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 Heidi Gardner (University of Aberdeen) and Peter Bower (University of Manchester). 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 trial report:** [**https://doi.org/10.3310/eme08030**](https://doi.org/10.3310/eme08030) **and the trial registration document:** [**https://www.isrctn.com/ISRCTN15283219**](https://www.isrctn.com/ISRCTN15283219)**.**  **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.]**  LONG LIMB is a trial investigating obesity in diabetic patients. Obesity affects the whole community, but some groups are affected disproportionately. Data for England in 2018/19 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 ethnic groups except Chinese, which was 35%. In the UK there are 2.5 million people who have been diagnosed with diabetes – an estimated 90% of those have type 2 diabetes. Type 2 diabetes is up to 6 times more likely in people of South Asian descent (Indian, Pakistani, Sri Lankan and Bangladeshi heritage) than in the white population. South Asians are estimated to be around 11% of the UK type 2 diabetes population minority ethnic individuals were 21% of the type 2 diabetes population in England in 2018/19. People of African and African-Caribbean descent are also known to have an increased risk of type 2 diabetes. A study which followed nearly 5000 middle-aged Londoners of European, South Asian, African, and African-Caribbean descent for more than 20 years, revealed that half of all people from South-Asian, African, and African-Caribbean descent will develop type 2 diabetes by age 80, compared with a fifth of people with European descent.  Around 4% of the population in England is morbidly obese (BMI>40). More women than men 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. Around 4% of the population in England is morbidly obese (BMI>40). More women than men 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.  South Asians experience significant morbidity and mortality from complications of diabetes – including diabetic retinopathy, coronary artery disease, cerebrovascular disease, and chronic kidney disease. Kidney disease is also known to progress faster in people of South Asian descent in comparison to people of European descent. The response to treatment may vary, with differences seen in studies where the trial population was Asian-dominant compared to non-dominant. There is also evidence that African-Caribbean people with diabetes have poorer outcomes than the general population.  The trial team should work to include South Asians, Africans and African-Caribbeans, particularly younger members of these communities, in this trial.  The trial population should look like population of the UK that are obese and living with type 2 diabetes population. This means that it needs to involve ethnic minority individuals, especially South Asians and Black Caribbeans, at higher levels than in the general population. |

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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 of obesity, and complications as a result the condition are increased, and age of onset is younger in diabetes in Black and Asian communities in comparison to white-British populations. Due to the increased health demands of these minority groups, they may stand to benefit more to the treatment. It is not clear whether the root cause of these differences is genetic, social, cultural, or a mix of factors, so it is difficult to suggest whether these groups will respond to the treatment in different ways. |

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| **3. Will my trial intervention and/or comparator make it harder for any of the groups identified in Question 1 to engage with the intervention and/or comparator?** [**( VIEW WORKSHEET )**](#WorksheetTWO) | |
| **[This question has been answered with a focus on ethnicity for the purposes of this example, though the questions have wider relevance than ethnicity.]**  The interventions are both surgeries; either the standard-limb or long-limb gastric bypass.  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 in the US, although awareness of it is higher in white people. Weight gain after surgery appears higher in some ethnic groups than others (e.g., Black individuals), which may affect willingness to take part. Other studies (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 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, this trial does not have any of these requirements.  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, 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.  The trial report’s section on patient and public involvement details partnerships between the trial’s research and clinical teams and the west-London brand of the British Obesity Surgery Patient Association (BOSPA), the National Obesity Forum, and the Diabetes Research Network PPI group. Members of these groups were asked the following questions: What are your initial feelings about the research? Do you think the research question is important? What issues do you feel with prevent people from taking part in the study? Do you feel that the treatment and assessment plan will be acceptable to the participants? It is not clear which ethnic groups were represented by the PPI representatives, but it’s reasonable to assume that some ethnic minority voices were included due to the scale of the groups involved and the geographic location of the west-London branch of the BOSPA. | |
| 1. **Will the way I have planned and designed my trial make it harder for any of the groups identified in Question 1 to consider taking part?** [**( VIEW WORKSHEET )**](#WorksheetTHREEA) |
| **[This question has been answered with a focus on ethnicity for the purposes of this example, though the questions have wider relevance than ethnicity.]**  It is not clear how participants are made aware of the trial, what information they receive, how consent is taken, or if/how consent information is understood. South Asian women, particularly older women, are known to make decisions about their healthcare in consultation with members of their family. Involvement of family members in the consent process should therefore be considered. Translation of at least some trial documentation is likely to be required.  Research visits at hospital sites are used for outcome data collection. 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.  The trial’s primary outcome and some of the secondary outcomes rely on a blood sample taken at each of the research visits. Weight, blood pressure and participant safety data are also collected. Participation could be limited for those that are scared of needles, but this is not a problem specific to any ethnic group. |

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

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

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

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

**Worksheet 1**

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

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

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| **Disease** | How might the prevalence of the disease vary between each ethnic group in the target population? | **Response:** The disease being studied is obesity in diabetic patients. Obesity affects the whole community, but some 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#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 ethnic 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.  In the UK there are 2.5 million people who have been diagnosed with diabetes – an estimated 90% of those have type 2 diabetes. [Type 2 diabetes is up to 6 times more likely in people of South Asian descent (Indian, Pakistani, Sri Lankan and Bangladeshi heritage)](https://www.diabetes.org.uk/resources-s3/2017-11/south_asian_report.pdf) than in the white population. [South Asians are estimated to be around 11% of the UK type 2 diabetes population minority ethnic individuals were 21% of the type 2 diabetes population in England](https://fingertips.phe.org.uk/profile/diabetes-ft/data#page/0/gid/1938133138/pat/44/par/E40000007/ati/154/are/E38000007/cid/4/tbm/1/page-options/ovw-do-0) in 2018/19.  People of African and African-Caribbean descent are also known to have an increased risk of type 2 diabetes.  [A study](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3304519/) which followed nearly 5000 middle-aged Londoners of European, South Asian, African and African-Caribbean descent for more than 20 years, revealed that half of all people from South-Asian, African and African-Caribbean descent will develop type 2 diabetes by age 80, compared with a fifth of people with European descent. |
| 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.  South Asians experience significant morbidity and mortality from complications of diabetes – including [diabetic retinopathy](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2646018/), [coronary artery disease, cerebrovascular disease](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4026332/), and [chronic kidney disease](https://care.diabetesjournals.org/content/29/6/1383). Kidney disease is also known to [progress faster](https://care.diabetesjournals.org/content/29/6/1383) in people of South Asian descent in comparison to people of European descent.  There is also evidence that African-Caribbean people with diabetes have poorer outcomes than the general population. The [prevalence](https://pubmed.ncbi.nlm.nih.gov/8762376/) of stroke and chronic kidney disease is higher in African-Caribbean people than in the general population of the UK. |
| 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.  [Children of all ethnic minority backgrounds](https://pubmed.ncbi.nlm.nih.gov/27426206/) are at greater risk for childhood-onset type 2 diabetes, particularly girls. In terms of adult age of onset, diabetes risk increases with age in all groups, but onset is much earlier in those of non-European heritage. People from Black African, African-Caribbean and South Asian backgrounds are at risk of developing type 2 diabetes [from the age of 25](https://www.diabetes.org.uk/preventing-type-2-diabetes/diabetes-risk-factors). This is much younger than the white population where risk increases from age 40.  Black Africans, African-Caribbeans and white Europeans tend to be diagnosed at around the same age (66-67 years), whereas South Asian men were [5 years younger on average](https://care.diabetesjournals.org/content/early/2012/09/06/dc12-0544.abstract) when diabetes was diagnosed at an even greater risk of related complications. | |
| 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 both 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. The prevalence of diabetes means that people from South Asian backgrounds and Black Africans and/or African-Caribbeans should be represented in this trial too. The trial has two recruiting sites, both based in [London](https://khub.net/documents/31798783/32039025/Obesity+and+ethnicity/834368ce-e47a-4ec6-b71c-7e4789bc7d19), which is the most diverse city in the UK and should therefore 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).  Evidence around social stigma in type 2 diabetes is not conclusive. A [qualitative synthesis](https://bmcendocrdisord.biomedcentral.com/articles/10.1186/s12902-016-0103-0) suggested that non-adherence to medicines could be the cause of poor clinical outcomes for South Asian patients, with the reasons for non-adherence being attributed to 1) beliefs about the need for and efficacy of medicines, 2) toxicity of medicines and polypharmacy, 3) the necessity of traditional remedies versus ‘western medicines’, 4) stigma and social support, and 5) communication. Stigma and social support was found to have a major influence on medicine taking, with South Asian patients being reluctant to disclose their use of insulin to their families and community. This is described in a [2004 publication](https://onlinelibrary.wiley.com/doi/pdf/10.1002/pdi.624) where a young South Asian girl with type 2 diabetes was unwilling to accept treatment as it was felt by both her and her family that acceptance of the diagnosis of diabetes would adversely affect her prospects for an arranged marriage. A [2013 systematic review of studies of barriers to self-management of type 2 diabetes](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5060817/pdf/HEX-18-0625.pdf).) among minority groups found views on stigma mixed, some thinking it was a barrier, others finding that type 2 diabetes being so common meant it was not stigmatized.  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). [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.  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:** Diabetes is sometimes called ‘high sugar’, (e.g. some South Asians). Other terms may be used 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:** Generally, several ethnic minority groups essential for the trial 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.  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. This thought process also applies to accepting surgical treatments, with people believing that a trial is not necessary because faith in God is needed more than medicine. | |
| How or when might people in each ethnic group access healthcare for this disease differently? | **Response:** In general terms, [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 described above, may mean healthcare support is sought differently by people from some ethnic groups because body size is not considered a health problem.  In terms of diabetes, a [2014 systematic review](https://diversityhealthcare.imedpub.com/cultural-barriers-impeding-ethnic-minority-groups-from-accessing-effective-diabetes-care-services-a-systematic-review-of-observational-studies.php?aid=1595) assessed cultural barriers that impede ethnic minority groups from accessing effective diabetes care services. Eight key cultural issues emerged, namely participants’ strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy levels, different beliefs about health and illness, belief in expert and professional support, low accessibility of culturally-appropriate services/information, and low concordance with western professional advice.  [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. As mentioned earlier, [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 interventions are both surgeries; either the standard-limb or long-limb gastric bypass.  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 white people. [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, this trial does not have any of these requirements. |
| How, and in what way, were people from each ethnic group involved in selecting or designing the trial intervention/comparator? | **Response:** The trial report’s section on patient and public involvement details partnerships between the trial’s research and clinical teams and the west-London brand of the British Obesity Surgery Patient Association (BOSPA), the National Obesity Forum, and the Diabetes Research Network PPI group. Members of these groups were asked the following questions: What are your initial feelings about the research? Do you think the research question is important? What issues do you feel with prevent people from taking part in the study? Do you feel that the treatment and assessment plan will be acceptable to the participants?  Three PPI representatives from the groups contributed to the development of the grant application, starting from its design, and to undertaking the research and the choice of research topics, and will help with dissemination of study findings through their organisations. It is not clear which ethnic groups were represented by the PPI representatives, but it’s reasonable to assume that some ethnic minority voices were included due to the scale of the groups involved and the geographic location of the west-London branch of the BOSPA. |
| 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 this trial. |
| 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:** 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. |
| 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 clinically focussed and do not give cause for concern with regards to limiting participation of any ethnic groups.  It is not clear what sort of medical history information are taken at baseline or later. |
| Other factors to consider: | |
| **Opportunity to participate** | How might the way(s) (and by whom) potential participants are made aware of the trial (e.g. posters in clinic, written letter from a doctor, asked by a nurse) limit the participation of each ethnic group in the target population? | **Response:** It is not clear how potential participants will be made aware of the trial, the report states that participants were recruited from the Imperial College Healthcare NHS Trust and King’s College Hospital NHS Foundation Trust by the clinical and research teams. It seems that 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:** The trial report does not detail the information that potential participants receive about trial.  As some ethnic groups including individuals for whom English may not be their first language are a key required group within the trial (e.g. South Asians, Indian subcontinent) then translation of written and oral material into some languages other than English is likely to be essential (see above). [Other cultural barriers for South Asians](https://onlinelibrary.wiley.com/doi/epdf/10.1111/dme.13895) (e.g. preference for traditional remedies, see earlier) may be as important, or more important, than linguistic barriers so should not be forgotten. [These beliefs, and linguistic issues, are likely to be more relevant among older generations](https://onlinelibrary.wiley.com/doi/epdf/10.1111/dme.13895).  It is unclear if the written/verbal information has been developed together with people from a range of ethnic groups. |
| How might cultural practices, beliefs and traditions change the way each ethnic group perceives the information they are given? | **Response:** As above. |
| 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 trial report does not detail the wat that consent is sought from participants.  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:** [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 family. Involvement of family members in the consent process should therefore be considered. | |
| How might the way the research team can check how well consent information is understood differ for each ethnic group? | **Response:** The protocol for this trial is not publicly available, and the registration documents do not detail if/how the research team will check how well consent information is understood.  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**

