



Original article

A heart failure program in low-income patients in Argentina (COMM-HF)

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ABSTRACT

Objective. In low- and middle-income countries, heart failure (HF) is the leading cause of death and disability. **Materials and methods.** A feasibility study was conducted to assess the fidelity, reach, and adoption of an educational program led by non-medical staff to improve outpatient care for patients hospitalized with HF in the local public health system. **Results.** Thirty patients were included, with a mean age of 55.3 years (63.3% male). A total of 97.3% of planned home visits and 90% of scheduled phone calls were completed. Counselling modules were delivered during 90.4% of home visits, with no significant challenges reported during implementation. At the end of follow-up, there was a trend towards improved lifestyle habits, a reduction in mean heart rate (78.0 to 68.3 beats per minute; $p = 0.016$), a decrease in the proportion of patients in NYHA functional class III (20% to 7.4%; $p = 0.041$), and a slight reduction in mean body mass index (29.5 vs. 28.9; $p = 0.042$). **Conclusions.** A home-based educational program, designed to optimize outpatient management of heart failure and led by non-medical healthcare personnel, was well-received and demonstrated feasibility for implementation in low-income patients relying solely on the Argentine public health system.

Keywords: Heart Failure; Community Health Workers; Implementation Science; Ambulatory Care; Treatment Adherence and Compliance; Argentina (Source: MeSH-NLM).

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Conflicts of interest

The authors declare no conflict of interest.

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RESUMEN

Programa de insuficiencia cardíaca en pacientes de bajos ingresos en Argentina (COMM-HF)

Objetivo. En los países de ingresos bajos y medianos la insuficiencia cardíaca (IC) es la principal causa de muerte y discapacidad. **Materiales y métodos.** Se desarrolló un estudio de factibilidad para evaluar la fidelidad, alcance y adopción de un programa educativo liderado por personal no médico para mejorar la atención ambulatoria en pacientes hospitalizados por IC en el sistema de salud público local. **Resultados.** Se incluyeron treinta pacientes con una edad media de 55,3 años, (varones: 63,3%). Se realizaron el 97,3% de las visitas domiciliarias y el 90% de las llamadas telefónicas planificadas. Se implementaron los módulos de consejería en el 90,4% de las visitas en el hogar y no se reportaron dificultades relevantes durante la implementación de estos. Al final del seguimiento se observó una tendencia a la mejoría de los estilos de vida, reducción en la frecuencia cardíaca media (78,0 a 68,3 latidos por minuto; $p = 0,016$), reducción en la proporción de pacientes en clase funcional III de la NYHA (20% a 7,4%; $p = 0,041$) y una ligera reducción en la media del índice de masa corporal (29,5 vs. 28,9; $p = 0,042$). **Conclusiones.** Un programa educativo domiciliario, diseñado para optimizar el manejo ambulatorio de la insuficiencia cardíaca y liderado por personal de salud no médico, tuvo buena aceptación y demostró ser factible de implementar en pacientes de bajos ingresos que cuentan exclusivamente con la cobertura del sistema de salud público argentino.

Palabras clave: Insuficiencia Cardíaca; Agentes Comunitarios de Salud; Ciencia de la Implementación; Atención Ambulatoria; Cumplimiento y Adherencia al Tratamiento; Argentina (Fuente: DeCS-BIREME).

Introduction

Heart failure (HF) remains the foremost cause of death and disability not only in low- and middle-income countries (LMICs) but also in high-income countries (HIC), affecting approximately 26 million people worldwide.⁽¹⁻⁴⁾ Despite advances in treatments, the burden of HF for health systems is still high, with elevated rates of hospitalizations, readmissions and mortality following acute HF admission.⁽⁵⁾ In Argentina, the risk of death is 5-10% in patients with mild symptoms and increases to 40% in those with at least one hospitalization. The main cause of decompensation in our country is the lack of access to medication or not respecting dietary hygiene measures.⁽⁶⁾

Patients and patients' families' low awareness of symptoms associated with HF and prognosis, delay in medical consultation and diagnosis, inappropriate medical treatment, lack of adherence to prescribed therapy, difficulties in access/low attendance rate to follow-up visits, and lack of collaboration across health care settings, have been cited as factors that contribute to adverse outcomes after discharge for acute HF.⁽⁷⁾ These barriers are higher in LMIC due to the large disparities in screening, diagnosis, treatment, and monitoring of patients across all settings.⁽⁸⁾

Patient-centered HF interventions have been shown to reduce symptom burden, improve health-related quality of life, reduce readmission rates, and enhance patient engagement.⁽⁹⁾ Furthermore, the promotion of shared decision-making with patients,⁽¹⁰⁾ the improvement of treatment adherence⁽¹¹⁾ and the involvement of the family have been shown to influence patients' success and stability of their behavior change in self-health care programs.⁽¹²⁻¹⁴⁾

Disease management programs to improve the transition process from in-hospital to home care have shown to reduce readmissions and mortality in HF patients in HICs.⁽¹⁵⁻¹⁸⁾ However, limited studies have been conducted for HF patients after discharge for an acute HF event in LMICs⁽¹⁹⁻²⁵⁾ and none have implemented the prevention strategies in patients' households.

Home visit disease management programs implemented through non-physician health workers (NPHWs) (i.e., the Heart Outcomes Prevention and Evaluation 4; HOPE-4), were found to be effective in improving cardiovascular disease outcomes compared with current strategies that are typically physician based.⁽²⁶⁾

The main objectives of the study were: i) to adapt a multi-component program, proven effective in improving outpatient care for hospitalized patients with CHF, to the local public healthcare system, and ii) to evaluate its acceptability, reach, and adoption, as well as to explore changes in clinical outcomes post-intervention.

Materials and methods

Study design

We conducted a non-controlled, before-and-after, non-randomized feasibility study, employing a consecutive convenience sampling method to enroll 30 successive patients

who were hospitalized for decompensated HF. Data collection occurred both before the intervention (baseline visit) and at the conclusion of the follow-up period. The intervention consisted of counseling sessions focused on HF ambulatory management, administered by a team of nurses. This intervention included an initial visit prior to hospital discharge, followed by five home visits and five telephone calls distributed over a five-month follow-up period.

Study population

We recruited 30 consecutive patients after hospitalization for decompensated HF. The participants were selected from a local public hospital (San Juan de Dios) serving the urban community of La Plata city, Buenos Aires province, Argentina. La Plata has a total surface area of 926 km² and 719,013 inhabitants.⁽²⁷⁾ Eligible participants aged ≥ 18 years and living with family or having caregivers. The inclusion criteria primarily focused on the presence of HF symptoms and a recent hospitalization due to HF. Patients with any left ventricular ejection fraction (LVEF) were eligible for inclusion. The LVEF was determined using two-dimensional echocardiography and calculated by the Simpson method.⁽²⁸⁾ The exclusion criteria were patients with mental disability that would impair their participation in this study, any clinical condition that affects the prognosis of life in the next 12 months, chronic HF in New York Heart Association (NYHA) functional class IV (as in public health system of the province of Buenos Aires they usually remain hospitalized due to the absence of outpatient care systems), patients who plan to move during the implementation of the study or live outside the study area hospital coverage and pregnant women.

The day before hospital discharge, the data collection personnel (independent of the intervention personnel) conducted the screening visit to confirm patients' eligibility and those who meet the inclusion criteria were invited to participate in the study. Laboratory results were not required to initiate follow-up, given the limited resources available at the hospital. After accepting and consenting, they collected the baseline data.

Intervention

Program adaptation

We adapted the program from the HOPE 4 study and the one developed by the World Health Organization (WHO)⁽²⁹⁾ following the new version of the "Framework for Reporting Adaptations and Modifications-Expanded (FRAME)".⁽³⁰⁾ We adapted the content of the training materials for decompensated HF patients using specific tools developed by the World Heart Federation (WHF). Roadmap, which are available in Spanish, and the HF guidelines developed by the European Society of Cardiology in collaboration with the HF Association.⁽⁶⁾

The delivery of the intervention was also adapted to relevant local contextual factors. A pilot assessment of the adapted tools was conducted to assess suitability prior to implementation (planned adaptation). The training sessions were conducted by local study investigators. Two nurses were evaluated on the standardized study procedures and certified at the end of the training program.

Program components

The program provided the participants with a digital scale, a pill box and a booklet containing educational material for the care of patients with HF (clinical control form (blood pressure [BP], heart rate and weight), warning signs and symptoms, and recommended lifestyles). The intervention was delivered by nurses ($n = 2$) to patients and their caregivers (family or a nominated friend). They conducted the initial visit prior to hospital discharge and five home visits, and five telephone calls distributed over the 5-month follow-up. Nurses provided counseling sessions about the importance of HF ambulatory management, such as adherence to drug treatment, adopting lifestyle recommendations, daily control of body weight, heart rate and BP, immunization and recognition of early signs of decompensation.⁽³¹⁾ The visit lasted approximately 45 minutes on average. Nurses were under the supervision of physicians and used simplified management algorithms. They were also trained to act as a liaison between patients and healthcare facilities in the case of detecting HF decompensation.

Study outcomes

Primary outcomes

a) reach, fidelity, and adoption

To measure the reach, we collected data on age, sex, educational level, comorbidities, level of employment, and health coverage. To measure the degree of fidelity and adoption of the multicomponent intervention, we assessed the proportion (%) of personnel in charge of the intervention who completed the training sessions and were certified, % of face-to-face visits scheduled and carried out to eligible participants, % of telephone interviews planned and conducted, % of educational sessions planned and provided to eligible participants, and number of family members/caregivers attending the scheduled home visit.

b) acceptability

We measured acceptability in three dimensions: i) level of acceptance of the intervention in the study personnel; ii) treatment acceptability and preference; and iii) barriers, facilitators, and contextual factors related to the implementation of the intervention in health providers.

Secondary outcomes

Level of adherence to medical treatment in patients with HF, readmissions for HF or death, health-related quality of life (HRQOL), physical activity in leisure time and active transportation, adding salt when cooking and at the table, consumption high sodium foods, alcohol intake, smoking status, NYHA functional class, BP, heart rate and body weight. BP and heart rate were assessed with participants seated, feet flat on the floor, back supported, and arms resting on a surface at heart level. Body weight was measured using a calibrated

digital scale, with participants wearing light clothing and no shoes. All measurements were taken in duplicate, and the average values were used for analysis to minimize variability. Moreover, the etiology of HF was determined based on information extracted from the medical records of the patients, which included documented clinical diagnoses, imaging studies, and other relevant data recorded by the treating physicians.

Data collection

The data collection process was carried out in two stages: prior to the start of the intervention (baseline visit) and at the end of follow-up. During the baseline visit, brief information on socioeconomic variables, medical history, drug treatment, salt and alcohol intake, and other indicators was collected using standardized questionnaires specially developed for this study. Physical activity in leisure time was assessed using the International Physical Activity Questionnaire (IPAQ). The questionnaire asked about frequency (days per week) and duration (minutes per day) of moderate and vigorous intensity activities in the last 7 days in leisure time and active transportation (walking and bicycling) domains. Only activities performed for 10 or more minutes were included in the calculation.⁽³²⁾

Treatment acceptability was measured with the Treatment Acceptability and Preference Questionnaire (TAPQ). The questionnaire is built on two constructs: perceptions about therapists and perceptions about therapy. Each domain is scored between 0 and 20, therefore the maximum total score is 40. The higher the score, the greater the satisfaction with the treatment.

Locally validated versions of the 12-Item Short Form Health Survey (SF-12) were used to measure health-related quality of life.⁽³³⁾ The eight health domains assessed by the SF-12 may be aggregated into two summary measures, the Physical Component Summary (PCS-12) and the Mental Component Summary (MCS-12), applying a scoring algorithm.⁽³⁴⁾

Adherence was assessed with the Spanish version of the Simplified Medication Adherence Questionnaire (SMAQ).⁽³⁵⁾ *This questionnaire consists of six questions that evaluate different aspects of patient compliance with treatment: forgetfulness, routine, adverse effects, and a quantification of omissions. A patient is classified as non-compliant if they respond to any of the questions with a non-adherence answer, and in terms of quantification, if the patient has lost more than two doses during the last week or has not taken medication during more than two complete days during the last three months. This questionnaire was validated in Spanish.*⁽³⁶⁾

Salt added when cooking and at the table and consumption of high sodium foods were assessed using simple questions with a 4-category answer format (always, frequently, sometimes, and never). Alcohol intake was assessed through the following questions: Do you drink alcoholic beverages? How many days per week do you consume alcohol? On those days that you consume, how many cups, cans or drinks do you have on average?

For the collection of qualitative data, trained personnel carrying out in-depth interviews collect data on the acceptability of the strategy in two nurses and two physicians in charge of implementing the study. Data on the barriers, facilitators and

contextual factors that have affected the implementation of the intervention were collected using semi-structured interview guides in all providers in the study. All the interviews were carried out with at least one of the participants in the study. Mostly individually, but some of them were in groups. The interviews lasted over thirty minutes each and took place in the hospital building. Qualitative data was collected prior to the start of providers and at the end of the study.

Statistical analysis

For quantitative analysis, descriptive statistics were used to summarize the general characteristics of the study population. Continuous variables were assessed for normality using the Shapiro-Wilk test. Variables following a normal distribution are presented as means with standard deviations (SD), while those that did not follow a normal distribution are presented as medians with interquartile ranges (IQR). Categorical variables are presented as counts and proportions. The statistical test used for comparisons was McNemar's test for paired categorical data and the paired t-test for normally distributed continuous variables. For non-normally distributed continuous variables, the Wilcoxon signed-rank test was applied. These tests were chosen to account for the within-subject autocorrelation inherent to the before-and-after study design.

The study outcomes, process indicators using the RE-AIM framework.⁽³⁷⁾ Statistical analyses were performed using STATA version 12.0 (Stata Corp., College Station, TX, USA). For the qualitative analysis, written transcripts of the interviews were classified and then codified according to the study objectives. The written transcripts were entered into ATLAS.ti version 7 software (ATLAS.ti Scientific Software Development GmbH) combined with the manual technique of information coding. Analytical dimensions were identified as constructs for the description of findings. The analytical dimensions identified were: i) acceptability and perceived benefits of the intervention; ii) implementation challenges and contextual barriers; and iii) opportunities for improvement and system-level gaps. Finally, data were abstracted and interpreted through content analysis.

Ethical aspects

This study was reviewed and approved by the Institutional Review Board of the Institutional Research Ethics Committee "Comité de Ética en Investigación Hospital San Martín de La Plata CEI-HSMLP" (HSMLP2020/0035). Participation in the study was voluntary. All participants signed an informed consent form, and the confidentiality of the information was guaranteed.

Results

Thirty consecutive patients were included in the study and received the intervention at home. The recruitment phase lasted 5 months (from January to May 2021). During the follow-up, 3 deaths occurred, and the rest of the participants completed

the study according to the protocol (Figure 1). The mean age of the study population was 55.3 years, constituted mostly by men (63.3%) with a low level of education (46.7% with primary education level or less) and a low proportion of active workers (66.7% unemployed, retired or homemakers) (Table 1).

The median household distance to the hospital was 25.7 km (range: 1.7-27.2 km). The median of household members was 3 and 96.7% of households were classified as poor according to the National Statistics and Census Institute. All participants (100%) were treated with beta blockers and angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, 86.7% with hydrochlorothiazide or furosemide and 56.7% with spironolactone or eplerenone. LVEF was mostly reduced (76.7%) with a mean LVEF of 31.8 (± 6.8). The two more frequent etiologies of cardiomyopathies were ischemic (40%) and valvular (16.7%). 73.3% of participants had hypertension, 30% diabetes, 26.7% were overweight and 46.7% were obese and 23.3% had atrial fibrillation (Table 1).

Feasibility outcomes and process indicators

All the study personnel (100%) attended the training session and were certified to conduct the present study. 97.3% of the planned household visits and 90% of the planned telephone calls were conducted. In patients' households, control of pillbox use, control of body weight registration, review of alarm signs and symptoms, and counseling session modules were implemented in 90.4% of visits (Table 2).

The counseling sessions most frequently requested by patients and household members were drug treatment, control of body weight, diet, self-healthcare and physical activity. Moderate attendance of family members/caregivers to the counseling sessions was observed, since only 58.3% of the sessions were provided only to the participant. Interestingly, the intervention personnel did not report lack of time, lack of patient interest or difficulties understanding the concepts during the implementation of the HF program. The level of

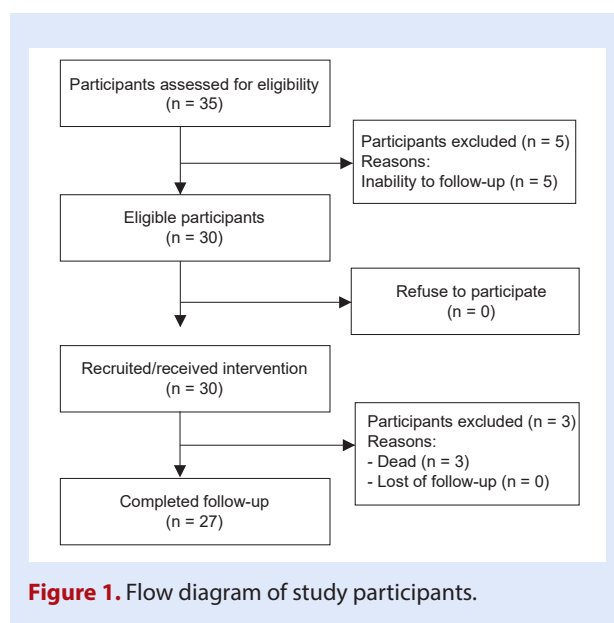


Figure 1. Flow diagram of study participants.

Table 1. Baseline characteristics of the study population (n = 30).

