Trials

STUDY PROTOCOL

Open Access

A type II hybrid implementation-effectiveness study of the BECOME intervention: integrating Behavioral Community-Based Approaches for Mental Health and Non-Communicable Diseases delivered by community health workers—study protocol for a stepped wedge cluster randomized controlled trial

Kripa Sigdel[1], Jyoti Nepal[1*], Archana Shrestha[2], Bala Rai[3], Bhawani Yogi[1], Dean Schillinger[4], Dikshya Sharma[1], Dipanker Prajapati[5], Elsa Heylen[4], Hira Kumari Niraula[3], Jene Shrestha[1], Meghnath Dhimal[6], Navin Kumar Sah[1], Phanindra Prasad Baral[7], Pinki Limbu[1], Prajwol Nepal[8], Puskar Paudel[1], Sajama Nepali[1], Sanjay Poudel[9], Saugat Joshi[1], Shristi Tiwari[1], Srijana Shrestha[10], Sabitri Sapkota[1†] and Bibhav Acharya[1,11†]

Abstract

Background Common mental health conditions (CMHCs) such as depression and anxiety often co-occur with non-communicable diseases (NCDs) like hypertension and diabetes, compounding disability and mortality particularly in low- and middle-income countries (LMICs), with under-resourced health systems. This comorbidity is driven by shared behavioral risk factors including stress, isolation, tobacco use, inactivity, poor diet, and nonadherence to treatment. The World Health Organization recommends evidence-based stress reduction (EBSR), behavioral activation (BA), and motivational interviewing (MI) to address these modifiable risks, but the implementation of such multi-component behavioral interventions in community-based settings remains limited. There is a critical gap in implementation research on how best to deliver these combined interventions through community health workers (CHWs) within public health systems. This study addresses that gap by evaluating the effectiveness, implementation, and scalability of the BEhavioral Community-based COmbined Intervention for MEntal health and noncommunicable diseases (BECOME). The trial assesses clinical outcomes, implementation outcomes using

[†]Sabitri Sapkota and Bibhav Acharya contributed equally as senior authors.

*Correspondence:
Jyoti Nepal
jyoti.nepal@possiblehealth.org
Full list of author information is available at the end of the article

the Reach-Effectiveness-Adoption-Implementation-Maintenance (RE-AIM) framework at patient, provider, and health system levels and conducts a comprehensive costing analysis to inform future scale-up.

Methods This is a stepped-wedge cluster randomized controlled trial involving 20 geographic clusters across two provinces of Nepal and 700 participants aged 40 years and above with at least one CMHC and one NCD. CHWs will be trained to deliver BECOME, comprising EBSR, BA, and MI, while the control period will include enhanced usual care. Primary outcomes include changes in CMHC severity and secondary outcomes include NCD outcomes, behavioral factors, and implementation processes. Focus group discussions and in-depth interviews with CHWs, patients, healthcare providers, and health system leaders will explore intervention acceptability and mechanisms of change. Structured costing analysis will estimate the intervention costs.

Discussion Participant recruitment began in July 2024 and is currently ongoing. We anticipate completing data collection for the primary outcome measures by January 2027, with the aim of disseminating preliminary findings within the same year. Findings from this study will provide evidence on the effectiveness and feasibility of a CHW-delivered, integrated behavioral intervention, BECOME, for CMHCs and NCDs in LMICs, informing potential scale-up.

Trial registration ClinicalTrials.gov, NCT06449521, Registered on 25 April 2024, https://register.clinicaltrials.gov/prs/beta/studies/S000DZJN00000112/recordSummary.

Keywords Implementation research, Behavioral intervention, Mental health, Non-communicable diseases, Community health workers, Nepal

Introduction

Common mental health conditions (CMHCs), such as depression and anxiety, are the leading causes of disability worldwide [1]. Non-communicable diseases (NCDs) like hypertension (HTN) and diabetes mellitus (DM) cause 75% of deaths annually, with 82% occurring in low- and middle-income countries (LMICs) [2]. In LMICs, up to 70% of individuals with CMHCs receive no care [3], and treatment for HTN and DM is often inadequate [4]. In Nepal, the study setting, HTN and DM are the primary causes of mortality [4, 5], while CMHCs are the leading contributors to disability [6, 7].

CMHCs frequently co-occur with NCDs [8, 9], with mental health symptoms reported by 30–32% of individuals with HTN or DM [10, 11]. Shared behavioral risk factors such as stress, social isolation, tobacco use, low physical activity, poor diet, and medication non-adherence contribute to both conditions, leading to morbidity and mortality [12–17]. Moreover, untreated CMHCs can worsen NCD outcomes and vice versa, underscoring the need for integrated approaches to care [18, 19].

To address this gap, the World Health Organization (WHO) has developed clinical guidelines for non-specialist providers, including the mental health Gap Action Program (mhGAP) Intervention Guide [20], and the Package of Essential Non-communicable Disease Interventions (PEN) [21, 22]. Both protocols recommend behavioral interventions such as evidence-based stress reduction (EBSR) [23–26], behavioral activation (BA) [27, 28], and motivational interviewing (MI) [29–31]. These low-cost, scalable techniques are suitable for delivery by non-specialists, including primary care providers and community health workers (CHWs) [32–34]. The unreliable medication supply chain in many LMICs [35] further underscores the need for behavioral interventions, which are time-limited, cost-effective, and acceptable to patients [36, 37]. Few studies have tested integrated behavioral interventions addressing both CMHCs and NCDs concurrently [38, 39].

However, behavioral care remains underutilized. In Nepal, most patients receive medications alone, with few accessing therapy [40–43]. Primary care providers (PCPs) often lack training in evidence-based techniques, relying instead on educational or judgmental approaches [44, 45]. Patients, however, frequently prefer counseling to medications [36, 43, 46]. National data also highlight high rates of behavioral risks such as tobacco use, poor diet, and medication non-adherence, indicating an urgent need for behavioral interventions [47, 48].

Clinic-based delivery of such interventions is constrained by short visit times and limited staffing [49, 50]. CHWs, embedded within communities and already central to health outreach in Nepal and other LMICs [51–55], offer a more practical solution. Evidence shows CHWs can effectively deliver EBSR [56], BA [57], MI [29], and NCD-related counseling [58–60]. Our prior work in Nepal [61–63], and research by others [64, 65], demonstrates that CHWs can effectively deliver culturally adapted behavioral interventions for both CMHCs and NCDs.

Yet two gaps persist: First, most CHW interventions target one or two conditions rather than coexisting CMHCs and NCDs [66, 67]. For example, combining

EBSR with MI could better support tobacco cessation if stress is a barrier [68], and pairing BA with MI could address isolation and inactivity synergistically [69, 70]. Second, CHWs face implementation barriers requiring strategies at the CHW level (ongoing skill support) [71, 72], interpersonal level (support from patients and PCPs) [73, 74], and system level (funding and leadership) [75–77].

To address these gaps, we propose BECOME (Behavioral Community-based COmbined Intervention for MEntal Health and NCDs), an integrated, CHW-delivered home-based intervention combining EBSR, BA, and MI. We have previously piloted its components and tested strategies to support CHW skills, provider and patient engagement, and system-level adoption [62, 63]. A robust evaluation is now needed to assess both the effectiveness and implementation of BECOME in LMIC settings. This paper presents a novel methodology that employs a community-based, stepped-wedge cluster randomized controlled trial (SWCRT) to conduct this evaluation.

This study has three objectives: Aim 1 is to assess BECOME effectiveness on depression, anxiety, diabetes, and hypertension using a SWCRT design. Aim 2 is to evaluate implementation outcomes via the RE-AIM (reach, effectiveness, adoption, implementation, maintenance) framework at patient, provider, and health system levels. Aim 3 is to conduct a comprehensive costing analysis to provide strategic economic insights supporting long-term BECOME scale-up.

Methods

Study design

This is a type–II hybrid implementation-effectiveness study, assessing both effectiveness and implementation where we employ a SWCRT design, with cluster-level randomization stratified by municipality. Each cluster (a ward of ~ 6000 people) includes a basic healthcare clinic and is served by one CHW, minimizing contamination risk. The 20 clusters are randomized into five steps using a random number generator, transitioning from control to intervention every 3 months in groups of four (Fig. 1). Participants in each cluster will be followed up for 12 months after the completion of the intervention. SWCRT is suitable as Government of Nepal (GoN) partners want BECOME deployed across all clusters during the study, and the small number of clusters in GoN's new CHW pilot program aligns well with this design. An open cohort model [78–80] is preferred to mimic real-world conditions, support scale-up, maintain target participation during intervention phases, and address attrition or eligibility changes, especially common in CMHCs and NCDs [81, 82].

Study setting

The study is being conducted in two municipalities in Nepal, Chandragiri and Bardibas, selected for their socio-economic and geographic diversity, as well as their alignment with GoN's pilot CHW program. Chandragiri, located in the hilly Bagmati Province, has a population of 136,860 with a literacy rate of 87.3% and a provincial Human Development Index (HDI) of 0.652 [83, 84]. Bardibas, in the plains of Madhesh Province, has a population of 74,361 and a literacy rate of 72.5% with an HDI of 0.561 [83, 84]. These municipalities represent both urbanizing and semi-rural areas, making them ideal for evaluating scalable, community-based health interventions across diverse populations. The CHW program employs salaried, licensed CHWs with 3 years of clinical training (proficiency certificate in nursing) and mobile tools [85, 86]. We focus on CHWs due to GoN's priority and MI's reliance on clinical skills [29]. The intervention is supported by Possible, a non-profit organization focused on innovation and research [87].

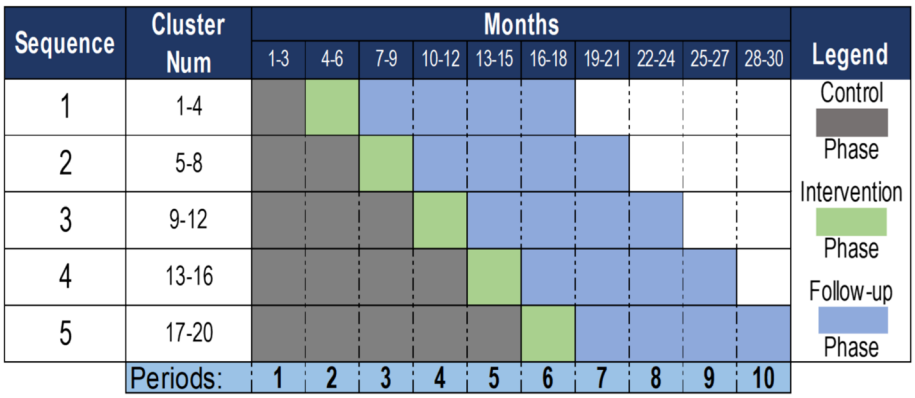


Fig. 1 Stepped-wedge schedule for 20 clusters with quarterly follow-ups during intervention rollout

Study population and eligibility criteria

Patient participants must be adult men/women aged ≥ 40 years residing in study clusters with no plans to relocate within 2.5 years. Eligible individuals must meet criteria for anxiety and/or depression (Hopkins Symptoms Checklist, HSCL-25, subscale ≥ 1.75) and have hypertension (systolic blood pressure–SBP ≥ 130 mm Hg or diastolic blood pressure–DBP ≥ 80 mm Hg) or diabetes (fasting blood glucose–FBG ≥ 126 mg/dl or random blood glucose ≥ 200 mg/dl). These criteria ensure inclusion of individuals with both CMHCs and NCDs. Individuals with significant cognitive impairment, disabling conditions, or pregnancy/postpartum status (≤ 6 weeks) are excluded due to differing care needs. Excluded patients are referred to higher-level care. Those reporting suicidalities are assessed, linked to crisis services, and re-approached for eligibility after stabilization.

CHWs must be actively working in the government pilot community health program (CHP) and trained in the BECOME intervention. No specific exclusion criteria apply to this group.

Eligible PCPs must be currently working in health facilities within the catchment areas. They must be willing to participate either in training alone or in both training and the study. We exclude those absent from health facilities within the catchment area during the study period.

Health system leaders (HSLs) include supervisors of CHWs, health coordinators from municipal offices within the catchment area, and elected representatives serving their term during the study period who are familiar with CHP. Additionally, other stakeholders who contributed to the design and implementation of CHP are eligible. We exclude those who are absent in the catchment area during the study period.

Randomization and blinding

The first step in the cluster randomization process is to identify the 20 clusters to be randomized from among the 14 and 15 clusters in the Bardibas and Chandragiri municipalities, respectively. We randomly select ten clusters from each municipality in the presence of Community Advisory Board (CAB) members to ensure transparency. Next, we randomly select four clusters for implementation of the BECOME intervention every 3 months. We video-record each randomization step to ensure transparency. We begin the initial household screening in the home located closest to the geographic center of the cluster. We then carry out subsequent screenings in the nearest neighboring household to the one previously screened, continuing this process until we recruit 35 eligible participants.

We blind the assessment staff (research outcome assessors, ROAs) by restricting their access to intervention materials, using unidentifiable ID numbers, preventing communication between CHWs and ROAs, and scheduling them to work at different times. If any accidental disclosures of cluster allocation occur, we document and address them within the study team and include them in the study analysis. At the end of the study, we plan to conduct qualitative interviews with all ROAs to document any such disclosures.

Sample size and power calculations

Power calculations assume 30 patient participants per cluster across 20 clusters over 18 months, with a SWCRT design involving five steps and six periods (Fig. 1). Anticipating some participants will regress to the mean and become ineligible, we will recruit 700 patients. Patients in the last four clusters to transition will be followed until month 30. Using the National Institute of Health (NIH) SWCRT sample size calculator [88], we estimated minimum detectable effect sizes with $\alpha = 0.05$, 80% power, and correlations: ICC = 0.2 [89], CAC = 0.7 [90], and IAC = 0.6 [81]. The attrition rate is set at 0.5 due to expected withdrawal, relocation, or ineligibility at treatment start, with up to 30% ineligibility for CMHCs [79, 81, 82]. These assumptions yield a standardized minimum detectable effect size of 0.34 about 1/3 SD on HSCL-25 indicating a small-to-medium effect [91].

Of 700 patient participants, 30 will complete in-depth interviews (IDIs) at 3 and 12 months to explore engagement barriers and facilitators. Ten focus group discussions (FGDs) with CHWs will assess intervention delivery, mHealth use, supervision, and support. Five PCPs and six health system leaders will participate in key informant interviews (KIIs) at similar intervals to explore CHW collaboration, perceived feasibility, and system-level support for BECOME scale-up and sustainability.

Recruitment and data collection

We base the sampling frame on the GoN's pilot CHP list and further validate and expand it using data from private health facilities and nonprofits. Among the 40,000 individuals aged ≥ 40 years in the 20 clusters, we estimate that 10% have at least one CMHC [92] or target NCD [93], ensuring a sufficient pool to maintain at least 35 participants per cluster per measurement period. Research staff develop the sampling framework in coordination with CHWs and municipal stakeholders. Screening begins at the household nearest to the cluster's geographical center and continues to adjacent homes until we enroll 35 eligible participants per cluster. Eligible participants provide written informed consent and complete baseline assessments via Research Electronic Data Capture (REDCap). ROAs, blinded to allocation, conduct 45- to 60-min face-to-face interviews in private settings every 3 months for

1 year following the intervention. We train and supervise ROAs to ensure interview quality, reduce bias, and protect participant confidentiality; and we provide a small financial incentive to participants. The qualitative team will conduct FGDs with CHWs and IDIs and KIIs with patient participants, PCPs, and HSLs.

Enhanced usual care

Participants receive enhanced usual care (EUC) following GoN protocols [86] in all the clusters. CHWs and PCPs receive targeted training on referral criteria and basic CMHC and NCD education. CHWs monitor symptoms and red flags every 3 months, provide health education, and refer patients as needed. PCPs at health posts conduct screening, monitor patients, provide lifestyle education, and prescribe/refill medications based on WHO's mhGAP [20] and PEN protocols [21]. They also refer patients to higher-level care when necessary.

Intervention components

EBSR: Involves diaphragmatic breathing and body scan techniques to manage stress and anxiety, recommended by WHO [20]. Delivered by trained CHWs over 2 weeks, each 20 to 30 min session includes instruction, demonstration, participant practice, feedback, and home practice assignments. Deep breathing is provided to all except those with respiratory issues, who receive body scan exercises. Culturally adapted materials and fidelity checklists exist [61].

BA: Encourages engagement in pleasurable and meaningful activities to reduce depression and increase physical activity. Offered over 2 weeks in 20 to 30 min sessions to patients with depression, BA supports mood improvement and active lifestyles. Training materials and fidelity checklists are available [61, 94, 95].

MI: A theory-driven counseling method to strengthen motivation for behavior change (e.g., tobacco cessation, nutrition), recommended by WHO PEN protocols [21, 22]. Delivered in four sessions, MI helps participants explore progress and overcome barriers. Adapted manuals and fidelity checklists are available [61, 94].

Delivery and duration: The 6–8 weeks intervention includes weekly 20 to 30 min CHW home visits. All receive 4 weeks of MI. Patients with one CMHC (anxiety or depression) receive 2 weeks of EBSR or BA; those with two CMHCs receive 4 weeks of both (Table 1). Participants who explicitly decline or choose to discontinue the intervention sessions, as well as those who become ineligible to participate in the study due to their health conditions, will be withdrawn from further session delivery after discussion in the study team. CHWs will refer these individuals to appropriate health facilities for further care, and they will continue to receive all other routine health services available within the community.

Retention

To improve retention, we leverage CHWs who have strong local networks and familiarity with households. ROAs verify and update participant contact information at each assessment. If participants are unreachable, ROAs follow a 14-day structured outreach protocol, including calls and home visits. The study team reaches out to CHWs for support if needed. Regular CHW visits for health surveillance are routine and unlikely to cause stigma. Quarterly CAB meetings serve as a source of guidance and provide independent feedback and critique to strengthen the research process that is respectful of, acceptable to, and responsive to the community.

Outcomes for Aim 1

The primary outcome measure is CMHC severity, measured by mean HSCL-25 score collected at 3-month intervals, alongside all other measures. Secondary measures include mean SBP and DBP for HTN, and mean FBG for DM. Behavioral measures include tobacco use, physical activity, diet quality, medication adherence, and adherence to follow-up (Table 2).

Outcomes and implementation strategies for Aim 2

To ensure sustainable implementation in real-world settings, we use three implementation strategies developed using the COM-B framework, which addresses capability (the individual's psychological and physical capacity

Table 1 Timeline of the BECOME intervention components

Timeline	BECOME components	Intervention target
Weeks: 1 and 2 (20–30 min each)	Evidence based stress reduction (Deep breathing or body scan)	Anxiety and stress management
Weeks: 3–4 (20–30 min each)	Behavioral activation	Depression
Weeks: 5–8 (20–30 min each)	Motivational interviewing	[a]NCD ([b]HTN and/or [c]DM) targeting behavior change or maintenance

[a] *NCD* non-communicable disease, [b]*HTN* hypertension, [c]*DM* diabetes mellitus

Table 2 Key model variables and associated components (collected quarterly except demographics)

Key model variables	Description of scales	Intervention components
Demographics	Age, education, languages spoken, religion, income, and caste	
Depression, anxiety Primary outcome	Hopkins Symptom Checklist (HSCL-25) includes depression and anxiety subscales on a 4-point like scale validated and used locally in Nepal	[a]EBSR for anxiety [b]BA for depression
[d]NCD outcomes Secondary outcomes	Mean systolic blood pressure (SBP), diastolic blood pressure (DBP), and fasting plasma glucose, measured by research staff with manual cuff and point of care test	[c]MI for all behavioral targets
Isolation and withdrawal	Behavioral Activation for Depression Scale (BADS-SF) 9-items to assess withdrawal from or engagement in rewarding activities, adapted by our team	BA for isolation and depression
Quality of life	WHO Quality of Life (WHOQOL) 26 items on physical health, psychological well-being and social functioning; validated in Nepal	All intervention components EBSR, BA, MI
Tobacco use	4 questions from Global Adult Tobacco Survey (GATS) to assess current and past smoked or smokeless tobacco use, quit attempts and intention to quit; used in Nepal	MI for tobacco avoidance
Diet quality	Diet Quality Questionnaire (DQQ) Binary questions about food groups (29 items) consumed in the previous day; adapted in many countries, including Nepal	MI for improving and maintaining diet quality
Physical activity	Global Physical Activity Questionnaire (GPAQ) 16 items to assess physical activity in work, travel and leisure; used in Nepal's national survey	MI for improving and maintaining physical activity
Medication adherence	4-day recall for medication adherence, adapted by our team in MI studies in Nepal, < 90% considered low adherence, based on current literature	MI for medication adherence
Regular clinic follow-up	Missed a scheduled follow-up clinic visit in 2 weeks or more used by our team in current MI studies in Nepal	MI for regular clinic follow up

[a] *EBSR* evidenced based stress reduction, [b]*BA* behavioral activation, [c]*MI* motivational interviewing, [d]*NCD* non-communicable disease

to engage in the behavior), opportunity (external factors that make the behavior possible or prompt it), and motivation (internal processes influencing behavior) to achieve CHWs' delivering BECOME effectively [96]. These strategies operate at intrapersonal, interpersonal, and health system levels. Implementation outcomes are assessed via the RE-AIM framework [97].

Strategy 1: mHealth app to enhance fidelity (intrapersonal level)

Maintaining fidelity is critical, as CHWs often revert to advice-giving instead of evidence-based techniques [71]. A decision support app tested with 30 CHWs in a pilot study [94] provides real-time guidance and audio recordings for supervisor feedback. Acceptability was high: 94% found it helpful, and 100% adopted it. Impact is measured via app usage, CHW FGDs, and fidelity scores (≥ 80% on BECOME checklist).

Strategy 2: CHWs' training PCPs to improve attitudes (interpersonal level)

Negative attitudes toward behavioral interventions among PCPs and patients can hinder adoption [73, 74]. Training PCPs in stress-relief techniques like EBSR and BA improves their attitudes and willingness to recommend these interventions [98]. Co-delivery of training by CHWs and mental health specialists enhances CHWs' credibility and PCP engagement, aligning with the COM-B framework [96, 99]. Measurements include pre/post attitude surveys, patient interviews, intervention reach, and quarterly perception surveys.

Strategy 3: Interdisciplinary case conferences (ICCs) to highlight CHWs' impact (health system level)

Limited recognition of CHWs is a barrier to sustainability [67]. ICCs, where CHWs and PCPs present cases together, improve health leaders' perceptions [96]. ICCs are integrated into biannual health leader meetings, with pre/post surveys and CHW support and maintenance tracked at 12 months.

Outcomes for Aim 3

Aim 3 supports policymakers in evaluating BECOME for scale-up by estimating average costs per beneficiary per CHW, analyzing cost variation across clusters and patient profiles, and assessing resource needs for scaling the implementation strategies.

Data management and analysis plan

ROAs collect data from the assessment tools (Table 2) using encrypted, password-protected tablets with the REDCap mobile app. Staff store data securely on devices until they upload it to a secure server. They store all identifying information such as consent forms and contact logs separately under lock and key. Staff do not store identifying information on the same devices or in the same locations as study data. CHWs record intervention sessions on encrypted, password-protected phones already used for patient data collection. They review audio recordings privately with research counselors for supervision and feedback. The research team randomly selects at least one recording per CHW for fidelity review using the BECOME fidelity rating scale adapted from WHO's Ensuring Quality in Psychological Support (EQUIP) platform. Only two authorized team members access these recordings, which they store temporarily on an encrypted, password-protected laptop and delete after review. A data manager, supervised by the senior statistician, reviews study data monthly to monitor completeness, accuracy, protocol adherence, and participant safety.

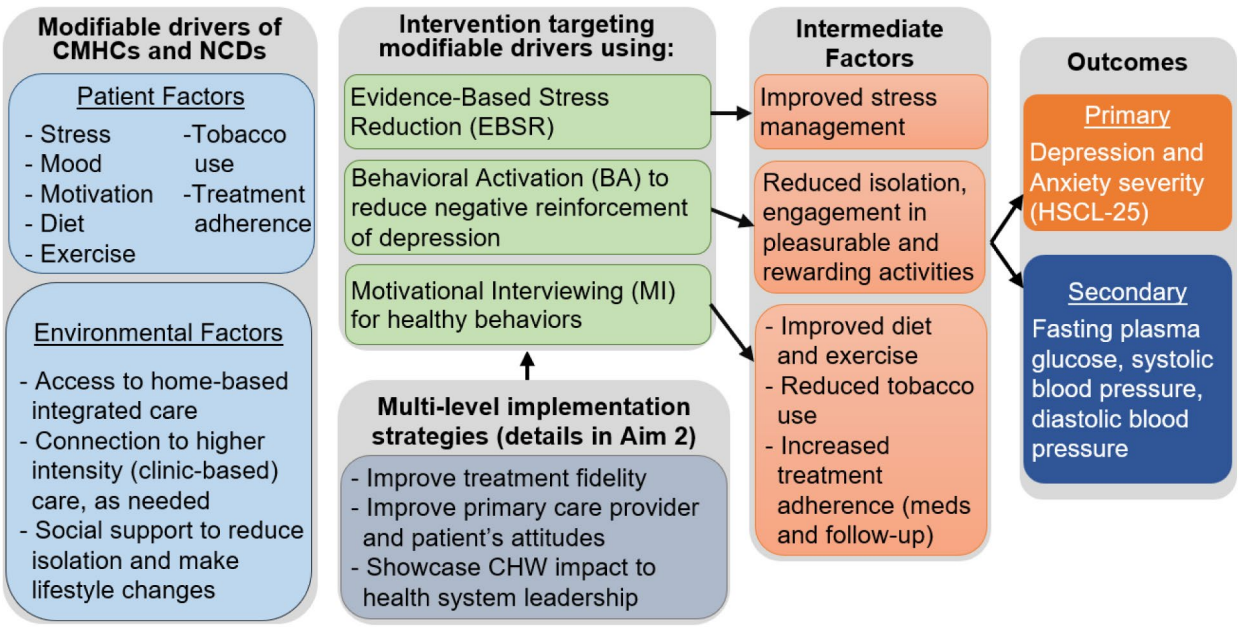
For Aim 1, we will use generalized linear mixed models to evaluate the BECOME intervention's impact on HSCL-25 scores, applying an intention-to-treat approach. Continuous outcomes will use a normal distribution with an identity link, with fixed effects for secular and intervention trends and random effects for individual, cluster, and time-level variability. The intervention effect will include a constant term and a treatment-by-time interaction, with random intercepts for participants and clusters. This method will also assess secondary outcomes (e.g., FBG, SBP, DBP). Binary outcomes (e.g., optimal adherence) will apply the same model structure with a Bernoulli distribution and logit link. Structural equation modeling will further explore direct, indirect, and synergistic effects of intervention components via mediators (Fig. 2).

Aim 2 involves a mixed-methods evaluation of implementation mechanisms using surveys and 71 in-depth interviews (30 patients–2 times, six leaders, five PCPs) and 10 FGDs, coded thematically in Dedoose. A preliminary codebook will be refined collaboratively, ensuring ≥ 80% intercoder reliability. Memos will explore links among strategies, mechanisms, and outcomes.

Additionally, CHW app usage data will be passively collected via the Community Health Toolkit, integrated into daily workflows without adding burden to CHWs.

Costing analysis plan for Aim 3

Aim 3 uses programmatic and financial data to conduct a comprehensive cost analysis of delivering BECOME. Costing will use a bottom-up (micro-costing) approach



CMHCs: Common Mental Health Conditions; NCDs: Non-communicable Diseases; CHW: Community Health Worker; HSCL-Hopkins Symptom Checklist

Fig. 2 Conceptual model to improve CMHCs and NCDs using EBSR, BA, MI, and implementation strategies

at the beneficiary level, calculating total cost per CHW visit and deriving average intervention costs, including its components [100]. Both recurrent costs and capital cost depreciation will be measured using time-defined activity-based costing (TDABC), which details resource use across care delivery [101–104].

Data sources include CHW time logs, CHW surveys on indirect resource use, researcher records of CHW, PCP training and ICC, along with financial records from municipalities and the BECOME team. CHW services are funded through municipal budgets under the Government of Nepal's CHW program. Prior costing from a similar rural CHW program in Nepal [105] informs our methods. The analysis will disaggregate costs by intervention component (EBSR, BA, MI) and function (patient care, supervision, data monitoring, administration), and detail start-up costs and cost heterogeneity by cluster and patient characteristics such as comorbidities and behavioral goals.

Participant safety, adverse event management, and data monitoring

The co-principal investigators (Co-PIs) supervise the study directly, with the site principal investigator (PI) and the research project manager overseeing daily operations. Co-investigators and domain-specific experts provide additional guidance and monitoring. All team members complete training in research ethics and human subject's protection and sign a confidentiality agreement before initiating any participant interaction. The study team actively safeguards the safety and confidentiality of all participants during assessments and intervention.

If a participant shows signs of ongoing distress despite CHW-delivered support, displays red flags per mhGAP or PEN protocols, or requests higher-intensity care for CMHCs or NCDs, the team refers them according to the referral pathway to the nearby hospitals. When ROAs identify any participant at high or acute risk of suicide, they follow the crisis management pathway and immediately connect them with a contracted crisis counselor for evaluation and support. If they require urgent intervention, the team coordinates with their emergency contact and refers them to a nearby tertiary care facility. If no immediate referral is needed, ROAs provide the participant with a resource card listing relevant support services. In both cases, a study team member and the crisis counselor follow up within 48 h to ensure the participant's safety and well-being.

All study staff report adverse events including breaches of confidentiality to the research project manager, who escalates them to the site PI. The team documents all adverse events in an Adverse Event Summary Log and attaches them to the Continuing Review or Study Closeout Forms, following each Institutional Review Board (IRB)'s reporting guidelines. For serious adverse events, the research coordinator immediately notifies the site PI, who then informs the IRB of the Nepal Health Research Council (NHRC) within 48 h and submits a detailed report within 2 weeks. We also conduct interim analyses between follow-up assessments to monitor changes in CMHCs and NCD severity, ensuring no unintended increases occur. We also document all adverse and serious adverse events to protect participant safety and evaluate any potential risks associated with the BECOME intervention.

An independent Data Safety and Monitoring Board (DSMB) oversees participant protection throughout the study. The board includes five experts in CMHCs, NCDs, biostatistics, and community-based research, and meets semi-annually (virtually or in person). The Co-PIs prepare and submit detailed reports for each meeting. The DSMB reviews participant safety protocols, confidentiality protections, and all adverse event reports. In the case of a serious adverse event, the DSMB chair may call an ad hoc meeting. The board may request additional information as needed. DSMB reports are shared with the Co-PIs and all participating IRBs to ensure transparency and accountability.

Trial quality control and auditing

The site Principal Investigator and Research Project Manager conduct weekly reviews to monitor study implementation and monthly reviews to assess recruitment, retention, participant safety, and any methodological issues. We submit biannual recruitment and performance progress reports to the National Institute of Mental Health (NIMH) and undergo annual continuing ethical review by both the NHRC and the University of California, San Francisco.

Our Nepal–US research team ensures structured implementation through pilot-tested manuals that standardize data collection and intervention delivery. CHWs complete competency-based certification using the BECOME fidelity checklist, and research staff receive training to meet performance standards. We re-train any staff who do not meet benchmarks before certification to maintain intervention quality. Monthly investigator calls, quarterly steering committee and implementation research committee meetings facilitate communication, coordination, and oversight, supporting consistent progress and collaborative management of the trial.

We used SPIRIT reporting guidelines to report this protocol [106].

Dissemination plan

We plan to actively disseminate study findings to inform public health policy, community programs, and future

Table 3 Schedule of enrollment, interventions, and assessments

Timepoint	**Study period**										
	Year 1	**Year 2**				**Year 3**				**Years 4 and 5**	
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Months		1–3	4–6	7–9	10–12	13–15	16–18	19–21	22–24	25–27	28–30
Preparation phase (develop protocol, hire/train staffs, etc.)	X										
Allocation											
Random allocation of 20 clusters (10 clusters from each site)		X									
Random allocation of 4 clusters per each intervention phase			X	X	X	X	X				
Enrollment											
Eligibility screening		X	X	X	X	X					
Informed consent		X	X	X	X	X					
Intervention											
Training of interventionists and intervention delivery (4 clusters receive intervention at each intervention phase)			X (cluster 1–4)	X (cluster 5–8)	X (cluster 9–12)	X (cluster 13–16)	X (cluster 17–20)				
Enhanced usual care (in remaining unselected clusters)		X	X	X	X	X					
Assessments											
Baseline		X	X	X	X	X					
Follow up			X	X	X	X	X	X	X	X	X
Analysis of											
Primary and secondary outcomes											X
Implementation outcomes											X
Cost-effectiveness											X

research. The results contribute to the development of integrated behavioral interventions for CMHCs and NCDs and offer a model for implementation in Nepal and similar low-resource settings. We plan to share findings with public health officials, regional and national policymakers, hospital administrators, non-governmental organizations, community members, and the international academic community. Dissemination efforts include submitting manuscripts to peer-reviewed journals, presenting at conferences, and organizing a dissemination meeting in Kathmandu in year 5 to directly engage stakeholders. We also plan to develop policy briefs and fact sheets to summarize key findings and recommendations, ensuring broad access and practical use of the study outcomes.

Following the current NIH–Data Management and Sharing Policy, we will submit de-identified quantitative participant-level data to the NIMH Data Archive within 1 year of study completion. At the time of publication, we will also share the corresponding statistical analysis code and codebooks for any qualitative data included in published findings.

Discussion

This study addresses a critical gap in the integrated management of co-occurring CMHCs and NCDs in low- and middle-income countries (LMICs), where fragmented care, stigma, and limited resources hinder effective service delivery. By training and mobilizing CHWs to deliver evidence-based behavioral interventions—EBSR, BA, and MI, the study leverages a scalable, task-shifted approach to bridge mental and physical health care in community settings. Delivering these interventions directly to patients' homes addresses structural barriers such as transportation costs, stigma associated with facility-based mental health care, and limited clinic capacity. This decentralized, community-based model enhances accessibility and feasibility, particularly in rural and under-resourced areas like Nepal. The SWCRT design offers a rigorous framework for evaluating both effectiveness and implementation while ensuring that all clusters eventually receive the intervention, addressing ethical concerns related to withholding care.

The study employs implementation strategies grounded in the COM-B model, which allows for systematic identification and mitigation of barriers to delivery. It also integrates the RE-AIM framework to assess multilevel implementation outcomes at the individual, provider, and system levels, enhancing the potential for generalizability and real-world translation. In addition to evaluating clinical and behavioral outcomes including depression and anxiety symptom reduction, improved medication adherence, tobacco cessation, and physical activity, the study includes a detailed costing analysis using the TDABC approach. This will enable policymakers to understand the financial implications of scaling up the intervention within the public health system and inform decisions on sustainability, resource allocation, and integration into existing service delivery platforms.

Despite inherent challenges, including the need to maintain intervention fidelity and mitigate participant attrition, the study incorporates multiple quality assurance mechanisms. These include standardized training and certification of CHWs using the BECOME fidelity checklist, ongoing supervision, and performance monitoring. The trial's embedding within a government-run pilot community health program and its alignment with existing Ministry of Health and Population structures enhance feasibility, acceptability, and the likelihood of long-term adoption.

Although the intervention's short duration may limit measurable impact on long-term NCD outcomes such as blood pressure or glycemic control, the study prioritizes early behavioral indicators and intermediate outcomes. These outcomes are predictive of improved clinical trajectories and align with WHO PEN and mhGAP guidelines. In addition, the study incorporates contingency planning for potential challenges, including alternative recruitment strategies and the replacement of inactive clusters.

With adequate statistical power to detect medium effect sizes even with a limited number of clusters, the study maintains scientific rigor while ensuring practical feasibility. Successful implementation within GoN health clusters will not only facilitate potential national scale-up but also generate critical implementation insights relevant to similar LMIC contexts seeking to integrate mental and physical health care through community-based platforms.

Trial status

This protocol version is 1.0 dated 14 June 2024. Participant recruitment began in July 2024 and is currently ongoing. We anticipate completing data collection for the primary outcome measures by January 2027, with the aim of disseminating preliminary findings within the same year. The detailed schedule of enrollment, intervention, and assessments is presented in Table 3.

Abbreviations

BA	Behavioral activation
BADS	Behavioral Activation for Depression Scale
BECOME	Behavioral Community-based Combined Intervention for Mental Health and Non-communicable Disease
CAB	Community Advisory Board
CHP	Community health program

CHW	Community health worker
CMHCs	Common mental health conditions
COM-B	Capability (C), opportunity (O), and motivation (M) are essential for any behavior (B) to change
Co-PI	Co-principal investigator
DBP	Diastolic blood pressure
DM	Diabetes mellitus
DQQ	Diet Quality Questionnaire
DSMB	Data Safety and Monitoring Board
EBSR	Evidence-based stress reduction
EUC	Enhanced usual care
FBG	Fasting blood glucose
FGDs	Focus group discussions
GATS	Global Adult Tobacco Survey
GoN	Government of Nepal
GPAQ	Global Physical Activity Questionnaire
HDI	Human Development Index
HSCL	Hopkins Symptom Checklist
HSL	Health system leaders
HTN	Hypertension
ICC	Interdisciplinary Case Conference
IDIs	In-depth interviews
IRB	Institutional Review Board
KIIs	Key informant interviews
LMICs	Lower middle-income countries
mhGAP	Mental Health Gap Action Program
MI	Motivational interviewing
NCDs	Non-communicable diseases
NHRC	Nepal Health Research Council
NIH	National Institute of Health
NIMH	National Institute of Mental Health
PCPs	Primary care providers
PEN	Package of essential non-communicable disease interventions
PI	Principal investigator
RE-AIM	Reach, effectiveness, adoption, implementation, and maintenance
REDCap	Research Electronic Data Capture
ROAs	Research Outcome Assessors
SBP	Systolic blood pressure
SWCRT	Stepped–wedge cluster randomized controlled trial
TDABC	Time–defined activity-based costing
WHO	World Health Organization
WHO EQUIP	WHO Ensuring quality in psychological support
WHO QOL	WHO Quality of life

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-026-09457-1.

Additional file 1: SPIRIT checklist BECOME.

Acknowledgements
We extend our sincere gratitude to the study participants and their families. We also acknowledge the support of local stakeholders in Bardibas and Chandragiri municipalities for facilitating the implementation of this research. Our appreciation extends to the Ministry of Health and Population, the Nursing and Social Security Division, Epidemiology and Disease Control Division, and the members of the Implementation Research Committee and Community Advisory Board for their guidance, support, and constructive feedback throughout the study.

Authors' contributions
BA and Sabitri S are the senior authors who conceived the research idea. BA, Sabitri S, Srijana S, KS (first author), AS, BR, HKN, Dean S, EH, MD, PPB, and DP contributed to the design of the study. PN contributed to the costing analysis plan. KS, Srijana S, BA, and PL developed the BECOME training manual. Dikshya S, SN, SJ, ST, PP, NKS, JS, and JN developed the questionnaires and interview guides. SP, BY, JN, KS, PL, and Dikshya S contributed to the mHealth tool development. KS and JN drafted the manuscript. All authors read and approved the final manuscript. All authors declare that they have no competing financial interests.

Funding
This research is supported by the National Institute of Mental Health of the National Institutes of Health under Award Number R01MH133231. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The study funder or sponsor does not have any direct role in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication.
National Institute of Mental Health,R01MH133231,Bibhav Acharya

Data Availability
We will submit de-identified participant-level data to the NIMH Data Archive. Alongside the dissemination of study findings, we will make all associated statistical code publicly available to ensure transparency and reproducibility.

Declarations

Ethics approval and consent to participate
The ethical approval for the study is obtained from institutional review boards of both University of California, San Francisco (IRB #22–38288) on 04/06/2023 and Nepal Health Research Council (registration #256/2023) on 07/13/2023. The trained ROAs obtain written informed consent from all participants prior to enrollment, and verbal consent before follow-up assessments, including IDIs. Any amendments to the trial protocol are communicated to the relevant ethical/institutional review boards, participants, and members of the data safety and monitoring board.

Consent for publication
Not applicable. We will provide the model consent form upon request.

Competing interests
The authors declare that they have no competing interests.

Author details
[1]Possible, Kathmandu, Bagmati, Nepal. [2]Department of Public Health, Kathmandu University School of Medical Sciences, Dhulikhel, Kavre, Nepal. [3]Nursing and Social Security Division, Department of Health Services, Kathmandu, Bagmati, Nepal. [4]Department of Medicine, University of California, San Francisco, San Francisco, CA, USA. [5]Department of Cardiology, Shahid Gangalal National Heart Center, Kathmandu, Bagmati, Nepal. [6]Research Section, Nepal Health Research Council, Kathmandu, Bagmati, Nepal. [7]Epidemiology and Disease Control Division, Ministry of Health and Population, Kathmandu, Bagmati, Nepal. [8]UNC Gillings School of Global Public Health, Chapel Hill, NC, USA. [9]SunyaEk Computing, Kathmandu, Bagmati, Nepal. [10]Psychology and Neuroscience Department, Wheaton College, Norton, MA, USA. [11]Department of Psychiatry, University of California, San Francisco, San Francisco, CA, USA.

Received: 7 July 2025 Accepted: 12 January 2026
Published online: 24 January 2026

References

1. GBD 2019 Mental Disorders Collaborators. Global, regional, and national burden of 12 mental disorders in 204 countries and territories, 1990–2019: a systematic analysis for the Global Burden of Disease Study 2019. The Lancet Psychiatry. 2022 Feb 1;9(2):137–50.
2. IHME. Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2019 (GBD 2019) Results. 2020.
3. Alonso J, Liu Z, Evans-Lacko S, Sadikova E, Sampson N, Chatterji S, et al. Treatment gap for anxiety disorders is global: results of the World Mental Health Surveys in 21 countries. Depress Anxiety. 2018;35(3):195–208.
4. Bhattarai S, Aryal A, Pyakurel M, Bajracharya S, Baral P, Citrin D, et al. Cardiovascular disease trends in Nepal–an analysis of global burden of disease data 2017. IJC Heart Vasc. 2020;1(30):100602.
5. Mishra SR, Neupane D, Bhandari PM, Khanal V, Kallestrup P. Burgeoning burden of non-communicable diseases in Nepal: a scoping review. Glob Health. 2015;11:1–0.
6. Dhimal M, Dahal S, Adhikari K, Koirala P, Bista B, Luitel N, et al. A nationwide prevalence of common mental disorders and suicidality in Nepal:

evidence from national mental health survey, 2019–2020. J Nepal Health Res Counc. 2022;19(4):740–7.
7. Nepal Health Research Council (NHRC), Ministry of Health and Population (MoHP), Institute for Health Metrics and Evaluation (IHME), Monitoring, Evaluation and Operational Research (MEOR). Nepal burden of disease 2019: a country report based on the 2019 Global Burden of Disease study. Kathmandu: NHRC, MoHP, IHME, MEOR; 2021.
8. Noël PH, Williams JW, Unützer J, Worchel J, Lee S, Cornell J, et al. Depression and comorbid illness in elderly primary care patients: impact on multiple domains of health status and well-being. The Annals of Family Medicine. 2004;2(6):555–62.
9. van der Feltz-Cornelis C, Allen SF, Holt RI, Roberts R, Nouwen A, Sartorius N. Treatment for comorbid depressive disorder or subthreshold depression in diabetes mellitus: systematic review and meta-analysis. Brain Behav. 2021;11(2):e01981.
10. Khaledi M, Haghighatdoost F, Feizi A, Aminorroaya A. The prevalence of comorbid depression in patients with type 2 diabetes: an updated systematic review and meta-analysis on huge number of observational studies. Acta Diabetol. 2019;56(1):631–50.
11. Li Z, Li Y, Chen L, Chen P, Hu Y. Prevalence of depression in patients with hypertension: a systematic review and meta-analysis. Medicine. 2015;94(31):e1317.
12. Patel V, Chatterji S. Integrating mental health in care for noncommunicable diseases: an imperative for person-centered care. Health Aff. 2015;34(9):1498–505.
13. Kalkhoran S, Benowitz NL, Rigotti NA. Prevention and treatment of tobacco use: JACC health promotion series. J Am Coll Cardiol. 2018;72(9):1030–45.
14. WHO. Global Recommendations on Physical Activity for Health. Geneva: World Health Organization; 2010.
15. Willett WC, Dietz WH, Colditz GA. Guidelines for healthy weight. N Engl J Med. 1999;341(6):427–34.
16. Pampallona S, Bollini P, Tibaldi G, Kupelnick B, Munizza C. Patient adherence in the treatment of depression. Br J Psychiatry. 2002;180(2):104–9.
17. Hennein R, Hwang SJ, Au R, Levy D, Muntner P, Fox CS, et al. Barriers to medication adherence and links to cardiovascular disease risk factor control: the Framingham Heart Study. Intern Med J. 2018;48(4):414–21.
18. Von Korff M, Scott KM, Gureje O. Global perspectives on mental-physical comorbidity in the WHO World Mental Health Surveys. New York: Cambridge University Press; 2009.
19. Moussavi S, Chatterji S, Verdes E, Tandon A, Patel V, Ustun B. Depression, chronic diseases, and decrements in health: results from the World Health Surveys. The lancet. 2007;370(9590):851–8.
20. World Health Organization. mhGAP intervention guide for mental, neurological and substance use disorders in non-specialized health settings: mental health Gap Action Programme (mhGAP) 2016.
21. WHO. Package of essential noncommunicable (PEN) disease interventions for primary health care in low-resource settings. Geneva, Switzerland: World Health Organization; 2010.
22. WHO. Package of essential noncommunicable (PEN) disease and healthy lifestyle interventions: training modules for primary health care workers. New Delhi: World Health Organization, Regional Office for South-East Asia; 2018.
23. Blanck P, Perleth S, Heidenreich T, Kröger P, Ditzen B, Bents H, et al. Effects of mindfulness exercises as stand-alone intervention on symptoms of anxiety and depression: systematic review and meta-analysis. Behav Res Ther. 2018;1(102):25–35.
24. Ng DL, Chai CS, Tan KL, Chee KH, Tung YZ, Wai SY, et al. The efficacy of a single session of 20-minute mindful breathing in reducing dyspnea among patients with acute decompensated heart failure: a randomized controlled trial. American Journal of Hospice and Palliative Medicine®. 2021;38(3):246–52.
25. Bell TP. Meditative practice cultivates mindfulness and reduces anxiety, depression, blood pressure, and heart rate in a diverse sample. J Cogn Psychother. 2015;29(4):343–55.
26. Call D, Miron L, Orcutt H. Effectiveness of brief mindfulness techniques in reducing symptoms of anxiety and stress. Mindfulness. 2014;5:658–68.
27. Dimidjian S, Barrera M Jr, Martell C, Muñoz RF, Lewinsohn PM. The origins and current status of behavioral activation treatments for depression. Annu Rev Clin Psychol. 2011;7(1):1–38.
28. Dimidjian S, Hollon SD, Dobson KS, Schmaling KB, Kohlenberg RJ, Addis ME, et al. Randomized trial of behavioral activation, cognitive therapy, and antidepressant medication in the acute treatment of adults with major depression. J Consult Clin Psychol. 2006;74(4):658.
29. Berhe KK, Gebru HB, Kahsay HB. Effect of motivational interviewing intervention on HgbA1C and depression in people with type 2 diabetes mellitus (systematic review and meta-analysis). PLoS ONE. 2020;15(10):e0240839.
30. Heckman CJ, Egleston BL, Hofmann MT. Efficacy of motivational interviewing for smoking cessation: a systematic review and meta-analysis. Tob Control. 2010;19(5):410–6.
31. Lundahl B, Moleni T, Burke BL, Butters R, Tollefson D, Butler C, et al. Motivational interviewing in medical care settings: a systematic review and meta-analysis of randomized controlled trials. Patient Educ Couns. 2013;93(2):157–68.
32. World Health Organization. Scaling up care for mental, neurological, and substance use disorders. Mental Health Gap Action Programme. 2008:1–44.
33. Barnett ML, Puffer ES, Ng LC, Jaguga F. Effective training practices for non-specialist providers to promote high-quality mental health intervention delivery: a narrative review with four case studies from Kenya, Ethiopia, and the United States. Cambridge Prisms: Global Mental Health. 2023;10:e26.
34. Anthonisen NR, Skeans MA, Wise RA, Manfreda J, Kanner RE, Connett JE, et al. The effects of a smoking cessation intervention on 14.5-year mortality: a randomized clinical trial. Annals of internal medicine. 2005;142(4):233–9.
35. Shrestha R, Yadav UN, Shrestha A, Paudel G, Makaju D, Poudel P, et al. Analyzing the implementation of policies and guidelines for the prevention and management of type 2 diabetes at primary health care level in Nepal. Front Public Health. 2022;9(10):763784.
36. Singla DR, Kohrt BA, Murray LK, Anand A, Chorpita BF, Patel V. Psychological treatments for the world: lessons from low-and middle-income countries. Annu Rev Clin Psychol. 2017;13(1):149–81.
37. Patel V, Saxena S, Lund C, Thornicroft G, Baingana F, Bolton P, et al. The Lancet Commission on global mental health and sustainable development. The lancet. 2018;392(10157):1553–98.
38. VanBuskirk KA, Wetherell JL. Motivational interviewing with primary care populations: a systematic review and meta-analysis. J Behav Med. 2014;37:768–80.
39. Jordans MJ, Luitel NP, Garman E, Kohrt BA, Rathod SD, Shrestha P, et al. Effectiveness of psychological treatments for depression and alcohol use disorder delivered by community-based counsellors: two pragmatic randomised controlled trials within primary healthcare in Nepal. Br J Psychiatry. 2019;215(2):485–93.
40. Salisbury TT, Kohrt BA, Bakolis I, Jordans MJ, Hull L, Luitel NP, et al. Adaptation of the world health organization electronic mental health gap action programme intervention guide app for mobile devices in nepal and nigeria: protocol for a feasibility cluster randomized controlled trial. JMIR research protocols. 2021;10(6):e24115.
41. Xu L, Lv X, Wang H, Liu Q, Zhou S, Gao S, et al. Trends in psychotropic medication prescriptions in Urban China from 2013 to 2017: national population-based study. Front Psych. 2021;25(12):727453.
42. Beck CA, Patten SB, Williams JV, Wang JL, Currie SR, Maxwell CJ, et al. Antidepressant utilization in Canada. Soc Psychiatry Psychiatr Epidemiol. 2005;40:799–807.
43. Bhardwaj A, Gurung D, Rai S, Kaiser BN, Cafaro CL, Sikkema KJ, et al. Treatment preferences for pharmacological versus psychological interventions among primary care providers in Nepal: mixed methods analysis of a pilot cluster randomized controlled trial. Int J Environ Res Public Health. 2022;19(4):2149.
44. Acharya B, Hirachan S, Mandel JS, van Dyke C. The mental health education gap among primary care providers in rural Nepal. Acad Psychiatry. 2016;40:667–71.
45. Shrestha A, Maharjan R, Karmacharya BM, Bajracharya S, Jha N, Shrestha S, et al. Health system gaps in cardiovascular disease prevention and management in Nepal. BMC Health Serv Res. 2021;21:1–3.
46. Ventevogel P. Integration of mental health into primary healthcare in low-income countries: avoiding medicalization. Int Rev Psychiatry. 2014;26(6):669–79.

47. Aryal KK, Mehata S, Neupane S, Vaidya A, Dhimal M, Dhakal P, et al. The burden and determinants of non communicable diseases risk factors in Nepal: findings from a nationwide STEPS survey. PLoS ONE. 2015;10(8):e0134834.
48. Bista B, Dhimal M, Bhattarai S, Neupane T, Xu YY, Pandey AR, et al. Prevalence of non-communicable diseases risk factors and their determinants: results from STEPS survey 2019. Nepal PloS one. 2021;16(7):e0253605.
49. Acharya B, Ekstrand M, Rimal P, Ali MK, Swar S, Srinivasan K, et al. Collaborative care for mental health in low-and middle-income countries: a WHO health systems framework assessment of three programs. Psychiatr Serv. 2017;68(9):870–2.
50. Irving G, Neves AL, Dambha-Miller H, Oishi A, Tagashira H, Verho A, et al. International variations in primary care physician consultation time: a systematic review of 67 countries. BMJ Open. 2017;7(10):e017902.
51. Jackson J, Dangal R, Dangal B, Gupta T, Jirel S, Khadka S, et al. Implementing collaborative care in low-resource government, research, and academic settings in Rural Nepal. Psychiatr Serv. 2022;73(9):1073–6.
52. Citrin D, Thapa P, Nirola I, Pandey S, Kunwar LB, Tenpa J, et al. Developing and deploying a community healthcare worker-driven, digitally-enabled integrated care system for municipalities in rural Nepal. InHealthcare 2018 (Vol. 6, No. 3, pp. 197–204). Elsevier.
53. Acharya B, Maru D, Schwarz R, Citrin D, Tenpa J, Hirachan S, et al. Partnerships in mental healthcare service delivery in low-resource settings: developing an innovative network in rural Nepal. Glob Health. 2017;13:1–7.
54. Ved R, Scott K, Gupta G, Ummer O, Singh S, Srivastava A, et al. How are gender inequalities facing India's one million ASHAs being addressed? Policy origins and adaptations for the world's largest all-female community health worker programme. Hum Resour Health. 2019;17:1–5.
55. Schurer JM, Fowler K, Rafferty E, Masimbi O, Muhire J, Rozanski O, et al. Equity for health delivery: opportunity costs and benefits among Community Health Workers in Rwanda. PLoS ONE. 2020;15(9):e0236255.
56. Barnett ML, Gonzalez A, Miranda J, Chavira DA, Lau AS. Mobilizing community health workers to address mental health disparities for underserved populations: a systematic review. Adm Policy Ment Health. 2018;45:195–211.
57. Patel V, Weobong B, Weiss HA, Anand A, Bhat B, Katti B, et al. The Healthy Activity Program (HAP), a lay counsellor-delivered brief psychological treatment for severe depression, in primary care in India: a randomised controlled trial. The Lancet. 2017;389(10065):176–85.
58. Gray KE, Hoerster KD, Taylor L, Krieger J, Nelson KM. Improvements in physical activity and some dietary behaviors in a community health worker-led diabetes self-management intervention for adults with low incomes: results from a randomized controlled trial. Translational Behavioral Medicine. 2021;11(12):2144–54.
59. Neupane D, McLachlan CS, Mishra SR, Olsen MH, Perry HB, Karki A, et al. Effectiveness of a lifestyle intervention led by female community health volunteers versus usual care in blood pressure reduction (COBIN): an open-label, cluster-randomised trial. Lancet Glob Health. 2018;6(1):e66-73.
60. Jeet G, Thakur JS, Prinja S, Singh M. Community health workers for non-communicable diseases prevention and control in developing countries: evidence and implications. PLoS ONE. 2017;12(7):e0180640.
61. Rimal P, Choudhury N, Agrawal P, Basnet M, Bohara B, Citrin D, et al. Collaborative care model for depression in rural Nepal: a mixed-methods implementation research study. BMJ Open. 2021;11(8):e048481.
62. Kumar A, Schwarz D, Acharya B, Agrawal P, Aryal A, Choudhury N, et al. Designing and implementing an integrated non-communicable disease primary care intervention in rural Nepal. BMJ Glob Health. 2019;4(2):e001343.
63. Acharya B, Tenpa J, Thapa P, Gauchan B, Citrin D, Ekstrand M. Recommendations from primary care providers for integrating mental health in a primary care system in rural Nepal. BMC Health Serv Res. 2016;16:1–8.
64. Worster DT, Franke MF, Bazúa R, Flores H, García Z, Krupp J, et al. Observational stepped-wedge analysis of a community health worker-led intervention for diabetes and hypertension in rural Mexico. BMJ Open. 2020;10(3):e034749.
65. Alaofè H, Asaolu I, Ehiri J, Moretz H, Asuzu C, Balogun M, et al. Community health workers in diabetes prevention and management in developing countries. Ann Glob Health. 2017;83(3–4):661–75.
66. Joshi R, Alim M, Kengne AP, Jan S, Maulik PK, Peiris D, et al. Task shifting for non-communicable disease management in low and middle income countries–a systematic review. PLoS ONE. 2014;9(8):e103754.
67. Long H, Huang W, Zheng P, Li J, Tao S, Tang S, et al. Barriers and facilitators of engaging community health workers in non-communicable disease (NCD) prevention and control in China: a systematic review (2006–2016). Int J Environ Res Public Health. 2018;15(11):2378.
68. Twyman L, Bonevski B, Paul C, Bryant J. Perceived barriers to smoking cessation in selected vulnerable groups: a systematic review of the qualitative and quantitative literature. BMJ Open. 2014;4(12):e006414.
69. Horne SJ, Topp TE, Quigley L. Depression and the willingness to expend cognitive and physical effort for rewards: a systematic review. Clin Psychol Rev. 2021;1(88):102065.
70. Coulter A, Entwistle VA, Eccles A, Ryan S, Shepperd S, Perera R. Personalised care planning for adults with chronic or long-term health conditions. Cochrane Database of Systematic Reviews. 2015(3).
71. Ludwick T, Turyakira E, Kyomuhangi T, Manalili K, Robinson S, Brenner JL. Supportive supervision and constructive relationships with healthcare workers support CHW performance: use of a qualitative framework to evaluate CHW programming in Uganda. Hum Resour Health. 2018;16:1–8.
72. Acharya B, Maru D, Ekstrand M. Improving engagement in care via community-based mHealth motivational interviewing tool for HIV-positive youth (COMMIT+). National Institutes of Health Research Portfolio Online Reporting Tools (NIH RePORT); 2019.
73. Gelhorn HL, Sexton CC, Classi PM. Patient preferences for treatment of major depressive disorder and the impact on health outcomes: a systematic review. The primary care companion for CNS disorders. 2011;13(5):27083.
74. Rowland N, Bower P, Mellor C, Heywood P, Godfrey C. Counselling for depression in primary care. The Cochrane database of systematic reviews. 2001(1):CD001025-.
75. Rowe AK, Rowe SY, Peters DH, Holloway KA, Chalker J, Ross-Degnan D. Effectiveness of strategies to improve health-care provider practices in low-income and middle-income countries: a systematic review. Lancet Glob Health. 2018;6(11):e1163–75.
76. Tseng YH, Griffiths F, De Kadt J, Nxumalo N, Rwafa T, Malatji H, et al. Integrating community health workers into the formal health system to improve performance: a qualitative study on the role of on-site supervision in the South African programme. BMJ Open. 2019;9(2):e022186.
77. Lehmann U, Twum-Danso NA, Nyoni J. Towards universal health coverage: what are the system requirements for effective large-scale community health worker programmes? BMJ Glob Health. 2019;4(Suppl 9):e001046.
78. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Med Care. 2012;50(3):217–26.
79. Copas AJ, Lewis JJ, Thompson JA, Davey C, Baio G, Hargreaves JR. Designing a stepped wedge trial: three main designs, carry-over effects and randomisation approaches. Trials. 2015;16:1–2.
80. Kasza J, Hooper R, Copas A, Forbes AB. Sample size and power calculations for open cohort longitudinal cluster randomized trials. Stat Med. 2020;39(13):1871–83.
81. Whiteford HA, Harris MG, McKeon G, Baxter A, Pennell C, Barendregt JJ, et al. Estimating remission from untreated major depression: a systematic review and meta-analysis. Psychol Med. 2013;43(8):1569–85.
82. Linden A. Assessing regression to the mean effects in health care initiatives. BMC Med Res Methodol. 2013;13:1–7.
83. Mishra M, Sijapati DB. Spatial distribution of population in Nepal: on the basis of 2078 census. Journal of Population and Development. 2023;4(1):68–80.
84. Dulal TD. Status of human development index with reference to Nepal. Journal of Population and Development. 2023;4(1):166–80.
85. Government of Nepal Ministry of Health and Population Department of Drug Administration: National List of Essential Medicines, sixth revision. Kathmandu, 2021.
86. Program NGoCH. National Guideline on Community Health Program 2078. 2021. p. 53.
87. Possible Nepal. Annual Impact Report 2023–2024.
88. National Institutes of Health. SWGRT calculator. Available from: https://researchmethodsresources.nih.gov/swgrt-calculator

89. Jordans MJ, Kohrt BA, Sangraula M, Turner EL, Wang X, Shrestha P, et al. Effectiveness of Group Problem Management Plus, a brief psychological intervention for adults affected by humanitarian disasters in Nepal: a cluster randomized controlled trial. PLoS Med. 2021;18(6):e1003621.
90. Hemming K, Kasza J, Hooper R, Forbes A, Taljaard M. A tutorial on sample size calculation for multiple-period cluster randomized parallel, cross-over and stepped-wedge trials using the Shiny CRT Calculator. Int J Epidemiol. 2020;49(3):979–95.
91. Cohen J. Statistical Power Analysis for the Behavioral Sciences. 2nd ed. 1988, p.567.
92. Jha AK, Ojha SP, Dahal S, Sharma P, Pant SB, Labh S, et al. Prevalence of mental disorders in Nepal: findings from the pilot study. J Nepal Health Res Counc. 2019;17(2):141–7.
93. Dhungana RR, Karki KB, Bista B, Pandey AR, Dhimal M, Maskey MK. Prevalence, pattern and determinants of chronic disease multimorbidity in Nepal: secondary analysis of a national survey. BMJ Open. 2021;11(7):e047665.
94. Acharya B, Maru D. Acceptability and feasibility of community-based mHealth motivational interviewing tool for depression (COMMIT-D) to improve adherence to treatment. National Institutes of Health Research Portfolio Online Reporting Tools (NIH RePORT). 2019.
95. Acharya B. Burnout videos for Nepali healthcare workers. 2022 May 16. Available from: https://www.youtube.com/playlist?list=PLV0sw4F9j1JkeGtpWGT6zoFs-vHhFJUVD
96. Michie S, Van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci. 2011;6:1–2.
97. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health. 1999;89(9):1322–7.
98. McHugh RK, Whitton SW, Peckham AD, Welge JA, Otto MW. Patient preference for psychological vs pharmacologic treatment of psychiatric disorders: a meta-analytic review. J Clin Psychiatry. 2013;74(6):13979.
99. Kohrt BA, Turner EL, Rai S, Bhardwaj A, Sikkema KJ, Adelekun A, et al. Reducing mental illness stigma in healthcare settings: proof of concept for a social contact intervention to address what matters most for primary care providers. Soc Sci Med. 2020;1(250):112852.
100. Cashin C, Ozaltin A. Costing of health services for provider payment: a practical manual based on country costing challenges, trade-offs, and solutions. Joint Learning Network for Universal Health Coverage; 2014.
101. McBain RK, Jerome G, Warsh J, Browning M, Mistry B, Faure PA, et al. Rethinking the cost of healthcare in low-resource settings: the value of time-driven activity-based costing. BMJ Glob Health. 2016;1(3):e000134.
102. Campanale C, Cinquini L, Tenucci A. Time-driven activity-based costing to improve transparency and decision making in healthcare: a case study. Qual Res Account Manag. 2014;11(2):165–86.
103. Kaplan RS. Improving value with TDABC. Healthc Financ Manage. 2014;68(6):76–84.
104. Keel G, Savage C, Rafiq M, Mazzocato P. Time-driven activity-based costing in health care: a systematic review of the literature. Health Policy. 2017;121(7):755–63.
105. Nepal P, Schwarz R, Citrin D, Thapa A, Acharya B, Acharya Y, et al. Costing analysis of a pilot community health worker program in rural Nepal. Global Health: Science and Practice. 2020;8(2):239–55.
106. Chan AW, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin JA, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ. 2013;9(346):e7586.

Publisher's Note