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Sharing responsibility: The public health impact of a nurse-led telemetric home blood pressure monitoring service

Submission date
21/10/2008

Recruitment status
No longer recruiting

Registration date
11/12/2008

Overall study status
Completed

Last Edited
14/02/2018

Condition category
Circulatory System

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Sharing responsibility: The public health impact of a nurse-led telemetric home blood pressure monitoring service - randomised controlled trial

Acronym
HITS (Health Impact of nurse-led Telemetry Services): Hypertension

Study objectives
1. To determine whether there is any reduction in average blood pressure and other specific cardiovascular risk factors in the group using the telemetric home blood pressure monitoring service compared to a control group receiving care as usual.
2. Is there any difference in adherence to lifestyle advice (smoking, diet, alcohol and salt intake, exercise) compared with a control group?
3. Is there any difference in the number and type of contacts with primary care amongst the group using telemetric home blood pressure monitoring compared with a control group?
4. What are people's experiences and opinions of this service including impact on behaviour, mood, positive and negative experiences and change in relationship with their health care provider?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Lothian Research Ethics Committee 1, Lothian NHS Board, approved on 03/10/2008 (ref: LREC 08 /S1101/38).

Study design
Randomised single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

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
Hypertension

Interventions
This is a randomised, single-centre trial of a telemetric home blood pressure monitoring service. This trial is also a qualitative study of a different model of service involving interviews and focus groups.

Patients in the intervention group will be given blood pressure monitors (Stabil-O-Graph20) which use Bluetooth to transmit readings via a (supplied) mobile phone to a remote server. The user may securely access their record on the server at any time (either at home if they have internet access, or in a library or other public internet access point). Their GP and practice nurse will also be able to access this record via the internet. Users will also receive regular automated text or email feedback (or both if they wish) based on the reading they just sent and their rolling average blood pressure over the past 10 readings. The system can be set to provide reminders to check blood pressure and alerts to both the user (via the mobile phone) and the GP practice (via email) when the rolling average blood pressure remains high. If an individual user is unable to use text or email, it will be possible to arrange for feedback and alerts to be printed in the practice and posted to them or a voicemail system to be used. This will continue for 6 months. The baseline measurements will be repeated for both the intervention and control group at six months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Average daytime systolic blood pressure at 6 months measured by ambulatory monitoring.

Secondary outcome measures
The following will be assessed at baseline and 6 months:
1. Average diastolic blood pressure
2. Serum cholesterol
3. Body mass index
4. Breath carbon monoxide
5. Spot urinary sodium/creatinine ratio
6. HbA1c
7. Self-reported alcohol intake and smoking
8. Anxiety and depression, assessed by the Hospital Anxiety and Depression (HAD) scale
9. Quality of life (Euroqol)
10. Self-efficacy and medication adherence
11. Grip strength
12. Self-reported exercise frequency
13. Self-reported exercise tolerance
14. Number of attendances at practice nurse, GP, accident and emergency and out of hours care
15. Prescriptions for anti-hypertensives taken from GP practice records
16. Number of telephone/email contacts with practice nurses and GPs
17. Health care providers' experiences and opinions of this service

Overall study start date
03/11/2008

Completion date
03/11/2009

Eligibility

Key inclusion criteria
1. Both males and females, aged over 18 years
2. On practices' hypertension registers
3. Last recorded surgery blood pressure over 150 mmHg systolic or 90 mmHg diastolic

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Secondary hypertension
2. Hypertension or renal disease being managed in secondary care
3. On practice stroke register
4. Treatment for cardiac event, or other life-threatening illness within the past 6 months or surgery within the last 3 months
5. Unable to consent
6. Unable to use self-monitoring equipment
7. Atrial fibrillation
8. Patients with diabetes will also be excluded from this trial because they have different blood pressure targets and excluding them will simplify the initial introduction of the home monitoring service for GPs and practice nurses
9. Pregnancy
10. Daytime ambulatory blood pressure <135/85 mmHg

Date of first enrolment
03/11/2008

Date of final enrolment
03/11/2009

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Centre for Integrated Healthcare
Edinburgh
United Kingdom
EH4 2LD

Sponsor information

Organisation
Napier University (UK)

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Sponsor type
University/education

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

ROR
https://ror.org/03zjvnn91

Funder(s)

Funder type
Charity

Funder Name
The BUPA Foundation (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/05/2013		Yes	No
Results article	further results	28/05/2013		Yes	No
Results article	results	31/01/2018		Yes	No