ORIGINAL RESEARCH

Using mHealth Tools to Improve Access and Coverage of People With Public Health Insurance and High Cardiovascular Disease Risk in Argentina: A Pragmatic Cluster Randomized Trial

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Background—Control of cardiovascular disease (CVD) risk factors is suboptimal in Argentina, despite the government's provision of free blood pressure and cholesterol-lowering medications for people without private insurance. We assessed whether community health workers' use of an integrated mHealth tool encourages patients to attend visits at primary care clinics to improve CVD risk management in 2 provinces of Argentina.

Methods and Results—We conducted a pragmatic cluster randomized trial, with primary care clinics randomly assigned to intervention or control. Eligible people were aged 40 to 79 years, lived in the catchment area of primary care clinics, possessed a mobile phone for personal use, had public health coverage, and a 10-year CVD risk ≥10%. In the control arm, community health workers screened for CVD risk using a paper-based tool and encouraged high-risk people to present to the primary care clinics for care. In the intervention arm, community health workers used the mHealth tool to calculate CVD risk and confirm a scheduled physician appointment. Primary outcomes were the proportion of participants who attended a baseline visit and completed at least 1 follow-up, respectively. We enrolled 755 people (376 interventions; 379 controls). Intervention participants were significantly more likely to complete baseline visits (49.4% versus 13.5%, *P* value 0.0008) and follow-up visits (31.9% versus 7.7%; *P* value 0.0041). The use of chronic medication and current smoking were significant predictors of primary outcomes.

Conclusions—Use of mHealth tools identifies patients at high CVD risk in their home, increases the likelihood of participating in chronic CVD risk factor management, and strengthens referrals.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT02913339. **(*J Am Heart Assoc*. 2019;8: e011799. DOI: 10.1161/JAHA.118.011799.)**

Key Words: Argentina • cardiovascular • mHealth • prevention • screening

Cardiovascular diseases (CVDs) are one of the leading causes of morbidity, mortality, and disability in low- and middle-income countries, including Argentina where the CVD burden and risk factors continues to rise.[1,2] The high disease burden highlights the need for effective and affordable interventions.[3] Evidence-based clinical practice guidelines recommend identifying and managing individuals at high CVD risk by using a combined strategy of lifestyle modification and appropriate medication for CVD prevention and control.[4] However, like other low- and middle-income countries, Argentina's challenges to improve the detection and management of CVD include low rates of awareness, shortages of trained healthcare workers for noncommunicable diseases, overcrowded primary care centers (PCCs), and overall lack of resources in the healthcare system.[5]

In response to the 2001 economic depression, the REMEDIAR and REDES Programs, now under the Plan for Universal Health Care (Cobertura Universal de la Salud) were funded by the Argentina Ministry of Health to provide free medications and health care to low-income, uninsured patients.[6,7] These programs have evolved to become the main public primary healthcare network in Argentina, covering

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Accompanying Table S1 and Figures S1, S2 are available at https://www.ahajournals.org/doi/suppl/10.1161/JAHA.118.011799

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Received December 14, 2018; accepted February 15, 2019.

Clinical Perspective

What Is New?

- In the intervention arm, we trained community health workers to use mHealth tools to first screen for cardiovascular disease risk in the participants' homes and to immediately schedule appointments for high-risk patients, by accessing electronic appointment calendars at the local primary care clinic using a secure Wi-Fi connection.
- When community health workers scheduled first appointments for high-risk patients to be assessed by a physician at the primary care clinic, significantly more patients attended their appointments (49.4%), compared with counterparts in the control arm who were advised to schedule appointments on their own (13.5%), consistent with usual care practice.

What Are the Clinical Implications?

- Control of cardiovascular disease risk factors in Argentina remains poor, despite the provision of free primary healthcare services provided to people without private insurance in a national government network of primary care clinics.
- Early detection of those at high risk for cardiovascular disease can lead to improved management and outcomes for cardiovascular disease.
- Given the shortage of formally trained health professionals such as physicians and nurses in this setting, training community health workers to use mHealth tools for screening and referral to local primary care clinics can lead to greater numbers of high-risk people being detected and having their condition appropriately managed.

almost all provinces and municipalities with almost 7000 centers for primary health care across the country (>90% of all public clinics).

Strategies to overcome an overburdened healthcare system include task shifting from formally trained healthcare professionals to lay health workers and support of appropriate information technology. Current evidence shows that CVD screening can be shifted effectively from formally trained health professionals to community health workers (CHWs) using a validated, low-cost, nonlaboratory-based screening tool.[8,9] Using a mobile phone app version of this screening reduces the time required and improves the cost-effectiveness of the intervention.[10,11]

To improve follow-up and management of CVD, people identified as high-risk need to have regular visits with physicians based on clinical treatment guidelines. The lack of an automated appointment scheduling system in PCCs in Argentina leads to these people being lost in the healthcare system, missing appointments, and even missing several months of care and treatment. The adoption of web-based scheduling appointment systems serve many purposes critical to managing chronic disease patients: managing clinic workload; rapidly identifying those who miss appointments in order to initiate patient follow-up; improving patient satisfaction because of reduced waiting time; and monitoring the percentage of patients who attend the clinics in a timely manner.[12]

High penetration of cell phones in 2018 (>130 per 100 inhabitants) in resource-poor settings of Argentina offers an opportunity to improve CVD prevention and control using mHealth technology.[13,14] Limited studies show that mHealth interventions possess a modest positive effect on process of care and clinical outcomes in chronic diseases in low- and middle-income countries.[15] In addition, the inclusion of reminder systems through text messages improves appointment attendance across a range of settings and patient populations.[16]

This study developed an mHealth tool (the app) that combined an automated CVD risk calculator, integrated to an electronic appointment scheduling system accessed via secure Wi-Fi or through mobile internet, and text messaging. We hypothesized that the use of mHealth tools by CHWs would improve the detection, referral, and management of people with moderate-to-high CVD risk living in the catchment area of PCCs in poor urban settings.

Many steps are necessary to improve risk factor control: including identification of patients through screening, referral to appropriate PCCs, and initiation and compliance with effective treatment. This study, funded by the National Institutes of Health's R-21 mechanism for Pilot studies in mHealth, addresses the first 2 of these steps. The primary aims of the study were to evaluate whether the use of the mHealth tools by CHWs led to appropriate identification of people with moderate and high CVD risk, and scheduling and attendance of subsequent referral visits for physician evaluation at PCCs. Secondary aims include measures of effective management of CVD risk within the primary care system in poor urban settings in Argentina.

Methods

Because of the sensitive nature of the data collected for this study, requests to access the data set from qualified researchers trained in human subject confidentiality protocols may be sent to the corresponding author.

Study Design

This was a pragmatic cluster randomized trial involving 8 PCCs within a national public health system (REMEDIAR and REDES Program) in Argentina. Details of the trial's design and analysis plan have been published elsewhere.[17]

Study Sites

Corrientes city and Almirante Brown are located in the northeast and center of the country. Corrientes has 352 646 inhabitants, most living in urban areas. It is one of the provinces with the highest percentage of unmet basic needs (15.1%) in Argentina. Furthermore, 39.5% of the population is living in poverty and 48% have no health insurance.[18,19] Almirante Brown is a district in the Province of Buenos Aires with a population of 555 731 inhabitants, most of them living in urban areas and 34.6% of the population is impoverished. Thirty-eight percent have no health coverage and 10.4% have unmet basic needs.[18,19] These 2 provinces are geographically situated ≈1000 km apart and have 64 public PCCs affiliated with the REMEDIAR and REDES Program: 30 in the district of Almirante Brown, located in the province of Buenos Aires and 34 in the city of Corrientes, province of Corrientes.

Clusters Definition, Randomization, and Masking

We defined as a cluster a public PCC affiliated with the REMEDIAR and REDES Program, located in poor urban areas and employing CHWs in addition to physicians and nurses. PCCs typically serve a population of 10 000 to 20 000 people in their catchment area.

Eight of the 24 eligible PCCs were selected for inclusion in the trial: 4 each (2 interventions; 2 controls) in Almirante Brown and Corrientes, respectively. Clusters were assigned (1:1) to either the intervention or control groups. To ensure reasonable balance between the 2 arms in both provinces, we used stratified, restricted randomization to allocate clusters. The strata were defined on the basis of the province where PCCs were located.

Cluster randomization was conducted at the data coordinating center at the Center for Health Decision Science at the Harvard T.H. Chan School of Public Health. The 8 PCCs were randomly assigned to the intervention or control (usual care) arm using the RAND function in Excel Pro Plus 2010 (Microsoft, Redmond, WA). Study administrative staff, healthcare professionals, CHWs, and participants were not blinded to the intervention assignment.

Study Participants

We included people aged 40 to 79 years who (1) resided in the catchment area of the participating PCCs, (2) owned a mobile phone for personal use, (3) had public health coverage, (4) had a 10-year CVD risk ≥10%, and (5) consented to participate in the study. Ineligible participants were those who were pregnant, bedbound, illiterate, unable to give informed consent, and planning to move away from the vicinity of the clinic in the following year. CHWs conducted home visits to assess eligibility and enroll participants in both the intervention and control arms between August 2016 and July 2017.

The institutional review boards of Partners Human Research Committee/Brigham and Women's Hospital and Hospital Italiano de Buenos Aires in Argentina approved the study. Written informed consent was obtained by all eligible participants who accepted participating in the study during screening activities conducted by CHWs.

Intervention Procedures

The intervention was multicomponent and its components pertained to the cluster and to the participants' level. At the cluster level it included an mHealth app to be used by CHWs to calculate CVD risk and schedule appointments at the PCC (Figure S1), a training session for the CHWs at the beginning of the intervention to use the app, a web-based clinical appointment system installed in PCCs, and training of the administrative staff of the PCC to use the system. At a participants' level, participants received SMS with reminders and educational messages.

Details of the mHealth app and of the web-based scheduling system were described and published elsewhere. Eight CHWs, 2 in each PCCs, were trained during a 1-day interactive workshop that focused on (1) improving knowledge and skills related to CVD and its risk factors; (2) blood pressure measurement; (3) using the mobile app to calculate CVD risk; and (4) scheduling an appointment at the clinic using a web-based electronic scheduling system via Wi-Fi or through a mobile internet connection.

As with the control arm, CHWs training sessions were followed by field observation during a 2-week run-in period before enrollment. CHWs were certified based on their proficiency using the mobile app to classify people with moderate and high CVD risk and to schedule appointments.

Administrative staff at the PCCs were also trained to use the electronic scheduling system to schedule appointments with healthcare professionals, monitor scheduled appointments, and manage providers' schedules.

The Intervention

CHWs conducted home visits in the catchment area of the PCC to identify people with moderate or high risk of CVD (Figure 1). If a participant with a CVD risk ≥10% was identified using the automated risk calculator, s/he scheduled an appointment right away by accessing the PCC's electronic scheduling system via mobile internet and selecting an available appointment slot with a primary care physician. The centralized database generated a confirmatory SMS that was sent within 5 minutes of the appointment being scheduled and listed the name of the physician, clinic, day, and

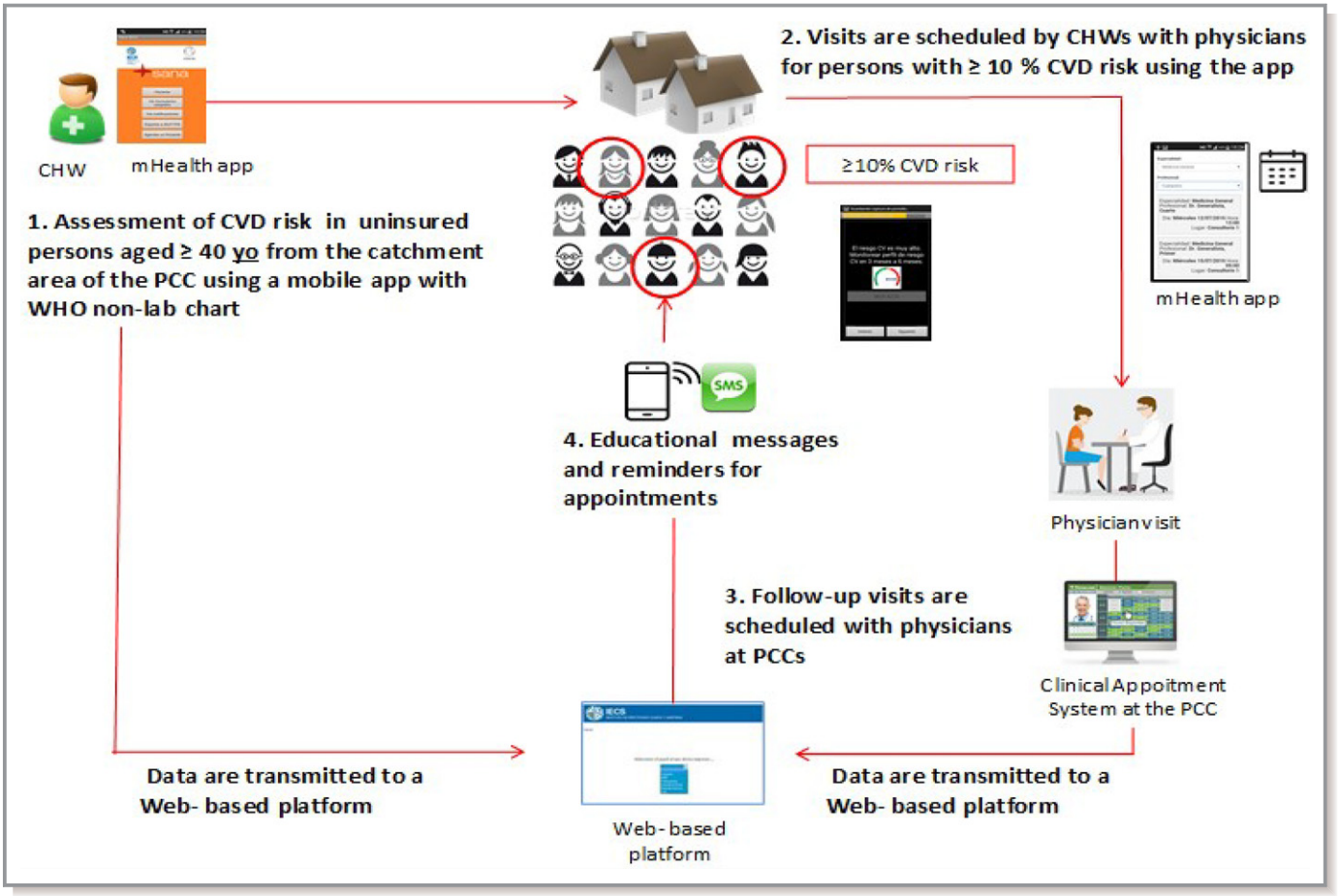

Figure 1. Process flow in the intervention arm. CHW indicates community health worker; CVD, cardiovascular disease; PCC, primary care center; WHO, World Health Organization.

time. An additional reminder was also sent to the participant 24 hours before the scheduled appointment. Participants also received educational weekly 1-way short text messages to promote follow-up and continuity with treatment during the 6-month follow-up period. All educational messages were created using content that was previously validated in this population for cultural appropriateness.[20] Individualized text messages were sent out to participants' mobile phones by a web-based platform located at the Institute for Clinical Effectiveness and Health Policy in Buenos Aires, Argentina.

Control Procedures

In the PCCs randomized to the control group, 8 CHWs, 2 per clinic were trained during a 1-day interactive workshop that focused on (1) improving knowledge and skills related to CVD and risk factors; (2) blood pressure measurement; (3) using the paper-based World Health Organization charts to calculate CVD risk; and (4) verbally encouraging participants with a 10-year CVD risk ≥10% to schedule an appointment at the PCC (Figure S2). Training sessions were followed by field observation during a 2-week run-in period before enrollment. CHWs were certified based on their proficiency using the World Health Organization chart to classify participants with high cardiovascular risk in the community. CHWs conducted home visits to identify participants with moderate or high CVD risk using the paper-based charts and if classified with a 10-year CVD risk ≥10%, participants were encouraged to go to the clinic and were scheduled an appointment at the clinic using a paper-based scheduling system.

Data Collection

We used data from 2 sources to determine outcomes: case report forms and medical records at PCCs. Case report forms were completed by CHWs at baseline and provided information about the participants' characteristics: age, sex, chronic diseases, history of CVD, and currently used chronic medications. In addition, 3 blood pressure measurements were obtained by CHWs at the baseline data collection visit

according to a standard protocol recommended by the American Heart Association, and the mean of all the measurements was used to calculate CVD risk.[21]

Trained researchers reviewed medical records and chronic prescription refills of study participants and primary data were collected by using a structured record review checklist to assess the study outcomes.

Prescriptions of the included participants were collected over a period of 6 months from the REMEDIAR pharmacies located at PCCs and were analyzed for use of chronic medication (antihypertensive medication, antidiabetic medication, and statins) (Table S1).

Outcomes

Primary outcomes were (1) proportion of participants classified as having a 10-year CVD risk ≥10% who successfully completed the baseline (first) visit to a PCC out of all those classified as having CVD risk >10% within 6 weeks after being screened by a CHW during a home visit, and (2) proportion of these participants who had successfully completed at least 1 follow-up visit after the baseline visit to a PCC within 4 months of the CHW screening.

Secondary outcomes include the proportion of these participants who were on appropriate medications for their respective chronic conditions (antihypertensive medication if systolic blood pressure ≥140 mm Hg, or statins if CVD risk ≥20% and antidiabetic medication if self-reported diabetes mellitus) (Table S1), clinical attendance (defined as participants who attended at least 1 clinical appointment during the study period), and the mean number of visits to the PCCs during the study period.

Statistical Analysis

The trial was designed to provide 80% of statistical power to detect a 40% or more relative increase in the proportion of participants with CVD risk ≥10% who completed a first visit at the PCCs and a 60% relative increase in the proportion of these participants who completed a follow-up visit at the clinic within 4 months of the baseline (α=0.05 for a 2-tailed test). Eight clinics (4 in each arm) with an average cluster size of 84 participants with CVD risk ≥10%, a 10% loss to follow-up or poor data quality, and an intracluster correlation coefficient (ICC) of 0.01 were assumed. The required sample size calculated was 740 people (92 per clinic).

All statistical analyses were based on the intention-to-treat principle. Baseline characteristics of patients between the intervention and control group were compared adjusting for cluster effects. Generalized estimating equations regression models were used to evaluate the effect of the intervention on primary and secondary outcomes. For the binary response data, we used the binomial distribution for the variance function, and the logit link function and cluster effects were accounted for by assuming an exchangeable working correlation structure. For the model about mean number of visits, we used the Poisson distribution for the variance function and the log link function, with the exchangeable working correlation structure.

Additional subgroup analyses by region and sex were specified a posteriori to examine differences. Results are presented as estimated proportions, adjusted estimated proportions by significant baseline difference, and net differences.

Finally, multivariate generalized estimating equations logistic regression analyses were performed to examine the relationship between relevant patient characteristics and the 2 primary outcomes. The independent variables considered (group, region, age, sex, education level, current smoking, use of chronic medication, and history of major CVD) were entered simultaneously to the logistic regression analysis as covariates. Adjusted odds ratios were obtained.

All the analysis was conducted using SAS version 9.3 (SAS Institute Inc, Cary, NC).

Independent Data Access and Analysis

The corresponding author had full access to all the data in the study, takes responsibility for its integrity and the data analysis, and had final responsibility for the decision to submit for publication. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Results

From August 2016 to July 2017, 990 people living in the catchment area within the selected PCCs were screened, and 755 met eligibility criteria and were enrolled (Figure 2). The mean age of participants with a 10-year CVD risk ≥10% was 54±8 years and 68.6% (518) were women. Baseline characteristics of participants with CVD risk ≥10% were balanced between intervention and control groups (Table 1). Although the intervention group had a slightly lower proportion of individuals with a self-reported history of hypercholesterolemia and a higher proportion of patients who reported use of antihypertensive medication, differences observed were not statistically different among the intervention and control groups.

Primary Outcomes and Secondary Outcomes

In the intervention arm, 49.4% of the participants who were found to have a moderate or high risk of CVD completed a

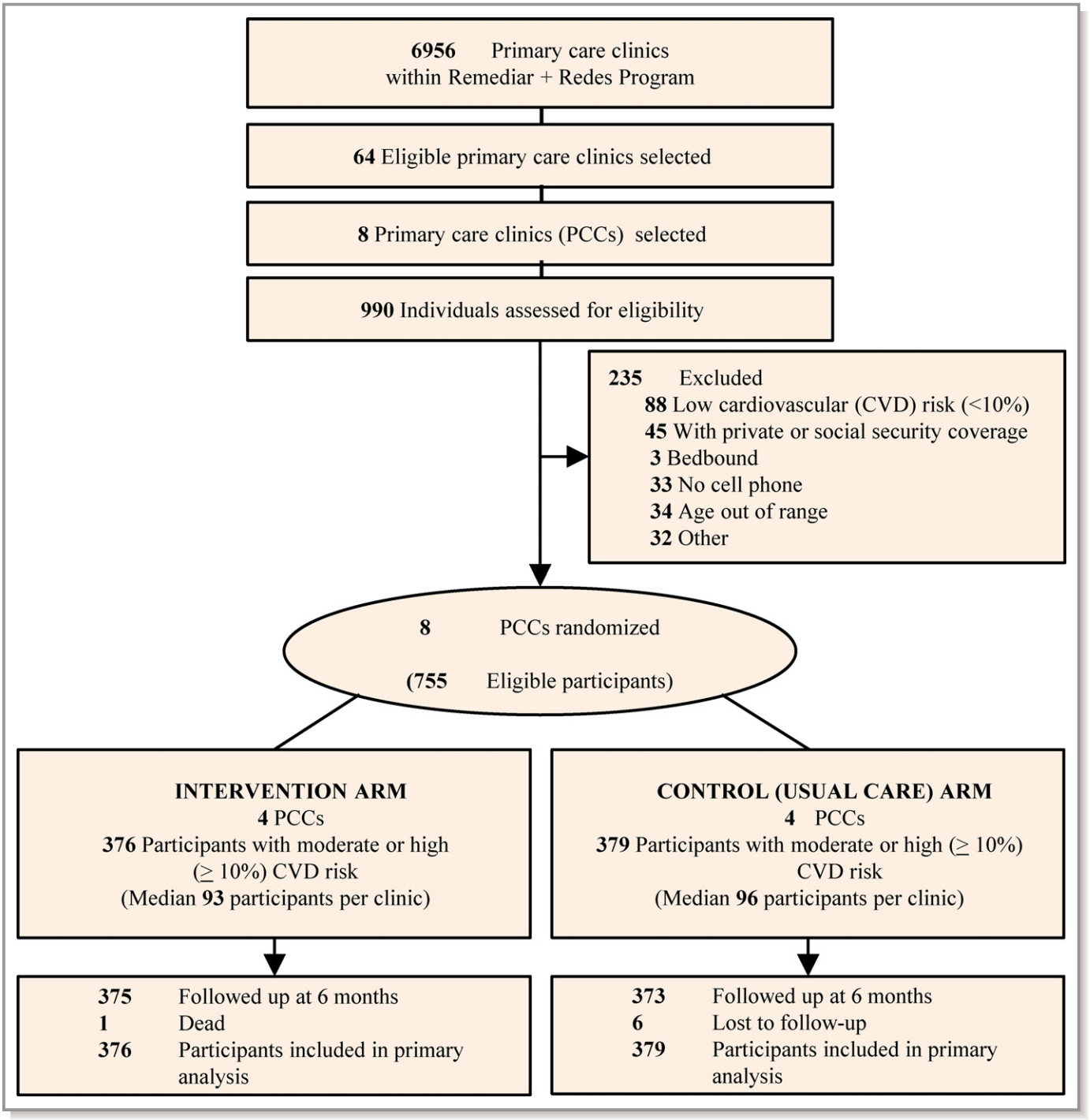

Figure 2. Flow diagram of trial participants.

first visit to PCCs within 6 weeks of being screened by a CHW, compared with 13.5% in the control group (Table 2). For follow-up visits, 31.9% of participants in the intervention group completed a visit within the 4 months of the first visit at the clinic compared with 7.7% in the control group.

Net increases in the proportion of participants with a 10-year CVD risk ≥10% who completed a baseline visit to the clinic and a follow-up visit were consistent with crude increases after adjusting for age, sex, education, history of major CVD, history of hypercholesterolemia, use of antihypertensive medications, and CVD risk. Overall, the clinical attendance rate was significantly higher in the intervention group, 59.8%, compared with the control group, 22.4% (Table 2).

At 6-month follow-up, no significant difference was observed between the intervention and the control group in

Table 1. Baseline Characteristics of the Study Population

	Intervention (n=376)	Control (n=379)	*P* Value
Age, mean (SD), y	54.0 (7.5)	54.1 (8.4)	0.7581
Female sex, n (%)	255 (67.8)	263 (69.4)	0.5144
No high school, n (%)	313 (83.2)	335 (88.4)	0.1623
Systolic BP*, mean (SD), mm Hg	144.6 (22.9)	145.8 (22.2)	0.6774
Diastolic BP*, mean (SD), mm Hg	85.5 (13.0)	85.5 (13.1)	0.8961
Currently smoking, n (%)	97 (25.8)	108 (28.5)	0.7457
History of major CVD†, n (%)	80 (21.3)	67 (17.7)	0.3270
History of hypertension, n (%)	337 (89.6)	350 (92.4)	0.5922
History of diabetes mellitus, n (%)	111 (29.5)	108 (28.5)	0.8069
History of hypercholesterolemia, n (%)	116 (30.9)	147 (38.8)	0.3267
Use of antihypertensive medications‡, n (%)	299 (79.5)	255 (67.3)	0.1965
Use of antidiabetic medications‡, n (%)	97 (25.8)	83 (21.9)	0.1030
Use of statins, n (%)	59 (15.7)	59 (15.6)	0.9445

BP indicates blood pressure ; CVD, cardiovascular disease.
*Mean blood pressure from baseline visit.
†Major cardiovascular disease includes myocardial infarction, stroke, and revascularization.
‡Medication was self-reported.

the proportion of participants who were on appropriate medication for their chronic conditions (Table 2).

Subgroup Analysis by Region and Sex

A positive effect was observed with increases in the proportion of participants with moderate and high CVD risk who completed a baseline visit and follow-up visit in both districts. The relative increase was similar but the absolute differences were different across the regions. In Corrientes, the effect size of the intervention for both primary outcomes was greater than in Almirante Brown. A significant and positive effect was observed in each region when we analyze the effect of the intervention in the proportion of participants who were under chronic medication (Table 3).

No differences were observed between female and male participants in primary outcomes, but males were more likely to be under chronic medication in the intervention group compared with males in control group, showing a statistically significant difference (54.9% versus 24.6%, *P*=0.0342) (Table 4).

Predictors of Clinical Attendance

The regression analyses showed that some of the patient characteristics collected such as an educational level of high school or higher and being under medications for chronic conditions at baseline were strong predictors of the primary outcomes. Tobacco use was associated with clinical attendance at the follow-up visit (Table 5).

Discussion

Summary of Findings

In this cluster-randomized study of healthy men and women who were at moderate to high risk of CVD, participants who were screened in their home by CHWs using a mobile phone app with digital integration to the clinic schedule were significantly more likely to attend a recommended first and follow-up visit with a primary care physician at the PCC compared with CHWs using the standard of care of a paper-based screening tool with verbal referral. Overall, the number of clinic visits was nearly 3 times as high in the intervention arm compared with control. These effects were similar across most subgroups including sex and region of country, but having a higher educational level or using other chronic medications increased the likelihood of responding to the intervention. Probability of being prescribed medications for risk reduction was not significantly increased. However, our study provides good data showing that using a proactive household approach that includes CHWs and an integrated mHealth tool (the app) for primary screening and appropriate referral with a physician at the PCCs increases awareness among people with moderate and high cardiovascular risk and strengthens the existing referral structure but failed to improve treatment of chronic conditions.

Task shifting and sharing has proven to be effective in the control of HIV and tuberculosis and now is emerging as an effective strategy in the control of CVDs in low- and middle-income countries.[22] In this sense, in 2016 the World Health Organization–led HEARTS technical package includes task

Table 2. Effects of the mHealth Intervention on Primary and Secondary Outcomes

	Proportion* (95% CI)		Net Difference (95% CI)	*P* Value	Adjusted Net Difference† (95% CI)	*P* Value
	Intervention (n=376)	Control (n=379)				
Participants classified as having CVD risk ≥10% who completed a baseline visit *at 6 wks* of the CHWs visit	49.4 (35.8, 63.1)	13.5 (5.9, 28.0)	35.9 (18.3, 53.5)	0.0008	34.1 (16.1, 52.1)	0.0006
Participants classified as having CVD risk ≥10% who completed a follow-up visit *at 4 mo of the baseline visit*	31.9 (22.8, 42.6)	7.7 (2.8, 19.8)	24.2 (11.6, 36.8)	0.0041	20.9 (9.2, 32.6)	0.0036
Participants who are on chronic medications for respective conditions 6–12 mo after enrollment‡,§	50.6 (31.5, 69.5)	28.7 (13.1, 51.8)	21.9 (−6.5, 50.2)	0.1487	20.8 (−8.3, 49.9)	0.1674
Participants classified as having CVD risk ≥10% who completed at least 1 follow-up visit *during the study period*	59.8 (45.4, 72.6)	22.4 (12.5, 36.7)	37.4 (18.9, 55.9)	0.0004	36.7 (17.3, 56.0)	0.0002
	n (95% CI)	n (95% CI)	n (95% CI)	*P* Value	n (95% CI)	*P* Value
Mean number of visits *in the study period*	1.1 (0.9, 1.5)	0.4 (0.2, 0.8)	0.7 (0.3, 1.1)	0.0077	0.6 (0.2, 1.0)	0.0094

CHW indicates community health worker; CVD, cardiovascular disease.
*Denominator includes all the participants enrolled in the study (intervention=376; control=379).
†Adjusted for age, sex, education, history of major CVD, history of hypercholesterolemia, self-reported use of antihypertensive medications, and CVD risk.
‡Patients with a 10-year CVD risk ≥10%.
§Antihypertensive medications if systolic blood pressure >140 mm Hg or self-reported hypertension, statins if CVD risk ≥20%, and antidiabetic medications if self-reported diabetes mellitus.

sharing as a key element for reducing the risk of premature mortality from CVDs.[23] The CHW–led, home-based intervention has also been successful in addressing other related chronic conditions and settings.[24,25] Strategies using mHealth have been considered a strengthening tool to overcome health system constrains.[26] A systematic review that evaluated the feasibility and effective use of mobile phone strategies by frontline health workers showed that CHWs are empowered by using mobile phone–based tools because these reinforce and improve the services they provide.[27] Tian et al also showed positive effects when an mHealth app that includes a decision support system was included as an aid to CHWs to guide and standardize the implementation of intervention to manage CVD in India and China.[28]

In this study, we implemented mobile phone strategies that focused on patient education, data collection, electronic decision support, and provider work planning and scheduling to address barriers to chronic care such as low awareness, long waiting times to make an appointment, forgetting appointments, and lack of care continuity. In this sense, mHealth was used as an aid by CHWs to guide CVD risk assessment at the people's home and to refer high CVD risk people to the clinic using a clinical appointment system integrated to the app, making the CHWs' screening and referral tasks more efficient. Using the web-based scheduling system, CHWs had complete control over scheduling available appointments in real time while in the patient's home. Similarly, allowing clinic administrative staff to use the same electronic scheduling system to make follow-up appointments for patients at the end of their first clinic visits also had a positive impact on the rate at which patients completed subsequent visits. The web-based nature of the program allowed for scheduling to occur at the clinic or in the community without adversely affecting workflow in the clinic. In addition, a text messaging intervention linked to an electronic scheduling system and directed to participants with appointment reminders and tailored educational messages increases awareness and promotes follow-up with chronic care. In accordance with other studies, we found that sending appointment reminders as text messages to patients' cell phones was an effective strategy to reduce nonattendance rates, showing that forgetfulness is an important reason of not showing up in chronic disease care.[29]

The success of the intervention is likely related to the improvement in the healthcare infrastructure, organizational changes required to implement the intervention, and its adoption by healthcare professionals at the affected PCCs.

DOI: 10.1161/JAHA.118.011799

Table 3. Effects of the mHealth Intervention on Primary and Secondary Outcomes by Region

	Almirante Brown				Corrientes			
	Proportion* (95% CI)		Adjusted Net Difference† (95% CI)	*P* Value	Proportion* (95% CI)		Adjusted Net Difference† (95% CI)	*P* Value
	Intervention (n=168)	Control (n=175)			Intervention (n=208)	Control (n=204)		
Participants classified as having CVD risk ≥10% who completed a baseline visit *at 6 wks* of the CHWs visit	41.7 (36.8, 46.7)	12.9 (4.5, 31.5)	28.8 (15.1, 42.5)	0.0075	57.0 (34.3, 77.1)	14.2 (4.0, 40.0)	42.8 (14.3, 71.3)	0.0150
Participants classified as having CVD risk ≥10% who completed a follow-up visit *within 4 mo of the baseline visit*	25.0 (21.9, 28.4)	5.3 (3.6, 7.8)	19.7 (15.8, 23.6)	0.0001	38.6 (25.6, 53.6)	10.3 (2.4, 35.0)	28.4 (8.1, 48.6)	0.0443
Participants who are on chronic medications for respective conditions 6–12 mo after enrollment‡,§	31.0 (26.2, 36.1)	11.4 (6.8, 18.5)	19.5 (12.0, 27.1)	0.0001	70.1 (59.1, 79.2)	46.1 (27.3, 66.0)	24.0 (1.2, 46.8)	0.0379
Participants who completed at least 1 follow-up visit *during the study period*	51.8 (41.1, 62.3)	21.2 (7.1, 48.6)	30.6 (7.0, 54.2)	0.0411	67.6 (45.0, 84.1)	23.5 (13.5, 37.8)	44.0 (20.2, 67.9)	0.0012
	n (95% CI)	n (95% CI)	n (95% CI)	*P* Value	n (95% CI)	n (95% CI)	n (95% CI)	*P* Value
Mean number of visits *in the study period*	0.4 (0.1, 0.9)	0.9 (0.8, 1.1)	0.6 (0.2, 1.0)	0.0538	0.5 (0.2, 1.2)	1.3 (1, 1.9)	0.9 (0.2, 1.5)	0.0409

CHWs indicates community health workers; CVD, cardiovascular disease.

*Denominator includes all the participants enrolled in the study (intervention=376; control=379).

†Adjusted for age, sex, education, history of major CVD, history of hypercholesterolemia, self-reported use of antihypertensive medications, and CVD risk.

‡Patients with a 10-year CVD risk ≥10%.

§Antihypertensive medications if systolic blood pressure >140 mm Hg or self-reported hypertension, statins if CVD risk ≥20%, antidiabetic medications if self-reported diabetes mellitus.

DOI: 10.1161/JAHA.118.011799

Table 4. Effects of the mHealth Intervention on Primary and Secondary Outcomes by Sex

	Female				Male			
	Proportion* (95% CI)				Proportion* (95% CI)			
	Intervention (n=255)	Control (n=263)	Net Difference (95% CI)	*P* Value	Intervention (n=121)	Control (n=116)	Net Difference (95% CI)	*P* Value
Participants classified as having CVD risk ≥10% who completed a baseline visit *at 6 wks* of the CHWs visit	50.0 (34.6, 65.4)	14.5 (6.2, 30.2)	35.5 (15.8, 55.2)	0.0021	48.3 (38.6, 58.1)	11.2 (4.5, 25.3)	37.1 (23.1, 51.0)	0.0002
Participants classified as having CVD risk ≥10% who completed a follow-up visit *within 4 mo of the baseline visit*	31.0 (20.0, 44.8)	9.2 (3.2, 23.7)	21.8 (6.1, 37.6)	0.0213	33.9 (28.1, 40.2)	4.3 (1.5, 11.5)	29.6 (22.1, 37.1)	0.0001
Participants who are on chronic medications for respective conditions 6–12 mo after enrollment[†,‡]	49.8 (29.1, 70.5)	29.9 (12.8, 55.5)	19.8 (−11.6, 51.3)	0.2347	54.9 (35.5, 72.9)	26.4 (13.8, 44.5)	28.5 (3.4, 53.6)	0.0342
Participants who completed at least 1 follow-up visit *during the study period*	61.6 (44.9, 76.0)	23.5 (13.8, 37.0)	38.2 (18.3, 58.0)	0.0006	56.7 (45.4, 67.3)	19.9 (9.0, 38.2)	36.8 (18.5, 55.2)	0.0014
	n (95% CI)	n (95% CI)	n (95% CI)	*P* Value	n (95% CI)	n (95% CI)	n (95% CI)	*P* Value
Mean number of visits *in the study period*	1.1 (0.8, 1.6)	0.5 (0.2, 0.9)	0.7 (0.2, 1.2)	0.0174	1.1 (0.9, 1.4)	0.3 (0.2, 0.7)	0.8 (0.5, 1.1)	0.0016

CHW indicates community health worker; CVD, cardiovascular disease.

*Denominator includes all the participants enrolled in the study (intervention=376; control=379).

[†]Patients with a 10-year CVD risk ≥10%.

[‡]Antihypertensive medications if systolic blood pressure >140 mm Hg or self-reported hypertension, statins if CVD risk ≥20%, antidiabetic medications if self-reported diabetes mellitus.

Table 5. Association of Patient Characteristics With Primary Outcomes

Characteristics	Attendance at the Baseline Visit at 6 Wks of the CHWs Visit OR (95% CIs)	Attendance at the Follow-Up Visit Within 4 Mo of the Baseline Visit OR (95% CIs)
Group		
Control	Reference	Reference
Intervention	6.1 (2.0, 18.3)*	4.8 (1.5, 14.8)*
Region		
Almirante Brown	Reference	Reference
Corrientes	1.6 (0.6, 4.2)	1.6 (0.7, 3.5)
Age	1.0 (0.98, 1.02)	1.01 (0.99, 1.03)
Sex		
Male	Reference	Reference
Female	1.1 (0.9, 1.5)	1.1 (0.7, 1.6)
Education level		
Less than high school	Reference	Reference
High school or more	1.4 (1.1, 1.8)*	1.8 (1.3, 2.6)*
Currently smoking		
No	Reference	Reference
Yes	0.7 (0.5, 1.1)	0.6 (0.5, 0.8)*
Use of medications for chronic conditions†		
No	Reference	Reference
Yes	1.9 (1.2, 3.2)*	2.0 (1.2, 3.2)*
History of major CVD‡		
No	Reference	Reference
Yes	0.9 (0.7, 1.3)	1.0 (0.7, 1.3)

CHW indicates community health worker; CVD, cardiovascular disease; OR, odds ratio.
*indicates a statistically significant difference between the Reference and comparison groups at alpha = 0.05.
†Medications for chronic conditions include self-reported use of antihypertensive medications, antidiabetic medications, or statins.
‡Major cardiovascular disease includes myocardial infarction, stroke, and revascularization.

The results were positive to improve detection and referral by CHWs to primary care clinics of people with moderate to high CVD risk. Although they do not aim to be generalizable, they can be transferable to similar settings, where access to health professionals and healthcare infrastructure is limited as a valuable first step towards developing future mHealth interventions in poor urban settings to manage CVD risk. In the few cases where electronic health records with scheduling capacity are used in low-income settings, an application with appropriate code can be developed to access those systems remotely.

A limitation of this study is that although we observed differences in the effect of the interventions in both districts, we were unable to assess the factors in the health system that might have affected the implementation and patient responses to the intervention in order to identify those who are more likely to benefit. Moreover, in the literature, there is little evidence regarding the optimal dosing, frequency, and content of text messages to address CVD management.[30,31]

While we did not find a statistically significant greater difference in the rate of appropriate medications in the intervention arm compared with the usual-care arm in the overall study, when we evaluated it by site, we found that within both sites, there was a significantly increased rate of appropriate prescriptions in the intervention arm compared with usual care. This may be a chance finding. Additionally, there is a numerical explanation related to the intracluster correlation among clusters in the study. The ICC within each site (Almirante Brown: 0.0760; Corrientes: 0.1490) is lower than the global ICC (global: 0.2420) considering both sites together. This is because there is much more variability in the proportion of appropriate prescriptions among the 4 clinics analyzed together than between the 2 clinics in each site.

Since appropriate medication was a secondary outcome in our study, we did have enough power to detect a significant difference given the lower ICC per site but not for the global comparison, where the ICC was higher.

Ultimately, a further study is needed to assess whether the increased visits to the PCC among people with high CVD risk leads to meaningful reductions in actual risk factors such as blood pressure and dyslipidemia as well as CVD events.

In conclusion, in this cluster randomized study of patients at moderate to high risk of CVD, the rates of clinic attendance and follow-up appointments at primary health centers were higher among those screened in community by CHWs using an mHealth app integrated with a digital clinical scheduling system compared with those using a paper system.

Acknowledgments

Additional nonauthor members of the working group who contributed to data collection and management are as follows: Mariano Althabe (Secretaria de Salud del Municipio de Almirante Brown, Almirante Brown, Prov. de Buenos Aires, Argentina), Jonatan Konfino (Secretaria de Salud del Municipio de Almirante Brown, Almirante Brown, Prov. de Buenos Aires, Argentina), Mabel Klehb, Mirta Premoli, Silvia Graciela Núñez and Stella Maris Antúnez (CAPS Don Orione, Municipio de Almirante Brown, Almirante Brown, Prov. de Buenos Aires, Argentina), Viviana Amarilla, María Ozorio and Ramona Alfonso (CAPS San José, Municipio de Almirante Brown, Almirante Brown, Prov. de Buenos Aires, Argentina), Macarena Canónico, Olga Fernández and Romina Challen (CAPS Los Alamos, Municipio de Almirante Brown, Almirante Brown, Prov. de Buenos Aires, Argentina), Marta Valdez and Patricia Macías (CAPS Rafael Calzada, Municipio de Almirante Brown, Almirante Brown, Prov. de Buenos Aires. Argentina), Silvana Grosso (Ministerio de Salud Publica de Corrientes, Prov. de Corrientes, Argentina), Maria Sara Rolon, Hugo Romero and Beatriz Rolon (CAPS 15 Presidente Arturo Illia, Prov. de Corrientes, Argentina), Maria Badaracco, Sandra Finos, and Patricia Hernández (CAPS 8 Santa Teresita, Prov. de Corrientes, Argentina), Silvia Alcaraz, Ángela Valenzuela, and Lorena Falcón (CAPS 4 Dr Graciano Lugo, Prov. de Corrientes, Argentina), Andrés Benetti, Carmen González, and Liliana López (CAPS 10 Dr Balbastro, Prov. de Corrientes, Argentina).

Sources of Funding

This work was supported by NIH: 5R21TW010173.

Disclosures

None.

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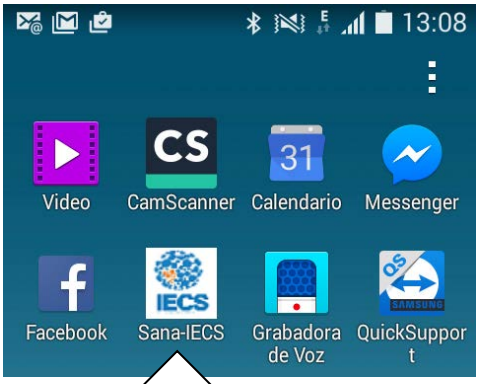
SUPPLEMENTAL MATERIAL

Table S1. List of chronic medications used for medical record review.

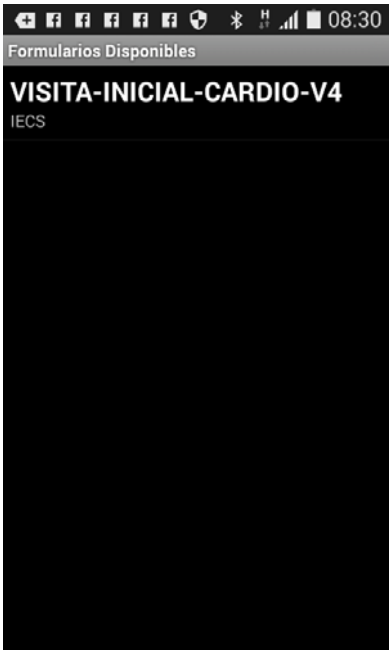
Antihypertensive medication
Atenolol
Furosemide
Hydrochlorothiazide
Amlodipine
Diltiazem
Metoprolol
Nebivolol
Telmisartan
Nifedipine
Enalapril
Carvedilol
Candesartan
Losartan
Antidiabetic medication
Glibenclamide
Glimepiride
Metformin
Cholesterol medication
Simvastatin
Atorvastatin
Fenofibrate

Figure S1. mHealth tools screenshots for CVD risk calculation and appointment scheduling.

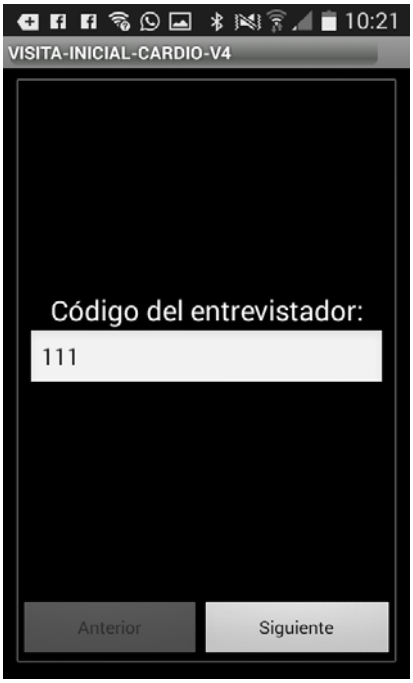


mHealth tools icon

Entry of new patient.



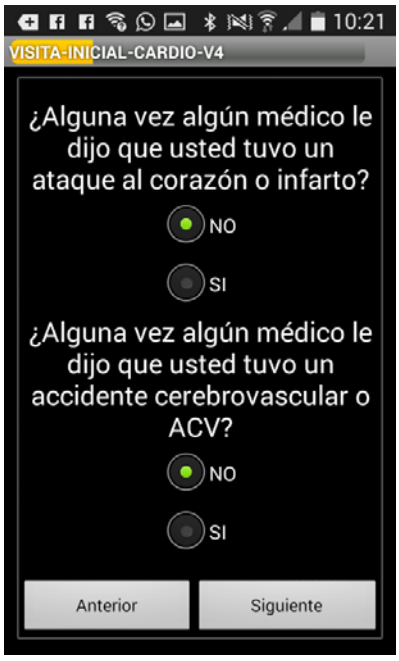
Initial visit form.



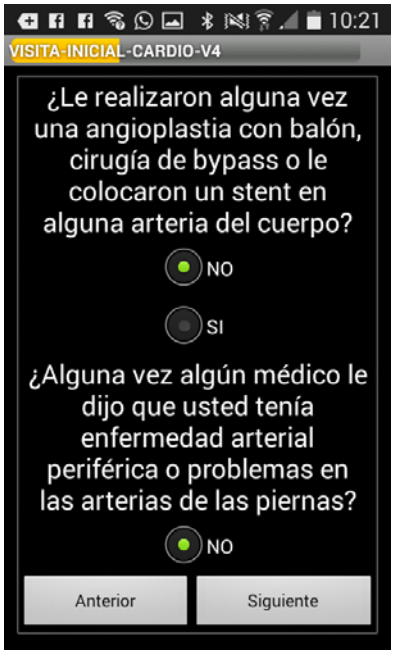
Interviewer code entry.

Date of the visit.

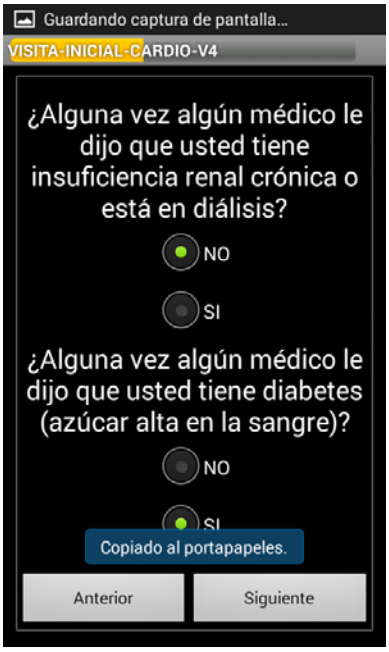
Entry of sex and age.



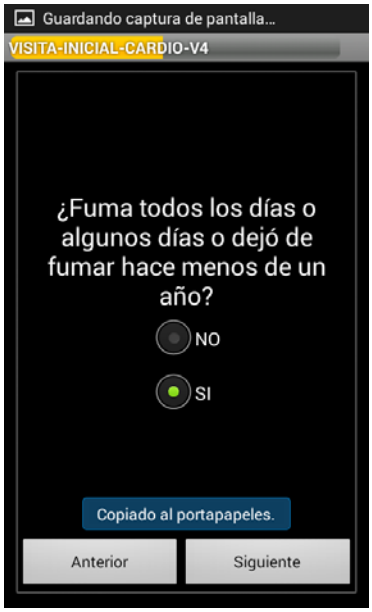
Presence of cardiovascular disease.



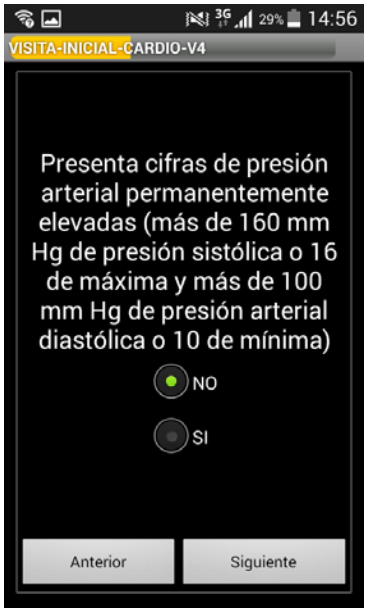
History of CVD procedures.



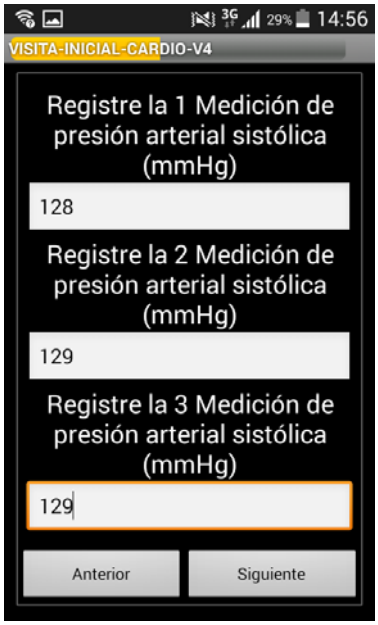
Other chronic diseases.



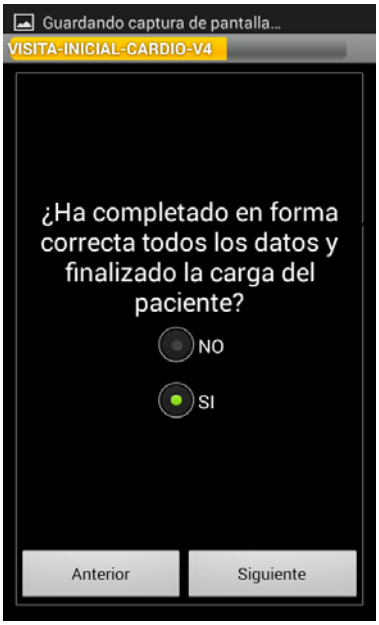
Tobacco use.



Elevated blood pressure values.



Entry of three systolic blood pressure measurements.



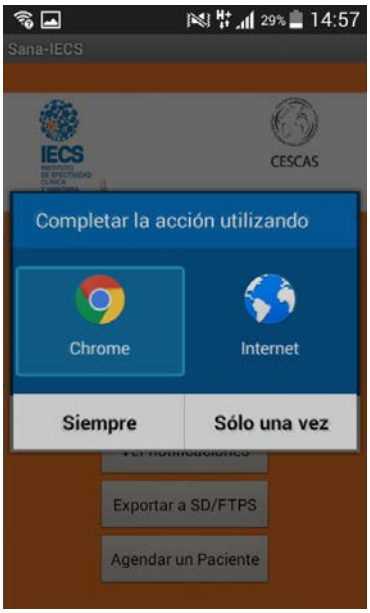
Mark YES
if you completed the form.

CVD risk

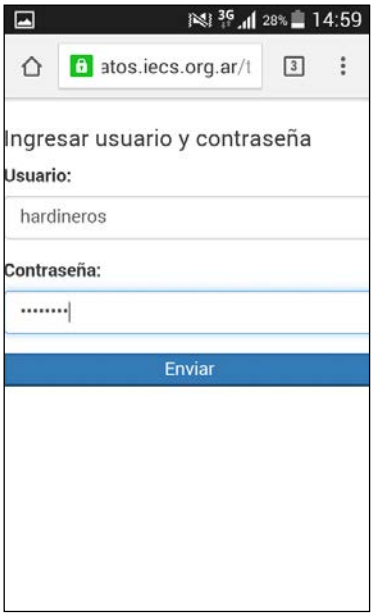
Participant ID entry

Schedule an appointment.

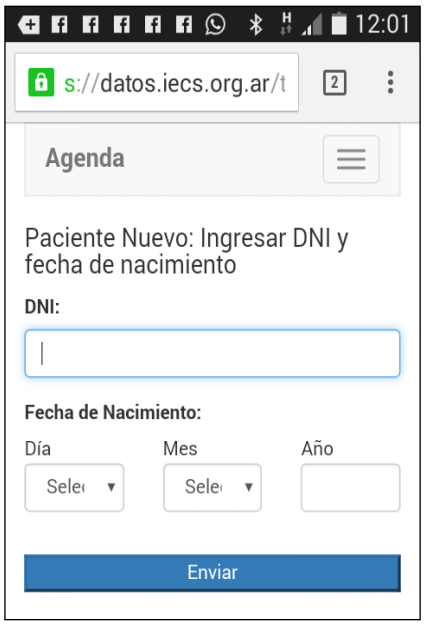
Save and send data to the server.



Establish secure Wi-Fi connection.



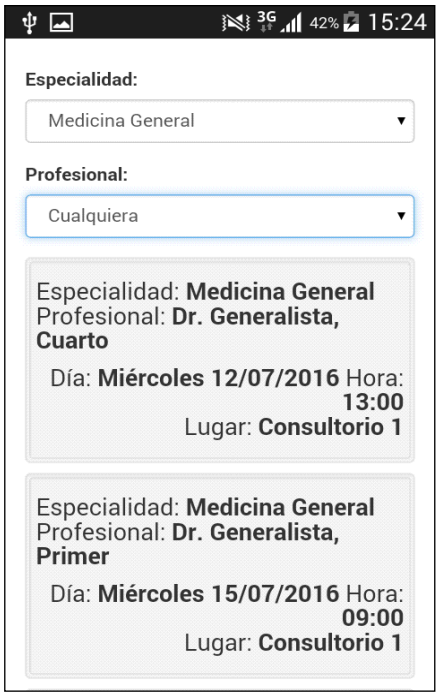
Web-based appointment system
Enter username and password.



Enter ID and birth date.

Enter name and cell phone number

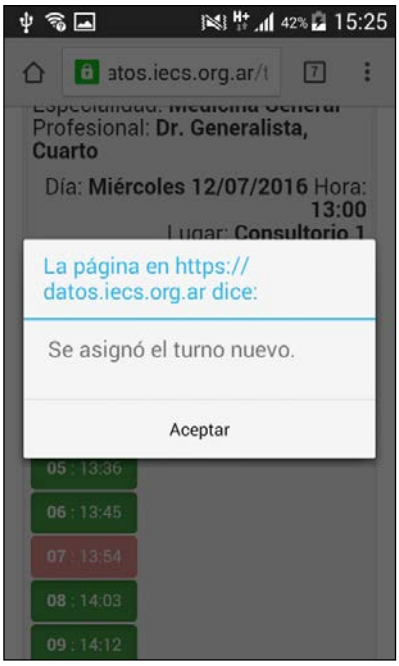
New appointment.



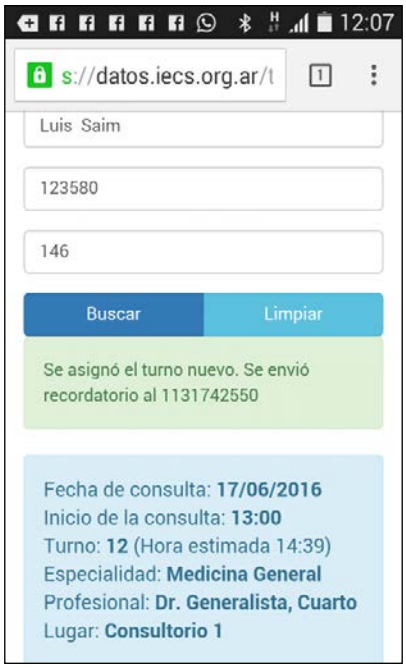
Physicians available at the clinic.

Select a slot to book an appointment.

Confirm the appointment requested.



Appointment assigned to the participant.



Appointment confirmation.

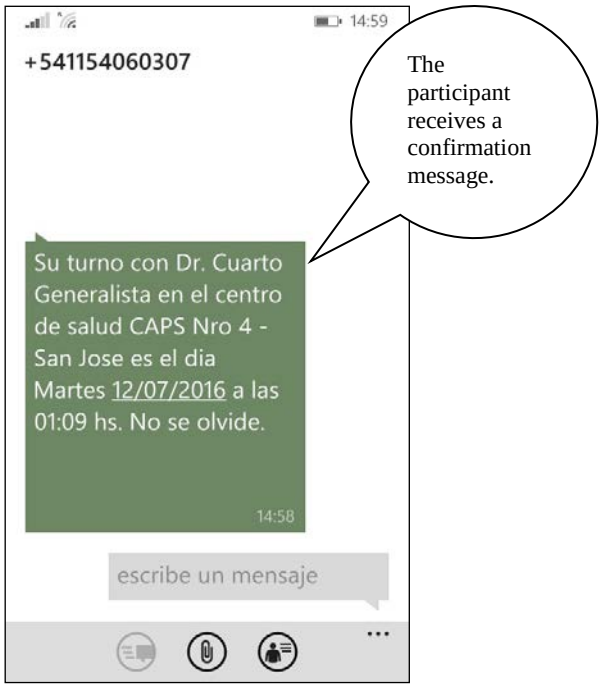
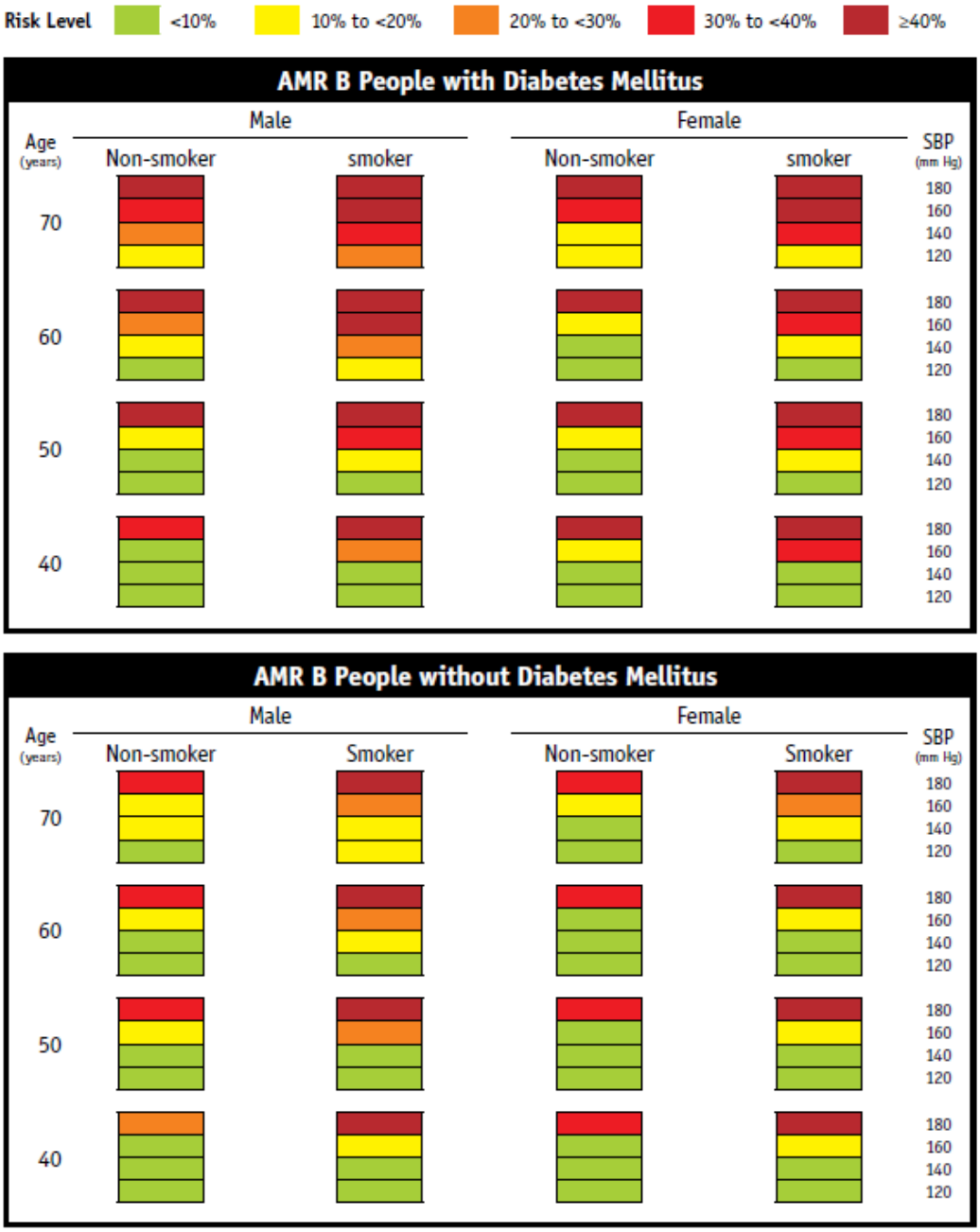

14:59
+541154060307
Su turno con Dr. Cuarto Generalista en el centro de salud CAPS Nro 4 - San Jose es el dia Martes 12/07/2016 a las 01:09 hs. No se olvide.
14:58
escribe un mensaje
The participant receives a confirmation message.

Figure S2. WHO/ISH risk prediction chart for AMR B. 10-year risk of a fatal or non-fatal cardiovascular event by sex, age, systolic blood pressure, smoking status and presence or absence of diabetes mellitus.



This chart can only be used for countries of the WHO Region of the Americas, sub-region B.