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Scaling up Science-based Care for Depression and Unhealthy Alcohol Use in Colombia: Design Considerations of an Implementation Science Project

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Abstract

Introduction.—Mental disorders are a major cause of the global burden of disease and significantly contribute to disability and death. This challenge is particularly evident in low- and middle-income countries (LMICs) where more than 85% of the world's population live. Latin America is one region composed of LMICs where the burden of mental disorders is high and the availability of mental health services is low. This is particularly evident in Colombia, a country with a long-standing history of violence and associated mental health problems.

Methods.—his manuscript describes the design of a multi-site implementation science project being conducted in 6 primary care systems in Colombia (entitled "Scaling up Science-based Mental Health Interventions in Latin America" or the "DIADA" project). This project, funded via a cooperative agreement from the U.S. National Institute of Mental Health, seeks to implement and assess the impact of a new model for promoting widespread access to mental health care for depression and unhealthy alcohol use within primary care settings and building an infrastructure to support research capacity and sustainability of the new service delivery model in Colombia. This care model centrally harnesses mobile health technology to increase the reach of science-based mental health care for depression and unhealthy alcohol use.

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Disclosure.

LAM is affiliated with the small business that developed the digital therapeutic used in this study. This relationship is extensively managed by her academic institution, Dartmouth College.

Results.—This initiative offers great promise to increase capacity for providing and sustaining evidence-based treatment for depression and unhealthy alcohol in Colombia.

Next Steps.—This project may inform models of care that can extend to other regions of Latin America and/or other LMICs.

Keywords

mental health; digital health; Colombia; implementation science; Latin America; primary care

Introduction

Mental disorders are increasingly recognized as a major cause of the global burden of disease, accounting for an estimated 7% of the disease burden worldwide and significantly contributing to disability and death.[1,2] The overall annual economic cost for mental disorders is estimated at over $2.5 trillion USD and is expected to exceed $16 trillion by 2030.[3, 4] Expanding access to mental health care in a manner that can rapidly scale and have a substantial population impact is a significant challenge globally.[5, 6]

This challenge is particularly evident in low and middle-income countries (LMICs) where more than 85% of the world's population live[7–9] Between 76–85% of persons with severe mental disorders in LMICs receive no treatment for these problems. The healthcare workforce in LMICs is also grossly insufficient – with an average of one psychiatrist to serve every 200,000 people and even fewer mental health providers trained in the delivery of psychosocial interventions. Only 36% of persons in LMICs are covered by mental health legislation, in stark contrast to 92% of persons in high-income countries.

Latin America is one region of the world composed of LMICs where the burden of mental health problems is high and services for mental health are low (and account for <2% of the health budget in the region).[10, 11] In the Latin American country of Colombia, non-communicable diseases account for 71% of the total disability-adjusted life years (DALYs),[12] with mental disorders accounting for almost 18% of those DALYs.[13] The most recent National Mental Health Survey in Colombia,[14, 15] showed that 10.1% of adult Colombians have a depressive or anxiety disorder, 4.3% have major depression, and approximately 12% have unhealthy alcohol use. Contributing to the mental health problems in Colombia is the long-standing violence in the country. Indeed, prior to the recent bilateral peace negotiations, Colombia had one of the longest internal armed conflicts in the world.[16] Only 11% of persons with a mental health disorder in Colombia receive mental health care.[15] In the cases where mental health care is provided, it can be highly effective.[17, 18,19]

In 2008, the World Health Organization (WHO) launched the Mental Health Gap Action Program (mhGAP) including strategies to scale up care for mental, neurological, and substance use disorders.[20] And in 2018, WHO launched the global SAFER alcohol intiative to reduce alcohol-related death and disability.[21] The Pan American Health Organization (PAHO) within the WHO also adopted a Plan of Action on Mental Health.[22]

Colombia has embraced this plan and developed a strategy to reinforce primary care-based care for common mental disorders.[23]

In order to achieve the stated goals of the model, a key element is to leverage empirically-supported mobile health technology to create a new model of mental health service delivery within primary care.[22] Advances in digital technologies have created unprecedented opportunities to facilitate the rapid and widespread "scaling-up" of evidence0based mental health care. The majority of the world's population has a mobile phone,[24] including over 90% of persons in Colombia.[25] Growing evidence suggests that increased access to these technologies is also evident in many traditionally underserved populations where disparities are prevalent.[26–28]

