Cluster Randomized Trial for Hypertension Control: Effect on Lifestyles and Body Weight

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Introduction: Lifestyle modification, such as healthy diet habits, regular physical activity, and maintaining a normal body weight, must be prescribed to all hypertensive individuals. This study aims to test whether a multicomponent intervention is effective in improving lifestyle and body weight among low-income families.

Study design: Cluster randomized trial conducted between June 2013 and October 2016.

Setting/participants: A total of 1,954 uninsured adult patients were recruited in the study within 18 public primary healthcare centers of Argentina.

Intervention: Components targeting the healthcare system, providers, and family groups were delivered by community health workers; tailored text messages were sent for 18 months.

Main outcome measures: Changes in the proportion of behavioral risk factors and body weight from baseline to end of follow-up. Data were analyzed in 2017.

Results: Low fruit and vegetable consumption (fewer than 5 servings per day) decreased from 96.4% at baseline to 92.6% at 18 months in the intervention group, whereas in the control group it increased from 97.0% to 99.9% (*p*=0.0110). The proportion of low physical activity (<600 MET-minutes/week) decreased from 54.3% at baseline to 46.2% at 18 months in the intervention group and kept constant around 52% (*p*=0.0232) in the control group. The intervention had no effect on alcohol intake (*p*=0.7807), smoking (*p*=0.7607), addition of salt while cooking or at the table (*p*=0.7273), or body weight (*p*=0.4000).

Conclusions: The multicomponent intervention was effective for increasing fruit and vegetable intake and physical activity with no effect on alcohol consumption, smoking, addition of salt, or body weight among low-income families in Argentina.

Trial registration: This study is registered at www.clinicaltrials.gov NCT01834131.
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INTRODUCTION

Despite extensive knowledge of hypertension prevention and treatment, the global prevalence of hypertension is high and increasing.[1] In many low- and middle-income countries, a rapid urbanization process caused important demographic, social, and economic changes with significant impact on lifestyles.[2,3] The reduction of physical activity (PA) and the increase of

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total calorie intake from unhealthy diets resulted in a higher prevalence of clinical risk factors such as hypertension, overweight, obesity, dyslipidemia, and diabetes.[3]

Argentina is not an exception. The nutritional transition was characterized by less consumption of fruits, vegetables, nuts, seeds, whole grains, fiber, and polyunsaturated fats and higher consumption of sodium, processed meats, red meat, trans fat, sugary drinks and alcohol.[4] Only 5% of the population consumed 5 or more servings of fruit or vegetables per day, and the prevalence of low PA increased from 46% in 2005 to 55% in 2013.[5,6] Furthermore, a higher prevalence of clinical risk factors has been observed among the lower-income population.[6]

In response to the existing socioeconomic disparities, the National Ministry of Health in Argentina created a program to provide free drugs to treat traditional risk factors in the uninsured population. Besides this effort, hypertension awareness, treatment, and control rates are unacceptably low, as only 63.0% are aware, 48.7% are treated, and only 21.1% are controlled.[7] The improvement of the hypertension control rate through pharmacologic treatments is important and should continue; however, lifestyle modification must be promoted more emphatically, especially in the lower-income population.

The Hypertension Control Program in Argentina was a cluster randomized trial testing a multicomponent intervention that targeted the healthcare system, providers, and family groups among low-income patients in Argentina.[8] This comprehensive intervention has been demonstrated to be effective in reducing blood pressure and improving hypertension control.[9] The aim of this study is to evaluate whether the multicomponent intervention is effective in modifying lifestyles and body weight among low-income families.

METHODS

The Hypertension Control Program in Argentina was a cluster randomized trial conducted among 18 primary care centers within the national public primary care system in Argentina. Details of the trial's rationales and study design have been published elsewhere.[8]

The selected primary care centers were located in a poor urban area and provided free health care and medication to uninsured patients; their staff was composed of general practitioners, nurses, and community health workers (CHWs). Eighteen centers were selected from 5 different provinces located in the north, northeast, and central-east regions. Nine centers were assigned to the comprehensive intervention arm and the other 9 centers to usual care. Cluster randomization was stratified by geographic region and conducted at the data coordinating center at Tulane University. The allocation was based on clusters. All individuals within each cluster were included consecutively to avoid selection bias. No action was taken to balance allocation for participants that refused consent. Given the nature of the behavioral intervention, neither participants nor implementers were blinded. The randomization schedules were generated using PROC Plan in SAS, version 9.4.

