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

**Submission date**
27/08/2018

**Recruitment status**
No longer recruiting

**Registration date**
03/09/2018

**Overall study status**
Completed

**Last Edited**
04/10/2024

**Condition category**
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
markus.gerber@unibas.ch

# Contact information

### Type(s)
Scientific

### Contact name
Prof Markus Gerber

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## 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
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 measure
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

## Secondary outcome measures
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 ($VO_2max$)
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 = weight (kg) / (standing height (meters) squared)
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 (TNFα), 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

### Overall study start date
01/06/2018

### 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 (HAMD17) 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

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
65 Years

### Sex
Both

### Target number of participants
334 (IG group = 167, PCG group = 167)

### 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

**Sponsor details**
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**Sponsor type**

Government

**Website**
www.snf.ch

**ROR**
https://ror.org/00yjd3n13

# Funder(s)

**Funder type**
Not defined

**Funder Name**
Swiss National Science Foundation

# Results and Publications

**Publication and dissemination plan**
The dissemination of the results will take place in a peer-reviewed journal and will be co-ordinated by the principal investigator.

**Intention to publish date**
31/01/2022

**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? |
|---|---|---|---|---|---|
| Protocol article | protocol | 20/06/2019 | 24/06/2019 | Yes | No |
| Results article | | 18/01/2023 | 07/02/2023 | Yes | No |
| Results article | process evaluation | 04/05/2023 | 09/05/2023 | Yes | No |
| Interim results article | Baseline data | 09/05/2023 | 17/07/2023 | Yes | No |

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|---|---|---|---|---|---|
| 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 |
| Results article | | 23/03/2024 | 04/10/2024 | Yes | No |