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Healthlines randomised controlled trial - cardiovascular disease risk

Submission date
05/07/2012

Recruitment status
No longer recruiting

Registration date
05/07/2012

Overall study status
Completed

Last Edited
21/02/2018

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
As the population ages, more and more people are suffering from long-term conditions (LTCs). Health services around the world are exploring new ways of supporting these people and there is great interest in the use of telehealth: technologies such as the internet, phone, text messaging and home self-monitoring. The Healthlines Trial aims to evaluate the effectiveness and cost-effectiveness of a NHS Direct-delivered telehealth intervention to support patients with raised risk of cardiovascular disease (CVD). A sub-study will also be conducted to establish if the numbers of patients recruited in to the study are increased by the use of a participant information sheet (PIS) and covering letter developed through a process of 'User Testing', compared to a routine participant information sheet. Other aim of the sub study is to explore whether user testing of the PIS and covering letter improves retention in the Healthlines Trials host studies.

Who can participate?
Patients aged 40-74 years will be recruited from 34 general practices near Bristol, Sheffield and Southampton. Patients will be identified using practice record searches. To be eligible, patients must have an estimated risk of a cardiovascularevent in the next 10 years risk of 20% or higher, and at least one of the following: a previous general practitioner (GP) recorded diagnosis of hypertension, a current systolic blood pressure of over 140, a body mass index (BMI) of over 30 or be a current smoker. They must also have access to a telephone, the internet and an email address for personal use.

What does the study involve?
After confirmation of eligibility and consent, patients will complete further questionnaires, and then be randomly allocated to one of two groups.
The two groups in the study are:
Usual Care: Care provided by GP or nurse at usual general practice as required.
Usual Care plus NHS Direct Healthlines: Usual Care, plus extra support provided by NHS Direct by telephone, email and internet, including regular contact to provide advice and encouragement and access to tailored online resources.
At 6 and 12 months patients will be asked to complete more questionnaires and be assessed by their practice nurse.

Sub-study: Patients who are being invited to participate in the Healthlines trial will be randomly allocated to one of two interventions:
1. Sent the original Healthlines trial participant information sheet and covering letter
2. Sent the user tested participant information sheet and covering letter

What are the possible benefits and risks of participating?
The study will be helpful in planning future services to be delivered by the NHS, which may benefit future patients. Participants may personally benefit from taking part by learning more about their own health, how to manage it, and having regularly scheduled health checks. As a result, their own health and well-being might improve. Participants in research have to give up some of their own time, which may not appeal to everyone. Some patients experience minor discomfort from having their blood pressure measured and having a blood sample taken, although this will be carried out by a nurse at your own GP practice. We do not anticipate any other risks associated with taking part in this study.

Where is the study run from?
The study is led by the University of Bristol, in collaboration with the Universities of Sheffield, Southampton and Manchester, and NHS Direct.

When is the study starting and how long is it expected to run for?
Patient recruitment started in October 2012 and is expected to end in February 2013, with further follow up of participants continuing until March 2014.

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Chris Salisbury
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Study website
http://www.bristol.ac.uk/healthlines

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12455

Study information

Scientific Title
Effectiveness and cost-effectiveness of an NHS Direct-delivered telehealth intervention to support the management of long term conditions: a pragmatic randomised controlled trial for patients with raised cardiovascular disease risk

Study objectives
As the population ages, more and more people are suffering from long term conditions (LTCs). Health services around the world are exploring new ways of supporting these people and there is great interest in the use of telehealth: technologies such as the internet, phone, text messaging and home self-monitoring. This study aims to evaluate the effectiveness and cost-effectiveness of a NHS Direct-delivered telehealth intervention to support patients with LTCs. A randomised controlled trial will be conducted with 640 patients with raised cardiovascular disease (CVD) risk as an exemplar LTC.

Added as of 26/04/2013:
Sub-study title
Systematic Techniques for Assisting Recruitment to Trials in Healthlines (MRC START in Healthlines)
The MRC START sub-study sits within the existing Healthlines trials study design. MRC START in Healthlines is a 'nested' RCT. Potential participants in the Healthlines trials will be randomised to MRC START to receive either the standard or the user tested versions of the Healthlines participant information sheets and covering letters.
Sub-study aims:
1. To establish if the numbers of patients recruited in to the Healthlines Trials are increased by the use of a participant information sheet and covering letter developed through a process of 'User Testing', compared to a routine participant information sheet.
2. To explore whether user testing of the PIS and covering letter improves retention in the Healthlines Trials host studies.

Ethics approval required
Old ethics approval format

Ethics approval(s)

NRES Committee South West - Frenchay, 07/02/2012, ref: 12/SW/0009/B

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

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

Interventions
Current interventions as of 26/04/2013:
Telephone and internet-based intervention delivered by NHS Direct, involving regular contact to provide advice and encouragement by phone and access to tailored online resources.
Follow Up Length: 12 months
Sub-study: Patients who are being invited to participate in the Healthlines trial will be randomly allocated to one of two interventions
1. Sent the original Healthlines trial participant information sheet and covering letter
2. Sent the user-tested participant information sheet and covering letter

Previous interventions until 26/04/2013:
Telephone and internet-based intervention delivered by NHS Direct, involving regular contact to provide advice and encouragement by phone and access to tailored online resources.
Follow Up Length: 12 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 26/04/2013:
1. QRisk2 score measured at 12 months
2. (Sub-study only) The number of patients consenting to participate in the Healthlines Trials

Previous primary outcome measures until 26/04/2013:
QRisk2 score measured at 12 months

Secondary outcome measures
Current secondary outcome measures as of 26/04/2013:
1. QRISK2 as a continuous variable
2. Quality of life (EQ-5D-5L)
3. Patient satisfaction
4. Patient perceived access to care
5. Exercise behaviour
6. Cardiovascular risk factors (BP, cholesterol, smoking status, weight, BMI, diet)
7. Use of telehealth interventions
8. Self management skills
9. Self efficacy
10. Medication adherence
11. Health literacy
12. Care coordination
13. (Sub-study only) Retention in the Healthlines studies. We will keep a record of all patients who were identified as potential participants and which intervention group they were in.

Previous secondary outcome measures until 26/04/2013:
1. QRISK2 as a continuous variable
2. Quality of life (EQ-5D-5L)
3. Patient satisfaction
4. Patient perceived access to care
5. Exercise behaviour
6. Cardiovascular risk factors (BP, cholesterol, smoking status, weight, BMI, diet)
7. Use of telehealth interventions
8. Self management skills
9. Self efficacy
10. Medication adherence
11. Health literacy
12. Care coordination

Overall study start date
11/06/2012

Completion date
31/07/2013

Eligibility

Key inclusion criteria
Current inclusion criteria as of 26/04/2013:
1. Access to a telephone (landline or mobile), the Internet and an e-mail address for personal use.
2. Aged between 40 - 74 years (on date of invitation to participate)
3. 10-year risk of cardiovascular event of ≥20% calculated using QRISK2
4. At least one of the following modifiable risk factors:
4.1. Current systolic blood pressure > or = 140mmHg
4.2. BMI > or = 30

4.3. Current smoker
5. Male or female

Previous inclusion criteria until 26/04/2013:
1. Access to a telephone (landline or mobile), the Internet and an e-mail address for personal use.
2. Aged between 40 - 74 years (on date of invitation to participate)
3. 10-year risk of cardiovascular event of ≥20% calculated using QRISK2
4. At least one of the following modifiable risk factors:
4.1. Previous GP recorded diagnosis of hypertension
4.2. Current systolic blood pressure = 140mmHg; BMI ≥ 30
4.3. Current smoker
5. Male or female

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 640; Description: 40 run-in phase participants (30 intervention, 10 controls).600 main trial participants (300 intervention, 300 controls)

Key exclusion criteria
1. Established diagnosis of cardiovascular disease, defined as history of heart attack, angina, heart failure, stroke or transient ischaemic attack.
2. Currently pregnant or planning to become pregnant within the next 12 months
3. Patients eligible for the NHS Health Checks Programme during the period of the trial (where local PCTs request this)
4. Bipolar disorder
5. Psychotic illness
6. Dementia or substantial cognitive impairmet
7. Severe learning disability
8. Substance dependenc
9. Receiving palliative car
10. Significant suicidal riks
11. GP determines that participation would cause distress (e.g. due to recent bereavement)
12. Inability to communicate verbally in English sufficiently to receive telephone-based support delivered in English. Patients who can communicate verbally in English but are unable to read English will be eligible provided they have a family member or friend who is willing and able to translate written materials (such as information sheets, consent forms and online material) for them.

Date of first enrolment
22/10/2012

Date of final enrolment
01/02/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Academic Primary Care
Bristol
United Kingdom
BS8 2PS

Study participating centre
School of Health and Related Research (ScHARR)
University of Sheffield
Sheffield
United Kingdom
S1 4DA

Sponsor information

Organisation
University of Bristol (UK)

Sponsor details
Senate House
Tyndall Avenue
Bristol
England
United Kingdom
BS8 1TH

Sponsor type
University/education

Website
http://www.bris.ac.uk/

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results of the trial and the economic evaluation will be published in due course, as a full report from NIHR and as academic journal articles.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/01/2014		Yes	No
Results article	results	05/06/2015		Yes	No
Results article	substudy results	19/07/2015		Yes	No
Results article	results	01/06/2016		Yes	No
Other publications		26/08/2016		Yes	No
Results article	results	26/09/2016		Yes	No