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 Seonaidh Cotton and Shaun Treweek, University of Aberdeen. The general approach to presenting information was also discussed with two Patient and Public partners, though not the detail of the information provided here. 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. The key documents we used regarding the trial were the registration document–** [**http://www.isrctn.com/ISRCTN00786323**](http://www.isrctn.com/ISRCTN00786323) **and the protocol (V13) (**[**https://fundingawards.nihr.ac.uk/award/09/127/53**](https://fundingawards.nihr.ac.uk/award/09/127/53)**).**  **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.]**  By-Band-Sleeve will compare three surgical approaches for treatment of severe and complex obesity. It is intended to inform clinical practice directly (i.e. the design approach is pragmatic). [Obesity is a common problem in the UK](https://files.digital.nhs.uk/52/FD7E18/HSE18-Adult-Child-Obesity-rep.pdf), e.g. 67% of men and 60% of women were overweight or obese in England in 2018. These rates included 26% of men and 29% of women who were obese, and 2% of men and 4% of women were morbidly obese.  [Obesity varies by ethnicity](https://www.ethnicity-facts-figures.service.gov.uk/health/diet-and-exercise/overweight-adults/latest#by-ethnicity-over-time) with Black individuals being more likely to be obese/overweight at over 70%, while Chinese, Asian, White Other, Mixed and Other ethnic groups were all less obese than the UK average. Just over 60% of White British people were obese/overweight in 2018/19.  **In summary**  Ideally treatments should be suitable for all those at risk from the disease, which for severe obesity is essentially the whole population but particularly White British and Black individuals, and those from more deprived areas. Overall, the trial should aim to look similar to UK census data on ethnic group distribution:   * 80.5% White British * 7.5% Asian * 3.4% Black * 2.2% Mixed * 5.4% Other White * 1% Other   The focus for ensuring the required ethnic diversity in this trial is to ensure the involvement of Black individuals. Over-sampling (i.e. >3.4%) from this population is likely to be helpful to applicability of the results to this at-risk group without compromising applicability to other groups, especially White British. |

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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 that BMI cut-offs for categories of obesity should vary by ethnic group](https://www.nice.org.uk/guidance/ph46/evidence/evidence-review-pdf-430354909) based on risk to future health. Generally this evidence finds that the BMI cut-off considered to represent obesity are lower for non-White groups than the 30 used for White individuals. [Around 4% of the population in England is morbidly obese (BMI>40)](https://commonslibrary.parliament.uk/research-briefings/sn03336/). [More women than men](https://files.digital.nhs.uk/EF/AB0F0C/HSE17-Adult-Child-BMI-rep-v2.pdf) are morbidly obese (5% vs 2%). This last study found that risk of diabetes from obesity was higher in Black and Asian ethnic groups than in White, especially for women.  [Body leanness is a societal preference in Western countries, which stigmatises those who are obese](https://khub.net/documents/31798783/32039025/Obesity+and+ethnicity/834368ce-e47a-4ec6-b71c-7e4789bc7d19). How this varies across (and within) ethnic groups is unclear. However, the correlation of obesity with other forms of marginalisation, such as poverty, disability, and racial and cultural discrimination, may lead to [many people from minority ethnic groups experiencing a ‘layering’ of stigma](https://khub.net/documents/31798783/32039025/Obesity+and+ethnicity/834368ce-e47a-4ec6-b71c-7e4789bc7d19). Some studies have found that [black women have less concern about being overweight](https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1365-277X.2011.01198.x) than white women but they recognise the health risk being overweight poses. |

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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.]**  There is evidence showing that [bariatric surgery is equally acceptable to African Americans and White adults](https://pubmed.ncbi.nlm.nih.gov/30478512/) in the US. [Weight gain after surgery](https://medicalxpress.com/news/2018-11-role-regaining-weight-gastric-bypass.html) appears higher in some ethnic groups than others (e.g. Black individuals), which may affect willingness to take part. [Other studies](https://www.ajmc.com/view/understanding-the-connections-between-race-and-bariatric-surgery) (also in the US) have found that obesity has not reduced quality of life as much in African Americans than White individuals, meaning they are less likely to take up an offer of bariatric surgery. | |
| 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.]**  A key criterion is that a patient has been referred for bariatric surgery and depending on differences in referral by ethnic group, this may build in an imbalance when compared to those who could benefit. The additional criterion regarding referral to a Tier 3 obesity program may also limit participation of some ethnic groups depending on the referral characteristics to these programs. Tier 3 programs require other interventions to be tried prior to surgery, which could conceivably disadvantage some groups (see above).  All materials appear to be available in English-only, and only in writing. This will likely reduce the ability of some individuals in some ethnic groups to part, largely because of low literacy. The number of questionnaire-based outcome measures will have the same effect.  It is not clear how individuals become aware of the trial but this is likely to be direct approach at the discretion of a staff member, which may limit the ability of some ethnic groups to take part. |

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:** Obesity affects the whole community but some ethnic groups are affected disproportionately.  [Data for England in 2018/19](https://www.ethnicity-facts-figures.service.gov.uk/health/diet-and-exercise/overweight-adults/latest" \l "by-ethnicity-over-time) show that over 60% of the White British population is obese/overweight, compared to over 70% for the Black population with rates being lower (though still over 50%) for all other ethic groups except Chinese, which was 35%.  There is [some evidence that BMI cut-offs for categories of obesity should vary by ethnic group](https://www.nice.org.uk/guidance/ph46/evidence/evidence-review-pdf-430354909) based on risk to future health. Generally this evidence finds that the BMI cut-off considered to represent obesity are lower for non-White groups than the 30 used for White individuals. This is considered particularly important for South Asians. |
| How might the severity of the disease vary between each ethnic group? | **Response:** [Around 4% of the population in England is morbidly obese (BMI>40)](https://commonslibrary.parliament.uk/research-briefings/sn03336/). [More women than men](https://files.digital.nhs.uk/EF/AB0F0C/HSE17-Adult-Child-BMI-rep-v2.pdf) are morbidly obese (5% vs 2%). This last study found that risk of diabetes from obesity was higher in Black and Asian ethnic groups than in White, especially for women. |
| How might the disease present in people from each ethnic group (this may include symptoms, type or pattern or rate of disease progression)? | **Response:** Weight is objective so in that regard presentation will be the same across all ethnic groups. However, the potential for different BMI cut-offs to classify severe obesity (see above) means that severe obesity will present at lower weights for some ethnic groups, especially Black and Asian groups. | |
| 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 prevalence of obesity means that White individuals are a key ethnic group for this trial and recruitment sites anywhere in the UK should be able to recruit this ethnic group. Recruitment of other key ethnic groups (e.g. Black, Asian) is likely to need recruitment sites in places with substantial populations of people from these ethnic groups (e.g. [London and Birmingham](https://khub.net/documents/31798783/32039025/Obesity+and+ethnicity/834368ce-e47a-4ec6-b71c-7e4789bc7d19)).  The trial does have sites in London, Birmingham and Leeds (and others) so should be able to recruit a diverse trial population. | |
| 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:** [Body leanness is a societal preference in Western countries, which stigmatises those who are obese](https://khub.net/documents/31798783/32039025/Obesity+and+ethnicity/834368ce-e47a-4ec6-b71c-7e4789bc7d19). Overweight people are often linked to socially undesirable behaviours, weakness of will, laziness and greed. Obesity can be seen as a symbol of affluence and success in some traditional, non-Western societies.  How this varies across (and within) ethnic groups is unclear. However, the correlation of obesity with other forms of marginalisation, such as poverty, disability, and racial and cultural discrimination, may lead to [many people from minority ethnic groups experiencing a ‘layering’ of stigma](https://khub.net/documents/31798783/32039025/Obesity+and+ethnicity/834368ce-e47a-4ec6-b71c-7e4789bc7d19).  Several ethnic minority groups, particularly Arabic, Black African and Black Caribbean, [have a deep mistrust of medical research stemming from a history of systemic racism within the medical and research worlds](https://www.demanddiversity.co/resources;%20https:/onlinelibrary.wiley.com/doi/epdf/10.1111/dme.13895).  It is important that the trial team provide clear, transparent information about the trial – why it is being done, what any potential participant may be asked to do, and clarity around potential benefits and harms. | |
| How might ways of describing the disease be different for each ethnic group? | **Response:** Some studies have found that [Black women have less concern about being overweight](https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1365-277X.2011.01198.x). We were unclear if there were differences among people from other ethnic groups. | |
| How might cultural practices, beliefs and traditions influence the acceptability of, and adherence to, the treatment(s) for each ethnic group? | **Response:** Generally, several ethnic minority groups essential for the trial (e.g. Black Africans) have a [deep mistrust of medical research](https://www.demanddiversity.co/resources).  In other regards it is unclear to what extent beliefs and traditions might affect acceptability of the surgical interventions in the trial. A study of the UK bariatric surgery register did show that surgery rates were similar for White, Asian and Black patients, which suggests [similar views on this type of surgery](https://care.diabetesjournals.org/content/diacare/39/6/949.full.pdf) (the situation was different in the US but this was considered to be due to differences in insurance coverage). Some studies have found that [Black women have less concern about being overweight](https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1365-277X.2011.01198.x) than White women but they recognise the health risk being overweight poses. | |
| How or when might people in each ethnic group access healthcare for this disease differently? | **Response:** This is unclear. However, [health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support](https://www.england.nhs.uk/wp-content/uploads/2017/07/inequalities-resource-sep-2018.pdf). This means that individuals from ethnic minority communities may present later than their white counterparts, which is likely to lead to increased complications and poorer health outcomes. Different beliefs about weight and obesity (see above) may mean healthcare support is sought differently by people from some ethnic groups because body size is not considered a health problem. | |
| 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 interventions are three types of laparoscopic surgery, compared to each other.  It is unclear how the interventions may limit participation. There is evidence showing that [bariatric surgery is equally acceptable to African Americans and White adults](https://pubmed.ncbi.nlm.nih.gov/30478512/) in the US, although awareness of it is higher in Whites. [Weight gain after surgery](https://medicalxpress.com/news/2018-11-role-regaining-weight-gastric-bypass.html) appears higher in some ethnic groups than others (e.g. Black individuals), which may affect willingness to take part. [Other studies](https://www.ajmc.com/view/understanding-the-connections-between-race-and-bariatric-surgery) (also in the US) have found that obesity has not reduced quality of life as much in African Americans than White individuals, meaning they are less likely to take up an offer of bariatric surgery.  [Some studies](https://bmjopen.bmj.com/content/9/11/e029525) have found that the requirements for pre-operative programs can disadvantage some across all ethnic groups because of e.g. weight loss requirements, mandatory appointments and physical activity requirements. However, By Band Sleeve has no such requirements.  In summary, it is unclear how the intervention will affect participation in the UK although an assumption that the intervention is equally attractive and feasible for all ethnic groups seems unlikely to be true. The influence of surgeons in referring and its impact on ethnic diversity should be considered too as surgeons do have a strong role in patient selection generally (from protocol). |
| How, and in what way, were people from each ethnic group involved in selecting or designing the trial intervention/comparator? | **Response:** It is not clear that any members of the public from any ethnic group were involved in the selection of interventions or comparator. Given the funder (the UK’s National Institute for Health Research) is likely that there are patient and public members on the Trial Steering committee. |
| 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:** All treatments will be delivered by surgeons and other staff working within the NHS. The ethnic profile of doctors in the NHS is [more diverse than the wider population](https://www.ethnicity-facts-figures.service.gov.uk/workforce-and-business/workforce-diversity/nhs-workforce/latest#by-ethnicity), 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](https://bmjopen.bmj.com/content/bmjopen/6/6/e011938.full.pdf) 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:** The intervention will be delivered face-to-face in hospital, although the patient will be under general anaesthetic at the time so will be unaware of the procedure.  Mode of delivery is unlikely to be a factor; if surgery is acceptable to an individual, there is no other way to deliver it than as in By Band Sleeve. |
| 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.  Health beliefs (see Worksheet 1) may mean that some ethnic groups’ resistance to seeking health care means care is not sought, or sought very late. Both may lead to poor outcomes. However, for a surgical intervention it is hard to imagine another environment than a hospital. |
| 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:** All interventions will be delivered in hospital and the timing of surgery is unlikely to be an issue, especially since the patient may already be in hospital for the procedure.  The procedure itself may not need great commitment but [preparation for surgery may be a challenge for some](https://bmjopen.bmj.com/content/9/11/e029525). All interventions need close follow up and more surgical procedures are not uncommon. Bands in particular need many visits to hospital for band adjustment (up to 7 in the first year from the protocol) and this may affect participation from some members of some the ethnic groups where transport and ability to leave work are problems. |
| 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:** A key criterion is that a patient has been referred for bariatric surgery and depending on differences in referral by ethnic group, this may build in an imbalance when compared to those who could benefit. The referral criterion is adjusted for Asians with regard to BMI. The additional criterion regarding referral to a Tier 3 obesity program may also limit participation of some ethnic groups depending on the referral characteristics to these programs. Tier 3 programs require other interventions to be tried prior to surgery, which could conceivably disadvantage some groups.  It is unclear what effect these referral pathways have but the ethnic diversity of the trial cannot be better than the ethnic diversity of the referral pathway.  The criterion ‘Committed to follow-up’ could, in principle, be used consciously or unconsciously to exclude some ethnic groups depending on how it is interpreted. It could, for example, be used as a proxy to exclude individuals where the next stage of the trial process, consent, is considered likely to be difficult for reasons of language, health literacy or other non-clinical reason. Alternatively, recruiters may simply fail to consider some individuals for the trial for reasons of perceived later practical difficulty. See below. |
| 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:** A member of healthcare or research staff will mention the trial directly to the potential participant and give them a patient information leaflet. Awareness of the trial is therefore at the recruiter’s discretion unless there are other ways in which awareness of the trial is raised.  Depending on the language skills of both staff member and potential participant/family members, and the difficulties of making that approach as perceived by the recruiter, a direct recruiter approach may limit the ability of some members of some ethnic groups (e.g. older South Asians, especially women; some White non-British) to take part. See below. |
| How might the information that tells potential participants about the trial (e.g. participant information leaflet) limit the participation of each ethnic group? | **Response:** It is unclear if the participant information leaflet and other materials are available in languages other than English, or are available in non-written forms The [study website](http://www.by-band-sleeve.bristol.ac.uk/info-for-patients/) only provides information in English.  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 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 (See Worksheet 1). |
| How might cultural practices, beliefs and traditions change the way each ethnic group perceives the information they are given? | **Response:** It is not clear that members of the public from any ethnic group have been involved in preparing the written materials, or influenced what staff tell potential participants. Differences regarding attitudes to the benefits/need for health research generally and concerns about drugs ingredients for some (e.g. Black and some Asian groups, see Worksheet 1) will probably limit their participation unless addressed in writing or verbally. Translation of material needs to consider these issues in addition to simple translation from one language into another.  In some Asian groups (e.g. Pakistani) [older women may look to their husbands or other male family member for guidance](https://www.demanddiversity.co/resources); discussions about participation will need to explicitly consider this. |
| 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:** It is not clear that members of the public from any ethnic group have been involved in preparing the consent materials, or whether they are available in languages other than English, which for reasons given above, may well limit the ability of some ethnic groups to participate. [Written consent may limit participation](http://arc-em.nihr.ac.uk/clahrcs-store/increasing-participation-black-asian-and-minority-ethnic-bame-groups-health-and-social) of some groups (e.g. South Asians) who may prefer verbal discussion to written documents. | |
| How might the way people would like to discuss participation with family before providing consent differ for each ethnic group? | **Response:** Individuals in some ethnic groups (e.g. [South Asian women](https://www.researchgate.net/publication/7480322_The_Influence_of_Family_on_Immigrant_South_Asian_Women%27s_Health)) are more likely to want to involve family in decisions and this may limit their ability to take part if this cannot happen. An awareness of the likely need to explicitly involve other family members, especially for older South Asian women and Arabic women, would help recruitment of individuals from these groups. | |
