

Who Gets Included? Equity in Digital and Decentralised Mental Health and Neurodevelopmental Trials: A Systematic Review

Sophie S Hall

Sophie.hall@nottingham.ac.uk

University of Nottingham

Charlotte L Hall

University of Nottingham

Christopher Partlett

University of Nottingham

Alexia Jeayes

University of Nottingham

Nikita Rattu

Nottinghamshire Healthcare NHS Foundation Trust

Helen Henshaw

University of Nottingham

Jennifer Martin

University of Nottingham

Emily Shoesmith

University of York

Systematic Review

Keywords: Mental health, digital health, randomised controlled trials, minority groups

Posted Date: January 29th, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-7565290/v1>

License: © ⓘ This work is licensed under a Creative Commons Attribution 4.0 International License. [Read Full License](#)

Additional Declarations: No competing interests reported.

Abstract

Decentralised clinical trials (DCTs) may improve access to digital mental health interventions, but equity remains limited. This review of 60 papers (58 DCTs) found key PROGRESS-Plus variables—race/ethnicity, socioeconomic status, occupation, and residence—were underreported. Underserved groups were consistently underrepresented. Barriers included digital exclusion and cognitive or sensory challenges, while therapist support and simplified onboarding facilitated participation. Standardised reporting and inclusive DCT design are needed.

BACKGROUND

Remote and digitised delivery of mental health care is increasingly recognised as essential to meet rising demand and improve accessibility nationally and globally (1–4). Digital tools, such as apps, teletherapy, and AI-driven diagnostics, offer scalable, cost-effective interventions that can reduce waiting times, ease pressure on services and support personalised care (5, 6). However, for the benefits of mental health digitisation to be realised by those most at need they need be evaluated in underserved populations.

Randomised Controlled Trials (RCTs) are regarded as the ‘gold standard’ for evaluating healthcare interventions (7), but their reliance on selective samples and inadequate demographic reporting (8–10), limits real-world applicability and produces a skewed data base on which decisions are made (11–14). Decentralised clinical trials (DCTs), also called ‘remote’, ‘online’, ‘site-less’, or ‘hybrid’ trial, conduct some or all activities outside traditional trial sites, and grew in popularity during COVID-19 (15–17). DCTs rely on digital technologies, offering a flexible, scalable model for evaluating digital mental health interventions, with potential to improve access, reduce costs, and support sustainability (18, 19). Whilst DCTs are increasingly positioned to promote inclusive research, evidence of their impact on equity remains uncertain, particularly in mental health, where challenges such as stigma, digital exclusion, and lack of face-to-face interaction/support can limit participation (20, 21). Neurodevelopmental conditions, such as autism and attention-deficit hyperactivity disorder (ADHD), frequently co-occur with mental health conditions (22, 23) and present similar challenges (24). In addition, requirements for digital literacy and access may further exclude disadvantaged groups disproportionately affected by mental health disorders (25–29). Frameworks like NIHR INCLUDE and recommendations by Aiyegbusi et al. (30, 31) provide guidance on engaging underserved groups, but their application to mental health DCTs is limited. Realising the inclusive potential of DCTs requires evaluating their effectiveness in reaching diverse populations and adapting designs to overcome intersecting barriers. The aims of this review were to:

1. Assess the extent to which equity-relevant data are reported in DCTs, using the Place, Race, Occupation, Gender/sex, Religion, Education, Socioeconomic status, Social capital + personas characteristics associated with discrimination (PROGRESS-plus) framework.
2. Explore whether specific population groups (using the PROGRESS framework) are under-represented in mental health/neuro-developmental conditions DCTs compared to general population statistics.
3. Identify barriers and enablers to inclusive participation in DCTs in a mental health/neuro-developmental context.

METHODS

We report methodology in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines using the Equity extension (32) (see Supplementary Material 1), following a preregistered International Prospective Register of Systematic Reviews protocol (CRD420251080321).

Patient and Public Involvement (PPI)

Four PPI members with mental health and neurodevelopmental conditions (including one Black female and one Asian female) were involved in the conception of the study. Their concerns regarding inclusivity in DCT informed the development of the data extraction tool. A PPI member also reviewed the data codes derived from the thematic analysis.

Inclusion criteria

Studies were assessed for inclusion based on the population, intervention, comparator, outcome and study design (33) (Table 1).

Table 1 Inclusion criteria based on population, intervention, comparator, outcome and study design	
Population	Children (aged up to 17 years) and/or adults (aged 18 years and above) with a diagnosis of a mental health or neurodevelopmental condition (as defined by the DSM-5 (38)), in any setting.
Intervention	Studies that described or evaluated decentralised, virtual, or remote interventions (fully or partially remote), e.g., teletherapy, app-based interventions, remote assessments. Interventions must involve assessment, treatment, prevention, or management of mental health or neurodevelopmental conditions.
Comparator	Studies with the following controls were considered: normal practice ('usual care'), waiting-list control, or any other intervention described by the authors as a comparator.
Outcomes	Studies that reported psychological, emotional and/or behavioural outcomes (e.g., agitation, anxiety, social behaviour).
Study designs	Randomised controlled trials (including randomised feasibility and pilot trials).

Exclusion criteria

Studies were excluded if they: (a) lacked demographic data or reflections on representation; (b) involved interventions unrelated to mental health or neurodevelopmental conditions; (c) delivered non-digital or non-remote interventions; (d) had no other online trial components beyond the intervention; or (e) were published before 2020, as the COVID-19 pandemic marked a shift in DCT adoption (34)ensuring the review reflects contemporary practices and technologies.

Search strategy

MEDLINE, PsycINFO, Embase, CINAHL, Cochrane Central, and Web of Science were searched up to 1 July 2025 using terms related to DCTs (e.g., decentralised, remote, digital), demographics (e.g., ethnicity, education), inclusivity, and mental health or neurodevelopmental conditions in children and adults. Searches were limited to English-language studies. The MEDLINE strategy is provided in Supplementary Material 2 and adapted for other databases. Key journals, reference lists of included studies, and relevant systematic reviews were hand-searched. Publications were managed in Covidence (Fig. 1). Titles and abstracts were independently screened by three authors (S.S.H., C.L.H., E.S.); disagreements led to inclusion in full-text review. Full texts were independently reviewed by the same authors, with discrepancies resolved through discussion.

Data extraction

Using a pre-defined data extraction spreadsheet in Microsoft Excel, relevant data were extracted by four authors (S.S.H., E.S., N.R., A.J.). Information included research methodology, sample size, type of intervention, remote trial design elements (e.g., recruitment strategies, screening, assessments), intervention setting, digital literacy and/or access, and demographic information (e.g., race/ethnicity, gender, age, religion, occupational level, educational level) as well as any identified barriers/enablers to engagement in the trial. A complete list of data extracted is provided in Supplementary Material 3. Data extraction commenced on 14th July 2025.

Risk of bias assessment

Given the objective of this review was to evaluate representation and the quality of demographic reporting, rather than the effectiveness or validity of study findings, a formal risk of bias assessment was not undertaken. The focus was placed on the completeness and transparency of reporting, as measured against established reporting guidelines (PROGRESS-Plus) (35)

rather than on the internal validity of the studies or the potential for systematic bias in their results, consistent with the approach taken in previous reviews (10, 36).

Data synthesis

We assessed reporting quality using PROGRESS-Plus guidelines (35). Four authors (S.S.H., E.S., N.R., A.J.) independently reviewed each paper, categorising each item as reported, not reported, or unclear. Supplementary materials were accepted if explicitly referenced. PROGRESS includes place of residence, race/ethnicity, occupation, gender/sex, religion, education, socioeconomic status (SES), and social capital. For synthesis, place of residence was coded as rural/urban; occupation as employed/unemployed; education as above/below compulsory level; social capital by relationship status; and SES as low-, middle-, or high-income using country-specific definitions. SES reporting varied (income frequency, household vs. individual, currencies), and no standard cut-offs were used; where available, numbers below the national poverty line were extracted separately. The “Plus” category captured additional characteristics, including non-mental health conditions and age. Descriptive statistics summarised demographics. Country-level synthesis included only countries represented in ≥ 2 studies; multi-country studies without disaggregated data were excluded. Where possible, chi-squared tests compared sample sociodemographics with national statistics. Perceived or measured barriers/enablers to participation were thematically analysed (37). One author (S.S.H.) generated initial codes, which were grouped into themes. A second author (E.S.) and a PPI member independently reviewed and validated theme construction.

RESULTS

Description of studies

Database and manual searching yielded a total of 6,760 records. After removal of duplicates and screening of titles, abstracts and full-text papers, 60 papers were included in the review (Fig. 1), reporting a total of 59 studies. Two papers refer to the same RCT (38, 39), but assessed different outcomes. Both RCTs met the inclusion criteria but as the data was derived from the same sample, demographics are only included once. A list of all included papers is provided in Supplementary Material 4.

Across the 58 included RCTs, sample sizes ranged from 8 to 1,225 participants (as reported at baseline). Most studies were conducted in the USA ($n = 15$; 25.4%), followed by the UK ($n = 8$; 13.6%), Australia ($n = 7$; 11.9%), Sweden ($n = 4$; 6.8%), and China ($n = 4$; 6.8%). Two studies (3.4%) were conducted in multiple geographic regions (e.g., USA and UK (40) and Netherlands and UK (41)). Interventions were delivered to a variety of study populations, primarily anxiety ($n = 10$; 16.9%), depression ($n = 8$; 13.6%), attention-deficit hyperactivity disorder (ADHD; $n = 8$, 13.6%), and autism ($n = 6$; 10.2%). Fourteen studies (23.7%) delivered interventions to participants with mixed diagnoses (e.g., anxiety and depression, post-traumatic stress disorder and depression, all mental health conditions).

The studies were split in terms of models of delivery, with 28 (47.5%) being fully remote, and 30 (50.8%) adopting a hybrid model that combined remote and in-person trial elements. Remote recruitment (e.g., via social media, online platforms, electronic health records) was reported in 40 studies (67.8%). Remote screening or eligibility assessments (e.g., via telephone, online self-reporting) were used in 41 studies (69.5%). Remote outcome assessments were performed in most studies ($n = 53$, 89.8%). Table 2 provides a full overview of study characteristics.

Table 2
Study characteristics

Author/Year	Country	Participants (n)	Diagnosis	Full or hybrid remote	Remote recruitment strategies (Y/N)	Remote screening and/or eligibility (Y/N)	Remote assessments/ follow-up (Y/N)
Andrews et al. (2023)	Australia	103	Anxiety or depression	Full	Yes	Yes	Yes
Backman et al. (2024)	Sweden	141	Autism	Full	Yes	Yes	Yes
Bennett et al. (2021)	UK	34	Any mental health condition	Hybrid	No	No	Yes
Bikic et al. (2018)	Denmark	70	ADHD	Hybrid	No	Yes	Yes
Bilan et al. (2025)	Spain	49	ADHD	Hybrid	No	Yes	No
Carl et al. (2020)	USA and UK	256	Generalised anxiety disorder	Full	Yes	Yes	Yes
Chan et al. (2023)	Hong Kong	320	Comorbid depressive disorder and insomnia	Full	Yes	Yes	Yes
Chien et al. (2024)	Hong Kong	50	Any neurodevelopmental conditions	Hybrid	Not clear	Not clear	Not clear
Clark et al. (2023)	UK	102	Social anxiety	Hybrid	No	No	Yes
Creswell et al. (2024)	UK	443	Anxiety	Hybrid	No	Yes	Yes
Dopfner et al. (2025)	Germany	431	ADHD	Hybrid	No	Yes	Yes
Eto et al. (2025)	Japan	30	ADHD	Full	Yes	Yes	Yes
Eylem et al. (2021)	Netherlands and UK	18	Suicidal ideation	Hybrid	Yes	Not clear	Yes
Fatouros et al. (2025)	Greece	200	Depression and generalised anxiety disorder	Full	Yes	Yes	Yes
Felder et al. (2020, 2022)	USA	208	Insomnia	Full	Yes	Yes	Yes
Grenier-Martin et al. (2022)	Canada	29	Intellectual and developmental disability	Hybrid	Yes	Not clear	Yes
Guzick et al. (2023)	USA	8	ADHD	Hybrid	Not clear	Yes	Yes
Guzick et al. (2024)	USA	57	ADHD	Full	Yes	Yes	Yes
Hall et al. (2024)	N/A	N/A	Across all conditions	N/A	N/A	N/A	N/A

Author/Year	Country	Participants (n)	Diagnosis	Full or hybrid remote	Remote recruitment strategies (Y/N)	Remote screening and/or eligibility (Y/N)	Remote assessments/ follow-up (Y/N)
Hartley et al. (2022)	Australia	16	Autism	Hybrid	Yes	Not clear	Yes
Haun et al. (2023)	USA	265 dyads	PTSD	Full	Yes	Yes	Yes
He et al. (2022)	China	148	Depression	Hybrid	Yes	Not clear	Yes
Heller et al. (2020)	Netherlands	159	Depression and anxiety	Hybrid	Yes	Not clear	Yes
Hoffmann et al. (2021)	Denmark	101	Anxiety	Full	Yes	Yes	Yes
Hollis et al. (2021)	UK	224	Tourette's syndrome	Hybrid	Yes	No	Yes
Huberty et al. (2021)	USA	239	Insomnia	Full	Yes	Yes	Yes
Jamali et al. (2022)	Iran	43	Autism	Full	Yes	Yes	Yes
Jent et al. (2021)	Spain	130	Disruptive behaviour	Hybrid	Not clear	Yes	Yes
Kalmbach et al. (2020)	USA	91	Insomnia	Full	Yes	Yes	Yes
Kandola et al. (2024)	UK	908	Depression	Full	Yes	Yes	Yes
Kenworthy et al. (2023)	USA	97	Autism	Hybrid	Not clear	No	Yes
Kwon et al. (2024)	Korea	74	ADHD	Hybrid	No	No	Yes
Lewis et al. (2024)	Australia	61	Autism	Full	Yes	Yes	Yes
Lindgren et al. (2020)	USA	38	Autism	Hybrid	Not clear	Not clear	Yes
Lippke et al. (2021)	Germany	300	Psychosomatic diagnosis	Hybrid	No	No	Yes
Malarkey et al. (2024)	USA	125	Insomnia	Hybrid	Yes	Not clear	Yes
March et al. (2023)	Australia	137	Anxiety	Hybrid	Not clear	Yes	Yes
March et al. (2025)	Australia	137	Anxiety	Full	Yes	Yes	Yes
McCloud et al. (2020)	UK	168	Anxiety and depression	Full	Yes	Yes	Yes
McLellan et al. (2024)	Australia	95	Anxiety	Hybrid	No	Yes	Yes
Mechler et al. (2022)	Sweden	272	Depression	Full	Yes	Yes	Yes

Author/Year	Country	Participants (n)	Diagnosis	Full or hybrid remote	Remote recruitment strategies (Y/N)	Remote screening and/or eligibility (Y/N)	Remote assessments/ follow-up (Y/N)
Moshe et al. (2022)	Germany	253	Depression	Hybrid	Yes	Not clear	Yes
Murray et al. (2021)	Australia	302	Bipolar disorder	Full	Yes	Yes	Yes
Nardi et al. (2022)	USA	27	Generalised anxiety disorder	Hybrid	Yes	No	Yes
Nissling et al. (2023)	Sweden	52	Anxiety	Full	Yes	Yes	Yes
Nordh et al. (2021)	Sweden	103	Social anxiety disorder	Hybrid	Yes	Yes	Not clear
Ong et al. (2024)	USA	178	PTSD and/or depression	Full	Yes	Yes	Yes
Piscitello et al. (2024)	USA	43	ADHD	Hybrid	Yes	Yes	Not clear
Possemato et al. (2022)	USA	81	Depression, anxiety and PTSD	Full	Yes	Yes	Yes
Richards et al. (2020)	UK	361	Depression and anxiety	Full	Yes	Yes	Yes
Sabri et al. (2025)	USA	144	PTSD and/or depression	Full	Yes	Yes	Yes
Sayal et al. (2025)	UK	1225	Emotional difficulties	Hybrid	No	Yes	Yes
Segal et al. (2020)	USA	460	Depression	Hybrid	Yes	Yes	Not clear
Seo et al. (2022)	South Korea	73	Postpartum depression	Full	Yes	Yes	Yes
Sun et al. (2021)	China	168	Perinatal depression	Hybrid	Not clear	Yes	Yes
Tan et al. (2023)	Malaysia	48	Depression and anxiety	Hybrid	No	No	Yes
Tan et al. (2024)	China	69	Learning disabilities	Full	Yes	Yes	Yes
Wong et al. (2021)	Hong Kong	79	Depression	Full	Yes	Yes	Yes
Wu et al. (2023)	China	93	OCD	Full	Yes	Yes	Yes

To what extent are equity-relevant data reported in DCTs in mental health, as defined by the PROGRESS-Plus guidelines?

In line with the PROGRESS-Plus guidelines, 59 of the included 60 papers (98.3%) reported participant demographics. One study did not report demographic characteristics, as this was a perspective piece, for which reporting was not applicable (42). Two papers reported on the same RCT, therefore demographics summarised below are taken from 58 studies (38, 39). The most frequently reported PROGRESS-Plus items related to gender (58/50: 100%) and age (58/50: 100%). The least frequently

reported PROGRESS-Plus items related to non-mental health disabilities (1/58: 1.7%), religion (3/58: 5.2%) and place of residence or setting (rural vs. urban areas) (7/58: 12.1%) (Table 3).

Table 3
Number of studies (total n = 58) reporting PROGRESS-Plus items

PROGRESS-Plus item	Number of studies reporting demographic information n (%)
Place (rural vs urban)	7 (12.1%)
Race/ethnicity	23 (39.7%)
Occupation	21 (36.2%)
Gender	58 (100%)
Religion	3 (5.2%)
Education	41 (70.7%)
Socioeconomic status	16 (27.6%)
Social capital	25 (43.1%)
Age	58 (100%)
Non mental health disability	1 (1.7%)

Demographic information from all included studies, disaggregated by country, is presented below. Descriptive statistics are limited to countries represented in at least two studies. Studies conducted across two or more countries in which data were not reported separately by country are excluded. A comprehensive overview of demographic information reported in each included study is available in Supplementary Material 5 (Supplementary Table 5a), alongside documentation of the source data used to acquire the representation of each sociodemographic variable by country (Supplementary Table 5b).

Place: Seven studies (12.1%) reported participants' place of residence categorised as rural or urban. Among the 1,211 participants reported in these seven studies, 626 (51.7%) resided in urban areas, 306 (25.3%) in rural areas, and data for 279 participants (23.0%) were either missing or not reported. One of the seven studies was in the USA (43) and one in China (44) demographics for these counties are reported in Supplementary Material 5 but were insufficient for further comparison. The remaining five studies were conducted in Australia (45–49), encompassing 533 participants: 260 (48.8%) lived in urban areas (population statistics: 86.5%), 160 (30.0%) in rural areas (population statistics: 13.5%), and residence data were unavailable for 113 participants (21.2%). Chi-squared tests identified there were significantly greater representation of rural based participants in these Australian studies compared to general population statistics ($p < .001$).

Race/ethnicity

Ethnicity data were reported in 23 studies (39.7%), encompassing a total of 5,381 participants. Among these, 4,054 individuals (75.3%) were identified as White, 493 (9.2%) as Asian, 268 (4.9%) as Black, 208 (3.9%) as 'Other', and 152 (2.8%) as of 'Multiple' ethnicities. From the 23 studies, ethnicity information was either missing or not reported for 261 participants (4.9%). Three studies were the only representation from that country (50–52), and one study reported demographics aggregated across multiple countries without separating data by country (53). Therefore, the tabulated papers include studies conducted in the USA (38, 43, 54–63), the UK (64–68), and China (44, 69) (Table 4). It was not possible to extract ethnicity of the population in China as China only officially report Han or non-Han statistics. Chi-squared test revealed a statistically significant difference between the racial representation reported in the included studies and national population statistics in the UK and USA, indicating over representation of white participants relative to their population proportions (p 's < .0001).

Table 4
Ethnicity reported across the included studies and separated by countries (represented in ≥ 2 studies)

	Total participants (n)	White n (%)	Asian n (%)	Black n (%)	Multiple n (%)	Other n (%)	Missing/not reported n (%)
Across all geographic regions (n = 23*)	5,381*	4,054 (75.3%)	493 (9.2%)	268 (4.9%)	152 (2.8%)	208 (3.9%)	261 (4.9%)
USA (n = 12)	2,117	1,564 (73.9%)	72 (3.4%)	224 (10.6%)	55 (2.6%)	129 (6.1%)	128 (6.0%)
USA Population Statistics		61.6%	4.8%	12.4%	10.2%	0.1%	
UK (n = 5)	2,355	2,011 (85.4%)	60 (2.5%)	18 (0.8%)	64 (2.7%)	72 (3.1%)	130 (5.5%)
UK Population Statistics		81.7%	9.3%	4%	2.9%	2.1%	
China (n = 2)	316	0 (0.0%)	305 (96.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	11 (3.5%)
*Including four studies that are only represented by one country or combined countries							

Occupation

Of the 21 studies (36.2%) that reported participants' occupational status, a total of 3,059 individuals were classified as either 'employed' (n = 2023, 66.1%) or 'not employed' (n = 649, 21.2%). From the 21 studies, occupational status data were missing or unreported for 387 participants (12.7%). Only one study, conducted in Hong Kong, provided detailed information on occupational type (70). Nine studies were the only representation from that country (45, 50, 52, 70–75), and one study reported demographics aggregated across multiple countries without separating data by country (41). Therefore, the tabulated papers include studies conducted in the USA (59, 62, 63, 76), the UK (64–67), and Sweden (77–79) (Table 5). Chi-squared test revealed a statistically significant difference between the representation of employed and unemployed participants reported in the included studies and national population statistics for all three countries (p 's < .001), with the data indicating underrepresentation of unemployed individuals relative to their population proportions (p 's < .0001).

Table 5

Occupational status reported across the included studies and separated by countries (represented in ≥ 2 studies)

	Total participants (n)	Employed n (%)	Not employed n (%)	Missing/not reported n (%)
Across all geographic regions (n = 21*)	3,059*	2,023 (66.1%)	649 (21.2%)	387 (12.7%)
USA (n = 4)	693	438 (63.2%)	234 (33.8%)	21 (3.0%)
USA Population Statistics		52.7%	42.8%	
UK (n = 4)	1,130	857 (75.8%)	174 (15.4%)	99 (8.8%)
UK Population Statistics		75.1%	24.9%	
Sweden (n = 3)	296	129 (43.6%)	64 (21.6%)	103 (34.8%)
Sweden Population Statistics		69%	31%	
*Including 10 studies that are only represented by one country or combined countries				

Gender

Among studies that reported gender (n = 58; 100%), a total of 10,401 participants were included. Of these, 6,685 (64.3%) identified as female, 2,691 (25.9%) as male, 30 (0.3%) as non-binary, and 15 (0.1%) as 'other'. Gender data were missing or not reported for 980 participants (9.4%) across the included studies reporting Gender. Eight studies were the only representation from that country (50, 52, 71, 72, 75, 80–82), and two studies reported demographics aggregated across multiple countries without separating data by country (41, 53). Therefore, the tabulated papers include studies conducted in the USA (38, 43, 54–63, 76, 83, 84), the UK (64–68, 85–87), Australia (45–49, 88, 89), Sweden (77–79, 90), China (44, 69, 91, 92), Germany (74, 93, 94), Hong Kong (70, 95, 96), Denmark (73, 97), and Spain (51, 98) (Table 6). Chi-squared test revealed a statistically significant difference between the representation of male and female participants reported in the included studies and national population statistics for all countries (p 's < .001) except Hong Kong ($p = 0.5$) and Denmark ($p = 0.2$) (both have comparatively small sample sizes) with the data indicating underrepresentation of males relative to their population proportions. It should be noted that despite the small sample size, Spain was significantly different to expected population statistics in the opposite manner to the other studies, with females being underrepresented. However, this is likely due to a reflection on poor reporting as one study (51) only reported the number of males participating, contributing to a comparably large amount of 'missing/not reported' data, as we cannot assume the remaining sample are female.

Table 6
Gender and sex reported across the included studies and separated by countries (represented in ≥ 2 studies)

	Total participants (n)	Females n (%)	Males n (%)	Non- binary n (%)	Other n (%)	Missing/not reported n (%)
Across all geographic regions (n = 58*)	10,401*	6,685 (64.3%)	2,691 (25.9%)	30 (0.3%)	15 (0.1%)	980 (9.4%)
USA (n = 15)	2,326	1,542 (66.3%)	765 (32.9%)	0 (0.0%)	3 (0.1%)	16 (0.7%)
USA Population Statistics		50.5%	49.5%			
UK (n = 8)	3,465	2,173 (62.7%)	700 (20.2%)	30 (0.9%)	3 (0.1%)	559 (16.1%)
UK Population Statistics		49.6%	51.4%			
Australia (n = 7)	851	568 (66.7%)	271 (31.8%)	0 (0.0%)	3 (0.4%)	9 (1.1%)
Australia Population Statistics		50.7%	49.3%			
Sweden (n = 4)	568	441 (77.6%)	118 (20.8%)	0 (0.0%)	0 (0.0%)	9 (1.6%)
Sweden Population Statistics		49.7%	50.3%			
China (n = 4)	478	327 (68.4%)	151 (31.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
China Population Statistics		48.8%	51.2%			
Germany (n = 3)	984	740 (75.2%)	143 (14.5%)	0 (0.0%)	0 (0.0%)	101 (10.3%)
Germany Population Statistics		50.6%	49.4%			
Hong Kong (n = 3)	449	136 (30.3%)	102 (22.7%)	0 (0.0%)	0 (0.0%)	211 (46.9%)
Hong Kong Population Statistics		55%	45%			
Denmark (n = 2)	171	77 (45.0%)	94 (55.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Denmark Population Statistics		50.3%	49.8%			
Spain (n = 2)	179	6 (3.4%)	92 (51.3%)	0 (0.0%)	0 (0.0%)	81 (45.3%)
Spain Population Statistics		50.9%	49.1%			
*Including 10 studies that are only represented by one country or combined countries						

Religion

Only three studies (5.2%), across different countries, reported data on participants' religious affiliation, comprising a total of 482 participants. One study conducted in the UK (67) included 361 participants, of whom 221 (61.2%) reported no religious affiliation, 88 (24.4%) identified as Christian, and 52 (14.4%) reported their religion as 'other'. A study in South Korea (75) included 73 participants, with 38 (52.1%) reporting no religion, 18 (24.7%) identifying as Buddhist, 13 (17.8%) as Christian, and 4 (5.5%) as Catholic. Lastly, in a study conducted in Malaysia (52), 38 of the 48 participants (79.2%) identified as Muslim, while 10 (20.8%) reported their religion as 'other'. There were no missing data on religious affiliation in any of the three studies that reported this information.

Education

Forty-one studies (70.7%) reported educational attainment. However, three of these studies presented only the mean number of years of education, which could not be categorised into educational levels (58, 71, 92). Therefore, 38 studies were classified based on whether participants had completed only compulsory education or education beyond the compulsory level (reporting on 5,698 participants). Of these, 4,310 (75.6%) participants had completed education beyond the compulsory level, 1,185 (20.8%) participants had completed compulsory education (e.g., primary and/or secondary school). Educational data were missing or not reported for 203 (3.6%) participants across the 41 studies.

Seven studies were the only representation from that country (50–52, 72, 73, 75, 81), and two studies reported demographics aggregated across multiple countries without separating data by country (41, 53). Therefore, the tabulated papers include studies conducted in the USA (38, 43, 54, 55, 59, 61–63, 76, 84), the UK (64–66, 87), Australia (45, 46, 49, 88), Germany (74, 93, 94), Hong Kong (70, 95, 96), Sweden (77–79), and China (44, 91). On average, across these studies, more than half of the participants had pursued education beyond the compulsory level. Only studies conducted in Germany and Sweden had samples in which the majority of participants had not continued their education beyond the compulsory level (Table 7). The chi-squared test indicated that participants who pursued education beyond the compulsory level were overrepresented compared to national population statistics in all countries (p 's < .001), except for Germany ($p = 0.3$) and Sweden ($p = 0.9$), where the difference not statistically significant.

Table 7

Educational data reported across the included studies and separated by countries (represented in ≥ 2 studies)

	Total participants (n)	Compulsory n (%)	Higher n (%)	Missing/not reported n (%)
Across all geographic regions (n = 38*)	5,698	1,185 (20.8%)	4,310 (75.6%)	203 (3.6%)
USA (n = 10)	1,683	152 (9.0%)	1,461 (86.8%)	70 (4.2%)
USA Populations Statistics		39%	61%	
UK (n = 4)	937	141 (15.0%)	796 (85.0%)	0 (0.0%)
UK Population Statistics		66%	33.8%	
Australia (n = 4)	275	26 (9.5%)	249 (90.5%)	0 (0.0%)
Australia Population Statistics		16%	84%	
Germany (n = 3)	984	602 (61.2%)	377 (38.3%)	5 (0.5%)
Germany Population Statistics		63%	37%	
Hong Kong (n = 3)	449	33 (7.3%)	389 (86.6%)	27 (6.1%)
Hong Kong Population Statistics		59%	41%	
Sweden (n = 3)	296	138 (46.6%)	94 (31.8%)	64 (21.6%)
Sweden Population Statistics		60%	40%	
China (n = 2)	217	2 (0.9%)	215 (99.1%)	0 (0.0%)
China Population Statistics		39%	61%	
*Including 9 studies that are only represented by one country or combined countries				

Socioeconomic status: Twenty studies reported participant income, however, one study reported frequency of financial stress and therefore was not included in this analysis (84). Of the remaining 19 studies, there was only one study conducted in each the following countries: Canada, Germany, South Korea (72, 74, 75). Five studies conducted in Australia (45–49) are included in the table, of which two reported Socio-economic Index for Areas percentiles (47, 48) making classification more reliable. One study in China reported income in USD (\$) (69) and one in RMB (Chinese Yuan) (52). One study in Hong Kong reported the number of participants with a monthly family income equal to or greater than the median (classified as middle) (96) and the other reporting monthly family income in HK\$ (70). One UK study reported Index of Multiple Deprivation quintiles (68) and one reported annual total household income (65). Of the five USA based studies, one reported the number of participants who had an income $\geq$ \$100,000 (38), these were classified as middle SES for the purpose of the table. One study only reported participants who were in poverty (57), and these were classified as low SES in the table. The remaining three papers reported

annual income (61, 63, 76). The data sources used for classification of income for each country is presented in Supplementary Material 6.

Table 8

Socioeconomic status as calculated based on area of deprivation status or income reported across the included studies and separated by countries (represented in ≥ 2 studies)

	Total Participants (n)	Low n (%)	Middle n (%)	High n (%)	Missing/not reported n (%)
Across all geographic regions (n = 19*)	3798	1087 (28.6%)	1203 (31.7%)	999 (26.3%)	509 (13.4%)
Australia (n = 5)	533	121 (22.7%)	201 (37.7%)	178 (33.4%)	33 (6.2%)
China (n = 2)	237	84 (35.4%)	107 (45.1%)	30 (12.7%)	16 (6.7%)
Hong Kong (n = 2)	129	65 (50.4%)	35 (27.1%)	36 (12.7%)	23 (6.8%)
UK (n = 2)	1668	539 (32.3%)	330 (19.8%)	629 (37.7%)	170 (10.2%)
USA (n = 5)	829	88 (10.6%)	468 (56.4%)	124 (15%)	149 (17.8%)
*Including 3 studies that are only represented by one country					

It was possible to extract a proxy for the number of participants potentially living in poverty as per their country's definition for seven studies, including three in Australia (45, 47, 48), one in Hong Kong (70), two in the UK (65, 68) and one in the USA (57). This data is presented in Table 9. See Supplementary Material 6 (Table 6b) for information on the classifications. Chi-squared tests were not computed on this sub-selection of papers. The data indicates considerable variation amongst papers in the degree to which the sample is representative of national poverty statistics.

Table 9
Number and % living in poverty represented in the sample

Author	Country	n (%) in poverty
March 2025	Australia	15 (10.9%)
March 2023	Australia	12 (8.7%)
Andrews 2023	Australia	15 (14.5%)
Total	Australia	42 (11.1%)
Australia Population Statistics		13.4%
Wong 2021	Hong Kong	39 (49.3%)
Hong Kong Population Statistics		20.2%
Creswell 2024	UK	35 (7.9%)
Sayal 2025	UK	214 (17.4%)
Total	UK	249 (14.9%)
UK Population Statistics		15%
Kalmbach	USA	16 (17.5%)
USA Population Statistics		11.4%

Social capital

Of the 25 studies (43.1%) that reported on social capital, 21 categorised participants by relationship status (e.g., married or in a relationship, single, divorced, separated, or widowed), while four studies used living arrangements as the categorisation (e.g., living alone, with family, or with other adults). Among the 21 studies that reported relationship status, data were reported for 3,531 participants. Of these, 2,106 (59.6%) were married, in a civil partnership, or in a long-term relationship; 470 (13.3%) were single and/or never married; 300 (8.5%) were divorced, separated, or widowed; and 2 participants (0.1%) chose not to disclose this information. Relationship status data were missing or not reported for 653 participants (18.5%).

Three studies were the only representation from that country (52, 71, 73), and two studies reported demographics aggregated across multiple countries without separating data by country (41, 53). Therefore, the tabulated papers include studies conducted in the USA (38, 43, 61–63, 84), China (69, 91, 92), Hong Kong (70, 95, 96), the UK (64, 65), and Germany (74, 94) (Table 9). National population statistics were not possible to obtain for China and Hong Kong. For the studies in UK, USA and Germany there was a greater representation of individuals who were married than would be expected based on their countries population statistics ($p < .0001$). See Table 10.

Table 10
Social capital reported across the included studies and separated by countries (represented in ≥ 2 studies)

	Total participants (n)	Married, civil partnership or relationship (n, %)	Never married or single (n, %)	Divorced, separated or widowed (n, %)	Prefer not to say (n, %)	Missing/not reported (n, %)
Across all geographic regions (n = 21*)	3,531	2,106 (59.6%)	470 (13.3%)	300 (8.5%)	2 (0.1%)	663 (18.5%)
USA (n = 6)	1,201	765 (63.7%)	175 (14.6%)	233 (19.4%)	0 (0.0%)	28 (2.3%)
USA Marriage Population Statistics		49.4%				
China (n = 3)	330	285 (86.4%)	37 (11.2%)	4 (1.2%)	0 (0.0%)	4 (1.2%)
Hong Kong (n = 3)	449	89 (19.8%)	59 (13.1%)	2 (0.4%)	0 (0.0%)	299 (66.6%)
UK (n = 2)	545	408 (74.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	137 (25.1%)
UK Marriage Population Statistics		46.9%				
Germany (n = 2)	553	337 (60.9%)	34 (6.1%)	39 (7.1%)	0 (0.0%)	143 (25.9%)
Germany Marriage Population Statistics		51%				
*Including 5 studies that are only represented by one country or combined countries						

Four studies reported social capital in terms of living arrangements. Three of these were conducted in Australia. One study (45) reported that participants lived with a mean of 1.67 other residents. Another found that 9 of 61 participants (14.8%) were from single-parent households (46), while a third reported that 86 of 95 participants (90.5%) were from two-parent households (49). The fourth study, conducted in Sweden (78), reported that among 52 participants, 47 (90.4%) lived with a family member, 1 (1.9%) with another adult, 2 (3.8%) lived alone, and data were missing for 2 participants (3.8%).

Non-mental health conditions: Only one study, which was conducted in South Korea (75), reported on 'diagnosis of physical illness (Yes: n = 9, 12.3%; No: n = 64, 87.7%).

Age: Age was predominantly reported in terms of mean values therefore it was not possible to categorise the sample accurately into age-brackets. From the 60 papers included in the review, age was presented in 59 papers (one being a perspective piece), but one included the duplication of the same sample. The majority of the studies delivered interventions to adults (34/58: 58.6%), followed by children under 15 years of age (19/58: 32.5%), two studies conducted in Sweden tested the intervention in adolescence (15–19 years) (2/58: 3.4%) (78, 90) and a third study in Sweden involved both younger adults and adolescence (16–25 years) (1/58: 1.7%) (77). Two other studies included a mixed age population of adults and children (1/58: 1.7%) (88) and children and adolescence (1/58: 1.7%) (68).

Digital literacy/access

Digital access was a common inclusion criterion for the trials (29/58 trials), as well as being mentioned in the perspective piece (42), typically participants were required to have a computer, smartphone, or tablet with stable internet (41, 49, 64, 68, 73,

79). Some studies specified device types (e.g., Apple/Android smartphones), specific internet speeds, or a regularly used email (59, 83, 87, 95) and a county specific (Australian) IP address (47). Reliable access to both internet and phone was also required in some cases (59). Technical issues were frequently reported, including connectivity problems and device limitations, which disrupted interventions and may have contributed to dropout (71, 88).

The role of digital skills was only considered by the perspective piece (42) and a 7/58 trials, typically in the form of assessing digital literacy/competence through self-report or purpose-built questionnaires (43, 77, 87, 89, 94). Some studies reported challenges when participants lacked digital familiarity, such as difficulties using computers (74, 92), but only one study (74) incorporated support mechanisms, such as how to check internet connectivity. The recent perspective piece (42) highlighted the importance of structured support programs offering digital skills training both online and in person. It also identified digital navigators—clinic staff trained to provide technical assistance—as a promising way to support users without overburdening clinical teams. These studies highlight that digital access and literacy are critical factors for equitable access and engagement in digital mental health research and interventions.

What are the identified barriers and enablers to participation in DCTs in a mental health context?

High dropout and recruitment challenges

Many studies reported challenges in keeping participants engaged and enrolled. High dropout rates were common (43, 44, 48, 72, 85–87, 92), and some trials struggled with recruitment, especially where stigma or low mental health literacy were factors (41, 50, 88). Participants drop out was associated with feeling confused or unsupported (48, 85). Some mistook surveys for the intervention or wanted more personal contact during onboarding (43). Dropout was also linked to factors like age, education, and social support (94), and some participants simply weren't comfortable with digital tools (92). However, measuring engagement itself is challenging. There is no standard way to define or track it—some use clicks, others look at time spent, or pages visited—making it hard to compare across studies and complicating efforts to identify best practices (42).

Support/navigators

Support from therapists or trained staff consistently emerged as a key facilitator of engagement in digital mental health trials. Participants often preferred therapist-assisted formats (45), and regular check-ins, whether via email or phone, helped sustain involvement (54, 80). Eto et al demonstrated that adapting face-to-face therapy techniques for digital delivery, such as co-creating worksheets and focusing on patient interests, could enhance engagement (71). In culturally specific contexts, like Muslim communities, directive guidance was especially valued, with unclear instructions perceived as incompetence (41).

Beyond therapeutic input, practical support and project navigators played a crucial role from on-boarding, technical demonstrations, through to reminders to prevent disengagement (43, 47, 80, 85, 87). However, in resource-limited settings or among people with severe anxiety, therapist-led models may not be feasible (42). Additional strategies to boost engagement were suggested included motivational interviewing, short instructional videos, and text reminders (51). However, not all digital support features, such as social networking tools, will be effective or accepted by all (88).

Participant burden

The burden of participation, whether cognitive, emotional, sensory, or logistical, was another major barrier. Complex onboarding processes, long sessions, and excessive paperwork discouraged engagement (43) and participants dropped out due to tedious content or lack of engagement (44, 81). In particular, children may struggle with focus and motivation (88) and some participants found digital formats (e.g., reading on screens) uncomfortable or inaccessible (92).

To mitigate these issues, studies recommended simplifying onboarding, reducing the use of passwords, digitising forms (42, 43) and simplifying data collection methods including the numbers of measures required (85). More specific recommendations were identified in one paper, which reported that expert as opposed to caregiver/lay explanations and demonstrations supported participant engagement with the intervention and short videos (~ 2 minutes) were more engaging than longer content (51). A further paper highlighted the potential of gamification and repeatable content may sustain interest, but this was

not assessed directly (88). Furthermore, online formats were beneficial to aspects of participant burden, including that associated with commuting time, reducing stigma, and supporting a more comfortable therapeutic relationship—possibly due to the “online disinhibition effect” (74).

DISCUSSION

This review of 60 papers (58 RCTs) found that, although DCTs are increasingly used in mental health research, reporting of equity-related demographics is inconsistent. Gender and age were universally reported, but items such as race/ethnicity, occupation, SES, place of residence, and religion were often missing. Evidence that DCTs enhance inclusion of underserved groups was limited. Barriers to equitable participation included digital access, literacy, and participant burden, while enablers included therapist/navigator support and simplified onboarding.

This review has several strengths. Unlike many others, it incorporated PPI from the outset, shaping the research focus and data extraction (99). To our knowledge, it is the first systematic review to apply PROGRESS-Plus to DCTs in mental health and to compare sociodemographic representation against national statistics. Previous reviews have focused on reporting quality (10, 100), whereas ours addressed representativeness. It is also uniquely specific to digital/remotely delivered mental healthcare, a global priority, and included international studies, strengthening generalisability. Our structured approach identified gaps in reporting of disadvantage-related demographics and highlighted at-risk groups for exclusion. Consistent with earlier findings, we show that despite claims that DCTs support inclusive participation, marginalised groups, particularly by ethnicity and SES, remain underreported, with religion, disability, and residence, are often overlooked (101–104). While digital literacy and comfort with telemedicine are improving (105, 106), remote/digital methods may not be sufficient to achieve inclusion in mental health research without consideration to specific methodological design. Nonetheless, the conclusions of this review should be interpreted alongside its limitations, such as that the exclusion of non-English studies and pre-2020 trials. Furthermore, inconsistent reporting of variables like socioeconomic status and social capital hindered synthesis, and dynamic demographics such as employment and education limit direct comparison with national statistics. Therefore, comparisons with national statistics should be interpreted as proxies rather than exact benchmarks.

These findings have important implications for the design and implementation of digital mental health trials (Fig. 2). For clinicians and service providers, the lack of consistent equity-relevant data reporting limits the ability to assess whether digital interventions are reaching and benefiting those most in need. Without robust demographic data, it is difficult to tailor interventions or address disparities in access and outcomes—particularly for groups historically underserved by mental health services (107, 108). For policymakers, the findings underscore the need for clearer guidance and accountability mechanisms to ensure equity is embedded in digital trial design and reporting. This includes mandating the collection and transparent reporting of PROGRESS-Plus variables, as recommended by the *PRISMA-Equity* extension and other equity-focused frameworks (32, 35), to monitor progress towards inclusive research and to inform equitable policy decisions.

Methodologically, equity must be embedded from the outset. Researchers need support to design trials that promote inclusion across the entire lifecycle, not just at recruitment. While our review focused on baseline representation, we found limited reporting on attrition by sociodemographic group, highlighting the need to prioritise equitable participation as well as access. DCTs can expand access to innovations in mental healthcare—but only if equity is embedded in their design and infrastructure. Realising this potential demands collaboration across disciplines, including methodologists, clinicians, industry, and patient representatives. It is also important to explore how different models of decentralisation (e.g., remote recruitment, virtual intervention delivery, and digital follow-up) affect participation, engagement, and outcomes across diverse groups. Inconsistent practices and limited reporting continue to obscure representativeness and limit generalisability.

Conclusion. Although DCTs are promoted as a way to broaden participation in mental health research, equity in access remains unachieved. Socially disadvantaged groups are inconsistently reported and often underrepresented. Without standardised, equity-focused data collection, it is difficult to identify who is included or excluded. As digital mental health expands, the field must address structural and methodological barriers alongside technological innovation.

Contributors

SSH, ES, HH, CP, and JM, were responsible for the concept. SSH, ES, CLH, NR, AJ were responsible for carrying out the searches and synthesis. SSH and ES drafted the manuscript with CP conducting statical evaluations. All authors critically revised the manuscript for important intellectual content and approved the final version. SSH is the guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Declarations

Competing interests:

The authors have no competing interests to declare.

Human Ethics and Consent to Participate declarations

Not applicable

Funding:

SSH time was supported by an NIHR Development and Skills Enhancement (DSE) Fellowship (NIHR306083). The time provided by CLH was supported by an NIHR Development and Skills Enhancement Award (NIHR304774). The NIHR had no role in design of the study, data collection, analysis, or interpretation; in the writing of the report; or in the decision to submit the article for publication. The views expressed are those of the authors and not necessarily those of the NIHR or Department of Health and Social Care.

Author Contribution

SSH, ES, HH, CP, and JM, were responsible for the concept. SSH, ES, CLH, NR, AJ were responsible for carrying out the searches and synthesis. SSH and ES drafted the manuscript with CP conducting statical evaluations. All authors critically revised the manuscript for important intellectual content and approved the final version. SSH is the guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Acknowledgement

We would like to thank our PPI group for their input and support throughout the review.

References

1. Department of Health and Social Care. Fit for the Future: 10 Year Health Plan for England. Gov.uk2025.
2. Organisation WH. Global strategy on digital health 2020–2025 2020 [Available from: <https://iris.who.int/bitstream/handle/10665/344249/9789240020924-eng.pdf?sequence=1>.
3. Word Health Organisation. Addressing the digital determinants of youth mental health and well-being: policy brief. 2025. Available from: <https://www.who.int/europe/publications/i/item/WHO-EURO-2025-12187-51959-79685> (accessed 8th September 2025).
4. Kuhn E, Saleem M, Klein T, Köhler C, Fuhr DC, Lahutina S, et al. Interdisciplinary perspectives on digital technologies for global mental health. PLOS Global Public Health. 2024;4(2):e0002867.
5. Liu M, Schueller SM. Moving evidence-based mental health interventions into practice: implementation of digital mental health interventions. Current treatment options in psychiatry. 2023;10(4):333–45.

6. Smuck M, Odonkor CA, Wilt JK, Schmidt N, Swiernik MA. The emerging clinical role of wearables: factors for successful implementation in healthcare. *NPJ digital medicine*. 2021;4(1):45.
7. Bothwell LE, Greene JA, Podolsky SH, Jones DS. Assessing the gold standard—lessons from the history of RCTs. *N Engl J Med*. 2016;374(22):2175–81.
8. BATTERY SC, Philip KE, Alghamdi SM, Williams PJ, Quint JK, Hopkinson NS. Reporting of data on participant ethnicity and socioeconomic status in high-impact medical journals: a targeted literature review. *BMJ open*. 2022;12(8):e064276.
9. Khanum M, Dawson S, Dos Santos J, Hajinur H, Conefrey C, Paramasivan S. Time to look beyond (and before) journal reporting requirements: a review of ethnicity reporting in UK clinical trial results publications in three high-impact journals. *Trials*. 2024;25(1):843.
10. Orkin AM, Nicoll G, Persaud N, Pinto AD. Reporting of sociodemographic variables in randomized clinical trials, 2014–2020. *JAMA Network Open*. 2021;4(6):e2110700-e.
11. Parikh H, Ross RK, Stuart E, Rudolph KE. Who Are We Missing?: A Principled Approach to Characterizing the Underrepresented Population. *Journal of the American Statistical Association*. 2025(just-accepted):1–32.
12. Wallace N, O'Keeffe S, Gardner H, Shiely F. Underrecording and underreporting of participant ethnicity in clinical trials is persistent and is a threat to inclusivity and generalizability. *Journal of Clinical Epidemiology*. 2023;162:81–9.
13. Daitch V, Turjeman A, Poran I, Tau N, Ayalon-Dangur I, Nashashibi J, et al. Underrepresentation of women in randomized controlled trials: a systematic review and meta-analysis. *Trials*. 2022;23(1):1038.
14. Ramos G, Hernandez-Ramos R, Taylor M, Schueller SM. State of the science: using digital mental health interventions to extend the impact of psychological services. *Behavior Therapy*. 2024;55(6):1364–79.
15. Orri M, Lipset CH, Jacobs BP, Costello AJ, Cummings SR. Web-based trial to evaluate the efficacy and safety of tolterodine ER 4 mg in participants with overactive bladder: REMOTE trial. *Contemporary clinical trials*. 2014;38(2):190–7.
16. Stern AD, Trusheim M. Transformation of the Clinical Trial Enterprise: Lessons Learned from the COVID-19 Pandemic: Office of the Assistant Secretary for Planning and Evaluation (ASPE); 2024 Feb 9. PMID: 39527681.
17. McCarthy MW, Lindsell CJ, Rajasingham R, Stewart TG, Boulware DR, Naggie S. Progress toward realizing the promise of decentralized clinical trials. *Journal of Clinical and Translational Science*. 2024;8(1):e19.
18. Kohl SH, Schmidt-Lucke C. Clinical trials to go green—A sustainable argument for decentralised digital clinical trials. *PLOS Digital Health*. 2023;2(10):e0000366.
19. Health NCCfM. Delivering greener, more sustainable and net zero mental health care: Guidance and recommendations. London: National Collaborating Centre for Mental Health; 2023.
20. Iflaifel M, Hall CL, Green HR, Willis A, Rennick-Egglestone S, Juszcak E, et al. Strategies to improve recruitment in mental health clinical trials: a scoping review (RE-MIND study). *Trials*. 2024;25(1):832.
21. Spanakis P, Mathers A, Walker L, Huxley P, Peckham E. The digital divide in people with severe mental illness: lessons learned and challenges lying ahead. *The British Journal of Psychiatry*. 2025:1–3.
22. Licari MK, Finlay-Jones A, Reynolds JE, Alvares GA, Spittle AJ, Downs J, et al. The brain basis of comorbidity in neurodevelopmental disorders. *Current developmental disorders reports*. 2019;6(1):9–18.
23. Rosen TE, Mazefsky CA, Vasa RA, Lerner MD. Co-occurring psychiatric conditions in autism spectrum disorder. *International review of psychiatry*. 2018;30(1):40–61.
24. Fletcher-Watson S, Brook K, Hallett S, Murray F, Crompton CJ. Inclusive practices for neurodevelopmental research. *Current Developmental Disorders Reports*. 2021;8(2):88–97.
25. van Rijssel TI, van Delden JJ, Lagerwaard B, Zuidgeest MG, van Thiel GJ. Diversity in decentralized clinical trials: prioritizing inclusion of underrepresented groups. *BMC Medical Ethics*. 2025;26:51.
26. Berardi C, Antonini M, Jordan Z, Wechtler H, Paolucci F, Hinwood M. Barriers and facilitators to the implementation of digital technologies in mental health systems: a qualitative systematic review to inform a policy framework. *BMC health services research*. 2024;24(1):243.

27. Kirkbride JB, Anglin DM, Colman I, Dykxhoorn J, Jones PB, Patalay P, et al. The social determinants of mental health and disorder: evidence, prevention and recommendations. *World psychiatry*. 2024;23(1):58–90.
28. Mutluer T, Aslan Genç H, Özcan Morey A, Yapici Eser H, Ertinmaz B, Can M, et al. Population-based psychiatric comorbidity in children and adolescents with autism spectrum disorder: a meta-analysis. *Frontiers in Psychiatry*. 2022;13:856208.
29. Xie C, Xiang S, Shen C, Peng X, Kang J, Li Y, et al. A shared neural basis underlying psychiatric comorbidity. *Nature medicine*. 2023;29(5):1232–42.
30. Aiyegbusi OL, Cruz Rivera S, Kamudoni P, Anderson N, Collis P, Denniston AK, et al. Recommendations to promote equity, diversity and inclusion in decentralized clinical trials. *Nature Medicine*. 2024:1–10.
31. Treweek S, Banister K, Bower P, Cotton S, Devane D, Gardner HR, et al. Developing the INCLUDE Ethnicity Framework—a tool to help trialists design trials that better reflect the communities they serve. *Trials*. 2021;22(1):337.
32. Welch V, Petticrew M, Tugwell P, Moher D, O'Neill J, Waters E, et al. PRISMA-Equity 2012 extension: reporting guidelines for systematic reviews with a focus on health equity. *PLoS medicine*. 2012;9(10):e1001333.
33. Saaiq M, Ashraf B. Modifying “Pico” question into “Picos” model for more robust and reproducible presentation of the methodology employed in a scientific study. *World journal of plastic surgery*. 2017;6(3):390.
34. Avula N, Kakach D, Tignanelli CJ, Liebovitz DM, Nicklas JM, Cohen K, et al. Strategies used for the COVID-OUT decentralized trial of outpatient treatment of SARS-CoV-2. *J Clin Transl Sci*. 2023;7(1):e242.
35. 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.
36. Murali M, Gumber L, Jethwa H, Ganesh D, Hartmann-Boyce J, Sood H, et al. Ethnic minority representation in UK COVID-19 trials: systematic review and meta-analysis. *BMC medicine*. 2023;21(1):111.
37. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative research in psychology*. 2006;3(2):77–101.
38. Felder JN, Epel ES, Neuhaus J, Krystal AD, Prather AA. Efficacy of Digital Cognitive Behavioral Therapy for the Treatment of Insomnia Symptoms Among Pregnant Women: A Randomized Clinical Trial. *JAMA Psychiatry*. 2020;77(5):484–92.
39. Felder JN, Epel ES, Neuhaus J, Krystal AD, Prather AA. Randomized controlled trial of digital cognitive behavior therapy for prenatal insomnia symptoms: effects on postpartum insomnia and mental health. *Sleep*. 2022;45(2).
40. Carl JR, Miller CB, Henry AL, Davis ML, Stott R, Smits JAJ, et al. Efficacy of digital cognitive behavioral therapy for moderate-to-severe symptoms of generalized anxiety disorder: A randomized controlled trial. *Depression and Anxiety*. 2020;37(12):1168–78.
41. Eylem O, van Straten A, de Wit L, Rathod S, Bhui K, Kerkhof AJFM. Reducing suicidal ideation among Turkish migrants in the Netherlands and in the UK: the feasibility of a randomised controlled trial of a guided online intervention. *Pilot and Feasibility Studies*. 2021;7(1):30.
42. Hall CL, Gómez Bergin AD, Rennick-Egglestone S. Research Into Digital Health Intervention for Mental Health: 25-Year Retrospective on the Ethical and Legal Challenges. *J Med Internet Res*. 2024;26:e58939.
43. Haun JN, Venkatachalam HH, Fowler CA, Alman AC, Ballistrea LM, Schneider T, et al. Mobile and Web-Based Partnered Intervention to Improve Remote Access to Pain and Posttraumatic Stress Disorder Symptom Management: Recruitment and Attrition in a Randomized Controlled Trial. *Journal of Medical Internet Research*. 2023;25(1):e49678.
44. He Y, Yang L, Zhu X, Wu B, Zhang S, Qian C, et al. Mental Health Chatbot for Young Adults With Depressive Symptoms During the COVID-19 Pandemic: Single-Blind, Three-Arm Randomized Controlled Trial. *J Med Internet Res*. 2022;24(11):e40719.
45. Andrews B, Klein B, Van Nguyen H, Corboy D, McLaren S, Watson S. Efficacy of a Digital Mental Health Biopsychosocial Transdiagnostic Intervention With or Without Therapist Assistance for Adults With Anxiety and Depression: Adaptive Randomized Controlled Trial. *Journal of Medical Internet Research*. 2023;25:e45135. doi: 10.2196/45135
46. Lewis S, Rinehart N, Mantilla A, Alvares G, Hiscock H, Marks D, et al. A pilot randomised controlled trial of a telehealth-delivered brief 'Sleeping Sound Autism' intervention for autistic children. *Sleep medicine*. 2024;124(100898759):162–73.

47. March S, Spence SH, Myers L, Ford M, Smith G, Donovan CL. Integrating Videoconferencing Therapist Guidance Into Stepped Care Internet-Delivered Cognitive Behavioral Therapy for Child and Adolescent Anxiety: Noninferiority Randomized Controlled Trial. *JMIR Ment Health*. 2025;12:e57405.
48. March S, Spence SH, Myers L, Ford M, Smith G, Donovan CL. Stepped-care versus therapist-guided, internet-based cognitive behaviour therapy for childhood and adolescent anxiety: A non-inferiority trial. *Internet Interv*. 2023;34:100675.
49. McLellan LF, Woon S, Hudson JL, Lyneham HJ, Karin E, Rapee RM. Treating child anxiety using family-based internet delivered cognitive behavior therapy with brief therapist guidance: A randomized controlled trial. *J Anxiety Disord*. 2024;101:102802.
50. Heller HM, Hoogendoorn AW, Honig A, Broekman BFP, van Straten A. The Effectiveness of a Guided Internet-Based Tool for the Treatment of Depression and Anxiety in Pregnancy (MamaKits Online): Randomized Controlled Trial. *Journal of medical Internet research*. 2020;22(3):e15172.
51. Jent JF, Rothenberg WA, Weinstein A, Stokes J, Barnett M, Srivatsa N, et al. Comparing Traditional and Ebook-Augmented Parent-Child Interaction Therapy (PCIT): A Randomized Control Trial of Pocket PCIT. *Behavior therapy*. 2021;52(6):1311–24.
52. Tan S, Ismail MAB, Daud TIM, Hod R, Ahmad N. A randomized controlled trial on the effect of smartphone-based mental health application among outpatients with depressive and anxiety symptoms: A pilot study in Malaysia. *Indian Journal of Psychiatry*. 2023;65(9):934EP-40.
53. Carl JR, Miller CB, Henry AL, Davis ML, Stott R, Smits JAJ, et al. Efficacy of digital cognitive behavioral therapy for moderate-to-severe symptoms of generalized anxiety disorder: A randomized controlled trial. *Depress Anxiety*. 2020;37(12):1168–78.
54. Guzik AG, Schneider SC, Kook M, Greenberg R, Perozo-Garcia A, Lee MP, et al. Internet-based, parent-led cognitive behavioral therapy for autistic youth with anxiety-related disorders: A randomized trial comparing email vs. telehealth support. *Behav Res Ther*. 2024;183:104639.
55. Guzik AG, Schneider SC, Perozo Garcia AB, Kook M, Greenberg RL, Riddle D, et al. Development and pilot testing of internet-delivered, family-based cognitive behavioral therapy for anxiety and obsessive-compulsive disorders in autistic youth. *Journal of Obsessive-Compulsive and Related Disorders*. 2023; Apr 1;37:100789
56. Huberty J, Puzia ME, Green J, Vlisides-Henry RD, Larkey L, Irwin MR, et al. A mindfulness meditation mobile app improves depression and anxiety in adults with sleep disturbance: Analysis from a randomized controlled trial. *Gen Hosp Psychiatry*. 2021;73:30–7.
57. Kalmbach DA, Cheng P, O'Brien LM, Swanson LM, Sangha R, Sen S, et al. A randomized controlled trial of digital cognitive behavioral therapy for insomnia in pregnant women. *Sleep Med*. 2020;72:82–92.
58. Kenworthy L, Childress D, Armour AC, Verbalis A, Zhang A, Troxel M, et al. Leveraging technology to make parent training more accessible: Randomized trial of in-person versus online executive function training for parents of autistic children. *Autism: the international journal of research and practice*. 2023;27(3):616–28.
59. Malarkey ME, Fu AJ, Mannan N, Shaw OM, Haight TJ, Cota MR, et al. Internet-Guided Cognitive Behavioral Therapy for Insomnia Among Patients With Traumatic Brain Injury: A Randomized Clinical Trial. *JAMA Network Open*. 2024;7(7):e2420090.
60. Ong LE, Speicher S, Villasenor D, Kim J, Jacobs A, Macia KS, et al. Brief Peer-Supported Web-Based Skills Training in Affective and Interpersonal Regulation (BPS webSTAIR) for Trauma-Exposed Veterans in the Community: Randomized Controlled Trial. *Journal of Medical Internet Research*. 2024;Oct 2;26:e52130.
61. Piscitello J, Leon D, Ramos MC, Robertson EL, Altszuler AR, Pelham WE. A randomized controlled trial of a virtually delivered group parent training for parents of children with adhd during an intensive summer treatment program. *Evidence-Based Practice in Child and Adolescent Mental Health*. 2025;10(2):450–64.
62. Possemato K, Wu J, Greene C, MacQueen R, Blonigen D, Wade M, et al. Web-Based Problem-solving Training With and Without Peer Support in Veterans With Unmet Mental Health Needs: Pilot Study of Feasibility, User Acceptability, and Participant Engagement. *Journal of Medical Internet Research*. 2022;24(1):e29559.

63. Segal ZV, Dimidjian S, Beck A, Boggs JM, Vanderkruik R, Metcalf CA, et al. Outcomes of Online Mindfulness-Based Cognitive Therapy for Patients With Residual Depressive Symptoms: A Randomized Clinical Trial. *JAMA Psychiatry*. 2020;77(6):563–73.
64. Clark DM, Wild J, Warnock-Parkes E, Stott R, Grey N, Thew G, et al. More than doubling the clinical benefit of each hour of therapist time: a randomised controlled trial of internet cognitive therapy for social anxiety disorder. *Psychological medicine*. 2023;53(11):5022EP-32.
65. Creswell C, Taylor L, Giles S, Howitt S, Radley L, Whitaker E, et al. Digitally augmented, parent-led CBT versus treatment as usual for child anxiety problems in child mental health services in England and Northern Ireland: a pragmatic, non-inferiority, clinical effectiveness and cost-effectiveness randomised controlled tri. *Lancet Psychiatry*. 2024;11(3):193–209.
66. Hollis C, Hall CL, Jones R, Marston L, Le Novere M, Hunter R, et al. Therapist-supported online remote behavioural intervention for tics in children and adolescents in England (ORBIT): a multicentre, parallel group, single-blind, randomised controlled trial. *The Lancet Psychiatry*. 2021;8(10):871–82.
67. Richards D, Enrique A, Eilert N, Franklin M, Palacios J, Duffy D, et al. A pragmatic randomized waitlist-controlled effectiveness and cost-effectiveness trial of digital interventions for depression and anxiety. *NPJ Digit Med*. 2020;3:85.
68. Sayal K, Wyatt L, Partlett C, Ewart C, Bhardwaj A, Dubicka B, et al. The clinical and cost effectiveness of a STandardised Dlagnostic Assessment for children and adolescents with emotional difficulties: the STADIA multi-centre randomised controlled trial. *J Child Psychol Psychiatry*. 2025;66(6):805–20.
69. Sun Y, Li Y, Wang J, Chen Q, Bazzano AN, Cao F. Effectiveness of smartphone-based mindfulness training on maternal perinatal depression: Randomized controlled trial. *Journal of Medical Internet Research*. 2021;23(1):e23410.
70. Wong VW, Ho FY, Shi NK, Tong JT, Chung KF, Yeung WF, et al. Smartphone-delivered multicomponent lifestyle medicine intervention for depressive symptoms: A randomized controlled trial. *J Consult Clin Psychol*. 2021;89(12):970–84.
71. Eto A, Endo A, Yoshida T, Seki Y, Taguchi K, Hongo M, et al. Videoconference-Based Cognitive Behavioral Therapy in Medication-Treated Adults with Attention-Deficit/Hyperactivity Disorder: A Randomized, Assessor-Blinded, Controlled Trial. *Psychotherapy and psychosomatics*. 2025(qha, 0024046):1–25.
72. Grenier-Martin J, Rivard M, Patel S, Lanovaz MJ, Lefebvre C. Randomized controlled trial on an online training to support caregivers of young children with intellectual and developmental disability managing problem behaviors at home. *Journal of Child and Family Studies*. 2022;31(12):3485–97.
73. Hoffmann D, Rask CU, Hedman-Lagerlof E, Jensen JS, Frosthalm L. Efficacy of internet-delivered acceptance and commitment therapy for severe health anxiety: results from a randomized, controlled trial. *Psychological medicine*. 2021;51(15):2685EP-95.
74. Lippke S, Gao L, Keller FM, Becker P, Dahmen A. Adherence with online therapy vs face-to-face therapy and with online therapy vs care as usual: Secondary analysis of two randomized controlled trials. *Journal of Medical Internet Research*. 2021;23(11):e31274.
75. Seo JM, Kim SJ, Na H, Kim JH, Lee H. Effectiveness of a Mobile Application for Postpartum Depression Self-Management: Evidence from a Randomised Controlled Trial in South Korea. *Healthcare (Basel)*. 2022;10(11).
76. Nardi W, Roy A, Dunsiger S, Brewer J. Analyzing the Impact of Mobile App Engagement on Mental Health Outcomes: Secondary Analysis of the Unwinding Anxiety Program. *Journal of Medical Internet Research*. 2022;24(8):e33696.
77. Backman A, Roll-Pettersson L, Mellblom A, Norman-Claesson E, Sundqvist E, Zander E, et al. Internet-delivered psychoeducation (SCOPE) for transition-aged autistic youth: Pragmatic randomized controlled trial. *Journal of Medical Internet Research*. 2024;26.
78. Nissling L, Weineland S, Vernmark K, Radvogin E, Engström AK, Schmidt S, et al. Effectiveness of and processes related to internet-delivered acceptance and commitment therapy for adolescents with anxiety disorders: a randomized controlled trial. *Res Psychother*. 2023;26(2).
79. Nordh M, Wahlund T, Jolstedt M, Sahlin H, Bjureberg J, Ahlen J, et al. Therapist-Guided Internet-Delivered Cognitive Behavioral Therapy vs Internet-Delivered Supportive Therapy for Children and Adolescents With Social Anxiety Disorder: A Randomized Clinical Trial. *JAMA Psychiatry*. 2021;78(7):705–13.

80. Fatouros P, Tsirmpas C, Andrikopoulos D, Kaplow S, Kontoangelos K, Papageorgiou C. Randomized controlled study of a digital data driven intervention for depressive and generalized anxiety symptoms. *NPJ Digit Med.* 2025;8(1):113.
81. Jamali AR, Zarei MA, Sanjari MA, AkbarFahimi M, Saneii SH. Randomized controlled trial of occupation performance coaching for families of children with autism spectrum disorder by means of telerehabilitation. *The British Journal of Occupational Therapy.* 2022;85(5):308–15.
82. Kwon SY, Seo G, Jang M, Shin H, Choi W, Lim YB, et al. The Effect of Mobile Neurofeedback Training in Children with Attention Deficit Hyperactivity Disorder: A Randomized Controlled Trial. *Clin Psychopharmacol Neurosci.* 2024;22(1):67–78.
83. Lindgren S, Wacker D, Schieltz K, Suess A, Pelzel K, Kopelman T, et al. A Randomized Controlled Trial of Functional Communication Training via Telehealth for Young Children with Autism Spectrum Disorder. *J Autism Dev Disord.* 2020;50(12):4449–62.
84. Sabri B, Perrin N, Hagos M. The Being Safe, Health and Positively Empowered Pilot Randomized Controlled Trial: A Digital Multicomponent Intervention for Immigrant Women With Cumulative Exposures to Violence. *Cultural Diversity and Ethnic Minority Psychology.* 2025;31(2):271EP-84.
85. Bennett SD, Heyman I, Coughtrey AE, Varadkar S, Stephenson T, Shafran R. Telephone-guided self-help for mental health difficulties in neurological conditions: a randomised pilot trial. *Archives of disease in childhood.* 2021;106(9):862–7.
86. Kandola A, Edwards K, Muller MA, Dührkoop B, Hein B, Straatman J, et al. Digitally managing depression: A fully remote randomised attention-placebo controlled trial. *Digit Health.* 2024;10:20552076241260409.
87. McCloud T, Jones R, Lewis G, Bell V, Tsakanikos E. Effectiveness of a Mobile App Intervention for Anxiety and Depression Symptoms in University Students: Randomized Controlled Trial. *JMIR Mhealth Uhealth.* 2020;8(7):e15418.
88. Hartley M, Dorstyn D, Due C. Challenges encountered with a mindfulness app: Lessons learnt from a pilot randomized trial involving caregivers and individuals with autism. *Research in Autism Spectrum Disorders.* 2022;96(Ahmed, K.L., Simon, A.R., Dempsey, J.R., Samaco, R.C., & Goin-Kochel, R.P. (2020). Evaluating two common strategies for research participant recruitment into autism studies: Observational study. *Journal of Medical Internet Research*, 22(9) <https://dx.doi.org/10.2196/19199>:1-9.
89. Murray G, Thomas N, Michalak EE, Jones SH, Lapsley S, Bowe SJ, et al. Mindfulness-Based Online Intervention to Improve Quality of Life in Late-Stage Bipolar Disorder: A Randomized Clinical Trial. *Journal of Consulting and Clinical Psychology.* 2021;89(10):830EP-44.
90. Mechler J, Lindqvist K, Carlbring P, Topooco N, Falkenström F, Lilliengren P, et al. Therapist-guided internet-based psychodynamic therapy versus cognitive behavioural therapy for adolescent depression in Sweden: a randomised, clinical, non-inferiority trial. *Lancet Digit Health.* 2022;4(8):e594-e603.
91. Tan Y, Lyu R, Lu S. Reducing parenting stress in Chinese parents of children with learning disabilities with a mindful parenting program: A randomized controlled trial. *Research in developmental disabilities.* 2024;151(8709782, rid):104794.
92. Wu Y, Li X, Zhou Y, Gao R, Wang K, Ye H, et al. Efficacy and Cost-Effectiveness Analysis of Internet-Based Cognitive Behavioral Therapy for Obsessive-Compulsive Disorder: Randomized Controlled Trial. *Journal of Medical Internet Research.* 2023;25e41283.
93. Döpfner M, Plück J, Rosenberger KD, Klemp MT, Mühlenmeister J, Wahnke L, et al. Efficacy of guided and unguided web-assisted self-help for parents of children with attention-deficit/hyperactivity disorder and oppositional defiant disorder: A three-arm randomized controlled trial. *J Child Psychol Psychiatry.* 2025. <https://doi.org/10.1111/jcpp.14153>
94. Moshe I, Terhorst Y, Paganini S, Schlicker S, Pulkki-Raback L, Baumeister H, et al. Predictors of Dropout in a Digital Intervention for the Prevention and Treatment of Depression in Patients with Chronic Back Pain: Secondary Analysis of Two Randomized Controlled Trials. *Journal of Medical Internet Research.* 2022;24(8):e38261.
95. Chan CS, Wong CYF, Yu BYM, Hui VKY, Ho FYY, Cuijpers P. Treating depression with a smartphone-delivered self-help cognitive behavioral therapy for insomnia: a parallel-group randomized controlled trial. *Psychol Med.* 2023;53(5):1799–813.
96. Chien C-W, Lin C-Y, Lai CYY, Graham F. Parent coaching to enhance community participation in young children with developmental disabilities: A pilot randomized controlled trial. *Research in developmental disabilities.* 2024;147(8709782,

rid):104696.

97. Bikic A, Leckman JF, Christensen T, Bilenberg N, Dalsgaard S. Attention and executive functions computer training for attention-deficit/hyperactivity disorder (ADHD): results from a randomized, controlled trial. *Eur Child Adolesc Psychiatry*. 2018;27(12):1563–74.
98. Bilan DS, Chicchi Giglioli IA, Cuesta P, Cañadas E, de Ramón I, Maestú F, et al. Decreased impulsiveness and MEG normalization after AI-digital therapy in ADHD children: a RCT. *Npj Ment Health Res*. 2025;4(1):1.
99. Zhou Q, He H, Li Q, Zhao J, Wang L, Luo Z, et al. Patient and public involvement in systematic reviews: frequency, determinants, stages, barriers, and dissemination. *Journal of Clinical Epidemiology*. 2024;170:111356.
100. Ong SW, Blagojevic C, Bryce A, Ovadia A, Slater M, Pryal D, et al. Reporting of sociodemographic characteristics of trial participants in infectious diseases clinical trials—a systematic review. *Clinical Microbiology and Infection*. 2025. <https://doi.org/10.1016/j.cmi.2025.04.030>
101. Vayena E, Blasimme A, Sugarman J. Decentralised clinical trials: ethical opportunities and challenges. *The Lancet Digital Health*. 2023;5(6):e390-e4.
102. Al M, Levison S, Berdel WE, Andersen DZ. Decentralised elements in clinical trials: recommendations from the European Medicines Regulatory Network. *Lancet (London, England)*. 2023;401(10385):1339.
103. Selvakumaran K, Sleeman KE, Davies JM. How good are we at reporting the socioeconomic position, ethnicity, race, religion and main language of research participants? A review of the quality of reporting in palliative care intervention studies. *Palliative Medicine*. 2024;38(3):396–9.
104. Cunningham S, Russell AM, Lidington E, Shiely F. Lack of data collection in clinical trials prevents us from evaluating inclusion of people with disabilities. *Journal of Clinical Epidemiology*. 2025;181:111715.
105. Rosa C, Marsch LA, Winstanley EL, Brunner M, Campbell AN. Using digital technologies in clinical trials: current and future applications. *Contemporary clinical trials*. 2021;100:106219.
106. Aiyegbusi OL, Davies EH, Myles P, Williams T, Frost C, Haroon S, et al. Digitally enabled decentralised research: opportunities to improve the efficiency of clinical trials and observational studies. *BMJ evidence-based medicine*. 2023;28(5):328–31.
107. Kammer-Kerwick M, Cox K, Purohit I, Watkins SC. The role of social determinants of health in mental health: an examination of the moderating effects of race, ethnicity, and gender on depression through the all of us research program dataset. *PLOS Mental Health*. 2024;1(3):e0000015.
108. Pierce M, McManus S, Jessop C, John A, Hotopf M, Ford T, et al. Says who? The significance of sampling in mental health surveys during COVID-19. *The Lancet Psychiatry*. 2020;7(7):567–8.

Figures

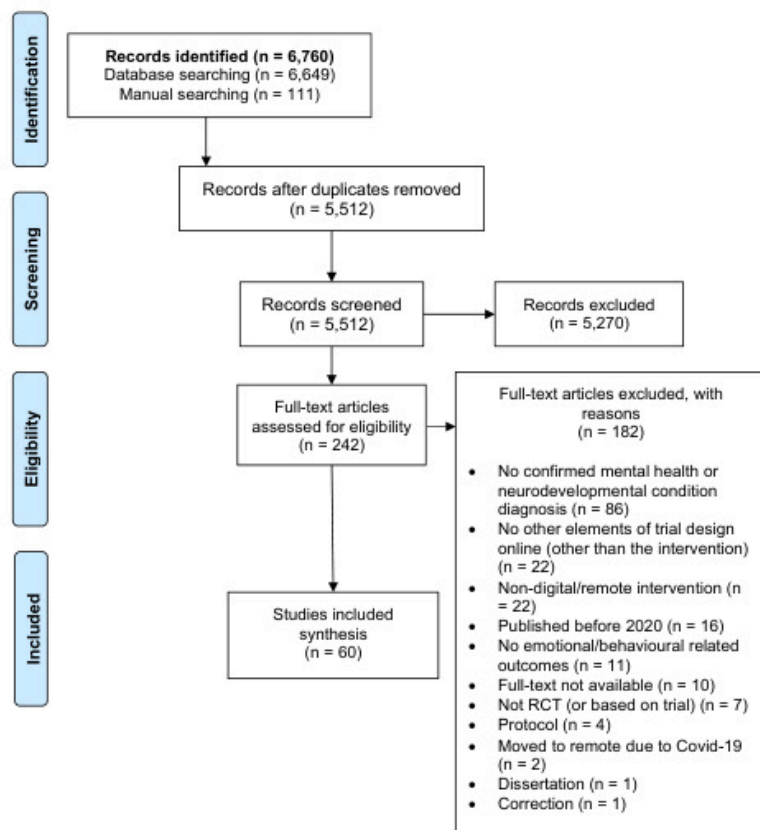


Figure 1. PRISMA diagram of paper selection process

Figure 1

See image above for figure legend.

- **Reporting gaps:** Most digital mental health DCTs report only age and gender; equity-relevant demographics (e.g., ethnicity, socioeconomic status, disability, religion, rurality) are rarely captured. Without these data, assessing representativeness is impossible.
- **Inclusive trial design:** Remote delivery alone does not guarantee equity. Trials must address barriers such as digital literacy, connectivity, stigma, and cognitive or emotional challenges that limit engagement.
- **Practical enablers:** Simplified onboarding, hybrid digital–face-to-face options, and tailored support (e.g., therapist or navigator roles) can increase participation and retention of underserved groups.
- **Framework use:** Applying PROGRESS-Plus systematically and benchmarking trial samples against national statistics can reveal who is being excluded and guide adaptive recruitment strategies.
- **Future research:** Digital mental health DCTs should explicitly test methods to reduce exclusion (e.g., providing devices/data, culturally adapted interfaces, accessible consent processes), embedding inclusivity as a core trial outcome.
- **Patient and Public Involvement:** Understanding the barrier and enablers to participation in DCTs by a range of mental health populations is essential to future design efforts.

Figure 2. Implications for Digital Mental Health

Figure 2

See image above for figure legend.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [HallTablesincludedinthemanuscriptSubmit.docx](#)
- [SupplementaryMaterial3.Listofdataextractedfromincludedpapers.docx](#)
- [SupplementaryMaterial6.Calculationsforincome.docx](#)
- [SupplementaryMaterial4.Listofincludedpapers.docx](#)

- [SupplementaryMaterial2.MEDLINEsearchstrategy.docx](#)
- [SupplementaryMaterial5.Sociodemographiccharacteristics.docx](#)
- [SupplementaryMaterial1.PRISMAEquityChecklist.docx](#)