Characteristics	n (%)
Age, mean (SD), years	55.3 (±12.4)
Male sex	19 (63.3)
Primary school or less	14 (46.7)
Unemployed / Retired / Homemaker	20 (66.7)
Household members, median (IQR)	3 (2-4)
Household at poverty level*	29 (96.7)
Medication at baseline	
Hydrochlorothiazide/ Furosemide	26 (86.7)
Angiotensin-converting enzyme inhibitors	16 (53.3)
Angiotensin receptor blockers	9 (30.0)
Beta-blockers	30 (100.0)
Spironolactone/Eplerenone	17 (56.7)
Sacubitril-Valsartan	1 (3.3)
Amiodarone/ Flecainide/ Disopyramide	2 (6.6)
Calcium channel blockers	1 (3.3)
Left ventricular ejection fraction (LVEF)	
Preserved	5 (16.7)
LVEF, %, Mean (SD)	58.6 (±11.4)
Intermediate	2 (6.6)
LVEF, %, Mean (SD)	47 (±0.0)
Reduced	23 (76.7)
LVEF, %, Mean (SD)	31.8 (±6.8)
Etiology	
Ischemic	12 (40.0)
Valvular	5 (16.6)
Hypertensive	1 (3.3)
Genetic	1 (3.3)
Chagas disease	1 (3.3)
Idiopathic	3 (1)
Unknown	3 (1)
Other†	4 (13.0)
Comorbidities	
Diabetes mellitus**	9 (30.0)
Hypertension***	22 (73.3)
Overweight‡	8 (26.7)
Obesity†	14 (46.7)
Atrial fibrillation	7 (23.3)
Thyroid disorders	3 (9.9)
COPD	2 (6.6)
Renal insufficiency	2 (6.6)

SD: standard deviation; IQR: interquartile range; BP: blood pressure; LVEF: left ventricular ejection fraction; COPD: Chronic obstructive pulmonary disease.

*total monthly household income lower than the monthly cost to cover the living expenses of a household with 3 members.

**diagnosis of diabetes in medical records or under drug treatment at baseline for diabetes control.

***participants with blood pressure values $\geq 140/90$ mmHg or diagnosis of hypertension in medical records.

‡body mass index 25 to 29.

†body mass index ≥ 30 .

‡ Peripartum myocardiopathy, Amyloidosis, Myocarditis.

Table 2. Feasibility outcomes and process indicators.

Component	n (%)
Training	
Nurses with complete training session	2/2 (100)
Data collection personnel with complete training session	2/2 (100)
Household	
Home visits conducted/planned	146/150 (97.3)
100% (5 visits)	27/30 (90.0)
80% (4 visits)	2/30 (6.7)
60% (3 visits)	1/30 (3.3)
Control of pillbox use	132/146 (90.4)
Control of body weight registration	132/146 (90.4)
Review of alarm signs and symptoms	132/146 (90.4)
Counseling session implemented	132/146 (90.4)
Drug treatment	130
Control of body weight	130
Diet	127
Self-healthcare	124
Physical activity	124
Smoke	120
Alcohol consumption	117
Psychological aspects	116
Immunization	114
Etiology and prognosis of heart failure	77
Sexual health	25
Family members/caregivers present at the counseling session, %	
0	77 (58.3)
1	50 (37.9)
2	5 (3.8)
Inconvenience during home program implementation	
Lack of time during the household visit	0/146 (0.0)
Lack of patient interest	0/146 (0.0)
Difficulties understanding the concepts provided	0/146 (0.0)
Telephone contact	
Telephone contact implemented	135/150 (90.0)
Reason for non-implementation	
Reason 1 - No answer phone	8
Reason 2 - Hospitalization	1

vs. 22.2%; $p=0.319$), but a trend to reduce active transportation (16.7% vs. 11.1%; $p=0.137$). On the contrary, although it does not reach statistical significance, it was observed an increase in the proportion of patients who reported not adding salt when cooking (46.7% to 67.7%; $p=0.827$) or at the table (66.7% to 77.8%; $p=0.563$), not consuming high sodium foods (30% to 63%; $p=0.624$), and a reduction in smoking status (13.3% to 3.7%; $p=0.624$) and alcohol intake (1.8 to 0.6 drinks/week; $p=0.789$).

Among the clinical outcomes, we observed a reduction in the mean heart rate (78.0 to 68.3 beats/minutes; $p=0.016$), a reduction in the proportion of patients in NYHA Functional class III (20% to 7.4%; $p=0.041$) and a slight reduction in body weight (mean: 29.5 kg vs. 28.9 kg; $p=0.042$). High adherence to drug treatment was observed both at baseline and at follow-up, with no significant differences between them (83.3% and 85.2%; $p=0.888$). The quality of life showed no changes in the mental or physical component at the end of the study. During the follow-

treatment acceptability and preference was good (total score 29/40) (**Table 2**).

Behavioral and clinical indicators

The behavioral and clinical outcomes are shown in **Table 3**. A low level of physical activity (PA) was observed at the beginning of the study. When we compared baseline and follow up outcomes, we observed no changes in the PA conducted in leisure time (23.3%

Table 3. Behavioral and clinical indicators.

Indicator	Baseline	Follow-up	p-value*
	n (%)	n (%)	
Total	30	27	
Physical activity in Leisure Time	7 (23.3)	6 (22.2)	0.319
Physical activity in Active Transportation	5 (16.7)	3 (11.1)	0.137
Adding salt when cooking, %			
Never	14 (46.7)	18 (67.7)	0.827
Sometimes	10 (33.3)	8 (29.6)	
Frequently	4 (13.3)	1 (3.7)	
Always	2 (6.7)	0 (0.0)	
Added salt at the table, %			
Never	20 (66.7)	21 (77.8)	0.563
Sometimes	8 (26.7)	6 (22.2)	
Frequently	2 (6.6)	0 (0.0)	
Always	0 (0.0)	0 (0.0)	
Consumption high sodium foods (cold cuts, canned foods, cheeses, bread, pizza), %			
Never	9 (30.0)	17 (63.0)	0.624
Sometimes	14 (46.7)	8 (29.6)	
Frequently	7 (23.3)	2 (7.4)	
Always	0 (0.0)	0 (0.0)	
Alcohol intake, drinks/week, mean (SD)	0.4 (±1.8)	0.1 (±0.6)	0.789
Current smoker, n (%)	4 (13.3)	1 (3.7)	0.207
Systolic BP, mean (SD), mmHg	117.8 (±18.3)	121.0 (±21.1)	0.509
Diastolic BP, mean (SD), mmHg	83.2 (±24.6)	74.5 (±12.5)	0.435
Heart rate, mean (SD), beats/minutes	78.0 (±13.4)	68.3 (±7.0)	0.016
Body weight, mean (SD), Kg	29.5 (±7.2)	28.9 (±6.3)	0.042
NYHA Functional class			
I	16 (53.3)	18 (66.7)	0.041
II	8 (26.7)	7 (25.9)	
III	6 (20.0)	2 (7.4)	
Treatment acceptability and preference score, mean (SD)	NA	29.6 (±4.5)	NA
Quality of life, physical component mean (SD)	42.4 (±9.4)	41.2 (±10.5)	0.525
Quality of life, mental component mean (SD)	49.8 (±11.1)	50.6 (±8.8)	0.751
Adherent to drug treatment	25 (83.3)	23 (85.2)	0.888
Deaths	-	3	NA

SD: standard deviation; NYHA: New York Heart Association; BP: blood pressure; NA: does not apply.

* McNemar's test was used for paired categorical data and the paired t-test for normally distributed continuous variables.

up phase, 3 patients died. The causes identified were pneumonia secondary to COVID-19 and two episodes of progression of patients' advanced HF.

Qualitative results

i) acceptability and perceived benefits of the intervention

Nurses and physicians expressed a positive perception of the intervention, highlighting its potential to improve adherence to the HF program and reduce hospital readmissions in underserved communities. These communities face significant barriers to healthcare access, such as low income, unemployment, limited

education, inadequate public transportation, insecurity, and poorly maintained infrastructure. The intervention also improved teamwork and communication among clinical staff. Nurses were particularly enthusiastic about their expanded role in patient care, viewing household visits as a critical component for building closer relationships with patients. As one nurse noted, "The relationship became closer with the entire health team, more content, providing more care," while another added, "Patients take responsibility for care, improved self-care." Physicians similarly emphasized the value of household visits in low-income communities, with one stating, "The physical presence of a trained nurse was definitely a huge benefit for the patients, there is no doubt."

ii) implementation challenges and contextual barriers

Despite the positive reception, several challenges to implementation were identified, particularly in low-resource settings. Physicians raised concerns about the feasibility of sustaining the intervention in the context of the public healthcare system, citing budget constraints and systemic fragmentation. As one physician explained, *"The implementation of the study in the future is quite a challenge, due to the lack of budget and fragmentation of the public system."* They suggested alternative approaches, such as leveraging telemedicine or digital platforms, as potentially more viable options for resource-constrained settings.

iii) opportunities for improvement and system-level gaps

Both nurses and physicians identified areas for improvement to enhance the intervention's effectiveness. Physicians recommended expanding training sessions for nurses prior to the study's implementation, particularly focusing on patient evaluation skills. Additionally, participants highlighted systemic gaps, such as the lack of access to essential medications for very low-income patients. Nurses reported that patients frequently struggled to obtain their prescribed medications, an issue that the study was unable to address adequately. Physicians emphasized that resolving this gap falls beyond the scope of clinical research, calling for provincial health authorities to improve logistics and ensure timely medication provision for underserved populations.

