

Assessing the impact of mobile health technologies in resource limited areas

Submission date 27/07/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 29/08/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/01/2019	Condition category Circulatory System	☐ 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 (mHealth) 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?

Dr Partho Sengupta

partho.sengupta@mountsinai.org

Contact information

Type(s)

Scientific

Contact name

Dr Partho Sengupta

Contact details

Icahn School of Medicine at Mount Sinai

1 Gustave L. Levy Place

New York

United States of America

10029

+1 212 659 9121

partho.sengupta@mountsinai.org

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Nested multi-centre randomized controlled trial

Study type(s)

Diagnostic

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 triaxial 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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

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

ROR
<https://ror.org/059gy7s73>

Funder(s)

Funder type
Research organisation

Funder Name
American Society of Echocardiography Foundation

Results and Publications

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