ISRCTN11394514 https://doi.org/10.1186/ISRCTN11394514

A trial of low-cost, technology-assisted, integrated care delivery programme to prevent serious cardiovascular events in disadvantaged populations

Submission date
04/09/2015

Recruitment status
No longer recruiting

Registration date
07/10/2015

Overall study status
Completed

Last Edited
07/10/2015

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Health workers in the community play an important part in providing healthcare to people in rural areas. In 1979, Iran introduced a new heath system to help disadvantaged groups receive adequate healthcare. Trained community health workers known as “Behvarzes” typically work in rural health centres in pairs or threes, and provide basic healthcare and support to people in rural and disadvantaged areas. In recent years, the Behvarzes have taken part in screening for diseases that could cause serious cardiovascular problems (heart attacks and strokes), such as diabetes or high blood pressure (hypertension). At present however, they are not well enough equipped to take preventative action against these conditions and so many patients have to seek help from doctors. A new system (SUPPORT-CVD) has been developed which uses a touch-screen computer tablet to provide cardiovascular healthcare information, as well as supporting communication between the Behavarze and doctors. The aim of this study is to find out whether the SUPPORT-CVD technology can help to better prevent and manage heart and circulatory problems among in rural communities.

Who can participate?
Adults over 45 years of age, who live in rural areas of Iran and attend the participating rural health centres.

What does the study involve?
Participating health centres are randomly allocated to one of two groups. Patients attending health centres in the first group (control group) are treated by Behvarzes who have been trained to use the PC tablet. The tablet provides the Behvarzes with the means to test patients to see if they are at risk of cardiovascular problems. The tablet then provides them with limited information about the health of patients over the next 6 months (follow up period). Patients in the second group are treated by Behvarzes who are trained to use the tablet but they are also able to treat patients, by providing medications to the patients who are at risk of heart disease or stroke. For the 6 month follow up period, the Behvarzes are able to access more complete

information about their patients' health. At the end of the follow up period, the amount of patients who have suffered from heart attacks and strokes is recorded for both groups.

What are the possible benefits and risks of participating?
Benefits of participating include the possibility of improving the way that heart disease is managed in rural areas. There are no notable risks of participating in this study.

Where is the study run from?
310 rural health centres in Iran.

When is the study starting and how long is it expected to run for?
November 2014 to June 2020

Who is funding the study?
1. Medical Research Council (UK)
2. Wellcome Trust (UK)
3. Department for International Development (UK)
4. Iranian Ministry of Health and Medical Education (Iran)

Who is the main contact?
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Study website
http://supportcvd.com/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15-15

Study information

Scientific Title
A study using advanced technologies to support Behvarzes in risk screening and management of serious heart and circulatory problems in people living in rural areas of Iran

Acronym
SUPPORT-CVD

Study objectives
A low-cost technology-assisted and community-based programme of evidence-based CVD management will reduce the risk of serious cardiovascular events by at least 20% in high-risk individuals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford Tropical Research Ethics Committee (OxTREC), 23/06/2015, ref: 15-15

Study design
Multi-centre two-armed partially blinded cluster randomised trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions

The core of the complex intervention is a medical device (software) that provides decision support to non-physical healthcare workers. To reduce treatment contamination between intervention and control participants and to avoid selection bias, a concealed and computer-generated cluster randomized trial is used in this study in which rural health centres and one of their affiliated health houses are used as the unit of randomization and not the trial participant. Participants will only be enrolled and asked for their consent after cluster randomization. Randomization will be performed by the statistical team at the NCDRC.

Control Clusters: Non-physician healthcare workers will be trained in use of a tablet PC application and point-of-care diagnostics for measurement of cardiovascular risk factors and collection of limited information about participants' health status during follow-up.

Intervention Clusters: Point-of-care diagnostics and a tablet PC application will be used to empower non-physician healthcare workers in risk measurement and communication with patients, drug prescription (including the use of four different types of polypill), and adherence management. The intervention includes continuous training and performance management of healthcare workers.

Follow-ups for both control and interventional clusters are every 6 months. In the intervention clusters, additional appointments will be booked for patients with abnormal clinical findings or those prescribed drugs to ensure tolerability, adherence and treatment modification.

Intervention Type
Other

Primary outcome measure
1. Rate of major cardiac events (non-fatal myocardial infarction or cardiac death) determined at the end of the study period
2. Rate of stroke (fatal and non-fatal) determined at the end of the study period

Secondary outcome measures
Total number of vascular events are measured at the end of the study. These are defined as cardiovascular death, myocardial infarction, stroke, heart failure death or hospitalisation, end-stage renal disease (chronic renal dialysis, renal transplant, death from renal disease), and cardiovascular (CV) hospitalizations for atrial fibrillation or angina, or arterial revascularization.

Overall study start date
01/11/2014

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Aged 45 years or above
2. Rural dwellers

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
55,000 participants of which 30,000 will be high-risk participants

Key exclusion criteria
Any reason that may either put the participant at risk because of participation in the trial, or the participant's ability to participate in the trial (e.g. dementia or end-stage cancer).

Date of first enrolment
01/10/2015

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Iran

Study participating centre
Non-Communicable Diseases Research Center
Endocrinology and Metabolism Research Institute (NCDRC)
Tehran University of Medical Sciences
Tehran
Iran
1599666615

Sponsor information

Organisation
University of Oxford

Sponsor details
Medical Research Services, University of Oxford
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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Iranian Ministry of Health and Medical Education

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Funder Name
Department for International Development

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The Trial Management Group will aim to publish the trial findings in an open access journal.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration