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Improving medication taking in patients with coronary heart disease using a mobile health technology, a feasibility study

Submission date
20/11/2019

Recruitment status
No longer recruiting

Registration date
26/11/2019

Overall study status
Completed

Last Edited
21/05/2020

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
Coronary heart disease (CHD) is the term that describes what happens when your heart's blood supply is blocked or interrupted by a build-up of fatty substances in the coronary arteries. There are some patients who require support to take their medication after leaving the hospital. Using text message reminders sent by healthcare staffs to patients' mobile phones may help them remember to take their medications after they have left the hospital. For patients in Iran who have heart disease, we do not know if nurses sending text message reminders to patients' phones to improve their medication-taking is possible and if it works. The study aims to explore these issues further.

Who can participate?
Patients aged 18 years or above with CHD visiting the study centre outpatient clinic called "Cardiac Rehabilitation"

What does the study involve?
Participants will be randomly assigned to receive daily text message reminders on their mobile phones for 12 weeks or to receive the usual care with no text reminders

What are the possible benefits and risks of participating?
This study will employ automated text message reminders for medications as a popular way which assist patient's medication adherence after discharge. Hence the use of this free of charge text message reminders may improve pharmaceutical care, nurse–patient interaction, and the effect and safety of medications. It finally may lead to delay disease progression and the development of complications, and also may contribute to reduced healthcare costs for health systems and the people who use them.
There are no drawbacks for the participants of this study.

Where is the study run from?
Tehran Heart Centre, Iran

When is the study starting and how long is it expected to run for?
February 2016 for a period of 12 weeks

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Sahar Khonsari
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Increasing cardiovascular medication adherence: a medical research council complex mHealth intervention to inform global practice, a feasibility study

Study objectives
1. The mHealth intervention will increase cardiovascular medication adherence in Iranian adults living with CHD.
2. The mHealth intervention will increase the secondary outcomes of the study including: Medication Adherence Self-Efficacy (MASE); cardiac Ejection Fraction (EF); cardiac Functional Capacity (FC); CHD-related readmission/mortality rate and Health-related Quality of Life (HR-QOL)

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 06/05/2015, School of Health in Social Science, The University of Edinburgh Research Ethics Committee (Doorway 6, Old Medical Quad, Teviot Place, City Edinburgh, EH8 9AG, UK; k.melia@ed.ac.uk; +44(0)131 650 3893), ref: NURS006
2. Approved 21/04/2015, Institutional Review Board of the University in Tehran (Ghods St., Keshavarz Blvr., Tehran, 1417653761, Iran; resdeputy@tums.ac.ir;:+98 2188987381-2), ref: 92-04-28-28802-145738

Study design
Mixed methods feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Prevention

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
Coronary heart disease

Interventions
A text-messaging mHealth intervention has been developed and piloted previously among Acute Coronary Syndrome patients in Malaysia that showed significant improvements in medication adherence and heart functional status. The present study will test the same intervention for Iranian CHD patients after undertaking the stages mapped in the MRC framework to ensure the intervention is appropriate to the Iranian context. The feasibility of the intervention has been tested where outcomes are focused on estimating sample size, identifying recruitment challenges/ attrition rate and feasibility. There will now be a full RCT to confirm mHealth effectiveness.

During the feasibility testing, SMS-based mHealth intervention will be developed, refined and piloted among 78 CHD patient in an Iranian CR setting over 12-weeks. Following the MRC framework, the evidence base will be identified, an appropriate theoretical model of adherence (self-efficacy) utilised, and the intervention will be piloted in terms of recruitment, retention, acceptability and efficacy.

The participants in the intervention group receive mobile phone/ mHealth medication adherence messages over 12 weeks. The researcher will follow up with the participants in the intervention group via telephone calls once every two weeks during the study to reassure the delivery of reminders and to enquire about any patient's emergency readmission.

All participants are randomised to achieve groups that are similar in terms of socio-demographic characteristics and treatments except receiving the study intervention. A random numbers table is used to generate the random allocation sequence (based on the daily admission rate, 20 random numbers were generated for each day). Patients are asked to choose between sealed non-transparent envelopes with a number inside. Odd numbers are allocated to the intervention group and even numbers to the usual care group.

Intervention Type
Behavioural

Primary outcome measure
Self-reported medication adherence using the Morisky Questionnaire at baseline and 12-weeks

Secondary outcome measures
At baseline and 12-weeks:
1. Behavioural measures:
1.1. Self-efficacy measured using MA Self-Efficacy (MASE) questionnaire
1.2. Health-related quality of life measured using HR-QOL
2. Heart function measured using:
2.1. Cardiac Ejection Fraction (EF)
2.2. Cardiac Functional Capacity (FC)
3. CHD-related readmission/mortality rate

Overall study start date
01/07/2015

Completion date
01/06/2016

Eligibility

Key inclusion criteria
1. Primary diagnosis of CHD
2. Admitted to the cardiac rehabilitation centre on any secondary preventative medication

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
60

Total final enrolment
78

Key exclusion criteria
1. Unwilling to participate in the study
2. Illiterate
3. Not available for the period of the study (including being unavailable by phone and/or travelling out of the country)
4. Diagnosed with a level of cognitive impairment such that the process of informed consent may be obscured
5. Physically unwell or diagnosed with a terminal illness

Date of first enrolment
01/02/2016

Date of final enrolment
01/03/2016

Locations

Countries of recruitment
Iran

Study participating centre
Tehran Heart Centre
North Kargar Street
Tehran
Iran
1411713138

Sponsor information

Organisation
Tehran University of Medical Science

Sponsor details

Tehran School of Nursing & Midwifery
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Iran
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international.fnm@iums.ac.ir

Sponsor type
University/education

Website
http://fnm.tums.ac.ir

ROR
https://ror.org/01c4pz451

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal and presentation of the study findings at international conferences and knowledge exchange events.

2018 thesis in https://era.ed.ac.uk/handle/1842/31042 (added 21/05/2020)

Intention to publish date
20/11/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. Access to electronic data hosted on the University password-protected and secured drive will be limited to study research group membership, which will be set up with information services support. The PI will decide whether users require read-only or read-write access. Off-campus access will be via the Virtual Desktop System. Data will not be stored on individual computers or laptops. Any portable electronic devices that contain identifiable data will be encrypted in line with the university data protection policy. If any sensitive data needs to be transmitted electronically, this will be done via encrypted email.

Suitability for sharing:
Data generated by the project may be shared after the completion of the feasibility trial and any further larger trial. It will be made available for sharing once appropriate changes (e.g. all participants assigned a unique identifier and any identifying details have been removed) have been made to honour assurances of confidentiality and anonymity.
Discovery by potential users of the research data:
Once the project and possible future trial are completed, data will be allocated a DOI and stored on the Edinburgh Napier University Open Access Research Repository (www.napier.ac.uk /research-and-innovation/repository) in accordance with the University research data deposit process. The DOI and the datasets will be made available to the UK Data Service ReShare.
Governance of access:
The PI will make the decision about whether to supply research data to a potential new user. The study policy to data sharing will be stated in any academic publications, with attention being paid to ensuring that metadata information is clearly presented within publications.
The study team's exclusive use of the data:
Data will be exclusive to the research team until the completion of the trial and publication of findings.
Regulation of responsibilities of users:
External users will be bound by a data-sharing agreement that will prohibit any attempt to (a) identify study participants form the released data or otherwise breach confidentiality (b) make unapproved contact with any study participants. MRC Policy and Guidance on Sharing of Research Data from Population and Patient Studies will be adhered to: https://www.mrc.ac.uk /publications/browse/mrc-policy-and-guidance-on-sharing-of-research-data-from-population-and-patient-studies/

IPD sharing plan summary

Stored in repository