Routine Outcome Monitoring for Geriatric Psychiatry & Science 2.0

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The primary aim of the Routine Outcome Monitoring for Geriatric Psychiatry & Science 2.0 project (ROM-GPS 2.0) is 1) to evaluate treatment outcome for affective disorders in specialised geriatric mental health care and 2) to examine the impact...

Ethical review	Approved WMO
Status	Pending
Health condition type	Mood disorders and disturbances NEC
Study type	Observational non invasive

Summary

ID

NL-OMON51956

Source
ToetsingOnline

Brief title
ROM-GPS 2.0

Condition

- Mood disorders and disturbances NEC

Synonym
affective disorders, depression

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Matching van deelnemende GGZ instellingen voor benodigd personeel

Intervention

Keyword: Aged, Anxiety disorder, Depressive disorder, Somatic symptom disorder

Outcome measures

Primary outcome

The primary outcome parameter for the full clinical cohort study is remission at one-year follow-up of the identified affective disorders at inclusion, and for the limited study, recovery at one-year follow-up as assessed by self-report questionnaire.

Parameters for the full study in addition include a battery of potential confounders, with specific attention for age-specific characteristics regarding cognitive functioning (including global cognitive functioning as well as executive functioning, processing speed and episodic memory), physical functioning (including multimorbidity, polypharmacy, and physical frailty), and social functioning (loneliness, social network size, role limitations).

Secondary outcome

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Study description

Background summary

Affective disorders, encompassing depressive-, anxiety-, and somatic symptom disorders, are the most prevalent mental disorders in later life. These disorders are often comorbid to each other and have limited diagnostic stability over time. Treatment protocols and guidelines in geriatric psychiatry largely rely on evidence from randomized controlled trials (RCTs) conducted in younger age samples and ignore comorbidity between these disorders. Moreover, the few studies conducted in older samples are often limited to the *younger old* and rarely include the most frail. Therefore, the effectiveness of

treatment for late-life affective disorders is largely unknown in routine clinical care, as is the impact of age-specific characteristics.

Study objective

The primary aim of the Routine Outcome Monitoring for Geriatric Psychiatry & Science 2.0 project (ROM-GPS 2.0) is 1) to evaluate treatment outcome for affective disorders in specialised geriatric mental health care and 2) to examine the impact of age-specific characteristics on the effectiveness.

Study design

Multicentre, longitudinal, observational study in specialised geriatric mental health care. All participating outpatient clinics have harmonized their intake procedures, including a protocolized diagnostic assessment including a well-validated psychiatric diagnostic interview (MINI). Eligible patients will be asked consent for full participation in the study, and if refused, for limited participation. Full participation consists of an extensive baseline and one-year follow-up assessment (site-visits) to evaluate treatment outcome over the first year of mental health care and two postal questionnaires at 4 and 8 months. For limited participation, we ask consent to extract routine clinical data from the patient*s electronic record and filling out a postal outcome questionnaire at one year.

Study burden and risks

In addition to routine clinical care (including a semi-structured diagnostic psychiatric interview as part of the harmonized and protocolized intake) informed consent will be asked for data extraction from the medical record (treatment characteristics) and filling out a brief outcome questionnaire after one year (~15 minutes) in case of limited participation. In case of full participation, additional consent is asked for 1) an extensive baseline assessment including self-report questionnaires, a physical examination and cognitive testing (~180 minutes), 2) an outcome assessment after one year including all baseline measures amenable to change (~180 minutes), and 3) two postal self-report questionnaires at 4 and 8 months (each ~15 minutes).
The patient burden in case of full participation consists of two additional (half-day) visits to the hospital. The risks of filling in the questionnaires as well as the physical examination and cognitive tests is negligible as all assessments have been validated for older people and are commonly used in routine clinical care and monitoring studies.
Observational data of routine clinical care in geriatric mental health care is of utmost relevance as older patients are often excluded from RCTs trials, especially those who suffer from multimorbidity, frailty or age-related cognitive decline (who are mostly seen in clinical practice). Such data cannot

be studied in healthy volunteers.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Age >=60 years,
2) Affective disorder according to DSM-5 criteria, i.e. a depressive, anxiety and/or somatic symptom disorder,
3) Informed consent.

Exclusion criteria

1) An established diagnosis of a neurodegenerative disorder,
2) Cognitive impairment defined as scoring less than 18 points on the Montreal Cognitive Assessment (MoCA) test,
3) (History of a) bipolar or psychotic disorder,
4) Severe substance-use disorder in need of specialised treatment,
5) Physically or mentally too handicapped to administer self-report questionnaires or perform cognitive testing,
6) Insufficient mastery of the Dutch language.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2023
Enrollment:	1400
Type:	Anticipated

Ethics review

Approved WMO

Date:	01-11-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL78777.042.21