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Healthlines Randomised Controlled Trial - Depression

Submission date	Recruitment status	[X] Prospectively registered
26/06/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/06/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/05/2016	Mental and Behavioural Disorders	

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. This study aims to evaluate the effectiveness and cost-effectiveness of a NHS Direct-delivered telehealth intervention to support patients with depression.

Who can participate?
Patients aged 18 and older will be recruited from 34 general practices near Bristol, Sheffield and Southampton. Patients will be identified using practice record searches or by direct referral by practice staff. To be eligible, patients need to have depression confirmed by assessment using a validated questionnaire, and must have access to a telephone, the internet and an email address for personal use.

What does the study involve?
Patients will complete further questionnaires, and then be randomly allocated to one of two groups. At 4, 8 and 12 months patients will be asked to complete more questionnaires. The two groups in the study are:
1. Usual care: care provided by GP or nurse at usual general practice as required.
2. 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.

What are the possible benefits and risks of participating?
The trial 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. They may feel uncomfortable answering some questions over the phone. However, the depression screening questions are from a standard questionnaire, which is designed to collect information about symptoms rather

than personal circumstances. Collecting this information is necessary for participation, but if this is too distressing, patients may ask us to phone on another occasion or can withdraw from the study. 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?
Recruiting patients to the trial starts in July 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
c.salisbury@bristol.ac.uk

Study website
http://www.bristol.ac.uk/healthlines/

Contact information

Type(s)
Scientific

Contact name
Prof Chris Salisbury

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12516

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 depression

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 depression as an exemplar LTC.

More details can be found at http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=12516

Added 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, REC ref: 12/SW/0009

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Current interventions as of 26/04/2013:
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.

Primary follow up is at 4 months, with further follow up at 8 and 12 months.

Follow Up Length: 12 month(s)

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:
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.

Primary follow up is at 4 months, with further follow up at 8 and 12 months.

Follow Up Length: 12 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Current primary outcome measures as of 26/04/2013:
1. Patient Health Questionnaire (PHQ)-9 Depression Score <10 AND an absolute reduction in PHQ-9 of at least 5 points after 4 months
2. (Sub-study only) The number of patients consenting to participate in the Healthlines Trials.

Previous primary outcome measures until 26/04/2013:
Patient Health Questionnaire (PHQ)-9 Depression Score <10 AND an absolute reduction in PHQ-9 of at least 5 points after 4 months

Secondary outcome measures
Current secondary outcome measures as of 26/04/2013:
1. PHQ-9 score as continuous variable
2. Quality of life (EQ-5D-5L)
3. Patient satisfaction
4. Patient perceived access to care
5. Exercise behaviour
6. Use of telehealth interventions
7. Self management skills
8. Self efficacy
9. Medication adherence
10. Health literacy; anxiety
11. Care coordination
12. (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. PHQ-9 score as continuous variable
2. Quality of life (EQ-5D-5L)
3. Patient satisfaction
4. Patient perceived access to care
5. Exercise behaviour
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8. Self efficacy
9. Medication adherence
10. Health literacy; anxiety
11. Care coordination

Overall study start date
11/06/2012

Completion date
31/07/2013

Eligibility

Key inclusion criteria
1. Target Gender: Male & Female; Upper Age Limit 100 years; Lower Age Limit 18 years (on date of invitation to participate)

2. Confirmed diagnosis of depression using the Clinical Interview Schedule
3. Revised (CIS-R) and PHQ-9 = 10
4. Access to a telephone (landline or mobile), the Internet and an e-mail address for personal use

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

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

Key exclusion criteria
1. Currently receiving case management from a specialist mental health worker
2. Currently receiving face-to-face, telephone or computerised CBT or similar psychotherapy
3. Have given birth in the previous 12 months
4. Bipolar disorder
5. Psychotic illness
6. Dementia or substantial cognitive impairment
7. Severe learning disability
8. Substance dependency
9. Receiving palliative care
10. Significant suicidal risk
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
06/07/2012

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
Research and Enterprise Development
3rd Floor, Senate House
Tyndall Avenue
Bristol
England
United Kingdom
BS8 1TH

Sponsor type
University/education

Website
http://www.bristol.ac.uk/red/

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	24/02/2016		Yes	No
Results article	results	01/06/2016		Yes	No