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Assessing the impact of mobile health technologies in resource limited areas

Submission date
27/07/2016

Recruitment status
No longer recruiting

Registration date
29/08/2016

Overall study status
Completed

Last Edited
29/01/2019

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
In recent years, heart disease has become more common in developing countries and less so in developed countries. This problem is made worse with resource-limited areas receiving a disproportionately low amount of global resources needed to look after patients including diagnostic tests and trained healthcare professionals. Coupled with the increase of rheumatic heart disease (a long-term heart condition which follows rheumatic fever, a sudden illness caused by a bacterial infection) and structural heart disease (an condition in which the heart does not function properly due to a problem with the valves or chambers), there is an urgent need to find a way to deliver cost-effective care. Smartphone-connected mobile health (mHeath) devices are providing new ways for patients to remotely monitor long-term conditions, and for providers to improve healthcare delivery at the point-of-care. Such mHealth devices include smartphone apps, wearable and wireless devices such as the smartphone-ECG (devices to monitor the electrical activity of the heart), sensor-based technologies, pocket-sized ultrasounds and miniaturized laboratory tests. The aim of this study is to investigate the effectiveness of these mHealth devices in the treatment of patients with rheumatic and structural heart disease in resource-limited areas.

Who can participate?
Patients with rheumatic or structural heart disease.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive standard health care. Those in the second group receive mHealth care at a mHealth clinic. This involves having their vital signs and health heart monitored using a range of mobile devices. Participants in both groups receive a complete transthoracic echocardiogram (ultrasound of the chest to view the heart) to establish the severity of their rheumatic or structural heart disease. Participants are followed up over 12 months to find out how quickly participants are able to receive surgery to correct their heart defect.

What are the possible benefits and risks of participating?
Participants benefit from receiving a more timely decision about treatment and a more comprehensive assessment of the severity of disease at the time they see a doctor. In addition,

participants in this study benefit from being closely monitored through follow up. There are no notable risks involved with participating.

Where is the study run from?
Sri Sathya Sai Institute of Higher Medical Sciences (India)

When is the study starting and how long is it expected to run for?
August 2014 to October 2015

Who is funding the study?
Academic Medical Center (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
sssihms (wf)/HR/14 /)

Study information

Scientific Title
A Randomized Trial of Mobile Health Device Assessments in Structural Heart Disease Clinics

Acronym

mHealth in Structural Heart Disease

Study objectives
A mHealth assessment with smartphone-based diagnostic devices such as the smartphone-ECG, handheld ultrasound, activity monitoring, and point-of-care laboratory tests accelerates medical-decision-making and shortens the time to definitive therapy among patients with structural heart disease in a resource limited area.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sri Sathya Sai Institute of Higher Medical Sciences - Institutional Review Board, 05/01/2014

Study design
Nested multi-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
1. Rheumatic Heart Disease
2. Structural Heart Disease

Interventions
Consecutive subjects are randomly assigned to an initial evaluation with mHealth or to standard-care. Study subjects are evaluated in either one of 5-mHealth or 5-standard-care sites.

Intervention group: Participants undergo an initial assessment of heart disease with mHealth devices including:
1. Structural abnormalities with handheld-echocardiography (Vscan®, GE Healthcare)
2. Vital signs with smartphone-connected oxymetry and blood pressure monitors (iHealthLabs®)
3. Functional assessments on a 6-minute walk test with a trial-axial activity monitor (Ozeri®)
4. Cardiac rhythm abnormalities with smartphone-connected-iECG (AliveCor®)
5. Point-of-care testing with fingerstick B-type natriuretic peptide (Alere)

Control group: Participants undergo a usual assessment with diagnostic tests that are available at the institution. This includes a physical examination, electrocardiography and radiographic and laboratory tests where necessary.

All study participants undergo a comprehensive transthoracic echocardiogram for anatomical assessments of the severity of rheumatic and structural heart disease and underwent a consultation by expert cardiologists prior to percutaneous valvuloplasty or a surgical valve replacement.

Intervention Type
Device

Primary outcome measure
Time to definitive treatment with valvuloplasty or valve replacement over 12-months is determined at the time of a healthcare encounter for valvuloplasty or valve replacement through monthly medical record review.

Secondary outcome measures
Occurrence of a cardiovascular hospitalization and/or death over 12-months is determined via monthly medical record review, community health worker visitation to the home, and text message follow up with the patient and care giver inquiring about a hospitalization and/or death.

Overall study start date
15/07/2013

Completion date
01/10/2015

Eligibility

Key inclusion criteria
1. Symptomatic outpatients with a new or an established diagnosis of rheumatic and structural heart disease, including valvular disease, left/right ventricular failure, rheumatic valvular disease, congenital heart defects
2. Adult, pediatric, and pregnant patients
3. Patients with a prior valvuloplasty or valve replacement for structural heart disease can also be included

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
286

Key exclusion criteria
1. Neonatal patients
2. Those with an unstable hemodynamic status

Date of first enrolment
10/08/2014

Date of final enrolment
01/10/2015

Locations

Countries of recruitment
India

Study participating centre
Sri Sathya Sai Institute of Higher Medical Sciences
EPIP Area, Whitefield
Karnataka
Bangalore
India
560 066

Sponsor information

Organisation
American Society of Echocardiography

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Sponsor type
Research organisation

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Funder(s)

Funder type
Research organisation

Funder Name
American Society of Echocardiography Foundation

Results and Publications

Publication and dissemination plan
Peer review medical journal with submission planned for 2016

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2018	29/01/2019	Yes	No