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Don’t stop me now! Sports to promote social integration in adults with early psychosis

Submission date	Recruitment status	[ ] Prospectively registered
19/06/2024	Recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
28/08/2024	Ongoing	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
11/03/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
In the early phases of psychosis individuals demonstrate difficulties with social participation. They often stop working, studying, and participating in leisure activities, and lose contact with peers. Additionally, physical health problems, such as metabolic risk factors, are often already present in the first phase of the disorder, and worsen as a result of inactive behavior. Researchers have proposed an individualized sport-based intervention for people in the early phase 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. On the basis of a previous feasibility study, the intervention and the study method have been improved and refined. Consequently, the aim of this study is to examine the effectiveness of a personalized sport intervention which aims to promote increase social (re) integration.

Who can participate?
Patients aged 18-65 years with early psychosis, currently in care at a mental health facility

What does the study involve?
The sport intervention consists of a minimum of 22 sessions in a 24 to 26 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 intervention is tailored to individual needs and goals in terms of duration, support and content.

What are the possible benefits and risks of participating?
Participants are expected to benefit from the intervention. The researchers expect that participants can be helped with participation in the community and may also have a positive health effect by increasing activity levels. Deterioration due to the intervention is not expected to happen. There are no risks involved in participating in the study.

Where is the study run from?
University of Groningen (Netherlands)

When is the study and how long is it expected to run for?
January 2024 to September 2026

Who is funding the study?
NWO, Nederlandse Organisatie voor Wetenschappelijk Onderzoek (Netherlands)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
Aut.19.014

Study information

Scientific Title
Don’t stop me now! A multicenter trial examining the effectiveness of a community-based sport intervention to promote social integration in adults with early psychosis

Acronym
DSMN

Study objectives
The aim of this study is to examine the effectiveness of a personalized sport intervention (Don't Stop Me Now!), which aims to increase social (re)integration in early psychosis. It is hypothesized that:
1. Participants report improved social integration after partaking in the sport intervention, as determined by an increase in the social network, improved social functioning and an increase in experienced social inclusion over time.
2. Participants report improvements in factors underlying social integration after partaking in the sport intervention, as determined by a decrease in self-stigma and negative symptoms, and an increase in physical activity and self-esteem over time.
3. Participants report improved social integration at 6 months follow-up after partaking in the sport intervention, as determined by reports on the lived experience of social integration by using qualitative interviews.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/05/2024, Medische Ethische Toestingscommissie UMCG (translation: Medical Ethics Review Committee UMCG) (Hanzeplein 1, Groningen, 9713 GZ, Netherlands; Monday & Tuesday: +31 (0)50 361 42 04, Wednesday & Thursday: +31 (0)50 361 18 29, Friday: +31 (0)50 361 98 33, +31 (0)50 361 42 04; metc@umcg.nl), ref: NL85697.042.23

Study design
Multicenter interventional multiple baseline single-case design (n = 1), in which each participant is examined as a single case and acts as their own control

Primary study design
Interventional

Secondary study design
Multiple baseline single-case design

Study setting(s)
Community, Fitness/sport facility, Other

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
Improving social integration in adults with early psychosis

Interventions
The intervention consists of a minimum of 22 sessions over 24 to 26 weeks, divided into 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 with the support of a community sports coach (focused on social (re)integration).

In Phase 1, participants attend weekly individual sessions with a psychomotor therapist to reintroduce them to physical activity. They select specific domains to work on from a provided toolbox, with exercises aligning with their goals. The final individual sessions prepare participants for the transition to group therapy, allowing for one rescheduled session due to illness or work.

Phase 2 involves group psychomotor therapy, where participants decide collectively on activities or sports, while working on personal goals. This phase aims to create a safe environment for participants to practice their goals and establish social connections. The phase includes two sessions with an expert-by-experience to discuss common challenges like self-stigma, and ends with the introduction of a community sports coach to ease the transition to phase 3.

Phase 3 is led by a community sports coach who promotes access to local sports, participants ensuring participants remain engaged in physical activity.

