Original Research

Structured Caregiver Feedback Enhances Engagement and Impact of Mobile Health Support: A Randomized Trial in a Lower-Middle-Income Country

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Abstract

Background: *Patients' engagement in mobile health (m-health) interventions using interactive voice response (IVR) calls is less in low- and middle-income countries (LMICs) than in industrialized ones. We conducted a study to determine whether automated telephone feedback to informal caregivers ("CarePartners") increased engagement in m-health support among diabetes and hypertension patients in Bolivia.* ***Materials and Methods:*** *Patients with diabetes and/or hypertension were identified through ambulatory clinics affiliated with four hospitals. All patients enrolled with a CarePartner. Patients were randomized to weekly IVR calls including self-management questions and self-care education either alone ("standard m-health") or with automated feedback about health and self-care needs sent to their CarePartner after each IVR call ("m-health+CP").* ***Results:*** *The 72 participants included 39 with diabetes and 53 with hypertension, of whom 19 had ≤6 years of education. After 1,225 patient-weeks of attempted IVR assessments, the call completion rate was higher among patients randomized to m-health+CP compared with standard m-health (62.0% versus 44.9%;* $p < 0.047$*). CarePartner feedback more than tripled call completion rates among indigenous patients and patients with low literacy (*$p < 0.001$ *for both). M-health+CP patients were more likely to report excellent health via IVR (adjusted odds ratio [AOR] = 2.60; 95% confidence interval [CI], 1.07, 6.32) and less likely to report days in bed due to illness (AOR = 0.42; 95% CI, 0.19, 0.91).* ***Conclusions:*** *In this study we found that caregiver feedback increased engagement in m-health and may improve patients' health status relative to standard approaches. M-health+CP represents a scalable strategy for increasing the reach of self-management support in LMICs.*

Key words: *behavioral health, cardiology/cardiovascular disease, extreme environments, mobile health, telemedicine*

Introduction

Low- and middle-income countries (LMICs) bear a disproportionate burden of chronic illnesses, including diabetes and hypertension.[1–4] Health services for treating these dual epidemics in LMICs are often unavailable or of low quality.[5] Fifty-seven countries face a critical shortage of health professionals, with a global deficit of more than 4 million.[6] Mobile health (m-health) tools are part of a comprehensive plan to improve chronic illness care in LMICs.[7–9] Trials indicate that interactive voice response (IVR)-based interventions effectively address diabetes risk factors such as poor diet and sedentary behavior,[10–12] and IVR-supported nurse follow-up can improve glycemic control and self-care after diabetes is diagnosed.[12–14] In Honduras, weekly IVR self-management support calls were associated with improved diabetes self-management and A1c levels,[15] and in Honduras and Mexico, a similar IVR-based intervention resulted in better blood pressure control and improved self-care among hypertensive patients.[16]

BARRIERS TO INTERVENTION ENGAGEMENT AND SCALING

Although IVR call completion rates in the United States are typically greater than 85%,[17] patients with diabetes and hypertension in Latin America complete IVR calls at lower rates, especially when they are over 60 years of age.[18,19] Informal caregivers play a crucial role in supporting diabetes

self-management[20,21] and may increase engagement in m-health interventions. Some IVR-based programs in the United States allow patients to participate with an informal caregiver ("CarePartner") who receives automated feedback based on the patient's IVR assessments. Caregiver feedback has been associated with increased IVR engagement among patients with diabetes or depression[17,22] and may improve patients' health and self-care.[23–25] More generally, patients with an active and involved informal caregiver often have better self-management practices and health outcomes than patients who manage their chronic disease in isolation.[26–29] An observational study including Spanish-speaking patients from three countries suggests that caregiver feedback may increase patients' likelihood of completing IVR calls in LMICs.[18]

STUDY PURPOSE

Here, we present the results of a randomized trial designed to determine whether caregiver feedback improves m-health engagement and outcomes for patients with diabetes and/or hypertension in Bolivia. Our primary hypothesis was that providing information and suggestions about self-care assistance to informal caregivers would increase caregivers' involvement and, ultimately, patients' likelihood of IVR call completion. We also tested whether feedback was especially important among patients at highest risk for poor intervention engagement (i.e., patients who were older, identified with a socioeconomically vulnerable indigenous community, or had poor health literacy or medication adherence). Finally, we hypothesized that patients whose caregivers received feedback would report better perceived health and functioning during their IVR assessments.

Materials and Methods

RECRUITMENT

The study was approved by Human Subjects Committees at the University of Michigan and the Universidad Católica Boliviana. Both universities had faculty and students participating in the process of finalizing the study protocol and data collection. Most participants were initially identified as part of a 2013 survey of 1,144 patients in four primary care centers in La Paz and El Alto, Bolivia. The purpose of that survey was to gather information for developing an m-health self-management support system.[19] In 2014, we attempted to recontact survey participants and invited 74 with diabetes and/or hypertension to participate in the present study. We supplemented this sample by recruiting 34 additional diabetes and hypertension patients in 2014 from the same clinic waiting rooms.

All participants were asked to identify an adult family member or friend who would be willing to receive telephone updates with feedback and suggestions based on the patient's IVR calls (their "CarePartner," described below). Patients who identified a CarePartner ($n=72$) were assigned to groups

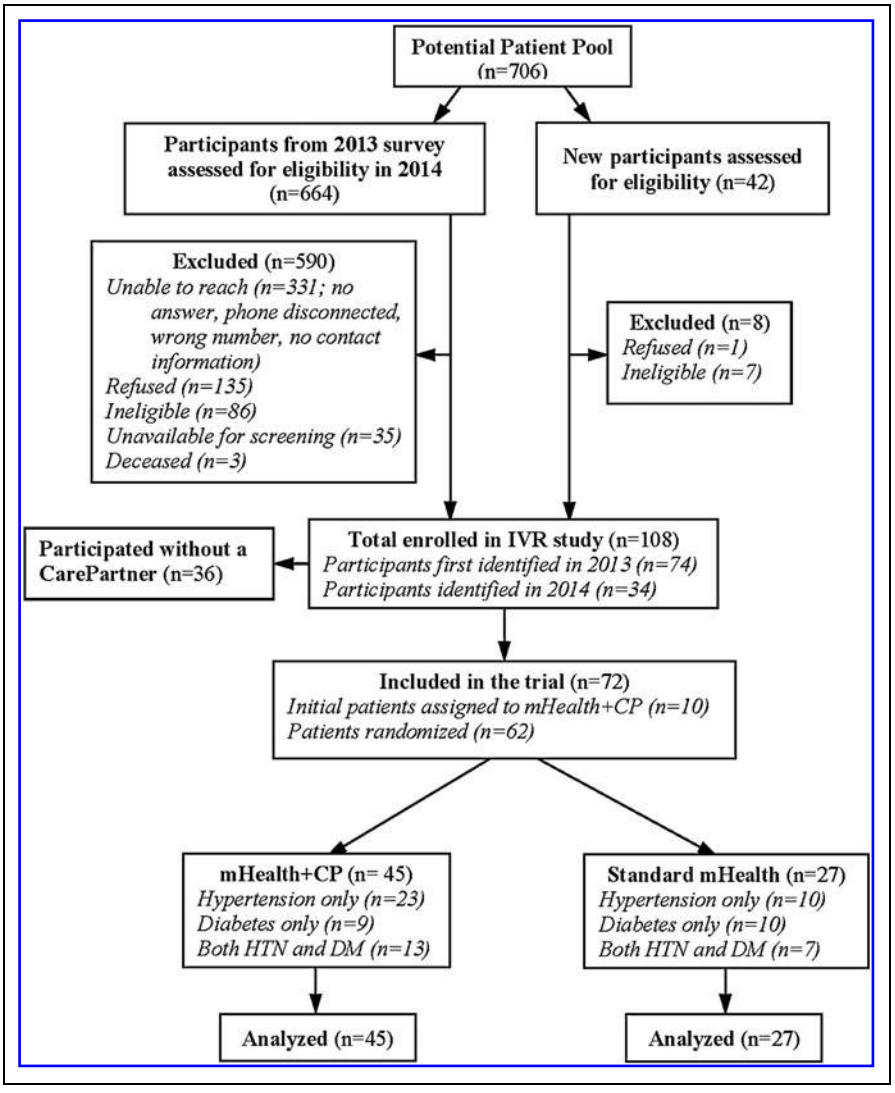

Fig. 1. CONSORT diagram for participants in the trial. DM, diabetes mellitus; HTN, hypertension; IVR, interactive voice response; mHealth, mobile health; mHealth+CP, mobile health+CarePartner.

receiving weekly IVR calls for up to 4 months, including self-management questions and tailored feedback either alone ("standard m-health") or with feedback sent to their CarePartner ("m-health+CP") (*Fig. 1*). All patients completed written informed consent. CarePartners provided verbal consent.

RANDOMIZATION

The first 10 eligible patients were assigned without randomization to m-health+CP in order to increase our capacity to rapidly ensure the proper functioning of the CarePartner feedback system. The remaining 62 patients were randomized with equal probability to both arms. Randomization was conducted using a random number generator after the patient and the CarePartner completed consent. There was no indication that the initial patients were different with respect to baseline characteristics than subsequent patients identified using the same process in the same sites; to maximize statistical power, those initial patients were included in analyses described below. Intervention effect estimates were at least as great when the initial 10 eligible patients were excluded in sensitivity analyses.

STANDARD M-HEALTH INTERVENTION

Patients received up to 4 months of weekly monitoring and self-management support calls at times they indicated were convenient, during which they responded to prerecorded questions using their touchtone keypad and received self-management education based on their responses. Calls originated from the IVR platform established at the Universidad Católica Boliviana in La Paz. Calls were made to the patient's mobile or landline telephone, with multiple call attempts. The IVR script followed a tree-structured algorithm and focused on symptoms, diet, medication use, and (for those using home physiologic monitors) glucose and blood pressure self-monitoring. Call content was specific to whether patients had diabetes versus hypertension; those with both conditions received both types of content in the same call. IVR scripts were developed in English with input from experts in diabetes and hypertension self-care and in primary care. Scripts were professionally translated into Spanish and reviewed by Bolivian health professionals and community members for cultural and linguistic appropriateness. Quality assurance testing was performed on IVR programming and Web site interfaces.[30]

Clinician notifications were issued when patients reported not taking medications as prescribed or (for those with home monitors) clinically worrisome values for home glucose readings or systolic blood pressures. Research staff triaged notifications via Web reports and e-mailed them to primary care teams. Research staff monitored patients' call completion via a secure Web site, and staff telephoned patients who did not complete their first call or missed three consecutive calls in order to troubleshoot and answer questions.

M-HEALTH+CP INTERVENTION

M-health+CP patients received identical IVR calls with clinician notifications as described above. In addition, their CarePartners automatically received IVR feedback summaries and suggestions for supporting the patient's self-care. Specifically, after each completed IVR call, the system sent a prerecorded call to the CarePartner's phone to update him or her about the patient's status, including guidance about how to support the patient's self-management. The notifications described in lay terms: (1) the health and self-care problems the patient reported; (2) why those problems increase the patient's risk for poor outcomes; and (3) what the CarePartner could do to assist his or her patient-partner. CarePartners were instructed to talk with their patient-partner once a week to review this information and address issues identified through the IVR calls. CarePartners also received an additional automated call if their patient-partner failed to complete an IVR call for 3 consecutive weeks, with a suggestion to contact the patient regarding his or her difficulty responding.

MEASUREMENTS

Baseline interviews. Patients completed baseline in-person interviews with bilingual research associates. Patients were classified as being of indigenous ethnicity if they reported speaking an indigenous language (either Aymara or Quechua) at home. Based on a widely used measure of functional health literacy,[31] patients were asked "How often do you have problems learning about your medical condition because of difficulty understanding written information?" Responses of "sometimes," "frequently," or "always" were classified as low literacy. Patients completed the eight-item Morisky Medication Adherence Scale and were coded as nonadherent if their score was above the recommended cutoff of 2.[32]

IVR-reported data. During each IVR assessment, patients reported their perceived health on the day of the call using a standard general health item[33]: "Thinking about your overall health, how are you feeling today (excellent, very good, good, fair, poor)?" Patients also were asked whether there were 1 or more days in the prior week in which they stayed in bed most of the time due to their health.

STATISTICAL ANALYSIS

We examined baseline differences by study arm in patients' sociodemographic and clinical characteristics. Next, we

examined patients' IVR call engagement using a dataset comprising one record for each week of attempted contact with an indicator for whether a call was successfully completed (yes versus no). We examined between-arm differences in call completion rates using a Pearson chi-squared test that took the panel-nature of the call-week data into account. Subsequent bivariate analyses examined variation in call completion rates across groups defined by patient characteristics that we hypothesized might modify the effect of caregiver feedback (i.e., patients' age, ethnicity [indigenous versus not], baseline medication adherence [low versus high], and health literacy [low versus other]).

We then fitted binomial logistic regression models to test the effect of study arm on call completion after adjusting for potential confounding by baseline imbalances across arms in gender, marital status, health literacy, and education. Analyses were based on the same call-week dataset described above, and the confidence interval (CI) for the effect of m-health+CP was adjusted for the clustering of call-weeks within patients. Subsequent logistic models included interaction terms for moderators identified in bivariate analyses. Specifically, each logistic multivariable model was fitted with the following: main effects for the m-health+CP arm and the potential moderator, an arm-by-moderator interaction term, and indicators for patients' gender, marital status, health literacy, and years of education.

Finally, we examined the effects of m-health+CP versus standard m-health on patients' likelihood of reporting excellent health and days in bed due to illness in the prior week. Multivariate analyses of these outcomes used the same analytic approach described above for call completion (logistic models with completed calls clustered within patients) and were adjusted for the patient's call completion rate, gender, marital status, health literacy, and education. Models also controlled for indigenous ethnicity because ethnicity was identified as a significant moderator of the effect of CarePartner feedback on patients' engagement with IVR calls.

Results

RECRUITMENT AND BASELINE CHARACTERISTICS

In total, 664 patients with chronic conditions were identified in 2013. Of these, 331 were unreachable in 2014, 135 refused participation in the follow-up survey, 86 were found to be ineligible for the IVR trial, and 38 patients were either unavailable for screening or deceased. The remaining 74 patients plus an additional 34 new patients were screened and enrolled in studies of the IVR system in 2014. Of those, 72 patients identified a CarePartner and were included in the trial (*Fig. 1*).

Table 1. Baseline Characteristics of the Sample

CHARACTERISTIC	TOTAL	M-HEALTH+CP	STANDARD M-HEALTH	*P* VALUE
All patients (*n*)	72	45	27	
Call weeks (*n*)	1,225	762	463	
Female	62.5 (45)	73.3 (33)	44.4 (12)	0.021
Age 60+ years	62.5 (45)	62.2 (28)	63.0 (17)	0.859
Married	56.9 (41)	46.7 (21)	74.0 (20)	0.017
Indigenous	29.2 (21)	31.1 (14)	25.9 (7)	0.575
Education (0–6 years)	26.4 (19)	20.0 (9)	37.0 (10)	0.137
Low FHL	37.5 (27)	44.4 (20)	25.9 (7)	0.094
Hypertension	73.6 (53)	80.0 (36)	63.0 (17)	0.137
Diabetes	55.6 (40)	48.9 (22)	66.7 (18)	0.199
CVD	31.9 (23)	31.1 (14)	28.0 (9)	0.926
Fair/poor health	59.7 (43)	57.8 (26)	63.0 (17)	0.581
Low adherence	51.4 (37)	53.3 (24)	48.1 (13)	0.566

Cell entries are column percentage (*n*).

CVD, cardiovascular disease; FHL, functional health literacy; m-health, mobile health; m-health+CP, mobile health + CarePartner.

Among the patients included in these analyses, 62.5% were women, 62.5% were 60 years of age or older, and 56.9% were in a committed relationship (*Table 1*). In total, 29.2% reported speaking an indigenous language at home. Twenty-six percent reported primary school education (6 years) or less, and 37.5% had poor health literacy. In total, 26.4% had diabetes only, 27.8% had diabetes and hypertension, and 45.8% had hypertension only. Most patients (59.7%) reported fair or poor perceived health at baseline, and 51.4% were classified as nonadherent to their diabetes and/or hypertension medication based on the Morisky scale. Roughly two-thirds of CarePartners (65.8%) were women, and 66.9% had at least 12 years of education. CarePartners were on average 42.2 years of age (standard deviation = 14.9); most (65.3%) were adult children, 20.8% were spouses, and the remainder were friends, siblings, or other social network members.

Randomization groups were similar on baseline variables, with a few exceptions (*Table 1*). Significantly more patients in the m-health+CP arm were women (73.3% versus 44.4%; $p = 0.021$), and fewer were in a committed relationship (46.7% versus 74.1%; $p = 0.017$). Although somewhat more m-health+CP patients reported low health literacy (44.4% versus 25.9%; $p = 0.094$), fewer m-health+CP patients than

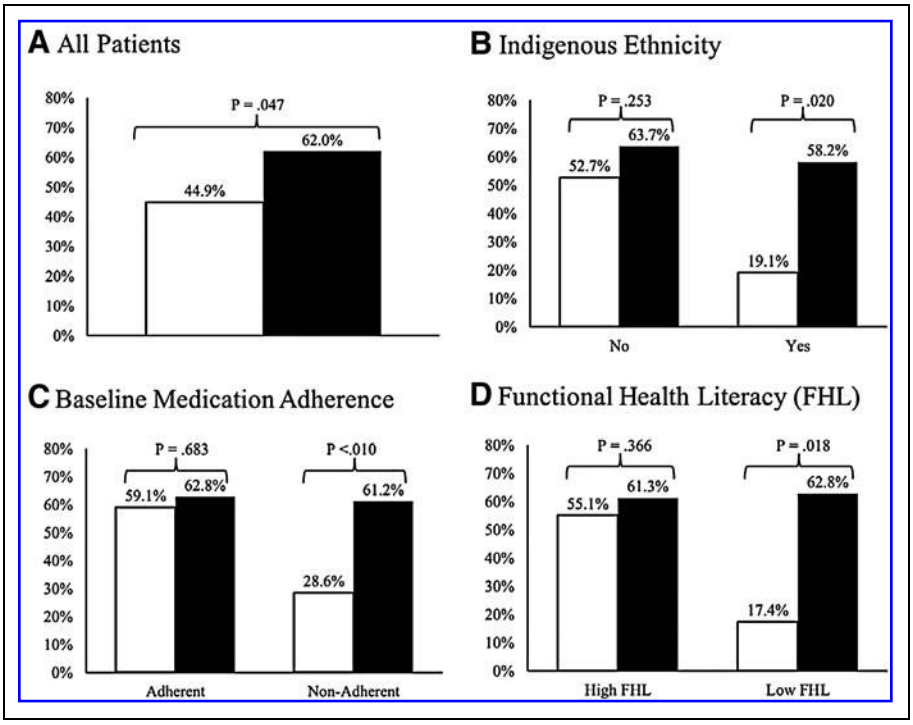

Fig. 2. (A–D) Unadjusted comparisons of interactive voice response call completion rates among patients randomized to standard mobile health without caregiver feedback (white bars) or mobile health with caregiver feedback (black bars).

standard m-health patients reported 6 or fewer years of education (20.0% versus 37.0%; $p = 0.137$). As noted above, multivariable analyses of call completion rates and patients' IVR-reported health status controlled for each of these covariates.

DIFFERENCES BY ARM IN PATIENTS' IVR CALL ENGAGEMENT

Participants were followed up for a total of 1,225 patient-weeks, during which patients completed calls in 53.7% of attempted call-weeks. Bivariate analyses indicated that m-health+CP patients completed significantly more IVR calls than standard m-health patients (62.0% versus 44.9%; $p < 0.047$) (*Fig. 2*).

Neither bivariate nor multivariable analyses suggested that the effect of CarePartner feedback varied according to the age of the patient participant (data not shown). However, analyses of other sociodemographic risk factors suggested that the incremental improvement in IVR engagement was most pronounced within subgroups of patients with the greatest need for self-management assistance (*Fig. 2*). Participants who spoke indigenous languages at home were more than three times as likely to complete IVR calls if randomized to m-health+CP (58.2% versus 19.1%; $p < 0.020$). Bivariate analyses also suggested that m-health+CP improved call completion by at least twofold among patients reporting poor medication adherence at baseline and threefold among those with low health literacy ($p < 0.05$ for both).

In multivariable analysis adjusted for patient gender, marital status, health literacy, and education, the odds of call completion were more than doubled in the m-health+CP arm compared with standard m-health (*Table 2*) (adjusted odds ratio [AOR] = 2.21; 95% CI, 1.12, 4.39, $p = 0.023$). Models examining interactions between randomization group and indigenous ethnicity, medication adherence, and health literacy (and controlling for baseline differences in potential confounders) each identified significant arm-by-moderator interactions ($p < 0.05$ for all comparisons).

DIFFERENCES ACROSS ARMS IN IVR-REPORTED HEALTH STATUS

In unadjusted analyses, m-health+CP patients were more than twice as likely as standard m-health patients to report excellent health during their calls (26.1% versus 12.4%; $p = 0.011$) (*Table 3*). After multivariable adjustment, m-health+CP patients continued to be significantly more likely than standard m-health patients to report excellent health during their IVR calls (AOR = 2.60; 95% CI, 1.07, 6.32). Multivariable analysis also revealed a significant relationship favoring m-health+CP with respect to patients' likelihood of staying in bed all or most of the day during the prior week due to illness (AOR = 0.42; 95% CI, 0.19, 0.91).

Discussion

We found that providing feedback to an informal caregiver substantially increased patients' engagement in this m-health self-care support intervention. This finding is important given the relatively low IVR engagement rates among patients in LMICs relative to patients in the United States and the importance of caregivers in supporting chronic illness self-care.

Given the significantly lower rates of IVR call completion among older adults in studies conducted in three Latin American countries,[15,18,19] we hypothesized that intervention effects would be more pronounced among patients older than 60 years of age. That hypothesis was not supported by the data. However, findings regarding variation in intervention

Table 2. Logistic Regression Models Predicting Weekly Call Completion

	MODEL 1	MODEL 2	MODEL 3	MODEL 4
M-health+CP				
Main effect	2.21[a]	0.95	0.74	0.83
95% CI	1.12, 4.39	0.36, 2.51	0.30, 1.85	0.43, 1.62
Indigenous ethnicity[b]				
Main effect		0.26[c]		
95% CI		0.10, 0.70		
Interaction with m-health+CP		5.87[c]		
95% CI		1.54, 22.35		
Low baseline adherence[b]				
Main effect			0.27[d]	
95% CI			0.10, 0.72	
Interaction with m-health+CP			5.05[a]	
95% CI			1.44, 17.64	
Low health literacy[d]				
Main effect				0.16[a]
95% CI				0.03, 0.96
Interaction with m-health+CP				10.48[a]
95% CI				1.51, 72.62

Main effects are adjusted odds ratios. Confidence intervals (CIs) were adjusted for the clustering of calls within patients.

[a]$p < 0.05$, [c]$p < 0.01$.

[b]Model included as additional covariates patient gender, marital status, health literacy, and years of education.

[d]Model included as additional covariates patient gender, marital status, and years of education.

m-health, mobile health; m-health+CP, mobile health + CarePartner.

Table 3. Intervention Effects on Patient Health and Self-Care Reports via Interactive Voice Response Assessments

	PATIENTS ($N = 72$)	
	EXCELLENT HEALTH (YES VERSUS NO)	DAYS IN BED (YES VERSUS NO)
Unadjusted percentage		
M-health+CP	26.1	23.2
Standard m-health	12.4	24.0
p value	0.011	0.920
Adjusted effect		
AOR	2.60	0.42
95% CI	1.07 6.32	0.19, 0.91
p value	0.034	0.029

Models controlled for the patient's number of completed interactive voice response assessments, potential baseline differences across groups (patient gender, marital status, health literacy, and years of education), and baseline characteristics associated with intervention effects on intervention completion rates (i.e., indigenous ethnicity, baseline medication adherence, and functional health literacy). Confidence intervals (CI) were adjusted for the clustering of assessments by patient.

AOR, adjusted odds ratios comparing mobile health + CarePartner (m-health+CP) with standard mobile health (m-health).

effects shown in *Table 2* and *Figure 2* suggest that caregiver feedback increased engagement most significantly among patients who are socioeconomically vulnerable. In particular, these results suggest that patients from indigenous communities in Latin America can benefit from participating in m-health services with an informal caregiver. This is important because indigenous patients experience poverty, limited healthcare access, discrimination, and substandard quality of care.[34]

M-health+CP patients reported better health status during IVR calls than standard m-health patients, even after adjusting for patients' IVR call completion rates, sociodemographic characteristics, and risk factors for health and self-care problems. These findings are consistent with results from U.S. studies, including nonrandomized studies of a similar intervention conducted with diabetes and depression patients and a recently completed randomized trial in which CarePartner feedback was associated with decreased problem reports among patients with heart failure.[23–25]

To our knowledge, this is the first binational collaborative trial to provide evidence that feedback to informal caregivers may significantly improve LMIC patients' engagement in m-health interventions. However, one major limitation is that our reliance on self-reported outcomes could have biased the results. For example, patients in the m-health+CP arm might have under-reported their difficulties in health and self-care to avoid burdening their CarePartner. It will be important to confirm these findings based on future studies with physiologic end points, such as A1c or blood pressures. Moreover, the overall sample as well as the subset of patients from indigenous communities may not be entirely representative of patients with chronic diseases in the Andean Region. Indeed, give the diversity of cultures in LMICs, it is difficult to imagine

what individual study could really be "representative" of that diversity; additional research and continual program tailoring will likely to be needed to ensure that interventions are sensitive to the evolving cultural and practical needs of communities around the globe.

Despite the substantial intervention effects on patients' IVR engagement, overall rates of completing IVR calls were still modest in comparison with rates reported in U.S. studies. More research is needed to determine what dose of m-health intervention is necessary and sufficient to improve patients' outcomes, as well as how services like this one can be optimized to reach those targets. Limited cultural adaptation of the IVR call content may have reduced the intervention's effectiveness. Follow-up in the current study was relatively brief, and the sample of participants was relatively small.

Interventions such as this one that benefit from involving family caregivers will have greater reach in collectivist cultures with a strong value placed on family networks. Latino and indigenous cultures tend to value family and informal support (*familismo*) more than "modern/Western" societies, so interventions that involve family caregivers may be particularly culturally relevant.[35] However, not all patients will have a willing and available caregiver, particularly if they are unmarried or socially isolated. In the current study, 75% of patients who were approached about participating in the IVR monitoring and self-care support pilot study chose to participate with a CarePartner (i.e., 108/144) (*Fig. 1*). This likely represents a lower bound on the proportion of otherwise-eligible patients who could include a loved one because the option was presented in a neutral way and no additional efforts were made to recruit CarePartners after patients' first day of contact.

In summary, this is the first randomized study to provide evidence that automated feedback to informal caregivers can significantly increase engagement in IVR interventions among patients in LMICs, and results were particularly encouraging among participants at greatest risk for poor self-care and health outcomes. The study also provides evidence that caregiver feedback can improve chronically ill patients' perceptions of their health status and functioning. Future studies with larger samples and objective outcomes are needed to confirm and extend the present findings.

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Disclosure Statement

No competing financial interests exist.

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