BloodPressure after PREeclampsia/HELLP by SELF monitoring study

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To evaluate the effectiveness of blood pressure (BP) home monitoring on the occurrence of hypertension, efficacy of BP treatment, QOL, health-related symptoms, work ability and life-style behaviour in women 40-60 yrs, after a previous PE in...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43149

Source
ToetsingOnline

Brief title
BP-PRESELF study

Condition

- Other condition

Synonym
elevated blood pressure, hypertension

Health condition

hoge bloeddruk

Research involving
Human

Sponsors and support

Primary sponsor: cardiologie
Source(s) of monetary or material Support: Interreg Rhein-Waal project Zorg verbindt project nr. 203072

Intervention

Keyword: bloodpressure, eHealth, hypertension, preeclampsia/HELLP

Outcome measures

Primary outcome

Mean systolic and diastolic BP levels, prevalence of hypertension and

medication use for hypertension at baseline, during study period and after 1

year of follow-up

Secondary outcome

- QOL measures (questionnaires)

- ability to work and work-related obstacles

- cardiac/ hypertensive symptoms and well-being

- cost-effectiveness and feasibility of BP self monitoring program

Study description

Background summary

Women with a previous history of preeclampsia (PE)/HELLP have a twofold higher risk of cardiovascular disease (CVD) and a fourfold increased risk to develop hypertension at a relative young age. In the latest 2016 ESC guidelines CVD prevention, previous PE has been acknowledged as a serious CVD risk factor in women. In clinical practice, however, these women are still underappreciated for their CVD risk. It has not been established yet how adequate lifelong prevention in these potentially high risk women can optimally be achieved from their childbearing years onwards.

Study objective

To evaluate the effectiveness of blood pressure (BP) home monitoring on the occurrence of hypertension, efficacy of BP treatment, QOL, health-related symptoms, work ability and life-style behaviour in women 40-60 yrs, after a previous PE in pregnancy

Study design

Randomized, open label study to compare eHealth guided self management of BP monitoring and lifestyle advice with *usual care*.

Intervention

eHealth guided measurements of BP at regular intervals and recurrent lifestyle advice will be compared with *usual care*.

Study burden and risks

All participants are asked for a baseline visit and follow-up visit at 1 year.
The intervention group will be asked to measure blood pressure at home , every month during 7 consecutive days, twice in the morning and twice in the evening.
Both participant groups will fill in a diary during 7 days a month on health complaints.

There are no health-related risks to participate in this study.

Contacts

Public
Selecteer

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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible for participation in this study, a subject must meet all of the following criteria:
- previous preeclampsia/HELLP syndrome, defined as diastolic BP*90 mmHg with proteinuria * 0.3gram/24 h, during one or more pregnancies, more than 1 year ago.
- *early* or *late* PE/HELLP
- age *40 and * 60 years

Exclusion criteria

-pregnant women or women wishing for future pregnancie(s)
- inability to perform self BP measurements
- not having a smartphone (Apple or Android)
- already having regular hypertension control by GP or medical specialist

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-06-2017
Enrollment:	300
Type:	Actual

Medical products/devices used

Generic name:	self monitoring blood pressure at home with smartphone storage
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-05-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	ID
CCMO	NL59836.091.16