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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

Registration date
10/07/2007

Overall study status
Completed

Last Edited
02/10/2017

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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?
Results article	results	01/05/2009		Yes	No