

Telemonitoring of uncontrolled hypertension

Submission date 23/05/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/07/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/06/2019	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes