



TRIAL FORGE

STRIDE 

Supporting Recruitment & retention
Improvements for Diverse Ethnicities

Design considerations for including diverse ethnic groups in diabetes 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

REPOSE (type 1 diabetes)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none">• Stigma disproportionately affects individuals with higher BMI, A1C, and poorer blood glucose control. While not linked to specific ethnic groups, it's plausible that communities with historical mistrust of medical professionals may experience heightened stigma (Liu, et al., 2017).

Mixed/Multiple ethnic groups

REPOSE (type 1 diabetes)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Stigma disproportionately affects individuals with higher BMI, A1C, and poorer blood glucose control. While not linked to specific ethnic groups, it's plausible that communities with historical mistrust of medical professionals may experience heightened stigma (Liu, et al., 2017). • Diabetes is often referred to as 'high sugar,' especially among South Asians, and various ethnic groups may use different terms for both type 2 and type 1 diabetes. • Generally, several ethnic minority groups have a deep mistrust of medical research. • Low health literacy in certain ethnic groups poses a barrier to seeking timely healthcare support, potentially resulting in later presentations, increased complications, and poorer health outcomes compared to white counterparts (NHS England, 2018). • Cultural barriers impede ethnic minority groups from accessing effective diabetes care services. Key issues include strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy, diverse beliefs about health, reliance on expert support, limited access to culturally-appropriate services, and low concordance with western professional advice (Zeh, Sandhu, Cannaby, & Sturt, 2014). • Face-to-face delivery poses challenges in transportation and time commitment, particularly affecting those with socioeconomic disadvantages. This may limit participation, especially for individuals from ethnic minority communities at a higher risk of socioeconomic disadvantage. • Translation of trial materials into languages other than English is crucial, especially for ethnic groups, like South Asians at higher risk of complications from type 1 diabetes, who are key participants in the trial. • Written consent may limit participation of some groups (e.g., South Asians) who may prefer verbal discussion to written documents (NIHR, 2023). • Ensuring comprehension of consent information poses a challenge, particularly regarding language proficiency and cultural awareness. Unless a research team member, typically white-British, receives training, understanding these aspects for ethnic groups other than white-British can be limited. • Ethnic minority patients express lower satisfaction and less positive care experiences compared to the white British group, even after statistical adjustment. They also report lower confidence in and understanding of healthcare professionals, including clinical nurse specialists, doctors, and ward nurses (Pinder, Ferguson, & Moller, 2016). • Paper diaries assume participants have time and energy, challenging those with full-time jobs, busy lives, and socioeconomic disadvantages, often intersecting with ethnic minority experiences.

CLARITY (diabetic retinopathy)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • The prevalence of diabetic retinopathy, sight-threatening diabetic retinopathy, and clinically significant macular edema are higher in people of South Asian, African, Latin American, and Indigenous tribal descent compared to the white population (Sivaprasad et al., 2012). • People from Black African, African-Caribbean and South Asian backgrounds are at risk of developing type 2 diabetes from the age of 25. This is much younger than the white population where risk increases from age 40 (Diabetes UK, 2023). • Diabetes is sometimes called 'high sugar', (e.g., some South Asians). Other terms may be used some ethnic groups. Diabetic retinopathy may be referred to by its symptoms, e.g., sight loss, blindness, or simply, eye disease. • Generally, several ethnic minority groups essential for the trial have a deep mistrust of medical research. The distrust in healthcare professionals and research may make people hesitant of research team accessing their medical records. • In general terms, health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support (NHS England, 2018). • Issues that impede ethnic minority groups from accessing effective diabetes care services: participants' strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy levels, different beliefs about health and illness, belief in expert and professional support, low accessibility of culturally-appropriate services/information, and low concordance with western professional advice (Zeh et al., 2014). • Ethnic minority patients report lower satisfaction and less positive experiences of care overall and ethnic minority patients remained less positive than those in the white British group, after statistical adjustment. Ethnic minority patients also reported lower confidence in, and less understanding of, healthcare professionals, including clinical nurse specialists, doctors, and ward nurses (Pinder et al., 2016). • If the trial has two groups, one of which requires more treatments than the other, increasing the time commitment for the trial, this could disproportionately impact people experiencing socioeconomic disadvantage (a significantly large portion of which are people from ethnic minorities). Socioeconomic disadvantage may also impact transport (getting to the hospital for trial). • As some ethnic groups including individuals for whom English may not be their first language are a key required group within the trial (e.g. South Asians, Indian subcontinent) then translation of written and oral material into some languages other than English is likely to be essential.

TriMaster (type 2 diabetes)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Children of all ethnic minority backgrounds are at greater risk for childhood-onset type 2 diabetes, particularly girls (Khanolkar et al., 2016). • People from Black African, African-Caribbean and South Asian backgrounds are at risk of developing type 2 diabetes from the age of 25 (Diabetes UK, 2023). • Generally, trials are known to lack diversity – much of this may be down to lack of trust in the medical and research systems due to historical abuse and exploitation of Black and minority ethnic populations. • Diabetes is sometimes called ‘high sugar’, (e.g. some South Asians). Other terms may be used some ethnic groups. • The drugs being tested in the trial may contain ingredients from animal origins – limiting participation of potential participants practicing Judaism, Islam or Hinduism. Sitagliptin, pioglitazone, and canagliflozin all contain magnesium stearate which is normally pork-derived but can also be found in butter, chicken, beef, fish and milk. Vegan and vegetarian-friendly sources are available, so it is important that the trial team consider this. The same is true for gelatin. • Issues that impede ethnic minority groups from accessing effective diabetes care services: participants’ strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy levels, different beliefs about health and illness, belief in expert and professional support, low accessibility of culturally-appropriate services/information, and low concordance with western professional advice (Zeh et al., 2014). • 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. • Black and minority ethnic populations are known to distrust the medical and research systems due to historical abuse and exploitation, so it may be that attending research visits at an NHS hospital site would limit participation. • Getting to hospital can be an issue for a variety of reasons including – poor transport links, the timing and length of research visits, financial reasons. Many of these factors disproportionately impact people from poor socioeconomic backgrounds, which often includes ethnic minority groups. • The trial team should bear in mind that religious celebrations such as Ramadan will take place during the period of the study. Ramadan is a community celebration for practising Muslims – over the month of Ramadan, individuals fast between dawn and sunset. Taking medicine orally is considered breaking the fast. Exceptions are made for people that cannot perform the fasting safely (including those with diabetes). Despite being exempt, many people with diabetes do choose to fast (Grindrod & Alsabbagh, 2017; International Diabetes Federation, 2019).

LONG LIMB (type 2 diabetes and obesity)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • There is some evidence that BMI cut-offs for categories of obesity should vary by ethnic group based on risk to future health. Generally, this evidence finds that the BMI cut-off considered to represent obesity are lower for non-white groups than the 30 used for white individuals (The National Institute for Health and Care Excellence, 2013). • Children of all ethnic minority backgrounds are at greater risk for childhood-onset type 2 diabetes, particularly girls (Khanolkar et al., 2016). • People from Black African, African-Caribbean and South Asian backgrounds are at risk of developing type 2 diabetes from the age of 25 (Diabetes UK, 2023). • Diabetes is sometimes called 'high sugar', (e.g. some South Asians). Other terms may be used some ethnic groups. • Health literacy is low among some ethnic groups, which is a barrier to seeking healthcare support. Individuals from ethnic minority communities may present later than their white counterparts. Different beliefs about weight and obesity may mean support is sought differently by people from some ethnic groups because body size is not considered a health problem (NHS England, 2018). • Issues that impede ethnic minority groups from accessing effective diabetes care services: participants' strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy levels, different beliefs about health and illness, belief in expert and professional support, low accessibility of culturally-appropriate services/information, and low concordance with western professional advice (Zeh et al., 2014). • Language and literacy factors are known factors that impact on overall health literacy. Study participants have reported that both the spoken and written health information provided were sometimes meaningless, even when translated into their own language (Claydon et al., 2023). • Weight gain after bariatric surgery appears higher in some ethnic groups than others (e.g., Black individuals), which may affect willingness to take part (Medicine, 2018). • Requirements for pre-operative programs can disadvantage some across all ethnic groups because of e.g., weight loss requirements, mandatory appointments, and physical activity requirements (Taylor et al., 2019). • Ethnic minority patients report lower satisfaction and less positive experiences of care overall (Pinder et al., 2016). • Written consent may limit participation of some groups (e.g., South Asians) who may prefer verbal discussion to written documents (NIHR, 2023). • Getting to the hospital and the time needed to complete the measures may disadvantage people experiencing socioeconomic disadvantage. People from ethnic minority communities are at higher risk of socioeconomic disadvantage.

PROPELS (type 2 diabetes)	
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INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Children of all ethnic minority backgrounds are at greater risk for childhood-onset type 2 diabetes, particularly girls (Khanolkar et al., 2016). • Diabetes is sometimes called 'high sugar', (e.g., some South Asians). Other terms may be used some ethnic groups. IGR is often referred to as 'pre-diabetes'. • Health literacy is low among some ethnic groups, which is a barrier to seeking healthcare support. Individuals from ethnic minority communities may present later than their white counterparts (NHS England, 2018). • Issues that impede ethnic minority groups from accessing effective diabetes care services: participants' strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy levels, different beliefs about health and illness, belief in expert and professional support, low accessibility of culturally-appropriate services/information, and low concordance with western professional advice (Zeh et al., 2014). • Language and literacy factors are known factors that impact on overall health literacy. Study participants have reported that both the spoken and written health information provided were sometimes meaningless, even when translated into their own language (Claydon et al., 2023). • With face-to-face delivery the main issue is likely to be getting to the sites and the time needed to complete the measures. These issues may disadvantage people experiencing socioeconomic disadvantage. People from ethnic minority communities are at higher risk of socioeconomic disadvantage. • Ethnic minority individuals are more likely to experience socioeconomic disadvantage; letters from healthcare professionals can often look 'official' – usually in a brown envelope, and may give the impression that they are a bill or other negative form of post, reducing the chance of the letter ever being opened and/or the amount of trust in the letter writer even before the letter is read. • Translation of written and oral material into some languages other than English is likely to be essential. • Written consent may limit participation of some groups (e.g., South Asians) who may prefer verbal discussion to written documents (NIHR, 2018). • Ethnic minority patients report lower satisfaction and less positive experiences of care overall (Pinder et al., 2016).

Asian/Asian British

REPOSE (type 1 diabetes)	
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Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Stigma disproportionately affects individuals with higher BMI, A1C, and poorer blood glucose control. While not linked to specific ethnic groups, it's plausible that communities with historical mistrust of medical professionals may experience heightened stigma (Liu, et al., 2017). • Diabetes is often referred to as 'high sugar,' especially among South Asians, and various ethnic groups may use different terms for both type 2 and type 1 diabetes. • Generally, several ethnic minority groups have a deep mistrust of medical research. • Low health literacy in certain ethnic groups poses a barrier to seeking timely healthcare support, potentially resulting in later presentations, increased complications, and poorer health outcomes compared to white counterparts (NHS England, 2018). • Cultural barriers impede ethnic minority groups from accessing effective diabetes care services. Key issues include strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy, diverse beliefs about health, reliance on expert support, limited access to culturally-appropriate services, and low concordance with western professional advice (Zeh, Sandhu, Cannaby, & Sturt, 2014). • Face-to-face delivery poses challenges in transportation and time commitment, particularly affecting those with socioeconomic disadvantages. This may limit participation, especially for individuals from ethnic minority communities at a higher risk of socioeconomic disadvantage. • Translation of trial materials into languages other than English is crucial, especially for ethnic groups, like South Asians at higher risk of complications from type 1 diabetes, who are key participants in the trial. • Written consent may limit participation of some groups (e.g., South Asians) who may prefer verbal discussion to written documents (NIHR, 2018). • Ensuring comprehension of consent information poses a challenge, particularly regarding language proficiency and cultural awareness. Unless a research team member, typically white-British, receives training, understanding these aspects for ethnic groups other than white-British can be limited. • Ethnic minority patients express lower satisfaction and less positive care experiences compared to the white British group, even after statistical adjustment. They also report lower confidence in and understanding of healthcare professionals, including clinical nurse specialists, doctors, and ward nurses (Pinder, Ferguson, & Moller, 2016). • Paper diaries assume participants have time and energy, challenging those with full-time jobs, busy lives, and socioeconomic disadvantages, often intersecting with ethnic minority experiences.
Only reported in Asian/Asian British participants	<ul style="list-style-type: none"> • South Asians face high morbidity and mortality from diabetes complications, including diabetic retinopathy, coronary artery disease, cerebrovascular disease, and faster-progressing kidney disease compared to people of European descent (Raymond, et al., 2009). • Some older and religious South Asians may be unwilling to participate in trials due to viewing their illness as an unalterable punishment from God or fearing the nature of research (Choudhury, et al., 2008).

	<ul style="list-style-type: none"> • South Asians may have a 5.2% lower response to written healthcare invitations compared to the general population, with community-oriented, in-person approaches being more effective (Douglas, et al., 2011). • Cultural barriers for South Asians, especially among older generations, include a preference for traditional remedies and linguistic issues (Goff, 2019). • South Asian women, especially older women, typically involve family members in healthcare decisions, highlighting the need to consider family participation in the consent process (Grewal, Bottorff, & Hilton, 2005).
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	<p>ethnic minorities). Socioeconomic disadvantage may also impact transport (getting to the hospital for trial).</p> <ul style="list-style-type: none"> • As some ethnic groups including individuals for whom English may not be their first language are a key required group within the trial (e.g. South Asians, Indian subcontinent) then translation of written and oral material into some languages other than English is likely to be essential.
Only reported in Asian/Asian British participants	<ul style="list-style-type: none"> • Patients of South Asian heritage had significantly higher systolic and diastolic blood pressure, and total cholesterol levels, than white European patients. This resulted in a significantly higher prevalence of diabetic retinopathy and maculopathy (Raymond et al., 2008). • South Asians experience significant morbidity and mortality from complications of diabetes – including diabetic retinopathy, coronary artery disease, cerebrovascular disease, and chronic kidney disease (Chandie Shaw et al., 2006; Raymond et al., 2008). • Non-adherence to medicines could be the cause of poor clinical outcomes for South Asian patients, with the reasons for non-adherence being attributed to 1) beliefs about the need for and efficacy of medicines, 2) toxicity of medicines and polypharmacy, 3) the necessity of traditional remedies versus ‘western medicines’, 4) stigma and social support, and 5) communication. Stigma and social support was found to have a major influence on medicine taking, with South Asian patients being reluctant to disclose their use of insulin to their families and community (Goenka et al., 2004; Kumar et al., 2016). • Some older and religious South Asians may be unwilling to participate in trials due to viewing their illness as an unalterable punishment from God or fearing the nature of research. This thought process also applies to accepting surgical treatments, with people believing that a trial is not necessary because faith in God is needed more than medicine (Choudhury, et al., 2008). • Cultural and social norms strongly influence health-seeking behaviours – research has shown that health promotion activities tend to be based on assumptions of individualism and self-investment, which may need to be re-thought for South Asian groups in particular (Lucas et al., 2013).