Another key element of Colombia's mental health care model is human resource development focused on the creation of mental health skills within primary care. Given the strikingly limited availability of the trained mental health workforce in Colombia, raising awareness of evidence-based screening and interventions for mental health within the primary care workforce is critical to integrated care. Mental health policy in Colombia has established mental health care as a fundamental right.[16, 29] and similar patterns are evident in other Latin American countries, including Chile and Peru.[30, 31]

In response to the mental health treatment service delivery needs in Latin America, an interdisciplinary team launched an implementation research project entitled "Scaling up Science-based Mental Health Interventions in Latin America" (also known as the DIADA project, "Detection and Integrated Care for Depression and Alcohol Use in Primary Care"). This initiative, funded via a "Scale-Up Hubs" cooperative agreement from the U.S. National Institute of Mental Health (NIMH),[32, 33] seeks to implement and assess the impact of a new model for promoting widespread access to mental health care (focused on care for depression and unhealthy alcohol use) within primary care settings and building an associated infrastructure to support research capacity and sustainability of the new service delivery model in Colombia. This initiative reflects a collaboration among partners at Pontificia Universidad Javeriana in Colombia, Dartmouth College in the U.S., NIMH, as well as many governmental, non-governmental, academic, industry, and multilateral organizations in Latin America.

In this new mental health service delivery model, we are harnessing mobile behavioral health technology for mental health (with a focus on depression and unhealthy alcohol use) and launching new mental health workforce training and service delivery models (including the integration of technology into service delivery). We are launching this project at multiple primary care sites in various parts of Colombia, with a plan to inform subsequent adoption in several other Latin American countries, including Chile and Peru.

This manuscript describes the design and methodological considerations of this multi-site implementation science project.

Methods

Overview

At the launch of this project, we conducted (in year one) a pilot test of this novel mental health care model for depression and unhealthy alcohol use at a single urban primary care site in Bogotá. This allowed us to refine implementation procedures and measurement before the launch of the main implementation science study. Specifically, we reduced the scope of research assessments to reduce participant burden and increased the frequency with which we provided remote expert consult with mental health experts on our team to complement our structured onsite trainings in mental health care. We are now expanding implementation across 6 primary care healthcare systems in urban and rural communities across Colombia on a staggered basis (in years two to five). Although this study is not a true stepped wedge design,[34] we implement across primary care systems on a staggered basis (launching in a new system about every 6 months) and expand the number of sites in which we implement over time. In this design, the order of launch of the sites was randomized after starting with a single site we identified in advance (in a non-randomized way) because it was a site in close proximity to our research team in Colombia and also functioned as our pilot site. By conducting this multi-site implementation research project, we can assess the extent to which the implementation model and associated outcomes are replicable across sites and/or the extent to which the model needs to be modified for differing contexts.

As detailed in the Measures section below, our primary evaluation of implementation outcomes is conceptually informed by the Outcomes for Implementation Research (OIR) taxonomy developed by Proctor and colleagues[35] (e.g., acceptability, adoption, appropriateness, feasibility, penetration), while the Consolidated Framework for Implementation Research (CFIR) was used to guide the evaluation of the determinants of implementation success (including barriers and facilitators to implementation such as organizational climate and organizational leadership).[36] We will also assess patient outcomes including depression, quality of life, and alcohol use (data are securely stored in REDCap).[37] Most data will be collected via quantitative measures, but we also conduct qualitative interviews with providers, administrative staff and patients pre-implementation and approximately every six months thereafter. Qualitative data will be analyzed via deductive analysis of the data using a matrix based on the relevant scientific literature and goals of this project, followed by a thematic analysis of the data that seeks to understand stakeholder perspectives within their sociocultural contexts. All study procedures were approved by the appropriate Institutional Review Boards and the NIMH Data and Safety Monitoring Board. See Box 1 for an overview of the project challenges, key advantages and study design solutions.

Novel Depression and Alcohol Care Model.—Patients will be offered a multi-component model of science-based care. Providers at each site will undergo an initial in-person training and periodic (in-person, virtual and online) refresher trainings/consultation in mental health care by psychiatrists from Javeriana University.

