

Brief exercise for depressive and anxiety symptoms among inpatients with severe mental illness

Submission date 05/05/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/06/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 23/06/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Exercise has a positive effect in treating depression and anxiety, but it is not been used much in Malaysia especially in the form of structured exercise programs. Most exercise programs are usually designed for patients who are more stable and do not require hospital admission. There is a lack of exercise programs designed for patients who are admitted to a ward due to their mental illness. Hence, researchers would like to develop a short-term structured exercise program design for participants who are admitted to hospital due to their mental illness. The aim of this study is to assess the feasibility of the program and its effects on symptoms of depression and anxiety.

Who can participate?

Patients aged 18 to 45 admitted to the psychiatric ward and diagnosed with a severe mental illness, with at least some anxiety or depressive symptoms

What does the study involve?

The study will involve participants being divided into two groups: treatment as usual (TAU) or exercise with TAU. TAU will be medication and the usual treatment for the illness while the second group will receive an add-on exercise program. The exercise involves structured exercise by an instructor 5 times per week, moderate intensity, aerobic in nature for a 10-day period.

What are the possible benefits and risks of participating?

The possible benefits of this participating in this program are associated with exercise, such as improving heart health and feelings of wellbeing and mental health. There might be some risk of injury or heart attack while doing exercise in general. However, the risk is very small as all participants will go for a medical screening before participating and the exercise will be supervised by a healthcare professional.

Where is the study run from?

University Kebangsaan Malaysia Medical Centre (UKMMC) (Malaysia)

When is the study starting and how long is it expected to run for?
September 2019 to February 2021

Who is funding the study?
University Kebangsaan Malaysia Medical Centre (UKMMC) (Malaysia)

Who is the main contact?
1. Assoc. Prof. Dr. Nik Ruzyanei Nik Jaafar
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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

FF-2019- 428

Study information

Scientific Title

A randomized controlled trial on the effect of a brief structured exercise therapy on depressive and anxiety symptoms among inpatients with severe mental illness: a pilot study

Acronym

B-SET-DAS

Study objectives

Hypothesis (Null):

There is no significant difference between the effects of a brief structured exercise therapy compared to control group treatment in reducing depressive or anxiety symptoms among patients with SMI.

2 Hypothesis (Alternative):

The brief structured exercise therapy compared to control group treatment, has more significant effects for reducing depressive or anxiety symptoms among patients with SMI.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/09/2019, Research Ethics Committee of National University of Malaysia (Tingkat 1, Blok Klinikal, Hospital Canselor Tuanku Muhriz, Pusat Perubatan UKM, Jalan Yaacob Latif, Bandar Tun Razak, 56000 Cheras Kuala Lumpur, Malaysia; +603 (0)9145 5046 / 5048; seoukmAnkm.edu.my), ref: UKM PPI111118/JEP-2019.493

Study design

Randomised 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

Schizophrenia, schizoaffective disorder, bipolar disorder and major depression

Interventions

The simple randomization will be done via lottery method without replacement. This will be done by placing papers with numbers in a bowl which are collected by patients. The numbers will be written as 1, 2, 3... to 34. Patients who obtained odd numbers will be selected into the control group while patients with even number will be selected into the exercise group. The numbers that are taken will not be put back, hence it is possible to get the same participant in both arms.

Psychiatric inpatients will be randomly allocated into two groups: brief structured exercise (BES) plus treatment as usual (TAU) vs TAU (control); participants are not blinded to the intervention.

The BES consists of 5 times of a 30 minutes exercise per session in a 10-day period; supervised by a trained healthcare provider following the FITT module, i.e. follow frequency, intensity, time and type, as an intervention for depressive and anxiety symptoms together with TAU. Patients in the control group will be given treatment as usual by a psychiatrist in charge of the patient who is not involved in the study. Treatment may consist of antidepressants, antipsychotics, mood stabilizers, anxiolytics or electroconvulsive therapy.

Total duration of follow up: 10 days (same as the length of intervention).

Intervention Type

Behavioural

Primary outcome measure

Feasibility: recruitment rate recorded as the number of eligible participants who consent to participate in the study in 3 months; the researchers will also record the number of patients who are screened for eligibility, the number of dropouts, and the reason for dropping out.

Secondary outcome measures

1. Depression measured using Patient Health Questionnaire (PHQ)-9 at day 1 and day 10
2. Anxiety measured using GAD-7 Generalized Anxiety Disorder 7 at day 1 and day 10

Overall study start date

14/09/2019

Completion date

13/02/2021

Eligibility

Key inclusion criteria

1. Inpatients who are diagnosed with severe mental illness, i.e. major psychiatric disorders including schizophrenia, schizoaffective disorder and major affective disorders e.g. major depressive disorder, bipolar disorder I based on DSM-5 by psychiatrists
2. Patients should have at least moderate symptoms of depression and/or anxiety; with depression score of ≥ 1 on PHQ-9 and/or anxiety score of ≥ 1 on GAD-7
3. Age 18 to 45 years old
4. Consented to participate in the program

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

34

Key exclusion criteria

1. Patients who are aggressive or have a risk of aggression. This is determined by using Brøset violence checklist (BVC) and patients who score > 0 will be excluded.
2. Patients who are being chemically and/or physically restrained
3. Patients in a high dependency unit

4. Do not consent to participate in the study
5. Cannot understand or speak the language used in the study (English or Malay)
6. Failed medical clearance by a healthcare professional to participate in exercise for the research

Date of first enrolment

12/05/2020

Date of final enrolment

02/02/2021

Locations

Countries of recruitment

Malaysia

Study participating centre

University Kebangsaan Malaysia Medical Centre

Jalan Yaacob Latif

Bandar Tun Razak

Cheras

Kuala Lumpur

Malaysia

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Sponsor information

Organisation

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Sponsor type

Hospital/treatment centre

Website

<http://www.ppukm.ukm.my/sppi>

ROR

<https://ror.org/01590nj79>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Kebangsaan Malaysia Medical Centre Fundamental Fund

Results and Publications

Publication and dissemination plan

The researchers plan to publish the study protocol and study findings in peer-reviewed, scientific psychiatric journals in December 2020 and soon after the completion of the study analysis; expected around June 2021 onwards.

Intention to publish date

01/06/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Assoc. Prof. Dr Nik Ruzyanei Nik Jaafar (njruzyanei@gmail.com) and Dr Muhammad Hafriz bin Osman (hafrizosman@gmail.com). The data will be available from the end date of the research until 3 years. Data will be shared for research purposes in a collective manner with no reference to an individual as stated in the research information sheet.

IPD sharing plan summary

Available on request