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<p>Only reported in Asian/Asian British participants</p>	<ul style="list-style-type: none"> • Type 2 diabetes is up to 6 times more likely in people of South Asian descent (Indian, Pakistani, Sri Lankan and Bangladeshi heritage) than in the White population (Khunti et al., 2009). • South Asians experience significant morbidity and mortality from complications of diabetes – including diabetic retinopathy, coronary artery disease, cerebrovascular disease, and chronic kidney disease (Chandie Shaw et al., 2006; Raymond et al., 2008). • There is evidence to suggest that genetics play a part in susceptibility for South Asians, so it is likely that the trial drugs may have different impacts on this population too (Khunti et al., 2009). • Non-adherence to medicines could be the cause of poor clinical outcomes for South Asian patients, with the reasons for non-adherence being attributed to 1) beliefs about the need for and efficacy of medicines, 2) toxicity of medicines and polypharmacy, 3) the necessity of traditional remedies versus ‘western medicines’, 4) stigma and social support, and 5) communication. Stigma and social support was found to have a major influence on medicine taking, with South Asian patients being reluctant to disclose their use of insulin to their families and community (Goenka et al., 2004; Kumar et al., 2016). • Some older and religious South Asians may be unwilling to participate in trials due to viewing their illness as an unalterable punishment from God or fearing the nature of research (Choudhury, et al., 2008). • South Asians are frequently excluded from research due to perceived cultural and communication challenges (Khunti, Kumar, & Brodie, 2009). • South Asian views on diabetes drugs are complex, with some considering them only for symptomatic benefit and tried to reduce the dose at every possible opportunity (Khunti et al., 2009). • Cultural and social norms strongly influence health-seeking behaviours – research has shown that health promotion activities tend to be based on assumptions of individualism and self-investment, which may need to be re-thought for South Asian groups in particular (Lucas et al., 2013).
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LONG LIMB (type 2 diabetes and obesity)	
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Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • There is some evidence that BMI cut-offs for categories of obesity should vary by ethnic group based on risk to future health. Generally, this evidence finds that the BMI cut-off considered to represent obesity are lower for non-white groups than the 30 used for white individuals (The National Institute for Health and Care Excellence, 2013). • Children of all ethnic minority backgrounds are at greater risk for childhood-onset type 2 diabetes, particularly girls (Khanolkar et al., 2016). • People from Black African, African-Caribbean and South Asian backgrounds are at risk of developing type 2 diabetes from the age of 25 (Diabetes UK, 2023). • Diabetes is sometimes called 'high sugar', (e.g. some South Asians). Other terms may be used some ethnic groups. • Health literacy is low among some ethnic groups, which is a barrier to seeking healthcare support. Individuals from ethnic minority communities may present later than their white counterparts. Different beliefs about weight and obesity may mean support is sought differently by people from some ethnic groups because body size is not considered a health problem (NHS England, 2018). • Issues that impede ethnic minority groups from accessing effective diabetes care services: participants' strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy levels, different beliefs about health and illness, belief in expert and professional support, low accessibility of culturally-appropriate services/information, and low concordance with western professional advice (Zeh et al., 2014). • Language and literacy factors are known factors that impact on overall health literacy. Study participants have reported that both the spoken and written health information provided were sometimes meaningless, even when translated into their own language (Claydon et al., 2023). • Weight gain after bariatric surgery appears higher in some ethnic groups than others (e.g., Black individuals), which may affect willingness to take part (Medicine, 2018). • Requirements for pre-operative programs can disadvantage some across all ethnic groups because of e.g., weight loss requirements, mandatory appointments, and physical activity requirements (Taylor et al., 2019). • Ethnic minority patients report lower satisfaction and less positive experiences of care overall (Pinder et al., 2016). • Written consent may limit participation of some groups (e.g., South Asians) who may prefer verbal discussion to written documents (NIHR, 2023). • Getting to the hospital and the time needed to complete the measures may disadvantage people experiencing socioeconomic disadvantage. People from ethnic minority communities are at higher risk of socioeconomic disadvantage.

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| | <ul style="list-style-type: none">• Swimming and using the gym are two of the most popular activities for everyone in the UK including South Asians, but many South Asian women are unable to use their local leisure centre because of culturally inappropriate facilities (Jepson et al., 2012).• Response to written invitations via healthcare staff may be 5.2% lower in South Asians than in general populations, with community oriented, in-person approaches being more successful (Douglas et al., 2011).• South Asians may need to exercise for longer than Europeans to gain the same level of physical benefit (Celis-Morales et al., 2013). |
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Black/African/Caribbean/Black British

REPOSE (type 1 diabetes)	
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INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Stigma disproportionately affects individuals with higher BMI, A1C, and poorer blood glucose control. While not linked to specific ethnic groups, it's plausible that communities with historical mistrust of medical professionals may experience heightened stigma (Liu, et al., 2017). • Diabetes is often referred to as 'high sugar,' especially among South Asians, and various ethnic groups may use different terms for both type 2 and type 1 diabetes. • Generally, several ethnic minority groups have a deep mistrust of medical research. • Low health literacy in certain ethnic groups poses a barrier to seeking timely healthcare support, potentially resulting in later presentations, increased complications, and poorer health outcomes compared to white counterparts (NHS England, 2018). • Cultural barriers impede ethnic minority groups from accessing effective diabetes care services. Key issues include strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy, diverse beliefs about health, reliance on expert support, limited access to culturally-appropriate services, and low concordance with western professional advice (Zeh, Sandhu, Cannaby, & Sturt, 2014). • Face-to-face delivery poses challenges in transportation and time commitment, particularly affecting those with socioeconomic disadvantages. This may limit participation, especially for individuals from ethnic minority communities at a higher risk of socioeconomic disadvantage. • Translation of trial materials into languages other than English is crucial, especially for ethnic groups, like South Asians at higher risk of complications from type 1 diabetes, who are key participants in the trial. • Written consent may limit participation of some groups (e.g., South Asians) who may prefer verbal discussion to written documents (NIHR, 2018). • Ensuring comprehension of consent information poses a challenge, particularly regarding language proficiency and cultural awareness. Unless a research team member, typically white-British, receives training, understanding these aspects for ethnic groups other than white-British can be limited. • Ethnic minority patients express lower satisfaction and less positive care experiences compared to the white British group, even after statistical adjustment. They also report lower confidence in and understanding of healthcare professionals, including clinical nurse specialists, doctors, and ward nurses (Pinder, Ferguson, & Moller, 2016). • Paper diaries assume participants have time and energy, challenging those with full-time jobs, busy lives, and socioeconomic disadvantages, often intersecting with ethnic minority experiences.
Only reported in Black/African/Caribbean/	<ul style="list-style-type: none"> • African-Caribbean individuals with diabetes exhibit poorer outcomes, with higher prevalence of stroke and chronic kidney disease compared to the general UK population (Chaturvedi & Fuller, 1996). • Evidence indicates higher use of insulin pumps over daily injections among white individuals compared to Black individuals, possibly due to healthcare and insurance barriers, as observed in the US (Diabetes in Control, 2023).

Black British participants	
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CLARITY (diabetic retinopathy)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • The prevalence of diabetic retinopathy, sight-threatening diabetic retinopathy, and clinically significant macular edema are higher in people of South Asian, African, Latin American, and Indigenous tribal descent compared to the white population (Sivaprasad et al., 2012). • People from Black African, African-Caribbean and South Asian backgrounds are at risk of developing type 2 diabetes from the age of 25. This is much younger than the white population where risk increases from age 40 (Diabetes UK, 2023). • Diabetes is sometimes called 'high sugar', (e.g., some South Asians). Other terms may be used some ethnic groups. Diabetic retinopathy may be referred to by its symptoms, e.g., sight loss, blindness, or simply, eye disease. • Generally, several ethnic minority groups essential for the trial have a deep mistrust of medical research. The distrust in healthcare professionals and research may make people hesitant of research team accessing their medical records. • In general terms, health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support (NHS England, 2018). • Issues that impede ethnic minority groups from accessing effective diabetes care services: participants' strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy levels, different beliefs about health and illness, belief in expert and professional support, low accessibility of culturally-appropriate services/information, and low concordance with western professional advice (Zeh et al., 2014). • Ethnic minority patients report lower satisfaction and less positive experiences of care overall and ethnic minority patients remained less positive than those in the white British group, after statistical adjustment. Ethnic minority patients also reported lower confidence in, and less understanding of, healthcare professionals, including clinical nurse specialists, doctors, and ward nurses (Pinder et al., 2016). • If the trial has two groups, one of which requires more treatments than the other, increasing the time commitment for the trial, this could disproportionately impact people experiencing socioeconomic disadvantage (a significantly large portion of which are people from ethnic minorities). Socioeconomic disadvantage may also impact transport (getting to the hospital for trial). • As some ethnic groups including individuals for whom English may not be their first language are a key required group within the trial (e.g.

	South Asians, Indian subcontinent) then translation of written and oral material into some languages other than English is likely to be essential.
Only reported in Black/ African/ Caribbean/ Black British participants	<ul style="list-style-type: none"> • African-Caribbean people with diabetes have poorer outcomes than the general population. The prevalence of stroke and chronic kidney disease is higher in African-Caribbean people than in the general population of the UK (Chaturvedi & Fuller, 1996).

TriMaster (type 2 diabetes)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Children of all ethnic minority backgrounds are at greater risk for childhood-onset type 2 diabetes, particularly girls (Khanolkar et al., 2016). • People from Black African, African-Caribbean and South Asian backgrounds are at risk of developing type 2 diabetes from the age of 25 (Diabetes UK, 2023). • Generally, trials are known to lack diversity – much of this may be down to lack of trust in the medical and research systems due to historical abuse and exploitation of Black and minority ethnic populations. • Diabetes is sometimes called ‘high sugar’, (e.g. some South Asians). Other terms may be used some ethnic groups. • The drugs being tested in the trial may contain ingredients from animal origins – limiting participation of potential participants practicing Judaism, Islam or Hinduism. Sitagliptin, pioglitazone, and canagliflozin all contain magnesium stearate which is normally pork-derived but can also be found in butter, chicken, beef, fish and milk. Vegan and vegetarian-friendly sources are available, so it is important that the trial team consider this. The same is true for gelatin. • Issues that impede ethnic minority groups from accessing effective diabetes care services: participants’ strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy levels, different beliefs about health and illness, belief in expert and professional support, low accessibility of culturally-appropriate services/information, and low concordance with western professional advice (Zeh et al., 2014). • 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. • Black and minority ethnic populations are known to distrust the medical and research systems due to historical abuse and exploitation, so it may be that attending research visits at an NHS hospital site would limit participation. • Getting to hospital can be an issue for a variety of reasons including – poor transport links, the timing and length of research visits, financial reasons. Many of these factors disproportionately impact people from

	<p>poor socioeconomic backgrounds, which often includes ethnic minority groups.</p> <ul style="list-style-type: none"> • The trial team should bear in mind that religious celebrations such as Ramadan will take place during the period of the study. Ramadan is a community celebration for practising Muslims – over the month of Ramadan, individuals fast between dawn and sunset. Taking medicine orally is considered breaking the fast. Exceptions are made for people that cannot perform the fasting safely (including those with diabetes). Despite being exempt, many people with diabetes do choose to fast (Grindrod & Alsabbagh, 2017; International Diabetes Federation, 2019).
Only reported in Black/ African/ Caribbean/ Black British participants	<ul style="list-style-type: none"> • People of African and African-Caribbean descent are known to have an increased risk of type 2 diabetes. There is also evidence that African-Caribbean people with diabetes have poorer outcomes than the general population (Khunti et al., 2016).

LONG LIMB (type 2 diabetes and obesity)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • There is some evidence that BMI cut-offs for categories of obesity should vary by ethnic group based on risk to future health. Generally, this evidence finds that the BMI cut-off considered to represent obesity are lower for non-white groups than the 30 used for white individuals (The National Institute for Health and Care Excellence, 2013). • Children of all ethnic minority backgrounds are at greater risk for childhood-onset type 2 diabetes, particularly girls (Khanolkar et al., 2016). • People from Black African, African-Caribbean and South Asian backgrounds are at risk of developing type 2 diabetes from the age of 25 (Diabetes UK, 2023). • Diabetes is sometimes called 'high sugar', (e.g. some South Asians). Other terms may be used some ethnic groups. • Health literacy is low among some ethnic groups, which is a barrier to seeking healthcare support. Individuals from ethnic minority communities may present later than their white counterparts. Different beliefs about weight and obesity may mean support is sought differently by people from some ethnic groups because body size is not considered a health problem (NHS England, 2018). • Issues that impede ethnic minority groups from accessing effective diabetes care services: participants' strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy levels, different beliefs about health and illness, belief in expert and professional support, low accessibility of culturally-appropriate services/information, and low concordance with western professional advice (Zeh et al., 2014).

	<ul style="list-style-type: none"> • Language and literacy factors are known factors that impact on overall health literacy. Study participants have reported that both the spoken and written health information provided were sometimes meaningless, even when translated into their own language (Claydon et al., 2023). • Weight gain after bariatric surgery appears higher in some ethnic groups than others (e.g., Black individuals), which may affect willingness to take part (Medicine, 2018). • Requirements for pre-operative programs can disadvantage some across all ethnic groups because of e.g., weight loss requirements, mandatory appointments, and physical activity requirements (Taylor et al., 2019). • Ethnic minority patients report lower satisfaction and less positive experiences of care overall (Pinder et al., 2016). • Written consent may limit participation of some groups (e.g., South Asians) who may prefer verbal discussion to written documents (NIHR, 2023). • Getting to the hospital and the time needed to complete the measures may disadvantage people experiencing socioeconomic disadvantage. People from ethnic minority communities are at higher risk of socioeconomic disadvantage.
Only reported in Black/ African/ Caribbean/ Black British participants	<ul style="list-style-type: none"> • People of African and African-Caribbean descent are known to have an increased risk of type 2 diabetes. There is also evidence that African-Caribbean people with diabetes have poorer outcomes than the general population (Khunti et al., 2016). • Black women have less concern about being overweight than white women but they recognise the health risk being overweight poses (Shoneye et al., 2011). • Obesity does not reduce quality of life as much in African Americans than white individuals, meaning they are less likely to take up an offer of bariatric surgery (Newswise, 2014).

PROPELS (type 2 diabetes)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Children of all ethnic minority backgrounds are at greater risk for childhood-onset type 2 diabetes, particularly girls (Khanolkar et al., 2016). • Diabetes is sometimes called 'high sugar', (e.g., some South Asians). Other terms may be used some ethnic groups. IGR is often referred to as 'pre-diabetes'. • Health literacy is low among some ethnic groups, which is a barrier to seeking healthcare support. Individuals from ethnic minority communities may present later than their white counterparts (NHS England, 2018). • Issues that impede ethnic minority groups from accessing effective diabetes care services: participants' strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy levels, different beliefs about health and illness, belief in expert and professional

	<p>support, low accessibility of culturally-appropriate services/information, and low concordance with western professional advice (Zeh et al., 2014).</p> <ul style="list-style-type: none"> • Language and literacy factors are known factors that impact on overall health literacy. Study participants have reported that both the spoken and written health information provided were sometimes meaningless, even when translated into their own language (Claydon et al., 2023). • With face-to-face delivery the main issue is likely to be getting to the sites and the time needed to complete the measures. These issues may disadvantage people experiencing socioeconomic disadvantage. People from ethnic minority communities are at higher risk of socioeconomic disadvantage. • Ethnic minority individuals are more likely to experience socioeconomic disadvantage; letters from healthcare professionals can often look 'official' – usually in a brown envelope, and may give the impression that they are a bill or other negative form of post, reducing the chance of the letter ever being opened and/or the amount of trust in the letter writer even before the letter is read. • Translation of written and oral material into some languages other than English is likely to be essential. • Written consent may limit participation of some groups (e.g., South Asians) who may prefer verbal discussion to written documents (NIHR, 2018). • Ethnic minority patients report lower satisfaction and less positive experiences of care overall (Pinder et al., 2016).
Only reported in Black/ African/ Caribbean/ Black British participants	<ul style="list-style-type: none"> • People of African and African-Caribbean descent are known to have an increased risk of type 2 diabetes. There is also evidence that African-Caribbean people with diabetes have poorer outcomes than the general population (Khunti et al., 2016). Cultural and social norms strongly influence health-seeking behaviours – research has shown that health promotion activities tend to be based on assumptions of individualism and self-investment, which may need to be re-thought for South Asian groups in particular (Lucas et al., 2013).

Other ethnic groups

REPOSE (type 1 diabetes)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Stigma disproportionately affects individuals with higher BMI, A1C, and poorer blood glucose control. While not linked to specific ethnic groups, it's plausible that communities with historical mistrust of medical professionals may experience heightened stigma (Liu, et al., 2017). • Diabetes is often referred to as 'high sugar,' especially among South Asians, and various ethnic groups may use different terms for both type 2 and type 1 diabetes. • Generally, several ethnic minority groups have a deep mistrust of medical research. • Low health literacy in certain ethnic groups poses a barrier to seeking timely healthcare support, potentially resulting in later presentations, increased complications, and poorer health outcomes compared to white counterparts (NHS England, 2018). • Cultural barriers impede ethnic minority groups from accessing effective diabetes care services. Key issues include strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy, diverse beliefs about health, reliance on expert support, limited access to culturally-appropriate services, and low concordance with western professional advice (Zeh, Sandhu, Cannaby, & Sturt, 2014). • Face-to-face delivery poses challenges in transportation and time commitment, particularly affecting those with socioeconomic disadvantages. This may limit participation, especially for individuals from ethnic minority communities at a higher risk of socioeconomic disadvantage. • Translation of trial materials into languages other than English is crucial, especially for ethnic groups, like South Asians at higher risk of complications from type 1 diabetes, who are key participants in the trial. • Written consent may limit participation of some groups (e.g., South Asians) who may prefer verbal discussion to written documents (NIHR, 2018). • Ensuring comprehension of consent information poses a challenge, particularly regarding language proficiency and cultural awareness. Unless a research team member, typically white-British, receives training, understanding these aspects for ethnic groups other than white-British can be limited. • Ethnic minority patients express lower satisfaction and less positive care experiences compared to the white British group, even after statistical adjustment. They also report lower confidence in and understanding of healthcare professionals, including clinical nurse specialists, doctors, and ward nurses (Pinder, Ferguson, & Moller, 2016). • Paper diaries assume participants have time and energy, challenging those with full-time jobs, busy lives, and socioeconomic disadvantages, often intersecting with ethnic minority experiences.

CLARITY (diabetic retinopathy)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • The prevalence of diabetic retinopathy, sight-threatening diabetic retinopathy, and clinically significant macular edema are higher in people of South Asian, African, Latin American, and Indigenous tribal descent compared to the white population (Sivaprasad et al., 2012). • People from Black African, African-Caribbean and South Asian backgrounds are at risk of developing type 2 diabetes from the age of 25. This is much younger than the white population where risk increases from age 40 (Diabetes UK, 2023). • Diabetes is sometimes called 'high sugar', (e.g., some South Asians). Other terms may be used some ethnic groups. Diabetic retinopathy may be referred to by its symptoms, e.g., sight loss, blindness, or simply, eye disease. • Generally, several ethnic minority groups essential for the trial have a deep mistrust of medical research. The distrust in healthcare professionals and research may make people hesitant of research team accessing their medical records. • In general terms, health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support (NHS England, 2018). • Issues that impede ethnic minority groups from accessing effective diabetes care services: participants' strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy levels, different beliefs about health and illness, belief in expert and professional support, low accessibility of culturally-appropriate services/information, and low concordance with western professional advice (Zeh et al., 2014). • Ethnic minority patients report lower satisfaction and less positive experiences of care overall and ethnic minority patients remained less positive than those in the white British group, after statistical adjustment. Ethnic minority patients also reported lower confidence in, and less understanding of, healthcare professionals, including clinical nurse specialists, doctors, and ward nurses (Pinder et al., 2016). • If the trial has two groups, one of which requires more treatments than the other, increasing the time commitment for the trial, this could disproportionately impact people experiencing socioeconomic disadvantage (a significantly large portion of which are people from ethnic minorities). Socioeconomic disadvantage may also impact transport (getting to the hospital for trial). • As some ethnic groups including individuals for whom English may not be their first language are a key required group within the trial (e.g. South Asians, Indian subcontinent) then translation of written and oral material into some languages other than English is likely to be essential.

TriMaster (type 2 diabetes)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Children of all ethnic minority backgrounds are at greater risk for childhood-onset type 2 diabetes, particularly girls (Khanolkar et al., 2016). • People from Black African, African-Caribbean and South Asian backgrounds are at risk of developing type 2 diabetes from the age of 25 (Diabetes UK, 2023). • Generally, trials are known to lack diversity – much of this may be down to lack of trust in the medical and research systems due to historical abuse and exploitation of Black and minority ethnic populations. • Diabetes is sometimes called ‘high sugar’, (e.g. some South Asians). Other terms may be used some ethnic groups. • The drugs being tested in the trial may contain ingredients from animal origins – limiting participation of potential participants practicing Judaism, Islam or Hinduism. Sitagliptin, pioglitazone, and canagliflozin all contain magnesium stearate which is normally pork-derived but can also be found in butter, chicken, beef, fish and milk. Vegan and vegetarian-friendly sources are available, so it is important that the trial team consider this. The same is true for gelatin. • Issues that impede ethnic minority groups from accessing effective diabetes care services: participants’ strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy levels, different beliefs about health and illness, belief in expert and professional support, low accessibility of culturally-appropriate services/information, and low concordance with western professional advice (Zeh et al., 2014). • 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. • Black and minority ethnic populations are known to distrust the medical and research systems due to historical abuse and exploitation, so it may be that attending research visits at an NHS hospital site would limit participation. • Getting to hospital can be an issue for a variety of reasons including – poor transport links, the timing and length of research visits, financial reasons. Many of these factors disproportionately impact people from poor socioeconomic backgrounds, which often includes ethnic minority groups. • The trial team should bear in mind that religious celebrations such as Ramadan will take place during the period of the study. Ramadan is a community celebration for practising Muslims – over the month of Ramadan, individuals fast between dawn and sunset. Taking medicine orally is considered breaking the fast. Exceptions are made for people that cannot perform the fasting safely (including those with diabetes). Despite being exempt, many people with diabetes do choose to fast (Grindrod & Alsabbagh, 2017; International Diabetes Federation, 2019).

LONG LIMB (type 2 diabetes and obesity)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • There is some evidence that BMI cut-offs for categories of obesity should vary by ethnic group based on risk to future health. Generally, this evidence finds that the BMI cut-off considered to represent obesity are lower for non-white groups than the 30 used for white individuals (The National Institute for Health and Care Excellence, 2013). • Children of all ethnic minority backgrounds are at greater risk for childhood-onset type 2 diabetes, particularly girls (Khanolkar et al., 2016). • People from Black African, African-Caribbean and South Asian backgrounds are at risk of developing type 2 diabetes from the age of 25 (Diabetes UK, 2023). • Diabetes is sometimes called 'high sugar', (e.g. some South Asians). Other terms may be used some ethnic groups. • Health literacy is low among some ethnic groups, which is a barrier to seeking healthcare support. Individuals from ethnic minority communities may present later than their white counterparts. Different beliefs about weight and obesity may mean support is sought differently by people from some ethnic groups because body size is not considered a health problem (NHS England, 2018). • Issues that impede ethnic minority groups from accessing effective diabetes care services: participants' strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy levels, different beliefs about health and illness, belief in expert and professional support, low accessibility of culturally-appropriate services/information, and low concordance with western professional advice (Zeh et al., 2014). • Language and literacy factors are known factors that impact on overall health literacy. Study participants have reported that both the spoken and written health information provided were sometimes meaningless, even when translated into their own language (Claydon et al., 2023). • Weight gain after bariatric surgery appears higher in some ethnic groups than others (e.g., Black individuals), which may affect willingness to take part (Medicine, 2018). • Requirements for pre-operative programs can disadvantage some across all ethnic groups because of e.g., weight loss requirements, mandatory appointments, and physical activity requirements (Taylor et al., 2019). • Ethnic minority patients report lower satisfaction and less positive experiences of care overall (Pinder et al., 2016). • Written consent may limit participation of some groups (e.g., South Asians) who may prefer verbal discussion to written documents (NIHR, 2023). • Getting to the hospital and the time needed to complete the measures may disadvantage people experiencing socioeconomic disadvantage. People from ethnic minority communities are at higher risk of socioeconomic disadvantage.

PROPELS (type 2 diabetes)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • Children of all ethnic minority backgrounds are at greater risk for childhood-onset type 2 diabetes, particularly girls (Khanolkar et al., 2016). • Diabetes is sometimes called 'high sugar', (e.g., some South Asians). Other terms may be used some ethnic groups. IGR is often referred to as 'pre-diabetes'. • Health literacy is low among some ethnic groups, which is a barrier to seeking healthcare support. Individuals from ethnic minority communities may present later than their white counterparts (NHS England, 2018). • Issues that impede ethnic minority groups from accessing effective diabetes care services: participants' strong adherence to cultural norms, religious beliefs, linguistic diversity, low health literacy levels, different beliefs about health and illness, belief in expert and professional support, low accessibility of culturally-appropriate services/information, and low concordance with western professional advice (Zeh et al., 2014). • Language and literacy factors are known factors that impact on overall health literacy. Study participants have reported that both the spoken and written health information provided were sometimes meaningless, even when translated into their own language (Claydon et al., 2023). • With face-to-face delivery the main issue is likely to be getting to the sites and the time needed to complete the measures. These issues may disadvantage people experiencing socioeconomic disadvantage. People from ethnic minority communities are at higher risk of socioeconomic disadvantage. • Ethnic minority individuals are more likely to experience socioeconomic disadvantage; letters from healthcare professionals can often look 'official' – usually in a brown envelope, and may give the impression that they are a bill or other negative form of post, reducing the chance of the letter ever being opened and/or the amount of trust in the letter writer even before the letter is read. • Translation of written and oral material into some languages other than English is likely to be essential. • Written consent may limit participation of some groups (e.g., South Asians) who may prefer verbal discussion to written documents (NIHR, 2018). • Ethnic minority patients report lower satisfaction and less positive experiences of care overall (Pinder et al., 2016).

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