ISRCTN14914508 https://doi.org/10.1186/ISRCTN14914508

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

Submission date
05/05/2020

Recruitment status
No longer recruiting

Registration date
19/06/2020

Overall study status
Completed

Last Edited
23/06/2020

Condition category
Mental and Behavioural Disorders

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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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 Rezak, 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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
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Kuala Lumpur
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Sponsor information

Organisation
University Kebangsaan Malaysia Medical Centre

ROR
https://ror.org/01590nj79

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Kebangsaan Malaysia Medical Centre Fundamental Fund

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 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