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DiAPAson study - daily time use, physical activity, and interpersonal relationships in patients with schizophrenia

Submission date
04/02/2020

Recruitment status
No longer recruiting

Registration date
17/02/2020

Overall study status
Completed

Last Edited
03/04/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Schizophrenia significantly affects the quality of life of people who suffer from it. One of the most crucial aspects of quality of life among people with Schizophrenia Spectrum Disorders (SSD) has to do with the daily use of time. Research has shown that people with SSD spend a lot of their time being inactive. Physical inactivity is also linked to increased physical morbidity and a general worsening of the quality of life. The aim of this study is to assess daily time use, physical activity, and interpersonal relationships in patients with schizophrenia.

Who can participate?
Patients aged 20-55 years with SSDs living in Residential Facilities (RF) or an outpatient during recruitment

What does the study involve?
Firstly, the researchers evaluate the daily use of time of 300 patients with SSDs living in Residential Facilities (RFs) and 300 outpatients matched by diagnosis, age and gender. This will be compared with data collected by the Italian Statistical Institute in a large sample of the general population. The researchers will explore time use via a daily diary asking participants to retrospectively report the time spent on different activities over three days. They will explore the quality of staff and patient relationships in RFs. They will also investigate the contribution of staff well-being and burnout to these relationships. Finally, they will assess the overall quality of care provided in each RF.
In a subgroup of patients and participants from the general population the researchers will use innovative measurement techniques to assess the use of daily time and the level of physical activity. They will give them a smartphone and an armband to wear for seven days. They will use an application on the smartphone to assess in real-time their daily activities and mood. Simultaneously they will measure their level of physical activity with a device.

What are the possible benefits and risks of participating?
The researchers believe this study is highly innovative for combining different type of assessments to produce an accurate picture of daily time use and levels of physical activity in

people affected by this severe mental disorder. Thus, it will help to identify the best therapeutic options to maintain sufficient amounts of activity as well as to provide improve quality of life in these patients. The study will offer a unique opportunity for an in-depth examination of the daily time use in different subgroups of people with SSDs. Also, it will allow the assessment of staff-patient relationships and patients' needs and satisfaction in Residential Facilities: it is long known that staff who are burned out and unsatisfied with work are likely to face many difficulties in dealing with patients suffering from severe, long-term mental disorders. Finally, a real-time survey of use of daily time will allow the researchers to explore multiple levels of complexity at once, gathering invaluable data about daily time use, physical activity and mood. The study does not present any kind of clinical risk to its participants.

Where is the study run from?
1. IRCCS Istituto Centro San Giovanni di Dio Fatebenefratelli, Psychiatric Epidemiology and Evaluation Unit (Italy)
2. Department of Mental Health and Dependence, AUSL of Modena (Italy)
3. Department of Mental Health and Dependence, ASST of Pavia (Italy)

When is the study starting and how long is it expected to run for?
December 2019 to December 2022

Who is funding the study?
Ministry of Health (Italy)

Who is the main contact?
Dr Giovanni de Girolamo
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Study website
https://www.diapason-study.eu/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RF-2018-12365514

Study information

Scientific Title
Daily time use, physical activity, quality of care and interpersonal relationships in patients with schizophrenia spectrum disorders: an Italian multicentre study

Acronym
DIAPASON

Study objectives
The assumption underlying the DiAPAson project is that patients with SSD, living in RFs or living independently in the community, spend more time during the day “doing nothing” compared to the general population. The researchers also assume that psychiatric severity, in particular the severity of negative symptoms, will be positively correlated with the amount of time spent doing nothing.

Also, the researchers hypothesize that significant discrepancies will be found comparing the assessment of daily time using a standard paper-and-pencil approach and the ESM methodology. Moreover, they assume that patients with SSD evaluated with real-time assessment through ESM and with appropriate body sensors (actigraphy) will show significant differences when compared to healthy controls: they suggest that specific patterns of associations related to the type of activity performed during the day, the level of energy perceived, PA level and mood will be found.

