

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

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	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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### Scientific

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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**

<b>Register</b>	<b>ID</b>
CCMO	NL86050.068.24