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Walking improves the cognitive function of schizophrenic subjects

Submission date
22/12/2020

Recruitment status
No longer recruiting

Registration date
26/01/2021

Overall study status
Completed

Last Edited
28/03/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Schizophrenia is a common and costly public health problem. Individuals affected by schizophrenia experience severe and chronic levels of disability that derive from acute psychotic symptoms, as well as cognitive impairments for which available treatments offer only limited benefits. Moreover, their life expectancy is up to 15 years shorter than that of the general population. Several studies have found that individuals with schizophrenia have high levels of heart disease risk factors such as obesity, dyslipidaemia, smoking, high blood pressure, high blood sugar, physical inactivity and lower fitness than the general population. The World Health Organization and the European Mental Health Action Plan 2013–2020 acknowledge the role of physical activity in mental health and encourage the inclusion of lifestyle changes in education and treatment programmes for people with mental illness, delivered in primary healthcare settings.
For these reasons, this study aims to investigate the feasibility and adherence of a long-term, moderate-intensity physical activity program for individuals with schizophrenia and its effects on heart disease risk factors and cognitive function.

Who can participate?
Patients diagnosed with schizophrenia since at least 1 year and taking the same antipsychotic medications for at least 3 months

What does the study involve?
Participants will be assigned to a guided walking group or to a cognitive rehabilitation program. The guided walking program will take place twice a week, under the supervision of exercise physiologists and with the support of health workers. The walking sessions of 1-hour duration will be carried out outdoors and on flat ground. To motivate and enhance compliance, a monthly meeting on the importance of regular physical activity will be organized.
The Cognitive Rehabilitation Program will be held in weekly 90-minutes sessions in a Psychiatric Rehabilitation Center of the Healthcare District of Ferrara and conducted by a specialized psychiatric therapist. This program will be carried out in groups of 5 – 10 participants, based on a Cognitive Remediation model. Each session consists of welcoming participants, reviewing tasks conducted in the last meeting, and assignment of new pen-and-pencil cognitive and metacognitive tasks. Tasks include games and exercises (e.g. sudoku, crosswords), as well as

discussions aimed at improving short- and long-term memory (e.g. repeating sequences of words and numbers), executive functions, social cognition, with a progressive adaptation of task difficulty.

What are the possible benefits and risks of participating?
The researchers have proposed the walking activity because it is feasible for most of the people, it is safe, cheap and requires no special equipment. They also chose walking because it can be performed in a group and the mental health benefits of regular physical exercise are observed. The researchers previously showed that a 6-12 months program of guided walking was followed by a significant reduction of heart disease risk in a large population of sedentary adults. This study aims to document the possibility of extending to these patients the reduction of heart disease risk factors that follow prolonged periods of physical activity. The researchers believe that there are no particular risks deriving from participation in the walking program proposed.

Where is the study run from?
The study is conducted by the Center for Exercise Science and Sports and the Institute of Psychiatry of the University of Ferrara (Italy) in collaboration with the Public Mental Health Department of the Local Healthcare Company. The walking session will be carried out in public green spaces.

When is the study starting and how long is it expected to run for?
January 2013 to December 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Improvement of Cognitive functions in sedentaRy schizophrEnic subjects following 1-year of guided Walking (CREW): a pilot study

Acronym
CREW

Study objectives
In the general population, regular physical activity is effective at improving cognitive function and reducing cardiovascular risk factors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/05/2013, Ethics Committee of the University of Ferrara (Comitato Etico di Area Vasta Emilia Centro (CE-AVEC), Azienda Ospedaliero Universitaria di Bologna, Policlinico Sant' Orsola Malpighi, via Giuseppe Massarenti 9, 40138 Bologna, Italy; +39 (0)532239990; urp@ospfe.it), ref: 22-13

Study design
Non-randomized intervention study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Schizophrenia

Interventions
Forty sedentary patients diagnosed with schizophrenia are allocated to a 1-year Guided Walking program (GW n=28), consisting of two walking sessions per week, or to a Cognitive Rehabilitation program (CR n=12). Participants were allowed to choose the mode of treatment.

The guided walking groups take place twice a week, under the supervision of exercise physiologists and with the support of health workers. The walking sessions are carried out outdoors and on flat ground. To motivate subjects and enhance compliance, monthly meetings on the importance of regular physical activity are held.

The Cognitive Rehabilitation Program is held in weekly 90-minutes sessions in a Psychiatric Rehabilitation center of the Healthcare District of Ferrara. Specialized psychiatric therapists conduct this program with groups of 5 – 10 participants, based on a Cognitive Remediation model. Each session consists of welcoming participants, reviewing tasks conducted in the last meeting, and assignment of new pen-and-pencil cognitive and metacognitive tasks. Tasks include games and exercises (e.g. sudoku, crosswords), as well as discussions aimed at improving short- and long-term memory (e.g. repeating sequences of words and numbers), executive functions, social cognition, with progressive adaptation of task difficulty. The total number of sessions is 50 for a duration of 12 months.

Intervention Type
Behavioural

Primary outcome(s)
1. Feasibility was evaluated through the number of dropouts between baseline the end of the study
2. Adherence was measured by the number of walking sessions attended by the participants during the one year program (using patient records)
2. Cognitive function assessed with the Screen for Cognitive Impairment in Psychiatry (SCIP) and the Frontal Assessment Battery (FAB) at baseline and after one year.

Key secondary outcome(s))
Cardiovascular risk factors were evaluated only in the subjects that followed the walking program (at baseline and after 1-year, at the end of the walking program):
1. Blood pressure (mmHg, sphygmomanometer)
2. Anthropometric variables - height (m), weight (kg), BMI (kg/m^2 and waist circumference (cm)
3. VO2peak was indirectly determined using the 1-kilometer walking test (1k-WT). Five minutes of slow walking preceded the test. Subjects were instructed to select a pace that they could maintain for 10 to 20 min at a moderate perceived exercise intensity, (11–13 on the 6–20 Borg

scale). Heart rate was monitored continuously using a Polar Accurex Plus heart rate monitor (Polar Electro, Kempele, Finland). The equation for VO2 peak determination considering age, BMI, HR and time to complete the 1 k-TWT was then applied

Completion date
22/12/2020

Eligibility

Key inclusion criteria
1. Patients diagnosed with schizophrenia since at least 1 year
2. On antipsychotic medications with the same therapeutic regimen for at least 3 months before enrolment
3. Free of symptomatic peripheral arterial occlusive disease and cardiovascular, pulmonary, neurological, metabolic, and orthopaedic disorders that could interfere with the walking activity

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Recent modification of therapeutic regimen
2. Presence of symptomatic peripheral arterial occlusive disease and cardiovascular, pulmonary, neurological, metabolic, and orthopaedic disorders that could interfere with the walking activity

Date of first enrolment
13/11/2017

Date of final enrolment
20/12/2019

Locations

Countries of recruitment
Italy

Study participating centre

University of Ferrara
Center for Exercise Science and Sports
Via Gramicia 35
Ferrara
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Sponsor information

Organisation
University of Ferrara

ROR
https://ror.org/041zkgm14

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/03/2022	28/03/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes