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mHealth for the early diagnosis and effective treatment of cutaneous leishmaniasis

Submission date
26/07/2021

Recruitment status
No longer recruiting

Registration date
08/10/2021

Overall study status
Completed

Last Edited
28/03/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cutaneous leishmaniasis is a parasitic disease of the skin transmitted by small flies. It tends to occur in remote areas where options for diagnosis and treatment are limited. The aim of this study is to find out whether a mobile phone (cellphone) app can improve the follow-up of people after treatment to better measure the side effects (adverse events) of treatment, and how many people are cured.

Who can participate?
All residents in three specific townships (veredas) of Tumaco municipality, Colombia, who have at least one lesion (sore) due to cutaneous leishmaniasis.

What does the study involve?
Participants are randomly allocated to be followed up with the help of the app or followed up as normal. Patients make several visits to CIDEIM in Tumaco. Visits 0 and 1 are for diagnostic confirmation and treatment formulation, respectively. Those allocated to the app receive additional home visits by a Community Health Volunteer. More specifically, at Visit 0, patients are assessed by a clinical prediction rule in the mobile app. Presumptive cases are considered as potential participants of the current trial, and a physical examination is performed. Those with active lesions suggestive of leishmaniasis are tested with routine methods. Patients with confirmed cutaneous leishmaniasis receive one of the treatments recommended by the Colombian Ministry of Social Protection: meglumine antimoniate or miltefosine, for 20 or 28 days respectively.

What are the possible benefits and risks of participating?
No direct benefit is expected although the results could provide evidence about mobile health apps. The possible risks are mostly related to confidentiality, i.e. information from the study becoming known to others. However, the information will be managed in accordance with current security practices and access to identifying information will be restricted.

Where is the study run from?
Centro Internacional de Entrenamiento e Investigaciones Medicas (CIDEIM) (Columbia)

When is the study starting and how long is it expected to run for?
February 2014 to December 2017

Who is funding the study?
National Institutes of Health (USA)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
20143239

Study information

Scientific Title
mHealth for the early diagnosis and effective treatment of cutaneous leishmaniasis: a randomized trial comparing the completeness of assessment of adverse events and therapeutic outcome in those whose follow-up is supported by eHealth, versus standard of care, in parasitologically confirmed cases

Study objectives
The use of low-cost technology and open source software will significantly benefit patient care, empower and train community health volunteers, and inform public health decisions and resource deployment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/08/2016, Comité Institucional de Ética de Investigación en Humanos (Institutional Ethics Committee for Human Research) of CIDEIM (Carrera 125 #19-225, Cali, 760031 Colombia; +57 (0)25552164, erey@cideim.org.co), ref: not applicable

Study design
Community-based interventional unblinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Diagnostic

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Cutaneous leishmaniasis (CL)

Interventions
Design:
This is a randomized trial with parallel arms comparing a) follow-up aided by Guaral +ST app to b) standard follow-up led by the IPS (Institución Prestadora de Salud or Institutional Health Service Provider).

Screening, diagnosis and treatment:
Patients make several visits to CIDEIM in Tumaco. Visits 0 and 1 are for diagnostic confirmation and treatment formulation, respectively. Those randomized to the intervention (app) arm receive additional home visits by a Community Health Volunteer (CHV). More specifically, at Visit 0, patients are assessed by a clinical prediction rule (CPR) implemented in the Guaral RPC mobile app. Presumptive cases are considered as potential participants of the current trial, and a physical examination is performed. Those with active lesions suggestive of leishmaniasis are tested via routine parasitological methods (smear or, if negative, culture aspirate). Patients with confirmed CL disease receive one of the treatments recommended by the Colombian Ministry of Social Protection: meglumine antimoniate or miltefosine, for 20 or 28 days respectively.

Randomization:
If a CHV is available, the patient is randomized between the two arms. The sequence was previously prepared by a statistician without contact with the patients. Variable size blocks were used, specifically of length 2, 4, 6, and 8, generated by the blockrand() function of R version 3.3.1, resulting in a sequence with 50 and 25 records for the intervention and control groups respectively, that is, a 2:1 ratio. This sequence is accessed by the CIDEIM's web application for enrollment of patients. The physician and principal investigator only find out each patient's arm after enrollment. After enrollment neither the investigators nor the patients were blinded to the allocation.

Intervention Type
Other

Primary outcome measure
The proportion of participants seen at ideal study week 26, evidenced by standard medical records in the control arm and data entered into the app by the community health worker in the mHealth arm

Secondary outcome measures

1. Adherence calculated as the percentage of the prescribed doses (in ampoules for meglumine antimoniate and in capsules for miltefosine) that are received by the patient during the planned treatment period (20 days for meglumine antimoniate and 28 days for miltefosine), as evidenced by a paper form completed by the patient in the control arm, and this paper form and/or data entered to the app by the community health worker in the mHealth arm
2. Adverse events recorded during the treatment period, in terms of symptoms and frequency in both arms, and of severity in the mHealth arm, as evidenced by a paper form completed by the patient in the control arm, and the paper form and/or data entered to the mobile app made by the community health worker in the mHealth arm
3. Therapeutic response evaluated based on epithelization at week 13, categorized as failure, improvement, or apparent cure; and categorized at week 26 as definitive cure or failure, recorded in person in the control arm, and via app photos in the mHealth arm.
4. The ideal study week when last seen, evidenced by record(s) in a paper form and/or standard medical records in the control arm, and in a paper form and/or mobile app in the mHealth arm

Overall study start date
19/02/2014

Completion date
21/12/2017

Eligibility

Key inclusion criteria
1. Residence in one of the three veredas (townships) previously identified as:
1.1. Having a relatively high incidence of CL in the Colombia National System of Public Health Surveillance (SIVIGILA)
1.2. Safe to work
1.3. Relatively accessible
2. At least one cutaneous lesion

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
69

Total final enrolment
104

Key exclusion criteria
1. Mucosal leishmaniasis
2. Contraindication to receive treatment in the area of residence, i.e. with condition which requires treatment in the IPS

Date of first enrolment
10/01/2017

Date of final enrolment
22/06/2017

Locations

Countries of recruitment
Colombia

Study participating centre
CIDEIM
Tumaco
Colombia
528501

Sponsor information

Organisation
Centro Internacional de Entrenamiento e Investigaciones Medicas

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Sponsor type
Research organisation

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ROR
https://ror.org/003s20294

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health

Alternative Name(s)
Institutos Nacionales de la Salud, US National Institutes of Health, NIH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The researchers propose to store the datasets in the OSF.io repository (https://osf.io/). The data will be publicly available without restriction. As a minimum, they intend to make available those data which are necessary to reproduce analyses in the published paper. They will not share identifiable information such as names, dates of birth, or ages above 89 years.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	28/01/2016	09/08/2021	No	Yes
Protocol file	version 1.1	15/02/2016	10/08/2021	No	No
Results article	results	27/03/2023	28/03/2023	Yes	No