



Racial and Ethnic Representation in Rehabilitation Trials in the UK



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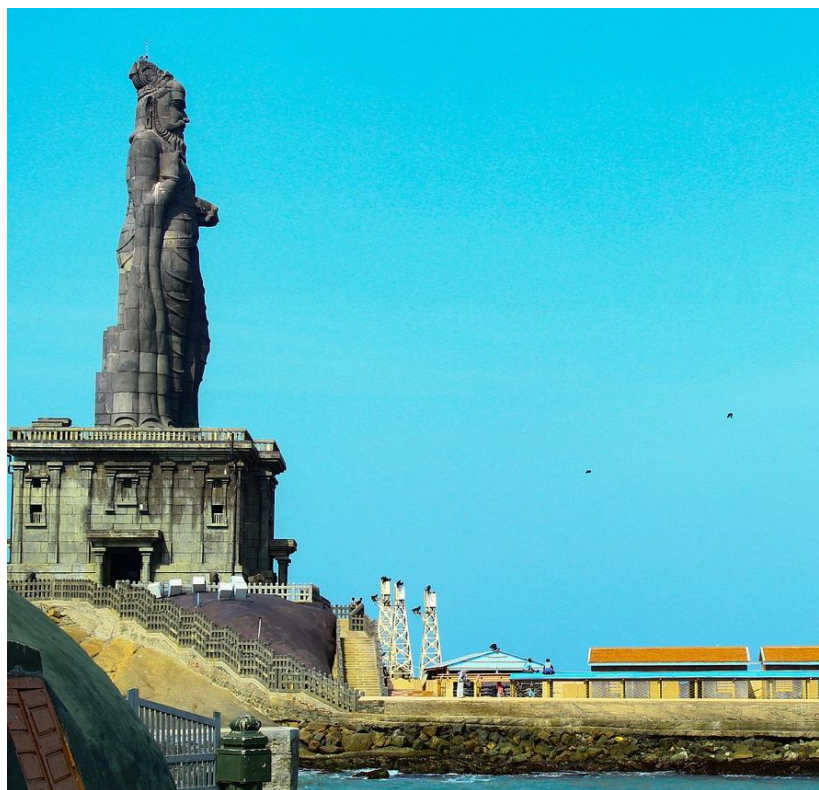
My cultural heritage gives me the strength to face the challenges that I have encountered.

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#SouthAsianHeritageMonth #SAHM2024

I am South Asian and ethnically
Tamil Indian





Outline

Race and Ethnicity

Current
demographics in
the UK

Brief review of
racial/ethnic
representation in
rehabilitation trials

Barriers to
inclusion

Enablers to
inclusion

Strategies to
improve reporting

Take aways

Q & A

Race and Ethnicity



Race – perceived biological/physical characteristics – hair, skin colour, facial features – people with similarities – broad; Examples - Black, White, Asian, Hispanic



Ethnicity – shared cultural characteristics – religion, language, traditions, cultural norms etc. – specific; Examples - Italian, Irish, Chinese, Indian



Overlap – some may identify as White-Irish, Black-Jamaican, Asian-Indian

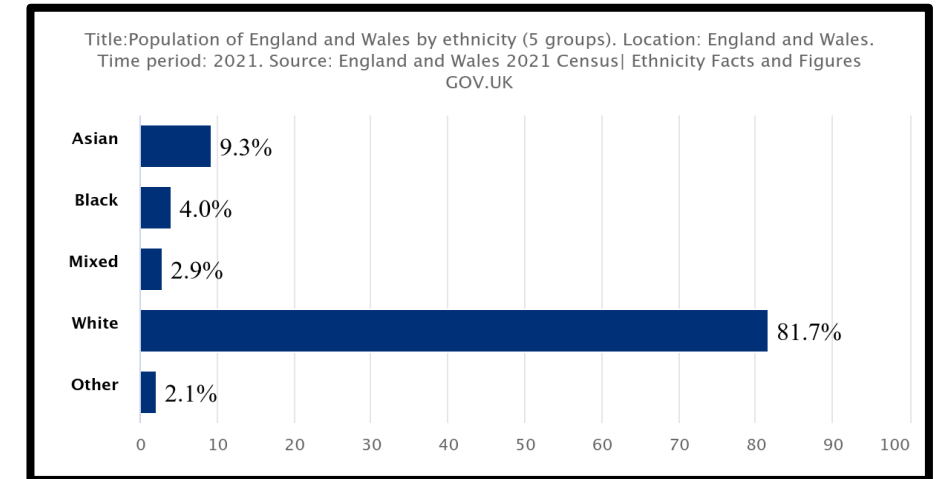
Ethnicity in the UK

‘Ethnicity’ is used rather than race for consistency

Ethnic minorities – all groups except the White British

Ethnicity in the UK

- The UK is ethnically diverse
- Increase in ethnic minority populations over time
- Ethnic minorities - more ill health, poorer health outcomes, negative healthcare experiences, underutilise services
- Examples:
 - Diabetes, asthma, and depression in South Asians
 - Heart diseases, psychotic disorders in Black communities



5. By ethnicity over time (5 groups)

Location: England and Wales
Time period: 2001 to 2021
Source: [England and Wales 2021 Census](#)

Population of England and Wales by ethnicity over time (5 groups)

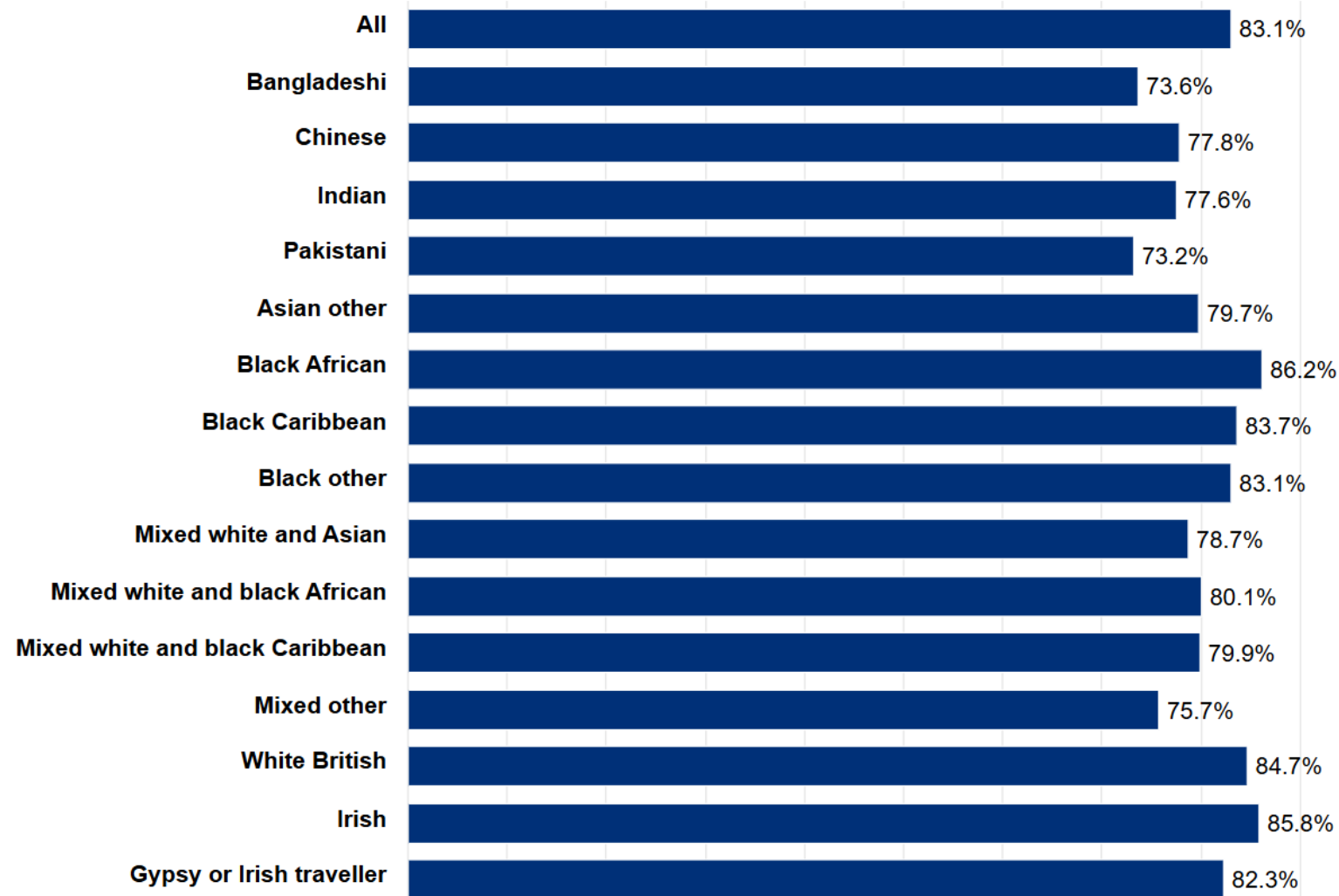
Ethnicity	% 2021	% 2011	% 2001
Asian	9.3	7.5	4.4
Black	4.0	3.3	2.2
Mixed	2.9	2.2	1.3
White	81.7	86.0	91.3
Other	2.1	1.0	0.9

