Building community capacity in mental health care with the Strong Minds–Strong Communities programme: a randomised controlled trial in the USA

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Summary

Background Provider shortages and lack of culturally responsive care limit mental health services in reaching multicultural populations worldwide. We examined the effectiveness of a psychoeducational intervention aimed at building community capacity to address depression and anxiety among racial, ethnic, and linguistic minoritised adults.

Methods Strong Minds–Strong Communities (SM–SC) was a 6-month, multicentre, longitudinal, randomised trial done in 37 community-based organisations and clinics in two US sites (Massachusetts and North Carolina). Adults aged 18 years and older speaking English, Spanish, Mandarin, or Cantonese, with moderate to severe depression or anxiety symptoms assessed using the Computerized Adaptive Test for Mental Health (CAT-MH), were eligible for inclusion. Participants were randomly assigned (1:1) to a psychoeducational intervention provided by community health workers or a usual care condition, which constituted receiving a US National Institutes of Health booklet about anxiety and depression. Both conditions included referrals for social determinants of health needs. Randomisation was stratified by site using computer-generated blocks of size 2. Investigators and participants were not masked to treatment allocation, but outcome assessors were. Primary outcomes were changes from baseline at months 6 and 12 in self-reported depression and anxiety symptoms using the Hopkins Symptom Checklist-25 (HSCL-25), level of functioning using the World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2·0), and perceived quality of care using the Global Evaluation of Care domain of the Perceptions of Care Outpatient Survey (PoC-OP) in the intention-to-treat population. The study is registered with ClinicalTrials.gov, NCT04092777, and has been completed.

Findings From Sept 4, 2019, to March 3, 2023, 5265 potential participants were approached for study inclusion. 2681 were excluded and 2584 were assessed for eligibility. A further 1417 were excluded, and 1167 were deemed eligible for study inclusion. 1044 participants were randomly assigned, 524 to the SM–SC intervention and 520 to the usual care group. The mean age of participants was 42·6 years (SD 13·3) and 875 (83·8%) were female, 165 (15·8%) were male, and four (0·4%) were other. Between baseline and 6 months, intervention participants reported greater improvements in depression and anxiety symptoms (standardised effect size, 0·39 [95% CI 0·27–0·52]), functioning (standardised effect size, 0·28 [0·16–0·39]), and perceived quality of care (standardised effect size, 0·47 [0·31–0·62]). These greater improvements in depression and anxiety symptoms, functioning, and perceived quality of care attenuated but remained significant 6 months post-intervention (standardised effect sizes of 0·28 [95% CI 0·16–0·40] for depression and anxiety, 0·21 [0·08–0·33]) for functioning, and 0·33 [0·16 –0·50] for perceived quality of care).

Interpretation The intervention shows that a culturally adapted intervention can improve depression and anxiety symptoms in Black, Latino, and Asian populations and provides an alternative to mental health care shortages by building community capacity.

Funding National Institute of Mental Health.

Introduction

Immigration has challenged public health around the world. Many counties lack sufficient resources to serve health-care needs, including a workforce to address linguistic, ethnic, racial, and cultural differences of new arrivals.[1] The influx of immigrants seeking better life opportunities, protection from violence, or fleeing war and torture has forced US, European, and Asian countries to recognise the need to serve multicultural populations,[1] often in need of mental health care.[2] According to the WHO 2022 Mental Health Report, nearly 1 billion people globally are living with a mental

Research in context

Evidence before this study

Substantial disparities in mental health care exist for racial, ethnic, and linguistic minoritised populations, who are less likely to start and remain in treatment and receive quality care. There is considerable empirical support for brief, manualised, and scalable skill-based interventions delivered by licensed clinicians or experts to reduce symptoms of depression or anxiety in adults. However, few providers that can offer culturally and linguistically responsive evidence-based mental health care, and a shortage of trained providers can exacerbate mental health service disparities for diverse communities. Community health workers with expertise in engaging with diverse communities and who might themselves have community connections have been successful in increasing mental health access for minoritised populations. We systematically searched PsychInfo and Web of Science for evidence of brief, scalable, or community health worker-led mental health interventions using the terms (("psychosocial intervention") OR ("mental health intervention")) AND ("community health worker") OR ("brief") OR ("scalable") without date or country restrictions. Only articles published in English were included. We found evidence for multiple brief community health worker-led mental health interventions for racial and ethnic minoritised groups, older adults, and individuals with disabilities. One was a problem-solving mental health intervention for low-income adolescents in India. Another was a combined behavioural activation and social learning intervention for older Latinx adults with anxiety and depression. A final example was a parenting and nutrition intervention that also had secondary effects on maternal depressive symptoms in Tanzania. Most of these studies only utilised participants from one specific racial or ethnic minoritised group. We could not find any randomised controlled trials that were administered in more than two languages or that utilised social determinants of health referrals as a control condition. We also did not find any randomised controlled trials that assessed whether mental health outcomes could vary as a function of the participant's language, race, or ethnicity.

Added value of this study

This study adds to growing the evidence base as an intervention that is culturally responsive, linguistically appropriate, and delivered by community health workers with clinical supervision. We evaluated the intervention's effectiveness in varied practices with different populations in diverse languages. Our study enabled the community engagement and organisational readiness necessary to build capacity to tackle mental health worker shortages. As such, the intervention provides an alternative for reducing mental health symptoms and improving functioning for minoritised populations. Our study builds off previous interventions designed to reduce mental health disparities of minoritised older adults. This study demonstrates the effectiveness of a new, standardised community health worker-led mental health intervention, delivered in English, Spanish, Mandarin, and Cantonese for racial, ethnic, and linguistic minoritised populations. Participants in both treatment and control conditions received referrals to address social determinants of health needs, and thus the culturally adapted, linguistically appropriate intervention was compared with a meaningful usual care condition. We found that participants assigned to the intervention reported a significant reduction in depression and anxiety symptoms and greater improvements in the level of functioning and perceived quality of care when compared with those assigned to usual care with social determinants of health referrals.

Implications of all the available evidence

The Strong Minds–Strong Communities intervention demonstrates significant potential in mitigating racial and ethnic disparities in mental health care through the role of community experts to fill gaps in mental health services. Although racial and ethnic disparities in mental health stem from multiple factors (both at the individual and structural level), a lack of language-matched mental health services can perpetuate disparities. Multiple studies have suggested that not being able to deliver services in the dominant language of the client can decrease the quality of mental health services and discourage racial and ethnic minoritised populations from initiating and engaging in treatment. Our findings support the inclusion of community health worker-led, linguistically appropriate interventions in mental health care. Future research should examine how investment in this model can address a range of practice and health-care system challenges.

health disorder.[3] A 2021 meta-analysis of migrant workers reported the prevalence of depression to be 39% and anxiety to be 27%.[4] WHO reports severe gaps in service coverage, with depression and anxiety progressively identified as a leading threat to population health in low-income and middle-income countries (LMICs).[3] This is partly due to those in need of mental health services being mostly undetected and untreated, leading to loss of productivity, premature death, and loss of quality of life.[5] For depression, receipt rates of minimally adequate treatment range from 23% in high-income countries to as low as 3% in LMICs.[3]

Most ethnic, racial, linguistic, and immigrant populations are exposed to a range of social determinants that place them at increased risk for mental health issues, including housing instability, racism and discrimination, acculturative stress, language barriers, limited social networks, and a lack of home-country connection.[6] Although culturally responsive health care (defined as intentionally adapting services and approaches to be

"rooted in respect and appreciation for the role of culture in the individual's and family's beliefs, attitudes, and behaviors"[7]) can help improve mental health symptoms at the population level, many randomised controlled trials of mental health interventions such as cognitive-behavioural therapy (CBT) are not culturally adapted or inclusive of diverse communities.[8]

Approximately 47·8 million immigrants (14·3%) are living in the USA,[9] many of whom come from countries where perceptions of mental disorders differ significantly from those of the clinicians responsible for their care.[10] Clinicians are required to provide culturally responsive care, yet doing so is difficult because addressing diverse cultural backgrounds requires specific training and time.[11]

Even in a high-income country such as the USA, millions of adults with past-year mental illness received no care or inadequate care, with lack of insurance coverage and unaffordable costs creating challenges.[12] Given structural and systemic constraints, racial, ethnic, and linguistic minoritised groups are more likely to receive poorer quality services.[12] This reflects the mental health system's lack of culturally responsive care to address language and social determinants and fulfil the needs of 67·8 million individuals who spoke a language other than English at home.[13] Most US adults with limited English proficiency speak either Spanish (63%) or Chinese (7%).[14] Individuals of Latinx and Asian descent together account for 84% of those in the USA with limited English proficiency, but only 18% of those proficient in English.[15] Culturally responsive care that sees the patient as the expert on their conditions and focuses on their definition of the problem and living circumstances[16] is crucial.

Inequities also emerge due to a shortage of trained providers, the absence of outreach to identify needs, and a lack of socio-culturally and linguistically adapted evidence-based practices.[12] Although Medicaid expansions through the Affordable Care Act in the USA could support addressing these mental health challenges, the treatment gap between White people and racial and ethnic minoritised groups, many of whom are immigrants, has not decreased.[17,18] Some immigrant groups only qualify for limited emergency coverage without access to quality mental health care.[19] Within such constraints, a proposed solution is building capacity by training individuals from the targeted communities to offer evidence-based programmes to address mental health needs.[20] This could contribute to closing the research-to-practice gap, particularly for racial, ethnic, and linguistically minoritised populations.[20]

Community health workers can offer needed services to address the lack of bilingual and bicultural clinicians and reduce mental health symptoms of diverse populations.[21] For the current project, we define community health workers as public health workers who apply their knowledge of the language and culture of the participants they work with to deliver evidence-based interventions and address personnel shortages.[22,23] A 2018 review of 39 randomised controlled trials (mostly international) that included community health workers delivering evidence-based mental health interventions in underserved communities found that the majority of interventions led to symptom reduction.[21] However, most of the studies were conducted outside of the USA, with small samples.[21] Compared with the control condition, community health workers trained in the CBT-based Thinking Healthy Programme reduced 6-month and 12-month perinatal depression in new mothers in Pakistan[24] and 3-month depressive symptoms in India.[25] A culturally responsive, lay health worker-delivered, CBT-based intervention with 50 older adults in rural China demonstrated a difference between intervention and usual care participants after 8 weeks.[26] Culturally responsive CBT treatments have also reduced anxiety, depression, and post-traumatic stress disorder in patients in Pakistan.[27] A community–academic research partnership with Latinx immigrants delivered a stress and coping intervention in Spanish that significantly improved stress management.[28]

Of the few community health worker-led trials in the USA, most target only one language or cultural group.[21] To our knowledge, none of these trials examined whether results vary by participant language, race, and ethnicity, or whether the mental health intervention is superior to usual care that attempts to address social determinants of health issues. Our study improves upon past work by testing the effectiveness of a 6-month psychosocial intervention, Strong Minds–Strong Communities (SM–SC). This intervention aims to improve self-reported depression and anxiety symptoms, level of functioning, and perceived quality of care from baseline to month 6 (intervention end) and month 12 (6 months post-intervention). We offered the intervention in community-based organisations or community clinics serving mostly low-income racial, ethnic, and linguistic minoritised communities in two US states.

Several studies suggest that the SM–SC intervention (previously the Engagement and Counseling for Latinos intervention, ECLA) is effective. The ECLA intervention reduced depression and anxiety symptoms and improved functioning compared with usual care when delivered via clinical staff.[29] Subsequent research also showed the intervention's effectiveness in reducing mood symptoms when community health workers provided it to older adults in combination with physical exercises.[22] The SM–SC community health worker training programme has also shown high acceptability and satisfaction (measured through a 6-item self-report scale and participant attendance of >50% of sessions) and increased competency of community health workers in mental health care provision.[22,30] We aimed to build on this accumulating evidence, and test the effectiveness and implementation of the SM–SC community health

worker training programme in a community context to fully assess its generalisability.[31]

Methods

Study design

The SM–SC trial was an investigator-initiated multicentre, randomised, controlled trial conducted at Massachusetts General Hospital in Boston and the University of North Carolina Greensboro. The Mass General Brigham Institutional Review Board (IRB) approved the trial (protocol 2018P002918), with review ceded from UNC Greensboro (protocol 19-0353). The synthesised trial protocol is available in appendix 3 (pp 4–14). An independent data safety and monitoring board oversaw the trial. All participants provided written or oral informed consent before enrolment. Bilingual research staff who assessed capacity to consent in the participant's primary language (English, Spanish, Mandarin, or Cantonese) obtained consent using a validated screener. Consent was transitioned from written to oral after the onset of the COVID-19 pandemic, as permitted after IRB review. The trial is registered with ClinicalTrials.gov, NCT04092777, and has been completed.

Participants

Staff recruited participants from 20 community-based organisations (non-profits that seek to provide support to members of their local community) and 17 clinics serving a high proportion of clients who identify as Latinx (primarily Spanish speaking), Asian (mainly Mandarin or Cantonese speaking), or Black (primarily English speaking). Eligible participants were adults aged 18 years or older who were fluent in English, Spanish, Mandarin, or Cantonese, with moderate to severe depression or anxiety symptoms, ascertained using the Computerized Adaptive Test for Mental Health (CAT-MH), a suite of validated computer adaptive tests.[32–34] A cut-off score of 50 or higher on the CAT-MH-Depression (when administered in English) or 42 or higher (when administered in Spanish or Cantonese) is indicative of moderate to severe depression. A cut-off score of 51 or higher on the CAT-MH-Anxiety (when administered in English) or 41 or higher (when administered in Spanish or Cantonese) is indicative of moderate to severe anxiety (Gibbons R, University of Chicago, personal communication). Both CAT-MH scores are based on responses to algorithm-selected items that minimise participant burden using item response theory methodology and were calibrated with case-control data (anxiety cases for CAT-MH-Anxiety and depression cases for CAT-MH-Depression).[32,34] Participant's gender (male, female, other) was self-reported. The study excluded potential participants if they did not meet the minimum threshold in a capacity to consent questionnaire; reported mania, active suicidal ideation, or substance use concerns (clinical concerns the intervention did not address); or were receiving ongoing or recent psychological services (either in the past

3 months or scheduled for the upcoming month), to avoid confounding effects. The intervention does not address substance use because, without access to medications, it was beyond the scope of work for community health workers, and thus a safety issue.

The study team presented to clinical and community-based organisation leaders to discuss outreach and recruitment opportunities and to generate feedback on appropriate recruitment procedures. Recruitment occurred in person or remotely by phone through outreach to clinicians, participant referrals, or clinical lists (appendix 3 pp 15–16). Community health workers offered the intervention in four languages spoken by these groups (Spanish, English, Mandarin, or Cantonese), which allowed us to offer participation to many immigrants.

Randomisation and masking

Eligible participants first conducted a baseline interview and were then randomly assigned (1:1) to receive either a ten-session psychoeducational intervention or usual care (control group) for up to 6 months. Randomisation was stratified by site using a computer-generated (NQuery software) block randomisation scheme of size two so that for every two participants, one was randomly assigned to each group by site. A masked data manager generated the allocation sequence using a pseudorandom numbers generator. Research staff enrolled patients after assessing eligibility. Investigators and participants were not masked to treatment allocation, but outcome assessors were masked. Follow-up assessments were conducted by telephone or in person at 3 months, 6 months, and 12 months after baseline.

Procedures

SM–SC is an evidence-based, culturally tailored intervention incorporating approaches adapted from CBT (eg, cognitive restructuring), mindfulness exercises, psychoeducation on healthy habits, motivational interviewing, and behavioural activation through pleasant activities and supportive relationships (appendix 3 p 16).[22] The intervention manual is organised in ten 1-h sessions and was provided individually in the participant's language by one of 20 trained community health workers.

Community health workers were recruited through job postings and advertisements and were required to have completed high school (the majority had some college education and higher), experience working within the community, and shared language and background with one of the target groups. Community health workers received 60–80 h of structured training on psychoeducation; skills covered in the manual; techniques supporting delivery (eg, motivational strategies, establishing a relationship, and cultural responsiveness); and supervision of manual delivery through audio-recorded practice, role plays, and pilot cases, with training processes that were identical across the two sites. Supervisors (licensed

See **Online** for appendix 3

psychologists or counsellors) determined competency of the community health workers based on 4 days of instruction, two 10-session role plays, two 10-session pilot cases, and 2 h of weekly supervision. Supervisors listened to audio-recorded role plays and pilot cases to assess 75% community health worker fidelity to intervention components. Community health workers then received ongoing 1-h supervision to offer the skills-based programme and monthly group training on specialised topics (appendix 3 p 17).

The study team culturally adapted the intervention (both in language and content) for use among a broad group of minoritised populations (Latinx, Asian, and Black) with few exclusionary criteria to improve generalisability and ease of implementation. We achieved cultural adaptation through formal stepped adaptation processes guided by Castro and Barrera's frameworks.[35] This included cultural translation of the manual and measures, review and edits by mental health clinicians from the target ethnic and racial groups, and adaptations that addressed issues of mental health literacy, social customs, social norms, and the role of race, ethnicity, language, and sociocultural context, following work done by Falgas-Bague and colleagues (appendix 3 pp 16–17).[30]

Community health workers delivered weekly SM–SC sessions by telephone, in person, or video conference across 6 months, including skills practice, symptom monitoring, and the creation of a self-care plan. To adapt to the COVID-19 pandemic, the study team updated the protocol to shift from in person to telephone and Zoom-based sessions. Care managers linked participants to social determinants of health referrals. Care managers generally had similar, non-clinical backgrounds to community health workers, but were differentiated by the training they received to provide the activities corresponding to their role. Research staff assessed social determinants of health referral needs using a tool that screened for food insecurity, housing instability, problems paying utilities, lack of transportation, difficulty paying for medications, unemployment, child or family care demands, and mental health care needs.[36]

The control condition (usual care) involved receipt of a National Institutes of Health booklet about anxiety and depression in Spanish, English, or Mandarin or Cantonese. A care manager contacted participants by telephone four times over 6 months to monitor depression and anxiety symptoms (using the Patient-Reported Outcomes Measurement Information System),[37] and suicidal thoughts and behaviours, thus mimicking the administration schedule in the intervention group. We instituted an emergency protocol for addressing suicidal behaviours and worsening of symptoms (appendix 3 pp 13–14). Similar to in the intervention group, the care manager offered referrals for social determinants of health, characterised by offering an appointment, recommendation, or contact information to participants in the control group. Staff conducted all elements of the study in the participant's language. Study progress and any risk issues or adverse events were systematically tracked using a monitoring registry. Licensed clinicians held weekly supervision with community health workers to address issues that arose in the intervention sessions, including increases in symptom scores. If a participant reported a plan or recent suicide attempt, staff enacted an emergency protocol and connected participants to an emergency services provider for assessment and referral. A recent suicide attempt was considered a serious adverse event.

Community health workers recorded all intervention sessions, and supervisors evaluated fidelity for 15% of each community health worker's cases (randomly selected using a number generator) using a 9–12-item form assessing manual compliance and session quality. Average fidelity across all five supervisors was 85·8 (range, 77·0–89·0; appendix 3 p 17). Ongoing supervision and training prevented fidelity drift over time. Supervisors focused on the fidelity of skill delivery and provided support for high-risk or emergency situations. Across both sites, we identified seven enrolled participants who reported a suicide attempt, considered a serious adverse event, and one death not by suicide, none of which were deemed related to the protocol.

Outcomes

The primary effectiveness endpoints were change in depression and anxiety symptoms from baseline at 6 months (intervention end) and 12 months (6 months post-intervention) using scores on the Hopkins Symptom Checklist-25 (HSCL-25);[38] level of functioning using scores on the 12-item World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0);[39] and perceived quality of care using scores on the Global Evaluation of Care domain of the Perceptions of Care Outpatient Survey (PoC-OP).[40] Scores on the HSCL-25 range from 1 to 4, with higher scores indicating worse depression and anxiety symptoms.[38] Scores on the WHODAS 2.0 range from 12 to 60, with higher scores indicating worse functioning.[39] Scores on the PoC-OP range from 0 to 100, with higher scores indicating better perceived quality of care (appendix 3 pp 17–18).[40] The key secondary effectiveness endpoints were change from baseline in CAT-MH-Depression score (range 0 to 100 with higher scores indicating worse depression symptoms)[32] and CAT-MH-Anxiety score (range 0 to 100, with higher scores indicating worse anxiety symptoms)[34] at 6 months and 12 months. The adaptive nature of the CAT-MH targets a participant's specific level of severity at that point in time. Because the same questions are not repeatedly administered, CAT-MH is ideal for longitudinal assessments. Thus, a pattern of change in CAT-MH scores consistent with that of the primary outcomes would strengthen the significance of our findings. We also evaluated primary and key secondary effectiveness endpoints in prespecified subgroup analyses

based on participants' race and ethnicity, language, and site. Other exploratory endpoints included change from baseline in HSCL-25, WHODAS 2.0, PoC-OP, CAT-MH-Depression, and CAT-MH-Anxiety scores at 3 months, about midway through the intervention. Finally, we evaluated the primary and key secondary effectiveness endpoints in exploratory subgroup analyses based on the participant's baseline severity of depression and anxiety. All measures showed adequate psychometric properties across languages (appendix 3 p 22).

Statistical analysis

A sample of 1044 participants provided adequate power to evaluate whether the effect of the intervention varied as a function of the participant's race, ethnicity, language, or site (appendix 3 p 18). Effect size estimates from our preliminary data suggested that the 10-session SM–SC psychoeducational intervention improved the primary outcomes of depression and anxiety symptoms and level of functioning with an effect size (Cohen's d) of 0·68 and 0·24, respectively.[29] With a two-sided significance level of 0·05, a sample of 1044 participants would provide the study with 87% power to detect a between-group difference of size 0·20 or higher in the primary effectiveness outcomes.

We analysed all primary and key secondary endpoints according to the intention-to-treat principle and included all participants who were randomly assigned to an intervention. The SM–SC intervention is designed to improve depression and anxiety symptoms, level of functioning, and perceived quality of care. To test global effectiveness, as well as specific improvements in each outcome, we adopted the step-down Benjamini–Hochberg approach to keep the false discovery rate to be less than 5%. This step-down procedure adjusted for the multiple comparisons across five outcome scores (HSCL-25, WHODAS 2.0, PoC-OP, CAT-MH-Depression, and CAT-MH-Anxiety) at two follow-up points (months 6 and 12). If the lowest of the ten p values was less than 0·005 (0·05÷10), it was considered significant; the second lowest p value was significant if less than 0·0056 (0·05÷9); the third lowest p value was significant if less than 0·006 (0·05÷8). Results are presented as point estimates and their standardised effect size (Cohen's d) with 95% CIs. The Cohen's d value is presented to provide a common metric for comparing the intervention effect across all primary and key secondary endpoints and to aid in interpreting the magnitude of the difference between intervention and control groups.

We separately analysed primary and key secondary effectiveness endpoints using a general linear model to estimate the treatment effect. Except for PoC-OP, all analyses included baseline outcome scores as covariates. All analyses, including PoC-OP, also included the site as a covariate. Because we recruited participants from 20 community-based organisations and 17 clinics across the two sites, we used generalised linear mixed models

with a random intercept accounting for clustering within community-based organisations and clinics for each primary and key secondary effectiveness endpoint in sensitivity analyses. We performed prespecified subgroup analyses of the primary and key secondary endpoints for participant's self-identified race and ethnicity (non-Latino White, non-Latino Black, non-Latino Asian, and Latino), language (English, Spanish, Mandarin, and Cantonese), and site (Massachusetts and North Carolina). We tested subgroup differences in three omnibus interaction tests examined for five outcome scores (HSCL-25, WHODAS 2.0, PoC-OP, CAT-MH Anxiety, and CAT-MH-Depression) at 6 months and 12 months, which resulted in 30 statistical tests. In prespecified subgroup analyses, no adjustment for the multiple comparisons was made. Thus, with a two-sided p value of 0·05, about two statistically significant interaction tests were expected based on chance alone (30×0·05).

Under the missing at random assumption, we handled missing values using 20 imputed data sets using model-based imputation for the primary and key secondary effectiveness endpoints at months 6 and 12. Similarly, we used model-based multiple imputation (20 imputed data sets) to handle missing data for the prespecified subgroup analyses of the primary and key secondary endpoints. All imputation models included the auxiliary baseline variables associated with missingness (appendix 3 p 19).

We similarly analysed change from baseline at the exploratory endpoint at month 3 and exploratory subgroup analyses based on participant's baseline severity of depression and anxiety using a general linear model, which included baseline scores (except for PoC-OP) and site as covariates. We performed analyses with Stata software, version 18, and RStudio software, version 2023.12.0.369 (Posit Software, PBC).

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Sept 4, 2019, and March 3, 2023, 5265 potential participants were approached for study inclusion. 2681 were excluded as they declined screening or did not meet the inclusion criteria, resulting in 2584 potential participants being assessed for eligibility. 1417 were then excluded, and 1167 were deemed eligible for study inclusion. Of these, 1044 participants were randomly assigned (524 to the SM–SC group and 520 to the usual care control group). Half of the participants were recruited in North Carolina and half in Massachusetts. 357 participants assigned to the SM–SC group completed the 6-month assessment and 349 completed the 12-month assessment, and 398 participants in the control group completed the 6-month assessment and 382 completed the 12-month assessment (figure 1).

337 (32·3%) participants were included in the study for their moderate to severe depression symptoms, 43 (4·1%) were included for their moderate to severe anxiety symptoms, and 664 (63·6%) were included for both moderate to severe depression and anxiety symptoms. On average, each of the 20 community health workers saw 25·7 cases, with total case numbers ranging from two to 54.

The distribution of baseline characteristics was well-balanced between the two groups (table). The mean age of participants was 42·6 years (SD 13·3) and 875 (83·8%) were female, 165 (15·8%) were male, and four (0·4%)

Figure 1: Trial profile
SM–SC=Strong Minds–Strong Communities.

were other. 654 (62·6%) participants were Latino, 149 (14·3%) were non-Latino Black, 137 (13·1%) were non-Latino Asian, and 92 (8·8%) were non-Latino White. Most participants were foreign-born (704 [67·4%]), had at least a high school diploma (640 [61·3%]), and were insured (683 [65·4%]).

After adjusting for multiple comparisons, all p values for the primary and key secondary endpoints remained significant (appendix 3 p 26). At the 6-month endpoint (end of intervention), intervention participants had a reduction in depression and anxiety symptoms (HSCL-25 scores) of 0·44 points, while control participants had a reduction of 0·24 points (difference, 0·20 points [95% CI 0·14–0·26]; Cohen's d, 0·39 [95% CI 0·27–0·52]; figure 2A). Intervention participants had a greater improvement in the level of functioning (WHODAS 2.0 scores) than did control participants (difference, 2·39 points [95% CI 1·38–3·40]; Cohen's d, 0·28 [95% CI 0·16–0·39]; figure 2B) and a notable higher improvement in perceived quality of care (PoC-OP scores; difference, 8·75 points [95% CI 5·87–11·63]; Cohen's d, 0·47 [95% CI 0·31–0·62]; figure 2C). At the 12-month endpoint (6 months post-intervention), intervention participants still reported greater improvements in HSCL-25 scores (difference, 0·14 points [95% CI 0·08–0·20]; Cohen's d, 0·28 [95% CI 0·16–0·40]), WHODAS 2.0 scores (difference, 1·78 points [95% CI 0·71–2·85]; Cohen's d, 0·21 [95% CI 0·08–0·33]), and PoC-OP scores (difference, 6·18 points [95% CI 3·00–9·35]; Cohen's d, 0·33 [95% CI 0·16 –0·50]), although intervention effects attenuated (standardised effect sizes were about 30% lower; figure 3).

The standardised effect sizes for HSCL-25 scores were in the small to medium range. However, they represented a sizable difference in the proportion of participants reporting clinically relevant symptoms of depression and anxiety (scores above 1·75). At the 6-month endpoint, 262 (50·3%) of control participants reported clinically relevant symptoms of depression and anxiety compared with 189 (36·0%) of intervention participants. The success rate difference was 14·7%. At the 12-month endpoint, 249 (47·8%) of control participants reported clinically relevant symptoms of depression or anxiety compared with 201 (38·4%) of intervention participants. The success rate difference over the 1-year follow-up was 8·8%. Nine adverse events were detected. They included two deaths unrelated to the study in the control group, and seven participants who reported a suicide attempt (three in the intervention group and four in the control group). Participants who reported a suicide attempt were immediately connected to an emergency services provider for assessment.

The pattern of change in key secondary endpoints was consistent with that of primary outcomes. At the 6-month endpoint, intervention participants had a reduction in depression symptoms (CAT-MH-Depression scores) of 19·1 points (on a scale from 0 to 100) and control
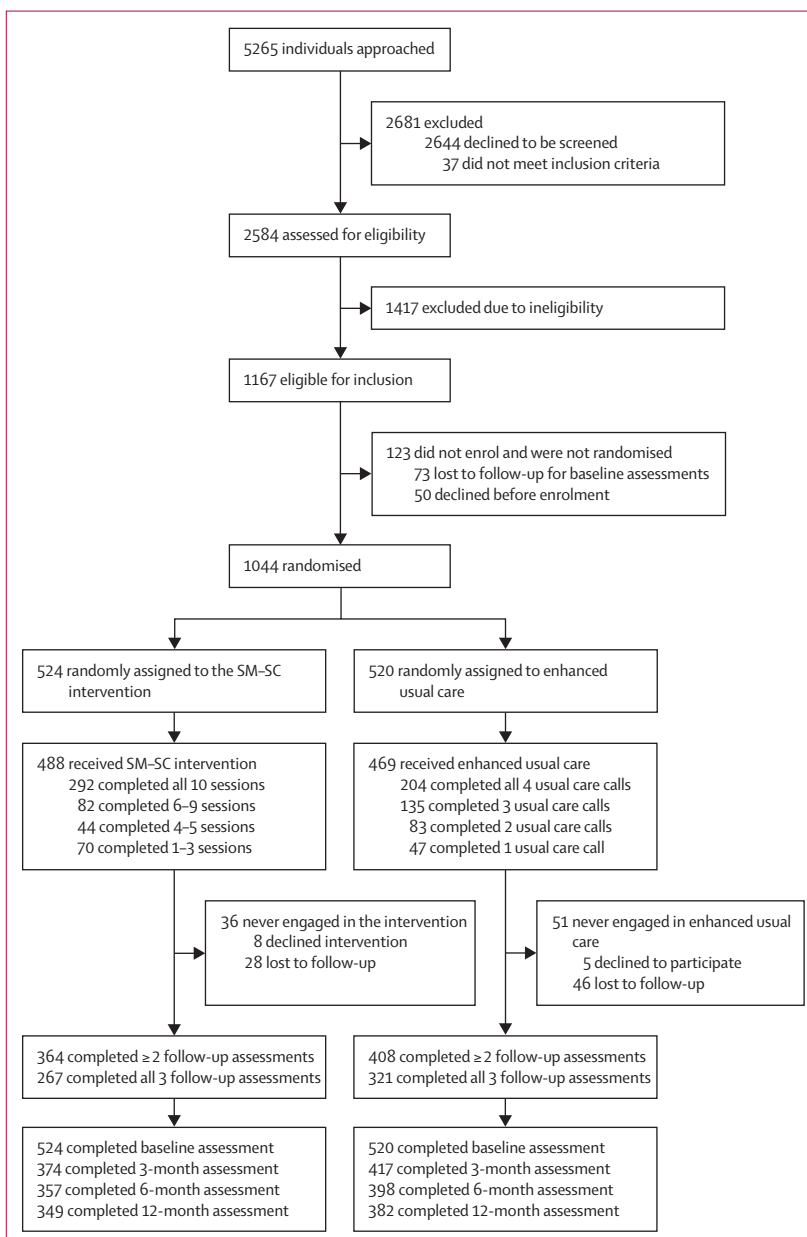
	Total sample (n=1044)	Control group (n=520)	SM–SC intervention group (n=524)
Survey language			
English	371 (35·5%)	197 (37·9%)	174 (33·2%)
Spanish	559 (53·5%)	269 (51·7%)	290 (55·3%)
Mandarin	72 (6·9%)	32 (6·2%)	40 (7·6%)
Cantonese	42 (4·0%)	22 (4·2%)	20 (3·8%)
Study location			
North Carolina	522 (50·0%)	261 (50·2%)	261 (49·8%)
Massachusetts	522 (50·0%)	259 (49·8%)	263 (50·2%)
Age, years	42·6 (13·3)	42·8 (13·4)	42·4 (13·2)
Gender			
Male	165 (15·8%)	88 (16·9%)	77 (14·7%)
Female	875 (83·8%)	429 (82·5%)	446 (85·1%)
Other	4 (0·4%)	3 (0·6%)	1 (0·2%)
Race and ethnicity			
Non-Latino White	92 (8·8%)	46 (8·8%)	46 (8·8%)
Non-Latino Black	149 (14·3%)	80 (15·4%)	69 (13·2%)
American Indian	3 (0·3%)	1 (0·2%)	2 (0·4%)
Non-Latino Asian	137 (13·1%)	68 (13·1%)	69 (13·2%)
Latino	654 (62·6%)	322 (61·9%)	332 (63·4%)
Mixed	7 (0·7%)	3 (0·6%)	4 (0·8%)
Other	2 (0·2%)	0	2 (0·4%)
Birthplace			
Born outside of the USA	704 (67·4%)	341 (65·6%)	363 (69·3%)
Born in the USA	340 (32·6%)	179 (34·4%)	161 (30·7%)
Education			
Less than high school	401 (38·4%)	194 (37·3%)	207 (39·5%)
High school and above	640 (61·3%)	326 (62·7%)	314 (59·9%)
Missing	3 (0·3%)	0	3 (0·6%)
(Table continues on next column)			

	Total sample (n=1044)	Control group (n=520)	SM–SC intervention group (n=524)
(Continued from previous column)			
Marital status			
Married or cohabitating	565 (54·1%)	280 (53·8%)	285 (54·4%)
Widowed, divorced, or separated	219 (21·0%)	109 (21·0%)	110 (21·0%)
Never married	257 (24·6%)	130 (25·0%)	127 (24·2%)
Missing	3 (0·3%)	1 (0·2%)	2 (0·4%)
Insurance status			
Uninsured	354 (33·9%)	167 (32·1%)	187 (35·7%)
Insured	683 (65·4%)	349 (67·1%)	334 (63·7%)
Missing	7 (0·7%)	4 (0·8%)	3 (0·6%)
Primary outcomes			
Psychological distress, (HSCL-25)	2·1 (0·5)	2·1 (0·5)	2·1 (0·5)
Functioning (WHODAS 2.0)	23·5 (8·8)	23·3 (8·6)	23·8 (8·9)
Perceptions of Care (PoC-OP)	NA	NA	NA
Secondary outcomes			
CAT-MH-Depression	57·3 (12·6)	56·8 (12·5)	57·9 (12·8)
CAT-MH-Anxiety	51·8 (17·7)	51·2 (17·9)	52·3 (17·5)

Data are n (%) or mean SD. SM–SC=Strong Minds–Strong Communities. HSCL-25=Hopkins Symptom Checklist-25. WHODAS 2.0=World Health Organization Disability Assessment Schedule 2.0. PoC-OP=Global Evaluation of Care domain of the Perceptions of Care Outpatient Survey. CAT-MH=Computerized Adaptive Test for Mental Health. NA=not available at baseline.

Table: Baseline characteristics

participants a decrease of 11·0 points, which represented a large effect size (difference, 8·07 points [95% CI 5·65–10·49]; Cohen's d 0·65 [95% CI 0·45–0·84]; figure 4A). Intervention participants also had a larger reduction in anxiety symptoms (CAT-MH-Anxiety scores) of 20·1 points compared with a decrease of 11·5 points among control participants (difference, 8·56 points [95% CI 5·84–11·27]; Cohen's d, 0·48 [95% CI 0·33–0·63]; figure 4B). Intervention participants still reported greater improvements in CAT-MH depression and anxiety scores 6 months post-intervention at the 12-month endpoint (difference, 5·14 points [95% CI 2·95–7·33]; Cohen's d, 0·41 [95% CI 0·24–0·59] for depression; and difference, 4·29 points [95% CI 1·59–6·99]; Cohen's d, 0·24 [95% CI 0·09–0·39] for anxiety; figure 4), with attenuated standardised effect sizes. All results from sensitivity analyses accounting for clustering within community-based organisations and clinics were almost identical (appendix 3 p 27).