All patients who consent to participate will be given access to the mobile therapeutic tool. A trained staff member at the primary care site will show them how to use the

tool. As reviewed above -- given the ubiquity of access to technology worldwide – digital therapeutic tools delivered on mobile platforms may enable widespread reach and scalability of evidence-based mental health interventions.[28, 38–40]

The mobile therapeutic tool provided to patient participants (Laddr®, Square2 Systems) offers science-based self-regulation monitoring and health behavior change tools. This includes tools for activating behavior change, solving problems and overcoming obstacles to effective behavior change, teaching skills and providing guidance on the execution of behavior change, and maintaining the end user's motivation to change. The uniqueness of Laddr lies in the fact that it integrates tools that have been developed via an iterative patient-centered approach and shown (in over a dozen NIH-supported studies) to be highly effective for a wide array of clinical phenomena ranging from, for example, substance use, alcohol use, mental health, risk-taking, chronic pain management, medication adherence, diet, exercise, diabetes management, and smoking.[41–47] Laddr is available on multiple platforms (including desktop, Android, iPad, and tablets). To our knowledge, Laddr is the only mobile ecosystem that employs the core science-based therapeutic processes that promote behavior change for a broad array of disorders to flexibly apply to a broad array of populations based on their goals and needs.

In the present study, the components of Laddr that have been shown to be effective in the treatment of depression and unhealthy alcohol use are offered to patients who meet diagnostic criteria for one or both of these disorders. This therapeutic content helps to activate/motivate behavior change based on an individual's values (a process know **"Behavioral Activation" [BA]**).[48, 49] In this process, individuals are provided with tools and strategies to help identify their values, in areas such as health, parenting, family relations, social relations, work/career, leisure, and/or personal growth. BA helps individuals take steps to create an environment that supports healthy and goal-directed behavior consistent with their values. It also includes systematic tracking of behavior and consequences of behavior to help identify and disrupt self-defeating behavioral patterns.

It also provides "**Problem Solving Therapy" [PST]**). PST is a practical and and effective intervention for many disorders, including depression. The goal of PST is to teach individuals skills in solving problems as a means of enabling them to self-manage and to control negative states and behavior. Its treatment process focuses on participants' appraisal of specific problems, their identification of the best possible solutions, and the practical implementation of those solutions, as well as increasing exposure to pleasant[50] events.

It teaches skills and provides guidance in the execution of behavior change (processes known as "**Cognitive Behavioral Therapy**" **[CBT]**[51, 52] and the "**Community Reinforcement Approach" [CRA]**[53] to behavior change). CBT teaches a broad array of skills and behaviors to manage problematic emotions, behaviors, and cognitive processes and increase and maintain health behaviors. Examples include managing negative thinking, identifying and altering cognitive distortions, communication skills, decision-making skills, stress management, and time management. CRA is an extension of CBT, designed to help individuals establish and maintain new healthy patterns of behavior and leverage social,

recreational, family and vocational reinforcers to help them in making positive behavior change.

Note that the research team created a version of Laddr that was translated to Spanish and edited to be culturally appropriate to Colombia before its use in this project. In this process, the team worked with translators and cultural experts in Colombia in forward and backward translation of app content as well as in the cultural adaptation of content (e.g., converting language regarding a standard drink of alcohol to include the local drink of “chica”).

Participants diagnosed with depression may also be offered access to anti-depressant medications, as determined in consultation with the primary care physician (in accordance with the Colombian clinical guidelines). Medications for treatment of alcohol use disorders are not currently available in Colombia.

The flow of participant activity is summarized in Figure 1 as an the online supplement.

Study Sites.

We are collaborating with six primary care networks spanning diverse rural, semi-rural and urban locations across Colombia. These sites also provide diversity in access to/usage of mobile technology. These sites serve between 14,000 and 200,000 patients. None of these primary care systems routinely screened for/treated depression or alcohol use disorders within their primary care programs prior to the launch of this project.

Study Procedures.

Participant Criteria.—Providers and administrative staff who provide implementation process and outcomes data in this study must be ≥ 18 years of age and have worked for the study site for at least 3 months. Patient participants must be ≥ 18 years; in care at one of our collaborating primary care sites; screen positive for minor (score of 5–9), moderate (score of 10–14), moderately severe (score of 15–19) or severe (score of 20–27) depression on the Patient Health Questionnaire (PHQ-9)[54] and/or screen positive for problematic alcohol use on the Alcohol Use Disorder Identification Test (AUDIT) developed by WHO (a score of ≥ 8)[55] and have a confirmed diagnosis of depression and/or alcohol use disorder based on clinical consultation at the primary care site; and be willing to provide informed consent to use the mobile intervention and complete study assessments.

Patients are excluded if they have been diagnosed with a co-occurring severe mental illness (e.g., schizophrenia, bipolar disorder, depression with psychotic features); alcohol withdrawal symptoms that require higher level of care (e.g., emergency or inpatient treatment); express suicidal intention or are intoxicated or otherwise incapable of informed consent.

Participant Recruitment, Screening and Informed Consent.—Patients are asked to complete screeners (for depression and problematic alcohol use) at the time of check-in upon arrival at the primary care site. Screeners are electronic and completed on a kiosk in the waiting rooms of the primary care sites.

The depression screener starts with the 2-item Whooley assessment[56]: (1) “During the last 30 days, have you been bothered by feeling down, depressed or hopeless?”; (2) “During the last 30 days, have you been bothered by little interest or pleasure in doing things?” A positive response on either or both questions will then lead to a PHQ-9[54] screener for depression.

The brief screener for alcohol, the AUDIT Consumption Questions (AUDIT-C),[57] consists of 3 questions: (1) “How often do you have a drink containing alcohol?”; (2) “How many standard drinks containing alcohol do you have on a typical day?”; and (3) “How often do you have six or more drinks on one occasion?”. The AUDIT-C is scored on a scale of 0–12. In men, a score of ≥ 4, and in women a score of ≥ 3, is considered positive. Persons who answer positively to the AUDIT-C are then asked to complete the full AUDIT.[55]

Screening results will be provided to the primary care clinician (electronically and/or via a printout delivered by the patient or a clinical staff member) when the patient enters an exam room to see the primary care clinician. In the event of a positive screen for depression and/or unhealthy alcohol use, the clinician will complete a more in-depth diagnostic interview. Each site has an internal protocol for evaluating and managing suicide risk. Patients who screen positively for depression (score of ≥ 5) and/or alcohol use problems (score of ≥ 8) and meet all other inclusionary criteria will be informed about the treatment options available to them. Patients who provide informed consent with research staff will then be asked to complete baseline assessments.

Clinicians are provided with an electronic decision aid tool (on a tablet) to guide them in offering evidence-based treatments to patients. This is designed as a matrix to help patients understand the options available to them as part of their care (including the advantages and disadvantage of the various options). We also offer videos and other educational resources (e.g., pamphlets) to help patients understand how the care options available to them work to support a process of shared decision-making.

All patients who join the study will be assigned a unique study identification number (which will be linked to all patient data collected from a given participant).

Measures.

A summary of measures employed in this study is provided in Table 1, and the flow and timing of data collection for all measures is presented in Figure 2 as an online supplement.

The primary assessment tool is the **Integrated Measure of Implementation Context and Outcomes in Low and Middle Income Countries (LMICs).**[58] This tool is composed of instruments for the Consumer (patient), Provider, and Organizational Staff as well as a Sustainability instrument. The **Consumer** instrument measures an intervention’s Acceptability (17 items), Adoption (12 items), Appropriateness (13 items), Feasibility (14 items), and Penetration (8 items). The **Provider** instrument measures Acceptability (16 items), Adoption (9 items), Appropriateness (16 items), Feasibility (20 items), Penetration (8 items), Organizational Climate (13 items), and Organizational Leadership (10 items). The **Organizational** measure includes 10 Acceptability items, 13 Adoption items, 12

Appropriateness items, 14 Feasibility items, 8 Penetration items, 15 Organizational Climate items and 10 Organizational Leadership items. Sample items from this assessment tool are provided in Box 2.

In addition, the **Sustainability instrument** was adapted from the Program Sustainability Assessment Tool (PSAT).[59,60] It assesses eight core domains that affect a program's capacity for sustainability, including environmental support, funding stability, partnerships, organizational capacity, program evaluation, program adaptation, communications, and strategic planning.[61] It has demonstrated internal consistency reliability, structural validity and usability.[59, 62]

Behavioral Health Integration in Medical Care Index (BHIMC) is a quantitative organizational measure of the level of behavioral health integration in medical practice settings. It evaluates policy, clinical practice and workforce dimensions of integration using mixed methods, i.e. combination of document review and observation. The BHIMC was translated to Spanish and adapted for use in Colombia.[63]

The costs of implementing the care model will be measured using the **Time-driven Activity-based Costing (TDABC) Approach**.[64] This method involves creating a detailed process map to illustrate every administrative and clinical process activated during the treatment of depression and alcohol use disorders over a complete care cycle.

Patient Outcomes.—The primary patient outcome measure we will use to assess our hypothesized reduction in depression is the standardized **Patient Health Questionnaire** (PHQ-8).[65] We will assess problematic alcohol use via the **Quick Drinking Screen (QDS)**,[66] (assessing past 30 days alcohol use). We will use the 12-item **WHO Disability Assessment Schedule 2.0 (WHODAS)**[67] to measure functional status and health-related quality of life. And we will use the General Anxiety Disorder screener **(GAD-7),** a 7-item screening questionnaire that has been validated in outpatient care settings.[68] The **Non-Study Medical and Other Services (NSMOS)** assesses patients' medical resource use that is not part of the intervention (e.g., non-treatment therapy visits, physician visits, residential and/or hospital detoxification, hospital and emergency department visits). The **Non-Medical Expenses for Depression.** This measure assesses the non-medical costs of depression.[69] This measure is in Spanish and has been used in Latin America and by our team at Javeriana. And the **Health and Work Performance Questionnaire (HPQ),** developed by WHO, assesses the impact of depression on work performance (including sickness absence, presenteeism, and critical incidents).[70]

Sample Size and Analysis Strategy.: We expect approximately 10 providers and 10 staff at each of the six sites will complete the implementation context and outcomes measure for 2–5 assessment time points per site (depending on when they launched). We will also collect data on these implementation measures from approximately 25 patients at each of the six sites for 2–5 assessment time points per site. Our organizational implementation measure (our primary outcome) will yield 80% power at the two-sided 0.05 significance level to detect differences pre- vs. post-implementation that are at least 0.55 – 0.73 times a standard deviation. The BHIMC and the TDABC are collected at the site level, once per site at each

of our six sites at each assessment time interval. Assessment of change across time will be primarily used to evaluate qualitative changes pre- and post-implementation, and large effect sizes (1.25 standardized effect or greater) will be observed with 80% power at the two-sided 0.05 significance level. This analysis is independent of the number of patients at each site that are exposed to this model of care.

At a sample size of 1200 patients completing patient-level clinical outcomes assessments (with, at least, two time-period measures per participant which is a highly conservative estimate of data collection), we will have 80% power at the two-sided 0.05 significance level to detect small pre- vs. post-implementation effect sizes of 0.13–0.17.

Organizational implementation outcomes and patient-level implementation outcomes will be analyzed via linear mixed effects models (LMM),[71] with the primary comparison being mean outcome before and after implementation of the novel care model. To account for potential correlation of observations within site, the model will include a random site effect; thus, all statistical tests comparing outcomes pre- and post- implementation will take this within-site non-independence into account.

Patient-level clinical outcomes will be evaluated via linear mixed effects models that include fixed effects for time from enrollment to evaluate whether patient-level outcomes improve over time in sites implementing the novel care model. The models will also include a random site effect to account for similarities of outcomes of individuals within the same site, and random individual-level intercept and slope terms, to account for non-independence of repeated assessments within individual.

We will also conduct cross-site analyses to examine the extent to which patterns of results are similar/differ across populations and contexts. To integrate data across studies to explore patterns and generality of outcomes, we will use structural equation modeling (SEM)-based meta-analysis and meta-analytic SEM (MASEM).[72, 73]

Results

Results to date from baseline data analyses have demonstrated that we can quantitatively detect the degree to which primary care systems offer integrated mental health care and identify areas for increasing capacity for care.[63] Further, our early experience implementing technology-assisted screening and decision support for depression and unhealthy alcohol use into the workflow of Colombian primary care systems has underscored the feasibility and acceptability of this model of care. And we have seen that this system of care markedly increases rates of screening and diagnosis of depression.[74] Indeed, after having launched at only 4 of our partnering sites to date, our partnering primary care sites have gone from not routinely screeing any patients for depression or alcohol use disorders to already screening over 13,000 individuals. And qualitative data from in-depth interviews and focus groups conducted with health professionals, administrative professionals, patients, and community organization representatives in our partnering primary care institutions in Colombia demonstrated that digital technology is perceived as useful in evaluating, diagnosing, and treating depression and unhealthy alcohol use in primary care. Perceived

potential challenges include technology access limitations and literacy challenges in certain communities.[75]