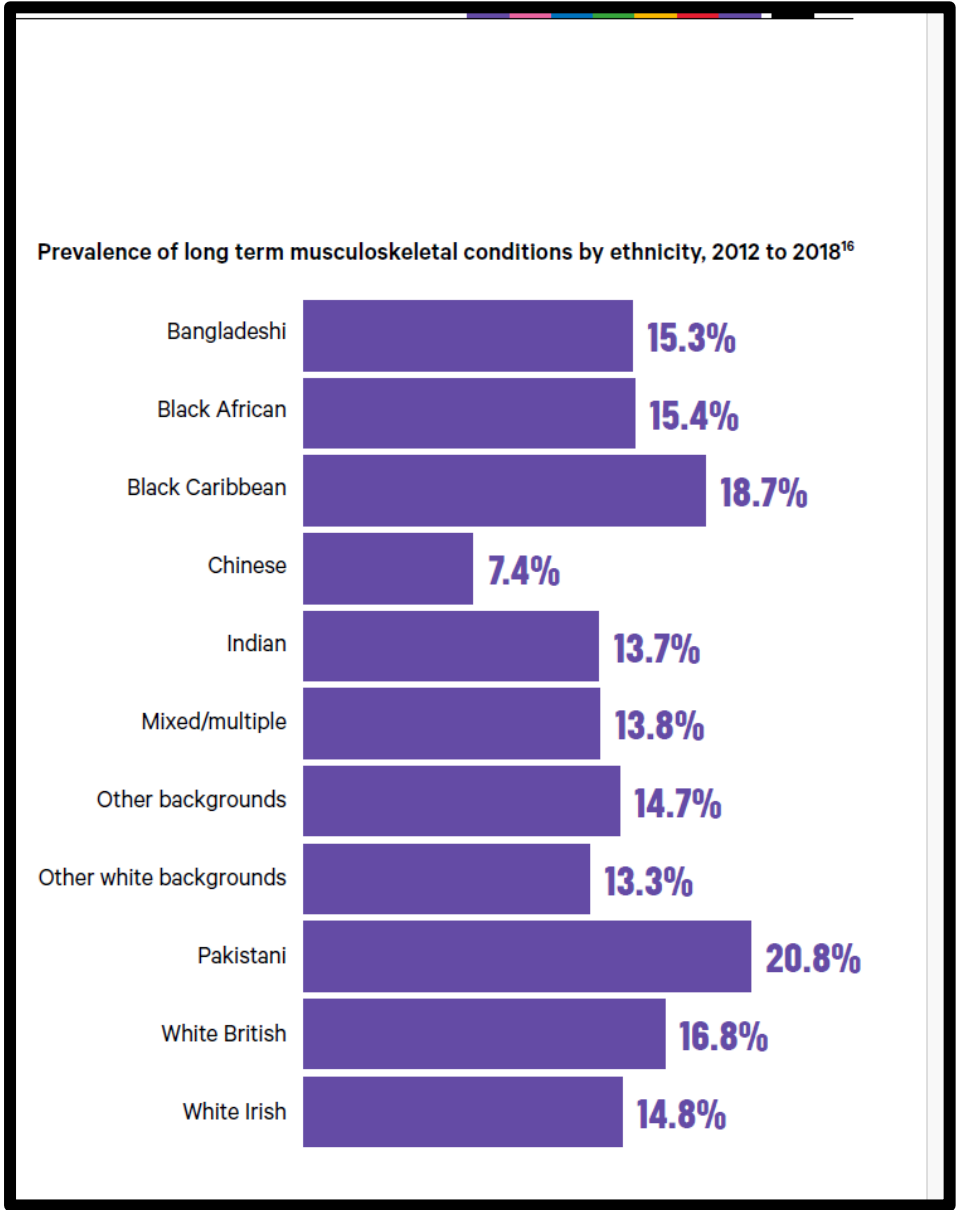
<https://www.ethnicity-facts-figures.service.gov.uk/>

Areas of England and Wales by ethnicity

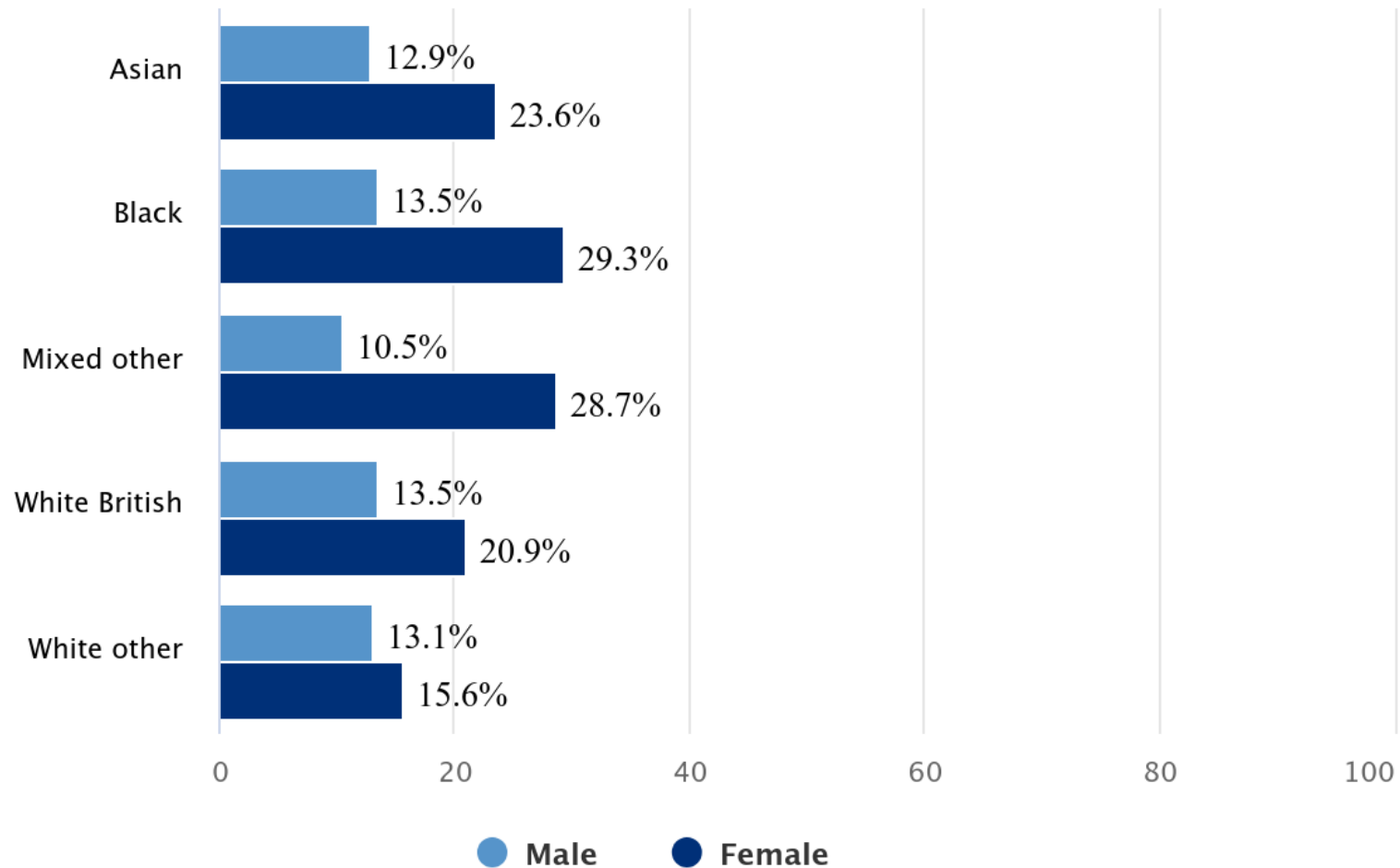
Geography ⬆	Asian ⬆	Black ⬆	Mixed ⬆	White British ⬆	White other ⬆	Other ⬆
	%	%	%	%	%	%
East Midlands	8.0	2.7	2.4	79.6	6.1	1.3
East of England	6.4	2.9	2.8	78.5	8.0	1.4
London	20.7	13.5	5.7	36.8	17.0	6.3
North East	3.7	1.0	1.3	90.6	2.5	1.0
North West	8.4	2.3	2.2	81.2	4.4	1.5
South East	7.0	2.4	2.8	78.8	7.5	1.5
South West	2.8	1.2	2.0	87.8	5.3	0.9
Wales	2.9	0.9	1.6	90.6	3.3	0.9
West Midlands	13.3	4.5	3.0	71.8	5.2	2.1
Yorkshire and The Humber	8.9	2.1	2.1	80.9	4.5	1.4

Percentage of patients reporting a positive experience of GP services, by ethnicity

