The Effects of Device-Guided Breathing Exercises on Blood Pressure, in Patients with Hypertension. A Randomized, Single-Blind, Controlled Trial

Published: 29-01-2008
Last updated: 11-05-2024

Primary:1. To determine the effect of a device slowing breathing (Resperate©) on BP in patients with treated hypertension with moderate BP control.Secondary:2. To determine the effect of a device slowing breathing (Resperate©) on Quality of life (...

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

Summary

ID

NL-OMON32130

Source
ToetsingOnline

Brief title
Breathing Exercises and Blood Pressure

Condition

- Other condition

Synonym
High Blood Pressure, Hypertension

Health condition

Hypertensie

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Stichting Medisch Research Fonds

Intervention

Keyword: Blood Pressure, Breathing Exercises, Music Therapy

Outcome measures

Primary outcome

Changes in office systolic blood pressure in the intervention group compared to changes in the controlgroup.

Secondary outcome

Changes in office diastolic blood pressure in the intervention group compared to changes in the controlgroup.

Changes in systolic and diastolic blood pressure as measured by the patient at home in the intervention group compared to changes in the controlgroup.

Changes in Quality of Life in the intervention group compared to changes in the controlgroup.

Study description

Background summary

It is suggested from results in literature that there is a direct baroreflex link between breath rate and heart rate and systolic blood pressure variability. Acute responses to slow and regular breathing are: 1. Increased baroreflex sensitivity and heart rate variability, reduced blood pressure and peripheral resistance. Previous studies, often without a (proper) control group and/or often initiated by the manufacturer of the Resperate, found positive

results. Our previous study could not reproduce these results in patients with hypertension and diabetes. Baroreflex sensitivity could be impaired as a result of diabetes itself, and therefore this could be the reason for not finding a beneficial influence of the Resperate on blood pressure. This, and the necessity to study this independently from the manufacturer led to the development of this study in patients with moderately controlled hypertension, but without diabetes.

Study objective

Primary:
1. To determine the effect of a device slowing breathing (Resperate©) on BP in patients with treated hypertension with moderate BP control.
Secondary:
2. To determine the effect of a device slowing breathing (Resperate©) on Quality of life (QoL) in patients with treated hypertension with moderate BP control.

Study design

randomised single blind.

Intervention

Resperate© is a device that helps to slow down breathing. This device can measure the breathing patterns through a breathing sensor mounted on the upper abdomen or chest. Furthermore, music-like sound patterns can be composed similar to this breathing pattern, which the patient can hear through the headphones of the Resperate©. By prolonging the expiration, which can be voluntarily used by the user, the frequency of respiration can be slowed down and become more stable (aim <10 breathings per minute).

Study burden and risks

The total amount of time needed for the 2 visits at the hospital is 60 minutes. At home, the patients are requested to measure their blood pressure before and after the intervention. This will all take about 20 minutes a day. There are no risks for the patients participating in this study because of the intervention.

Contacts

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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 are required to meet the following criteria: over 18 years old, known hypertension with a systolic BP (SBP) between 130-170 mm Hg at the previous visit to the internal outpatient department and at the last visit to the internist (which is the same day as baseline measurement) and treated with one or more anti-hypertensive drugs, which have not been changed for the preceding three months. At baseline the SBP should be between 140-160 mm Hg, measured by the investigator.

Exclusion criteria

Patients with known diabetes, heart failure (NYHA III-IV) and/or patients with pulmonary disease (for example asthma, chronic obstructive pulmonary disease and pulmonary fibrosis) will be excluded by the discretion of the treating internist. Patients with insufficient knowledge of the Dutch language to understand the requirements of the study will be excluded too.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-02-2008
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	29-01-2008
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL20147.075.07