Study Population

Participants were recruited for the study between June 2013 and April 2015 and followed to October 2016. The eligibility criteria were that the participants should be men and women aged ≥21 years with systolic blood pressure ≥140 mmHg or diastolic ≥90 mmHg measured on at least 2 separate visits, and whose spouses or adult hypertensive family members aged ≥21 years living in the same household were willing to participate in the study. All the analyses presented in this article included both hypertensive patients and their eligible family members. A flow diagram of trial participants is depicted in Figure 1. Study data were collected at baseline and at 6, 12, and 18 months. The comprehensive intervention program was implemented for 18 months and included education of healthcare providers, home-based education promoting lifestyle modification, adherence to drug treatment, and a mobile health intervention.
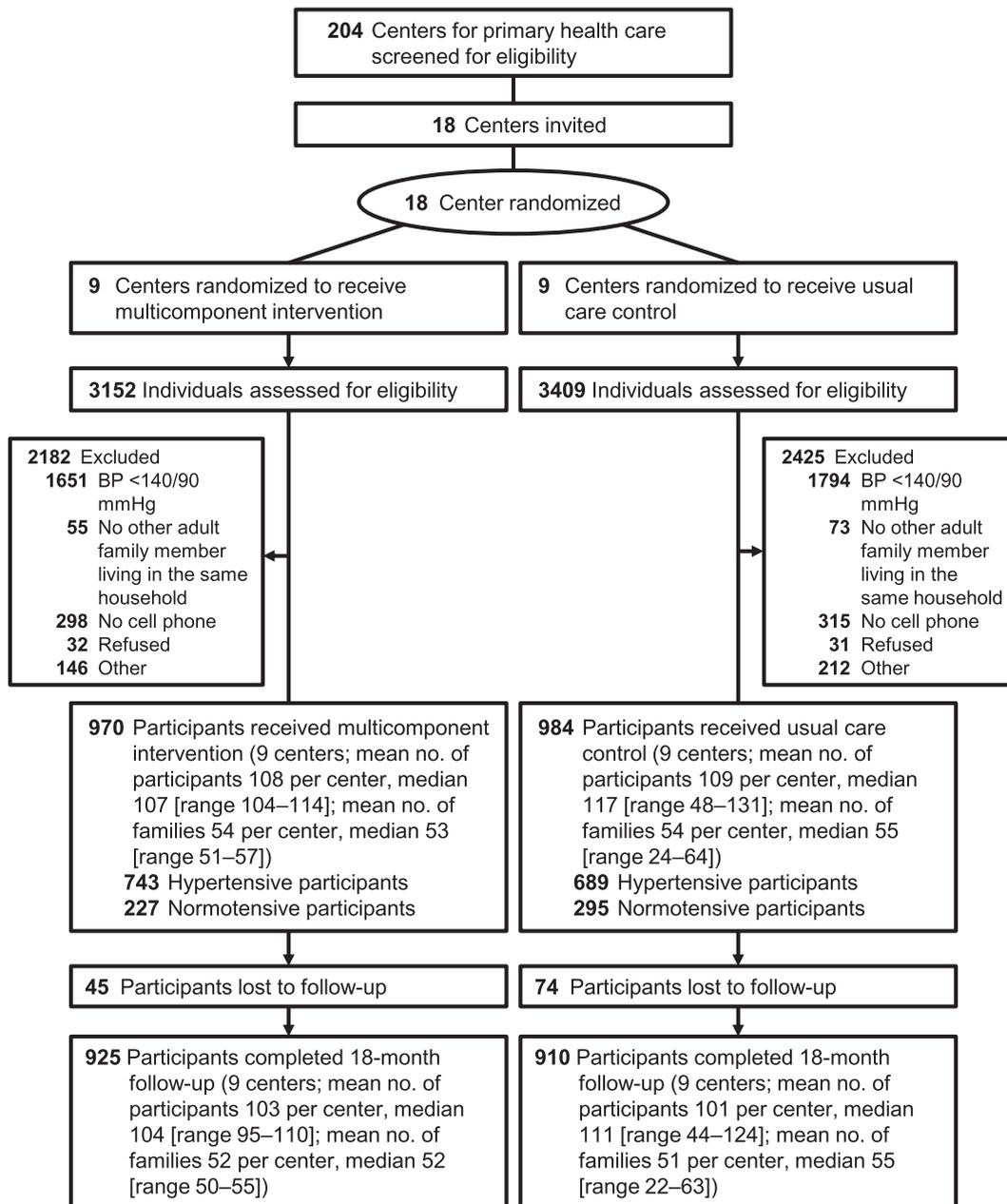
The study protocol was approved by the IRBs of Tulane University and Hospital Italiano de Buenos Aires in Argentina. Written informed consent was obtained for all participants during screening. There was no selective inclusion of participants based on race or gender. The CONSORT guideline for reporting randomized trials was used for the present article.[10]

Intervention

The CHW intervention was the key element, with a complementary text messaging intervention. As individuals from the community, with similar ethnicity, language, SES, and life experiences, CHWs served as a source of education, motivation, and social support, and as facilitators of healthcare utilization for patients and their families.

The CHWs, who were part of the primary care staff of the public primary care centers, were recruited and trained in motivational interviewing techniques,[11] measuring blood pressure,[12] facilitating behavioral change based on the Stages of Change Model,[13,14] providing management skills to improve medication adherence, and lifestyle modifications. The culturally appropriate behavioral change messages were based on 2 manuals validated for CHWs in Argentina.[15,16] The interactive training was conducted in a 2-day session, followed by onsite field testing and certification. CHWs visited participants' homes monthly for the first 6 months and every other month thereafter.

The family-based intervention started with an initial 90-minute home visit at a time when all family members in the household could be present to discuss general knowledge about hypertension prevention and treatment. During subsequent 60-minute monthly or bimonthly follow-up visits, CHWs provided tailored counseling to participants and their families on medication adherence, home blood pressure monitoring, and lifestyle modification. CHWs provided participants with instruction on reaching and maintaining a healthy weight, adopting the Dietary Approaches to Stop Hypertension diet (recommendations and recipes were adapted considering foods and beverages available in Argentina), reducing dietary salt intake, limiting alcohol consumption, and increasing PA. Home visits also focused on goal setting, problem solving, social support, and maintaining motivation during

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┌─────────────────────────────────────────┐
│  204 Centers for primary health care     │
│      screened for eligibility            │
└─────────────────────────────────────────┘
                    │
┌─────────────────────────────────────────┐
│  18 Centers invited                      │
└─────────────────────────────────────────┘
                    │
           (  18 Center randomized  )
              /              \
┌──────────────────────┐  ┌──────────────────────┐
│ 9 Centers randomized │  │ 9 Centers randomized │
│ to receive multi-    │  │ to receive usual     │
│ component intervention│  │ care control         │
└──────────────────────┘  └──────────────────────┘
         │                          │
┌──────────────────────┐  ┌──────────────────────┐
│ 3152 Individuals     │  │ 3409 Individuals     │
│ assessed for         │  │ assessed for         │
│ eligibility          │  │ eligibility          │
└──────────────────────┘  └──────────────────────┘
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2182 Excluded
  1651 BP <140/90 mmHg
    55 No other adult family member living in the same household
  298 No cell phone
    32 Refused
  146 Other

2425 Excluded
  1794 BP <140/90 mmHg
    73 No other adult family member living in the same household
  315 No cell phone
    31 Refused
  212 Other

970 Participants received multicomponent intervention (9 centers; mean no. of participants 108 per center, median 107 [range 104–114]; mean no. of families 54 per center, median 53 [range 51–57])
  743 Hypertensive participants
  227 Normotensive participants

984 Participants received usual care control (9 centers; mean no. of participants 109 per center, median 117 [range 48–131]; mean no. of families 54 per center, median 55 [range 24–64])
  689 Hypertensive participants
  295 Normotensive participants

45 Participants lost to follow-up

74 Participants lost to follow-up

925 Participants completed 18-month follow-up (9 centers; mean no. of participants 103 per center, median 104 [range 95–110]; mean no. of families 52 per center, median 52 [range 50–55])

910 Participants completed 18-month follow-up (9 centers; mean no. of participants 101 per center, median 111 [range 44–124]; mean no. of families 51 per center, median 55 [range 22–63])

Figure 1. Flow diagram of trial participants.
Note: Normotensive participants were family members of hypertensive participants who had systolic blood pressure <140 mmHg, diastolic blood pressure <90 mmHg, and no use of antihypertensive medications.
BP, blood pressure.

challenging situations. The research team conducted 3 audits of CHWs' sessions with participants to assess the fidelity of the intervention and provide feedback.

Individualized messages were developed using educational materials. Text messages were sent weekly from a web-based platform to participants and family members using a one-way outgoing message system. These were individualized text messages to promote lifestyle changes and reminders to reinforce medication adherence (Appendix Table 1, available online). The centers randomized to the control group continued with their usual care.

Measures

The outcomes for the present study were the differences between the intervention and control groups in the proportion of behavioral risk factors, overweight, obesity, and body weight, from baseline to end of follow-up in the study population. Trained and certified research nurses who did not engage in intervention collected all study data at baseline and at 6, 12, and 18 months of follow-up in participants' homes using standard questionnaires and measurement methods.

Details regarding data collection instruments, specific wording, and answer categories can be found in Appendix Table 2, available

online. Briefly, selected questions from the Pan American version of STEPS were used to assess fruit and vegetable intake, alcohol consumption, and current smoking status.[17] Low intake of fruit and vegetables was defined as fewer than 5 servings per day.[18] Weekly alcohol drinking was defined as having an alcoholic drink at least once a week. Current smoking was defined as those who had smoked 100 cigarettes in their lifetime and who currently smoked cigarettes.[19,20] Obesity was defined as a BMI ≥ 30 kg/m^2 and overweight as BMI ≥ 25 kg/m^2 and <30 kg/m^2.[21] PA was assessed using the International PA Questionnaire short form.[22] Low PA was defined as <600 MET-minutes/week.[23] Salt intake was assessed as added salt while cooking and at the table (*always, almost always, sometimes*, and *rarely* or *never*).

Statistical Analysis

The intention-to-treat principle was used for all analyses. Baseline characteristics between the intervention and control groups were described. Generalized estimating equations were used to analyze outcomes, in which participants were nested within families, which were nested in centers, which were further nested in the randomization groups. Data from baseline and 6, 12, and 18 months were considered for the repeated measures analysis, using an unstructured variance−covariance matrix. Binomial distribution and a logit link function were assumed for binary outcomes and normal distribution with an identity link for body weight. The interaction term between time and group was evaluated to test the effect of the intervention. A two-sided *p*-value <0.05 was considered statistically significant and no correction was made for multiple testing. The unadjusted and adjusted estimated proportions were reported. The adjusted proportions were obtained by considering a model including the following individual-level variables: age, sex, history of major cardiovascular disease, history of hypercholesterolemia, alcohol drinking, PA, baseline BMI, and systolic blood pressure at baseline. Point estimates and 95% CIs at each time period were obtained for each randomization group. A very low proportion of missing data was found; therefore, no specific method was used to

address this issue. Data analysis was conducted in 2017 using PROC GENMOD in SAS, version 9.4.

RESULTS

A total of 6,956 hypertensive patients and their family members were screened, and 1,954 who met eligibility criteria were enrolled in the study. Of these, 970 participants were recruited from 9 intervention centers, and 984 participants from 9 control centers (Figure 1). The participation rate among eligible patients was 96.8% (970 of 1,002) for the intervention group and 96.9% (984 of 1,015) for the control group. The follow-up rate at 18 months was 95.4% (925 of 970) for the intervention group and 92.5% (910 of 984) for the control group.

Most of the baseline characteristics of study participants were balanced between the intervention and control groups (Table 1). The mean age of the study population was 55 years, 51% were women, more than half were obese, and >30% were overweight. Individuals in the intervention group showed some small differences in relation to the control group. Respectively, they performed less PA; added more salt while cooking and at the table; and had a higher history of major cardiovascular disease, hypercholesterolemia, and hypertension. By contrast, higher consumption of fruits and vegetables was observed in the intervention group than in the control group.

During the 18-month intervention, CHWs completed 94.3% (8,272 of 8,772) of the expected home visits; 98.9% of the participants received at least 1 CHW home visit, and >75% received the expected messages weekly

Table 1. Baseline Characteristics of the Study Participants

Characteristics	Intervention, n/n (%) (n=970)	Control, n/n (%) (n=984)	p-value[a]
Age, years[b]	55.4 (12.1)	54.6 (11.9)	0.1350
Female sex	497/970 (51.2)	508/984 (51.6)	0.8635
Currently, smoking	200/969 (20.6)	209/984 (21.2)	0.7446
Weekly alcohol drinking	339/967 (35.1)	332/984 (33.7)	0.5403
Low physical activity (<600 MET-minutes/week)	512/966 (53.0)	479/984 (48.7)	0.0562
Low intake of fruit and vegetables (<5 servings per day)	917/966 (94.9)	963/982 (98.1)	**0.0002**
Added salt while cooking (Almost always or always)	506/968 (52.3)	447/984 (45.4)	**0.0025**
Added salt at the table (Almost always or always)	89/970 (9.2)	72/984 (7.3)	0.1353
Overweight (BMI ≥ 25 kg/m^2 and <30 kg/m^2)	337/969 (34.8)	333/982 (33.9)	0.6865
Obesity (BMI ≥ 30 kg/m^2)	507/969 (52.3)	493/982 (50.2)	0.3493
Hypertension	743/970 (76.6)	689/984 (70.0)	**0.0010**
History of major cardiovascular disease	103/970 (10.6)	67/983 (6.8)	**0.0029**
History of hypercholesterolemia	369/970 (38.0)	309/984 (31.4)	**0.0021**
History of diabetes	193/968 (19.9)	175/984 (17.8)	0.2239

Note: Boldface indicates statistical significance (*p*<0.05).
[a]Generalized estimating equations were used to compare baseline variables accounting for cluster effects from families and clinics.
[b]Mean (SD).

during the study period. When analyzing the effects of the multicomponent intervention on lifestyle modification among study participants (Table 2), it was observed that the proportion of individuals eating fewer than 5 servings per day of fruits and vegetables decreased from 96.4% at baseline to 92.6% at 18 months in the intervention group, whereas in the control group it increased from 97.0% to 99.9% (p=0.0110). The proportion of low PA (<600 MET-minutes/week) decreased from 54.3% at baseline to 46.2% at 18 months in the intervention group and kept constant around 52% (p=0.0232) in the control group. The intervention did not show any effect on alcohol intake (p=0.7807), smoking (p=0.7607), addition of salt while cooking or at the table (p=0.7273), overweight/obesity (p=0.3421), or body weight (p=0.4000) (Appendix Table 3, available online).

DISCUSSION

This cluster randomized trial demonstrates that a home-based intervention led by CHWs and complemented by text messages promoting lifestyle changes is effective in increasing self-reported fruit and vegetable intake and PA among low-income patients in Argentina. These findings have important public health implications, given that 55% of the Argentinian population aged >18 years did not reach the minimum recommended level of PA (600 MET-minutes/week) and 95% ate fewer than 5 portions of fruit or vegetables per day.[6]

It is interesting to note the reduction in the self-reported consumption of alcohol, added salt while cooking or at the table, and current smoking in both groups of the study. Because certified research nurses (who did not engage in the intervention) collected all study data, the authors cannot exclude the observer or Hawthorne effect in the control group. This effect is a type of reactivity in which individuals modify an aspect of their behavior in response to their awareness of being observed, which is frequently found in clinical trials.[24−26] Furthermore, it may be argued that the low-income population in Argentina is more aware of the risk of drinking alcohol,[27] smoking,[28,29] and sodium intake[30] owing to stronger health policies rather than the benefits of increasing the consumption of fruits and vegetables or PA level.

Increasing the PA level is a complex undertaking because PA is not only related to the lack of personal motivation.[31] The most frequent barriers described in the adult population are lack of time, low economic resources, low education, lack of nearby sports facilities, insecurity, difficulty to integrate a sports group, lack of motivation, lack of enthusiasm, loneliness, or lack of physically active friends.[32,33] Additionally, women report the lack of family support as well as physical appearance.[34] An important

review described the absence of clear effectiveness of the multicomponent community-wide interventions aimed to increase PA.[35] However, interventions delivered by CHWs were especially effective. In a systematic review of PA promotion by CHWs, 61.5% of the included studies reported positive results for different parameters of PA, and 72.4% were classified as having a low or moderate risk of bias.[36]

Similarly, some studies led by CHWs increased fruit and vegetable consumption. One study conducted in California tested the effect of promoting healthy eating among mothers in a family-based intervention, delivered by CHWs (*"promotores"*). The mothers in the intervention group reported an increase in daily vegetable servings (p<0.05); however, no changes were observed in fruit consumption.[37] Two other studies conducted in the U.S. found similar results.[38,39]

Interventions including CHWs show diverse results regarding body weight change. Although a randomized study was effective in reducing body weight among low-income Hispanic adults,[40] a study in which CHWs led a lifestyle behavior intervention among Latino women did not find a significant change in this outcome.[41]

This is the first randomized cluster trial conducted in a low-income, urban population in the Southern Cone of Latin America. The implementation process of the study provided several valuable lessons to the research team about how to implement a multicomponent intervention in low-resource settings. The leading role of CHWs in the intervention program was the key to success. In Argentina, CHWs are already employed in the public health system, mostly focused on infectious disease control and maternal and child health care. Part of the intervention was to redirect the CHW activities to hypertension management, through training sessions. They provided health coaching to patients and families on hypertension care and lifestyle modification, listened to patients and their family members, motivated them, and were their social support helping them overcome several of the described barriers.[42] Because CHWs are individuals from the community, with similar ethnicity, language, SES, and life experiences, their health messages for lifestyle modification are well accepted and adopted by the community and have proven to be effective.[43]

Although it is not possible to know which component of the comprehensive intervention was the most effective in achieving these results, it is worth highlighting the central role of the CHWs in the success of this intervention. CHWs were very committed to their tasks, owing to the new role of leading health care for hypertensive patients and families in their community. The high commitment probably had a significant impact on the acceptance of their messages in changing lifestyles. In addition, the involvement and support among family members to

Table 2. Effects of the Multicomponent Intervention on Behavioral Risk Factors and Body Weight

Variable	Proportion (95% CI)		p-value[a]	Adjusted proportion[b] (95% CI)		p-value[a]
	Intervention	Control		Intervention	Control	
Low intake of fruits and vegetables (<5 servings per day)			**<0.0001**			**0.0110**
At baseline	95.2 (93.8, 96.3)	98.0 (96.9, 98.7)		96.4 (94.5, 97.6)	97.0 (89.2, 99.2)	
At month 6	94.3 (93.1, 95.4)	99.1 (98.6, 99.4)		95.4 (93.9, 96.5)	99.0 (98.2, 99.5)	
At month 12	93.3 (92.0, 94.5)	99.6 (99.2, 99.8)		94.1 (92.8, 95.2)	99.7 (99.1, 99.9)	
At month 18	92.2 (90.3, 93.7)	99.8 (99.5, 99.9)		92.6 (90.7, 94.1)	99.9 (99.2, 100)	
Weekly alcohol drinking (drinks alcohol at least once in a week)			0.3075			0.7807
At baseline	34.8 (32.0, 37.8)	34.0 (31.1, 36.9)		31.0 (27.1, 35.3)	30.9 (27.2, 34.9)	
At month 6	33.0 (30.4, 35.7)	32.8 (30.1, 35.5)		29.6 (26.5, 32.9)	29.2 (26.2, 32.4)	
At month 12	31.2 (28.6, 33.9)	31.6 (28.9, 34.4)		28.2 (25.4, 31.2)	27.6 (24.8, 30.5)	
At month 18	29.5 (26.7, 32.4)	30.4 (27.6, 33.4)		26.8 (23.8, 30.0)	26.0 (23.1, 29.1)	
Current smoking			0.6321			0.7607
At baseline	20.7 (18.3, 23.3)	21.3 (18.8, 24.0)		19.4 (16.6, 22.4)	19.8 (16.9, 23.0)	
At month 6	19.9 (17.6, 22.4)	20.3 (18.1, 22.7)		18.5 (16.0, 21.2)	18.7 (16.3, 21.3)	
At month 12	19.2 (16.9, 21.6)	19.3 (17.1, 21.7)		17.6 (15.3, 20.2)	17.7 (15.5, 20.1)	
At month 18	18.4 (16.1, 21.0)	18.4 (16.0, 21.0)		16.8 (14.4, 19.4)	16.7 (14.4, 19.2)	
Low physical activity (<600 MET-minutes/ week)			**0.0002**			**0.0232**
At baseline	53.4 (50.5, 56.3)	49.6 (46.6, 52.6)		54.3 (49.9, 58.7)	52.5 (48.4, 56.5)	
At month 6	51.2 (48.7, 53.7)	50.4 (47.8, 53.1)		51.7 (48.4, 54.9)	52.4 (49.2, 55.6)	
At month 12	49.0 (46.4, 51.7)	51.3 (48.5, 54.0)		48.9 (46.1, 51.8)	52.3 (49.5, 55.2)	
At month 18	46.8 (43.7, 50.0)	52.1 (48.9, 55.3)		46.2 (43.0, 49.6)	52.2 (49.0, 55.5)	
Added salt while cooking (Almost always or always)			0.1245			0.7923
At baseline	49.0 (46.1, 51.9)	44.0 (41.1, 47.0)		41.8 (37.6, 46.1)	39.9 (36.3, 43.6)	
At month 6	44.1 (41.6, 46.5)	40.4 (37.6, 43.2)		39.7 (36.5, 42.9)	37.6 (34.5, 40.7)	
At month 12	39.2 (36.7, 41.8)	36.8 (34.1, 39.6)		37.6 (34.9, 40.4)	35.3 (32.4, 38.2)	
At month 18	34.6 (31.6, 37.7)	33.4 (30.5, 36.4)		35.5 (32.5, 38.7)	33.0 (30.1, 36.1)	
Added salt at the table (Almost always or always)			**0.0130**			0.3755
At baseline	8.6 (7.1, 10.3)	6.7 (5.3, 8.4)		5.5 (3.8, 7.8)	3.1 (1.9, 5.1)	

(continued on next page)

Table 2. Effects of the Multicomponent Intervention on Behavioral Risk Factors and Body Weight (*continued*)

Variable	Proportion (95% CI)		p-value[a]	Adjusted proportion[b] (95% CI)		p-value[a]
	Intervention	Control		Intervention	Control	
At month 6	7.4 (6.2, 8.8)	4.6 (3.7, 5.8)		5.2 (4.0, 6.8)	2.6 (1.8, 3.8)	
At month 12	6.3 (5.2, 7.8)	3.2 (2.3, 4.3)		5.0 (3.9, 6.3)	2.2 (1.5, 3.1)	
At month 18	5.4 (4.1, 7.1)	2.1 (1.4, 3.3)		4.7 (3.6, 6.2)	1.9 (1.2, 3.0)	
Added salt while cooking or at the table (Almost always or always)			0.4745			0.7273
At baseline	52.5 (49.6, 55.3)	45.4 (42.5, 48.4)		46.0 (41.7, 50.4)	40.2 (36.6, 44.0)	
At month 6	48.0 (45.5, 50.4)	41.5 (38.8, 44.3)		44.1 (40.9, 47.3)	38.0 (34.9, 41.1)	
At month 12	43.5 (40.9, 46.1)	37.7 (35.0, 40.6)		42.1 (39.4, 44.9)	35.8 (33.0, 38.7)	
At month 18	39.1 (36.0, 42.3)	34.1 (31.1, 37.2)		40.2 (37.0, 43.4)	33.7 (30.7, 36.8)	
Overweight or obesity[c]			0.3366			0.3421
At baseline	86.7 (84.1, 89.0)	85.2 (82.4, 87.5)		87.4 (84.7, 89.7)	86.3 (83.7, 88.6)	
At month 6	87.0 (84.7, 89.0)	84.9 (82.5, 87.0)		87.6 (85.2, 89.7)	86.1 (83.8, 88.1)	
At month 12	87.2 (85.0, 89.1)	84.7 (82.4, 86.7)		87.9 (85.6, 89.8)	85.8 (83.7, 87.8)	
At month 18	87.4 (85.2, 89.4)	84.5 (82.0, 86.6)		88.1 (85.7, 90.1)	85.6 (83.2, 87.7)	

Note: Boldface indicates statistical significance (*p*<0.05).
[a]*p*-value of the interaction term between time and group.
[b]Proportions were estimated from the generalized estimation equation model, which was adjusted for age, sex, history of major cardiovascular disease, history of hypercholesterolemia, alcohol drinking, physical activity, baseline BMI, and systolic blood pressure at baseline.
[c]BMI ≥25 kg/m^2.

reach the goal of changing lifestyles was very important in achieving this success.

This study used a cluster randomized trial targeting providers and patients and systematically recruited hypertensive patients and their family members to reduce selection bias.[44] Additionally, this study has some characteristics that make it original:

1. It was conducted with low-income patients.
2. Patients only received health care from the resource-limited Argentine public primary care system.
3. The intervention was led by CHWs at hypertensive patients' homes and conducted with all family members and spouses.
4. The intervention included a mobile health component as a web-based platform to deliver healthy text messages weekly.

Limitations

Changes in self-reported measures, such as dietary intake or PA, may be less reliable than objective measures. However, the focus of this study was to detect differences between baseline and follow-up. Moreover, the short International PA Questionnaire has shown good reliability (*r* =0.76)[45], and STEPS questions are used worldwide for surveillance of national and regional trends in risk factors.[46−48] In addition, brief questions to measure fruit and vegetable intake are known to provide valid measures.[49] Reporting bias may occur if people in the intervention group are biased toward their own perceptions regarding the intervention efficacy (not blinded). Blood pressure was the primary outcome that guided the design and sample size. Except for body weight, the present outcomes were not prespecified and the changes might be considered exploratory.

Some challenges arise in the interpretation of the lack of positive results on self-reported smoking, alcohol consumption, or added salt while cooking or at the table. The lack of power to detect a positive effect of the intervention cannot be excluded. The low prevalence of these outcomes at baseline and the reduction observed between baseline and 18 months in both groups (potential observer or Hawthorne effect in the control group) might conceal some small effects of the intervention.

Even though the clusters were randomized, and the recruitment of the participants and their families was systematic, the participants' consent was not, which raises the possibility of some recruitment bias reflected in the small differences observed in Table 1. To account for these baseline imbalances, statistical adjustment for important covariables was performed, thus limiting potential confounding effects. In addition, it is important to note that both groups exhibited a similar and elevated follow-up rate, limiting the potential selection bias.

CONCLUSIONS

This multicomponent family-based intervention led by CHWs was effective in increasing self-reported fruit and vegetable intake and PA level, helping to reduce blood pressure and improving the hypertension control rate among low-income hypertensive patients. The intervention did not have an effect on alcohol consumption, smoking, addition of salt while cooking or at the table, or body weight. Future studies should address the long-term effects of this multicomponent intervention to evaluate if the observed reduction in behavioral risk factors is sustainable.

These results add to previous findings that the Hypertension Control Program in Argentina is effective in reducing blood pressure and improving hypertension control among this vulnerable population.[9] This intervention could be part of any national health system package to achieve the WHO's goal of reducing the prevalence of hypertension by 25% and achieving 50% treatment of eligible individuals with drug therapy and counseling to prevent heart attacks and strokes in low-income populations.[50]

SUPPLEMENTAL MATERIAL

Supplemental materials associated with this article can be found in the online version at https://doi.org/10.1016/j.amepre.2019.05.011.

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