

# Assessing the efficacy of exercising with the RESPeRATE device to lower blood pressure in diabetic hypertensives

**Submission date**  
23/05/2007

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
10/07/2007

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
02/10/2017

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Moshe Schein

### Contact details

Hadassah Hospital  
Family Medicine Unit  
Jerusalem  
Israel  
91120

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MS2

# Study information

## Scientific Title

Assessing the efficacy of exercising with the RESPeRATE device to lower blood pressure in diabetic hypertensives: a randomised controlled trial

## Study objectives

Exercising with the RESPeRATE device, if done appropriately at home for eight weeks, can reduce high Blood Pressure (BP) safely and efficaciously in diabetic hypertensives.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approval received from the Hadassah Hospital Jerusalem Ethics Committee on the 11th June 2004.

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Home

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Diabetes, hypertension

## Interventions

The intervention is a 15-minute daily session of slow breathing exercise guided by the RESPeRATE device (<http://www.resperate.com>). The device monitors the user's breathing rate and pattern using a breathing sensor and composes music in real time to match the user's breathing inhalations and exhalations. The user then follows these tones that become longer and longer, so that gradually the breathing rate decreases and expiration becomes longer.

The treatment lasted for eight weeks. There were two visits for baseline, one for follow up after four weeks and one for termination after eight weeks. The control group continued with their usual care and had the same office visits and tests.

## Intervention Type

Device

**Phase**

Not Specified

**Primary outcome measure**

Blood pressure: during each visit BP was measured.

**Secondary outcome measures**

Secondary outcomes are the validated QSD "Questionnaire of Stress in Diabetics", diastolic BP, fasting glucose, HbA1C and fructosamine.

Questionnaire and blood tests for glucose, HbA1C and fructosamine were taken at baseline and end of follow-up.

**Overall study start date**

01/09/2004

**Completion date**

31/12/2006

**Eligibility****Key inclusion criteria**

1. Non-insulin dependent diabetes mellitus
2. Average BP level, as measured in visits one and two: Systolic Blood Pressure (SBP) above 130 mmHg, and difference in BP levels between the two visits was not greater than 5 mmHg for SBP and 2 mmHg for Diastolic Blood Pressure (DBP)
3. Aged 40 to 79 years
4. No change in prescribed anti-hypertensive therapy, pharmacological or lifestyle modification for one month prior to visit one

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

70

**Key exclusion criteria**

1. Taking insulin
2. Active ischaemic heart disease/unstable angina
3. Major stroke with major impairment
4. Pregnant woman
5. Obesity: body mass index greater than 40
6. Major psychiatric disorder
7. Unable to operate a portable tape

- 8. Blind or deaf
- 9. Participates in another study

**Date of first enrolment**

01/09/2004

**Date of final enrolment**

31/12/2006

## Locations

**Countries of recruitment**

Israel

**Study participating centre**

Hadassah Hospital

Jerusalem

Israel

91120

## Sponsor information

**Organisation**

InterCure (Israel)

**Sponsor details**

6 Habbal Shem Tov Street

Lod

Israel

71285

**Sponsor type**

Industry

**Website**

<http://www.resperate.com>

## Funder(s)

**Funder type**

Industry

**Funder Name**

InterCure (Israel)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/05/2009		Yes	No