Next Steps

We now plan to complete all participant recruitment in this study in Colombia by the end of 2020 and to broadly disseminate results in scientific and non-scientific outlets (including with our diverse partners in Latin America). We also plan to conduct trainings on this model of care in primary care systems in Chile and Peru (who have been participating in our project in Colombia from its inception). Overall, this project will create new knowledge to inform unprecedented, science-based approaches to scaling-up mental health implementation research in Latin America. And this project will inform how to best implement and expand mental health care capacity with innovative digital technologies. This project will also build significant capacity in Latin America for delivering science-based mental health care to meet a large unmet need as well as for conducting systematic mental health research. If successful, this approach can be expanded over time to embrace other areas of mental health (e.g., severe mental illness), chronic disease management, as well as health promotion prevention interventions based on community needs and priorities in Latin America. This project may also serve as an important demonstration project to low resource contexts globally as they tackle the significant burden of mental disorders and scale-up access to evidence-based models of mental health service delivery.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Box 1.

Key Challenges, Advantages and Design Solutions

Key Challenges
• High rates of depression and unhealthy alcohol use in Colombia • Limited mental health workforce in Colombia • Mental health care is often confined to specialty psychiatric hospitals and urban settings in Colombia.
Key Advantages
• Training primary care providers in depression and alcohol use care and embedding it in the workflow of primary care greatly increases provider and organizational capacity for care. • Employing digital technology to conduct validated screenings for depression and alcohol use disorders; provide clinicians with decision support tools to guide best practices in care; and provide direct-to-patient behavioral therapy on mobile platforms markedly increases access to evidence-based mental health care in Colombia.
Design Solutions
• Multi-site implementation research design ensures experimental rigor while ensuring all partnering sites implement science-based, mental health care for depression and unhealthy alcohol use in primary care. • Primary focus on organizational-level outcomes allow for an examination of how the model of care increases capacity for mental health care and how generalizable findings are across rural, semi-urban, and urban settings in Colombia. • Examination of patient level outcomes allow for examination of patients' engagement in mental health care and their clinical trajectories over time.

Box 2.

Examples of Questions on Integrated Measure of Implementation Context and Outcomes in Low- and Middle-Income Countries (LMICs) measure: Patient, Provider and Organizational Staff Versions[1]

Consumer (Patient) Instrument
Adoption
Have you used the skills you learned in THE PROGRAM? Would you refer others with similar problems to THE PROGRAM? Would you return to THE PROGRAM services if you felt like you needed them in the future?
Acceptability
Overall, did you like THE PROGRAM? Do you feel that the skills you learned in THE PROGRAM are useful? Did you feel that you understood the way things were explained to you during THE PROGRAM?
Appropriateness
Does THE PROGRAM fit with your personal values? Do you think THE PROGRAM helped with you your problems? Do you believe the skills taught in THE PROGRAM would be relevant to other people like yourself?
Feasibility
Were the THE PROGRAM sessions scheduled with enough flexibility to meet your needs? Did you have the emotional support that you needed from your family and friends to attend THE PROGRAM?
Penetration
Are people in the community aware that THE PROGRAM services are available? Would most people in the community who need mental health services seek THE PROGRAM services?
Provider Instrument
Adoption
Have you discussed with others (e.g. family, friends, coworkers, or any other people) what THE PROGRAM is in general terms? Have you discussed with others (e.g. family, friends, coworkers, or any other people) THE PROGRAM's impact on clients? Will providing THE PROGRAM be a high priority for you in the future?
Acceptability
Do you like *providing* THE PROGRAM? Do you feel good about THE PROGRAM as a treatment for client's mental health problems? Do you feel that the skills you have learned by providing this service will be useful in helping clients?
Appropriateness
How well does THE PROGRAM fit with the cultural values of your clients? Is THE PROGRAM effective for your clients' mental health problems? Is providing THE PROGRAM something you feel you should be doing as part of your job?
Feasibility
Are you sufficiently skilled at providing THE PROGRAM to your clients? Do you have enough time to regularly provide THE PROGRAM to those who need it? Do you have sufficient access to continued clinical support and training?
Penetration
Are people in the community aware that THE PROGRAM is available? Would most people in your community who need them, seek THE PROGRAM?
Organizational Climate
Is your morale at work high? Do you think THE PROGRAM fits with the goals of your organization? Do you think providing THE PROGRAM is useful for your organization?
Organizational Leadership