Discussion

Our results showed that the proposed multicomponent intervention was feasible and well accepted in improving the management of patients after hospitalization for decompensated HF in a public hospital providing health care to low-income patients in Argentina. We must emphasize that this study was conducted during the COVID-19 pandemic, which imposed significant challenges on the study personnel, setting it apart from any previous research endeavors.

Besides the mentioned epidemiological context, high-level fidelity and adoption of the intervention were observed, since nurses were able to implement 97.3% of the planned home visits, provided the planned intervention (pillbox use, body weight registration, alarm signs/ symptoms and counseling sessions) in 90.4% of visits and completed the telephone interview in 90% of cases. As a result of the comprehensive approach of the study, we found an improvement in patients' behaviors since 9.6% quit smoking, 21% eliminated the addition of salt when cooking, 11.1% the salt at the table, and 33.3% the consumption of high sodium foods.

High levels of adherence to pharmacological treatment and low alcohol consumption were observed throughout the study. However, there was no significant impact on physical activity. It is important to note that during this period, the country was in

phases 1-2 of social, preventive, and mandatory isolation due to the COVID-19 pandemic.⁽³⁸⁾ Additionally, patients were just beginning to access the first dose of their vaccination scheme, resulting in restricted outings.

The mentioned changes in patient's behaviors impacted clinical outcomes since patients improved their functional capacity (FC) according to the classification of the NYHA (12.6% reduction in FC III), reduced the heart rate (10.5 beats/minute), and reduced body weight during the follow-up (29.5 kg to 28.9 kg). The quality of life showed no changes in the mental (score: 51 points) or physical (score: 41 points) components at the end of the study but was significantly lower compared to the general population of Argentina (53 to 56 points and 49 to 50 points, respectively).⁽³⁹⁾

The population included in the present study was younger (mean: 55.3 years) than the ones included in two Argentine registries, the OFFICE-IC⁽⁴⁰⁾ (mean: 65.8 years) and the ARGEN-IC (mean: 72.2 years).⁽⁴¹⁾ The level of education was very low since 46% had only primary education or no formal educational level, which conditioned the reading of medical indications without the assistance of any member of the health staff. The high proportion of unemployed patients (66%) may also constitute a significant barrier to access to pharmacological treatment.⁽⁴²⁾ Home visits followed by telephone contacts, the provision of a digital scale, a pill box, and education sessions, contributed greatly to overcoming the aforementioned barriers.

Regarding the clinical characteristics of the study population, the prevalence of hypertension, diabetes, overweight and obesity was high, according to other national and international publications.^(43,44) The proportion of participants with preserved ejection fraction (HFpEF), mildly reduced ejection fraction (HFmrEF) and reduced ejection fraction (HFrEF) are like the ones observed in other studies.^(45,46) The high proportion of patients with valvular etiology (16.7%) could be justified by the impact of rheumatic disease, still predominant in countries undergoing demographic transition.⁽⁴⁷⁾ The prevalence of atrial fibrillation, one of the most frequent comorbidities caused by numerous hospitalizations, was lower (23.3%) than the usual prevalence in chronic HF (approximately 30%). This finding could be justified by the low proportion of thyroid disorders in the selected sample. Finally, the total mortality was 10% (3 patients) in the follow-up period. The causes identified, and the prevalence were in line with other international publications.⁽⁴⁸⁾

The level of adherence to pharmacological treatment was high throughout the study, since 83.3% of participants at baseline and 85.2% at the end of the study were classified as adherent. This prevalence was unusually high, since the usual level of adherence observed in the general population with similar sociodemographic characteristics attending the public health care system in Argentina is significantly lower (28% to 38%).⁽⁴⁹⁾ Possible explanations for this finding are the participation bias in the study that generates closer health care and courtesy bias. It is important to mention that the performance of the instrument used to assess adherence is unknown, since to our knowledge it had not been previously used in HF patients.

The drugs prescribed or acquired (accessibility to drug treatment) were suboptimal, because although 100% were under treatment with beta-blockers, only 86.9% were under treatment

with angiotensin-converting enzyme inhibitors or angiotensin receptor blockers or neprilysin receptor antagonists, 56.7% used mineralocorticoid receptor blockers and no patients was under treatment with sodium-glucose co-transporter 2 inhibitors.⁽⁵⁰⁾ The difficulty in accessing these treatments in the public care system and their high cost threaten the fulfillment of these objectives. On the contrary, 86.7% of the patients were under treatment with hydrochlorothiazide or furosemide, drugs with a lower cost but without impact on the mentioned outcomes.⁽⁵¹⁾

The barriers to accessibility to health services and, therefore, to the prevention, diagnosis, treatment and rehabilitation of patients in other communities have been adequately described. In addition, the geographical distance (25.7 km) from the patients' homes to the hospital and the low socioeconomic status significantly influence their accessibility to the different pharmacological treatments.^(52,53)

Several international studies have also implemented home care programs for patients with chronic HF and demonstrated to improve ventricular function and reduce readmissions and mortality from any cause.⁽⁵⁴⁾ In Argentina, the DIAL study was an important multicenter randomized trial (1,518 participants) that implemented a telephone-based intervention focused on monitoring the ambulatory clinical status and providing education to HF patients, showing to be effective in reducing the incidence of hospitalizations for HF and other cardiovascular causes.⁽¹²⁾ There are several noteworthy differences between the two studies. The DIAL study specifically targeted participants who were part of a national multicenter chronic HF registry in Argentina and were receiving optimal medical treatment at the beginning of the study. This indicates that these participants were in a relatively better condition, with respect to economic resources and accessibility to health care and treatments.

The intervention proposed by the present study included strategies especially effective for low-income and low-educated populations. The home visits approach, the provision of a digital scale, a pillbox, and education sessions to patients and family members⁽⁸⁾ strongly contributed to improving adherence to medical recommendations and to overcome the accessibility to health care barriers.

The strengths of this study lie in the fact that: i) it demonstrated the potential benefits of including nurses with a more relevant role in the ambulatory management of HF patients belonging to low-income communities; ii) it generated data to inform the design and implementation of this low-cost intervention at a larger scale; and iii) the qualitative data analysis allowed to understand this study proposed strategy better, and to consider the positive and negative experiences of the intervention, identify opportunities to improve implementation strategies, and understand the contributions to health care practices.

Some limitations of the study should be mentioned. First, sampling was not random; therefore, the results cannot be extrapolated to the reference population of the hospital. In addition, the low number of participants and the lack of a control group do not allow ensuring a causal relationship of the intervention with the behavioral and clinical benefits observed in the study. Second, clinical measurements data (BP, weight, and height), although performed using standardized procedures,

may carry some measurement error since many homes did not present the ideal conditions to carry them out. However, random errors do not have any consistent effects across the sample and are valuable as they describe the ambulatory patient status. Finally, interviewer bias might have influenced participants' responses, potentially reflecting the interviewers' expectations rather than the participants' authentic perspectives. Likewise, social desirability bias could have prompted participants to give socially acceptable responses, leading to overreporting of positive behaviors and underreporting of negative ones. However, the risk of these biases is likely minimal, as the interviewers underwent thorough training to employ neutral questioning techniques and adhered to a semi-structured interview guide to maintain consistency and reduce influence.

Public health implications

The study contributed to the sustainable development goals proposed by the WHF, which promotes the development of national policies and health systems approaches through the adoption of the WHF Roadmaps initiative.

In alignment with the United Nations' goals, the study made a significant contribution to reducing premature CVD mortality caused by non-communicable diseases through prevention and treatment (Goal 3.4), as well as improving universal health coverage (Goal 3.8).⁽⁵⁵⁾

The implementation of this type of strategies in the public health care system in LMICs is a great challenge since it requires strong political decision, an important budget, interdisciplinary management and the permanence of the program over time to later obtain the reduction of the morbidity, mortality and costs associated with heart failure.

In conclusion, the proposed nurse-led intervention was feasible and well accepted in improving the ambulatory management of HF in low-income patients covered by the public health system in Argentina. Nurses should have a more relevant role in the clinical management of HF patients after hospital discharge, since it stimulates teamwork among medical staff, and improves quality of care.

Author's Contributions

RP: Conceptualization, Methodology, Writing, Project Administration and Original Draft Preparation, Supervision. **LMO, NR and MJM:** Implementation of the study, Review & Editing; **LMB:** Training, Methodology, Writing. **LG:** Formal Analysis and Data Curation. **JM, JPL-L, EC-V, MJ, TA, AB, GC, ASB,** Conceptualization, Review & Editing; **VI:** Resources, Review & Editing. **JMB, MM** implementation of the study, writing - Review & Editing and **DFE:** Supervision and coordination of the study, Validation, Writing - Review & Editing.

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