



TRIAL FORGE

STRIDE 

Supporting Recruitment & retention
Improvements for Diverse Ethnicities

Design considerations for including diverse ethnic groups in COVID trials

This document summarises findings from the INCLUDE Ethnicity Frameworks completed for the STRIDE project. The identified challenges have been organised into the five main Office for National Statistics ethnicity categories: White, Mixed/Multiple ethnic groups, Asian/Asian British, Black/African/Caribbean/Black British, and Other ethnic groups. The intention is to support trial teams working in cancer, cardiovascular diseases, diabetes, maternal and infant health, mental health, smoking cessation, COVID, surgery, and dental health. By consulting these summaries, teams can quickly see the key challenges they may need to consider when designing inclusive trials and enabling participation from people across diverse ethnic backgrounds. Where a challenge is relevant to more than one ethnic group, it appears under each applicable heading. The challenges span factors such as cultural beliefs, practical concerns, and aspects of trial design.

White

Principle (COVID-19 treatment)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Written materials can exclude people with low literacy levels of any ethnicity, even fluent English speakers. This can be assessed using the Flesch-Kincaid Grade Levels (recommended score 7-8).

RECOVERY (COVID-19 treatment)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Convalescent plasma is introduced as part of the main randomisation in part B – Jehovah's Witnesses will not accept blood products. • Depending on the language skills of both staff member and potential participant/family members, and the difficulties of making that approach as perceived by the recruiter, a direct recruiter approach may limit the ability of some members of some ethnic groups (e.g. older South Asians, especially women; some White non-British) to take part. • Written materials can exclude people with low literacy levels of any ethnicity, even fluent English speakers. This can be assessed using the Flesch-Kincaid Grade Levels (recommended score 7-8).

Mixed/Multiple ethnic groups

COVAC 1 (COVID-19 vaccine)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Black and south Asian groups may be more likely to test positive for COVID-19, with Pakistani ethnicity at highest risk (Niedzwiedz et al., 2020). • The risk of death is much higher in minority ethnic groups than in the White population (Office for National Statistics, 2020). • It is likely that social media stories within some ethnic communities will work against participation in vaccine trials by Black, Asian and minority ethnic groups (Reuters, 2020). • Influenza vaccine uptake in children is lower in school with higher populations of Black, Asian and minority ethnic children. This is possibly related to parent's perceptions about immunisations and beliefs about biological ethnic differences altering parent's perceived susceptibility to disease and vaccine side effects (Forster et al., 2016). • Religious beliefs may prevent some groups (e.g. Sikhs) taking a drug that includes (or is perceived to contain) ingredients made from pigs; Hindus may have similar problems with ingredients derived from cows. • Health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support (NHS England, 2018). • Older people in most minority ethnic groups are more likely to believe that faith in God is needed more than medicine, a theme also recognised by younger members of those communities. • Health beliefs may mean that some ethnic groups' resistance to seeking health care means they are less likely to attend in a hospital environment. • If clinic hours are working hours (i.e. 9am to 5pm in the UK), this is likely to disadvantage those who work during these hours but are unable to take time off to come to the clinic. Ethnic minority groups are more likely to have jobs where this is a problem. • Sexually active women from all four minority ethnic groups were less likely than White women to use reliable methods of contraception (Saxena et al., 2006). • The opportunity to participate seems largely self-led, which means those who have a general distrust of medical research (e.g. Arabic, Black Caribbean, Black African) are unlikely to join. • Reliance on written materials in English is likely to limit participation of individuals from any ethnic group with low literacy levels. • Some data may be extracted from medical and general practice records and it is possible that some members of some ethnic groups may not want anyone (at least not an unknown member of NHS staff) going through their own medical record, or that of their family member. • For those aged 16-44, recent internet users broadly similar across ethnic groups – in older ages, the proportion in Black, Asian and minority ethnic tends to fall more quickly than in White groups (UK Government, 2019).

Principle (COVID-19 treatment)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Written materials can exclude people with low literacy levels of any ethnicity, even fluent English speakers. This can be assessed using the Flesch-Kincaid Grade Levels (recommended score 7-8). • People of Chinese, Indian, Pakistani, other Asian, Caribbean and other Black ethnicity had between 10 and 50% higher risk of death when compared to White British (Public Health England, 2020). • Black, Asian and minority ethnic individuals may well present with more severe disease, because of e.g. higher incidence of chronic diseases and multiple long-term conditions such as diabetes. • Several ethnic minority groups, particularly Arabic, Black African and Black Caribbean, have a deep mistrust of medical research stemming from a history of systemic racism within the medical and research worlds (Goff, 2019). • Drug capsules can contain animal products, religious beliefs may therefore prevent certain groups (e.g. Sikhs, Hindus) from taking them. There are vegetarian and vegan alternatives, so it is important that the trial team bears that in mind when explaining the trial drugs to potential participants and also when they are sourcing the drugs for the trial. • Health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support (NHS England, 2018). • Older people in most minority ethnic groups are more likely to believe that faith in God is needed more than medicine, a theme also recognised by younger members of those communities. • The opportunity to participate is largely self-led, which means those who have a general distrust of medical research (e.g. Arabic, Black Caribbean, Black African) may be unlikely to join. • Reliance on materials in English is likely to limit participation of individuals from ethnic groups who may not understand English. • People from some ethnic groups – particularly the older members of their communities that this trial focuses on – are likely to want to consult with members of their family, or perhaps other members of their community (religious leaders for example). • Some data may be extracted from medical and general practice records and it is possible that some members of some ethnic groups may not be comfortable with the trial team (i.e. an unknown group of people) having access to their medical records.

RECOVERY (COVID-19 treatment)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Convalescent plasma is introduced as part of the main randomisation in part B – Jehovah's Witnesses will not accept blood products. • Depending on the language skills of both staff member and potential participant/family members, and the difficulties of making that approach as perceived by the recruiter, a direct recruiter approach may limit the ability of some members of some ethnic groups (e.g. older South Asians, especially women; some White non-British) to take part. • Written materials can exclude people with low literacy levels of any ethnicity, even fluent English speakers. This can be assessed using the Flesch-Kincaid Grade Levels (recommended score 7-8). • Black and south Asian groups may be more likely to test positive for COVID-19, with Pakistani ethnicity at highest risk (Niedzwiedz et al., 2020). • The risk of death is much higher in minority ethnic groups than in the White population (Office for National Statistics, 2020). • Several ethnic minority groups, particularly Arabic, Black African and Black Caribbean, have a deep mistrust of medical research (Goff, 2019). • Some ethnic groups have expressed a preference for traditional, herbal or homeopathic medicine (e.g. Indian, Arabic, Black Caribbean, Black African and Chinese). • Health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support (NHS England, 2018). • Older people in most minority ethnic groups are more likely to believe that faith in God is needed more than medicine, a theme also recognised by younger members of those communities. • Religious beliefs may prevent some groups (e.g. Sikhs) taking a drug that includes (or is perceived to contain) ingredients made from pigs; Hindus may have similar problems with ingredients derived from cows. Prednisolone and azithromycin tablets both contain magnesium stearate which may be of animal origin. • Ethnic minority patients report lower satisfaction and less positive experiences of care overall (Pinder et al., 2016). • Exclusion criterion 'No medical history that might, in the opinion of the attending clinician, put the patient at significant risk if he/she were to participate in the trial' could, in principle, be used consciously or unconsciously to exclude some ethnic groups depending on how broadly 'medical history' is interpreted. It could, for example, be used as a proxy to exclude individuals where the next stage of the trial process, consent, is considered likely to be difficult for reasons of language, health literacy or other non-clinical reason. • Reliance on written materials in English is likely to limit participation of individuals from any ethnic group with low literacy levels. Older people from some ethnic groups cannot read the language they speak. • Some data may be extracted from medical and general practice records and it is possible that some members of some ethnic groups may not want anyone (at least not an unknown member of NHS staff) going through their own medical record, or that of their family member.

Asian/Asian British

COVAC 1 (COVID-19 vaccine)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Black and south Asian groups may be more likely to test positive for COVID-19, with Pakistani ethnicity at highest risk (Niedzwiedz et al., 2020). • The risk of death is much higher in minority ethnic groups than in the White population (Office for National Statistics, 2020). • It is likely that social media stories within some ethnic communities will work against participation in vaccine trials by Black, Asian and minority ethnic groups (Reuters, 2020). • Influenza vaccine uptake in children is lower in school with higher populations of Black, Asian and minority ethnic children. This is possibly related to parent's perceptions about immunisations and beliefs about biological ethnic differences altering parent's perceived susceptibility to disease and vaccine side effects (Forster et al., 2016). • Religious beliefs may prevent some groups (e.g. Sikhs) taking a drug that includes (or is perceived to contain) ingredients made from pigs; Hindus may have similar problems with ingredients derived from cows. • Health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support (NHS England, 2018). • Older people in most minority ethnic groups are more likely to believe that faith in God is needed more than medicine, a theme also recognised by younger members of those communities. • Health beliefs may mean that some ethnic groups' resistance to seeking health care means they are less likely to attend in a hospital environment. • If clinic hours are working hours (i.e. 9am to 5pm in the UK), this is likely to disadvantage those who work during these hours but are unable to take time off to come to the clinic. Ethnic minority groups are more likely to have jobs where this is a problem. • Sexually active women from all four minority ethnic groups were less likely than White women to use reliable methods of contraception (Saxena et al., 2006). • The opportunity to participate seems largely self-led, which means those who have a general distrust of medical research (e.g. Arabic, Black Caribbean, Black African) are unlikely to join. • Reliance on written materials in English is likely to limit participation of individuals from any ethnic group with low literacy levels. • Some data may be extracted from medical and general practice records and it is possible that some members of some ethnic groups may not want anyone (at least not an unknown member of NHS staff) going through their own medical record, or that of their family member. • For those aged 16-44, recent internet users broadly similar across ethnic groups – in older ages, the proportion in Black, Asian and minority ethnic tends to fall more quickly than in White groups (UK Government, 2019).
Only reported in Asian/Asian British participants	<ul style="list-style-type: none"> • Terminology used by some to describe the virus (e.g. 'Chinese virus') was likely to stigmatise some Asian groups (World Health Organisation, 2020).
Principle (COVID-19 treatment)	

Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Written materials can exclude people with low literacy levels of any ethnicity, even fluent English speakers. This can be assessed using the Flesch-Kincaid Grade Levels (recommended score 7-8). • People of Chinese, Indian, Pakistani, other Asian, Caribbean and other Black ethnicity had between 10 and 50% higher risk of death when compared to White British (Public Health England, 2020). • Black, Asian and minority ethnic individuals may well present with more severe disease, because of e.g. higher incidence of chronic diseases and multiple long-term conditions such as diabetes. • Several ethnic minority groups, particularly Arabic, Black African and Black Caribbean, have a deep mistrust of medical research stemming from a history of systemic racism within the medical and research worlds (Goff, 2019). • Drug capsules can contain animal products, religious beliefs may therefore prevent certain groups (e.g. Sikhs, Hindus) from taking them. There are vegetarian and vegan alternatives, so it is important that the trial team bears that in mind when explaining the trial drugs to potential participants and also when they are sourcing the drugs for the trial. • Health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support (NHS England, 2018). • Older people in most minority ethnic groups are more likely to believe that faith in God is needed more than medicine, a theme also recognised by younger members of those communities. • The opportunity to participate is largely self-led, which means those who have a general distrust of medical research (e.g. Arabic, Black Caribbean, Black African) may be unlikely to join. • Reliance on materials in English is likely to limit participation of individuals from ethnic groups who may not understand English. • People from some ethnic groups – particularly the older members of their communities that this trial focuses on – are likely to want to consult with members of their family, or perhaps other members of their community (religious leaders for example). • Some data may be extracted from medical and general practice records and it is possible that some members of some ethnic groups may not be comfortable with the trial team (i.e. an unknown group of people) having access to their medical records.
Only reported in Asian/Asian British participants	<ul style="list-style-type: none"> • Terminology used by some to describe the virus (e.g. 'Chinese virus') was likely to stigmatise some Asian groups (World Health Organisation, 2020). • Internet access by 65-74 is 20% lower for Asians (around 65%) than for White British population (UK Government, 2019).

RECOVERY (COVID-19 treatment)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Convalescent plasma is introduced as part of the main randomisation in part B – Jehovah's Witnesses will not accept blood products. • Depending on the language skills of both staff member and potential participant/family members, and the difficulties of making that approach as perceived by the recruiter, a direct recruiter approach may limit the ability of some members of some ethnic groups (e.g. older South Asians, especially women; some White non-British) to take part. • Written materials can exclude people with low literacy levels of any ethnicity, even fluent English speakers. This can be assessed using the Flesch-Kincaid Grade Levels (recommended score 7-8). • Black and south Asian groups may be more likely to test positive for COVID-19, with Pakistani ethnicity at highest risk (Niedzwiedz et al., 2020). • The risk of death is much higher in minority ethnic groups than in the White population (Office for National Statistics, 2020). • Several ethnic minority groups, particularly Arabic, Black African and Black Caribbean, have a deep mistrust of medical research (Goff, 2019). • Some ethnic groups have expressed a preference for traditional, herbal or homeopathic medicine (e.g. Indian, Arabic, Black Caribbean, Black African and Chinese). • Health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support (NHS England, 2018). • Older people in most minority ethnic groups are more likely to believe that faith in God is needed more than medicine, a theme also recognised by younger members of those communities. • Religious beliefs may prevent some groups (e.g. Sikhs) taking a drug that includes (or is perceived to contain) ingredients made from pigs; Hindus may have similar problems with ingredients derived from cows. Prednisolone and azithromycin tablets both contain magnesium stearate which may be of animal origin. • Ethnic minority patients report lower satisfaction and less positive experiences of care overall (Pinder et al., 2016). • Exclusion criterion 'No medical history that might, in the opinion of the attending clinician, put the patient at significant risk if he/she were to participate in the trial' could, in principle, be used consciously or unconsciously to exclude some ethnic groups depending on how broadly 'medical history' is interpreted. It could, for example, be used as a proxy to exclude individuals where the next stage of the trial process, consent, is considered likely to be difficult for reasons of language, health literacy or other non-clinical reason. • Reliance on written materials in English is likely to limit participation of individuals from any ethnic group with low literacy levels. Older people from some ethnic groups cannot read the language they speak. • Some data may be extracted from medical and general practice records and it is possible that some members of some ethnic groups may not want anyone (at least not an unknown member of NHS staff) going through their own medical record, or that of their family member.

<p>Only reported in Asian/Asian British participants</p>	<ul style="list-style-type: none"> • Terminology used by some to describe the virus (e.g. 'Chinese virus') was likely to stigmatise some Asian groups (World Health Organisation, 2020). • In some Asian groups (e.g. Pakistani) older women may look to their husbands or other male family member for guidance; discussions about participation will need to explicitly consider this. • Some ethnic groups (e.g. South Asians) are more likely to want to involve family in decisions and this may limit their ability to take part if this cannot happen.
--	--

Black/African/Caribbean/Black British

COVAC 1 (COVID-19 vaccine)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Black and south Asian groups may be more likely to test positive for COVID-19, with Pakistani ethnicity at highest risk (Niedzwiedz et al., 2020). • The risk of death is much higher in minority ethnic groups than in the White population (Office for National Statistics, 2020). • It is likely that social media stories within some ethnic communities will work against participation in vaccine trials by Black, Asian and minority ethnic groups (Reuters, 2020). • Influenza vaccine uptake in children is lower in school with higher populations of Black, Asian and minority ethnic children. This is possibly related to parent's perceptions about immunisations and beliefs about biological ethnic differences altering parent's perceived susceptibility to disease and vaccine side effects (Forster et al., 2016). • Religious beliefs may prevent some groups (e.g. Sikhs) taking a drug that includes (or is perceived to contain) ingredients made from pigs; Hindus may have similar problems with ingredients derived from cows. • Health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support (NHS England, 2018). • Older people in most minority ethnic groups are more likely to believe that faith in God is needed more than medicine, a theme also recognised by younger members of those communities. • Health beliefs may mean that some ethnic groups' resistance to seeking health care means they are less likely to attend in a hospital environment. • If clinic hours are working hours (i.e. 9am to 5pm in the UK), this is likely to disadvantage those who work during these hours but are unable to take time off to come to the clinic. Ethnic minority groups are more likely to have jobs where this is a problem. • Sexually active women from all four minority ethnic groups were less likely than White women to use reliable methods of contraception (Saxena et al., 2006). • The opportunity to participate seems largely self-led, which means those who have a general distrust of medical research (e.g. Arabic, Black Caribbean, Black African) are unlikely to join. • Reliance on written materials in English is likely to limit participation of individuals from any ethnic group with low literacy levels. • Some data may be extracted from medical and general practice records and it is possible that some members of some ethnic groups may not want anyone (at least not an unknown member of NHS staff) going through their own medical record, or that of their family member. • For those aged 16-44, recent internet users broadly similar across ethnic groups – in older ages, the proportion in Black, Asian and minority ethnic tends to fall more quickly than in White groups (UK Government, 2019).
Only reported in Black/African/Caribbean/Black British participants	<ul style="list-style-type: none"> • Discussion of HIV (linked to an exclusion criterion) may be sensitive/carry stigma for some ethnic groups, especially Black African and Black Caribbean groups (National AIDS Trust, 2003).
Principle (COVID-19 treatment)	

Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Written materials can exclude people with low literacy levels of any ethnicity, even fluent English speakers. This can be assessed using the Flesch-Kincaid Grade Levels (recommended score 7-8). • People of Chinese, Indian, Pakistani, other Asian, Caribbean and other Black ethnicity had between 10 and 50% higher risk of death when compared to White British (Public Health England, 2020). • Black, Asian and minority ethnic individuals may well present with more severe disease, because of e.g. higher incidence of chronic diseases and multiple long-term conditions such as diabetes. • Several ethnic minority groups, particularly Arabic, Black African and Black Caribbean, have a deep mistrust of medical research stemming from a history of systemic racism within the medical and research worlds (Goff, 2019). • Drug capsules can contain animal products, religious beliefs may therefore prevent certain groups (e.g. Sikhs, Hindus) from taking them. There are vegetarian and vegan alternatives, so it is important that the trial team bears that in mind when explaining the trial drugs to potential participants and also when they are sourcing the drugs for the trial. • Health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support (NHS England, 2018). • Older people in most minority ethnic groups are more likely to believe that faith in God is needed more than medicine, a theme also recognised by younger members of those communities. • The opportunity to participate is largely self-led, which means those who have a general distrust of medical research (e.g. Arabic, Black Caribbean, Black African) may be unlikely to join. • Reliance on materials in English is likely to limit participation of individuals from ethnic groups who may not understand English. • People from some ethnic groups – particularly the older members of their communities that this trial focuses on – are likely to want to consult with members of their family, or perhaps other members of their community (religious leaders for example). • Some data may be extracted from medical and general practice records and it is possible that some members of some ethnic groups may not be comfortable with the trial team (i.e. an unknown group of people) having access to their medical records.
Only reported in Black/ African/ Caribbean/ Black British participants	<ul style="list-style-type: none"> • Highest age standardised diagnosis rates of COVID-19 per 100,000 population were in people of Black ethnic groups (Public Health England, 2020).

RECOVERY (COVID-19 treatment)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Convalescent plasma is introduced as part of the main randomisation in part B – Jehovah's Witnesses will not accept blood products. • Depending on the language skills of both staff member and potential participant/family members, and the difficulties of making that approach as perceived by the recruiter, a direct recruiter approach may limit the ability of some members of some ethnic groups (e.g. older South Asians, especially women; some White non-British) to take part. • Written materials can exclude people with low literacy levels of any ethnicity, even fluent English speakers. This can be assessed using the Flesch-Kincaid Grade Levels (recommended score 7-8). • Black and south Asian groups may be more likely to test positive for COVID-19, with Pakistani ethnicity at highest risk (Niedzwiedz et al., 2020). • The risk of death is much higher in minority ethnic groups than in the White population (Office for National Statistics, 2020). • Several ethnic minority groups, particularly Arabic, Black African and Black Caribbean, have a deep mistrust of medical research (Goff, 2019). • Some ethnic groups have expressed a preference for traditional, herbal or homeopathic medicine (e.g. Indian, Arabic, Black Caribbean, Black African and Chinese). • Health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support (NHS England, 2018). • Older people in most minority ethnic groups are more likely to believe that faith in God is needed more than medicine, a theme also recognised by younger members of those communities. • Religious beliefs may prevent some groups (e.g. Sikhs) taking a drug that includes (or is perceived to contain) ingredients made from pigs; Hindus may have similar problems with ingredients derived from cows. Prednisolone and azithromycin tablets both contain magnesium stearate which may be of animal origin. • Ethnic minority patients report lower satisfaction and less positive experiences of care overall (Pinder et al., 2016). • Exclusion criterion 'No medical history that might, in the opinion of the attending clinician, put the patient at significant risk if he/she were to participate in the trial' could, in principle, be used consciously or unconsciously to exclude some ethnic groups depending on how broadly 'medical history' is interpreted. It could, for example, be used as a proxy to exclude individuals where the next stage of the trial process, consent, is considered likely to be difficult for reasons of language, health literacy or other non-clinical reason. • Reliance on written materials in English is likely to limit participation of individuals from any ethnic group with low literacy levels. Older people from some ethnic groups cannot read the language they speak. • Some data may be extracted from medical and general practice records and it is possible that some members of some ethnic groups may not want anyone (at least not an unknown member of NHS staff) going through their own medical record, or that of their family member.

Other ethnic groups

COVAC 1 (COVID-19 vaccine)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Black and south Asian groups may be more likely to test positive for COVID-19, with Pakistani ethnicity at highest risk (Niedzwiedz et al., 2020). • The risk of death is much higher in minority ethnic groups than in the White population (Office for National Statistics, 2020). • It is likely that social media stories within some ethnic communities will work against participation in vaccine trials by Black, Asian and minority ethnic groups (Reuters, 2020). • Influenza vaccine uptake in children is lower in school with higher populations of Black, Asian and minority ethnic children. This is possibly related to parent's perceptions about immunisations and beliefs about biological ethnic differences altering parent's perceived susceptibility to disease and vaccine side effects (Forster et al., 2016). • Religious beliefs may prevent some groups (e.g. Sikhs) taking a drug that includes (or is perceived to contain) ingredients made from pigs; Hindus may have similar problems with ingredients derived from cows. • Health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support (NHS England, 2018). • Older people in most minority ethnic groups are more likely to believe that faith in God is needed more than medicine, a theme also recognised by younger members of those communities. • Health beliefs may mean that some ethnic groups' resistance to seeking health care means they are less likely to attend in a hospital environment. • If clinic hours are working hours (i.e. 9am to 5pm in the UK), this is likely to disadvantage those who work during these hours but are unable to take time off to come to the clinic. Ethnic minority groups are more likely to have jobs where this is a problem. • Sexually active women from all four minority ethnic groups were less likely than White women to use reliable methods of contraception (Saxena et al., 2006). • The opportunity to participate seems largely self-led, which means those who have a general distrust of medical research (e.g. Arabic, Black Caribbean, Black African) are unlikely to join. • Reliance on written materials in English is likely to limit participation of individuals from any ethnic group with low literacy levels. • Some data may be extracted from medical and general practice records and it is possible that some members of some ethnic groups may not want anyone (at least not an unknown member of NHS staff) going through their own medical record, or that of their family member. • For those aged 16-44, recent internet users broadly similar across ethnic groups – in older ages, the proportion in Black, Asian and minority ethnic tends to fall more quickly than in White groups (UK Government, 2019).

Principle (COVID-19 treatment)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Written materials can exclude people with low literacy levels of any ethnicity, even fluent English speakers. This can be assessed using the Flesch-Kincaid Grade Levels (recommended score 7-8). • People of Chinese, Indian, Pakistani, other Asian, Caribbean and other Black ethnicity had between 10 and 50% higher risk of death when compared to White British (Public Health England, 2020). • Black, Asian and minority ethnic individuals may well present with more severe disease, because of e.g. higher incidence of chronic diseases and multiple long-term conditions such as diabetes. • Several ethnic minority groups, particularly Arabic, Black African and Black Caribbean, have a deep mistrust of medical research stemming from a history of systemic racism within the medical and research worlds (Goff, 2019). • Drug capsules can contain animal products, religious beliefs may therefore prevent certain groups (e.g. Sikhs, Hindus) from taking them. There are vegetarian and vegan alternatives, so it is important that the trial team bears that in mind when explaining the trial drugs to potential participants and also when they are sourcing the drugs for the trial. • Health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support (NHS England, 2018). • Older people in most minority ethnic groups are more likely to believe that faith in God is needed more than medicine, a theme also recognised by younger members of those communities. • The opportunity to participate is largely self-led, which means those who have a general distrust of medical research (e.g. Arabic, Black Caribbean, Black African) may be unlikely to join. • Reliance on materials in English is likely to limit participation of individuals from ethnic groups who may not understand English. • People from some ethnic groups – particularly the older members of their communities that this trial focuses on – are likely to want to consult with members of their family, or perhaps other members of their community (religious leaders for example). • Some data may be extracted from medical and general practice records and it is possible that some members of some ethnic groups may not be comfortable with the trial team (i.e. an unknown group of people) having access to their medical records.

RECOVERY (COVID-19 treatment)	
Trial registration document	
INCLUDE Framework	
Challenges	
<p>Reported across several ethnic backgrounds</p>	<ul style="list-style-type: none"> • Convalescent plasma is introduced as part of the main randomisation in part B – Jehovah's Witnesses will not accept blood products. • Depending on the language skills of both staff member and potential participant/family members, and the difficulties of making that approach as perceived by the recruiter, a direct recruiter approach may limit the ability of some members of some ethnic groups (e.g. older South Asians, especially women; some White non-British) to take part. • Written materials can exclude people with low literacy levels of any ethnicity, even fluent English speakers. This can be assessed using the Flesch-Kincaid Grade Levels (recommended score 7-8). • Black and south Asian groups may be more likely to test positive for COVID-19, with Pakistani ethnicity at highest risk (Niedzwiedz et al., 2020). • The risk of death is much higher in minority ethnic groups than in the White population (Office for National Statistics, 2020). • Several ethnic minority groups, particularly Arabic, Black African and Black Caribbean, have a deep mistrust of medical research (Goff, 2019). • Some ethnic groups have expressed a preference for traditional, herbal or homeopathic medicine (e.g. Indian, Arabic, Black Caribbean, Black African and Chinese). • Health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support (NHS England, 2018). • Older people in most minority ethnic groups are more likely to believe that faith in God is needed more than medicine, a theme also recognised by younger members of those communities. • Religious beliefs may prevent some groups (e.g. Sikhs) taking a drug that includes (or is perceived to contain) ingredients made from pigs; Hindus may have similar problems with ingredients derived from cows. Prednisolone and azithromycin tablets both contain magnesium stearate which may be of animal origin. • Ethnic minority patients report lower satisfaction and less positive experiences of care overall (Pinder et al., 2016). • Exclusion criterion 'No medical history that might, in the opinion of the attending clinician, put the patient at significant risk if he/she were to participate in the trial' could, in principle, be used consciously or unconsciously to exclude some ethnic groups depending on how broadly 'medical history' is interpreted. It could, for example, be used as a proxy to exclude individuals where the next stage of the trial process, consent, is considered likely to be difficult for reasons of language, health literacy or other non-clinical reason. • Reliance on written materials in English is likely to limit participation of individuals from any ethnic group with low literacy levels. Older people from some ethnic groups cannot read the language they speak. • Some data may be extracted from medical and general practice records and it is possible that some members of some ethnic groups may not want anyone (at least not an unknown member of NHS staff) going through their own medical record, or that of their family member.

References

- Niedzwiedz, C. L., O'Donnell, C. A., Jani, B. D., Demou, E., Ho, F. K., Celis-Morales, C., Nicholl, B. I., Mair, F. S., Welsh, P., Sattar, N., Pell, J. P., & Katikireddi, S. V. (2020). Ethnic and socioeconomic differences in SARS-CoV-2 infection: prospective cohort study using UK Biobank. *BMC Medicine*, 18(1). <https://doi.org/10.1186/s12916-020-01640-8>
- Forster, A. S., Rockliffe, L., Chorley, A. J., Marlow, L. A. V., Bedford, H., Smith, S. G., & Waller, J. (2016). Ethnicity-specific factors influencing childhood immunisation decisions among Black and Asian Minority Ethnic groups in the UK: a systematic review of qualitative research. *Journal of Epidemiology and Community Health*, 71(6), 544–549. <https://doi.org/10.1136/jech-2016-207366>
- NHS England. (2018). Improving Access for all: Reducing Inequalities in Access to General Practice Services. <https://www.england.nhs.uk/wp-content/uploads/2017/07/inequalities-resource-sep-2018.pdf>
- Saxena, S., Copas, A. J., Mercer, C., Johnson, A. M., Fenton, K., Eren, B., Nanchahal, K., Macdowall, W., & Wellings, K. (2006). Ethnic variations in sexual activity and contraceptive use: national cross-sectional survey. *Contraception*, 74(3), 224–233. <https://doi.org/10.1016/j.contraception.2006.03.025>
- UK Government. (2019). Internet use. [Www.ethnicity-Facts-Figures.service.gov.uk. https://www.ethnicity-facts-figures.service.gov.uk/culture-and-community/digital/internet-use/latest/#by-ethnicity-and-age-group](https://www.ethnicity-facts-figures.service.gov.uk/culture-and-community/digital/internet-use/latest/#by-ethnicity-and-age-group)
- Goff, L. M. (2019). Ethnicity and Type 2 diabetes in the UK. *Diabetic Medicine*, 36(8), 927–938. <https://doi.org/10.1111/dme.13895>
- Pinder, R. J., Ferguson, J., & Møller, H. (2016). Minority ethnicity patient satisfaction and experience: results of the National Cancer Patient Experience Survey in England. *BMJ Open*, 6(6), e011938. <https://doi.org/10.1136/bmjopen-2016-011938>
- World Health Organisation. (2020). Social Stigma associated with COVID-19. https://www.who.int/docs/default-source/coronaviruse/covid19-stigma-guide.pdf?sfvrsn=226180f4_2
- Public Health England. (2020). Disparities in the risk and outcomes of COVID-19. Public Health England.
- National AIDS Trust. (2003). HIV-Related Stigma and Discrimination: Racial & Ethnic Minorities . https://lx.iriss.org.uk/sites/default/files/resources/HIV-related%20stigma%20and-%20discrimination_racial%20and%20ethnic%20minorities.pdf
- Office for National Statistics. (2020, May). Coronavirus (COVID-19) related deaths by ethnic group, England and Wales - Office for National Statistics. [Www.ons.gov.uk. https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/articles/coronavirusrelateddeathsbyethnicgroupenglandandwales/2march2020to10april2020#ethnic-group-differences-in-deaths-involving-covid-19-adjusted-for-main-socio-demographic-factors](https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/articles/coronavirusrelateddeathsbyethnicgroupenglandandwales/2march2020to10april2020#ethnic-group-differences-in-deaths-involving-covid-19-adjusted-for-main-socio-demographic-factors)
- Reuters. (2020, June). Fact check: The British government is not targeting BAME communities for coronavirus vaccine trials. Reuters. <https://www.reuters.com/article/uk-factcheck-bame-vaccine/fact-check-the-british-government-is-not-targeting-bame-communities-for-coronavirus-vaccine-trials-idUSKBN23V223/>