|  |  |  |
| --- | --- | --- |
| **What** | How, and in what way, were people from each ethnic group in the target population involved in selecting the trial outcomes? | **Response:** The trial report’s section on patient and public involvement details partnerships between the trial’s research and clinical teams and the west-London brand of the British Obesity Surgery Patient Association (BOSPA), the National Obesity Forum, and the Diabetes Research Network PPI group. Members of these groups were asked the following questions: What are your initial feelings about the research? Do you think the research question is important? What issues do you feel with prevent people from taking part in the study? Do you feel that the treatment and assessment plan will be acceptable to the participants? This feedback influenced the direction of both the trial and the mechanistic studies included in the trial report.  Three PPI representatives from the groups contributed to the development of the grant application, starting from its design, and to undertaking the research and the choice of research topics, and will help with dissemination of study findings through their organisations. It is not clear which ethnic groups were represented by the PPI representatives, but it’s reasonable to assume that some ethnic minority voices were included due to the scale of the groups involved and the geographic location of the west-London branch of the BOSPA. |
| 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 trial’s primary outcome and some of the secondary outcomes rely on a blood sample taken at each of the research visits. Weight, blood pressure and participant safety data are also collected. Participation could be limited for those that are scared of needles, but this is not a problem specific to any ethnic group.  It is not clear what background information are collected from the patient. |
| 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 (e.g., use of public transport) and the time needed to complete the measures (e.g., leaving work or getting away from caring responsibilities to attend appointments). These issues may disadvantage people experiencing socioeconomic disadvantage. People from ethnic minority communities are at higher risk of socioeconomic disadvantage, and participation could therefore be limited. |
| 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 likely to be collected during research visits at hospital sites – see worksheet 3b 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:** The prevalence of the disease may differ for ethnic minority groups, as discussed previously, but there is no reason to believe that the impact(s) of the trial intervention will differ between ethnic groups. |
| 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 disproportionate effects of diabetes on people with South Asian, African and African-Caribbean 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**

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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 trial report is published open access in the NIHR Journals Library, and though it doesn’t mention a dissemination plan at all, it does refer to dissemination in the patient and public involvement section. The patient support groups discussed previously will be approached to help disseminate the findings of the trial to the local patient and healthcare communities – how this will take place is currently being decided on.  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, as can social media. |
| Other factors to consider: | |
| **How** | How might planned reporting and dissemination methods limit engagement with each ethnic group in the target population? | **Response:** As above. |
| 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:** As 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.

|  |  |  |
| --- | --- | --- |
| **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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