Finally, the researchers assume that staff well-being and burnout levels will be associated with the quality of staff-patient relationships and specific patients' outcomes, and that ratings of RF quality, using the QuIRC, will be positively associated with patients’ satisfaction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Ethical Committees (ECs) of the three main participating centers:
1. Approved 31/07/2019, EC of IRCCS Istituto Centro San Giovanni di Dio Fatebenefratelli (25125 Brescia – Via Pilastroni, 4; Tel: +39 (0)30/3501586; Email: ceioc@fatebenefratelli.it), no. 211/2019
2. Approved 25/09/2019, EC of Area Vasta Emilia Nord (Comitato Etico dell’Area Vasta Emilia Nord, Via del Pozzo, 71 – 41124 Modena; Tel: +39 (0)59 422 4472; Email: randighieri.silvia@aou.mo.it), no. 0025975/19
3. Approved 02/09/2019, EC of Pavia (Fondazione IRCCS Policlinico "San Matteo", Istituto di

Ricovero e Cura a Carattere Scientifico di diritto pubblico, Vie Golgi 19 - 27100, Pavia; Tel: +39 (0) 382 503408 — 501594 - 503457; Email: comitato.bioetica@smatteo.pv.it), no. 20190075685

Study design
36-month observational multicentre project

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Schizophrenia spectrum disorders (SSD)

Interventions
Study 1
The sample will include 300 residential patients diagnosed with SSD (G1), matched by age and gender to 300 outpatients (G2). Normative data (G3a) will be extracted from the ISTAT's survey "Uso del tempo quotidiano", a national survey that assesses how people spend their time, conducted in 2013 in Italy by the National Institute of Statistics (ISTAT, https://www4.istat.it/it/prodotti/microdati#file_ricerca) in a large, representative sample of the Italian population including approximately 27,000 families (with a total of about 60,000 surveyed individuals) living in 508 municipalities (out of over 8,000 Italian municipalities) of different size.
General assessment, together with demographics, will include psychiatric symptoms (in particular negative symptoms), psychosocial functioning and time perception. Variables related to daily time use will include the number of daily hours spent in different activities: Paid work, Study, Travel, Time spent doing nothing/resting, Social/leisure activities, Activities related to child/household care, Voluntary activities, Sport, and Hobbies. Time use assessment will consist in a daily diary (to be filled three times per week) and a semi-structured interview, both used by the ISTAT for the national survey on time use, asking participants to retrospectively report the daily time spent in different activities. Time spent in each activity will be calculated in the number of hours per week.

Study 2
The sample will include the 300 patients living in RFs (G1), and the RF staff. Patients will be evaluated using a set of standardized instruments. The variables being studied will encompass: quality of care & quality of relationships between patients and staff, level of well-being and level of burnout of RFs' staff, quality of the facility (i.e., living environment; treatments and interventions, therapeutic environment, self-management and autonomy; social interface; human rights; recovery-based practice).

Study 3
The sample will include a sub-group of at least 50 RFs patients (drawn from G1), 50 outpatients (drawn from G2) and 50 healthy controls from the general population matched by age and gender. This latter group will also fill in the TUS. Healthy controls will be recruited through ads, both using the project's website, and spreading the news of the study through social networks. The researchers will perform a time use evaluation with ESM and these reports will be compared with retrospective assessments to evaluate the degree of consistency between the two information sources. Patients and healthy controls doing the ESM assessment will also be asked to wear a multi-sensor device (actigraphy) to assess levels of PA during one week. For the ESM assessment, participants will be equipped with smartphones where a DiAPAson app will be installed. The answer to the smartphone's prompt will allow the researchers to easily evaluate:
1. The specific activity carried out by the patient (e.g., paid work, leisure, resting/doing nothing)
2. Mood (e.g., rating of different adjectives on a scale from 0 to 100; i.e., "sad", "happy" etc)
3. Perceived level of energy (rating of different adjectives on a scale from 0 to 100; i.e., "active", "tired" etc)

Intervention Type
Mixed

Primary outcome measure
Objective 1:
1. Daily use of time (e.g., use of time spent in different activities) of patients with SSD living in RFs, compared to SSD outpatients and to a large sample of the general population, measured via a daily diary (TUS) for two days over a 7-day period after baseline assessment
2. Time perception measured using Zimbardo Time Perspective (ZTPI) at baseline assessment

Objective 2:
1. Quality of staff-patients' relationships for patients living in RFs, measured with Working Alliance Inventory Short Patient and Therapist versions (WAI-PT and WAI-TP) at baseline assessment
2. Staff well-being measured with General Health Questionnaire (GHQ-12) at baseline assessment
3. Burnout measured with Maslach Burnout Inventory (MBI) at baseline assessment

Objective 3:
1. Real-time ESM data (e.g., daily time use, with specifications, such as sleep, work, transportation, hobbies, etc; mood and perceived level of energy) collected via a smartphone app over a 7-day period (8 times a day in semi-random intervals) at least 2 weeks after TUS administration
2. Levels of physical activity in three groups (e.g., RF patients and outpatients with SSD, compared to healthy subjects) assessed via a multi-sensor monitor (actigraphy) over a 7-day period at least 2 weeks after TUS administration

Secondary outcome measures
Objective 1:
1. Severity of psychiatric symptoms (in particular negative symptoms) measured using Brief Psychiatric Rating Scale (BPRS); The Brief Negative Symptom Scale (BNSS); Specific Levels of Functioning Scale (SLOF); World Health Organization Quality of Life Brief version (WHOQOL-

bref; WHODAS 2.0) at baseline assessment
2. Amount of time spent doing nothing and being sedentary (number of hours) measured via a daily diary (TUS) for two days over a 7-day period after baseline assessment

Objective 2:
1. Quality of RFs measured using Quality Indicator for Rehabilitative Care (QuIRC-SA) at baseline assessment
2. Patients' needs and satisfaction assessed using Camberwell Assessment of Need Patient and Staff versions (CAN); Ward Atmosphere Scale (WAS), Verona Service Satisfaction Scale (VSSS) at baseline assessment

Objective 3:
Comparison of real-time ESM data about daily time use (measured via smartphone app) with retrospective paper-and-pencil assessments (measured with TUS) at least 2 weeks after TUS administration

Overall study start date
02/12/2019

Completion date
01/12/2022

Eligibility

Key inclusion criteria
All groups:
1. Aged between 20-55 years old
2. Good knowledge of the Italian language

G1 and G2:
1. SSD diagnoses according to DSM-5 (APA, 2013)
2. Being a patient living in an RF or an outpatient during recruitment

Participant type(s)
Mixed

Age group
Adult

Lower age limit
20 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
700

Key exclusion criteria
All groups:
1. Inability to provide informed consent (because of low education, or cognitive impairment)
2. Severe cognitive deficit (MMMSE equal or lower than 24.0)
3. A diagnosis of substance use disorder in the last year according to DSM-5 criteria (APA, 2013)
4. History of clinically significant head injury
5. Cerebrovascular, neurological disease
6. Expected discharge from the RF within 1 month

G3b and G3c:
1. Being an RF inpatient or being a DMH's outpatient during recruitment

Date of first enrolment
01/06/2020

Date of final enrolment
01/12/2021

Locations

Countries of recruitment
Italy

Study participating centre
IRCCS Istituto Centro San Giovanni di Dio Fatebenefratelli, Psychiatric Epidemiology and Evaluation Unit
Via Pilastroni, 4
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Sponsor type
Research organisation

Website
https://www.fatebenefratelli.it/strutture/irccs-brescia

Funder(s)

Funder type
Government

Funder Name
Ministero della Salute

Alternative Name(s)
Italian Ministry of Health, Italy Ministry of Health, Ministry of Health of Italy, Ministry of Health - Italy, Ministry of Health, Italy

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Italy

Results and Publications

Publication and dissemination plan
The study protocol is currently under submission. DiAPAson's publication and dissemination plan will encompass participation in international congresses as well as publication in high-impact peer-reviewed journals.

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available in the UniData - Bicocca Data Archive repository (https://www.unidata.unimib.it/?lang=en), which is the official repository of the University of Milan Bicocca. The research team will obtain oral and written informed consent to participate in the study from all participants before enrolment.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2020	10/06/2020	Yes	No
Results article		18/11/2022	04/06/2024	Yes	No
Results article		10/10/2024	14/10/2024	Yes	No
Results article		18/03/2025	19/03/2025	Yes	No
Results article		02/04/2025	03/04/2025	Yes	No