The intervention is customized for individual needs and uses a pretest-posttest design for each phase, with a 6-month follow-up. Participants have randomized baseline periods (12-21 days) to control for time effects, then start phase 1 simultaneously to ensure a joint start in phase 2. To assess the intervention's effect, four types of assessments will be conducted: quantitative questionnaires, actigraph sampling, experience sampling methodology (ESM), and qualitative interviews. Quantitative questionnaires will measure social integration and its components, providing a broad overview of changes. Actigraph sampling will objectively assess physical activity. ESM will evaluate social integration daily, capturing subtle changes and testing the design's effectiveness. Qualitative interviews at the six-month follow-up will offer a deeper understanding of participants' experiences with social reintegration.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 11/03/2025:

The primary outcome is to determine whether the intervention improves social integration through sports at post-treatment. The criteria used to measure social integration, and its underlying components, are as follows:
1. Daily assessments of social integration and its underlying components using a digital diary measured with the Experience Sampling Method. This is assessed for five consecutive days at the beginning and end of each phase of the intervention (eight times in total). The 30 ESM questions cover all domains of the intervention, including social integration (social network, social functioning and social inclusion), self-stigma, physical activity, self-esteem and negative symptoms.
2. Daily assessments of objective sedentary behavior and physical activity measured using ActiGraph GT9X+ accelerometers. Participants will wear the ActiGraph GT9X+ accelerometers during the daily assessment periods (five consecutive days at the beginning each phase; five times in total).

Descriptive outcomes:
3. It will be (descriptively) reported whether individuals have successfully commenced and continued (regular) sports activities in the community (outside of mental health facilities) at both post-treatment and 6 months follow-up, using a goal attainment scale.
4. Social functioning measured using the Social Functioning Scale (SFS) at the beginning and end of the intervention
5. Social network measured using the Social Network Quality (SNQ) at the beginning and end of the intervention
6. Social exclusion measured using the 1-item social exclusion assessment at the beginning and end of the intervention
7. 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
8. Self-stigma measured using the Internalized Stigma of Mental Illness Inventory (ISMI) at the beginning and end of the intervention
9. 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
10. 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 of each phase of the intervention
11. Recovery measured using the Questionnaire about the Process of Recovery (QPR) at the beginning and end of the intervention.

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Previous primary outcome measure:

The primary outcome is to determine whether the intervention improves social integration through sports at post-treatment. The criteria used to measure social integration, and its underlying components, are as follows:
1. Daily assessments of social integration and its underlying components using a digital diary measured with the Experience Sampling Method. This is assessed for five consecutive days at the beginning and end of each phase of the intervention (eight times in total). The 30 ESM questions cover all domains of the intervention, including social integration (social network, social functioning and social inclusion), self-stigma, physical activity, self-esteem and negative symptoms.
2. Daily assessments of objective sedentary behavior and physical activity measured using ActiGraph GT9X+ accelerometers. Participants will wear the ActiGraph GT9X+ accelerometers during the daily assessment periods (five consecutive days at the beginning each phase; five times in total).

Descriptive outcomes:
3. It will be (descriptively) reported whether individuals have successfully commenced and continued (regular) sports activities in the community (outside of mental health facilities) at both post-treatment and 6 months follow-up, using a goal attainment scale.
4. Social functioning measured using the Groningen Social Behaviour Questionnaire (GVSG) at the beginning and end of the intervention
5. Social network measured using the Social Network Quality (SNQ) at the beginning and end of the intervention
6. Social exclusion measured using the 1-item social exclusion assessment at the beginning and end of the intervention
7. 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
8. Self-stigma measured using the Internalized Stigma of Mental Illness Inventory (ISMI) at the beginning and end of the intervention
9. 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
10. 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 of each phase of the intervention

Secondary outcome measures
Subjective experience of social integration assessed using semi-structured interviews at 6-month follow-up

Overall study start date
01/01/2024

Completion date
01/09/2026

Eligibility

Key inclusion criteria
1. Between 18 and 65 years of age
2. Are in the first five years of a psychotic disorder
3. The desire or intention for (more or restart of) physical activity
4. Subjective experiences of reduced (social) participation
5. Read and speak Dutch fluently
6. Should be capable of following the research procedures
7. Willing and able to provide Informed Consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Significant hearing or visual problems
2. No internet connection at home or on mobile phone
3. Physical conditions (e.g., illness or pregnancy), defects or injuries that make sports unwise or impossible
4. Currently already practices a group sport
5. Currently receiving psychomotor therapy in a group

Date of first enrolment
01/07/2024

Date of final enrolment
01/03/2026

Locations

Countries of recruitment
Netherlands

Study participating centre
GGZ Drenthe
Denneweg 9
Assen
Netherlands
9404 LA

Study participating centre
Dimence Zwolle
Grasdorpstraat 6
Zwolle
Netherlands
8012 EN

Study participating centre
KieN VIP Leeuwarden
Oosterkade 72
Leeuwarden
Netherlands
8911 KJ

Study participating centre
Universitair Centrum Psychiatrie Groningen
Hanzeplein 1
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Sponsor type
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ROR
https://ror.org/0107rkg57

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, 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

Publication and dissemination plan
Planned publication in a peer-reviewed journal(s)

Intention to publish date
01/01/2027

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

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