

Implementation and Scale-Up of Integrated Depression Care in South Africa: An Observational Implementation Research Protocol

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Abstract

Background: People with chronic general medical conditions who have comorbid depression experience poorer health outcomes. This problem has received scant attention in low- and middle-income countries. The aim of the ongoing study reported here is to refine and promote the scale-up of an evidence-based task-sharing collaborative care model, the Mental Health Integration (MhINT) program, to treat patients with comorbid depression and chronic disease in primary health care settings in South Africa.

Methods: Adopting a learning-health-systems approach, this study uses an onsite, iterative observational implementation science design. Stage 1 comprises assessment of the original MhINT model under real-world conditions in an urban subdistrict in KwaZulu-Natal, South Africa, to inform refinement of the model and its implementation strategies. Stage 2 comprises assessment of the refined model across urban, semiurban, and rural contexts. In both stages, population-level effects are assessed by using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) evaluation framework with various sources of data, including secondary data collection and a patient cohort study (N=550). The Consolidated Framework for Implementation Research is used to understand contextual determinants of implementation success involving quantitative and qualitative interviews (stage 1, N=78; stage 2, N=282).

Results: The study results will help refine intervention components and implementation strategies to enable scale-up of the MhINT model for depression in South Africa.

Next steps: Next steps include strengthening ongoing engagements with policy makers and managers, providing technical support for implementation, and building the capacity of policy makers and managers in implementation science to promote wider dissemination and sustainment of the intervention.

Highlights

This study protocol uses an onsite, iterative, observational implementation research design and a learning-health-systems approach to assess the implementation of an evidence-based collaborative model for integrated primary care for depression.

Potential refinements to all components of the model at multiple levels (patient, provider, system) are evaluated simultaneously, in contrast to evaluating the contribution of a fixed implementation strategy on the basis of a set of predetermined outcomes.

The learning-health-systems approach promotes the model's alignment with and response to the priorities and practicalities of implementation across diverse, real-world settings, which should optimize implementation and wider dissemination.

South Africa faces a substantial burden of multimorbid chronic diseases, including HIV, cardiovascular disease, diabetes, common mental disorders (CMDs) (e.g., depression, anxiety), and substance use disorders (1–4). Depression is of particular concern. Depression is the most prevalent disorder in South Africa (5), and people with chronic general medical diseases are more likely to experience depression than the general population (6, 7). Furthermore, depression comorbid with chronic physical conditions compromises patient self-care and adherence to treatment regimens for general medical diseases (8–10), and this patient population experiences poorer health outcomes and increased mortality (11, 12).

In the context of a 75% treatment gap for CMDs in South Africa (13), the country's national mental health policy emphasizes the integration of mental health care, including depression care, into primary health care (PHC) via task sharing (14). This focus is in line with health systems reforms toward horizontal integrated programming to respond to the burden of multimorbid diseases in South Africa (14).

PHC-based task sharing as part of pharmacological and psychosocial treatment models for CMDs has proven effective in low- and middle-income countries (LMICs) (15, 16). Furthermore, integrated collaborative stepped care that includes task sharing has been found to be efficient and effective for depression care. Most of this evidence comes from controlled trials in high- and middle-income countries (17–19). Few evidence-based models of collaborative stepped care pertain to integrated depression care in real-world, lower-resource contexts (20–22). Additionally, evidence is lacking on implementation strategies that enable uptake of integrated primary care for depression within routine primary care in LMICs.

A collaborative task-sharing model for integrated primary care for depression was developed through the Program for Improving Mental Health Care (PRIME) in South Africa (PRIME-SA) (23). The model's efficacy and effectiveness were evaluated through a repeat cross-sectional survey in clinics and a comparison group cohort study, which had good outcomes at the facility and patient level (24), and through a pragmatic cluster randomized controlled trial using study-employed lay counselors (25), which found that the model did not produce inferior outcomes compared with care as usual when psychological treatment was provided by mental health specialists (26). However, uptake of the model—in particular, PHC providers' identification and referral of chronic care patients with comorbid depression—was poor.

In accordance with the translational research continuum (27), this evidence-based model represents the initial Mental Health Integration (MhINT) model evaluated by this observational implementation science protocol to understand how to promote implementation and broader dissemination of the model. Funding obtained from the Centers for Disease Control and Prevention (U2GGH001197) was used to provide technical support to the KwaZulu-Natal Department of Health (DoH) in the KwaZulu-Natal province of South Africa in order to scale up this model in one district, as a test site. The intervention components of the initial MhINT model involve the provision of psychoeducation, screening, and strengthened clinician assessment and diagnosis of depressive symptoms at the PHC facility level (see Figure A1 in the online supplement). The latter is achieved through the provision of enhanced mental health training in the use of Adult Primary Care (APC), known internationally as the Practical Approach to Care Kit (PACK) (28). APC is a clinical decision-making tool providing integrated evidence-based guidelines for the diagnosis and treatment of chronic conditions. It is intended for use by all health care practitioners working at the primary care level and has been rolled out nationally by the South African National Department of Health.

Referral pathways are also strengthened. Depending on severity of depressive symptoms, patients are referred to either nonspecialist clinic-based staff trained to provide psychosocial counseling using cognitive behavioral techniques and problem solving, both shown to have an evidence base for delivery within nonspecialized health care settings (15); clinic-based PHC doctors with strengthened training to initiate psychotropic medication; or mental health specialists at the district level. To optimize scale-up of this task-sharing model by the DoH, an initial set of implementation strategies was chosen on the basis of practical experience and process evaluation conducted during the formative and outcome evaluation of the PRIME-SA model (23, 24).

Table 1 describes the roles of various health systems actors in implementing this initial model, including the initial set of implementation strategies employed by MhINT. We have aligned these roles to the implementation strategies specified by the Expert Recommendations for Implementing Change (29). We describe the Southern African Research Consortium for Mental Health Integration (SMhINT) evaluation protocol. Our aim is to observe real-world implementation of the initial MhINT model described above in order to identify opportunities to refine and adapt this initial model and to optimize widespread implementation and dissemination of the model in South Africa.

Methods

Learning-Health-Systems Approach

We are guided by a learning-health-systems approach, where policy makers, researchers, service providers, and patients work as a collective to iteratively coproduce new knowledge and engage in shared decision making to strengthen the health system and health outcomes (30). Critically, learning health systems strive to identify

interventions and implementation strategies that work in routine contexts: generating new evidence through research when required, solving practical problems of service delivery, and engaging in rigorous evaluation of program effectiveness to improve quality across the health system (30). This study builds on a sustained partnership between the investigators and the South African Departments of Health at the national, provincial, and district levels through the PRIME and MhINT programs, collectively amounting to 6 years of collaboration.

Study Design

We will use an onsite, iterative, observational implementation science design (27) structured around the four phases of intervention scale-up established by Barker et al. (31): an initial “setup” phase, during which the initial MhINT model is introduced into the system; an early assessment and refinement of the initial model into a “scalable unit” for inclusion in routine PHC services; an assessment of the scalable unit across a variety of contexts that would be encountered at scale; and a “going-to-full-scale” phase, during which a larger number of sites adopt the refined MhINT model. The initial setup phase, involving the introduction of the MhINT model into the study site district, was completed between 2016 and 2018. This protocol covers the assessment and refinement of the model into a scalable unit and the assessment of the scalable unit across contexts (renamed as stages 1 and 2, respectively). Barker et al.’s fourth phase is beyond the scope of this study.

We combine the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework (32) and the Consolidated Framework for Implementation Research (CFIR) (33) with mixed-methods data collection (34) (see Figure A2 in the online supplement). Within the context of our overall aim, the study objectives are described in Box 1.

RE-AIM outlines the critical elements of the population-level effects of health interventions (32). Definitions of the RE-AIM elements are provided in Table 2. Semistructured interviews targeting CFIR domains will be used to explore the implementation component of RE-AIM. CFIR delineates constructs associated with implementation success across several domains: intervention characteristics, such as goodness of fit; inner setting or health system characteristics that may aid or abet integration, including organizational culture; characteristics of the outer setting or external environment, such as policies and community needs; characteristics of individuals, including patient and provider needs; and implementation processes, such as harnessing of support from key stakeholders to improve uptake (33, 35). This study received ethical approval from the University of KwaZulu-Natal Biomedical Research Ethics Committee (reference: BF190/17).

Study Sites

The study site is the Amajuba district in the northwest of KwaZulu-Natal, where the MhINT model was implemented. Amajuba has three diverse subdistricts: Newcastle (urban), Dannhauser (semiurban), and eMadlangeni (rural) (Table 2). Assessment of the initial MhINT setup model (objectives 1.1 and 1.2) will be undertaken in 10 of the 14 PHC facilities in the urban Newcastle subdistrict. Assessment of the refined MhINT scalable unit model (objectives 2.1 and 2.2) is planned to take place across all three subdistricts, providing the opportunity to observe how the refined model and implementation strategies perform in the initial urban site (Newcastle) and whether adaptations are needed for semiurban and rural contexts. All PHC facilities are serviced by full-time PHC nurses, including professional nurses with a 4-year degree or diploma, enrolled nurses who have a 2-year diploma, sessional PHC doctors, and HIV counselors. Limited mental health specialists (N=3) are available at referral facilities.

Study Procedures

Objectives 1.1 and 2.1: RE-AIM assessment.

In order to assess the RE-AIM outcomes, a number of data sources, summarized in Table 3, were used with accompanying subprotocols for the collection of these data. We provide more details on the subprotocols below.

Secondary data on project implementation, including project records and routinely collected data, will be gathered from all participating clinics from the start to the end of the cohort studies in stages 1 and 2. Routine service delivery data on screening and treatment rates will be extracted from the provincial District Health Information System. Data that are collected only by facilities (e.g., tracking delivery of some implementation strategies, including morning talks) will be extracted by field-workers. MhINT project monitoring data will include counseling intervention fidelity, measured by using fidelity checklists and records from supervisory visits; referral rates extracted from referral forms; facility and staff characteristics gleaned from facility profiles; patient counseling uptake assessed from patient tracking forms; and implementation of training packages and use of standardized operating procedures, extracted from training records and continuous quality improvement reports.

The cohort study will estimate how depression diagnoses made by nurses and referral for depression management affected participants’ depression outcomes, treatment adherence, stress, disability, income, and employment.

Enrollment of eligible participants for the cohorts will be done by trained research workers with the nine-item Patient Health Questionnaire (PHQ-9) and will occur before consultation with a nurse. Professional nurses will not know participants' PHQ-9 scores; any diagnosis of depression by professional nurses will be based on APC guidelines and will be independent of enrollment procedures. Whether each participant has been diagnosed as having depression by a nurse is determined with an exit interview conducted after the participant's consultation with a nurse. Participants will be divided into three groups: patients diagnosed and referred for care by the nurse, patients diagnosed and not referred, and patients not diagnosed. Data will be collected at baseline at patients' first point of contact with the program and at 3-months and 9-month follow-ups to ascertain stability of effects.

A target sample of 550 participants is set for the cohort study (not diagnosed, N=200; diagnosed and not referred, N=150; diagnosed and referred, N=200). This sample is estimated to provide 86% power to detect a difference in mean PHQ-9 score of 2.0 points (5.3 versus 7.3) between the diagnosed and referred and undiagnosed groups, with 5% significance, assuming SD=5.1, intraclass correlation=0.1, and a 20% loss to follow-up (mean \pm SD=7.3 \pm 5.1 is from the 6-month follow-up in the PRIME trial). (Scores on the PHQ-9 range from 0 to 27, with cut-off scores signifying depression being determined by validation studies in different contexts.) The sample of 200 participants in the diagnosed and referred group and 150 in the diagnosed but not referred group will provide 81% power to detect a difference in mean PHQ-9 score of 2.0 points (5.3 versus 7.3) between the groups, with 5% significance, also assuming SD=5.1, intraclass correlation=0.1, and a 20% loss to follow-up. The number of patients recruited in each clinic may vary, depending on the number consecutively enrolled, in order to meet the total sample sizes required. Inclusion criteria are age \geq 18 years, having time and ability to complete the full interview, willingness to provide informed consent, and reporting a PHQ-9 score \geq 9. Exclusion criteria are reporting a PHQ-9 score $<$ 9 and inability to provide informed consent (e.g., presence of severe intellectual disability, currently experiencing an acute medical issue, or lack of private space for the interview). Field-workers will be trained to make these assessments. Patients with severe depression and who have had end-of-life thoughts for 7 days or more in the past 2 weeks will be accompanied by project staff to a clinic's professional nurses for care; project staff will be instructed not to leave the patient unattended until the patient has been seen by a professional nurse.

After providing written informed consent, participants will be interviewed in the local language (isiZulu) or English. Data will be collected by using digital handheld devices and uploaded onto a secure server at the University of KwaZulu-Natal. Data quality assurance will be managed through daily quality checks of uploaded data and in vivo observations of interviews to ensure fidelity of questionnaire administration. The research team will contact all participants enrolled at baseline for follow-up (irrespective of whether they refused or discontinued recommended clinical care) via telephone, home visits, etc.

Sociodemographic variables, including sex, age, language, ethnic group, educational and employment status, income, and household composition will be recorded at baseline. Questions about employment and income will be repeated at follow-up interviews after 3 and 9 months to track whether the intervention affects change in economic status. Depression symptoms will be measured with the PHQ-9, which is aligned with DSM-IV-TR diagnostic criteria for major depressive disorder (36). The PHQ-9 has been validated for diagnosis of depression, with a cutoff score of \geq 9 in the chronic care population in South Africa (37). The PHQ-9 score will be the primary outcome of the cohort study. General disability will be measured with the 12-item World Health Organization Disability Assessment Scale, version 2.0, which has been used across cultures, including in South Africa (38). Treatment adherence to prescribed medications will be measured with the Visual Analog Scale (39), which has been used in South Africa (40) and other settings with limited resources and is a cost-effective alternative to measuring medication levels from biological samples (41, 42). The Perceived Stress Measure is a 10-item self-report measure that assesses the extent to which situations in a person's life are appraised as stressful and has been used previously in South Africa (43).

The primary analyses will compare mean PHQ-9 scores measured at 3 months and the proportion of participants whose PHQ-9 scores decreased by at least 50% from baseline to 3 months. Comparisons will be made among the diagnosed but not referred group, the diagnosed and referred group, and the undiagnosed group, adjusting for propensity scores using the t-effects package in Stata, version 16. The propensity scores will be the predicted probabilities of receiving a diagnosis of depression and being referred, respectively, at the baseline visit. These propensity scores will be drawn from logistic regression models, with baseline PHQ-9 scores, age, sex, and socioeconomic indicators as explanatory variables. These propensity scores will also be used to compare PHQ-9 scores and all other outcomes at 3 and 9 months. The comparisons between groups will account for intraclass correlation of outcomes between clinics by using robust adjustment. We will also use multilevel mixed models to analyze pooled panel data from baseline and 3 and 9 months, with group, time, and sociodemographic variables as covariates and with patient and clinic as random effects. Finally, linear and logistic regression analyses will investigate additional predictors, moderators, and mediating factors of the outcomes (44).

A costing analysis will be performed in stage 2 of the study for each subdistrict. We will estimate the incremental cost per outcome (change in PHQ-9 score, adherence, etc.), estimate the cost to scale up, and perform a budget impact analysis from the program/payer perspective (i.e., DoH). We will estimate economic costs, including actual financial outlays and costs of donated time and volunteer time (see Table A1 in the online supplement).

We will estimate the incremental costs of implementing the intervention compared with the current standard for each subdistrict. Intervention costs will include costs associated with start-up, personnel, transport, communication, consumables, and overhead costs. Cost data will be collected from the study budget, clinic expense reports, published information on labor costs, and staff interviews. To assess staff time spent on the intervention, we will conduct time and motion studies in all subdistricts while the intervention is running at full capacity. Together, the microcosting data, time and motion studies, and clinical outcomes will be used to estimate the average cost of providing services.

The costing results will be reported separately for each subdistrict. For all key inputs and outputs, we will follow the standard guidelines of the Second Panel of Cost-Effectiveness in Health and Medicine (45). We will conduct sensitivity analyses around key cost inputs to account for the uncertainty in our results. For budget impact analysis, we will consider direct program costs in the different subdistricts. Direct medical costs will be measured to ensure that DoH costs reflect the opportunity cost of the resources used in delivering services. Furthermore, the top-down approach of expense report collection will be compared with the bottom-up microcosting approach in order to triangulate and refine our cost estimates.

Objectives 1.2 and 2.2: CFIR interviews.

After 12 months of data collection assessing the RE-AIM outcomes, qualitative and quantitative interviews targeting CFIR domains will be performed to understand these RE-AIM outcomes in both stages 1 and 2. Structured quantitative interviews will comprise the Organizational Readiness for Implementing Change, a 12-item measure of change commitment and change efficacy based on Weiner's theory of organizational readiness for change (46), and the Mental Illness: Clinicians' Attitudes Scale, a 16-item mental health-related stigma scale (47). Interview guides will be translated into isiZulu and "back-translated" to ensure accuracy.

All facility managers and service providers from the facilities across the subdistricts will be requested to complete the quantitative interviews. Semistructured qualitative interviews will be conducted with facility-level managers, district managers, service providers, and patients (stage 1, N=78; stage 2, N=282) by trained interviewers (for a breakdown of sample sizes, see Table A2 in the online supplement). With the exception of the counselors (all of whom will be interviewed), participants will be sampled purposively according to the following strata: facility-level managers according to high- and low-performing clinics, individual professional nurses according to high and low diagnoses rates, and patients according to high and low uptake rates of counseling sessions. Interviews will be audiotaped and conducted in isiZulu or English, depending on participant preference and following informed consent procedures. When necessary, audiotaped interviews will be translated from isiZulu into English and transcribed, and back-translation checks will be performed by multilingual members of the research team. Any discrepancies will be reconsidered in consultation with a third multilingual researcher (48). Transcripts will be analyzed with the framework analysis typically used in health policy research. A thematic framework will first be developed by using the CFIR domains. Transcript content will then be coded by using the thematic framework while allowing inductive themes to emerge. Cases will be grouped by the aforementioned participant strata to identify multilevel barriers and enabling factors (49).

Objectives 1.3 and 2.3: participatory concept mapping.

Purposively selected key stakeholders will be engaged in a participatory concept mapping exercise to reflect on the results of objectives 1.1, 1.2, 2.1, and 2.2. Collaborative learning sessions—specifically, process mapping and nominal group techniques for developing priorities—will be used to brainstorm potential strategies to overcome identified barriers and optimize facilitating factors. Identified strategies will be sorted and rated according to perceived importance and feasibility for participants. Approximately 22 stakeholders, grouped according to their designation as managers, providers, or patients, will be involved in workshops at each stage (see Table A3 in the online supplement). We will include a national representative responsible for community mental health services, all members of the provincial mental health directorate, key district managers responsible for primary health care and mental health, operational managers from all participating facilities, a range of high- and low-referring nurses purposively selected, and outreach team leaders and community health workers purposively selected on the basis of high and low number of referrals from the community level. Patients will also be purposively selected in order to provide a range of individuals with both high and low uptake of the counseling intervention. Informed by this process, the initial MhINT model will be refined in stage 1 to develop a MhINT scalable unit that will then be assessed across the diverse subdistricts in stage 2. Subgroup analysis for each site will use the methods outlined above for the RE-AIM framework and CFIR interviews. The same process will be repeated in stage 2 to further refine the model for broader scale-up.

Results

Given that strengthening health systems requires adaptability, collaborative mechanisms, and routine data gathering (50), the adoption of a learning-health-systems approach reflected in the two-stage design will facilitate the iterative examination of findings of this observational research design, in collaboration with patients, providers, health managers, and researchers. Shared decisions, identified in stage 1, on how to address bottlenecks to uptake of the initial setup MhINT model, will lead to the coproduction of novel and localized interventions and strategies for optimizing implementation and scale-up (i.e., the scalable unit), which will be tested in stage 2 across three diverse contexts (urban, semiurban, and rural). Assessment of the varying strengths and limitations of the refined model in these three contexts will allow us to identify distinct implementation strategies needed to strengthen integration in urban, semiurban, and rural contexts. The findings should help strengthen the MhINT model with interventions and implementation strategies to assist the South African government in scaling up to “full scale.” The findings will also build on previous research from other countries, which suggests a need to integrate mental health care into primary health care with an approach that strengthens the whole health system (51). This study will also provide knowledge on strategies to optimize scale-up of collaborative care in integrated care for depression comorbid with chronic general medical conditions in other settings with limited resources.

Discussion and Next Steps

Global mental health stakeholders have increasingly recognized the need for systems change to enable the integration of mental health, inclusive of depression, into PHC (52); the primacy of open and flexible models that allow for cross-context adaptations (53); and the paucity of studies testing optimal implementation strategies to promote scale-up of integrated depression care in routine primary care in LMICs (22). Against this backdrop, and while the results of this study protocol remain to be seen, the design of this study may be helpful for other implementation research collaborations that aim to promote uptake of depression care integrated into routine primary care services. Notably, the iterative learning-health-systems approach is important for ensuring the uptake and sustainability of interventions and implementation strategies (54).

However, compared with controlled implementation research designs, this approach provides less control over the research process and requires greater investment of researchers’ time and resources in negotiations and capacity building activities (55). Furthermore, in light of a higher probability of sustaining mental health integration in the presence of systems reforms that enable chronic care (51), investment of time and resources into such systems strengthening initiatives may also be necessary to create this enabling environment.

Next steps for the researchers engaged in the SMhINT study include sustaining ongoing engagements with policy makers, planners, and managers; providing technical support for health systems strengthening to facilitate implementation; and building the capacity of policy makers and managers in implementation science to promote wider dissemination and sustainment of the intervention.

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TABLE 1. Overview of MhINT model provider roles, technical support, and implementation strategies^a

Provider	Role	MhINT technical support
Mental health coordinator/district mental health task team	Provides overall coordination, monitoring, and evaluation	District mental health task team supported through 2-day workshop and mentoring support to undertake a situational analysis that informs a district mental health care plan, which is incorporated into district plans
Psychologist	Provides training and supervision	Psychologists oriented and trained through a 4-day workshop in their roles of providing training, supervision, and emotional support to PHC level within a task-sharing approach
Registered psychological counselors/social PHC coordinators and operational managers	Provide training and supervision; support lay counselors Support mental health integration using CQI	Orientation and training of registered counselors or equivalent through a 4-day workshop to train and supervise PHC facility-based nonspecialist counselors 2-day training workshop in CQI tools with <u>MhINT-provided mentorship</u> for PHC coordinators and facility managers in CQI to support PHC facilities in integration of depression care
Facility managers	Oversee implementation and integration	Orientation to responsibilities of different role players in collaborative care model through a half-day workshop; capacitated in CQI for monitoring implementation and data management
PHC staff nurses/enrolled nurses	Conduct initial mental health screening of the PHC facility population	Per DoH guidelines, MhINT did not initially provide technical support
PHC clinical nurse practitioners	Identify CMDs; provide brief intervention, referral, and reassessment	Existing facility trainers capacitated through a 3-day workshop to provide onsite sessions orienting clinical nurse practitioners to person-centered care and their role of case managers within the collaborative care model; equipped facility trainers with clinical communication skills for person-centered care, use of APC for treatment and referral of CMDs
PHC doctors	Initiate medication; monitor psychotropic medication	Oriented to collaborative care model and APC; capacitated in mhGAP guidelines through a half-day workshop
Lay counselors/enrolled nurses	Provide evidence-based counseling (CMDs and adherence)	Oriented to collaborative care model; capacitated in manualized depression counseling package with problem-solving and cognitive-behavioral techniques through a 5-day workshop; training is followed by individual in vivo supervision and monthly emotional support by the psychological counselors/social workers
Outreach team leaders (PHC clinical nurse practitioners/enrolled nurses)	Supervise community health workers; conduct home visits <u>for patients with</u> difficult cases	As per DoH guidelines, MhINT did not initially provide technical support
Community health workers	<u>Conduct</u> case identification, psychoeducation, and tracing and linkage to care	As per DoH guidelines, MhINT did not initially provide technical support

MhINT implementation strategy	ERIC strategy	Purpose
Situational analysis	Conduct local needs assessment	Inform development of district mental health plan
Train-the-trainer model for building capacity	Use train-the-trainer strategies	Efficiently train primary care providers
Supportive supervision	Audit and feedback; provide clinical supervision	Mentor providers, monitor competency, and offer emotional support
APC decision support tool	Remind clinicians	Promote nurse-led identification and management of patients with depression and other CMDs

Continuous quality improvement ^c	Develop and organize quality monitoring systems	Identify implementation bottlenecks and propose solutions through learning collective
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^aAPC, adult primary care; CMD, common mental disorders; CQI, continuous quality improvement; DoH, KwaZulu-Natal Department of Health; ERIC, Expert Recommendations for Implementing Change project; mhGAP-IG, _____; MhINT, Mental Health Integration program; PHC, primary health care.

^bIncludes orientation workshops, training, and mentorship. Details of the MhINT training and orientation workshops can be found in the training and orientation manuals on the Centre for Rural Health website (www.crh.ukzn.ac.za).

^cSystem level.

^dFacility level.

^eProvider level.

TABLE 2. Characteristics of Amajuba subdistricts: Newcastle, Dannhauser, and Emadlangeni^a

Characteristic	Newcastle	Dannhaus	Emadlang
	(urban)	(semiurban)	(rural)
Land area (km ²)	1,855	1,516	3,539
Population	363,236	105,341	36,869
Poverty rate (%)	56.3	78.6	80.7
N of households	90,347	20,844	6,667
Income			
No income (%)	28	83	34
Health resources			
Hospitals	3	0	1
Community health centers	0	1	0
PHC facilities	14	10	2
WBPHCOTs	5	5	2 ^b
Mobile points	12	36	79
Mental health specialists			
Psychologists	2	0	0
Sessional psychiatrists	1	0	0

^aPHC, primary health care; WBPHCOTs, _____.

^bOne per PHC.

TABLE 3. Key variables and data sources for objectives 1.1, 1.2., 2.1, and 2.2^a

Key variable	Source	Subprotocol	Frequency
Reach^b			
% of patients screened for CMDs at community level lost to follow-up ^c	Clinic records	Secondary data	Quarterly
Characteristics of chronic care patients lost to follow-up screened and not screened at community level	Clinic records	Secondary data	Quarterly
% of chronic care patients screened for CMDs at facility level	DHIS data	Secondary data	Quarterly
Characteristics of chronic care patients screened and not screened at facility level	Patient cohorts	Cohort	Quarterly
% of positive chronic care patients screened who screened positive for depression	Cohort data	Cohort	Once
Characteristics of chronic care patients who screened positive and negative for depression ^e	Cohort data	Cohort	Once
% of chronic care patients screening positive who are diagnosed and referred	Cohort data	Cohort	Once
Characteristics of chronic care patients screening positive who are diagnosed and referred	Cohort data	Cohort	Once
% of chronic care patients referred for counseling who receive at least one counseling session	Cohort data, project records	Cohort, secondary data	Once, quarterly
Characteristics of referred patients receiving one or more counseling sessions/not receiving any sessions	Cohort data, CFIR interviews with patients receiving one or more counseling sessions and those receiving no sessions	Cohort, qualitative data	Once
% of clinic population receiving mental health treatment initiation	DHIS data	Secondary data	Monthly
Effectiveness^d			
Depressive symptoms	Patient cohorts	3-month cohort data	Once
Disability	Patient cohorts	3-month cohort data	Once
Adherence to prescribed medications	Patient cohorts	3-month cohort data	Once
Perceived stress	Patient cohorts	3-month cohort data	Once
Adoption^e			
Facility-level rate of morning talk	Facility records	Secondary data	Monthly
Characteristics of facilities with greater/fewer morning talks on CMDs per month	Facility profiles, ORIC, MICA, CFIR interviews with facility managers and counselors/health promoters	Secondary data, quantitative data, qualitative data	Annually, once
Facility-level rate of screening of chronic care patients for CMDs	DHIS data	Secondary data	Monthly
Characteristics of facilities achieving KwaZulu-Natal Department of Health screening targets (35% of head count/less than 35% of head count)	Facility profiles, ORIC, MICA, CFIR interviews with facility managers and enrolled nurses	Secondary data, quantitative data, qualitative data	Annually, once
Facility-level rate of diagnosis and referral of chronic care patients screening positive for depression	Cohort	Cohort data	Once
Characteristics of facilities with higher/lower rate of diagnosis and referral of chronic care patients screening positive for depression	Facility profiles, ORIC, MICA, CFIR interviews with facility managers and PHC nurses	Secondary data, quantitative data, qualitative data	Annually, once

Facility-level rate of referred patients' uptake of one or more counseling sessions	MhINT project records	Secondary data	Quarterly
Characteristics of facilities with higher/lower referred patient uptake of one or more counseling sessions	Facility profiles, ORIC, MICA, CFIR interviews with facility managers and counselors	Secondary data, quantitative data, qualitative data	Annually, once
Facility-level rate of mental health treatment initiation over time	DHIS data	Secondary	Monthly
% of providers who diagnosed one or more patients with CMD	MhINT project records	Secondary data	Monthly
Characteristics of providers who refer/do not refer	CFIR interviews with nurses who refer/do not refer	Qualitative data	Once
Implementation^f			
Consistency of morning talks over time per facility	Facility records, CFIR interviews with facility managers and counselors/health promoters	Secondary data, qualitative data	Quarterly, once
Quality and consistency of screening over time per facility	Facility records, CFIR interviews with facility managers and enrolled nurses	Secondary data, qualitative data	Quarterly, once
Quality and consistency of diagnosis and referrals per facility	Cohort, MhINT project records over time, CFIR interviews with facility managers and PHC nurses	Cohort, secondary data, qualitative data	Quarterly, once
Fidelity of counseling intervention	Fidelity checklists, CFIR interviews with clinic counselors	MhINT project data, qualitative data	Once
Cost of intervention ^g	Costing analysis	Costing	Quarterly
Adaptations to intervention	Project CQI records, CFIR interviews with facility managers	Secondary data, qualitative data	Quarterly, once
Maintenance^h			
Stability of effects of the intervention on patient-level outcomes of effectiveness over time	Patient cohort	3- and 9-month cohort data	Once
Characteristics of patients who had stability of effects over time and those who did not	Patient cohort, CFIR interviews with patients who maintained stability of effects over time and those who relapsed	3- and 9-month cohort data, qualitative data	Once
Institutionalization of intervention	Audit of routine use of MhINT tools, processes, and training materials at district level; CFIR interviews with district managers	Secondary data, qualitative data	Once

