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Group therapy for a healthier lifestyle in psychiatric patients

Submission date	Recruitment status	[X] Prospectively registered
18/10/2024	Recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
30/10/2024	Ongoing	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
14/11/2024	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People with severe mental illness (SMI) often have unhealthy eating habits, even though they usually understand what a healthy diet is and want to follow it. This study aims to compare the effects of a new group therapy approach with the usual treatment methods.

Who can participate?
People between 18 and 65 years old with a diagnosis of depression, bipolar disease or psychosis with a Body-Mass-Index (BMI) over 25 and the desire to lose weight.

What does the study involve?
The study involves two groups and participants will be assigned randomly to one of the groups. The control group involves the usual treatment (nutritional counseling and standard group therapy). The intervention group involves the usual treatment, but the standard group therapy is replaced with a new group therapy specificially designed to help patients change their dietary behavior. The new group therapy takes place once a week for a duration of 8 weeks. All patients will be tested before and after the treatment (blood sample, stool sample, dietary behavior, physical activity, psychological assessment, sociodemographic data, medical history, current medication and treatment).

What are the possible benefits and risks of participating?
There is no additional risk for the control group. For the intervention group, there is a minimal risk associated with the psychotherapy elements of the new group therapy, which has not been tested yet.
Nutritional counseling is known to have positive effects on dietary behavior. In general, group therapy is an effective psychotherapeutic intervention.
Participants will receive CHF 100 for their time spent.

Where is the study run from?
The Psychiatric University Hospital Zurich, Switzerland.

When is the study starting and how long is it expected to run for?
October 2024 to June 2027

Who is funding the study?
Stiftung zur Förderung von Psychiatrie und Psychotherapie (Zürich, Switzerland)
Fonds für wissenschaftliche Zwecke im Interesse der Heilung von psychischen Krankheiten (Zürich, Switzerland)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
181024

Study information

Scientific Title
Behavioral therapy to induce a healthier lifestyle and more self-efficacy in psychiatric patients (HEALTH study): A naturalistic randomized controlled trial

Acronym

HEALTH

Study objectives
Study participants receiving the HEALTH intervention will have better anthropometric measures (BMI and WHR) after the intervention (T1) and in the long term (T2) compared to individuals receiving TAU only.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 13/11/2024, Kantonale Ethikkommission Zürich (Stampfenbachstrasse 121, Zürich, 8090, Switzerland; +41 43 259 79 70; info.kek@kek.zh.ch), ref: 2024-02177

Study design
Monocenter open-label randomized head-to-head study with two study arms

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
Psychosis, depression, bipolar disease

Interventions
HEALTH Intervention:
The intervention is planned to consist of 8 group sessions in groups of 5–10 patients every 7 days.
The sessions cover the following main topics:
- Healthy diet
- Physical activity
- Circadian rhythm
Therapeutic focus is set on: behavioral therapy support to identify and change problem behavior, small goals (microsteps), and enhance self efficacy.

The control group will receive treatment as usual (TAU):
Nutritional counseling plus group sessions in a standard group therapy (e.g. art therapy or recreational contact group).

RedCap software will be used for assignment either to the intervention or control group (allocation ratio 1:1, block randomization).

Intervention Type
Behavioural

Primary outcome measure
1. BMI is measured using weight and height at baseline (T0), week 9 (T1), and week 24 (T2)
2. WHR is measured using a measuring tape at baseline (T0), week 9 (T1), and week 24 (T2)

Secondary outcome measures
1. Inflammatory markers are measured using a venous blood sample of 24 ml at baseline (T0), week 9 (T1), and week 24 (T2)
2. Gut microbiome composition is measured using a stool sample at baseline (T0), week 9 (T1), and week 24 (T2)
3. Dietary behavior is measured using the Rapid-Eating-Assessment of Participants-Short version (REAP-S), Food-Frequency-Questionnaire (FFQ), Practical Knowledge about Balanced Meals scale (PKB-7), and Salzburg Emotional Eating Scale (SEES) at baseline (T0), week 9 (T1), and week 24 (T2)
4. Physical activity is measured using the Xiaomi Smart Band 8 and a self-rating scale for physical activity at baseline (T0), week 9 (T1), and week 24 (T2)
5. Psychological assessment is measured using the Goal Attainment Scale (GAS), Beck Depression Inventory (BDI), Self-efficacy Scale (SWE), Symptom-Checklist (SCL-K-9), World Health Organization Quality of Life (WHOQOL-BREF), and Schlafqualitäts-Fragebogen (PSQI) at baseline (T0), week 9 (T1), and week 24 (T2)

Overall study start date
18/10/2024

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Age 18-65 years
2. SMI including ICD-10 F2 or F3 diagnosis
3. BMI >25 kg/m² and desire to lose weight

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Comorbid substance use disorder (F1) or eating disorder (F5)
2. Current medical conditions such as acute infectious disease
3. Taking medication to reduce weight (e.g. GLP-1 receptor agonists) and participating in another nutritional counselling

Date of first enrolment
01/01/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Switzerland

Study participating centre
Psychiatrische Universitätsklinik Zürich
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Sponsor information

Organisation
University of Zurich

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Sponsor type
University/education

Website
http://www.uzh.ch/index_en.html

ROR
https://ror.org/02crff812

Funder(s)

Funder type
University/education

Funder Name
University of Zurich / Psychiatric University Clinic Zurich; Fonds für wissenschaftliche Zwecke im Interesse der Heilung von psychischen Krankheiten.

Funder Name
Stiftung zur Förderung von Psychiatrie und Psychotherapie

Results and Publications

Publication and dissemination plan
After the statistical analysis of this trial the sponsor will make every endeavor to publish the data in a peer-reviewed scientific journal. It is intended to make the publications available via open-access options. Also, the core results will be presented at scientific conferences. Those participants who expressed interest in the results will also be informed about the results using a presentation for laymen.

Intention to publish date
31/12/2028

Individual participant data (IPD) sharing plan
The datasets generated during and / or analysed during the current study will be available upon request from Dr. med. Florian Hotzy (florian.hotzy@pukzh.ch).

IPD sharing plan summary
Available on request