# Effect of brain breaks video exercise on psychological variables, motivation to physical activity and amount of physical activity among people with type 2 diabetes mellitus

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
31/07/2020		∐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/08/2020	Completed	[X] Results		
<b>Last Edited</b> 18/08/2022	Condition category Nutritional, Metabolic, Endocrine	Individual participant data		

#### Plain English summary of protocol

Background and study aims

Psychology and motivation have been widely accepted as important factors in performing regular physical activity (PA). The present study focuses on the PA level of the adults with type 2 diabetes mellitus (T2DM), as PA is considered an effective way to help to control blood sugar levels. By giving a PA-based intervention (brain breaks video) to T2DM patients (intervention group), the present study aims to improve patients' motivation towards PA.

Who can participate?

Patients aged 18 and over, diagnosed with T2DM for at least 1 year

#### What does the study involve?

Participants are randomly allocated into two groups; the intervention group perform PA based on the brain breaks video, and the control group receive only a brochure related to the benefits of PA on diabetes. After 8 weeks, participants fill in questionnaires to evaluate their psychological variables and amount of PA. After the study end, the control group receive the brain break exercise video similar to the video received by the intervention group.

What are the possible benefits and risks of participating?

Participants' motivations towards PA could be improved. With a good psychological condition, participants will be more encouraged to perform regular PA. Regular PA can help participants to control their blood sugar level. Better blood sugar control could provide a better quality of life among participants. The researchers could not find any risks that could happen to participants as they believe that the given intervention is not invasive. However, participants could experience a minor injury while performing the PA based on the given brain breaks video.

Where is the study run from? Hospital Universiti Sains Malaysia (Malaysia) When is the study starting and how long is it expected to run for? September 2018 to January 2020

Who is funding the study? Universiti Sains Malaysia (Malaysia)

Who is the main contact? Aizuddin Hidrus aizuddinh88@gmail.com

# **Contact information**

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# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

USM/JEPeM/18040201

# Study information

#### Scientific Title

Transtheoretical model of psychological factors influencing physical activity among patients with type 2 diabetes mellitus in Hospital Universiti Sains Malaysia

# **Study objectives**

There is an improvement on the psychological variables (processes of change, decision balance, exercise self-efficacy), motivation for physical activity and amount of physical activity among type 2 diabetes mellitus patients in Hospital USM, Kelantan after being given the brain breaks exercise video intervention.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Approved 05/07/2018, Human Research Ethics Committee USM (HREC) (Universiti Sains Malaysia, Kampus Kesihatan, 16150 Kubang Kerian, Kelantan, Malaysia; +609 (0)767 3000/2354/2362; jepem@usm.my), ref: USM/JEPeM/18040201

#### Study design

Randomized controlled trial

#### Primary study design

Interventional

#### Study type(s)

**Treatment** 

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

Psychological variables, motivation for physical activity and amount of physical activity among people with type 2 diabetes mellitus

#### **Interventions**

Patients who volunteer to participate are randomised into intervention and control group using block randomisation (computerized). To reduce selection bias during randomisation, the block size used is randomly mixed (2,4, or 6) (Efird, 2010; Kim & Shin, 2014). The sizes and types of block determined by the computer as another way to reduce selection bias.

#### 1. Intervention group:

The participants are invited into 'Whatsapp' group. Participants are invited to a seminar to introduce the Brain Break exercise video to promote PA and to improve their health. Demonstration of watching and following the instruction in the video is conducted during the first seminar. Brain Break exercise (or web-based structured) that stimulates participants' health and learning as well as being specifically designed for the individual setting to motivate the patients to enhance their exercise using computerised web-based exercise and provide an opportunity not only to be physically active during their breaks but also learn new motor skills. language, art, music and different cultures (Chin et al., 2013). The web-based exercise is only 10 minutes, and the patients can follow the exercise wherever they are using their mobile phone or computer. An adherence log-book is given to track their exercise frequency. The researcher sends a kind reminder to the participants to have PA through watching the video on each alternative day. The duration of this intervention is 4 months (or 16 weeks). At week 8, participants are asked to fill in questionnaires (similar to questionnaires used at Phase 1) to evaluate their psychological variables (TTM variables and motives to PA) and amount of PA. On the last week of intervention, all participants are invited into a group seminar where at the end of the seminar, again, they complete the questionnaires (similar with questionnaires used at Phase 1) to assess their post-intervention stage of exercise behaviour change.

## 2. Control group:

Participants only receive a brochure containing a brief introduction to the benefits of PA on health. At week 8, participants are asked to fill in questionnaires (similar to questionnaires used at Phase 1) to evaluate their psychological variables (TTM variables and motives to PA) and amount of PA. After the 4-month period, they complete the questionnaires (similar with questionnaires used at Phase 1) to assess their post-intervention stage of exercise behaviour change. After the study end, the control group receive the brain break exercise video similar to the video received by the intervention group during the study.

#### Intervention Type

Behavioural

#### Primary outcome(s)

- 1. Process of change measured by POC scale
- 2. Decisional balance measured by DB scale
- 3. Self-efficacy measured by ESE scale
- 4. PA motivation measured by PALMS scale
- 5. Amount of PA measured by IPAQ

All of the outcomes are measured at baseline (pre-intervention), 1st month, 2nd month, 3rd month, and 4th month (post-intervention)

## Key secondary outcome(s))

- 1. Weight measured using a monthly questionnaire (demographic section) for 4 months
- 2. HbA1c obtained from the participants' medical records
- 3. Amount of PA measured monthly by questionnaire, IPAQ

All of the outcomes are measured at baseline (pre-intervention), 1st month, 2nd month, 3rd month, and 4th month (post-intervention)

#### Completion date

30/01/2020

# **Eligibility**

### Key inclusion criteria

- 1. Patients clinically diagnosed with T2DM for at least 1 year
- 2. Patients with Malaysian nationality
- 3. Patients who 18 years and above
- 4. Patients are able to read and understand Bahasa Malaysia
- 5. Patients who are able to fulfil the given questionnaires
- 6. Patients who understand the information explained by the researcher and agree to be included in the study
- 7. Patients who give their written consent to participate in the Community trial

#### Participant type(s)

**Patient** 

# Healthy volunteers allowed

No

## Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Total final enrolment

#### Key exclusion criteria

- 1. Patients that have any mental disorders
- 2. Patients with disabilities that avoiding them from physically active
- 3. Patients who withdraw in the middle or at the end of the intervention before answering the questionnaire of post-trial

# Date of first enrolment

01/01/2019

### Date of final enrolment

01/10/2019

# Locations

#### Countries of recruitment

Malaysia

## Study participating centre Hospital Universiti Sains Malaysia

Universiti Sains Malaysia Kubang Kerian Kota Bharu, Kelantan Malaysia 16150

# Sponsor information

#### Organisation

Universiti Sains Malaysia

#### **ROR**

https://ror.org/02rgb2k63

# Funder(s)

## Funder type

University/education

#### **Funder Name**

Universiti Sains Malaysia

# **Results and Publications**

# Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Aizuddin Hidrus (aizuddinh88@gmail.com). The data can be requested after the researchers have published the study. Normally they provide the data as a supplemental file to the journal where they submit the manuscript for publication consideration. Other researchers can obtain the data from the journal repository after the study is published.

#### IPD sharing plan summary

Available on request

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/04/2020	15/02/2022	Yes	No
Results article		26/08/2021	15/02/2022	Yes	No
Results article		08/07/2022	, ,		No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes