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Telehealth In Latin America: A Look At The Studies Registered In Clinicaltrials.Gov

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Abstract

The characteristics and trends of telehealth research in Latin America, especially randomized controlled clinical trials, have been little explored. The objective of this work was to characterize the studies registered in clinicaltrials.gov on telehealth in Latin America. A descriptive study was carried out where research on telehealth in Latin America registered until 2018 in clinicaltrials.gov was evaluated. The type of study related to disease or topic, country, initiative and type of institution was evaluated. 37 registered jobs were located. Those referring to telehealth were mainly parallel assignment type controlled trials (81.1%). The most addressed diseases were: high blood pressure (23.9%), diabetes (11.3%) and cardiovascular diseases (9.9%). 64.9% of the works were of local initiative, in which Brazil (29.3%) and Argentina (14.6%) were the countries with the highest number of investigations. In conclusion, there is a low number of Latin American studies registered in clinicaltrials.gov, which focused mainly on chronic diseases and were developed by local initiative. More randomized controlled clinical trials on telehealth in the Latin American context are required to help consolidate its development.

Keywords: Telemedicine; Latin America; clinical trials; cohort studies

ABSTRACT

The characteristics and trends of telehealth research in Latin America, especially clinical trials, have been little explored. The objective was to characterize the studies registered in clinicaltrials.gov about telehealth in Latin America. We performed an observational and descriptive study and evaluated the telehealth research in Latin America registered until 2018 in clinicaltrials.gov. The type of study, disease, country, initiative and type of institution were evaluated. We found 37 studies registered. The studies on telehealth were mainly clinical trials of parallel assignment type (81.1%). The most discussed diseases were: arterial hypertension (23.9%), diabetes (11.3%) and cardiovascular diseases (9.9%). The 64.9% of the works were local initiatives, with Brazil (29.3%) and Argentina (14.6%) being the countries with the highest number of investigations. In conclusion, there is a low number of Latin American studies registered in clinicaltrials.gov, the studies focused mainly on chronic diseases and were developed by local initiative. We need more clinical trials on telehealth in the Latin American context to help to consolidate its development.

Keywords: Telemedicine; Latin America; clinical trial; cohort studies

INTRODUCTION

Telehealth has been defined as the use of medical information that is exchanged from one place to another through electronic communication - information and communication technologies (ICT) - with the aim of improving health care. [1] Telehealth is used as a strategy to increase accessibility to health services for the population residing in remote locations, improve the quality of care through training and decision-making support for professionals located in rural areas, and increase the efficiency of health services to optimize resources and reduce costs. [2] Telehealth is already public policy in Europe, the Americas, Asia and

Africa. However, there are variations regarding its implementation and development. [2]

Doctors are unevenly distributed in practically all Latin American countries; This represents limited access to health services. [3] Telehealth can address such challenges, which is why it is expanding in Latin America, but its widespread and sustainable use has not yet been consolidated on a national and regional scale, due to legal, financial, technological, organizational and human factors. . [3] This highlights the need to strengthen the implementation and scalability of telehealth programs supported by solid recommendations based on scientific evidence that seek to ensure their sustainability.

Randomized controlled clinical trials (RCTs) are the standard for establishing intervention effectiveness in health care delivery, although they may be limited in their generalizability and unable to explain intervention adaptations or factors that may influence on results in different contexts and for different populations. [1] Telehealth research requires appropriate methodological designs [1,4] that serve as a substrate for systematic reviews that support decisions in telehealth services. [5] These designs include cluster trials, pragmatic trials, adaptive trials, factorial designs, and stepping wedge designs. [1,4] On the other hand, observational research in telehealth is the most abundant, as in the rest of biomedical research, although observational studies present methodological limitations that generate biases and confusion factors, which means that causal inferences are not can be reliably extracted. [6]

The characteristics and trends of telehealth research in Latin America, especially controlled clinical trials, have been little studied. [7] Understanding the current situation of telehealth research is important for the construction of evidence-based

health informatics, and consequently for decision making. Abstract information on controlled trials can be accessed from several international trial registries available online. [8] One of the most recognized international registries is clinicaltrials.gov, [9] which currently contains information from almost 270,000 studies in more than 200 countries. [8] The clinicaltrials.gov registry has primarily clinical trials, but also cohorts and expanded access (for drugs or biologics that do not qualify for enrollment in a clinical trial). [8] The objective of this study was to characterize the studies registered in clinicaltrials.gov on telehealth in Latin America.

METHODS

An observational and descriptive study was carried out through the open clinicaltrials.gov database. The search was carried out on February 15, 2019 and the data was extracted directly from the registry on that date. Studies on telehealth identified in clinicaltrials.gov [9] developed in the Latin American countries Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay were included. , Peru, Dominican Republic, Uruguay, Venezuela.

