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**](C://Users/AzarAlexander-Sefre/Downloads/3031580.pdf) **sent to the funder (NIHR) and the** [**registration document**](https://www.isrctn.com/ISRCTN58667926)**. 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.]**  This trial was run in the UK’s capital, London, and aimed to record the physical health risks and lifestyle choices of those with early psychosis, devise a way to help people make healthier choices and test whether this improved their quality of life. People with severe mental illness (SMI) tend to have poor physical health, and a marked increased mortality rate. There are genetic factors at play, however people with SMI are more likely to lead unhealthy lifestyles, which leads to increased risk of developing preventable illnesses such as cardiovascular disease and diabetes. It is estimated that 50% of people with SMI also have a substance use disorder. The trial is funded by the National Institute for Health Research (NIHR) (UK), meaning the findings are intended to be of immediate clinical relevance. The trial consisted of 3 work packages, package 1 performed a longitudinal study with people presenting with first episode psychosis aged between 16-65, with physical health and substance use measurements being collected over 1 year. Package 2 involved the development of a health promotion intervention, which was to be delivered by the patient’s usual care providers. Package 3 was a phase III randomised controlled trial to determine the clinical and cost effectiveness of using this intervention in people with an established psychotic disorder aged 18-65.  In the UK, the estimated [prevalence of psychotic disorders is 0.7%](https://www.nice.org.uk/guidance/cg155/resources/psychosis-and-schizophrenia-in-children-and-young-people-final-scope2) across all ages. [African Caribbean groups](https://pubmed.ncbi.nlm.nih.gov/15902407/) have particularly high rates of psychotic disorders when compared to the white population of the UK. [In the past year in the UK, the percentage of people who were positively screened for a psychotic disorder were](https://www.ethnicity-facts-figures.service.gov.uk/health/mental-health/adults-experiencing-a-psychotic-disorder/latest): Asian – 0.9%, Black – 1.4%, Mixed/Other – 0.0%, White – 0.5%. There were dramatic differences between sexes, for example 3.2% of black men receiving a positive diagnosis, compared with 0.3% of white men. Asian men were the next most likely to receive a positive diagnosis at 1.3%. On average, across all ethnicities, men are more likely to be positively screened for a psychotic disorder than women.  It is well established that people with SMI have higher mortality rates when compared to the general population, irrespective of ethnicity. In England, [data from 2016 to 2018,](https://www.gov.uk/government/publications/premature-mortality-in-adults-with-severe-mental-illness/premature-mortality-in-adults-with-severe-mental-illness-smi) showed that people with SMI are 4.5 times more likely to die prematurely (before the age of 75) than those who do not have SMI. A correlation between premature mortality and areas of deprivation was also found. When considering the mortality rate as result of natural causes (e.g. cardiovascular illness, diabetes), [white British and Irish people with SMI have a higher mortality rate when compared with other ethnic groups.](https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(17)30097-4/fulltext#:~:text=Our%20findings%20suggest%20that%20people,compared%20with%20the%20general%20population.)  White British – 1.6%, Irish – 2.37%, Black African – 0.5%, Black Caribbean – 0.7%, South Asian – 1.0%  Package 1 of this trial showed that white men were found to be particularly vulnerable to obesity, with a mean increased waist size of 4.9cm over the 1 year. Men of black and minority ethnic groups instead gained a mean 1.6cm around the waist. Patients from black and minority ethnic groups are more likely develop glucose dysregulation over the first year of presentation with first episode psychosis than patients of white ethnicity, suggesting a differential pattern of emergence of glucose dysregulation. The study also found that almost half of all participants were current cannabis users, however it is not clear what the ethnicities were of these participants. [In the UK, data shows](https://www.ethnicity-facts-figures.service.gov.uk/health/alcohol-smoking-and-drug-use/illicit-drug-use-among-adults/latest) that black adults and white British adults are more likely to use illicit drugs than other ethnic group adults, at 11.7% and 8.9% respectively.  The above proportions should be considered when establishing participation of different ethnicities in the trial. The proportion of minority ethnic individuals, predominantly black groups, need to represent the higher percentage of individuals in society being diagnosed with a psychotic illness. However, additional consideration needs to be placed on the finding that white groups with SMI appear to have a higher mortality risk as a result of natural causes. There is a case for over-sampling white men specifically to allow greater certainty regarding conclusions drawn from their participation in the trial. |

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| **2. Are the groups identified in Question 1 likely to respond to the treatment in different ways?** [**( VIEW WORKSHEET )**](#WorksheetONE) |
| As discussed in question 1, prevalence of psychosis is higher in black and Asian populations when compared with their white or mixed counterparts. UK data shows that black adults are the least likely to receive mental health treatment – [at 6%, compared to 13% in white adults.](https://webarchive.nationalarchives.gov.uk/ukgwa/20180328140249/http:/digital.nhs.uk/catalogue/PUB21748) Similarly, even though black Asian and minority ethnic groups are at higher risk of developing a mental health disorder, it is [less likely that they will receive support for their condition.](https://webarchive.nationalarchives.gov.uk/ukgwa/20180328140249/http:/digital.nhs.uk/catalogue/PUB21748) 20% of participants in this trial had diabetes, which is a well-associated high risk disease for people who have a SMI. [Diabetes is more common in south Asian and black ethnic groups](https://www.gov.uk/government/news/38-million-people-in-england-now-have-diabetes#:~:text=Diabetes%20is%20more%20common%20in,15.2%25%20compared%20to%208.0%25).) at 15.2%, when compared with white, mixed or other ethnic groups at 8.0%. It was not clear from this trial, how many of the 20% with diabetes were from black and Asian ethnic groups.  Mental health stigma is widespread, irrespective of ethnicity and has been described as a significant public health concern. It is estimated to be more severe for racial-ethnic minority groups in society, with higher risk of prejudice and discrimination being experienced because of belonging to two stigmatised groups – minority and mentally ill. There is evidence that mental illness is more highly stigmatised in some ethnic minority groups. In Indian and South Asian households, mental illness may be seen as a ‘taboo’ subject and results in some people feeling the need to hide their illness to uphold their social status or reputation. Black African communities are more likely to manage adversities on their own and more inclined to rely on spirituality, as opposed to seeking medical attention. There is also a higher risk of ‘self-stigma’ in these minority groups, in turn directly affecting the likelihood of seeking help and support.  It is difficult to determine how ethnicity/race contributes to psychosis diagnosis. With clinicians being the diagnosticians, there is risk for misinterpretation and bias can play a role. It is important to note that although there is much evidence to suggest black and ethnic minority groups are more likely to receive a severe mental health diagnosis, this does not imply that one ethnicity (e.g. black people) actually develops more severe symptoms than another ethnic group. It is possible that clinician’s lack of awareness or bias of certain cultural issues, or inability to speak the patient’s native language can affect the diagnosis a patient receives. It also can mean that some ethnic groups do not feel able to appropriately describe their symptoms. Black African and Asian groups may be more likely to describe their symptoms using physical terminology, such as describing physical pain when trying to describe an emotional symptom. Clinicians who are not culturally aware are at risk of not recognising these symptoms appropriately.  In the UK, black and ethnic minority groups are more likely to be diagnosed with a psychotic disorder and are more likely to seek help through A&E or when they are in a crisis. This could suggest that psychoses are more severe in black and ethnic minority groups because they are less likely to seek help or support earlier on in their illness, when less severe. UK data has also shown that [people from lower socioeconomic statuses](https://www.mentalhealth.org.uk/explore-mental-health/statistics/poverty-statistics#:~:text=A%20growing%20body%20of%20evidence,and%20experiencing%20mental%20health%20problems.) are at higher risk of developing mental health problems overall. In the UK, [poverty affects ethnic minority groups more than their white counterparts.](https://www.jrf.org.uk/report/poverty-rates-among-ethnic-groups-great-britain) There is also a link to premature mortality and deprivation. |

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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) | |
| Black and ethnic minority groups in the UK are more likely to disengage from mental health services and experience a poor outcome from treatment.  The identity of the clinicians leading a trial could [limit participation if social identities are not shared](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6953572/), as this can lead to distrust and unease. There was limited information available about the ethnicities of who was responsible for leading the intervention/comparator sessions, and if opinions of different ethnic groups were considered when designing this trial. However as mentioned, a lack of shared social or ethnic identity between clinician and patient could limit participation of certain ethnic groups. It has been shown that 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. Improvements in participation could be seen by increasing the presence of minority clinicians in the wider care team, which may support more trust building between care team and patient. Economic and social disadvantage can also amplify identity differences. Several studies have shown that ethnic minority populations are less likely to start, continue or finish mental health treatments. [Shared decision making](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3580315/) is also important to increase participation, as this can either encourage or discourage collaborative engagement between patient and clinician.  Some ethnic groups may prefer a clinician of the same gender, as this can result in someone feeling more at ease ‘opening up’ or expressing themselves. Where possible using the patient’s first language can support problem solving and aid the clinician to understand the problem through the patient’s eyes. This trial requested participants to be fluent in English to take part. Although the reasons for this may be justified, this may limit participation of ethnic minority groups most affected by psychosis. For example, migrant groups, who are also at high risk of developing psychotic disorders, tend to rely on people who share their language and cultural practices.  The mode of delivery of sessions could limit participation for various reasons. Face-to-face sessions could be a barrier for people who would struggle to pay for travel to and from the clinic. In London, poverty rates are highest for Bangladeshi and Pakistani households and lowest for white households. In turn meaning that it may be more difficult for some ethnic groups to attend face-to-face sessions. Group sessions can limit participation for certain ethnic groups too if care is not taken to develop an appropriate dynamic. South Asian women are least likely to utilise mental health services. This would be an example of where it would be important to develop a culturally sensitive group, where each of the patients feel their cultural, ethnic and spiritual beliefs were understood by the group leader. Literacy levels are known to be lower in populations with SMI. This will directly affect all modes of delivery, especially for self-reported measures such as the questionnaires used in this study. Level of family commitment can affect someone’s ability to attend more lengthy and intense sessions. In 2011, 18.9% of black households were single parent households, the highest of all other ethnic groups for this category. Black ethnic groups may therefore struggle to participate in sessions that require more time away from home. | |
| 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) |
| Participants were identified through inpatient units and community care teams. Limited trial information is available on who was responsible for first approaching patients and who took them through the screening procedure. There is a risk that this could affect recruitment, based on bias and cultural awareness of the staff involved. As previously discussed, black groups may be more wary of white clinicians and would potentially be more trusting if a black clinician approached them to participate.  This trial did not provide the option for a translator and all participants had to be fluent in English. This is most likely to affect the participation of some non-British white and Asian groups, who are less likely to speak English as their first and main language. It is unclear whether people were given the option to read the information sheet in their native language, an option that may not only increase recruitment but also support participants from all groups to fully inform themselves about the trial – possibly leading to higher engagement rates. It is also unclear whether the information sheet was written with input from people from different ethnicities.  Individualistic and collective perspectives can influence how likely someone is to rely on their wider social circles for support. 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 [and](https://pubmed.ncbi.nlm.nih.gov/22869345/) they may be more likely to have an individualistic perspective. [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 and Black African communities may be more likely to rely on religious leaders for support and guidance. Depending on the participant, the trial team may decide to speak with their family as this could ensure that the participant fully understands what the trial entails. This may be most beneficial for people who have low literacy levels or 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. No information was available regarding how understanding was confirmed for this trial.  The trial team consulted PPI in the design of this trial, including co-hosting focus groups with organisations of ethnic minority groups e.g. with Family Health Isis, a local African and Caribbean mental health organisation. It was unclear how many representatives from each ethnic group were involved, however.  The trial relied heavily on self-reported measures, which were validated for use with participants with psychosis. However, potential problems are associated with the accuracy of such measures. Many participants in this trial chose not to self-administer the measures, believed to be because of the nature of the illness (which can result in lack of motivation, low mood, cognitive impairment), and low literacy levels. Instead, researchers were often required to read aloud each item and present the corresponding scale on which participants would indicate their response. Researchers would have to read out each item in a non-biased manner, but it is known that the way in which data collection is conducted, or by whom it is conducted, can have unintended potential consequences on study findings. It was unclear who the people were in this trial who were responsible for this, what their ethnic/cultural backgrounds were or if they were experienced at collecting this type of data from a variety of different ethnic groups. |

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

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

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

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

**Worksheet 1**

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

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

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| **Disease** | How might the prevalence of the disease vary between each ethnic group in the target population? | Response:  There is a higher [incidence of SMI in ethnic minority and migrant groups.](https://pubmed.ncbi.nlm.nih.gov/22457710/) There is an over-representation in minority ethnic groups in the UK with SMI, [with black Caribbean, black African and South Asian](https://pubmed.ncbi.nlm.nih.gov/22457710/) people being more likely to receive a schisophrenia diagnosis when compared with white people.  Symptoms related to psychosis are higher in black men than any other ethnic group – 3.2% in black men, 1.3% in Asian men and 0.3% in white men. A significant variation was not seen among women of different ethnic groups.  Package 1 of the study demonstrated that the use of substances such as tobacco and alcohol and less healthy dietary and exercise choices among people with first episode psychosis are common and that cardiometabolic risk continues to increase over the course of the year, with rates of obesity rising from 17.8% to 23.7%. 20% of the trial population with established psychosis had diabetes. [People with diabetes](https://pubmed.ncbi.nlm.nih.gov/16344421/) and SMI have fewer routine eye checks, poorer glycaemic and lipid control, and perhaps ultimately have a 50% poorer survival rate, than those with a diagnosis of diabetes alone. [Diabetes is more common in south Asian and black ethnic groups](https://www.gov.uk/government/news/38-million-people-in-england-now-have-diabetes#:~:text=Diabetes%20is%20more%20common%20in,15.2%25%20compared%20to%208.0%25).) at 15.2%, when compared with white, mixed or other ethnic groups at 8.0%. It was not clear from this trial, how many of the 20% with diabetes were from black and Asian ethnic groups. |
| How might the severity of the disease vary between each ethnic group? | Response:  UK data shows that black adults are the least likely to receive mental health treatment – [at 6%, compared to 13% in white adults.](https://webarchive.nationalarchives.gov.uk/ukgwa/20180328140249/http:/digital.nhs.uk/catalogue/PUB21748) Similarly, even though black Asian and minority ethnic groups are at higher risk of developing a mental health disorder, it is [less likely that they will receive support for their condition.](https://webarchive.nationalarchives.gov.uk/ukgwa/20180328140249/http:/digital.nhs.uk/catalogue/PUB21748)  National UK data shows that African and Caribbean men are more likely to develop some type of mental health problem in their life (e.g. schisophrenia, post-traumatic stress disorder). Interestingly this is not the case in countries that have a predominantly black population. This has been suggested to be an environmental risk that related to this group’s experiences in for example the US or UK.  UK data has shown that [people from lower socioeconomic statuses](https://www.mentalhealth.org.uk/explore-mental-health/statistics/poverty-statistics#:~:text=A%20growing%20body%20of%20evidence,and%20experiencing%20mental%20health%20problems.) are at higher risk of developing mental health problems. In the UK, [poverty affects ethnic minority groups more than their white counterparts.](https://www.jrf.org.uk/report/poverty-rates-among-ethnic-groups-great-britain) Bangladeshis – 65%, Pakistanis – 55%, black Africans – 45%, black Caribbeans – 30%, white other – 25% and white British – 20%. |
| How might the disease present in people from each ethnic group (this may include symptoms, type or pattern or rate of disease progression)? | Response:  It is difficult to determine how ethnicity/race contributes to psychotic condition diagnosis. With clinicians being the diagnosticians, there is risk for misinterpretation and bias can play a role. It is important to note that although there is much evidence to suggest black and ethnic minority groups are more likely to receive a severe mental health diagnosis, this does not imply that one ethnicity (e.g. black people) actually develops more severe symptoms than another ethnic group. There appears to be little research devoted to understanding racial bias amongst clinicians and rate of misdiagnosis of symptoms in different ethnicities.  [A study was conducted to determine the reasons for this overrepresentation.](https://pubmed.ncbi.nlm.nih.gov/26886264/) It found that instead of misdiagnosis or racism being the primary drivers for over-representation, it was instead that Black and Minority Ethnic patients can present with a combination of more serious mental health conditions. This can then be perceived with higher risks (e.g. risk of self-neglect, risk to others) and having less social support. It was acknowledged that discriminatory systems could not be entirely ruled out as a contributing factor with issues such as perception of risk. In the same study, there was confirmation of black African and Caribbean men having a higher chance of being sectioned through criminal justice routes. |
| 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:  [There is evidence to suggest that there is a greater](https://www.centreformentalhealth.org.uk/sites/default/files/2018-10/Against%20the%20odds%20-%20Up%20My%20Street%20evaluation.pdf) likelihood of Black and Minority Ethnic groups being diagnosed with schisophrenia in predominantly white geographical areas (e.g. northern Europe and the United States). For example, rates of psychosis and detention in psychiatric settings are [significantly higher in the UK and in the Netherlands compared](https://pubmed.ncbi.nlm.nih.gov/14754830/) with rates for African Caribbean men resident in the Caribbean. [Higher prevalence rates](https://pubmed.ncbi.nlm.nih.gov/17440031/) have also been noted in the United States. Academics have suggested that these differences are likely to be related to aspects of African Caribbean psychosocial experiences in certain countries.  [UK data spanning 2007 until 2014](https://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(19)30126-9/fulltext) showed that in more ethnically diverse areas, ethnic minority groups with SMI have a lower risk of death when compared with white British groups. This was interpreted to mean that ethnic minority groups diagnosed with SMI have lower mortality rates if they reside in areas of own-group ethnic density.  This trial was run in London, UK, which is more ethnically diverse than other regions of the UK. White British people account for 43.4%, dramatically lower than England and Wales overall (at 78%). The next most common ethnic groups in London are white other at 14.6%, black African at 7.9% and Indian at 7.0%. Being more ethnically diverse than the rest of the UK, London will naturally have access to a higher number of ethnic minority participants. However, based on the data above, it could be argued that the trial should be run outside of London, where there is less own-group ethnic density.  [There is large variation in likelihood to receive vital medical checkups between areas in the UK](https://www.diabetes.org.uk/about_us/news/half-of-people-with-Type-2-diabetes-and-severe-mental-illness-can%E2%80%99t-access-support) for people who have type 2 diabetes and a SMI. There is as much as a 60% difference between some areas, e.g. 78% of people with type 2 diabetes and SMI in Hackney, compared with 18% in Wolverhampton. |
| 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:  Mental health stigma is widespread, irrespective of ethnicity and has been described as a significant public health concern. It is estimated to be more severe for racial-ethnic minority groups in society, with higher risk of prejudice and discrimination being experienced because of belonging to two stigmatised groups – minority and mentally ill.  In some ethnic communities, mental illness is more highly stigmatised than others. It is a multidimensional issue, that not only can determine negative public opinion, but it can also contribute to self-stigma and the chances of someone seeking treatment/support for their mental health condition. [Research has shown that non-white groups perceive mental illness](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-020-08964-3) to be more dangerous and express more need to segregate from those who have mental illness. There is also further difference in perception of danger with mental illness between minority groups. There is also intersectionality between experiences of stigma, with structural and interpersonal discrimination and low socioeconomic status also affecting level of stigma perceived and experienced. |
| How might ways of describing the disease be different for each ethnic group? | Response:  It is possible that clinician’s lack of awareness or bias of certain cultural issues, or inability to speak the patient’s native language can affect the diagnosis of the patient. It can also mean that some ethnic groups do not feel able to appropriately describe their symptoms in a second tongue.  It is a taboo subject in some Indian and South Asian households to have a mental health diagnosis, and this can cause some people from this community to hide it – in attempt to uphold their reputation or social status. In turn, this negatively impacts their ability to access mental health services.  [There is also research to suggest](https://www.nami.org/Your-Journey/Identity-and-Cultural-Dimensions/Black-African-American) that black ethnic groups may consider mental illness to equate being considered as “crazy” in their social circles. Black people may also be more like to use physical descriptions when attempting to describe their mental health, such as describing bodily aches when talking about depression. If a clinician is not culturally aware, they may not be competent to adequately recognise such symptoms. This has also been found to be a similar issue with Asian groups. |
