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A feasibility study of a mental health mobile app in the Dominican Republic: The untold story

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ABSTRACT

Mobile health (mHealth) interventions include mental health apps (MHapps). There are hundreds of MHapps, which have been touted as a means of revolutionizing mental health care delivery. In spite of the rosy outlook and promise of MHapps, there are challenges to implementation in Low and Middle Income Countries (LMICs). We report on several domains of implementation: acceptance, appropriateness, engagement, and work processes assessed in two samples of clinicians and patients designed to develop and test the feasibility of a Spanish language Cognitive Behavioral VoiceThread® app for Dominican primary care patients with depression. Results indicated that feasibility of our eMH intervention was compromised by appropriateness of the target audience and the eligibility criteria used, including language, age, access to phones, and access to the internet. Both participants and clinical providers had varying degrees of engagement in the MHapp. Clinical providers had a desire for increased knowledge and capacity building, but also unspoken expectations and misaligned incentives. For participants, there were logistical and emotional barriers to use, some of which could not be fully determined in this study due to a lack of feasibility in terms of a low retention rate. Corresponding to these issues, we identified four potential solutions: 1) understanding of characteristics of end-users; 2) engagement of key stakeholders; 3) working within the existing infrastructure; and 4) addressing the social determinants of health. Unforeseen strengths also emerged as a result of our investigations. The challenges encountered in this pilot study can be viewed as evidence of failure or part of the incremental steps necessary to build future success.

KEYWORDS

Behavioral health; depression; feasibility; hispanics; latinos; LMIC; mHealth; mobile apps; primary care

Introduction

Mental illnesses are among the leading causes of years lived with disability; however, 80% of people with mental illness in Low and Middle Income countries (LMICs) are unable to access treatment (Whiteford et al., 2013).

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Increasing income inequality worldwide and disparities in health care resources contribute to morbidity and poor health outcomes in LMICs. The ubiquity of cellular phones and their unobtrusiveness may provide a means of delivering mental health care that is more private and less stigmatizing through mHealth. mHealth is a type of eHealth that the World Health Organization (WHO, 2011) defines as medical care or monitoring that is delivered through mobile devices (World Health Organization, 2011). The WHO has found that mHealth interventions for chronic disease management are utilized in the majority of its member nations and have reached more than 31 million people worldwide (World Health Organization, 2011). There are various types of mHealth interventions including: interactive voice response (IVR), smartphone applications, short messaging service (SMS), and telephone-based peer support (TBPS). eMental Health (eMH) is "the use of telecommunication and information technologies to deliver mental health services at a distance" (Vis et al., 2018). eMH has been successfully used to deliver treatment, real-time monitoring, and symptom management, psychoeducation, screening, promotion of behavioral change, coaching, social support, and self-management for a wide variety of mental illnesses including anxiety, depression, post-traumatic stress disorder, and borderline personality disorder (Donker et al., 2013; Labrique, Vasudevan, Kochi, Fabricant, & Mehl, 2013; Wang et al., 2014). Apps that deliver eMH interventions are referred to as mental health apps or MHapps. There are hundreds of MHapps available; however, few MHapps available for consumers incorporate evidenced-based features, such as Cognitive Behavioral Therapy (CBT), and few have evidence of effectiveness (Bakker, Kazantzis, Rickwood, & Rickard, 2016).

There are 4.3 billion mobile subscribers and access to mobile phones globally is 91% (Sourabh, 2013). mHealth has been touted as a means of revolutionizing health care delivery and "the capabilities of mobile technology are now central to global health thinking" (Mohammadi, 2015). In spite of the rosy outlook and promise of mHealth and eMH, in particular, there are challenges to implementation and translational research that need to be considered. These challenges relate to human factors, the infrastructure of health service delivery, and research capacity to evaluate technological innovations in the use of eMH.

MHealth in Latin America

In Latin America, including the Dominican Republic (DR), wired networks and connectivity are rapidly expanding (The World Folio, 2013) and penetration has reached 112%, meaning some people have more than one phone (The World Folio, 2013). Unfortunately, technology is changing at a rate

that often precedes research evidence, and there are only a few examples of concerted efforts in mHealth interventions. The importance of information technology in the region is being fostered by The Observatory for the Information Society in Latin America and the Caribbean (OSILAC) (United Nations Economic Commission for Latin America, 2013) and The Global Observatory for eHealth (GOe) (WHO, Global Observatory for eHealth. Atlas—eHealth country profiles based on the findings of the second global survey on eHealth, 2010), which are designed to monitor the growth of internet technology and raise awareness of the need for eHealth practices. The Ibero-American Network of Mobile Technology and Health was created to promote research and development of mHealth in Latin America. Results of their efforts were highlighted in the international workshop RITGMOS 2015, and featured the use of mobile applications and instant messaging (SMS) as mHealth tools to benefit and improve the quality of diagnosis, treatment and monitoring, self-care, and quality of life among the population of Latin America (Saigi-Rubio, Novillo-Ortiz, & Piette, 2017). Peru and Mexico were highlighted for their use of mHealth for treatment adherence, epidemiological surveillance, and chronic disease self-management (Ramírez, Guillen, & Cifuentes, 2016; Richards, 2013; Ruiz, Proaño, Ponce, & Curioso, 2015). However, in general, efforts to promote the use of mHealth are in its infancy and mental health is underrepresented among mHealth strategies. In many Latin American countries, the lack of infrastructure, both physical and technological, presents a real barrier to the adoption and use of mHealth. In Colombia, there is a clear policy on eHealth and health service needs of the population; however, the potential use of technology is limited by poor coverage, few trained personnel, and cost (Frenk, 2015). A survey of Latin American and Caribbean countries found that slightly more than half had an Information and Communication Technology policy, whereas very few, including the DR, had electronic health (eHealth) policies (Jimenez-Marroquin, Deber, & Jadad, 2014). This absence of a concerted government level investment in eHealth has resulted in limited outcomes and translational research. The quality of existing mHealth research in Latin America is limited by small sample sizes, lack of valid diagnostic measures, and insufficient safeguards for confidentiality, anonymity, and information security (Ramírez et al., 2016; Richards, 2013).

Barriers to conducting eMH translational research in LMICs, including Latin America

Results of some systematic reviews conducted in the United States and theoretical articles describe a number of challenges to the development of an evidence basis for mHealth apps that are relevant to MHapps. These

include Food and Drug Administration (FDA) regulatory issues, Health Insurance Portability and Accountability Act (HIPPA) and privacy issues, integration with existing health systems, and financial sustainability (Terry, 2015). These challenges, although noteworthy, are not easily amenable to change at the project level (WHO, 2015) and do not address the crux of the issues facing implementation of an MHapp in an LMIC (Amerson & Strang, 2015). Translational research is comprised of dissemination and implementation (May, Johnson, & Finch, 2016; Proctor et al., 2009). Dissemination of eMH has been successful in HICs given that stakeholders and policy makers support eMH health care delivery to expand access. The most frequently used evidenced-based eMH depression treatment is CBT (Cuijpers, Andersson, Donker, & van Straten, 2011). In the form of self-help web apps and mobile apps, studies have shown effectiveness in the treatment of mild to moderate depression in nonclinical settings (Andersson, Topooco, Havik, & Nordgreen, 2016; Sander, Rausch, & Baumeister, 2016; Wang et al., 2014), although implementation in the clinical setting is more challenging.

Most eMH interventions are developed and tested in High Income countries. Global research funding priorities are set by High Income Countries (HICs) and have favored communicable disease research in LMICs. Significantly less research funding has been dedicated to chronic disease and mental health services research (The Global Emergency Medicine Think Tank Clinical Research Working Group, 2017). The vast majority of research related to mHealth in LMICs, including Latin America, has been in the areas of behavioral change in infectious disease surveillance, and maternal and child health. mHealth interventions have also been used a platform to enhance workforce training and monitoring, track vital statistics, and as sensors and diagnostics (Bakker et al., 2016).

Although the use of the internet, mobile phones, and the development of applications and online sources of information currently are in high demand in LMICs, little has been done to integrate these communication methods as tools for the dissemination of mental health interventions. Sociocultural norms influence attitudes towards health services, including how eMH solutions will be utilized (Dobson et al., 2017; O'Connor & O'Donoghue, 2015; The Global Emergency Medicine Think Tank Clinical Research Working Group, 2017). In Latin America and the Caribbean, societal stigma related to mental health creates a reluctance to seek out psychologists, or psychiatrists. Persons with mental health problems prefer, instead, the advice of family members or religious leaders when experiencing symptoms of emotional distress (Caplan et al., 2016). eMH can enable people to access services in their own environment, avoiding the stigma associated with disclosure of a mental health problem (Fraser & Blaya,

2010; Pagalday-Olivares et al., 2017). However, stigma may be one of the reasons that research specific to MHapps and other eMH interventions is virtually nonexistent in Latin America.

The Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) (Glasgow, Vogt, & Boles, 1999) framework has been used to identify barriers and facilitators to eMH uptake in HICs (Donker et al., 2013), and these fall into several domains, as follows: acceptance, appropriateness, engagement, resources, work processes, and leadership. These issues are also very relevant to research related to eMH delivery in LMICs, but may be more clearly illustrated in a real world context. The objective of this manuscript is to discuss the feasibility of implementation of MHapps research in an LMIC, the DR, and to provide some potential solutions.

Methods

We report on the barriers to implementation of a proof of concept study designed to develop and test the feasibility of disseminating a culturally adapted Spanish language Cognitive Behavioral guided self-help VoiceThread mobile app® (CBT-VT app) for Dominican primary care patients with depression. The application, El Buen Consejo Movil (EBCM) (the Sound Advice) was developed and piloted in three government-owned primary care clinics in Santo Domingo and Boca Chica, DR. We opted to not provide a phone to participants, because the provision of a smart phone (valued at $75 U.S. dollars) could be considered a coercion to participate in the research study. Thus, we provided an incentive of initially one month's internet access or 4 gigabytes (valued at $17) with an additional month upon follow-up. Feasibility data were ascertained from two separate samples during 2016–2018. The study was approved by a University Institutional Review Board (IRB), the Research Department of the University Autónoma de Santo Domingo, and the Ministry of Health in the DR.

The Specific Aims of the study were to:

1. Assess access to smart phones and the internet among this population and acceptability of app usage.
2. Assess the feasibility and acceptability of using EBCM. Feasibility included recruitment, adherence and retention, clinical relevance, and staff engagement.

Study design. A mixed-method longitudinal design was used to evaluate the feasibility and acceptability of EBCM. We used an iterative design process for development and evaluation of mHealth technology, the

Accelerated Creation to Sustainment (ACTS) model (Mohr et al., 2017). This model avoids some of the pitfalls of translational research in the context of mHealth interventions. In the traditional model of translational research, an app is developed outside of and apart from the deployment setting, and is implemented in the real-world setting only when fully developed. In the ACTS model, creation, development, implementation, and evaluation occur simultaneously and cyclically throughout the phases of Create, Trial, and Sustain (Mohr et al., 2017). Therefore, based on the analysis of results from our first sample, we modified the sample, setting, intervention, and objectives for our second sample. We retained the objective of assessing the feasibility and acceptability of using EBCM. An additional objective for the second sample was to increase staff engagement and understanding of the intervention for future deployment in that setting.

Subjects and Setting Sample 1. A convenience sample of 36 participants was recruited from two primary care sites. The sample size was based upon our *a priori* recruitment criteria of 60% of eligible participants recruited and consented. Using a sample size estimate based on confidence intervals of estimates (Hooper, 2019; Hertzog, 2008), with a sample size of 36, we would be able to estimate a recruitment rate of 60% to within a 95% confidence interval of +/- 13%. We opted for this range because of the recommended sample size of less than 40 for feasibility of recruitment in pilot studies and a greater acceptability of wider confidence intervals (Hertzog, 2008). The sites were selected based on where providers had received the WHO Mental Health Gap Action Programme (mhGAP) training in integrated behavioral health care. The goals of mhGAP were to increase access to health care for mental, neurological, and substance abuse disorders through integrated behavioral health care. Through mhGAP, primary care providers throughout the country were trained in identification and management of common behavioral health disorders such as depression, dementia, epilepsy, and alcohol misuse, thus, primary care providers had a protocol for screening and treating Major Depressive Disorder (MDD) (World Health Organization, 2010). These primary care sites, known as Primary Attention Units (UNAPS), had been selected by the Office of the Minister of Mental Health and were located in the National District, specifically in Boca Chica, Santo Domingo, and Santo Domingo Este.

Recruitment Sample 1. The PRIME-MD PHQ-9 was used to assess presence of depressive symptoms (Kroenke, Spitzer, & Williams, 2001). The PHQ-9 is a 9-item scale that assesses all DSM-V symptoms of depression during the past two weeks. It is a widely-used measure of depression severity in primary care, that has been validated for Spanish-speaking populations (Baca et al., 1999; Diez-Quevedo, Rangil, Sanchez-Planell, Kroenke, & Spitzer, 2001; Wulsin, Somoza, & Heck, 2002). The PHQ-9 was selected

because the questions were similar to the depression screening questions used by mhGAP. After screening and scoring the PHQ-9, the participant was informed of the results of the screening, and the significance of the results, in a culturally appropriate manner. With the patient's written consent, results were shared with the patient's primary care physician. Patients who met inclusion criteria were invited to participate in the study of EBCM. The consent form was read aloud to participants and a formal written consent was obtained. The inclusion criteria was: age greater than or equal to 18, PHQ-9 (Kroenke, Spitzer & Williams, 2001) score indicative of depression by algorithm, and greater than or equal to 5 and less than 15 (indicating mild to moderate depressive disorder) on a validated Spanish translation of the PHQ-9, access to a working mobile smart phone, receipt of primary care from the UNAP, able to speak and understand Spanish and read at a third grade level (for texting within the app). The exclusion critera was: age less than 18 years, PHQ-9 score not indicative of depression by algorithm and less than 5; or greater than or equal to 15, a history of psychiatric hospitalization or bipolar disorder, severe mental disorder, actively suicidal, significant cognitive impairment, hearing or speech impairment that would preclude listening to and/or verbally responding to the app, non-Spanish speaking, a life expectancy of less than six months.

Subjects and Setting Sample 2. Upon review and analysis of data from the first two sites and concerns over the absence of screening and a referral system for persons with mental health care needs, we opted for a third site where mhGAP was being implemented with greater fidelity and mental health professionals were present on-site. This UNAP was located in Santo Domingo Este. At this site, the research team presented the goals and objectives of the study to the entire clinical staff. In discussion of the proposed research, the Medical Director and Regional Health Director felt that ECBM might be appropriate for clinic staff. Moreover, to enhance staff engagement and understanding of the intervention, the PI and Co-Investigators decided that the clinical staff should be given a trial period of the app to experience the intervention. We informed the staff that we wanted their feedback on the app's perceived appropriateness for the target audience, the clinic's patients. We also wanted to assess the potential for staff members to monitor the app and fully integrate the intervention within the daily work-flow of the clinic.

