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The effect of controlled swinging movement on prediabetic and diabetic patients

Submission date
06/11/2019

Recruitment status
No longer recruiting

Registration date
13/11/2019

Overall study status
Completed

Last Edited
20/05/2021

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Diabetes is a lifelong condition that causes a person's blood sugar level to become too high and is a universal social catastrophe. There are 425 million cases of diabetes in the world. The amount of sugar in the blood is controlled by a hormone called insulin, which is produced by the pancreas (a gland behind the stomach). When food is digested and enters the bloodstream, insulin moves glucose out of the blood and into cells, where it's broken down to produce energy. However, with diabetes, the body is unable to break down glucose into energy. This is because there's either not enough insulin to move the glucose, or the insulin produced does not work properly.

A gentle swinging motion of the whole body (controlled vestibular stimulation) can have an effect on the production of other hormones in the body which may reduce the damage caused by high blood sugar (hyperglycaemia). The study aims to evaluate the effect of controlled vestibular stimulation on anxiety, blood pressure, blood glucose levels in prediabetes and type 2 diabetes

Who can participate?
Prediabetic and diabetic (type 2) patients aged 30-60 years

What does the study involve?
Vestibular stimulation (rocking using a swing for 20 minutes per day for three months) is given as an intervention and changes in measures of diabetes symptoms will be measured before and after the intervention

What are the possible benefits and risks of participating?
Controlled vestibular stimulation helps in controlling anxiety, blood pressure, blood glucose levels and oxidative injury caused by hyperglycaemia. There is no risk involved in participating in the study as it is a noninvasive intervention.

Where is the study run from?
Little Flower Hospital and Research centre, India

When is the study starting and how long is it expected to run for?
August 2016 to April 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public

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Study information

Scientific Title
Modulation of physiological and biochemical parameters by controlled vestibular stimulation in prediabetes and Type 2 diabetes mellitus

Acronym
CVS

Study objectives
There will be a significant difference in biochemical and physiological parameters of prediabetic and type 2 diabetic patients before and after controlled vestibular stimulation

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 03/08/2016, Institutional ethics committee of Little Flower Hospital and Research Centre (Angamaly, Kerala, India; +91 484 2452546; admin@lfhospital.org), ref: IEC / LFMRC/ 2016 /1

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prediabetes and Type 2 Diabetes Mellitus

Interventions
Prediabetic patients and Type 2 diabetic patients were randomly divided into experimental and control groups by block randomization with equal numbers of patients in each group.

Controlled vestibular stimulation is provided to the subjects in the two experimental groups by using a swing to produce a to and fro motion 20 minutes per day for 3 months. Physiological and biochemical parameters were taken from all patients before starting of intervention and after 3 months

Intervention Type
Other

Primary outcome(s)
Blood glucose levels measured using fasting blood sugar and HbA1c at baseline and three months

Key secondary outcome(s)
At baseline and three months:
1. Anthropometry:
1.1. Waist to Hip Ratio (cm)
1.2. Body Mass Index (BMI) (kg/m²)
2. Physiological variables:
2.1. Heart rate (bpm)
2.2. Blood pressure (mmHg)
2.3. SPO2
3. Anxiety level measured using the stress assessment questionnaire - STAI (State Trait Anxiety Inventory)
4. Lipid profile (blood test):
4.1. Total Cholesterol (TC)
4.2. High Density Lipoprotein (HDL)
4.3. Low Density Lipoprotein (LDL)
4.4. Very Low Density Lipoprotein (VLDL)
4.5. Triglycerides (TG)
4.6. TC/HDL Ratio
5. Oxidative stress markers (blood test):

5.1. Malondialdehyde level (MDA) (spectrophotometric method)
5.2. Superoxide dismutase (SOD) (spectrophotometric method)

Completion date
04/04/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 19/05/2021:
Pre-Diabetic patients:
1. Fasting blood glucose level between 100 mg/dl and 125 mg/dl or HbA1C between 5.7% and 6.4%
2. Male and female patients aged 30-60 years
Diabetic patients:
3. Fasting blood glucose level >126 mg/dl or HbA1C >6.4% or taking oral hypoglycemic agents or insulin
4. Male and female patients aged 30-60 years

Previous inclusion criteria:
Pre-Diabetic patients:
1. Fasting blood glucose level between 100 mg/dl and 125 mg/dl or HbA1C between 5.7% and 6.4%
2. Male and female patient with age 20 - 70 years
Diabetic patients:
3. Fasting blood glucose level >126 mg/dl or HbA1C >6.4% or taking oral hypoglycemic agents or insulin
4. Male and female patient with age 20 - 70 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
240

Key exclusion criteria
1. Type 1 diabetes mellitus or gestational diabetes mellitus
2. Undergone any vestibular stimulation programs
3. Critically ill
4. Diagnosed with any cardiac diseases, cerebrovascular, renal diseases and liver diseases
5. On oral medication for hypertension and hyperlipidemia

6. Any planned surgery during the course of study
7. Pregnant or planning to get pregnant during the course of study
8. Taking vitamin supplements
9. Chronic smokers and severe alcoholic
10. Current continuous renal replacement therapy
11. Current use of steroids
12. Previous or current treatment with deep brain stimulation
13. Previous known disease, injury, or surgical intervention involving the brain or central nervous system
14. Moderate or greater hearing loss or presence of a cochlear implant
15. Diagnosed vestibular dysfunction
16. Any history of previous ear or eye surgery
17. Active ear infections or a perforated tympanic membrane
18. Presence of a serious or unstable medical or psychological condition which, in the opinion of the investigator, would compromise the subject's safety or successful participation in the study

Date of first enrolment
30/08/2016

Date of final enrolment
30/04/2019

Locations

Countries of recruitment
India

Study participating centre
Little Flower Hospital and Research centre
Angamaly
Kerala
India
683572

Sponsor information

Organisation
Little Flower Hospital and research centre

ROR
https://ror.org/0375jhj23

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/07/2020	19/05/2021	Yes	No