The search was carried out with the descriptors of the Medical Subject Headings (MeSH) thesaurus of the US National Library of Medicine (telemedicine, remote consultation, telepathology, teleradiology, telerehabilitation, wireless technology), in addition to other free terms. The search strategy was: “telemedicine OR telemonitoring OR remote consultation OR telecardiology OR telesurgery OR mobil health OR mhealth OR telehealth OR ehealth OR teleradiology OR telepathology OR telerehabilitation OR medicine technology OR wireless technology”. All keywords or probable free terms were used to improve the

number of studies retrieved; However, the number of results obtained with said strategy did not increase. The advanced search engine was used, using the search strategy and the country of interest without any other limitations or filters. The search was repeated for each country until the list of Latin American countries was completed.

Interventions registered in multiple countries that respond to a single project were considered a single study. The type of study, the disease or topic addressed, the initiative (local or foreign) and the institution that generated the research were characterized. Additionally, the number of studies per year of registration, the number of studies per year of completion, and the type of institution or sector were described. The analysis was performed in STATA v.14 ® software, where descriptive measures were reported.

RESULTS

37 studies on telehealth were identified. The first study was registered in 2008. From that year onwards there was a discontinuous registration of studies until 2018. In 2009 and 2010 no studies were registered. The maximum number of studies registered in a year was in 2015 with a total of 8 trials (22.2%), and the highest number of studies completed in the same period was eight, which corresponded to the year 2018. In addition, eight of the studies registered up to the time of the review had not yet been completed (Fig .).

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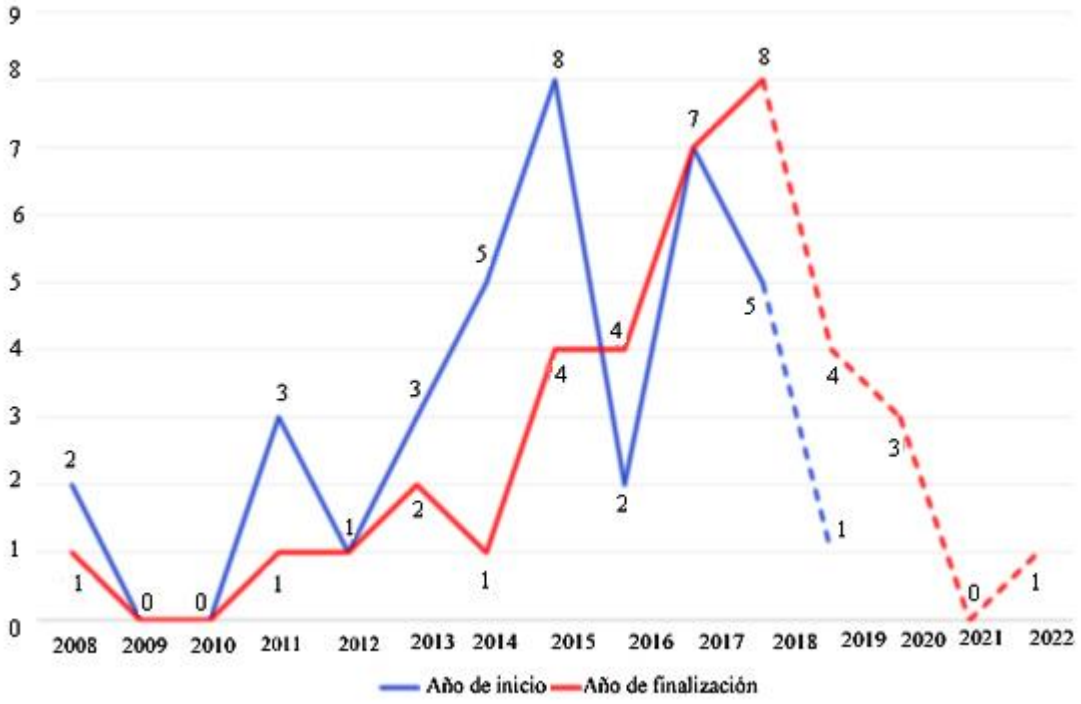

Fig. - Studies registered up to the time of review.

We found that 81.1% of the studies were parallel assignment trials. The main diseases studied were hypertension (23.9%), diabetes (11.3%) and cardiovascular diseases (9.9%). The countries that had the most registered studies were Brazil (29.3%) and Argentina (14.6%). The majority were carried out by local authors from the country where the study was carried out (64.9%). The main institutions that carried out research in the region were the University of Michigan, in the United States (18.9%), and the Hospital de Clínicas de Porto Alegre, in Brazil (10.8%), as shown in the table .

