Gene Environment interactions in Mental health trajectorieS of Youth (Youth-GEMS)

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The objective of this study is to characterise and validate multidimensional latent risk and resilience mental health trajectories in a trans-syndromal sample of help-seeking young people, including identifying genetic, environmental, biological,...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON57257

Source
ToetsingOnline

Brief title
Youth-GEMS

Condition

- Other condition

Synonym
"Mental health problems" and "mental health disorders"

Health condition

Young people between the age of 12-24 years, accessing outpatient specialized mental health services for the first time

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Horizon Europe programme Staying Healthy 2021 under Grant Agreement N 101057182.

Intervention

Keyword: environment, gene, mental health, youth

Outcome measures

Primary outcome

The main outcome will be overall mental health measured with MyLifeTracker.

This is a scale that consists of five items targeting areas of importance to

youth: general well-being, day-to-day activities, relationships with friends,

relationships with family, and general coping.

Secondary outcome

Secondary outcomes include the following areas: clinical, cognition,

self-reported assessment, digital phenotyping, and biological data.

Participants can be asked to participate in subparts of the study. Among

others, a qualitative study will be performed to retrieve more insight into the

lived experience of participants. Additionally, a subgroup will use 'experience

sampling method'. For all subparts, participants will be asked to give

additional informed consent.

Study description

Background summary

Improving characterization of mental health trajectories and its potential determinants in young people will enable the identification of actionable targets and guide targeted preventive and therapeutic interventions to reduce mental illness burden across the lifespan. Studies in help-seeking young people (i.e., showing early manifestations of mental distress and already in need of care) are necessary to complement the information provided by previous studies assessing the effect of genetic and environmental factors on mental health trajectories in the general population so as to increase their clinical translatability. The complex and dynamic nature of mental illness requires trans-syndromal multimodal studies using large-scale multidimensional data analysis to achieve this aim.

Study objective

The objective of this study is to characterise and validate multidimensional latent risk and resilience mental health trajectories in a trans-syndromal sample of help-seeking young people, including identifying genetic, environmental, biological, clinical, cognitive, and digital predictors of functional outcomes, over a 24-month follow-up period.

Study design

This study is a prospective, non-interventional, observational study consisting of the following assessments, at baseline, and at 3, 6, 12, 18 and 24 month follow-up.

Study burden and risks

The risks and burden associated with this study are minimal, collecting digital and clinical data as well as biomaterials (saliva, blood) only after informed consent. Although there are a substantial number of assessments, only the first visit is in-site, and the time allocated for it is coherent with standard clinical psychological assessments. A risk is a breach in data-protection. However, all GDPR rules are complied with and no information traceable to the participant will be used after informed consent, only coded information.
The potential individual benefits are those associated with close monitoring and thorough examination of participants. The use of self-reported measures may identify potential risks in the participants (e.g., suicide, traumatic experiences) that may be unknown to the clinicians. These events will be reviewed and communicated to the treating clinician and to other institutions, if required, according to applicable local regulations.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

• Age between 12-24 years.
• Less than one month from the first contact with mental health services.
• Good command of the languages used in the study.
• Written informed consent by the participant, their parents if minors, or legal representatives if appropriate.

Exclusion criteria

• Intellectual disability with associated functional impairment.
• Severe neurological or medical condition.

• Genetically confirmed neurobehavioral syndromes.
• Participants that exhibit significant difficulties to complete the self-reported questionnaires or those whose genetic or biological analysis confirm an underlying health or genetic condition will be excluded.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2024
Enrollment:	175
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	24-01-2025
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL86050.068.24