ISRCTN14328965 https://doi.org/10.1186/ISRCTN14328965

Exercise to promote social integration after a first psychotic episode: examining the feasibility of a study design

Submission date 31/08/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 21/09/2022	**Overall study status** Completed	
Last Edited 16/03/2023	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Already from the early stages of a psychotic disorder, individuals demonstrate difficulties with social integration. They often stop working, studying, participating in leisure activities, and lose contact with peers. In order to prevent the progressively worsening social impairment often present in psychotic disorders, it is crucial to intervene early. Researchers propose an individualized sport-based intervention for young people in the first episode of psychosis, with a strong focus on integrating sports outside of mental health care institutions in daily life. By making use of community sport coaches, this intervention aims to build a bridge between activities in the context of mental health care and social participation in the community. In preparation of a larger intervention study, the aim of this feasibility study is to test and improve the personalized sport intervention, which aims to promote physical activity, decrease self-stigma and increase social (re)integration, for young people in the first episode of psychosis.

Who can participate?
Individuals between 18-35 years of age, in the first 5 years of a psychotic disorder, currently in care at GGZ Drenthe. The most important inclusion criteria are the desire or intention for physical activity and reduced social integration.

What does the study involve?
The intervention consists of a minimum of 20 sessions in a 20 to 22-week time frame, consisting of three phases: individual psychomotor therapy (focusing on goal setting and regaining trust in one’s own physical capabilities), a group intervention combining psychomotor therapy and sport (focusing on social connectedness) and finally sporting in the local community (focused on social (re)integration). The intention is to make the intervention flexible to personal wishes and needs. Participants will be assessed using interviews, questionnaires and daily diary assessments in order to assess the feasibility of the intervention. Before and after the intervention the participants will partake in two interviews and two sessions of questionnaires. During the intervention participants will partake in eight phases of daily diary assessments, including wearing an activity monitor.

What are the possible benefits and risks of participating?
The participants in the study are expected to benefit from the intervention. It is expected that participants will have improved participation in the community by the end of the intervention, and may also have positive health benefits through increasing activity levels. Deterioration due to the intervention is not expected to happen.
There are no risks involved in participating in the study. The burden associated with participation consists of participating in two interviews and a meeting about the study protocol (180 minutes), the sports intervention (19 hours for a duration of roughly 20 weeks), two sessions of questionnaires (140 min.) and eight phases of daily dairy assessments (120 minutes per phase).

Where is the study run from?
GGZ Drenthe (Netherlands)

When is the study starting and how long is it expected to run for?
January 2022 to August 2023

Who is funding the study?
1. Netherlands Organisation for Scientific Research (NWO) (Netherlands)
2. GGZ Drenthe (Netherlands)

Who is the main contact?
Marieke Pijnenborg, g.h.m.pijnenborg@rug.nl

Contact information

Type(s)
Scientific

Contact name
Dr Laura Steenhuis

ORCID ID
https://orcid.org/0000-0002-1256-3754

Contact details
Denneweg 9
Assen
Netherlands
9404 LA
+31 (0)683790269
l.a.steenhuis@rug.nl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Aut.19.014

Study information

Scientific Title
Don't Stop Me Now! A feasibility study for a community-based sport intervention to promote social integration in young adults with a first episode of psychosis

Acronym
DSMN

Study objectives
The aim of this study is to examine the feasibility of a newly developed personalized and phased sports intervention for individuals with a first episode of psychosis. For this feasibility study, it is hypothesized that:
1. The sports intervention is applicable and flexible for the target group
2. That the chosen design has an appropriate recruitment strategy (willingness of clinician to inform participants, willingness of patients to participate and adequate adherence rate)
3. That the effects can be measured in a multiple baseline single-case design using the chosen outcome measures, and that the frequency and duration of the experience sampling method are appropriate

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/07/2022, the Medical Ethical Committee of the University Medical Center Groningen (Hanzeplein 1, Postbus 30 001, 9700 RB Groningen, the Netherlands; +31 (0)50 361 4204; metc@umcg.nl), ref: METc 2021.706

Study design
Multiple baseline single-case design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Enhancing social integration for young adults with a first episode of psychosis

Interventions
This feasibility study uses a multiple baseline single-case design (n = 1). A single case design is a within-subject design, with a control phase as baseline followed by an experimental phase. In this form, each participant functions as their own 'control group'. This design is especially useful to test the effectiveness of interventions that are used in daily life and where a personal approach or adaptation to the individual is necessary for success.

In a single-case design, certain behaviors (e.g. frequency of social contacts) are assessed to determine their initial, stable expression (i.e., baseline), followed by a period in which assessments are continued when an intervention is applied on that behavior (i.e. intervention phases). By successively administering an intervention to different behaviors after initial behaviors have been recorded (baseline), a multiple baseline design allows for inferences about the effect of the intervention. With a 'single case' design it is possible to study both individuals, as well as small groups of people.

This study consists of a pretest-posttest design for each phase (1, 2 and 3) of the current intervention. Each participant will have a different (and randomly chosen) duration of the baseline period in order to avoid bias (minimum = 12 days, maximum = 21 days).

The total intervention consists of a minimum of 20 sessions in a 20 to 22-week time frame, consisting of three phases: individual psychomotor therapy (focusing on goal setting and regaining trust in one's own physical capabilities), a group intervention combining psychomotor therapy and sport (focusing on social connectedness) and finally sporting in the local community (focused on social (re)integration). The intention is to make the intervention flexible to personal wishes and needs, so that someone can continue a little longer or receive some extra support if this is necessary.

Intervention Type
Behavioural

Primary outcome(s)
The criteria used to judge the acceptability and feasibility of the intervention study are as follows:
1. Participants' satisfaction with the intervention measured using a client thermometer and a qualitative interview at the end of the intervention
2. Percentage of participants starting the intervention and percentage of participants completing the intervention, measured using a participant log file at the start and the end of the intervention
3. Number of participants approached to partake in the intervention and number of participants willing to participate in the intervention, measured using a recruitment log file at the start and the end of recruitment
4. Percentage of measurements which are completed by the participants, measured using an assessment log file at all measurement times in the study (at the start and the end of each phase of the design; eight in total)

Key secondary outcome(s))
1. Symptoms measured using the Positive and Negative Syndrome Scale (PANSS) and the Brief Negative Symptom Scale (BNSS) at the beginning and end of the intervention
2. Social integration measured using Assessment of Life Habits (LIFE-H) at the beginning and end of the intervention
3. Social functioning measured using the Groningen Social Behaviour Questionnaire (GVSG) at the beginning and end of the intervention
4. Social network measured using the Social Network Quality (SNQ) at the beginning and end of the intervention
5. Social exclusion measured using the 1-item social exclusion assessment at the beginning and end of the intervention
6. Self-stigma measured using the Internalized Stigma of Mental Illness Inventory (ISMI) at the beginning and end of the intervention

7. Self-esteem measured using the Rosenberg Self-Esteem Scale (RSES) and the Dresden Body Image Questionnaire, Dutch translation (DBIQ-NL) at the beginning and end of the intervention
8. Physical activity measured using the International Physical Activity Questionnaires (IPAQ) at the beginning and end of the intervention, and an actigraph accelerometer for five consecutive days at the beginning and end of each phase of the intervention
9. Digital diary measured with the Experience Sampling Method assessed for five consecutive days at the beginning and end of each phase of the intervention

Completion date
01/08/2023

Eligibility

Key inclusion criteria
1. Aged between 18 and 35 years
2. Have received their diagnosis of a psychotic disorder no more than 5 years ago
3. The desire or intention for (more or restart) physical activity
4. Subjective experiences of reduced (social) participation
5. Do not currently practice sports
6. Read and speak Dutch fluently
7. Should be capable of following the research procedures
8. Willing and able to provide Informed Consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
3

Key exclusion criteria
1. History of psychotic disorder (before the current episode), according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria
2. Significant hearing or visual problems impairments
3. No internet connection at home or on mobile phone
4. Physical conditions (e.g. illness or pregnancy), defects or injuries that make sports unwise or impossible

Date of first enrolment

01/10/2022

Date of final enrolment
01/01/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
GGZ Drenthe
Denneweg 9
Assen
Netherlands
9404 LA

Sponsor information

Organisation
GGZ Drenthe

ROR
https://ror.org/0107rkg57

Organisation
University of Groningen

ROR
https://ror.org/012p63287

Funder(s)

Funder type
Government

Funder Name
Nederlandse Organisatie voor Wetenschappelijk Onderzoek

Alternative Name(s)

Netherlands Organisation for Scientific Research, Dutch National Scientific Foundation, Dutch National Science Foundation, Dutch Research Council (Nederlandse Organisatie voor Wetenschappelijk Onderzoek), NWO:Nederlandse Organisatie voor Wetenschappelijk Onderzoek, Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO), Dutch Research Council, The Dutch Research Council (NWO), Dutch Research Council, Netherlands, NWO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Netherlands

Funder Name
GGZ Drenthe

Alternative Name(s)
Geestelijke Gezondheidszorg Drenthe

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes