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/hta25770**](https://doi.org/10.3310/hta25770) **and the trial registration document:** [**https://www.isrctn.com/ISRCTN83465245**](https://www.isrctn.com/ISRCTN83465245)**.**  **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.]**  The disease being studied is impaired glucose regulation (IGR). IGR describes the state where blood glucose levels are raised above the normal range but do not meet the criteria for type 2 diabetes. IGR can progress to diabetes, so targeting those people with IGR provides an opportunity to prevent type 2 diabetes.  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, and minority ethnic individuals accounted for 21% of the type 2 diabetes population in England in 2018/19. South Asian without diabetes are 3 times more likely to develop cardiovascular disease than the white majority population, but combined with type 2 diabetes, this risk rises even further, particularly for adults with type 2 diabetes aged 20 to 60.  People from South Asian background are more likely to store fat around their middle, this visceral fat can build up around organs like the liver and pancreas and is thought to be one of the major reasons why South Asian individuals at are higher risk of developed type 2 diabetes.  Note: When we say South Asian, we tend to mean people from an Indian, Pakistani, or Bangladeshi background, and research confirms that these individuals are at higher risk of developing type 2 diabetes. South Asian can also refer to people from neighbouring countries such as Afghanistan, Sri Lanka, and Nepal, but currently we don’t know as much about their specific risk of developing type 2 diabetes.  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. People from Black African, African-Caribbean, and South Asian backgrounds are at risk of developing type 2 diabetes from the age of 25. 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 when diabetes was diagnosed at an even greater risk of related complications.  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. There is also evidence that African-Caribbean people with diabetes have poorer outcomes than the general population. The prevalence of stroke and chronic kidney disease is higher in African-Caribbean people than in the general population of the UK. |

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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.  Recent research from the University of Glasgow’s Institute of Cardiovascular and Medical Sciences, suggests that South Asians need to exercise for longer than Europeans to gain the same level of physical benefit. So while the behavioural treatment in the PROPELS trial aims to increase physical exercise measured by steps taken per day, it may be that the potential benefits of this intervention are lower for people with South Asian heritage. |

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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 trial report’s acknowledgements section mentions and thanks patient and public involvement groups. Both the Walking Away and Walking Away Pus interventions evaluated in this trial were developed using iterative development cycles with patient and public involvement embedded throughout. In particular, patient and public involvement facilitated through the NIHR ARC East Midlands (formerly CLAHRC) contributed to how diabetes risk was communicated in Walking Away for use within multi-ethnic populations. The dietary section was also based on patient and public involvement suggesting that the focus on physical activity should be complimented by also communicating the key dietary factors related to diabetes risk.  The interventions are both behavioural. The control group is given an information leaflet containing information on risk factors for type 2 diabetes and cardiovascular disease and how physical activity can be used to prevent them. The walking away group will receive the same booklet as group 1 and will also be offered a group−based structured educational programme aimed at promoting increased ambulatory activity by targeting perceptions and knowledge of diabetes risk, physical activity self−efficacy, barriers to physical activity and self−regulatory skills based on pedometer use. Walking away plus participants will receive the same booklet as the control group, and the same education programme and support describe in the walking away group, as well as a mobile health intervention that provided automated, individually tailored text messages to prompt pedometer use and goal setting and provide feedback.  It is unclear how the interventions may limit participation. There is evidence to suggest that there are structural barriers to South Asians taking part in regular exercise. A qualitative study found that South Asians living in Scotland view physical activity in a similar way to the general population, have similar motivations and they enjoy (or would like to enjoy) more or less the same activities (particularly swimming, walking, and using the gym). Whilst some of the barriers identified in this study were similar to much of the population (cost, childcare, and lack of time or motivation), people with South Asian heritage may also face barriers which can severely restrict choice, particularly for women. For example, swimming and using the gym are two of the most popular activities for everyone in the UK including South Asians, but many South Asian women are unable to use their local leisure centre because of culturally inappropriate facilities. Many South Asian people (particularly women) are thus effectively denied access to some of the leisure services. The barriers outlined above impacted not only on the adults we interviewed, but also the type and amount of physical activity that their children participated in. A study of self-reported physical activity in England compared South Asian ethnic groups with the white British group, and demonstrated that differences exist between the groups in various types of physical activity, except for walking. This is good news for the PROPELS trial, which focuses on improving activity in terms of number of steps taken per day.  Walking Away was delivered by two trained educators to groups of up 10 participants, with participants invited to bring a family member or a guest if they wished. Sessions were delivered in a variety of settings chosen for proximity to the recruiting GP surgeries, including at the surgeries themselves, in nearby community centres and at hospital sites.  It is unclear what impact these factors will have in the trial. Clear, culturally sensitive communication between the educators, and the patient and family will, be helpful for the trial. | |
| 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.]**  Individuals were eligible for the trial if they were aged 40-74 years, or 25-74 years if they were South Asian, had a recorded plasma glucose or HbA1c value in the prediabetes range during the previous 5 years, had access to a mobile telephone and were willing to use it as part of the study. Individuals were excluded from the trial if they were: unable to take part in ambulatory-based activity, pregnant, involved in other related intervention studies, diagnosed with diabetes or diabetes was detected at baseline visit, unable to understand basic written and verbal English, and/or unable to give informed consent.  The widened age bracket for people from South Asian backgrounds is a positive step by this trial, but the exclusion criteria do present potential issues for the inclusion of ethnic minority individuals.  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. Other cultural barriers for South Asians (e.g., preference for traditional remedies) 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. In addition, the need for access and use of a mobile telephone (and presumably Wi-Fi or mobile data), may exclude people experiencing socioeconomic disadvantage. We know that ethnic minority individuals are more likely to experience socioeconomic disadvantage, so this inclusion criterion has the potential to disproportionately impact ethnic minority participation.  The primary method of recruitment was through primary care by using data collected by the NHS Health Checks programme, a screening programme run in England designed to identify and treat vascular disease risk (heart disease, stroke, diabetes, and kidney disease) in all individuals aged 40–74 years, which has led to many primary care practices recording their patients’ HbA1c or fasting glucose values. The trial team worked in collaboration with practices providing the Health Checks programme to recruit individuals who were identified as having prediabetes. Eligible individuals were sent an invitation letter, a brochure about the study and a reply slip. Those recruited directly from primary care were sent the invitation letters by the primary care practice at which the search was conducted. Those recruited from existing research databases were sent the invitation by the principal investigator of that study. Individuals who were interested in taking part were asked to return the reply slip directly to the PROPELS trial research team. An appointment was then arranged for a baseline visit and the individual was sent the full study patient information sheet along with a confirmation letter.  Some research suggests that the response to written invitations via healthcare staff may be 5.2% lower in South Asians than in general populations, with community oriented, in-person approaches being more successful.  Data collection clinics were run by research nurses in the Leicester Diabetes Centre, in the MRC Epidemiology Unit in Cambridge, and at other local community centres and clinic areas. The Leicester Diabetes Centre is a partnership between the University of Leicester and the NHS, so some of the data may be collected by staff working for 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. |

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 impaired glucose regulation (IGR). IGR describes the state where blood glucose levels are raised above the normal range but do not meet the criteria for type 2 diabetes. IGR can progress to diabetes, so targeting those people with IGR provides an opportunity to prevent type 2 diabetes.  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, and minority ethnic individuals accounted for 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. South Asian without diabetes are [3 times more likely](https://www.diabetes.co.uk/south-asian/) to develop cardiovascular disease than the white majority population, but combined with type 2 diabetes, [this risk rises even further](https://www.diabetes.co.uk/south-asian/), particularly for adults with type 2 diabetes aged 20 to 60.  People from South Asian background are mor[e likely to store fat around their middle](https://www.diabetes.org.uk/node/12895), this visceral fat can build up around organs like the liver and pancreas and is thought to be one of the major reasons why South Asian individuals at are higher risk of developed type 2 diabetes.   [Note](https://www.diabetes.org.uk/node/12895): When we say South Asian, we tend to mean people from an Indian, Pakistani, or Bangladeshi background, and research confirms that these individuals are at higher risk of developing type 2 diabetes. South Asian can also refer to people from neighbouring countries such as Afghanistan, Sri Lanka, and Nepal, but at the moment we don’t know as much about their specific risk of developing type 2 diabetes.  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:** 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:** [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 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, one in Leicester and one in Cambridge. Data from the 2011 census showed that Leicester was the [most ethnically diverse region](https://www.bbc.co.uk/news/uk-england-leicestershire-20678326) in the UK, with 50.52% of people identifying as white (lower than the English average of 85.42%). Asians were the second largest ethnic group in Leicester, with 37.13% of people identifying as such. Cambridge also has a [significant ethnic minority population](https://www.cambridge.gov.uk/media/1266/what_more_do_we_know_about_people_in_cambridge_2017v2.pdf), largely due to students attending the University. The total non-white population of Cambridge is 17.5%, with the largest groups being Chinese (3.6% of total population), followed by Asian or Asian British (3.4% of total 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:** 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. IGR is often referred to as 'pre-diabetes’. | |
| 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 interventions in the trial.  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 point of view is likely to be found more in older individuals, and people that are more religious.  The interventions being tested in the PROPELS trial are behavioural, which may reduce barriers as participants are not being asked to ingest a medication. | |
| 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.  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 behavioural. The control group is given an information leaflet containing information on risk factors for type 2 diabetes and cardiovascular disease and how physical activity can be used to prevent them. The walking away group will receive the same booklet as group 1 and will also be offered a group−based structured educational programme aimed at promoting increased ambulatory activity by targeting perceptions and knowledge of diabetes risk, physical activity self−efficacy, barriers to physical activity and self−regulatory skills based on pedometer use. Walking away plus participants will receive the same booklet as the control group, and the same education programme and support describe in the walking away group, as well as a mobile health intervention that provided automated, individually tailored text messages to prompt pedometer use and goal setting and provide feedback.  It is unclear how the interventions may limit participation. There is evidence to suggest that there are structural barriers to South Asians taking part in regular exercise. A [qualitative study](https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0045333) found that South Asians living in Scotland view physical activity in a similar way to the general population, have similar motivations and they enjoy (or would like to enjoy) more or less the same activities (particularly swimming, walking, and using the gym). Whilst some of the barriers identified in this study were similar to the majority of the population (cost, childcare, and lack of time or motivation), people with South Asian heritage may also face barriers which can severely restrict choice, particularly for women. For example, swimming and using the gym are two of the most popular activities for everyone in the UK including South Asians, but many South Asian women are unable to use their local leisure centre because of culturally inappropriate facilities. Many South Asian people (particularly women) are thus effectively denied access to some of the leisure services. The barriers outlined above impacted not only on the adults we interviewed, but also the type and amount of physical activity that their children participated in. [Evidence](https://academic.oup.com/jpubhealth/article/26/3/250/1540969) [from](https://academic.oup.com/jpubhealth/article/24/3/170/1503859) [research](https://academic.oup.com/ije/article/28/2/281/655239) suggests that South Asian and British minority ethnic children tend to exercise less than the general population. The barriers we identified also meant that it was difficult for parents (particularly mothers) to exercise with their children and provide a range of physical activity opportunities for them.  A [study of self-reported physical activity](https://jech.bmj.com/content/70/6/602) in England compared South Asian ethnic groups with the white British group, and demonstrated that differences exist between the groups in various types of physical activity, except for walking. This is good news for the PROPELS trial, which focuses on improving activity in terms of number of steps taken per day. |
| 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 acknowledgements section mentions and thanks patient and public involvement groups. Both the Walking Away and Walking Away Pus interventions evaluated in this trial were developed using iterative development cycles with patient and public involvement embedded throughout. In particular, patient and public involvement facilitated through the NIHR ARC East Midlands (formerly CLAHRC) contributed to how diabetes risk was communicated in Walking Away for use within multi-ethnic populations. The dietary section was also based on patient and public involvement suggesting that the focus on physical activity should be complimented by also communicating the key dietary factors related to diabetes risk. |
| 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:** Walking Away was delivered by two trained educators to groups of up 10 participants, with participants invited to bring a family member or a guest if they wished. Sessions were delivered in a variety of settings chosen for proximity to the recruiting GP surgeries, including at the surgeries themselves, in nearby community centres and at hospital sites.  It is unclear what impact these factors will have in the trial. Clear, culturally sensitive communication between the educators, and the patient and family will, be helpful for 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:** As above, the Walking Away intervention will be delivered face-to-face, and then telephone support is offered. For the Walking Away Plus intervention tailored text messaging is also given. As mentioned previously with regards to eligibility criteria, the use and reliance on telephone/mobile phone use has the potential to limit participation for people experiencing socioeconomic disadvantage. With the face-to-face delivery the main issue is likely to be getting to the sites (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). Again, 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: | |
| **Where** | How might where the intervention/comparator is delivered (e.g. hospital, general practice, local library) limit the participation of people from each ethnic group in the target population? | **Response:** As above. |
| Other factors to consider: | |
| **When & Intensity** | How might when the intervention/comparator is delivered (e.g. during working hours) or the intensity (e.g. number of times it is delivered, over what period, time commitment for each session and overall) limit participation of people from each ethnic group in the target population? | **Response:** The trial report does not detail when the Walking Away education sessions were delivered, but it looks like most of the trial intervention is delivered at home once this education session has been completed. The trial team should work to offer flexibility with when these sessions are delivered to ensure that as many people as possible are able to attend, and that timings (e.g., during working hours) do not disproportionately impact people from one ethnicity over another. It would also be useful for the trial team to think about providing childcare or childcare vouchers for participants to ensure that parental responsibilities do not act as a barrier to participation.  The annual nature of the group Walking Away sessions was designed to fit with primary care pathways, in which annual clinical follow-up is recommended for those with a high risk of chronic disease, such as prediabetes. |
| 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:** Individuals were eligible for the trial if they were aged 40-74 years, or 25-74 years if they were South Asian, had a recorded plasma glucose or HbA1c value in the prediabetes range during the previous 5 years, had access to a mobile telephone and were willing to use it as part of the study. Individuals were excluded from the trial if they were: unable to take part in ambulatory-based activity, pregnant, involved in other related intervention studies, diagnosed with diabetes or diabetes was detected at baseline visit, unable to understand basic written and verbal English, and/or unable to give informed consent.  The widened age bracket for people from South Asian backgrounds is a positive step by this trial, but the exclusion criteria do present potential issues for the inclusion of ethnic minority individuals.  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). In addition, the need for access and use of a mobile telephone (and presumably Wi-Fi or mobile data), may exclude people experiencing socioeconomic disadvantage. We know that ethnic minority individuals are more likely to experience socioeconomic disadvantage, so this inclusion criterion has the potential to disproportionately impact ethnic minority participation, and there is [evidence](https://academic.oup.com/fampra/article/21/6/636/508715?login=false) to suggest this would be the case for people from a South Asian background. At the very least, the trial team should think about covering costs for Wi-Fi or mobile data for participants.  It is not clear what sort of medical history information are taken at baseline or later. A blood test is required at baseline, which may deter people with a needle phobia, but there’s no evidence to suggest that this would disproportionately impact people from any ethnicity. |
| 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:** The primary method of recruitment was through primary care by using data collected by the NHS Health Checks programme, a screening programme run in England designed to identify and treat vascular disease risk (heart disease, stroke, diabetes and kidney disease) in all individuals aged 40–74 years, which has led to many primary care practices recording their patients’ HbA1c or fasting glucose values. The trial team worked in collaboration with practices providing the Health Checks programme to recruit individuals who were identified as having prediabetes and were not currently on a systematic diabetes prevention pathway. Eligible individuals identified as having a HbA1c or blood glucose value in the prediabetes category during the previous 5 years were sent an invitation letter, a brochure about the study and a reply slip. Those recruited directly from primary care were sent the invitation letters by the primary care practice at which the search was conducted. Those recruited from existing research databases were sent the invitation by the principal investigator of that study. Individuals who were interested in taking part were asked to return the reply slip directly to the PROPELS trial research team. An appointment was then arranged for a baseline visit and the individual was sent the full study patient information sheet along with a confirmation letter.  [Some research](https://trialsjournal.biomedcentral.com/articles/10.1186/1745-6215-12-220) suggests that the response to written invitations via healthcare staff may be 5.2% lower in South Asians than in general populations, with community oriented, in-person approaches being more successful. Social class may also play a part here, as we know that ethnic minority individuals are more likely to experience socioeconomic disadvantage; letters from healthcare professionals can often look ‘official’ – usually in a brown envelope, and may give the impression that they are a bill or other negative form of post, reducing the chance of the letter ever being opened and/or the amount of trust in the letter writer even before the letter is read. |
| 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 contained in the invitation letter or the brochure that accompanied it.  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).  The trial report’s acknowledgements section mentions and thanks patient and public involvement groups. Both the Walking Away and Walking Away Pus interventions evaluated in this trial were developed using iterative development cycles with patient and public involvement embedded throughout. In particular, patient and public involvement facilitated through the NIHR ARC East Midlands (formerly CLAHRC) contributed to how diabetes risk was communicated in Walking Away for use within multi-ethnic populations. The dietary section was also based on patient and public involvement suggesting that the focus on physical activity should be complimented by also communicating the key dietary factors related to diabetes risk. |
| 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 way that consent is sought from participants.  As mentioned above, patient and public involvement was included in this study, but it is not clear from the trial report whether members of the public from any ethnic group were 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. The eligibility criteria suggest that trial documentation was only available in English. [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 trial report does not detail whether the research team assessed how well consent information was 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**

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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 trial report’s acknowledgements section mentions and thanks patient and public involvement groups. The trial team worked with these groups to explore the types of messaging that may best motivate behaviour change following attending a Walking Away course. There is no mention of if/how people from any ethnic group were involved with selecting the trial outcomes, just the messaging that was used to encourage data collection to support those outcomes. The text message content in Walking Away Plus was informed by involving those within the community who had previously attended the Walking Away programme. |
| 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 was the change in ambulatory activity (steps/day) between baseline and 48 months, assessed by a wearable accelerometer. Acceleration data are captured and stored, and data processing undertaken on a commercially available analysis tool.  There is a significant list of secondary outcomes which are supported by data collected by the accelerometer mentioned above, as well as biochemical changes measured with a blood test, weight, height, fat mass measurements, and various questionnaires to assess depression, anxiety, diet, sleep, health related quality of life, and illness perception.  The main issues are likely to be around the data collected to support outcomes, rather than the outcomes themselves. As mentioned earlier, 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). In addition, the need for access and use of a mobile telephone (and presumably Wi-Fi or mobile data), may exclude people experiencing socioeconomic disadvantage. We know that ethnic minority individuals are more likely to experience socioeconomic disadvantage, so this inclusion criterion has the potential to disproportionately impact ethnic minority participation, and there is [evidence](https://academic.oup.com/fampra/article/21/6/636/508715?login=false) to suggest this would be the case for people from a South Asian background. At the very least, the trial team should think about covering costs for Wi-Fi or mobile data for participants.  Participation could be limited for those with a needle phobia, but this is not a problem specific to any ethnic group.  It is also important to note that general scepticism of research from ethnic minority individuals is not insignificant. There is a lot of data being collected here, which may be a red flag for some. |
| Other factors to consider: | |
| **Who** | How might the people who collect data limit the participation of each ethnic group in the target population? | **Response:** Data collection clinics were run by research nurses in the Leicester Diabetes Centre, in the MRC Epidemiology Unit in Cambridge, and at other local community centres and clinic areas. The Leicester Diabetes Centre is a partnership between the University of Leicester and the NHS, so some of the data may be collected by staff working for 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. |
| 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 collection clinics were run by research nurses in the Leicester Diabetes Centre, in the MRC Epidemiology Unit in Cambridge, and at other local community centres and clinic areas.  The main issue is likely to be getting to the sites (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:** Some of the data are likely to be collected during research visits at clinic sites – see worksheet 3b for discussion of the potential issues with this. As well as in person visits, trial data are collected in a variety of ways – participants were asked to wear the accelerometer for 7 consecutive days, and then return it and a log sheet to the research team in a pre-paid envelope. There is no evidence to suggest how this would impact one ethnic group over another, other than potentially the location of where participants live and whether there are post boxes/offices close by. It is not clear how the questionnaires were completed – online/on paper/in person/at home, so assessing how trial data from these may be different for people from different ethnic groups is difficult. See previous comments around use of Wi-Fi and the intersection between ethnicity and socioeconomic disadvantage. |
| Other factors to consider: | |
| **Benefits** | How might the benefits of the trial intervention(s) differ between each ethnic group in the target population? | **Response:** [Recent research](https://www.bjfm.co.uk/south-asians-need-to-exercise-for-longer-than-europeans) from the University of Glasgow’s Institute of Cardiovascular and Medical Sciences, suggests that South Asians need to exercise for longer than Europeans to gain the same level of physical benefit. So while the behavioural treatment in the PROPELS trial aims to increase physical exercise measured by steps taken per day, it may be that the potential benefits of this intervention are lower for people with South Asian heritage. |
| 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 heritage, and African and African-Caribbean heritage to a lesser degree.  The need for this pre-planned subgroup analysis suggests that over-sampling of South Asian participants 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 a dissemination plan in not mentioned at all. Reporting trial results in scientific or research publications is not conducive to reaching members of the public from any ethnic group.  Patient and public involvement is mentioned in the acknowledgements section of the report, but there is no specific mention of how patients or the public were involved in the reporting and dissemination of the trial results.  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 (particularly South Asians), 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.

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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.

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

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