

Lifestyle physical activity counselling for in-patients with major depressive disorder

Submission date 27/08/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 03/09/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/10/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Major depressive disorder, commonly referred to as depression, is a widespread and burdensome condition. It is associated with the second greatest number of life years lost due to premature death or disability and will most likely be the leading cause in 2030. Physical activity has proven to be an effective treatment as a complement to drugs and psychotherapy. However, people suffering from major depressive disorders are particularly vulnerable to physical inactivity and lack of physical activity maintenance because of other disorders and problems with motivation. Therefore, physical activity counselling may have the potential to increase lifestyle physical activity and cardiorespiratory fitness in this population, thus not only tackling mental but also physical health problems. The aim of the present study is to compare two types of physical activity interventions to increase physical activity in people with major depressive disorder.

Who can participate?

People aged 18-65 who have depression, can speak and read German and do not currently participate in physical activity may participate in this study. Additionally, inactive, German-speaking women and men, aged 18-65, without a current or previous diagnosis of major depression may take part as a group to be compared with the group of patients

What does the study involve?

Hospitalised participants will be randomly assigned to one of two groups - the intervention group or the control group. The intervention group will receive individually tailored physical activity counseling, which includes three face-to-face meetings, and continuous remote counseling upon leaving the clinic. The control group, the group which is to be compared to the intervention group, will receive written information regarding a healthy lifestyle along with one face-to-face meeting in which the written information will be discussed and further emphasised with a short animated film. All hospitalised patients will continue receiving the standard medical and psychiatric care. Additionally, the initial measurements taken from the hospitalised patients will be compared to healthy peers, who will not be receiving any treatment. Measurements of physical activity will be taken upon hospitalisation, six weeks after hospitalisation, and 12 months after the end of hospitalisation. Measurements from the healthy counterparts will be taken once.

What are the possible benefits and risks of participating?

The possible benefit of taking part is that participants will receive their personal health profile including insight into their cardiovascular risk factors, fitness and activity levels as well as sleep quality. Ultimately, participating in the study may lead to increases in physical activity, which in turn may effect long-term response and remission rates in patients with major depression. This does not only secure a personal benefit but it also benefits people suffering from the same disorder. There are no known specific risks of participating.

Where is the study run from?

Department of Sport, Exercise and Health of the University of Basel, Switzerland and four Swiss clinics specialised in psychiatric care

When is the study starting and how long is it expected to run for?

June 2018 to January 2022

Who is funding the study?

The Swiss National Science Foundation (Switzerland)

Who is the main contact?

Prof. Dr. Markus Gerber

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

1

Study information

Scientific Title

Lifestyle Physical Activity Counselling for IN-PATients with major depressive disorder: Randomized controlled trial on physical activity, cardiorespiratory fitness, depression, and cardiovascular health risk markers

Acronym

PACINPAT

Study objectives

Compared to treatment as usual, individually-tailored physical activity counselling in patients with major depressive disorders will lead to clinically relevant increases in physical activity and cardiorespiratory fitness, and these outcomes will persist beyond clinical discharge.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 06/09/2018, Ethics Committee of Northwest and Central Switzerland (Ethikkommission Nordwest- und Zentralschweiz [EKNZ], Hebelstrasse 53, 4056 Basel, +41 (0)61 268 13 50; eknz@bs.ch), ref: 2018-00976

Study design

Interventional multi-centre two-arm double-blind randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Depression

Interventions

Patients will be randomly assigned (stratified by age, gender, and depression severity) to an extended personalised physical activity and exercise counselling program (intervention group) or to general instructions about health-enhancing physical activity (placebo control group). To ensure allocation concealment, allocation to groups will be done by a computer-generated code after the baseline assessment has taken place. To minimise subjective biases, patients do not know whether they have been allocated to the intervention or placebo control group. Before providing informed consent, patients will be informed that the goal of the study is to test different methods to promote a more physically active lifestyle among patients with major depressive disorders who do not meet levels of physical activity recommended by the American College of Sports Medicine. Clinicians, researchers, and physical activity facilitators will not be blinded to treatment allocation because of the nature of the study. However, outcomes will be assessed by researchers who do not know whether a patient belongs to the intervention or placebo control group.

Patients assigned to the intervention group will receive 12 months of individually tailored physical activity counselling to provide support and encouragement to increase physical activity during and after clinical treatment. This intervention is based on a standardised, theory-based, short, low cost lifestyle physical activity counselling program, which was specifically designed for

an in-patient rehabilitation setting. It consists of three face-to-face meetings in which tailored exercise prescriptions and behavioural change techniques will be delivered. The exercise prescriptions follow the standards of the American College of Sports Medicine and behavioural change techniques include motivational and volitional strategies to promote and foster long-term behavioural change. Additionally, after hospitalisation, remote meetings will continue until 12 months after discharge, whereby three methods of administration will feature bi-weekly telephone counselling, SMS prompts, and smartphone app notifications.

Patients assigned to the placebo control group will receive written information about health-enhancing physical activity based on the "Core document for Switzerland" published by the Federal Office of Sport in collaboration with other institutions. Additionally, the patients will receive written and oral standard recommendations regarding exercise and physical activity in the treatment of depression. Before the end of the in-patient treatment patients will have a face-to-face meeting in which the key contents of the "core document" will be discussed supported by a short animation film.

Intervention Type

Behavioural

Primary outcome(s)

1. Objective physical activity, assessed using an Actigraph accelerometer for a seven day period with a sampling epoch of 10 seconds. Time spent in moderate physical activity and vigorous physical activity will be determined based on the accelerometer counts and the ActiLife® computer software. Only days with at least 13 hours of wear time will be considered as a valid measure of daily activity. Participants will need at least five valid days, ≥ 4 weekdays and ≥ 1 a weekend day, for the data to be included in the data analyses. This will be assessed at the baseline (1-2 weeks after hospitalisation), 6 weeks after hospitalisation and at the follow-up (12 months after hospitalisation)
2. Physical activities during which the accelerometer cannot be worn (i.e. swimming), assessed using a non-wear time sheet

Key secondary outcome(s)

The following will be assessed at the baseline (1-2 weeks after hospitalisation), 6 weeks after hospitalisation and at the follow-up (12 months after hospitalisation):

1. Self-reported physical activity, assessed using the Simple Physical Activity Questionnaire (SIMPAQ)
2. Cardiorespiratory fitness, assessed using the Åstrand indirect test of maximal oxygen uptake ($VO_2\text{max}$)
3. Autonomic function, assessed using electrocardiography (ECG)
4. Cognitive and social determinants of exercise, assessed using various validated questionnaires:
 - 4.1. 1-item proxy for perceived fitness
 - 4.2. 3 items regarding exercise-related self-efficacy
 - 4.3. 16 items regarding exercise-related outcome expectancies
 - 4.4. 1 item regarding exercise intention
 - 4.5. 12 item SSK-Scale for self-concordance
 - 4.6. 10 items regarding action and coping planning
 - 4.7. 19 items regarding perceived exercise barriers
 - 4.8. 7 items regarding exercise-related social support
5. Depression severity, assessed using:
 - 5.1. Hamilton Rating Scale for Depression 17-item (HAMD17)
 - 5.2. Beck Depression Inventory (BDI)
6. Self-perceived physical and psychological health, assessed using the Medical Outcomes Study

12-item Short Form Health Survey (SF-12)

7. Insomnia symptoms, assessed using the 7-item Insomnia Severity Index (ISI)

8. Cognitive function, assessed using the Test of Attentional Performance

9. Cardiovascular health risk markers:

9.1. Blood pressure, assessed using an Omron® digital blood pressure monitor

9.2. Body mass index (BMI) assessed by body weight (measured using a digital weighing scale BC-545, Tanita, USA) and body height (measured using a stadiometer) using the formula $BMI = \text{weight (kg)} / (\text{standing height (meters)}^2)$

9.3. Percentage body fat, assessed using bioelectrical impedance analysis using a digital weighing scale (BC-545)

9.4. Waist circumference, assessed using flexible tape at the natural waist

9.5. Total/LDL/HDL cholesterol, triglycerides and HbA1c, assessed using antecubital vein blood tests, drawn before 7:30 and 10:00 am after fasting since 22:00 pm the day before

10. Biomarkers of major depressive disorder:

10.1. Cortisol awakening response, assessed using saliva samples taken 0, 10, 20, and 30 minutes after awakening using "Salviette" device

10.2. Brain-derived neurotrophic factor (BDNF), assessed using ELISA (BDNF Emax Immunoassay System, Promega, USA)

10.3. Tumor necrosis factor-alpha (TNF α), assessed using a solid phase Enzyme Amplified Sensitivity Immunoassay TNF- α –ELISA from DRG (Switzerland)

10.4. Insulin-like growth factor (IGF-1), assessed using ELISA (DRG IGF-I 600 ELISA Kit (DRG, Switzerland))

11. Serotonin transporter (5-HTT) polymorphic promoter region (5-HTTLPR) as a potential moderator of intervention effects, assessed using 9 ml EDTA blood

Completion date

31/01/2022

Eligibility

Key inclusion criteria

1. Aged 18-65 years

2. Major depressive disorders according to ICD-10 diagnostic criteria (F31 type II, F32 or F33)

3. 17-item Hamilton Rating Scale for Depression (HAM-D17) score ≥ 17 (moderate depression)

4. Beck's Depression Inventory II (BDI-II) score ≥ 17 (borderline clinical depression)

5. Currently not meeting the American College of Sports Medicine's physical activity recommendations (International Physical Activity Questionnaire (IPAQ) < 150 minutes/week of moderate-to-vigorous physical activity)

6. Read and signed written informed consent

7. Ability to read and speak German

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Key exclusion criteria

1. History of bipolar disorder type I (F31 type I)
2. History of schizophrenia or schizoaffective disorder
3. Current active alcohol or drug abuse or dependence
4. Pathological electrocardiogram (ECG)
5. Any significant medical condition that contraindicates safe participation in physical activity
6. Pregnancy or breastfeeding
7. Active suicidal intent
8. Evidence of significant cardiovascular, neuromuscular or endocrine disorders limiting regular physical activity as per American College of Sports Medicine absolute contraindications to exercise

Date of first enrolment

15/10/2018

Date of final enrolment

15/10/2020

Locations

Countries of recruitment

Switzerland

Study participating centre

Psychiatric Services Solothurn

Weissensteinstrasse 102

Solothurn

Switzerland

4500

Study participating centre

Psychiatric Clinics of the University of Basel

Wilhelm Klein-Strasse 27

Basel

Switzerland

4012

Study participating centre
Psychiatric Clinic Wyss
Fellenbergstrasse 34
Münchenbuchsee
Switzerland
3053

Study participating centre
Psychiatric Clinic Sonnenhalde
Gänshaldenweg 28
Riehen
Switzerland
4125

Sponsor information

Organisation
Swiss National Science Foundation

ROR
<https://ror.org/00yjd3n13>

Funder(s)

Funder type
Not defined

Funder Name
Swiss National Science Foundation

Results and Publications

Individual participant data (IPD) sharing plan

Data will be made publicly available as supplementary online material and stored in digital archives that correspond with FAIR Data Principals after publication of the data (in form of an SPSS file). Variables are clearly labelled in the SPSS file and described in the SPSS variable view. For each publication, a separate SPSS file will be created with the data used for the specific data analyses.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/01/2023	07/02/2023	Yes	No
Results article	process evaluation	04/05/2023	09/05/2023	Yes	No
Results article		23/03/2024	04/10/2024	Yes	No
Protocol article	protocol	20/06/2019	24/06/2019	Yes	No
Interim results article	Baseline data	09/05/2023	17/07/2023	Yes	No
Interim results article	Baseline data	15/02/2023	17/07/2023	Yes	No
Interim results article	Baseline data	01/11/2022	17/07/2023	Yes	No
Interim results article	Baseline data	29/10/2021	17/07/2023	Yes	No
Other publications	Cardiorespiratory fitness and cardiovascular risk among in-patients with depression compared to healthy controls	20/06/2023	17/07/2023	Yes	No
Other publications	Participant experiences	01/10/2022	17/07/2023	Yes	No
Other publications		06/09/2024	04/10/2024	Yes	No