

TELEHYPE TELEmonitoring and self-management of uncontrolled HYPertension

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular hypertensive disorders
Study type	Interventional

Summary

ID

NL-OMON40260

Source

ToetsingOnline

Brief title

TELEHYPE

Condition

- Vascular hypertensive disorders

Synonym

high blood pressure, hypertension

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: blood pressure, chronic disease, self-management, telemonitoring

Outcome measures

Primary outcome

The primary outcome is the proportion of patients with controlled office blood pressure (OBP) (ie, <140/90 mm Hg or <130/80 mm Hg if diabetes or chronic kidney disease is present) at 12 months.

Secondary outcome

Secondary outcome parameters are: home blood pressure, health-related quality of life, self-management characteristics, patient utilities and costs-effectiveness.

Study description

Background summary

Raised blood pressure is highly important as a risk factor for cardiovascular comorbidity and mortality world-wide. Despite the availability of effective therapy, many patients with hypertension are still undiscovered or not adequately treated, resulting in high rates of poorly controlled hypertension.. Home based blood monitoring may provide a useful tool to improve the control of blood pressure. In addition, the availability of novel innovative e-health techniques may enhance self-management in a 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 uncontrolled hypertension has not been determined yet.

Study objective

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.

Study design

Pragmatic Randomised Controlled Trial

Intervention

Intervention group will receive telemonitoring and internet-based self-management support for hypertension (TISH) focussed on blood pressure and cardiovascular risk factors with the PatientCoach-platform during one-year additional to usual care. Control-group will receive usual care alone.

Study burden and risks

Patients in the intervention group will receive blood pressure monitor and will be familiarised with PatientCoach shortly after randomisation and patients will be asked to measure blood pressure twice in the morning and evening three times weekly. Every three months all participants will digitally receive a set of questionnaires, which can be filled out using a personal computer with internet connection.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Patients with hypertension, with a systolic blood pressure > 140 mmHg
- Patients who are willing to measure their blood pressure at home
- Access to internet at home and ability to use it

Exclusion criteria

- Relevant somatic or psychiatric co-morbidity that interferes with the study
- Systolic blood pressure >200 mm Hg

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	11-02-2014

Enrollment: 300
Type: Actual

Medical products/devices used

Generic name: home blood pressure monitoring
Registration: Yes - CE intended use

Ethics review

Approved WMO
Date: 13-11-2013
Application type: First submission
Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Approved WMO
Date: 31-10-2014
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

CCMO

ID

NL45863.058.13