Recruitment Sample 2. All clinical staff (n = 30; 5 nurses, 14 CHWs, and 9 doctors and 2 mental health providers) who were present in the clinic and available during the times the research team was present were invited to participate in the five-day trial of EBCM. Staff members who were willing, formally consented to study participation. The consent, conducted privately, included permission to complete a brief demographic

questionnaire, and the PHQ-9, and to provide feedback and evaluation of the contents of the app. The inclusion criteria for staff was: age 18 and above, had worked at the primary site for a minimum of 6 months, and present at the clinic for a minimum of 15 hours per week. The exclusion criteria was: age under 18, plans to be away from the clinic for greater than one week, severe mental disorder, actively suicidal, cognitive impairment, hearing or speech impairment that would preclude listening to and/or verbally responding to the app.

Intervention. After baseline data collection, participants were provided with prepaid internet access for one month and EBCM was downloaded to their phone. The intervention was based on the Spanish language depression prevention course, "The Healthy Management of Reality," an evidence-based CBT group therapy program developed by Muñoz (2007). The language and contents of the course had been culturally modified for the Dominican population with ongoing collaboration with mental health professionals in the DR and the United States. Subsequently, the face-to-face program (Muñoz, 2007) was modified for use in the app. Modifications were designed to compensate for the absence of therapist/patient live interaction by incorporating daily salutations and dichos (short parables or instructive comments) in short one to two-minute audio commentaries. These modifications were piloted among a convenience sample of 24 interview participants (14 patients and 10 clinic staff in different capacities) in a primary care clinic in Santo Domingo, DR.

EBCM was designed to be used as a stand-alone tool to provide psychoeducation for depression or to augment treatment as usual (TAU). The contents of EBCM, delivered in two daily recorded messages, was not considered to be psychotherapy, but rather guided self-help for depressive symptoms and negative mood states. EBCM was downloaded to VoiceThread's cloud-based platform, a proprietary, secure mobile platform that facilitates multimodal communication among users (see Figure 1). Participants could respond to questions posed in the prerecorded psychoeducational strategies with a voice recording or text describing their thoughts, mood states, or perceptions or record a numerical value on the mood thermometer. Participants were assigned to groups of five or six and could read or listen to responses of other participants. All answers and participant responses were stored on the mobile phone. The recorded responses were accessed by the study team via their own password-protected access to the participants' individually assigned program. Since EBCM was not a free-standing app, but was downloaded to the VT platform, individuals did not receive tailored messages or strategies that were customized to individual responses. The five major parts to the EBCM consisted of psychoeducation and how to identify triggers for negative or

Figure 1. VoiceThread Functionality.

positive moods and thoughts, daily self-monitoring of moods and thoughts, symptom management, and cognitive behavioral strategies using a tool-box approach (see Figure 2).

Participants received an introductory session that explained basic usage of the app, including how to create a password for their app (and their phone, if not already password protected). To prevent unauthorized use of the app, we instructed participants to not share their passwords with anyone. Participants were given demonstrations to practice using the app. They created a pseudonym and recorded an introductory statement using their pseudonym that appeared within the app with the initials of the pseudonym. Knowledge of how to use the app was evidenced by a return demonstration of usage.

Monitoring of response to treatment. Participants were monitored for adherence to treatment. The PI reviewed the responses to each session on a daily basis and offered each participant feedback based upon responses and improvement or worsening of mood scale. Participants who did not respond to the app by the third day received a text message reminder to encourage use of the app.

Data Collection. Data collection for Sample 1 occurred at baseline, when semi-structured individual interviews were used to assess demographics, mental and physical health, and use of mental health care. Demographic items were selected based on a review of the literature pertaining to predictors of depression (Oslin et al., 2002; Wang et al., 2014). Participants were also asked to respond to questions about whether they owned a mobile

Figure 2. EBCM intervention.

phone, if it was a smart phone, and if they had experience using mobile apps. At the end of the four-week intervention, the PHQ-9 was administered. All three interviewers were Spanish speakers. Data collection for Sample 2 occurred at baseline and at the end of the five-day trial period of EBCM.

Acceptability of the CBT-VT. Final feedback of the acceptability and feasibility of EBCM was based upon the open-ended questionnaire developed by Ainsworth et al. (Ainsworth et al., 2013) and was administered in a face-to-face interview. Acceptability of the contents of EBCM was evaluated based upon open-ended and Likert scale questions in the domains of content, technology, interaction with others, privacy, and confidentiality. Content questions included the degree to which recommended strategies could be used in daily living, a self-assessment of mood state after participating in the sessions, and confidence in being able to maintain the strategies. Technology questions were based upon

ease of usage, comfort level in using the app, and barriers to using the app.

In addition, within the app, every two days, we posed a short series of questions, "What was useful about today's session," "What was not useful," and "How can we improve the session?"

Clinical staff in Sample 2 were asked to comment on the quality and cultural appropriateness of the revised graphic images within the newly added animations, the perceived acceptability of the contents for patients, and if they could see themselves having a role in monitoring participants' responses to the app.

Evaluation of Implementation and Analysis of Processes. Our framework for analysis of processes related to implementation was based upon the determinants of practices relevant to implementing eMH in primary care identified by Vis et al. (2018) in their systematic review of eMH for mood disorders. These determinants included: "(1) acceptance of eMH by patients and staff, (2) appropriateness or clinical relevance of eMH, (3) engagement of participants [patients and staff] in implementing and delivering eMH, (4) resources for implementing and delivering eMH, and (5) work processes in delivering eMH" (Vis et al., 2018). We used inductive analysis to ascertain how implementation and process outcomes fit within the above-stated implementation determinants. Interview data were reviewed and systematically analyzed by the investigators (the first and second author) using qualitative descriptive techniques for thematic analysis (Braun & Clark, 2006).

We used deductive analysis to identify *a priori* criteria of feasibility of implementation, based on the Cochran Criteria for bias in interventional studies (Editorial Board, Cochrane Back Review Group, 2009; Higgins & Green, 2011), and the researcher's experiences recruiting in the primary care setting, including as follows:

Recruitment. 60% of eligible participants recruited and consented.

Retention/Attrition. Less than 25% attrition

Results/Summary of findings

The first sample had a mean age of 36 and the majority of these participants were women, 15 (83%), and from the DR, 14 (78%) (see Table 1). The other participants were from the United States and Venezuela. In this sample, 140 were screened for depression of whom 57 (41%) screened positive for depression, 21 were ineligible to participate in the study, two (1.4%) due to age under 18, 11 (8%) were ineligible due to lack of a smart phone, and 8 (6%) due to severity of depression or suicidal ideation (see Figure 3). The absence of a smart phone was more likely to occur among participants from the clinic in Boca Chica. Of the 36 participants who met

Table 1. Description of the Sample 1 ($n = 18$).

Variable	*N (%)*
Age (mean)	36
Gender	
Male	3 (17)
Female	15 (83)
Country or origin	
Dominican Republic	14 (78)
Venezuela	3 (16)
United States	1 (6)
Read anything about mental health	
Yes	9 (50)
No	9 (50)
Residence in Dominican Republic	
0–5 Years	3 (17)
5–10 Years	0 (0)
11–15 Years	1 (5)
15–20 Years	2 (11)
20+ Years	12 (67)
Highest level of education	
Eighth grade or less	1 (5)
Less than high school	3 (17)
High school graduate	3 (17)
Technical school/Some University	7 (38)
College graduate	4 (22)
Marital status	
Married or living with a partner	11 (61)
Widowed/Separated/Divorced	4 (22)
Single or never married	3 (17)
Occupational status	
Full-time	3 (17)
Part-time	7 (39)
Unemployed	7 (39)
Student	0 (0)
Disability	1 (5)
Monthly income level (Dominican pesos)	
Less than $2,000 (US Dollars <$46))	2 (11)
$2,000–$8,999 (US Dollars $46–$209)	7 (39)
$9,000–$17,999 (US Dollars $209–$363)	5 (28)
More than $18,000	2 (11)
Self-rated physical health	
Excellent	4 (22)
Good	5 (28)
Fair	6 (33)
Poor	2 (11)
Did not answer	1 (5)
Self-rated mental health	
Excellent	4 (22)
Good	6 (33)
Fair	5 (28)
Poor	2 (11)
Did not answer	1 (5)
Current mental illness treatment	
Yes	2 (11)
No	16 (89)
Past mental illness treatment	
Yes	2 (11)
No	16 (89)

inclusion criteria, eighteen (50%) completed baseline data, of whom nine (50%) used the app and 3 (33%) completed all four weeks of the intervention (see Figure 3).

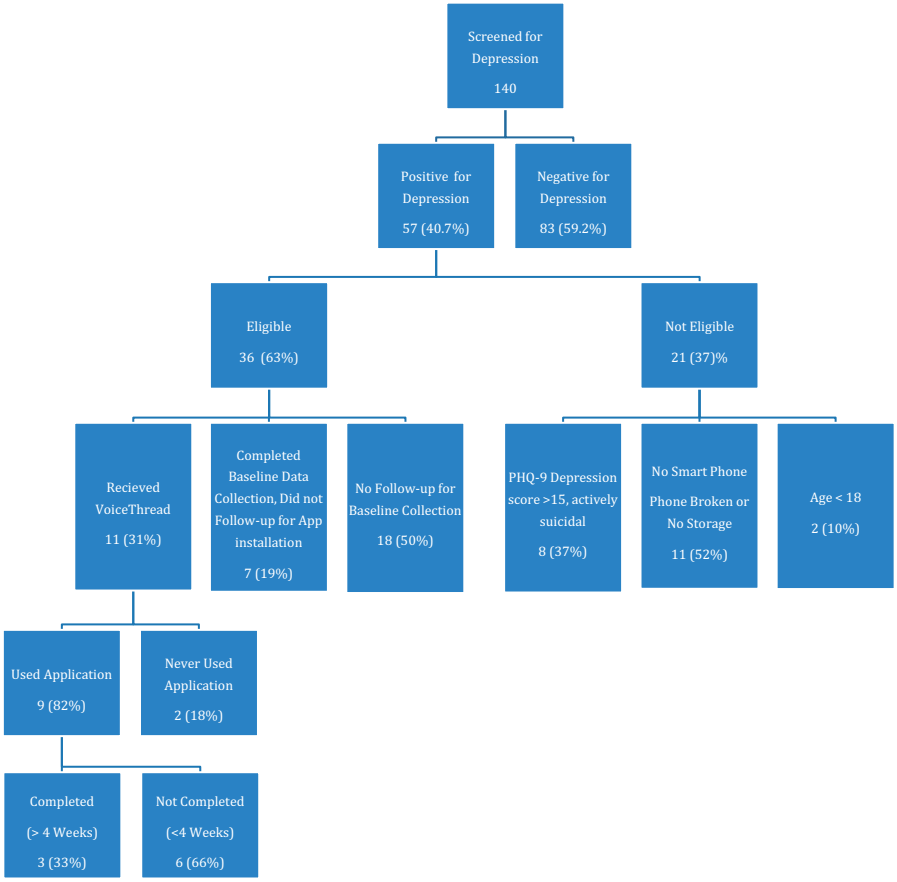

Figure 3. Subject Screening Results–Sample 1. Patients.

The second sample (clinic staff) had a mean age of 42 and all of the participants were from the DR (n = 21) (see Table 2). In this sample, 3 (14%) screened positive for depression. Seven people (33%) were ineligible to participate in the study; one person was ineligible due to lack of a cell phone, three people were ineligible due to lack of a smart phone, two people were ineligible due to lack of capacity on their phones, and one person was ineligible due to cognitive impairment (see Figure 4). For those participants who could not access the app on their phones or who did not view the entire program, the program was presented to them on a computer during the final individual and group interviews. We elicited feedback on the content and appropriateness of EBCM for their patient population (n = 6).

Determinant 1. Acceptance of eMH by patients and staff

In response to our initial series of questions about phone usage, a large majority of the participants had cell phones, and 81% had smart phones.

Table 2. Description of Sample 2 ($n = 21$).

Variable	*N (%)*
Age (mean)	42
Gender	
Male	3 (14)
Female	18 (86)
Country or origin	
Dominican Republic	21 (95)
Read anything about mental health	
Yes	14 (66)
No	7 (33)
Highest level of education	
Eighth grade or less	1 (5)
Less than high school	2 (9.5)
High school graduate	1 (5)
Technical school/Some university	8 (38)
College graduate	2 (9.5)
Graduate school	7 (33)
Marital status	
Married or living with a partner	14 (67)
Widowed/Separated/Divorced	5 (24)
Single or never married	2 (9.5)
Occupational status	
Full-time	8 (38)
Part-time	13 (62)
Occupation	
Physician	4 (19)
Nurse	4 (19)
Psychologist	1 (5)
Health Worker	9 (43)
Medical Supervisor	2 (9)
Pharmacist	1 (5)
Monthly income level (Dominican pesos)	
$2,000–$8,999 (US Dollars $46–$209)	5 (24)
$9,000–$24,999 (US Dollars $209–$581)	4 (19)
$25,000–$35,999 (US Dollars $518–$837)	4 (19)
More than $36,000	1 (5)
Self-rated physical health	
Excellent	6 (29)
Good	7 (33)
Fair	8 (38)
Poor	
Self-rated mental health	
Excellent	9 (43)
Good	10 (47)
Fair	1 (5)
Poor	1 (5)
Depression screening result	
Positive	3 (14)
Negative	18 (86)
Previous history of mental health problem	
Yes	2 (10)
No	19 (90)
Cell phone availability	
Yes	20 (95)
No	1 (5)
Smart phone availability	
Yes	18 (86)
No	3 (14)

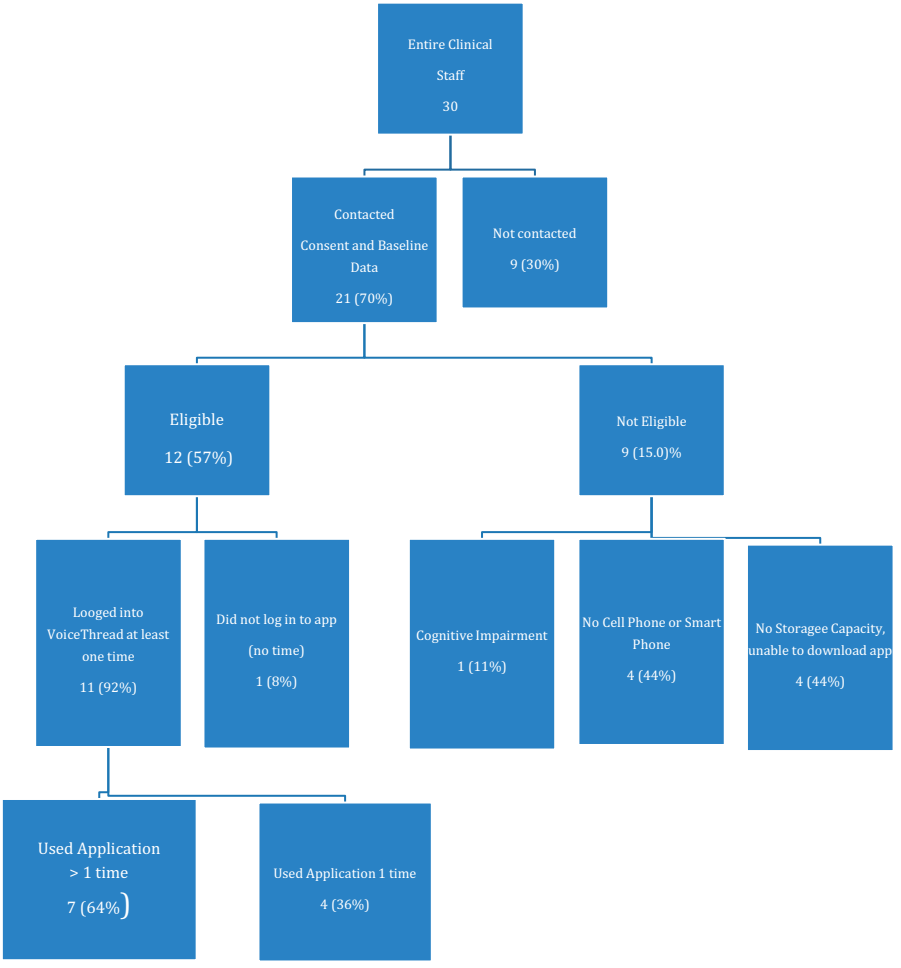

Figure 4. Subject Screening Results--Sample 2. Clinicians.

Almost all reported interest in mobile application therapy due to its convenience, privacy, and affordability, and most found the sample of suggested CBT strategies and "advice" to be relevant, comprehensible, and culturally appropriate.

Determinant 2. Appropriateness or clinical relevance of eMH

Clinicians and patient participants perceived that the app was clinically relevant and appropriate. When asked if the contents were useful or not useful, most participants responded that "todos son muy utiles," ("everything was very useful") (male, Boca Chica). Clinicians felt that the information provided in the app and for potential users with depression was appropriate: "Sobre el contenido me parece bien porque ayuda a saber como manejarse" ("In respect to the content, it seemed to be good, because

it helps to learn how to get along") (female, community health worker (CHW), Santo Domingo Este). Nevertheless, the appropriateness of our eMH intervention was diminished as a result of the design of the study and the selection of the target population in Sample 1. These challenges included language barriers, age, access to phones, and access to the internet.

Language. Some participants in the clinic in Santo Domingo were ineligible because they did not speak Spanish. Although this clinic drew from a population residing in the nearby extremely impoverished neighborhood, we had not anticipated that the number of patients who did not speak Spanish would be so high. Many of the patients were from Haiti and unable to understand Spanish. The language of our app was in Spanish and there were insufficient budgetary resources for translation, validation, and creation of the app in Creole.

Age. Our age eligibility criteria for use of the app were limited to adults, aged 18–64. This was due to the fact that our MHapp was based upon the "The Healthy Management of Reality," a program developed for adults. There were also ethical and logistical barriers to conducting research with minors as participants, including the lack of access to child psychiatrists. Nevertheless, our primary care clinics primarily served young women of childbearing age who were seeking prenatal care or vaccinations for their children. This population was at high risk for post-partum depression, and many met all of the other eligibility requirements for the study. However, a number of these women were found to be ineligible because they were under the age of 18.

Access to phones. Some potential participants did not have smart phones. Other participants shared their phones with their family members limiting regular access to the intervention and potentially, limiting the privacy of usage. Some participants only had access to the phone in their own homes. They did not carry their phone with them due to fear of theft, thus limiting access to the self-monitoring aspects of the CBT intervention. Of the participants who had access to smartphones, the majority had sufficient memory on their phones to be able to download the app, but some continued to experience technical difficulties, such as forgetting their password, or subsequent damage to their phones.

Access to the internet and technological literacy. Although most people had smartphones and access to WIFI in their own homes or at internet cafes, they did not use their phones to surf the internet; rather, the utility of internet connectivity was to enhance communication and social interaction through WhatsApp and Facebook. Two of the participants who were provided the app, but did not use it, were participants who had limited technological literacy.

Determinant 3. Engagement of participants and clinical staff in implementing and delivering eMH

Both patient participants and clinical staff had various degrees of engagement in the MHapp for entirely different reasons. Clinical providers expressed a desire for increased knowledge and clinical capacity. In Sample 2, the completion rate over a five-day period was 17% (2 out of 12). However, we were able to ascertain follow-up data from all but one of the clinicians. Among those who could access the app, the most common reasons cited for noncompletion were lack of time, technical difficulties, such as slowness of the internet and inability to download the videos, forgetting their log-in, and security features on the phone that prevented usage. In Sample 1, a barrier to staff engagement was unspoken expectations and misaligned incentives among the providers.

Clinical staff-misaligned incentives. In the clinics selected by the Ministry of Health, the doctors who had been trained in mhGAP were informed of the study, had met with the PI and Co-Investigators and discussed the goals of the program. During our presentation of the research project, we assessed the doctor's willingness to participate in the implementation of the research. Providers were informed that they would be responsible for screening and referring patients with elevated levels of depression, in accordance with their prior mhGAP training. The two providers in each of two sites stated that their motivation for participation was to potentially enhance identification of depression, increase access to care for patients with depression, and to increase staff capacity in understanding of depression. Both providers were offered the opportunity to participate as Co-Investigators upon completion of the Human Subjects training, provided by the first author. The Principal Investigator (first author) had previously facilitated this training for Co-investigators and Research Assistants, who were compensated for the time dedicated to training. For one of the two doctors, a non-stated incentive for participation was the expectation of what she referred to as an "*incentivo*" or a personal direct payment for herself and the clinic staff. This expectation was expressed as a demand for payment one day prior to commencement of the research and equal to approximately one month's salary. Due to the fact that this physician had not completed Human Subjects training, we had not defined a research-specific role for her. Her role was consistent with usual clinical day-to-day responsibilities. To facilitate the implementation of the study, we created additional non-research responsibilities related to coordinating student learning experiences, and the physician was remunerated.

Engagement of patient participants. Participants who used the app were engaged and reported that they found the advice helpful. Per comments within the app and one of the final interviews, EBCM offered good

advice, reduced stress, and they felt comforted by knowing that other people were experiencing similar feelings. Both patient participants who completed the final evaluations would recommend the app to other people. Within the app participants volunteered: "escucho sus consejos e aprendido mucho más a yevar un estilo de vida más relajado sin pensar mucho en cosas que no sean constructivas" ("I listen to the advice and I have learned a lot about how to have a more relaxed lifestyle without thinking too much about things that are not constructive") (female, Santo Domingo). "Buen del temometro me siento bien. No estoy enfadada. Eso me ayuda esta mas trankila" ("Good, with the mood thermometer, I feel good. I'm not fed up. This helps me to be more at peace") (female, Santo Domingo).

Only one person expressed negative feelings about the app. During the final interview, she voiced her ambivalent feelings that although she liked the interaction with other people and she felt good knowing that other people were having similar experiences, she did not like to share her feelings in public. She did not fully understand the messages in terms of content and only found some of them to be useful, such as the breathing exercises. Her personal problems and difficulties at home continued. Moreover, although she did receive personal responses to her comments, she was looking for a greater level of tailored responses, rather than the initial prerecorded messages that were directed at the entire group. She had really wanted individual psychotherapy and misunderstood the limitations of the app.

At least five participants responded several times a week. However, most participants failed to use EBCM for the entire four-week duration (see Figure 3). In Sample 1, the completion rate for the entire four weeks was 8.33 (3 out of 36), and a third of the participants in Sample 1 who had started using the app could not be reached for follow-up. There were numerous logistical and emotional barriers to use, some of which could not be fully determined in this study due to a low retention rate which did not meet our *a priori* criteria for retention (see Figure 3). When contacted by phone during the period of the intervention, a few participants stated that they were unable to complete the program due to difficult life circumstances, including employment issues, undocumented immigrant status, child care, or elder care responsibilities. One participant reported having used up the allotted month's internet access in one week. Another participant reported that he thought it would be more like the apps you get in the app store, with games and points.

Determinant 4. Work processes in delivering EBCM

Work processes are the necessary tools and methods required to carry out and monitor the intervention. Challenges to the conduct of our study were

in the areas of research design including: the time dedicated to consent and the need for multiple clinic visits to provide access to the app; and the lack of standardized measures to assess patient appropriateness for the intervention and monitor outcomes.

Consenting and baseline data collection. In our first sample, many participants were lost during the process of reading aloud a twelve-page consent form, and baseline data collection. Per our University's interpretation of IRB regulations, the consent form was required to provide sufficient detail about the contents of each instrument, the manner in which HIPPA would be adhered to (although HIPPA is not enacted in the DR) and separate consent forms pertaining to HIPPA and permission to record the participant's voice during the app usage. The process of reading aloud the consent form took over 30 minutes, which proved to be difficult for participants who were interrupting their work day to attend the clinic. Therefore, some participants were given the consent form to read at a convenient time and were asked to return if interested. For participants who did return, the multi-step process of accessing the app store, obtaining a gmail account for access to the app, downloading the app, traveling to a local store to purchase the on-going internet access for use of the app, demonstrating the app, and ensuring knowledge of how to use the app was a very lengthy process which precluded full participation.

Lack of standardized measures. During the initial screening process, the PHQ-9 served as the instrument to screen potential participants for depression. The PHQ-9 was selected due to its ability to validly and reliably measure depression across cultures (Huang, Chung, Kroenke, Delucchi, & Spitzer, 2006). In a United States sample of primary care patients, which included Spanish speakers, there were a sensitivity of 88% and a specificity of 88% for major depression at a score of greater than or equal to 10 based on a structured clinical interview (Kroenke et al., 2001). Nevertheless, in the absence of a population-based validation of the PHQ-9 in the DR, and the lack of research capacity to conduct a structured clinical diagnostic interview for sensitivity and specificity analyses, we really could not be sure if the recommended cut-point of scores of 5, 10, and 15 referring to mild, moderate, and severe depression were valid in the DR. Participants may have been enrolled who did not have depression. In fact, a recent study of primary care patients in Spain suggests that 12 is a more valid cut-point for diagnosing depression than the usually recommended cut-point of 10 (Munoz-Navarro, 2017). In conjunction with the medical provider at the site, we performed an extensive clinical interview with patients who indicated suicidal ideation or moderately severe to severe depression (scores of 15 and above). Nevertheless, this clinical interview did not meet the gold standard of a structured clinical diagnostic interview, and it is possible that

people with severe depression who should have been excluded from the study remained in the study. Lastly, in discussions with the co-investigators and medical providers, it was determined that the question regarding suicidal thoughts was not worded in the best manner to elicit an accurate response. Thus, the wording was subtly modified to add in a more culturally acceptable "Are there times when you feel tired of living? Do you feel that everything would be better if you were not living?" rather than "Do you have thoughts that you would be better off dead?"

Determinant 5. Resources for implementing research and delivering EBCM

A number of barriers were encountered that affected research implementation including lack of research capacity and lack of government prioritization of integrated behavioral health care.

Lack of research capacity. There are a limited number of mental health services researchers in the country. Most faculty with doctoral degrees are fully engaged in teaching and administration and most mental health professionals are not engaged in research. The lack of protected time for research that is characteristic of many institutions of higher education in the United States is even more pronounced in academia in LMICS. The IRB in our affiliated University was not fully functioning. Moreover, clinicians in LMICs are not trained in research, nor provided incentives to conduct research other than surveillance activities. Graduate students who were serving as Research Assistants had not had the opportunity to participate in clinical trials and had minimal training to conduct qualitative interviews, ensure fidelity to the intervention, and create plans for data management and analyses.

Mental health services infrastructure. Government clinics were selected based upon their participation in mhGAP, and thus, the providers in the primary care clinics selected for this study were familiar with depression screening instruments and evaluation of depression. However, due to limited resources, full implementation and outcomes evaluation of mhGAP had not been undertaken. Regular screening for depression was not occurring, and linkages for referrals to mental health providers had not been fully established at the onset of the program, but were developed as the program progressed.

Our third clinical site, the UNAP in Santo Domingo Este, represented the ideal structure for integrated behavioral health. All of the staff had had mhGAP training, rather than one or two physicians (as was the case in the previous sites), so although depression screening was not taking place, there was greater mental health literacy among the clinic staff. Nevertheless, the integration of EBCM into the daily work flow of the clinic would prove to

be difficult. As there was no routine screening process for mental health disorders, identifying those in need of interventions was based solely on clinical judgment and many patients had unaddressed mental health needs (according to the mental health providers). Moreover, in our meeting with clinical staff to establish a feasible workflow in terms of how patients using the MHapp could be monitored and who would be the best person to monitor the patients, the Medical Director volunteered that the CHWs had the most flexible schedules and could take on this task. However, our interviews with the staff presented a differing viewpoint. When asked if it would be possible to dedicate 20 minutes a day to reading and responding to patients within the app the CHWs had the following comments:

> "Bueno, yo no tengo tiempo. No se los demás" ("Well, I don't have time. I don't know about the rest") (CHW).
>
> And nurses also: "Yo salí desde las 7 de mañana de mi casa" (I leave from my house at 7:00 in the morning) (Nurse).
>
> "Yo creo que eso depende de la disponibilidad de cada persona" ("It depends on the availability of each person" (CHW).

Discussion and proposed solutions

Lessons learned from implementation of an MHapp in primary care in the DR are both positive and negative. The challenges encountered in these pilot studies can be viewed as evidence of failure or part of the incremental steps necessary to build future success. Corresponding to our determinants of practice outlined above: acceptance, appropriateness, engagement, work processes, and resources, we propose four key strategies to address the challenges to implementation of a technologically-based intervention in a middle-income country: 1) understanding of characteristics of end-users; 2) engagement of key stakeholders; 3) working within the existing infrastructure to increase capacity and ensure effective work processes; 4) addressing the social determinants of health; and 5) building upon strengths.

Understanding of characteristics of the end user

The lengthy process of app development can result in obsolescence of technological interventions before they are implemented in the real world setting. Therefore, understanding the end-user in terms of motivations, user characteristics and environment are critical. We utilized these principles to assess potential usability and acceptance and developed a greater appreciation of sociocultural differences in population health needs and mHealth usage. We also recognized the necessity of including service users

and caregivers in participatory research, planning, and policy making (Semrau et al., 2016).

One of the notable characteristics of the end user we encountered was the youthfulness of the primary care population and child-bearing population relative to that of the United States. The DR has one of the highest rates of adolescent pregnancy in the Caribbean and globally (Pantaleon, 2015). Adolescent mothers who are without resources and social support are at high risk for post-partum depression. MHapps that incorporate CBT methods are effective for this population (Kauer et al., 2012), and therefore, the age of eligibility for investigations of MHapps in countries with high rates of adolescent pregnancy should be lowered to include these potential participants.

Strategies to enhance retention and adherence. The issues we encountered in respect to retention and adherence are not unique to LMICs. In fact, studies conducted in HICs have shown a completion rate for internet treatment to be as low as 1% with an initial log-in rate of 10% (Christensen et al., 2009). The science of persuasive system design provides an evidence basis for elements of mHealth interventions that increase adherence (Kelders, Kok, Ossebaard, & Van Gemert-Pijnen, 2012). Persuasive technology includes both human-computer interactions and computer-mediated communication (Kelders et al., 2012). Elements of persuasive technology used to support behavior change can be grouped according to Primary Task Support, Dialogue Support (also referred to as Social Accountability), and Social Support (Mohr, Cuijpers, & Lehman, 2011). Primary Task Support includes reducing complex tasks into simplified behaviors and ensuring that participants are familiar with the language, concepts, and terms that are used in MHapps prior to deployment (Latif et al., 2017).

Consistent with the findings in our research, due to global migration and ethnic diversity, language diversity has been identified as a key barrier in the use of MHapps in LMICs (Brian & Ben-Zeev, 2014). There are many countries that use multiple languages in the same conversation which requires that the user interface be designed accordingly (Chiu, Dimaras, Downie, & Gallie, 2015). Alternatively, imagery and graphics can be used to remedy low-literacy and language barriers (Medhi, Prasad, & Toyama, 2007). Design recommendations to improve the usability for low-literacy populations and non-native speakers would include the provision of voice-based interfaces (e.g., spoken instructions and audio annotations), local language support, and the minimization of complex navigation and inputs (Medhi et al., 2011).

Our use of existing software, VoiceThread®, allowed us to fully utilize the ACTS model and develop and evaluate the design of the app without

Figure 5. Targeting to population.

concerns about the cost or time dedicated to modify an app specifically developed for this particular intervention. In our successive iterations of the design of EBCM, we employed another aspect of persuasive technology by targeting our messages and imagery to a Caribbean primary care population. Based on the characteristics of the sample ascertained in our first two clinics, we added animations that depicted younger women in domestic situations and service professions (see Figure 5). We also ascertained from feedback from participants that depression often manifests as anger, and can result in angry outbursts at children and loved ones. We utilized this feedback in the animations. However, when asked to react to the animations, many people judged the actions of the mother with depression harshly. Participants felt that the degree of anger at a child who had not done anything wrong was not normal. However, one person suggested that this was not necessarily a person with depression, because she sees this behavior all the time.

Social presence. Stand-alone apps for depression, anxiety, and other disorders are significantly more effective when used as guided self-help or monitored by a health-care professional, rather than when used independently (Cuijpers, Donker, van Straten, Li, & Andersson, 2010). A provider's recommendation to use an app enhances adherence to the app. Social presence or the sense that there is a human interaction within the app may help avoid the high drop-out rates in eMH research within the primary care setting (Anderson et al., 2016). Nevertheless, MHapps are not a substitute for the sustained, trusting, and ongoing relationship that a patient has with their provider, which in and of itself is therapeutic (Agius &

Stangeland, 2016). It is important that providers are aware of the effectiveness of the app and are part of an overall systematic plan to incorporate app usage into routine care. In our study, the absence of reinforcement of app usage by the primary care provider may have contributed to low retention rates. Additionally, our Research Assistant for the first sample was responsible for conducting the final interviews. She joined us after the study had commenced and had not participated in the earlier recruitment and data collection. Therefore, she had not had the opportunity to personally meet the participants. Her relative lack of social presence may have contributed to the difficulties we encountered in follow-up and responsiveness among the initial sample. In contrast, we saw the participants in the second sample on a daily basis and could trouble-shoot if they had not logged in and we set up the expectation that their feedback was important throughout our conversations.

Engagement of Key Stakeholders. Ensuring patient, provider, and staff understanding, and buy-in of the new innovation is likely to increase uptake (Hall, Fottrell, Wilkinson, & Byass, 2014; Semrau et al., 2016). Engaging key stakeholders in critical components of design features can aid in dissemination. Our decision to allow the staff in Sample 2 to experience the MHapp, gain comfort in its use, and ascertain their opinions as to the apps' clinical appropriateness facilitated buy-in and future deployment. A more challenging aspect of provider buy-in is the often tenuous alliance between researchers' objectives and the clinic's priorities. Our needs for data collection and exploration of clinic staff's potential role in the dissemination and use of the app exposed work-flow barriers to real-world implementation. Nevertheless, we also identified facilitators to implementation including the establishment of relationships with clinic staff and the provision of hands-on experiences with EBCM, the proposed intervention. We also clearly discovered the need to assess incentives for participation.

Realigned incentives. The reliance upon funding from HICs to fund research in LMICs is unavoidable and a necessary means to reduce global health care disparities (Bhutta, 2002). This unequal distribution of resources and power requires careful considerations of not only the ethical issues involved in the research, but an understanding of the perceptions of the collaborators and participants as to what constitutes equitable distribution of resources within the specific domains of the collaborators' role in the project. A social justice perspective would seek to mitigate power differentials and argue for shared decision-making and distribution of research funding based upon mutually agreed upon contributions to the research. A medical provider could be considered to be assisting in the research by screening and providing access to the participants, who are patients. Nevertheless, the ethical issue of coercion of participants comes into play if

the medical provider is receiving remuneration for recruitment of patients. Clearly, communication is crucial to ensuring that the research goals fit the priorities for the particular clinic, but more importantly that unspoken agendas and expectations are ascertained. A careful discussion of the medical providers' perceived role in the research, desired contribution to the research, expectations of direct financial gain, and a resolution of perceived inequities in the distribution of resources are essential components to ensure the projects' success. Situating the research within the existing infrastructure requires maximization of effective work processes.

Working within the existing infrastructure to increase capacity and ensure effective work processes. Infrastructure resources consist of the availability and quality of office rooms, telecommunications equipment, computers, and the associated primary care processes and referral systems, and access to consults and secondary and tertiary levels of care (Donker et al., 2013). Integrated behavioral health care is an essential primary care process to facilitate the implementation of eMH. Integrated health care may include stepped care models based upon symptom presentation and patient needs, decision support for providers, co-location of behavioral health and physical health treatment and at a minimum, integrated funding, and outcomes measurement (Hilty, Johnston, & McCarron, 2016). The use of mobile technology can enhance linkages between the health sector, community, the individual, or other institutions or resources, promoting the development of integrated primary care in LMICs. Integration eMH and MHapps may require modification of existing workflow to support the dissemination of the intervention. Task sharing can include non-mental health professionals delegated to the task of telephone or SMS monitoring of responses to treatment, which is a critical component to enhance treatment engagement and retention. To enhance sustainability, clearly defined roles for all members of the team, including a work-flow schema, are an essential aid to implementation (Mohr, Burns, Schueller, Clarke, & Klinkman, 2013).

Recommendations for consenting and baseline data collection. We developed a multi-step process of dissemination of the intervention to enhance feasibility in the primary care setting. This encompassed modifications to baseline data collection, down-loading the app, demonstrating use of the app and supplying internet access.

Creating a consent process that effectively conveys the purpose and participation requirements of a research study to low-literacy populations in a culturally-sensitive manner is extremely challenging in global health research (Igoumenidis & Zyga, 2011). At the time of this study, the standard IRB protocol required a consent to include a detailed description of the study including funding, recruitment processes, eligibility criteria, the

contents of instruments, rationale for asking for participation, risks, benefits, and contact information. Amerson and Strang (2015) suggest that this consent process may not be the best method to ensure understanding because participants may find the process boring and burdensome. Therefore, they recommend that only the essential and most relevant information be included. The revised Common Rule, which goes into effect January 2019, includes changes to the requirements for informed consent. These changes will streamline the informed consent process for primarily educational and non-pharmaceutical interventions.

A systematic and streamlined approach to data collection is essential to avoid drop-out at the pre-intervention stage of the study. Through trial and error, we developed a system for collecting baseline data and providing access to the app in the most efficient manner. We created a bilingual video of the protocol that could be disseminated to all research assistants to ensure fidelity to the intervention.

Eligible participants who consented to be in the study had baseline data collected using the Qualtrics data collection system (Qualtrics LLC, 2002). We chose Qualtrix because it is one of the few web-based survey systems that can also be used off-line, which is critical in LMICs. Participants were assigned a participant identifier (e.g., CBTVT18218) and a pre-made corresponding email (e.g., CBT-VT1_8.2.18@gmail.com); this step was necessary for the deidentification of the participants while still ensuring a way of monitoring participants throughout the duration of the intervention. This step also expedited the process for participants who did not have email access or did not remember their login credentials for the sign-up process. After assigning a participant number with corresponding email, participants received the intervention platform via wireless downloading through their phone's application marketplace (App Store or the Google Play Store). The application VoiceThread® was downloaded onto the smart phone device. Participants logged onto the application through a pre-made account set up by the investigators; the login credentials corresponded to the participant number and a generic password was created in advance for efficiency.

Ensuring confidentiality and privacy. Participants set up an online anonymous profile by accessing the "Profiles" and "Identities" tabs and changing the assigned name to a preferred pseudonym; this step allowed the participants to remain anonymous yet be able to exist as a user with a "name" on the application. The pseudonym was matched up confidentially to the participant number to monitor progress later in the intervention. The changes were saved and the participant was introduced to the features of the application.

Increasing research capacity. Capacity building for policy makers, service users, and researchers is one of the most critical aspects in strengthening mental health services. A needs assessment using a SWOT analysis

(identification of strengths, weakness, opportunities, and threats) (Semrau et al., 2018) can help define a systematic coordinated approach to capacity building. Moreover, research activities need to be supported and valued by institutions to avoid the "brain drain" and migration of experienced researchers to HICs (Evans-Lacko et al., 2016). Clinical providers and graduate students have limited experience in designing research, collecting data, and analyzing results (The Global Emergency Medicine Think Tank Clinical Research Working Group, 2017). These processes can be facilitated through the unique features of eMH which permit data collection through surveys, and/or in-app questionnaires as well as biometric monitoring for real-time results. WHO has a number of manuals that provide detailed information on processes such as "Monitoring and Evaluating Digital Health Interventions" (World Health Organization, 2016).

Enhancing research capacity requires a number of programmatic processes including training and mentorship for all levels of research experience, identifying leaders in capacity development, using multimodal communication strategies for distance learning and project implementation, and providing training in outcomes evaluation to clinical sites using a train-the-trainer approach for sustainability (Thornicroft, Cooper, Van Bortel, Kakuma, & Lund, 2012). The contents of trainings should be tailored to individual countries (Thornicroft et al., 2012). Most efforts to increase research capacity and strengthen provider knowledge of quality improvement strategies entail the provision of short courses and workshops. The Collaborative Institutional Training Initiative (CITI) in the ethical conduct of Human Subjects Research is free and can be offered as college level coursework in research or public health classes. For more advanced researchers, the United States National Institute of Health (NIH) offers a free in-depth course on how to conduct clinical research. The Introduction to the Principles and Practice of Clinical Research (IPPCR) focuses on biostatistical methods, study design, protocols, evaluation and quality assurance, and is appropriate for multidisciplinary health care professionals and researchers (NIH Clinical Center, 2018).

The social determinants of health as it pertains to eMH. The social determinants of health as it pertains to eMH comprise the environment or conditions that affect health outcomes and decision making tasks in the use of eMH (O'Connor & O'Donoghue, 2015). The influence of a country's context, contributions to health care, and income inequality have a major influence on the uptake and dissemination of mHealth interventions. For the effectiveness of mHealth, it is necessary to contextualize the sociocultural and health realities, as well as the availability and access to information and communication technology (ICT), requirements in infrastructure, financing, human resources, and the delimitation of ethical

principles and human rights in access to mental health care. The national health expenditure as a percent of GDP of 2.9 for the DR is one of the lowest in the region, and income inequalities are great (Moore, Carter, Nietert, & Stewart, 2011). Mental health is typically under-resourced in LMICS, and local or regional providers have little input into mental health services or policies which are allocated at a national level, often by administrators with limited knowledge of mental health systems (Alfonsson, Olsson, Linderman, Winnerhed, & Hursti, 2016).

We found that both providers and patients were keenly aware of the socioeconomic barriers to health and well-being. Nevertheless, it was often their conclusion that depression was solely a product of environmental stressors. The grinding poverty, experienced by undocumented immigrants from Venezuela, or young single mothers, rendered the CBT strategies of our MHapp an afterthought and almost irrelevant solution. Thus, it was important to facilitate provider communication around depression and mental illness using a language that resonated with both provider and patients.

Limitations. Our findings of a lack of feasibility may have been limited by extraneous barriers to the completion of our study that confounded our results. As mentioned above, our limited research capacity meant that none of the authors had protected time to conduct the research, and all had other full-time responsibilities. This affected the length of time dedicated to data collection, and follow-up. Moreover, the lack of substantial funding for the study limited our ability to hire research assistants for significant periods of time to collect data in our absence. Although, Moore et al. (Alfonsson et al., 2016) posit that inadequate funding can compromise a pilot study to such an extent that it should not be undertaken, this obfuscates the inherent biases and politics of funders in terms of who and what gets funded, and would eliminate potentially valuable insights gained by small-scale studies, as well as the opportunity to increase research capacity. While it is possible that increased time and money might have led to evidence of greater feasibility, we feel confident that most of the identified barriers to the conduct of the research would have still been present to some degree, as these barriers represent systemic infrastructure and institutional issues. An absence of institutional research infrastructures, including IRBs and limited trained research personnel, lack of standardized databases, and data collection methods have affected research output in LMICs (The Global Emergency Medicine Think Tank Clinical Research Working Group, 2017).

Conclusions

The feasibility of mHealth interventions is effected by the inherent challenges in the conduct of research studies in LMICs, including the failure to

recognize local customs and host country context and to adapt research procedures to these circumstances, while maintaining translational research rigor (Amerson & Strang, 2015). Although many of the issues we presented in this manuscript are unique to LMICs, translation of evidenced-based eMH interventions remains challenging even in HICs. The low effectiveness of mHealth interventions in the clinical setting can be attributed to the lack of validity of research methods that isolate intervention development from the real world setting, use an asynchronous approach to design, evaluation and implementation; and focus on the technology to the exclusion of considerations for supportive accountability and the necessity for human presence and support (Alfonsson et al., 2016; Hilty, Johnston, & McCarron, 2016). The methodology used in this study starts with implementation in the real world setting, and, based on participant or end-user feedback, iteratively continues to redesign and improve upon core features of the technology and the deployment environment. The critical issues of retention and adherence are problems encountered in well-funded, large scale trials in HICs (Eysenbach, 2005; Waller & Gilbody, 2009). For Mhapps targeted to populations with depression, adherence is compromised by the amotivational syndrome that is a characteristic of depression, irrespective of the nature of the intervention (Mohr et al., 2011). However, as seen in this study, the greatest barrier to eMH implementation is human factors, not technological ones (Luo, Hilty, Worley, & Yager, 2006). Although we encountered numerous challenges to our MHapp intervention, there were unanticipated benefits and a slow but steady march towards progress. We embarked on key processes identified in the literature (WHO, 2015) that laid the groundwork for incorporating cultural context in the intervention. We also developed strong collaborations which will enable us to sustain the intervention through the iterative process of refining our product and outcomes. We developed an ongoing and effective system of communication through WhatsApp, Free Conference Calls, and group meetings. Over time, we helped create liaisons between primary care providers and specialty mental health care which strengthened referral systems. Our coauthor recently completed a much needed epidemiological study of depression in primary care in the DR, and we have increased research capacity by training students in the Ethical Conduct of Research and offering hands-on experience in the conduct of research. At a national level, the country's health indicators are improving, the economy is rapidly growing, and extreme poverty is decreasing. Therefore, the climate is positive for eHealth growth. Although we reported on the difficulties of implementation of EBCM, there were also unforeseen successes that suggest that further development and implementation of MHapps is a worthwhile venture.

Disclosure statement

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