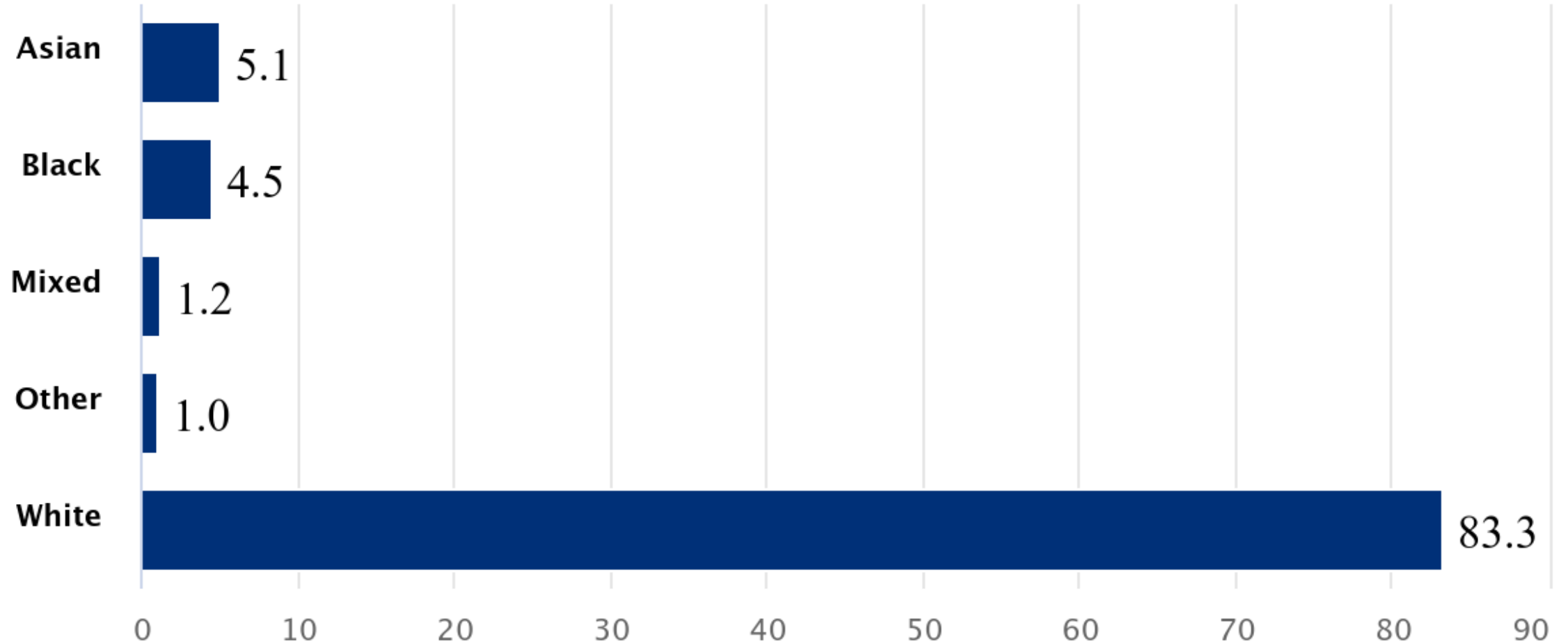




Title: Percentage of adults who experienced a common mental disorder in the past week by sex and ethnicity. Location: England. Time period: 2014. Source: Adult Psychiatric Morbidity Survey: Survey of Mental Health and Wellbeing, England, 2014| Ethnicity Facts and Figures GOV.UK



Title: Percentage of adults receiving long-term support, by ethnicity . Location: England.
Time period: 31 March 2016 to 31 March 2021. Source: Short and Long Term (SALT) data collection| Ethnicity Facts and Figures GOV.UK



Why representation in clinical research matters?

Lack of representation:

Compromises generalisability of research findings

Leads to health disparities at a wider population level

May hinder innovation

Leads to distrust in the research system

Rehabilitation clinical trials in global registries

Registry	Total clinical trials	Total rehabilitation clinical trials	Included rehabilitation clinical trials*
European Union Clinical Trials Register	41,189	49	27
Australian New Zealand Clinical Trials Registry	30,831	612	31
International Standard Randomised Controlled Trial Number Registry	21,385	1080	16
German Clinical Trials Register	13,005	248	1
Clinical Research Information Service of Republic of Korea	6767	10	5
Thai Clinical Trials Registry	5417	1	1
Japan Primary Registries Network	3734	24	5
Pan African Clinical Trial Registry	3057	34	7
Total Number	125,385	2058	93

*Not all rehabilitation clinical trials were included due to the inclusion criteria (see Materials and Methods).



Registry (n)*	Number of trials reporting sex	Number of trials reporting age	Number of trials reporting ethnicity or race
Australian New Zealand clinical trials registry (n=31)	9 (29.0%)	18 (58.1%)	1 (3.2%)
European union clinical trials register (n=27)	22 (81.5%)	22 (81.5%)	8 (29.6%)
International standard randomised controlled trial number registry (n=16)	15 (93.8%)	16 (100%)	1 (6.3%)
Pan African clinical trial registry (n=7)	1 (14.3%)	2 (28.6%)	0 (0%)
Clinical research information service of Republic of Korea (n=5)	4 (80%)	4 (80%)	0 (0%)
Japan primary registries network (n=5)	5 (100%)	5 (100%)	0 (0%)
German clinical trials register (n=1)	0 (0%)	0 (0%)	0 (0%)
Thai clinical trials registry (n=1)	1 (100%)	1 (100%)	0 (0%)
Total (n=93)	57 (61.3%)	68 (73.1%)	10 (10.8%)

*n = number of included rehabilitation trials.

- Clinical trial registries with a results section or link to study results
- 10 registries
- Rehabilitation trials represented 1.7% of all trials in included registries
- Trials mostly in MSK and Stroke
- Only 2 registries [EU CTR, ISRCTN] had ethnic/race sections -90% trials didn't use them
- 10/93 trials reported race or ethnicity

Rehabilitation clinical trials in multiple long-term conditions

- 2024 Systematic review
- Studies between 1990-2023, Europe and North America
- Hospital and community-based interventions in people with MLTC
- Cochrane Library, MEDLINE, CINAHL and Scopus
- 13 trials; 4 from UK
- 4/13 trials (2 from UK) reported race or ethnicity
- Three were predominantly White participants; in another, Black were overrepresented
- Most studies needed knowledge of English
- No translators/adaptable interventions
- Lack of reporting on ethnicity
- Underrepresentation of ethnic minority groups in MLTCs intervention studies



Stroke motor recovery trials

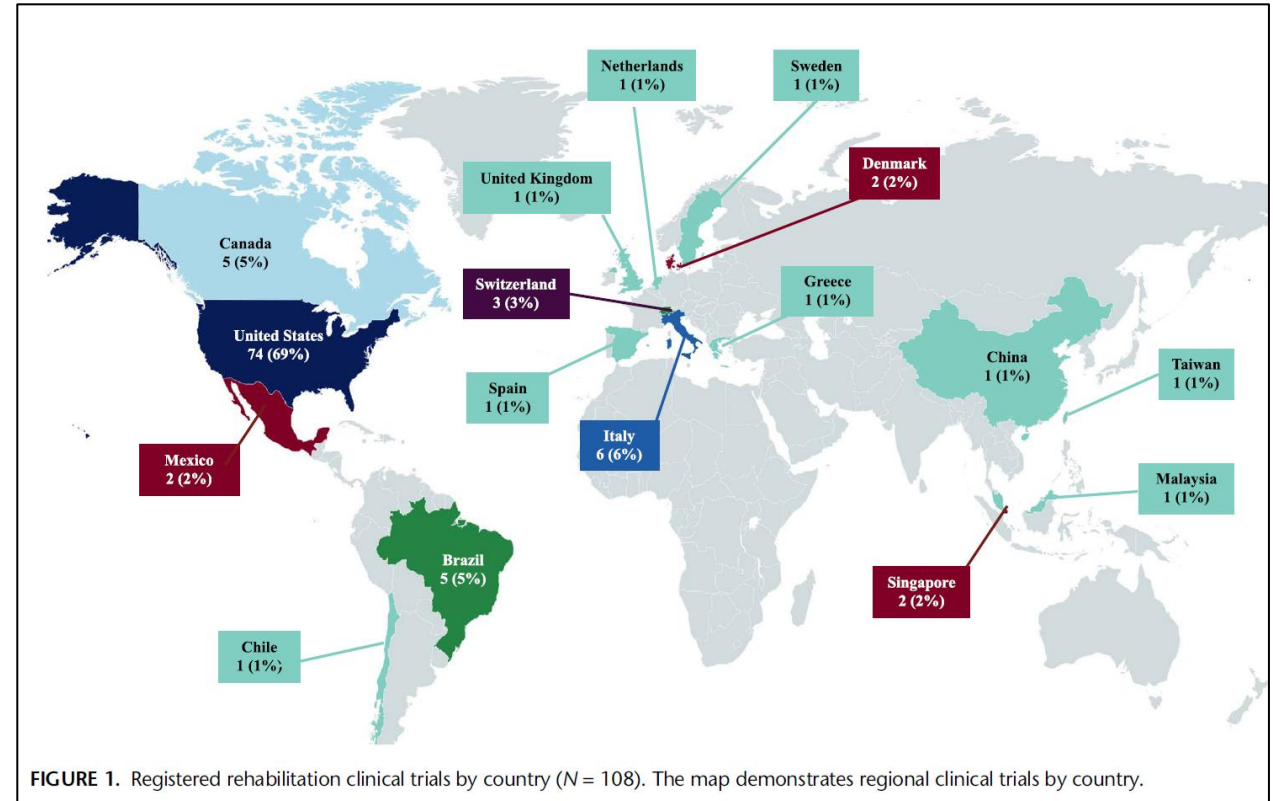
- 2025 Systematic review
- Studies between 2019-2023, only US based studies
- 68 trials (2,801 people with Stroke)
- 1073 participants were female (38%)
- 43/68 (63%) did not report any racial demographics
- 54/68 (79%) did not report ethnicity
- In 29 trials reporting race*:
 - 59% participants were White
 - 34% Black
 - 0.4% Native American
 - 4% Asian
 - 3% Other
- In 16 studies that reported ethnicity*, Hispanic participants represented 13% of the total



*From publications or trial registries

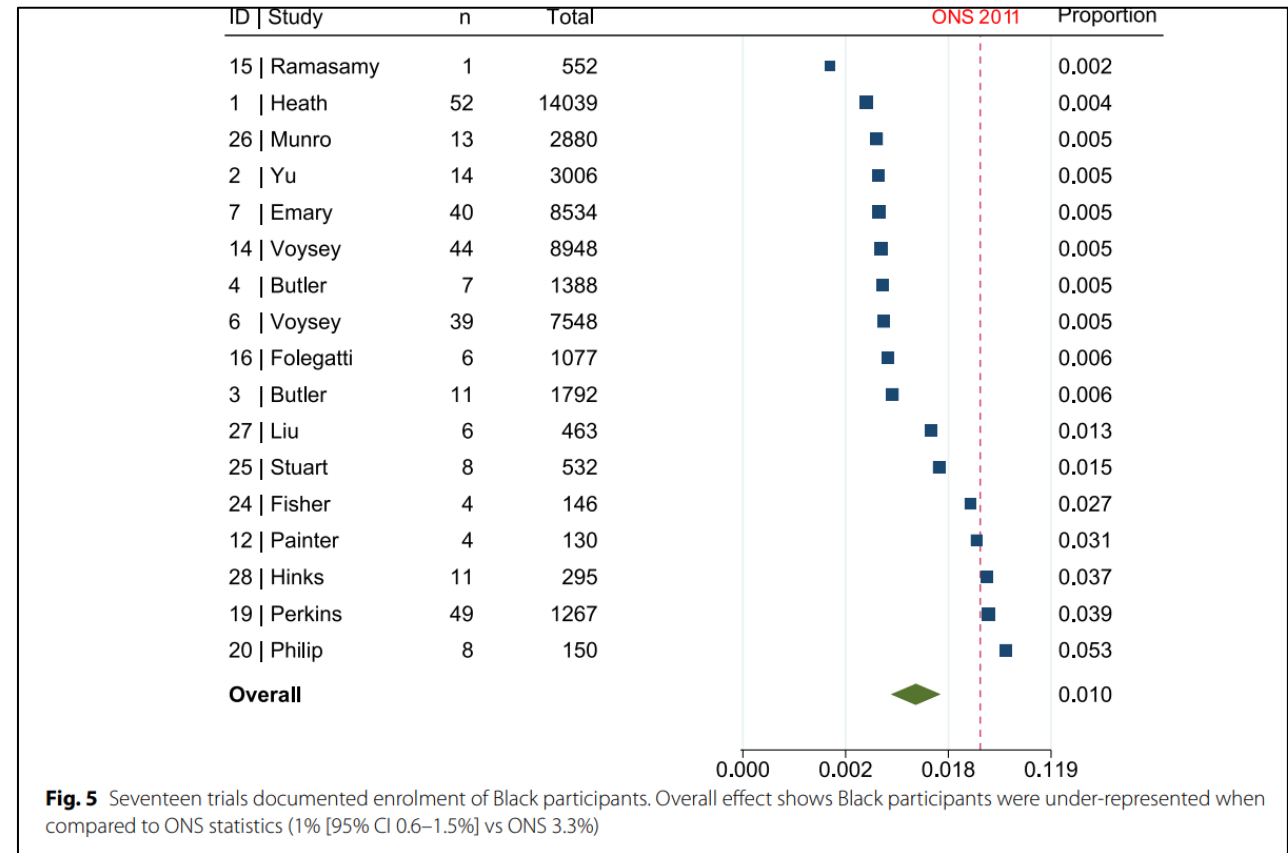
Analysis of rehabilitation clinical trials in clincialtrials.gov

- Rehabilitation trials registered within ClinicalTrials.gov –completed/results
- Rehabilitation interventions in adults; Studies between 2011-2020
- Stroke followed by MSK studies
- Interventions – Technology, PA, Exercise
- Only 40.1% (44) and 26.9% (29) of US-based trials reported race and ethnicity
- 70% were White, 20% Black, 1% Asian
- 23 trials included a small number of Hispanic or Latino participants



COVID trials in the UK

- 2023 Systematic review
- UK-based COVID vaccine or therapeutic treatment trials
- Studies between 2020-2022
- 30 trials with 118,912 participants
- 17 trials reported the number of people enrolled by individual ethnicity
- Three studies recruited from minority communities
- Asian, Black and Mixed ethnic groups under-represented



UK-based rehabilitation trials

Trial	Interventions	Total	White	Ethnicity
EXERT 2007	GP referral for leisure centre-based exercise, community-based walking and advice only in 40–74-year-old adults	943	717 (76%)	135 Asian (14%)
OTCH 2015	Occupational therapy intervention for residents with stroke related disabilities in UK care homes	1042	Not reported	Not reported
CORKA 2020	Outpatient physiotherapy versus home-based rehabilitation for patients after knee arthroplasty	621	Not reported	Not reported
OTTER 2021	Splints for thumb base osteoarthritis	349	338 (97%)	Not reported
GRASP 2021	Progressive exercise programme with a best practice physiotherapy advice, with or without corticosteroid injection, in adults with a rotator cuff disorder	708	648 (91.5%)	58 other
BOOST 2022	Physiotherapy Delivered Physical and Psychological Group Intervention for Older Adults With Neurogenic Claudication	435	400 (92%)	35 Not reported
RETAKE 2024	Early vocational rehabilitation versus usual care to support return to work after Stroke	583	453 (84%)	Black 42 (7.8%) Asian 25 (4.6%) Mixed 4 (0.7%) Other 17 (3.1%)

Barriers to inclusion

Cultural beliefs and attitudes –population specific – stigma, old age, risk-taking, guinea-pig perception, religious reasons, privacy issues, social approval

Access to trials – lack of knowledge/info about trials, no invitation, lack of recruitment staff, lack of outreach activities

Practical issues – transport, costs, time, childcare, work

Lack of trust with the research process

Language

Lack of communication strategies – health literacy, appropriate communication methods

Bodicoat DH, Routen AC, Willis A, Ekezie W, Gillies C, Lawson C, Yates T, Zaccardi F, Davies MJ, Khunti K. Promoting inclusion in clinical trials—a rapid review of the literature and recommendations for action. *Trials*. 2021 Dec;22:1-1.

2013 NIHR mental health portfolio survey - 64% of RCTs excluded people unable to communicate in English

Enablers to inclusion/Recruitment strategies

- No conclusive evidence on the effects of recruitment strategies
- What is required?
 - Personalisation
 - Culturally sensitive ways of recruitment, consent and trial procedures – consider religious beliefs, social norms and language requirements
- Multi-strategy approach at study team and community levels

Biggs K, Dix C, Shiely F et al. Effective interventions to increase representation of under-served groups in randomised trials in UK and Ireland: a scoping literature review [version 1; peer review: 3 approved]. NIHR Open Res 2024, 4:12 (<https://doi.org/10.3310/nihropenres.13524.1>)

Masood Y, Bower P, Waheed MW, Brown G, Waheed W. Synthesis of researcher reported strategies to recruit adults of ethnic minorities to clinical trials in the United Kingdom: A systematic review. Contemporary Clinical Trials. 2019 Mar 1;78:1-0.

Bodicoat DH, Routen AC, Willis A, Ekezie W, Gillies C, Lawson C, Yates T, Zaccardi F, Davies MJ, Khunti K. Promoting inclusion in clinical trials—a rapid review of the literature and recommendations for action. Trials. 2021 Dec;22:1-1.

Enablers to inclusion/Recruitment strategies

Trust building – educational sessions for communities, testimonials (social proof), referrals from close circle

Research team - Cultural competency training, representative staff –ethnic matching, gender matching

Community partnerships – advisory board, outreach, sustainability, religious leaders, organisations, day centres

Language - Bilingual staff, materials in languages, accessible formats, interviews in different languages

Communication – reminder calls, FB, out of hours contact, cancellations FU, send updates

Solutions for practical issues – flexible timings, home-based assessments, incentives

Other – e-tracking participants, partnering with local health practices, simple eligibility criteria, English not to be a criterion, simple tool to test proficiency, branded items for studies, create local registry

Strategies to improve reporting

CONSORT-Equity extension –
recruitment, analysis (for
reporting of characteristics
such as socioeconomic status,
race, ethnicity)

PROGRESS-Plus framework

Role of sponsors, journals in
quality of reporting

Develop hypotheses, analyses
to include ethnicity data

Recruitment by ethnicity –
include in quality assessment

PROGRESS-PLUS Framework

- Place of residence (rural/urban)
- Race/Ethnicity/Culture/Language
- Occupation
- Gender/Sex
- Religion
- Education
- Socioeconomic status
- Social capital (social networks, relationships)
- PLUS – personal characteristics (Age, Disability); features of relationships (excluded from school); time-dependent relationships (leaving the hospital, any instances of temporary vulnerability)

O'Neill J, Tabish H, Welch V, Petticrew M, Pottie K, Clarke M, et al. Applying an equity lens to interventions: using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. *Journal of Clinical Epidemiology*. 2014;67(1):56–64. doi:10.1016/j.jclinepi.2013.08.005

<https://methods.cochrane.org/equity/projects/evidence-equity/progress-plus>

CONSORT-Equity extension checklist

- The CONSORT-Equity 2017 extension focuses on improving the reporting of equity considerations in RCTs with emphasis on characteristics, context, and interventions that may affect disadvantaged populations
- Goal is to improve the applicability of trial findings to diverse populations and to inform decision-making that promotes health equity

NIHR resources for inclusive research

As of November 27, 2024, all NIHR funding applications must demonstrate how the proposed research addresses existing inequalities in health and social care

- Research Inclusion Strategy 2022-2027
<https://www.nihr.ac.uk/about-us/who-we-are/research-inclusion/strategy-2022-27>
- Inclusive Research Funding Application Guidance
<https://www.nihr.ac.uk/about-us/who-we-are/research-inclusion/funding-application-guidance>
- NIHR INCLUDE frameworks <https://www.nihr.ac.uk/about-us/our-key-priorities/under-served-communities.htm>
- EDI Toolkit <https://arc-eoe.nihr.ac.uk/public-involvement-research-inclusion/research-inclusion>
- NIHR Reaching Out: A Practical Guide <https://arc-nenc.nihr.ac.uk/resources/nihr-reaching-out-a-practical-guide-to-being-inclusive-in-public-involvement-in-health-research/>
- Research Inclusion Reporting Guidance <https://oxfordbrc.nihr.ac.uk/diversity-and-inclusion/>
- Inclusive research training –Open access course <https://oxfordbrc.nihr.ac.uk/diversity-and-inclusion/>



Take aways

- Lack of reviews on ethnicity representation in UK-based rehabilitation trials
- Current evidence:
 - Underreporting of ethnicity data
 - Underrepresentation of ethnic diversity
- Plenty of NIHR resources
- PROGRESS-PLUS and CONSORT-Equity guidance for reporting recruitment, retention of participants from ethnic groups and analysis of ethnicity data

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