| 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:  [In the US, data suggests](https://pubmed.ncbi.nlm.nih.gov/8864145/) that minority groups are less likely or fail to seek help for their mental health illness when compared with the white population. In the UK, black and ethnic minority groups are more likely to be diagnosed with a psychotic disorder and are more likely to seek help in A&E or when they are in a crisis. This could suggest that psychoses is more severe in black and ethnic minority groups for the reason that they are less likely to seek help or support earlier on in their illness, when less severe. |
| 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:  Black and ethnic minority groups in the UK are more likely to disengage from mental health services and experience a poor outcome from treatment.  [There could be limited participation if social identities are not shared](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6953572/) between clinicians and patients, as this can lead to distrust and unease. Economic and social disadvantage can also amplify these identity differences. Several studies have shown that ethnic minority populations are less likely to start, continue or finish mental health treatments. [Shared decision making](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3580315/) is also important to increase participation, as this can either encourage or discourage collaborative engagement between patient and clinician.  As discussed in previous sections, where possible using the patient’s first language can support problem solving and aid the clinician understand the problem through the patient’s eyes. This trial requested participants to be fluent in English to take part. Although the reasons for this may be justified (e.g. lack of money to hire translators), this may limit participation of participants from more ethnic minority groups most affected by psychosis.  [Migrant groups are at high risk of developing a psychotic disorder](https://www.thelancet.com/pdfs/journals/lanpsy/PIIS2215-0366(20)30059-6.pdf). They are also a group that rely heavily on individual from the same region of origin for support with language barriers and cultural identity challenges. |
| How, and in what way, were people from each ethnic group involved in selecting or designing the trial intervention/comparator? | Response:  PPI was used to assist in the design of this trial. Focus groups with ethnic minority organisations were used to co-host the sessions. It was unclear how many representatives from each ethnic group were included and to what extent different cultural practices were addressed as part of the design.  Expert carer input was also sought after; however it was unclear whether these caregivers had experience or cultural understanding of different ethnic groups living with SMI. |
| 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:  As mentioned above, 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:  Face-to-face 1:1 sessions could be a barrier for people who would struggle to pay for travel to and from the clinic – participants were recompensed for time but there was no further financial incentive. Sometimes even reimbursing travel comes with challenges as this does not help those who do not have the finances to begin with. In London, poverty rates are highest for Bangladeshi and Pakistani households and lowest for white households. The timing of appointments can also cause challenges for those who work and have families to support. Unless there is flexibility with appointment times, some people will be unable to attend, no matter the mode of delivery.  On the topic of poverty and socioeconomic status, this can directly impact a person’s ability to use technology in the home, thus meaning video calls etc could be more of a challenge. Age can also impact someone’s ability to use and understand how to use technology in the home.  Group sessions can limit participation for certain ethnic groups if care is not taken to develop a caring, understanding dynamic. Naturally there will be a divide between some ethnic groups, ages, genders. For example, South Asian women are least likely to utilise mental health services. It would therefore be important to develop a culturally sensitive group, where each of the patients felt their cultural, ethnic, and spiritual beliefs were understood by the group leader.  Language and literacy can also directly impact all modes of delivery. A self-report questionnaire was used in this study, where literacy levels will affect ability to complete. |
| 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:  In the UK, it has been shown that groups other than white groups, [report inferior NHS experiences](https://bmjopen.bmj.com/content/12/3/e053827). This potentially explains their lower reported trust in the government and healthcare professionals. Lower trust in institutions could affect where some groups feel most comfortable – they may feel more at ease in their local library than hospital for example. |
| 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:  [People with SMI have low rates of employment](https://www.england.nhs.uk/mental-health/adults/cmhs/), with only 8% being in employment, compared with 75% in the general population. Therefore, taking place during working hours may not be as much of a barrier for this target population.  The level of family commitment that someone has can affect their ability to attend more lengthy and intense sessions. [In 2011,](https://www.ethnicity-facts-figures.service.gov.uk/uk-population-by-ethnicity/demographics/families-and-households/latest) 47% of Asian households were made up of married couples, the highest percentage of all ethnic groups. This could imply that this group may have more support to care for dependents (however it does get a little more complicated with the relationship between men and women, with women tending to hold more responsibility). 18.9% of black households were single parent households, the highest of all other ethnic groups for this category. With black ethnic groups being more at risk of being diagnosed with psychosis, this could affect their ability to participate in sessions that require more time away from home. |
| 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:  Most inclusion criteria are clinical focused, the key one that isn’t:   * Proficient in English with no need for an interpreter   Overall, this inclusion criteria will disproportionately affect ethnic minority groups. For example, ethnic migrant groups are likely to have higher rates of psychosis. This may pose challenges in locating accurate medical notes if they were previously treated in another country. This inclusion criteria may hamper participation directly as well, as they will be more likely to require translation services to take part. |
| 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:  Participants were identified through inpatient units and community care teams. Limited trial information is available on who was responsible for first approaching patients and who took them through the screening procedure. There is a risk that this could affect recruitment, based on bias and cultural awareness of the staff involved.  As previously discussed, black groups may be more wary of white clinicians and potentially be more trusting if a black clinician approached them to participate.  Posters in clinics may be suitable for groups that are likely to utilise mental health services, e.g., White groups, however, they would not be suitable for those who tend to first receive treatment through A&E or in crisis e.g., black groups. Limited information is available regarding how different ethnic groups were made aware of the study. |
| How might the information that tells potential participants about the trial (e.g. participant information leaflet) limit the participation of each ethnic group? | Response:  The participant information sheets tend to be a lengthy document that requires a good level of English to fully understand and be informed of the trial procedures. This trial did not provide the option for a translator. This is most likely to affect the participation of some Asian groups, who do not speak English as their first language.  A higher percentage of Asian ethnic groups in the UK do not speak English as their first language, when compared with black ethnic groups. The highest group that do not speak English as their first language in the UK are non-British white groups, [with only 36% of them speaking English as their main language.](https://www.ethnicity-facts-figures.service.gov.uk/uk-population-by-ethnicity/demographics/english-language-skills/latest#by-ethnicity)  It is unclear whether people were given the option to read the information sheet in their native language, an option that may not only increase recruitment but also support participants from all groups fully inform themselves of the trial – possibly leading to higher engagement rates. It is also unclear whether the information sheet was written with input from people from different ethnicities.  The information sheets for this trial were not available. The images and content of the information can influence participation of different groups. For example, if pictures/images of people were included, they should be as representative as possible of the different ethnic groups. |
| 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:  As discussed, language is likely to be the main barrier preventing some ethnic groups from participating in this trial. It is unclear if information sheets were provided in different languages for people who preferred to read in their own language, but still had good spoken English.  As previously discussed, the staff member involved in obtaining consent could also influence someone’s trust in the trial. | |
| 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. As discussed, 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:  The trial team consulted PPI in the design of this trial, including co-hosting focus groups with organisations of ethnic minority groups e.g. with Family Health Isis, a local African and Caribbean mental health organisation. It was unclear how many representatives from each ethnic group were involved, however. |
| 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:  Cardiometabolic risk markers, including rates of obesity and central obesity, and levels of glycated haemoglobin (HbA1c) and lipids, were the main outcomes in the first part of the study, with descriptive data presented on substance use. There may be some extent of embarrassment or stigma associated with, for example, being obese that could lead to 1) unwillingness to participate as will need to disclose this data 2) lying on the self-reported questionnaire. However, this is difficult to associate with one ethnicity more than another. There is a chance women may feel more embarrassed than men, however again this is uncertain.  There may also be shame associated with illicit drug use in some cultures more so than others, e.g., data implies that less Asian groups use illicit drugs, when compared with black and white groups. Questions regarding this could be off-putting if the reasons for asking are not sensitively and suitably explained.  The primary outcome measure for the randomised controlled trial was the physical or mental health component Short Form questionnaire-36 items quality-of-life scores at 12 months. Literacy levels are known to be low in people with SMIs. Self-reported questionnaires may limit participation if people feel unable to understand and write what is required. |
| Other factors to consider: | |
| **Who** | How might the people who collect data limit the participation of each ethnic group in the target population? | Response:  The trial relied heavily on self-reported measures, which were validated for use with participants with psychosis. However, potential problems are associated with the accuracy of such measures, which must be acknowledged. Many participants in this trial chose not to self-administer the measures, largely because of the nature of the illness (which can result in lack of motivation, low mood, cognitive impairment), and low literacy levels. Instead, researchers were often required to read aloud each item and present the corresponding scale on which participants would indicate their response. Researchers would have to read out each item in a non-biased manner, but it is known that the way in which data collection is conducted, or by whom it is conducted, can have unintended potential consequences on study findings.  It was unclear who the people were in this trial who were responsible for this, what their ethnic/cultural backgrounds were or if they were very experienced collecting this type of data from a variety of different ethnic groups. |
| Other factors to consider: | |
| **How** | How might data collection methods limit the participation of each ethnic group in the target population? | Response:  See above two responses. |
| Other factors to consider: | |
| **Where** | How might where data are collected limit the participation of each ethnic group in the target population? | Response:  Data are collected by self-report through questionnaires. This might limit the participation of some ethnic groups because of literacy and language issues. |
| 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:  See worksheet 3b. | |
| Other factors to consider: | | |
| **Benefits** | How might the benefits of the trial intervention(s) differ between each ethnic group in the target population? | Response:  The health promotion intervention, designed for NHS clinicians to give to their own patients on top of routine care, was found not to be effective for improving quality of life or reducing cardiometabolic risk.  Information on benefits in each ethnicity was not available. | |
| 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 response 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:  The trial may have benefited from a pre-planned sub-group analysis looking at each of the trial outcomes by ethnic group, especially given the higher prevalence of psychotic disorders in black and Asian ethnic groups, but also given the increased risk of diabetes in these groups too.  An additional sub-group analysis would be especially interesting to understand the potential link between larger waist size increase in white men with a psychotic disorder, and if there this provides any explanation for a higher mortality rate. | |
| 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:  PPI was sought after to develop and design this trial. There was limited information available on the ethnicities of the people who ran the PPI, however it was noted that a local African and Caribbean mental health organisation co-hosted on the day.  Two mental health carers attend the study management meetings to advise on various topics including dissemination. However, there was no reference to how different ethnic groups were considered in relation to planning the reporting and dissemination of trial results. |
| Other factors to consider: | |
| **How** | How might planned reporting and dissemination methods limit engagement with each ethnic group in the target population? | Response:  The 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-man 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.

|  |  |  |
| --- | --- | --- |
| **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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A picture containing flower, drawing

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

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

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

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