

Healthlines randomised controlled trial - cardiovascular disease risk

Submission date 05/07/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 05/07/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/02/2018	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English Summary

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 cardiovascular event 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

Contact name

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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 hypothesis

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)

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

Condition

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

Overall study end date

31/07/2013

Eligibility

Participant 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 $\geq 20\%$ calculated using QRISK2
4. At least one of the following modifiable risk factors:
 - 4.1. Current systolic blood pressure $> \text{ or } = 140\text{mmHg}$
 - 4.2. BMI $> \text{ or } = 30$

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 $\geq 20\%$ 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 ≥ 140 mmHg; 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)

Participant 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 impairment

7. Severe learning disability

8. Substance dependence

9. Receiving palliative care

10. Significant suicidal risks

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.

Recruitment start date

22/10/2012

Recruitment end date

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