Do the leaders at your organization have clear quality standards for implementation of THE PROGRAM? Do the leaders at your organization remove obstacles to implementation of THE PROGRAM? Do the leaders at your organization support provider efforts to use THE PROGRAM?
Organizational Staff Instrument
Adoption
Have you discussed with others (e.g. family, friends, coworkers, or any other people) what THE PROGRAM is in general terms? Have you discussed with other staff what you need to do to continue to use THE PROGRAM in the future? Would you support the use of THE PROGRAM in the future?
Acceptability
Do you feel that your organization has benefited from providing THE PROGRAM? Do you feel that providing THE PROGRAM has helped create opportunities for your organization? Do you like that your organization provides THE PROGRAM?
Appropriateness
Does THE PROGRAM fit with the cultural values of the people with whom your organization works? Is THE PROGRAM useful for the mental health problems of people who need this type of service? Does THE PROGRAM fit with your organization's goals? Is providing THE PROGRAM a priority for leaders at your organization?
Feasibility
Is total counselor time available for implementing THE PROGRAM sufficient at your organization? Is total administrative support time for implementing THE PROGRAM sufficient at your organization?
Penetration
Are people in the community aware that THE PROGRAM services are available? Are clients who seek help able to begin THE PROGRAM with little wait time? Would most people in the community seek THE PROGRAM services if needed?
Organizational Climate
Do you feel you are well informed on things you should know about within your organization? Does your organization keep you well informed on what you need to know to do your work? Do staff at your organization have a high amount of morale?
Organizational Leadership
Do the leaders at your organization have clear quality standards for implementation of THE PROGRAM? Have the leaders at your organization removed obstacles to implementation of THE PROGRAM?

[1] Each scale is scored on a 4-point ordinal scale ranging from 0 "not at all" to 3 "a lot", with an additional category for "don't know/not applicable". Every participant is trained on (providers, organizational staff) or informed about (patients) the novel model of care for depression and unhealthy alcohol use under evaluation in this study (defined as "the program" in these measures) before they are asked to complete these measures. And after a given site launches the model of care, the providers, organizational staff and patients have direct experience with this model of care defined as "the program" in this measure.

Highlights

- Training primary care providers in depression and alcohol use disorder care and embedding it in the workflow of primary care greatly increases provider and organizational capacity for care.
- Employing digital technology to conduct validated screenings for depression and alcohol use disorders; provide clinicians with decision support tools to guide care; and provide direct-to-patient behavioral therapy markedly increases access to evidence-based depression and alcohol care in Colombia.
- This project will create new knowledge to inform science-based approaches to scaling-up mental health implementation research for depression and alcohol use care and build science-based programs in Colombia.

Table 1.

Summary of Study Outcomes Organized Using the Study Implementation Model

		Data Source		
Construct	**Assessment Tool**	**Organizational Staff**	**Providers**	**Patients**
Primary Implementation Outcome Measures *(informed by Outcomes for Implementation Research framework)*				
Acceptability	Integrated Measure of Implementation Context and Outcomes in Low- and Middle-Income Countries (IMICO)	X	X	X
Adoption	IMICO	X	X	X
Appropriateness	IMICO	X	X	X
Feasibility	IMICO	X	X	X
Penetration	Program Sustainability Assessment Tool (PSAT)	X	X	X
Sustainability	PSAT	X		
Determinants of Implementation Success *(informed by Consolidated Framework for Implementation Research)*				
Organizational Climate	Qualitative Interviews	X	X	
Organizational Leadership	Qualitative Interviews	X	X	
Overall perceptions of mental health care model	Qualitative Interviews	X	X	X
Secondary Implementation Outcomes Measures				
Behavioral health integration in medical setting	Behavioral Health Integration in Medical Care Index (modified for Colombia)	X		
Cost of Implementation	Time-Drive Activity-based Costing (TDABC)	X		
Medical resource use outside study site	Non-Study Medical and Other Services (NSMOS)			X
Depression impact on work performance	Health and Work Performance Questionnaire (HPQ)			X
Patient Clinical Outcomes				
Depressive symptomatology	Patient Health Questionnaire (PHQ-8)			X
Past month alcohol use	Quick Drinking Screen (QDS)			X
Health-related quality of life	World Health Organization Disability Assessment Schedule (WHODAS)			X
Anxiety symptomatolog0079	General Anxiety Disorder screener (GAD-7)			X