ISRCTN10969896 https://doi.org/10.1186/ISRCTN10969896

Telemonitoring of uncontrolled hypertension

Submission date 23/05/2019	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 01/07/2019	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 28/06/2019	**Condition category** Circulatory System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Raised blood pressure (hypertension) is a highly important risk factor for heart disease and death worldwide. Despite the availability of effective treatments, many patients with hypertension are still undiscovered or not adequately treated, resulting in high rates of poorly controlled hypertension. Home-based blood pressure monitoring may provide a useful tool to improve the control of blood pressure. In addition, the availability of new innovative e-health techniques may improve self-management in the way the patient participates in the prevention of progression of his or her own disease. However, the effectiveness of lowering blood pressure using digital self-management support in combination with home blood pressure monitoring in patients with newly diagnosed hypertension has not been determined yet. The aim of this study is to assess the one-year (cost)effectiveness of telemonitoring of blood pressure and self-management support via an internet-based service in addition to usual care in patients with newly diagnosed hypertension.

Who can participate?
Patients from primary care practices with uncontrolled hypertension starting with a lifestyle intervention or medication

What does the study involve?
Participants are randomly allocated to the intervention group or the control group. The intervention group receive telemonitoring and internet-based self-management support for hypertension (TISH) focused on blood pressure and heart disease risk factors with the PatientCoach-platform over one year in addition to usual care. The control group receive usual care alone. The proportion of patients with controlled blood pressure is measured at 12 months.

What are the possible benefits and risks of participating?
All components of the PatientCoach system are non-invasive. The additional risks of participating in this study are considered very low, as all participants receive usual care. The intervention group will receive additional online support, in some cases the e-consult might replace the need for a visit to the general practice. All questionnaires are web-based and can be filled out at home. Therefore, the burden for the patient is considered low. An exemption of insurance for this study is given by the Ethical Committee of the Leiden University Medical Center.

Where is the study run from?
Leiden University Medical Center (Netherlands)

When is the study starting and how long is it expected to run for?
August 2013 to January 2020

Who is funding the study?
Netherlands Organisation for Health Research and Development

Who is the main contact?
Dr Jacob Sont
j.k.sont@lumc.nl

Study website
http://www.iemo.nl/index.cfm?p=28AFA0B2-A1A6-7E26-B1EA9CE3DDE23553

Contact information

Type(s)
Scientific

Contact name
Dr Jacob Sont

ORCID ID
http://orcid.org/0000-0002-5840-0651

Contact details
Department of Biomedical Data Sciences, section Medical Decision Making
J10-86
Leiden University Medical Center
Albinusdreef 2
Leiden
Netherlands
2333ZA
+31 (0)71 5264578
j.k.sont@lumc.nl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ABR nr NL45683.058.13

Study information

Scientific Title
TELEHYPE: a trial of TELEmonitoring and self-management support of patients with uncontrolled HYPErtension

Acronym
TELEHYPE

Study objectives
To assess the one-year (cost)effectiveness of telemonitoring of blood pressure and self-management support via an internet-based service in addition to usual care as compared to usual care alone in a pragmatic trial in patients with uncontrolled hypertension.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/11/2013, Medical Ethical Committee of the Leiden University Medical Center, (Commissie Medische Ethiek, H1-Q, Leiden University Medical Center PO Box 9600, NL-2300 RC Leiden, The Netherlands), Protocolnr P13.187

Study design
Parallel-group randomised pragmatic trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
Not available in web format, pleas use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Patients with hypertension, with a systolic blood pressure > 140 mmHg

Interventions
Patients will be randomised to either:
1. Telemonitoring and internet-based self-management support for hypertension (TISH) focused on home blood pressure, co-morbidities and cardiovascular risk factors
2. Usual Care (UC) strategy
with 1-year treatment period with 3-monthly evaluation measurements.

Telemonitoring of home measured blood pressure and Internet-based Self-management support for hypertension (TISH) will include usual care and the PatientCoach self-management programme. Home blood pressure monitoring is defined as regular blood pressure monitoring at home by the patient (HBPM). According to the Dutch NHG guidelines, systolic HBMP is normal if < 135 (12). Telemonitoring blood pressure can be defined as the combination of HBPM and the usage of different monitoring options in the online PatientCoach programme, including the integration with care from the general practitioner/nurse practitioner. PatientCoach facilitates and guides discussion between care providers and patients in such a way that the patient determines his or her health goal, identifies steps to achieve the goal, identifies barriers to reaching the goal, and plans for overcoming the barriers, including obtaining needed resources.

Intervention Type
Behavioural

Primary outcome measure
The proportion of patients with controlled OBP (i.e., <140/90 mm Hg or <130/80 mm Hg if diabetes or chronic kidney disease is present) at 6 and 12 months

Secondary outcome measures
1. Self-management skills and health education impact are measured by the Health Education Impact Questionnaire at baseline and 12 months
2. Motivation/user acceptance are measured by the Technology Acceptance Questionnaire at baseline, 4 and 12 months
3. Patient utilities are measured by the EQ-5D-3L at baseline, 4 and 12 months
4. Therapy adherence is measured by the Medication Adherence Rating Scale (MARS)) at baseline, 4 and 12 months

Overall study start date
08/08/2013

Completion date
01/01/2020

Eligibility

Key inclusion criteria
1. Patients with hypertension, with a systolic blood pressure > 140 mmHg
2. Patients who are willing to measure their blood pressure at home before and during 12 months of treatment
3. Access to the internet at home and ability to use it

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Serious psychological problems that may interfere with compliance or reliability of the measurements
2. Relevant somatic or psychiatric co-morbidity that interferes with the study
3. Systolic blood pressure >200 mmHg
4. Progressive signs of organ damage
5. Already using a home blood pressure device
6. Unable to understand the Dutch interface of PatientCoach

Date of first enrolment
07/04/2014

Date of final enrolment
23/05/2017

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center
Albinusdreef 2
Leiden
Netherlands
2333ZA

Sponsor information

Organisation
Leiden University Medical Center

Sponsor details
Albinusdreef 2
Leiden
Netherlands
2333ZA
+31 (0)71 5264578
j.k.sont@lumc.nl

Sponsor type
University/education

Website
www.lumc.nl

ROR
https://ror.org/05xvt9f17

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/01/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as this was not included in the informed consent letter to the patient.

IPD sharing plan summary
Not expected to be made available