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The effects of group occupational therapy on cognition and psychosocial functioning in adults with schizophrenia

Submission date
10/07/2026

Recruitment status
No longer recruiting

Registration date
10/07/2026

Overall study status
Completed

Last Edited
27/10/2026

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 long-term mental health condition that can affect memory, attention, planning, and day-to-day activities. This study aims to find out whether taking part in a structured group occupational therapy programme, alongside usual mental health care, can improve thinking skills, mental health symptoms, daily functioning, quality of life, and satisfaction with mental health services. The researchers also want to understand whether improvements in thinking skills are linked to improvements in other areas of health and wellbeing.

Who can participate?
Adults aged 18 years to 70 years who have been diagnosed with schizophrenia may be able to take part if they have been clinically stable for at least 6 months, have been receiving care from the Psychiatric Department of the General Hospital of Argolida for at least 1 year, and are able to give informed consent. People with certain neurological or developmental conditions, severe cognitive impairment not related to schizophrenia, severe brain injury, current alcohol or substance misuse, an acute psychotic episode, or those taking part in another structured psychosocial programme cannot take part.

What does the study involve?
Participants are randomly assigned to one of two groups. One group receives their usual mental health care together with a structured group occupational therapy programme. The other group receives usual mental health care only.

The occupational therapy programme lasts for 12 weeks and involves two 90-minute group sessions each week. Sessions take place in small groups and include activities designed to improve thinking skills, everyday functioning, and social participation.

All participants complete assessments before the study starts and again after 3 months. These assessments measure areas such as memory, attention, thinking skills, mental health symptoms, quality of life, daily functioning, and satisfaction with health services.

What are the possible benefits and risks of participating?
Participants who receive the occupational therapy programme may experience improvements in thinking skills, daily functioning, quality of life, and mental health symptoms. The study will also help researchers better understand how occupational therapy may support people living with schizophrenia.

The study information available does not describe any specific risks. However, participants will be asked to attend regular group sessions and complete assessments. As with any research study, there may be some inconvenience from the time required to take part.

Where is the study run from?
The study is run from the Psychiatric Department of the General Hospital of Argolida in Argos, Greece.

When is the study starting and how long is it expected to run for?
The first participant joined the study on 1 September 2025. Recruitment ended on 31 October 2025. Participants took part in the intervention for 12 weeks, and the study was completed on 30 June 2026.

Who is funding the study?
The study is investigator initiated and funded. The sponsor is the University of West Attica.

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title

Effects of a structured group occupational therapy programme plus treatment as usual compared with treatment as usual alone on cognition, psychopathology, functioning, quality of life and satisfaction with health services in adults with schizophrenia: a randomised controlled trial

Study objectives
1. To evaluate the effectiveness of a structured group occupational therapy programme, in addition to treatment as usual, on cognitive functioning in adults with schizophrenia
2. To examine the effects of the intervention on psychopathology, including positive symptoms, negative symptoms and general psychopathology
3. To assess the impact of the intervention on psychosocial functioning and health-related quality of life
4. To evaluate participants' satisfaction with the mental health services received following the intervention
5. To explore the associations between changes in cognitive functioning and changes in psychopathology, functioning and quality of life

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 31/01/2024, Research Ethics Committee, University of West Attica (Agiou Spyridonos Street, Aigaleo, 12243, Greece; +30 210 5387294; ethics@uniwa.gr), ref: 5765/31-01-2024

2. Approved 09/06/2023, Scientific Council, General Hospital of Argolida (191 Korinthou Street, Argos, 21231, Greece; +30 27513 60140; epistimoniko@gna.gr), ref: 11414/09-06-2023

3. Approved 12/05/2023, 6th Regional Health Authority, Peloponnese, Ionian Islands, Epirus and Western Greece (Ypatis 1 & New National Road Patras–Athens, Patras, 26441, Greece; +30 2613 600618; o.papalexi@dypede.gr), ref: 28008/12-05-2023

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Schizophrenia in adults receiving public mental health services

Interventions
Participants are randomly allocated to either an intervention group or a control group using a computer-generated randomisation sequence with allocation concealment through sealed opaque envelopes. The intervention group receives treatment as usual (TAU) plus a structured group occupational therapy programme delivered over 12 weeks, consisting of two 90-minute sessions per week. The programme is delivered in small groups (10–11 participants) and includes occupation-based activities targeting cognitive functioning, executive functions, functional performance and social participation. The control group receives treatment as usual only, without participation in the occupational therapy programme. All participants undergo the same assessment procedures at baseline and after completion of the 12-week intervention using standardized cognitive, clinical and functional outcome measures.

Intervention Type
Behavioural

Primary outcome(s)
1. Global cognitive functioning measured using Addenbrooke's Cognitive Examination III (ACE-III) at Baseline (T0) and 3 months (T1)

2. Global cognitive functioning measured using Mini-Mental State Examination (MMSE) at Baseline (T0) and 3 months (T1)

3. Visuospatial and executive functioning measured using Clock Drawing Test (CDT) at Baseline (T0) and 3 months (T1)

Key secondary outcome(s)
1. Psychopathology measured using PANSS at Baseline (T0) and 3 months (T1)

2. Health-related quality of life measured using SF-36 at Baseline (T0) and 3 months (T1)

3. Satisfaction with health services measured using VSQ-9 at Baseline (T0) and 3 months (T1)

4. Psychosocial functioning measured using Global Assessment of Functioning (GAF) at Baseline (T0) and 3 months (T1)

5. Executive function and processing speed measured using Trail Making Test (TMT Parts A and B) at Baseline (T0) and 3 months (T1)

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Adults aged 18–70 years with a diagnosis of schizophrenia (ICD-10 F20)
2. Clinically stable for at least six months
3. Receiving follow-up care from the Psychiatric Department of the General Hospital of Argolida

for at least one year
4. Able to provide informed consent and participate in group occupational therapy

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
86

Key exclusion criteria
1. Neurological or developmental disorders
2. Intellectual disability or severe cognitive impairment unrelated to schizophrenia
3. Severe traumatic brain injury, current alcohol or substance abuse/dependence
4. Acute psychotic episode or severe relapse at enrolment
5. Inability to provide informed consent
6. Participation in another structured psychosocial intervention during the study

Date of first enrolment
01/09/2025

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
Greece

Study participating centre
Psychiatric Department, General Hospital of Argolida
191 Korinthou Street
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Sponsor information

Organisation
University of West Attica

ROR
https://ror.org/00r2r5k05

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/09/2026	27/10/2026	Yes	No