^aCFIR, Consolidated Framework for Implementation Research; CMD, common mental disorder; CQI, continuous quality improvement; DHIS, District Health Information System; MhINT, Mental Health Integration program; MICA, Mental Illness: Clinicians' Attitudes Scale; ORIC, Organizational Readiness for Implementing Change; PHC, primary health care.

^bIndividual-level analyses of the proportion and characteristics of the target population that received the intervention along the continuum of care.

^cData collected only in step 3 when the revised scale-up unit is assessed.

^dReal-world effectiveness on patient-level outcomes.

^eOrganizational-level outcome referring to the proportion and characteristics of settings/service providers who adopt the intervention.

^fExtent to which the intervention was implemented with consistency and fidelity along the continuum of care, adaptations made during the study, and cost.

^gOrganizational-level institutionalization of the program over time and individual-level sustainability of health outcomes.

BOX 1. Objectives of the Mental Health Integration (MhINT) program assessment study

Stage 1: Assessment of the Initial MhINT Model (Urban Setting)

Objective 1.1: Assess the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) evaluation framework outcomes of the initial “setup” MhINT model in one subdistrict.

Objective 1.2: Assess Consolidated Framework for Implementation Research (CFIR) determinants of the dissemination, impact, and sustainability of the initial setup MhINT model across multiple domains.

Objective 1.3: Engage in a participatory process with key stakeholders to recommend refinements to strengthen the MhINT model and its implementation strategies into a “scalable unit.”

Stage 2: Assessment of the Scalable Unit Across Diverse Contexts (Urban, Semiurban, Rural Settings)

Objective 2.1: Assess the RE-AIM outcomes of the strengthened MhINT scalable unit across diverse contexts (urban, semiurban, and rural).

Objective 2.2: Assess CFIR determinants of the dissemination, impact, and sustainability of the scalable unit MhINT model across diverse contexts (urban, semiurban, rural) to inform further adaptations for going to “full scale.”

Objective 2.3: Engage in a participatory process with key stakeholders to recommend refinements to strengthen the MhINT model and its implementation strategies into a full-scale model for wider scale-up.

BOX 2. Key challenges, opportunities, and design solutions of the Mental Health Integration (MhINT) program assessment study

Key Challenges

Prior research found poor uptake of routine services of the initial MhINT evidence-based collaborative care package for integrated depression care being evaluated by the Southern African Research Consortium for Mental Health Integration (SMhINT) evaluation protocol.

In particular, identification and referral of comorbid depression in primary care patients (i.e., the first steps in the treatment cascade) were poor.

This deficiency highlighted the need for implementation science to help understand how to improve uptake and embed the package in routine care.

Key Advantages

The public health priority of integrated depression treatment for patients with multimorbid chronic diseases in South Africa has heightened, given evidence of poorer health outcomes among chronic patients with comorbid depression.

Health systems reforms have created an opportunity to shape policy for integrated horizontal programming in South Africa.

Funding for technical support for the scale-up of the initial MhINT package in one district has provided the opportunity to iteratively evaluate how to refine the package and implementation strategies for broader scale-up.

Design Solutions

The adoption of a learning-health-systems approach and iterative two-stage research design across varying contexts will enable the research team to be responsive to context and Department of Health needs.

The strong collaborative relationship with the Department of Health will enable key learnings to be translated into policy changes necessary for institutionalization and broader scale-up.

Locating the SMhINT study within broader efforts to support the Department of Health in health systems reforms toward horizontal programming will enable earlier embedding of integrated depression care within these reforms.