| How might the way the research team can check how well consent information is understood differ for each ethnic group? | **Response:** The chief 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:** It is not clear whether any members of the public from any ethnic group were involved in the selection of trial outcomes. |
| 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:** There are a lot of outcomes, many of them written, self-completed questionnaires, which will limit participation of people from any ethnic group with low literacy. It is unclear whether these measures have been validated across different ethnic groups, or in languages other than English. Some measures (waist circumference) need some layers of clothing removed, which may be an issue for more conservative members of any ethnic group. Once question is relates to [depression, which carries stigma](https://www.mentalhealth.org.uk/a-to-z/b/black-asian-and-minority-ethnic-bame-communities) in some Black, Asian and ethnic minority groups. A substantial amount of data collection is likely to limit participation of Black individuals, and some Asian individuals as they are [known to trust medical and research professionals less](https://www.demanddiversity.co/resources).  Blood is taken and participation could be limited for those that are scared of needles, but this is not a problem specific to any ethnic group. |
| Other factors to consider: | |
| **Who** | How might the people who collect data limit the participation of each ethnic group in the target population? | **Response:** It is not clear who the people collecting the data are – likely to be NHS staff. Potential issues are discussed in worksheet 2. |
| Other factors to consider: | |
| **How** | How might data collection methods limit the participation of each ethnic group in the target population? | **Response:** See above under ‘*What*’. |
| Other factors to consider: | |
| **Where** | How might where data are collected limit the participation of each ethnic group in the target population? | **Response:** Data are likely to be collected in hospital (there are some online and options). The main issue is likely to be getting to the hospital and the time needed to complete the measures, which may well disadvantage individuals from Black, Asian and ethnic minority backgrounds on socioeconomic grounds (e.g. need to use public transport) and/or because of being less likely to leave work for a daytime appointment. |
| 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:** Data are collected during research visits at hospital sites – see worksheet 2 for discussion of the potential issues with this. |
| Other factors to consider: | |
| **Benefits** | How might the benefits of the trial intervention(s) differ between each ethnic group in the target population? | **Response:** There is evidence of a [differential effect for some ethnic groups](https://medicalxpress.com/news/2018-11-role-regaining-weight-gastric-bypass.html) (e.g. Black) so it would be worth considering adjustment/exploration of effect by ethnic group. |
| 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– worth considering exploration of differences by ethnic group. |
| 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 potential for poorer outcomes for people with African and African-Caribbean heritage. It is unlikely that any subgroup will be adequately powered, although over-sampling of some ethnic groups may help (and would be unlikely to adversely affect applicability to the majority population). |
| 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. |
| 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:** It is not clear if or how any patient or public partners were involved in planning the reporting and dissemination of the trial results. |
| Other factors to consider: | |
| **How** | How might planned reporting and dissemination methods limit engagement with each ethnic group in the target population? | **Response:** The protocol details scientific presentations and publications, as well as dissemination through patient organisations and newsletters to patients, which may limit engagement with all ethnic groups.  The reporting and dissemination methods described in the protocol also appear to be largely one-way communication methods. Different methods are likely to increase engagement with ethnic groups in different ways, so there should be a variety of dissemination methods developed that are tailored to various groups of the public. |
| 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:** Similar to the points made above – using written material as the primary 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](https://centreforbmehealth.org.uk/resources/toolkits/) (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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[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/)

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