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:  The sample size for the Phase II study is 120 participants; for the Phase III study it is 300 patients. There is no information available on the planned analysis, but the sample size may be too small for meaningful sub-group analyses. | |
| Other factors to consider: | | |
| **Interim analyses** | How should any interim analysis handle variation between ethnic groups in the target population? | | Response:  There is no information available on planned interim analysis. Any interim analysis could look for signals in harms or benefits in one or more ethnic groups. |
| 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. |
| 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:  The dissemination plan that is available on in the ISRCTN registration documents (<https://www.isrctn.com/ISRCTN14240288>) does not indicate any planned PPI input in the reporting and dissemination of trial results. The registration document indicates that a lay summary will be made available on the Cancer Research UK website. |
| Other factors to consider: | |
| **How** | How might planned reporting and dissemination methods limit engagement with each ethnic group in the target population? | Response: As noted above, a lay summary will be made available on the Cancer Research UK website. This may limit engagement. Written information that people have to find for themselves is not conducive to engagement by any ethnic group. Different methods of dissemination may help to increase engagement with the findings of the study. |
| 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: See response to “how” above. |
| 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.

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| --- | --- | --- |
| **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.

Acknowledgements

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[Centre for Black and Minority Ethnic Health](https://centreforbmehealth.org.uk/)

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[Health Research Board Trial Methodology Research](https://www.hrb-tmrn.ie/)

[Network](https://www.hrb-tmrn.ie/)

**A picture containing food, drawing

Description automatically generated**[NIHR-Medical Research Council Trial Methodology](https://www.methodologyhubs.mrc.ac.uk/about/tmrp/)

[Research Partnership](https://www.methodologyhubs.mrc.ac.uk/about/tmrp/)

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