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?** |
| **The key document used regarding the trial was the** [**final report**](https://doi.org/10.3310/pgfar08060) **and the** [**registration document**](https://www.isrctn.com/ISRCTN62237498)**. Given the above, the information in the worksheets may not be a proper reflection of the trial because we did nothave access to all the trial materials. The information is therefore intended to be illustrative, not definitive.**  The trial was run across UK nursing homes, the participants being nursing home residents with dementia. There are 46 million people with dementia worldwide, including 850,000 people in the UK, of whom an estimated 250,000 live in care homes. In the USA, 64% of people receiving Medicare in nursing homes have dementia. People with dementia have complex care needs, particularly those residing in care homes. The majority of these individuals have moderate or severe dementia, and their care needs are influenced by a combination of cognitive, functional and communication impairments, and medical comorbidities, and a high frequency of behavioural and psychological symptoms of dementia (BPSD). The Well-being and Health for people with Dementia (WHELD) programme grant was run in parallel with the national dementia strategy for England and the Prime Minister’s challenge on dementia implementation activities, and within the context of a national drive to improve health-care service provision and care home services for people with dementia. The trials consisted of 6 work packages.   * Package 1 – systematic reviews of psychosocial and person-centred care interventions for people with dementia living in care homes. * Package 2 – modelling and adaptation of interventions for use within an NHS context. * Package 3 – factorial pilot evaluation of non-pharmacological interventions in combination with person-centred care training in care homes (in 16 care homes) * Package 4 - evidence-based and user-driven optimisation of the WHELD programme for use in a real-world setting. * Package 5 - randomised controlled trial and field testing of the WHELD programme in care homes (in 69 care homes, 1006 participants) * Package 6 – dissemination of study outcomes and impacts.   [A longitudinal study of UK dementia diagnosis](https://www.ucl.ac.uk/news/2022/sep/dementia-rates-over-20-higher-among-black-adults-uk-average) from 1997 to 2018 found that overall prevalence of dementia among people over 65 is 11.8%. In comparisons between ethnic groups, they found that after controlling for factors such as age, sex and socioeconomic status, black people had a 22% higher incidence of dementia recorded than white people, while recorded incidence in the South Asian population was 17% below the average. The researchers also found that among people dying from dementia, people of South Asian origin were dying three years younger on average than white people studied, while black people were dying 2.7 years younger than white people.  [UK government data shows](https://www.ethnicity-facts-figures.service.gov.uk/health/social-care/adult-social-care-long-term-support/latest) that White people make up 80.6% of the nursing home patient population, Black people – 3.0%, Asian people – 2.0%, Mixed people – 0.6%, Other – 0.6%. (UK population in general: White people – 74.4%, Black people – 4.0%, Asian – 9.0%, Mixed people – 2.9%, Other – 2.1%)  The study will be applicable for people receiving dementia care, especially those residing in care homes. Although this should theoretically apply to patients of any ethnic group, the relatively high population of White patients in nursing homes comparing to Black patients who have a higher prevalence of dementia and die younger from it, could limit the applicability of the findings. Even though Asian populations in nursing homes are even lower, they also have a lower incidence of dementia. It is impossible to make any concrete conclusions because the study does not collect any ethnicity data. |

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| **2. Are the groups identified in Question 1 likely to respond to the treatment in different ways?** [**( VIEW WORKSHEET )**](#WorksheetONE) |
| The treatment in the study was applied in package 3 and package 5. Package 3 included a 9-months WHELD programme in 16 care homes. Eight care homes were randomly assigned to receive antipsychotic review, social interaction or exercise. The primary outcome measure was antipsychotic use, secondary measures – BPSD and mortality. Package 5 included a large randomised controlled trials of the optimised intervention compared with usual care. The intervention WHELD programme focused on training in person care for care staff, promoting tailored person-centred activities and social interactions and the development of a system for triggering appropriate review of antipsychotic medications by the prescribing physician. Primary outcome measure – quality of life; secondary – agitation, neuropsychiatric symptoms, global severity of dementia, mood, antipsychotic use, unmet needs, quality of interactions, pain, mortality, cost.  Ethnic minority patients tend to have more advanced cognitive dysfunction (as assessed by the MMSE) and were more functionally impaired (as assessed by the Blessed Dementia Rating Scale) at the time of initial diagnosis. These findings may be due to reporting bias, testing bias, or both; it is also possible that cognitive decline is more rapid among ethnic minorities, especially Black people. Black people with dementia (both U.S.-born African Americans and African Caribbean) are more likely to have psychotic symptoms, while whites were more likely to have depression.  UK government data shows that White people make up 80.6% of the nursing home patient population, Black people – 3.0%, Asian people – 2.0%, Mixed people – 0.6%, Other – 0.6%. (UK population in general: White people – 74.4%, Black people – 4.0%, Asian – 9.0%, Mixed people – 2.9%, Other – 2.1%). Black people have a 22% higher incidence of dementia recorded than white people, while recorded incidence in the South Asian population is 17% below the average. As the WHELD programme relies on specific staff training, social interactions and person-centred activities, response to these may possibly differ depending on ethnic groups. The cultural views on dementia are starkly different in various communities, ranging from beliefs on the cause of it (“Jinns”, black magic, God, evil spirits etc.) to language gaps that lack a word for dementia or use words that can be derogatory. In many Indian languages, ‘pagal’ describes behaviours similar to dementia but refers to madness caused by evil spirits or past misdeeds. In Chinese communities, while there are various words to describe dementia symptoms, the Mandarin word ‘chai-dai’ means idiocy or dull-wittedness.  Another important factor in the trial is antipsychotic use, which the programme is trying to reduce, especially in package 3. Among people with dementia in the UK, [a review](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6980848/) found that Asian and Black individuals are no more likely to take an antipsychotic drug, but those that had were prescribed them for 17 and 27 days/year more respectively. |

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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) | |
| [UK government data shows](https://www.ethnicity-facts-figures.service.gov.uk/health/social-care/adult-social-care-long-term-support/latest) that White people make up 80.6% of the nursing home patient population, Black people – 3.0%, Asian people – 2.0%, Mixed people – 0.6%, Other – 0.6%. (UK population in general: White people – 74.4%, Black people – 4.0%, Asian – 9.0%, Mixed people – 2.9%, Other – 2.1%)  The study intervention will be available for people receiving dementia care residing in care homes. Since ethnic minority people are less likely to reside in nursing homes, this could limit their access to the WHELD programme treatment. This would mean that they would need to use more antipsychotic medication that their White counterparts who can access the new treatment in nursing homes. The study itself does not include any ethnicity data, so it is impossible to say how many ethnic minority individuals took part in 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) |
| Since the trial is planned and designed around nursing home residents, see answer to question 3. |

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:  [A longitudinal study of UK dementia diagnosis](https://www.ucl.ac.uk/news/2022/sep/dementia-rates-over-20-higher-among-black-adults-uk-average) from 1997 to 2018 found that overall prevalence of dementia among people over 65 is 11.8%. In comparisons between ethnic groups, they found that after controlling for factors such as age, sex and socioeconomic status, black people had a 22% higher incidence of dementia recorded than white people, while recorded incidence in the South Asian population was 17% below the average. The researchers also found that among people dying from dementia, people of South Asian origin were dying three years younger on average than white people studied, while black people were dying 2.7 years younger than white people. |
| How might the severity of the disease vary between each ethnic group? | Response:  See above response regarding dementia mortality. |
| How might the disease present in people from each ethnic group (this may include symptoms, type or pattern or rate of disease progression)? | Response:  [One study](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2608323/) found that black participants with dementia evaluated at California Department of Health Alzheimer's Disease Diagnostic and Treatment Centers reported a shorter duration of illness at the time of initial diagnosis. However, after adjusting for years of education, blacks with dementia had more advanced cognitive dysfunction (as assessed by the MMSE) and were more functionally impaired (as assessed by the Blessed Dementia Rating Scale) at the time of initial diagnosis. These findings may be due to reporting bias, testing bias, or both; it is also possible that cognitive decline is more rapid among African-American elders with dementia.  Black people with dementia (both U.S.-born African Americans and African Caribbean) were more likely to have psychotic symptoms, while whites were more likely to have depression ([Cohen and Magai, 1999](https://www.ncbi.nlm.nih.gov/books/NBK25535/)). | |
| 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:  [UK government data shows](https://www.ethnicity-facts-figures.service.gov.uk/health/social-care/adult-social-care-long-term-support/latest) that White people make up 80.6% of the nursing home patient population, Black people – 3.0%, Asian people – 2.0%, Mixed people – 0.6%, Other – 0.6%. (UK population in general: White people – 74.4%, Black people – 4.0%, Asian – 9.0%, Mixed people – 2.9%, Other – 2.1%). Black people have a 22% higher incidence of dementia recorded than white people, while recorded incidence in the South Asian population is 17% below the average. | |
| 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:  Cultural values may include beliefs that dementia-related changes are part of the normal aging process rather than an abnormal process, such that in some groups and communities, cognitive decline may not elicit concern until symptoms are well beyond the early or mild stages ([Hart, Gallagher-Thompson, Davies, Diminno, and Lessin, 1996](https://www.ncbi.nlm.nih.gov/books/NBK25535/)).  Individuals within some cultures may be more likely to view cognitive decline as disgraceful and something that should be kept within the family. A dementing illness may be difficult to accept when the ethnic elder may be the historian, mediator, and provider of emotional and financial support for many generations of family members living in the same home ([Baker, 1992](https://www.ncbi.nlm.nih.gov/books/NBK25535/)). | |
| How might ways of describing the disease be different for each ethnic group? | Response:  [A report](https://www.alzheimers.org.uk/sites/default/files/2021-09/ethinic_minorities_increasing_access_to_diagnosis.pdf) by the Alzheimer’s society found that, in communities with a belief in reincarnation, dementia can be seen as a punishment for behaviour in a past life. Amongst Eastern European communities, understanding of dementia can sometimes relate to experiences of persecution. In some Muslim communities, mental health and neurological conditions including dementia are often attributed to ‘Jinns’ – supernatural creatures that harm humans or drive them mad. Some African-Caribbean communities see dementia as a result of possession by evil spirits. Other communities may see dementia as a form of evil spirits, witchcraft, Black Magic, or God’s will.  In many communities there is no word for dementia, or it is neither easily translatable or commonly used, particularly in some South Asian and Chinese communities. Words to describe dementia can also be derogatory in some communities, which entrenches stigma and limits recognition of dementia as a condition. In many Indian languages, ‘pagal’ describes behaviours similar to dementia but refers to madness caused by evil spirits or past misdeeds. In Chinese communities, while there are various words to describe dementia symptoms, the Mandarin word ‘chai-dai’ means idiocy or dull-wittedness. | |
| How might cultural practices, beliefs and traditions influence the acceptability of, and adherence to, the treatment(s) for each ethnic group? | Response:  [African communities](https://journals.sagepub.com/doi/abs/10.1177/2156759X0801100302) are more likely to manage adversities on their own and more inclined to rely on spirituality, as opposed to seeking medical attention. Africans may rely more on religious ministers than psychiatrists and psychologists.  [Asian Americans](https://pubmed.ncbi.nlm.nih.gov/18229996/) have been shown to show more stigma to mental health than the white American population. There is much variation within an ethnic group too, for example Chinese Americans are less likely to use mental health services due to the perceived shame that is associated with a diagnosis. Whereas [Filipino Americans](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7578164/) are less like to seek support due to mistrust of systems. Filipino Americans are more likely to seek help from friends and family, as opposed to mental health services, affected in part by immigration status, health insurance and issues with language. | |
| How or when might people in each ethnic group access healthcare for this disease differently? | Response:  Hispanic and black adults are less likely to use nursing homes than white adults, and this difference is magnified when taking into account black and Hispanic adults poor health and fewer socioeconomic resources ([Mieke Beth Thomeer, Stipica Mudrazija and Angel, 2015](https://academic.oup.com/psychsocgerontology/article/73/4/e11/2631931)). | |
| Other factors to consider: | | |

**Worksheet 2**

This this worksheet provides some questions **to guide your thinking about ethnic group involvement when answering Question 3** of the INCLUDE Key Questions.

**Intervention and comparator factors that might affect how some groups engage with the intervention and/or comparator\***

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| --- | --- | --- |
| **What** | How might the intervention(s) and comparator limit participation of people from each ethnic group in the target population? | Response:  The intervention is only available in nursing homes which have a small population of ethnic minority individuals. |
| How, and in what way, were people from each ethnic group involved in selecting or designing the trial intervention/comparator? | Response:  There is no information on patient and public involvement in the design on the trial intervention and comparator. No ethnicity information at all was collected throughout the trial. |
| 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:  A lack of shared social or ethnic identity between clinician and patient could limit participation of certain ethnic groups. [Trust in the doctor-patient relationship is a core element of successful treatment.](https://labblog.uofmhealth.org/rounds/minority-patients-benefit-from-having-minority-doctors-but-thats-a-hard-match-to-make-0) Black patients may be more wary of white doctors than black doctors, and white doctors may feel less comfortable treating ethnic minority patients compared with white patients. A study found that black doctors were more likely to write detailed notes for their black patients. Due to many reasons, the diversity of the physician workforce is unlikely to mirror the population any time soon, therefore it is important to find appropriate solutions in the meantime. Even just increasing the presence of minority clinicians in the wider care team may make a difference.  [In the UK, 77.9% of NHS staff are white and 22.1% are from all other ethnic groups.](https://www.ethnicity-facts-figures.service.gov.uk/workforce-and-business/workforce-diversity/nhs-workforce/latest) Asian, Chinese, and mixed ethnic groups make up a larger percentage. There are more non-medical staff in the NHS who belong to black groups. This could directly impact the experience of black people taking part in this trial – the ethnicity most at risk of being diagnosed with psychosis.  Same gender preference of clinician with the patient may also have an effect on participation. Certain ethnic groups may feel more at ease ‘opening up’ or expressing themselves with a clinician of the same gender, e.g., south Asian women. |
| 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:  All interventions were delivered face-to-face in a nursing home. Since the participants are all nursing home residents, the only limiting factor is the proportion of ethnic groups in nursing homes, discussed in questions above. |
| 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:  See answers to above questions regarding the proportion of ethnic groups in nursing homes. |
| 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:  See answers to above questions regarding the proportion of ethnic groups in nursing homes. |
| 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 only eligibility criteria were that the person is living in care homes and has a dementia diagnosis. This may exclude individuals from ethnic minority communities as they are often less likely to reside in nursing homes. |
| 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:  Since the study only recruited nursing home residents, see above answers about nursing home ethnic group proportions. |
| How might the information that tells potential participants about the trial (e.g. participant information leaflet) limit the participation of each ethnic group? | Response:  Not applicable, as the study only recruited nursing homes. |
| How might cultural practices, beliefs and traditions change the way each ethnic group perceives the information they are given? | Response:  British white groups who have never immigrated to another country are likely to not have a great sense of ethnic identity, when compared with ethnic groups who live in a foreign country. This has been shown to affect their idea of receiving care [from an individualistic point of view, to a collective.](https://pubmed.ncbi.nlm.nih.gov/22869345/) Ethnic minority groups in the UK are more likely to have a collective point of view and lean on their social circles for support and care, as opposed to institutions. |
| 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:  There was no information in the study on how consent was collected. | |
| How might the way people would like to discuss participation with family before providing consent differ for each ethnic group? | Response:  As already mentioned, individualistic and collective perspectives can influence how likely someone is to rely on their wider social circles for support.  [Asian ethnic groups](https://spcare.bmj.com/content/5/Suppl_2/A65.1) are more likely to rely on their wider family when making healthcare decisions. Black African communities are likely to rely on religious leaders for support and guidance. | |
| How might the way the research team can check how well consent information is understood differ for each ethnic group? | Response:  Depending on the individual and their relationship with their family/support network, speaking with their family could also ensure the participant fully understands the trial procedures. This may be most beneficial for people who have not read the trial information in their native language, or those who rely heavily on their family to make healthcare decisions, e.g., Asian groups.  There is no information available regarding how understanding is confirmed for this trial. | |
| 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:  There is no information on ethnic groups involved provided in the trial. |
| 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:  Data such as quality of life collected in package 5 that require a survey to be filled in might limit participation due to language barriers or literacy levels. There is no information provided on whether or not questionnaires were available in languages other than English. |
| 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 unclear who the people were who collected the data in this study. This might be the nursing home staff or outside trial staff. There is also no information on the ethnic backgrounds of the staff and whether or not they were experienced in working with people from different cultures. |
| Other factors to consider: | |
| **How** | How might data collection methods limit the participation of each ethnic group in the target population? | Response:  Questionnaires might limit participation due to language barriers or literacy levels. |
| Other factors to consider: | |
| **Where** | How might where data are collected limit the participation of each ethnic group in the target population? | Response:  See above answers on proportion of ethnic groups in nursing homes. |
| 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:  There is no information on what trial data was made available to participants. | |
| Other factors to consider: | | |
| **Benefits** | How might the benefits of the trial intervention(s) differ between each ethnic group in the target population? | Response:  See above answers on proportion of ethnic groups in nursing homes. | |
| 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:  See above answers on proportion of ethnic groups in nursing homes. | |
| 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:  There is no information on ethnic group proportions thus it is impossible to say whether subgroup analysis would be possible. | |
| Other factors to consider: | | |
| **Interim analyses** | How should any interim analysis handle variation between ethnic groups in the target population? | | Response:  The interim analysis should look at any differences in each ethnic group. Over-sampling may need to be considered to account for any findings. |
| 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:  Should there be any reason to stop the trial early, ethnic group variations should be considered. Again, due to the pronounced differences in prevalence of disease, prevalence of comorbid diseases and higher mortality rates in some ethnic groups, this should be an important consideration. |
| 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:  There is no information on people’s involvement in the planning the reporting and dissemination of the trial results. No ethnicity data is available. |
| Other factors to consider: | |
| **How** | How might planned reporting and dissemination methods limit engagement with each ethnic group in the target population? | Response:  The full NIHR publication is open access, but there was limited information on how the trial results were disseminated to participants.  From the outset, it would be appropriate to consider all methods for dissemination and discuss the applicability to each ethnic group. Patient representatives as part of PPI could advise on this too. Publications would likely not be patient friendly enough and largely inappropriate considering this disease population tend to have low literacy levels. |
| 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:  Dissemination intended for the public should always be considered, i.e., simple, lay language. Where possible, other languages, and literacy should be considered for each of the ethnic groups in the community and use appropriate channels too. |
| Other factors to consider: | |

Worksheet for thinking through measures to address factors that might prevent full community involvement

Use this worksheet to list key factors that might affect the involvement of some ethnic groups in the target population of your trial, along with measures to mitigate the effect of those factors and their cost. Add extra rows as needed.

Please remember that there are also differences *within* ethnic groups, especially between generations and between men and women. No ethnic group is homogenous.

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| **Factors that may prevent full community involvement** | **Proposed measures (several options may be needed)\*** | **Cost of measures** |
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\*See https://centreforbmehealth.org.uk/resources/toolkits/ for suggestions for how to address factors that affect community-wide involvement.

Acknowledgements

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

**A close up of a logo

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

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

**A picture containing food, drawing

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

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

**A close up of a sign

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[Council](https://www.ukri.org/)

