ISRCTN14952589 https://doi.org/10.1186/ISRCTN14952589

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
31/07/2020

Recruitment status
No longer recruiting

Registration date
16/08/2020

Overall study status
Completed

Last Edited
18/08/2022

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
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?
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Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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)

Secondary outcome measures
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)

Overall study start date
01/09/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
70

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
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/02rgb2k63

Funder(s)

Funder type
University/education

Funder Name
Universiti Sains Malaysia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. No additional documents are available.

Intention to publish date
31/08/2020

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	18/08/2022	Yes	No