The results of prespecified subgroup analyses at the primary 6-month and 12-month endpoints are shown in figure 2 and figure 3. For the level of functioning (WHODAS 2.0 scores) at the 12-month endpoint, there was an indication of greater treatment effectiveness among non-Latino White participants and null effectiveness among non-Latino Asian participants, which combined Mandarin and Cantonese speakers (p for interaction=0·02; figure 3). There was also an indication of greater treatment effectiveness in anxiety symptoms per the CAT-MH at the 6-month endpoint among Mandarin-speaking participants and null effectiveness among Cantonese-speaking participants (p for interaction=0·02; appendix 3 pp 28–29). The point estimates for all the treatment effects were in the predicted direction, except for HSCL-25 scores in the Cantonese group. This discrepancy is not definitive because of the small sample size but is important to note. Results were generally consistent at the exploratory endpoint at 3 months in that participants in the intervention group had greater improvements in all primary (HSCL-25, WHODAS 2·0, and PoC-OP scores) and key secondary outcomes (CAT-MH depression and anxiety scores) even before the intervention period ended (appendix 3 p 26). The results of exploratory subgroup analyses at the primary and key secondary endpoints also
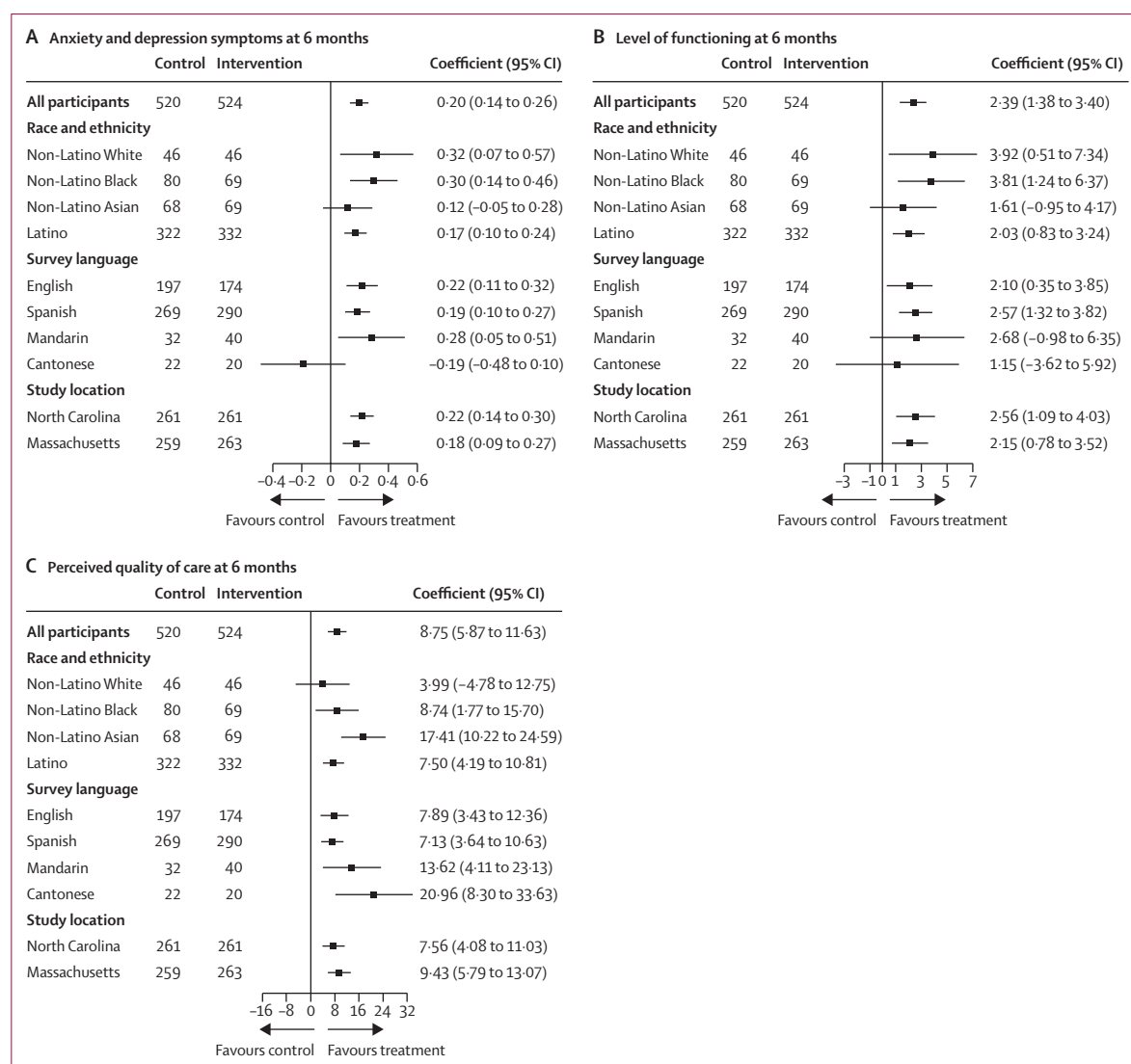
Figure 2: Depression and anxiety symptoms (A), level of functioning (B), and perceived quality of care (C) at the 6-month primary endpoint
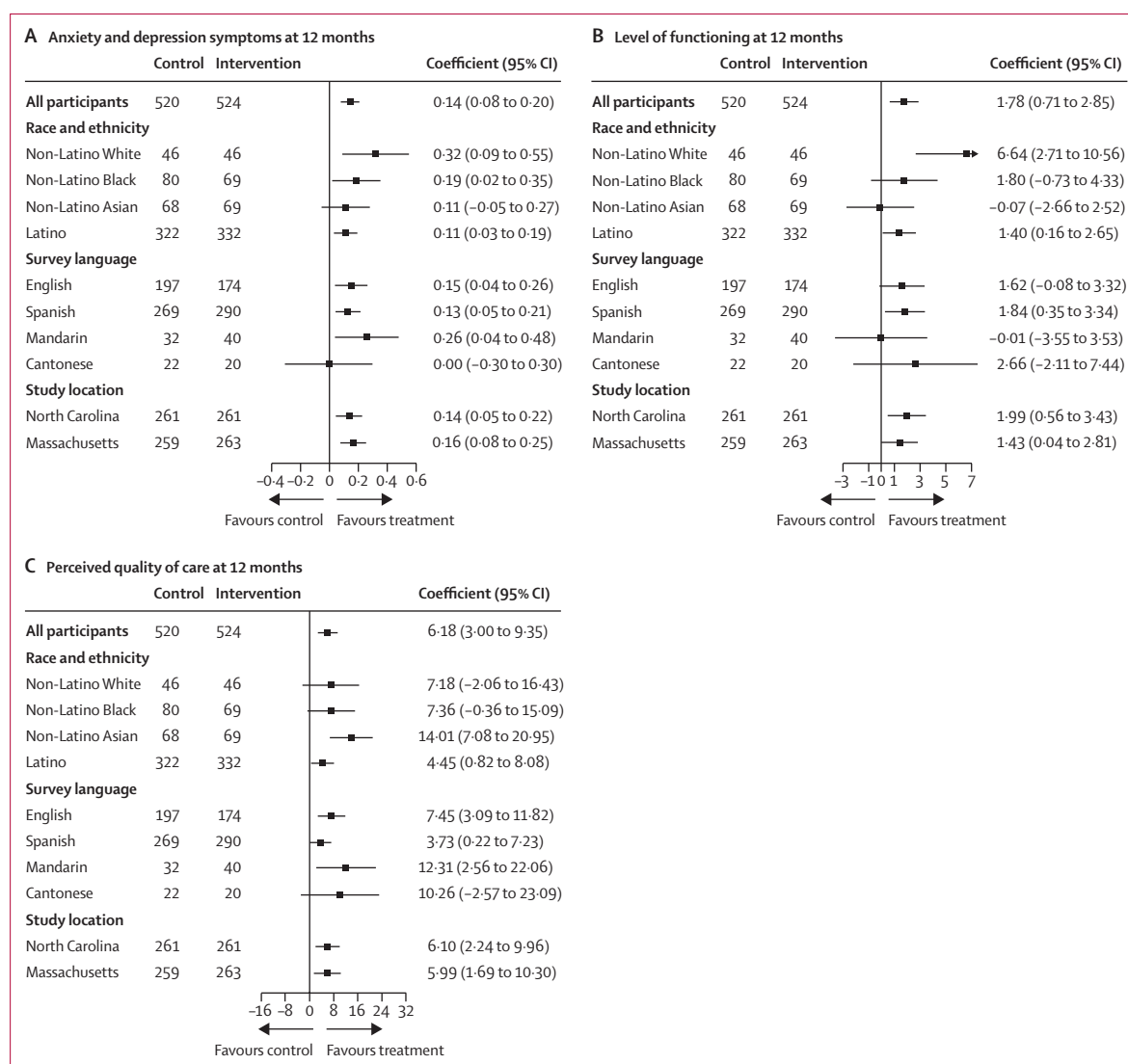Data are presented for both treatment groups and for prespecified subgroup analyses.

indicated that the intervention effect did not vary as a function of baseline severity of depression or anxiety symptoms (appendix 3 p 34).

Discussion

Our study in two US states with similar immigrant populations to US estimates (12·7% across Massachusetts and North Carolina versus 14·3% in the USA)[41,42] shows promise as a prevention and disparities reduction strategy that can help to alleviate the problem of mental health worker shortages and reduce the research-to-practice gap. Overall, this study demonstrates the effectiveness of a structured, community health worker-led, culturally adapted psychoeducational programme for adults with moderate or severe depression or anxiety delivered in the

participant's language (English, Spanish, Mandarin, or Cantonese).

Few researchers have collaborated with community health workers to test psychosocial interventions in non-English languages for large, diverse populations in the USA. In a systematic review of the literature, we found no randomised controlled trials of community health worker-led mental health interventions conducted in more than two languages, or that utilised social determinant referrals as a control group, in either the USA or internationally. However, findings are consistent with the few other interventions identified in a systematic review conducted by Barnett and colleagues,[21] which showed that community health worker-led interventions in the USA performed significantly better than a comparison condition on the mental health outcome

A Anxiety and depression symptoms at 12 months

	Control	Intervention	Coefficient (95% CI)
All participants	520	524	0·14 (0·08 to 0·20)
Race and ethnicity			
Non-Latino White	46	46	0·32 (0·09 to 0·55)
Non-Latino Black	80	69	0·19 (0·02 to 0·35)
Non-Latino Asian	68	69	0·11 (–0·05 to 0·27)
Latino	322	332	0·11 (0·03 to 0·19)
Survey language			
English	197	174	0·15 (0·04 to 0·26)
Spanish	269	290	0·13 (0·05 to 0·21)
Mandarin	32	40	0·26 (0·04 to 0·48)
Cantonese	22	20	0·00 (–0·30 to 0·30)
Study location			
North Carolina	261	261	0·14 (0·05 to 0·22)
Massachusetts	259	263	0·16 (0·08 to 0·25)

–0·4 –0·2 0 0·2 0·4 0·6
Favours control ← → Favours treatment

B Level of functioning at 12 months

	Control	Intervention	Coefficient (95% CI)
All participants	520	524	1·78 (0·71 to 2·85)
Race and ethnicity			
Non-Latino White	46	46	6·64 (2·71 to 10·56)
Non-Latino Black	80	69	1·80 (–0·73 to 4·33)
Non-Latino Asian	68	69	–0·07 (–2·66 to 2·52)
Latino	322	332	1·40 (0·16 to 2·65)
Survey language			
English	197	174	1·62 (–0·08 to 3·32)
Spanish	269	290	1·84 (0·35 to 3·34)
Mandarin	32	40	–0·01 (–3·55 to 3·53)
Cantonese	22	20	2·66 (–2·11 to 7·44)
Study location			
North Carolina	261	261	1·99 (0·56 to 3·43)
Massachusetts	259	263	1·43 (0·04 to 2·81)

–3 –1 0 1 3 5 7
Favours control ← → Favours treatment

C Perceived quality of care at 12 months

	Control	Intervention	Coefficient (95% CI)
All participants	520	524	6·18 (3·00 to 9·35)
Race and ethnicity			
Non-Latino White	46	46	7·18 (–2·06 to 16·43)
Non-Latino Black	80	69	7·36 (–0·36 to 15·09)
Non-Latino Asian	68	69	14·01 (7·08 to 20·95)
Latino	322	332	4·45 (0·82 to 8·08)
Survey language			
English	197	174	7·45 (3·09 to 11·82)
Spanish	269	290	3·73 (0·22 to 7·23)
Mandarin	32	40	12·31 (2·56 to 22·06)
Cantonese	22	20	10·26 (–2·57 to 23·09)
Study location			
North Carolina	261	261	6·10 (2·24 to 9·96)
Massachusetts	259	263	5·99 (1·69 to 10·30)

–16 –8 0 8 16 24 32
Favours control ← → Favours treatment

Figure 3: Depression and anxiety symptoms (A), level of functioning (B), and perceived quality of care (C) at the 12-month primary endpoint
Data are presented for both treatment groups and for prespecified subgroup analyses.

measured, including depression and anxiety. Our findings are also consistent with Barnett and colleagues' findings on sustained effects at follow-up assessment[21] and with successful USA-based and internationally based randomised controlled trials of community health worker-led interventions published after Barnett and colleagues' review.[43–45]

Most enrolled participants had both moderate to severe depression and anxiety symptoms, and a higher proportion of participants were enrolled because of depression symptoms alone, which was consistent with previous prevalence estimates of depression and anxiety for native-born and first-generation and second-generation immigrants in the USA.[46] With extensive training and continued clinical supervision, community health workers maintained high fidelity rates to the SM–SC manualised intervention, leading to significant participant symptom improvement. Results showed programme effectiveness for primary outcomes in the small to moderate effect size range and significant effects in the secondary outcome, sustained at 12-month follow-up. These effect sizes were similar to other smaller community health worker-led studies and to those observed in interventions delivered by mental health professionals.[47] Effects were evident across most racial, ethnic, and language groups, underscoring the potential to task-shift the delivery of psychoeducational interventions to community health workers to improve efficiency and optimize resource allocation, thus expanding the mental health workforce.

In our study, the few exceptions were the non-Latino Asian group (which included Mandarin and Cantonese
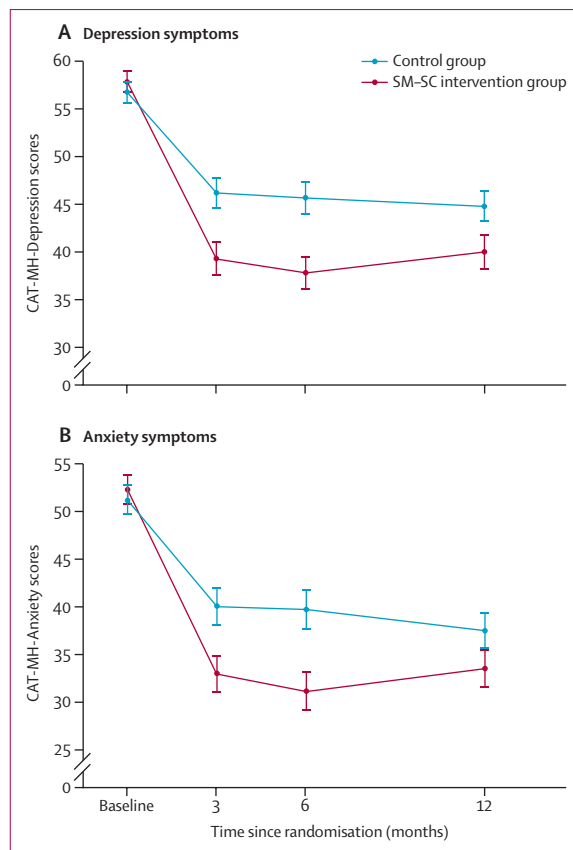
Figure 4: Depression and anxiety symptom CAT-MH scores up to 12 months
CAT-MH=Computerized Adaptive Test for Mental Health. SM–SC=Strong Minds–Strong Communities.

speakers) for the level of functioning (WHODAS 2.0 scores) at the 12-month endpoint and the Cantonese-speaking group for anxiety symptoms (CAT-MH scores) at the 6-month endpoint. The results from our prespecified subgroup analyses suggested that the Cantonese participants drove any indication of a null intervention effect in the non-Latino Asian group. Given that the level of functioning improved among Mandarin participants when separated from Cantonese participants, our findings emphasise the importance of not aggregating non-Latino Asian populations as a monolithic group. Because the intervention sample size for the Cantonese-speaking group was small, we cannot yet conclude that the intervention was ineffective. However, our Chinese research assistants noticed challenges with some of the terminology used in the assessment interviews, consistent with other clinical observations with Cantonese participants.[48] Furthermore, the difficulties navigating the differences between written and spoken Cantonese reported by Chinese community health workers might be related to the fact that 40·5% of Cantonese speakers completed less than a high school education compared with only 12·5% of Mandarin speakers. It is possible that education or health literacy could explain the differences

between these groups. Notably, the Cantonese group had the strongest intervention effect for greater perceived quality of care, highlighting a possible disconnect between their experience of the intervention and its functional benefits. Findings point to the importance of additional research on this understudied group, including potential interactions between intervention effectiveness, language, and education level (which this study was not powered to test). The result of greater treatment effectiveness among non-Latino White participants for the level of functioning (WHODAS 2.0 scores) at the 12-month endpoint might be similarly linked to having less hardship and more personal, social, and economic resources that benefit their health.[49] There are many well-documented drivers of inequity, such as housing and food insecurity, that are exacerbated for minoritised populations.[49] By 12 months there might have been challenges to implement some of the skills adopted because of persistent stressors.

The SM–SC intervention adds to the rapidly growing research base of community health worker models of mental health service delivery that can effectively address global and domestic disparities in care.[21] Our findings support the need to diversify the workforce to allow for race, ethnic, and language-concordant services that are culturally responsive. Lack of cultural and language-concordant services can lead to premature service termination of minoritised populations.[20] Our study included elements that have been shown to bridge cultural mistrust (eg, racial and language matching)[50] and emphasised cultural responsiveness components similar to those mentioned by Bhui and colleagues.[51] Whereas cultural competence focuses only on increasing cultural knowledge and awareness, our interventions extend beyond awareness to promote responsiveness through a "strengths-based approach to service delivery rooted in respect and appreciation for the role of culture".[52] Furthermore, community health workers reported several intervention components as central to their ability to co-create meaning through their interaction with participants. These components included concordance, such as shared identity with their patients (eg, language and racial and ethnic concordance), but were also grounded in cultural responsiveness through tailoring sessions to their patients using a collaborative approach and receiving community health worker-led supervision by culturally and linguistically matched licensed clinicians.

The present study has several limitations, including a 12-month follow-up to assess the intervention's sustainability. Future studies should evaluate whether the intervention might retain its effects on the outcomes over longer durations. We also had a small sample size in the Cantonese-speaking group, which did not allow us to further investigate the discrepancy in HSCL-25 scores. Future work is needed to examine the potential sources of this discrepancy. The research was only conducted in two states of the USA, a high-income country. However, because many sites were community-based organisations

with limited resources and personnel, the intervention showed promise for working in other settings with similarly low resources (ie, other states in the USA). Although community-based organisations participated in a partnership agreement and contributed to study implementation and recruitment, the study did not include Community Advisory Boards, partly because of the pandemic. Study resources were focused on adapting to a remote intervention, delivering equipment to homes, purchasing participant phones or internet plans, and addressing unexpected challenges, including the closure of community programmes. The lack of a Community Advisory Board delayed obtaining information about the need of community-based organisations for financial literacy regarding the cost of maintaining the intervention and the high cost of maintaining a licensed supervisor in these settings. Rather than a formal Community Advisory Board, we met regularly with community sites for the project to discuss challenges and obtain input on strategies. Furthermore, cutoff values of the CAT-MH to assess eligibility and the study's secondary outcomes have not been validated in the peer-reviewed literature, which has implications for instrument validation in future work and the replicability of observed findings. Finally, this current study presents only the effectiveness results and not dissemination outcomes that are being separately assessed.

Our study had several important strengths, including randomised assignment with an active control condition (care manager calls to monitor symptoms and provide resources), standardised outcome measures, and careful intervention fidelity monitoring. Our sample was more racially, ethnically, and linguistically diverse than studies carried out in academic institutions, but 85% of participants were female and primarily immigrants, which limits its generalisability. Although a large proportion of female participants is common among depression and anxiety studies,[53] it underscores the need to improve our efforts toward greater inclusion of male and non-binary participants from linguistic minority populations. Study enrolment commenced before the start of the COVID-19 pandemic; SM–SC was originally intended as a primarily in person programme, but was then changed to be delivered on virtual platforms (telephone and videoconference). Because few participants received solely in-person sessions, we could not examine delivery mode as a potential moderator.

To ensure the continued viability of SM–SC and other future community health worker-led interventions, the sustainability of the community health worker role within the health-care system should be addressed. Currently, there is no national US training or certification programme for community health workers since requirements vary by state,[54] with different stakeholders (eg, governments, health-care institutions)[55] and Medicaid reimbursement rules.[56] Although standardised certification requirements can increase community health workers career opportunities and credibility,[56] mandatory training and certification requirements, along with stringent financial and linguistic requirements, could exclude members of under-represented communities from becoming community health workers.[56] This could inadvertently undermine core approaches that are integral to and uniquely tied to the community health worker field.[56]

Our findings could have important implications for efforts to mobilise community health workers, as they are crucial for enabling task-shifting to deliver evidence-based mental health care, supervised by licensed clinicians in settings with severe workforce shortages. Policymakers and other stakeholders could consider implementing several actions to support community health worker-led interventions. These actions include (but are not limited to) generous compensation and reimbursement policies, fair and balanced requirements to support the growth and integration of community health workers and community health worker-led interventions, professional supervisors to support community health workers and help with burnout, and respect and acknowledgment of community health workers as knowledgeable members of the organisation.

The use of community health workers permits a more rapid expansion of the mental health care workforce by offering an alternate pathway for community members with a shared language and lived experience to enter the mental health field and offer much-needed services. Providing high-quality, evidence-based care with community experts entails extensive training, ongoing support, and supervision, which requires investment in the mental health care system. Training in the intervention is the first step to building organisational capacity, and along with enhancing the infrastructure of organisations to implement programmes on their own, can ultimately lead to wider dissemination.[57]

However, the scope of practice regulations in many states could limit the implementation of such programmes and raise liability concerns, previously raised with nurse practitioners,[58] and more recently with community health workers.[59] Supervision for community health workers should support them to conduct their highest quality work while simultaneously ensuring that task-shifting does not overstep the line into direct clinical care. Community health workers are natural helpers in their communities, and this investment in training and supervision provides evidence-based tools to improve their communities' mental health. This can result in fewer care disparities and increased community and human capital.[60] It is an opportunity to achieve the US Department of Health and Human Services 2022–26 Strategic Plan of "expanding equitable access to comprehensive, community-based, innovative, and culturally competent healthcare services while addressing social determinants of health".[61] Only then can we ensure mental healthcare for all.

Contributors
MA and GLS obtained funding, conceptualised this study, and led the investigation and writing of the Article. MA, MC-G, GLS, and SLM

contributed to the writing of the first draft of the manuscript. MA, GLS, SLM, CP, KME, IF-B, and LF contributed to intervention management and administration. CP, KME, LF, and AS contributed to data curation. MC-G conducted data analysis, and PES verified data analysis and edited the methods section. MC-G and SLM accessed and verified the underlying data. All authors confirm they had full access to all the data in the study and accept responsibility for the decision to submit for publication.

Declaration of interests
We declare no competing interests.

Data sharing
The data collected for this study will not be made publicly available to others due to the sensitivity of the data involving a racial and ethnic minoritised sample, which includes undocumented immigrants, and our agreements with the Institutional Review Board. In our consent forms, we promised that none of the information would be shared, except among research staff. We cannot provide the data unless they were highly de-identified, which would take a substantial amount of time.

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