Table Characteristics of Latin American studies on telehealth registered in clinicaltrials.gov

Type of study (N= 37)	**No. %**
- Intervention (Clinical trial)	3. 4 91.9

Type of study (N= 37)	No.	%
Parallel assignment	30	81.1
Single Group Assignment	3	8.1
Factor assignment	1	2.7
- Observational: Cohort	3	8.1
Disease or issue (N =71)*		
Hypertension	17	23.9
Diabetes	8	11.3
Cardiovascular diseases	7	9.9
Depression	5	7.0
Obesity	5	7.0
Cerebrovascular diseases	4	5.6
Chronic kidney diseases	4	5.6
Gestation	3	4.2
Others	25	35.2
Countries where the research was carried out (N= 40)**		
Brazil	12	29.3
Argentina	6	14.6
Mexico	4	9.8
Peru	4	9.8
Bolivia	3	7.3
Chili	3	7.3
Colombia	3	7.3

Type of study (N= 37)	No.	%
Guatemala	2	4.9
Honduras	2	4.9
Dominican Republic	1	2.4
Uruguay	1	2.4
Initiative (N= 37)		
Local	24	64.9
International	13	35.1
Type of institution (N= 37)		
University	28	75.7
Private non-university institution	6	16.2
Public non-university institution	3	8.1
Institution (N= 37)		
University of Michigan (United States)	7	18.9
Porto Alegre Clinical Hospital (Brazil)	4	10.8
Cayetano Heredia Peruvian University (Peru)	3	8.1
Federal University of Bahia (Brazil)	2	5.4
Federal University of Minas Gerais (Brazil)	2	5.4
Others	19	51.4

*Some projects evaluated more than one disease or topic.

**Some studies were conducted in more than one country (multinational studies).

Source: Data based on clinicaltrials.gov

The table shows the list of all studies identified and analyzed in the present study.

Table Studies on telehealth in Latin America registered in clinical trial.gov, in the period 2008-2018

Study name	Acronym	Start year	Ending year
Developing Accessible Telehealth Programs for Hypertensive Patients in Latin America	-	2011	2015
A Longitudinal Survey of Health in Bolivia		2014	2018
AniMovil mHealth Support for Depression Management in a Low-Income Country	AniMovi	2018	2019
Cardiac Telerehabilitation: Attendance and Effectiveness	-	2018	2018
Developing Accessible Telehealth Programs for Hypertensive Patients in Latin America	-	2011	2012
Developing Accessible mHealth Programs for Depression Management in Bolivia	-	2014	2015
Developing Accessible Telehealth Programs for Diabetes and Hypertension Management in Bolivia	-	2014	2015
Effect of the Teleconsultation of Renal Nutrition on Renal Function and Glycemic Control in Patients With DKD	-	2017	2018
Effectiveness of a mHealth Intervention for the Treatment of Depression in People With Diabetes or Hypertension in Peru	LATIN-MHPeru	2017	2018

Study name	Acronym	Start year	Ending year
Effectiveness of a Psychoeducation and Support Protocol by Telephone in the Aid of Caregivers of Patients With Dementia	-	2017	2019
e-Health Education Program at Workplace	e-Health	2017	2018
Evaluation of the Effects of Teleconsultations on an Endocrinology Referral List	-	2015	2016
Home Blood Pressure SMS Telemonitoring in the Primary Care Setting		2018	2018
Hypertension Control Program in Argentina	HCPIA	2013	2016
Impact of Automated Calls on Pediatric Patient Attendance in Chile (Health Call)	-	2013	2016
Implementation of Foot Thermometry and SMS and Voice Messaging to Prevent Diabetic Foot Ulcer	-	2015	2017
International Registry for Ambulatory Blood Pressure and Arterial Stiffness Telemonitoring	(VASOTENS)	2015	2017
Messages For Your Health: A Cancer Screening Prevention Study	-	2015	2017
mHealth Interventions to Improve Access and Coverage of Uninsured People With High Cardiovascular Risk in Argentina. (mHealth)	-	2014	2014
Mobile Health Intervention for Active	-	2018	2020

Study name	Acronym	Start year	Ending year
Tuberculosis			
Online Platform for Healthy Weight Loss	POEMS	2017	2018
Perinatal mHealth Intervention in Guatemala	-	2015	2020
Psychiatric Care Via Videoconferencing	-	2012	2015
Satellite-supplementation of Medical Outreach Clinics: a Feasibility Study	-	2013	2013
Scaling Up Science-based Mental Health Interventions in Latin America (DIADA)	DIADA	2018	2020
Technological Platforms and Telerehabilitation in Heart Surgery	-	2016	2016
Telemedicine Qualifying Transition Between Tertiary and Primary Health Care in Stable Coronary Artery Disease Patients	Tele-DAC	2014	2017
Telemonitoring of Uncontrolled Hypertension	ERNESTINE	2016	2019
Telesonography Adaptation and Use to Improve the Standard of Patient Care Within a Dominican Community	-	2008	2008
Tele-spirometry in Primary Care - Randomized Clinical Trial Cluster: the Effectiveness of Telemedicine in Asthma	RESPIRANET-A	2015	2017
Tele-spirometry in Primary Care-Randomized Clinical Trial Cluster:Telemedicine in Chronic	RESPIRANET-C	2015	2017

Study name	Acronym	Start year	Ending year
Obstructive Pulmonary Disease			
TXT2HEART COLOMBIA: Evaluation of the Efficacy and Safety of Text Messages to Improve Adherence to Cardiovascular Medications in Secondary Prevention	TXT2HEART COLOMBIA	2017	2019
Use of Mobile Technology to Prevent Progression of Pre-hypertension in Latin-American Urban Settings	-	2011	2013
Virtual Reality to Reduce Anxiety in Ambulatory Surgical Operations (VRSurg)	VRSurg	2008	2011
Virtual Rehabilitation and Conventional Therapeutic Exercises in the Treatment of Individuals Post Stroke	-	2015	2017
Virtual Rehabilitation and PNF in the Recovery of the Motor Function Post Stroke	-	2017	2018

Source: Data based on clinicaltrials.gov.

DISCUSSION

The number of studies carried out in Latin American countries is considerably lower than that found in developed countries, as demonstrated by a previous study on France, in which a total of 39 studies were found in a shorter period of years. [10] This finding would confirm the limited contribution of ICT to well-being in developing countries, such as those in Latin America, [11] which would be

explained by the late start of the use of ICT in these countries or by their low scientific production in telemedicine. [7]

Most of the studies carried out were of the intervention type (trials). Of these trials, the largest number were parallel assignment; There was only one factorial assignment and none of special design (cluster trials, pragmatic trials, adaptive trials, and stepping wedge trials). This would be explained by the categorization of the "intervention model" (type of intervention) that clinicaltrial.gov restricts in its registry, as it considers single group assignment, parallel assignment, cross-type assignment, and factorial assignment as the only options. . [8] However, it is possible that these studies are not being prepared with a focus on the implementation of telehealth projects, which require special designs. On the other hand, it is observed that there is no continuous growth of studies over the years, in contrast to the growth of public policies on telehealth in Latin America, [2, 12] which would mean that telehealth policies and programs are being generated based on on international experiences rather than on their own.

Most studies address chronic diseases, probably because there is a current trend of population aging, which will eventually result in a future increase in the occurrence of chronic diseases and comorbidities, [13] and will substantially increase health care costs. and resource utilization. [14] In this context, telemedicine or telehealth would be tested as a viable option to improve care for these diseases, due to the advantages it offers (improved accessibility, quality and efficiency of health services). [13] Research into acute clinical conditions (emergencies and intensive care) is a pending area to explore, although several studies outside of Latin America are demonstrating success; that is, low mortality rates compared to those of the traditional care model. [15, 16]

It is striking that Mexico, Costa Rica and Panama do not lead in number of studies despite the fact that these countries were the first to adopt telehealth as a national project (before 2002), compared to other countries that show a better positioning. such as Brazil, Argentina and Peru, which did so after 2007. [17] It is possible that once established as national projects, there was no interest in demonstrating their efficacy, effectiveness, efficiency, safety or in seeking innovations validated through ECCA. Another explanation is that there are not enough resources to carry out studies with this type of design given the complexity, time and cost that they require. [18]

This is the first study that addresses telehealth research in Latin America through a study registry specialized in controlled trials. A limitation of the study is the possible underestimation of any study not registered on the clinicaltrial.gov platform; However, an important approach to telehealth research in Latin America is shown. We recommend encouraging telehealth research through ECCA in the Latin American region, as well as replicating this study in other international registries to corroborate our findings. Likewise, we consider it pertinent to carry out bibliometric studies to complement the analysis of Latin American scientific production.

In conclusion, there is a need to strengthen telehealth programs with the support of solid recommendations based on scientific evidence that seek to guarantee their sustainability. We found a low number of Latin American studies registered in clinicaltrials.gov, as well as the absence of continued growth. Most studies were parallel assignment controlled trials. These studies focused mainly on chronic diseases and were developed by local initiative. Additional randomized controlled clinical trials are required to evaluate the efficacy, effectiveness, efficiency and

safety of telehealth in the Latin American context, and thus help consolidate its development.

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