

Investigating the effects of community interventions to improve youth mental health

Submission date 12/03/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/04/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/05/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The study addresses youth mental health among emerging adults. Through an interventional study in five countries, the research aims to provide data on youth mental health and on the effects of community interventions for improving youth mental health.

Who can participate?

People aged 15-24 years old

What does the study involve?

The study involves community interventions and online mental health training.

What are the possible benefits and risks of participating?

The benefits of participating are better mental health. No risks are anticipated.

Where is the study run from?

The study is run by the University of Applied Sciences Emden-Leer in five countries (Belgium, Germany, Moldova, Poland, and Portugal).

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

January 2024 to April 2026.

Who is funding the study?

The study is funded by the European Commission under the Horizon 2020 program.

Who is the main contact?

Prof Dr. Jutta Lindert, jutta.lindert@hs-emden-leer.de

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Prof Jutta Lindert

ORCID ID

<https://orcid.org/0000-0001-5368-3886>

Contact details

University of Applied Sciences Emden-Leer, Constantiaplatz 4
Emden
Germany
26723
+491774158919
Jutta.Lindert@hs-emden-leer.de

Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

Study information**Scientific Title**

Investigating the effects of community interventions to improve youth mental health in comparison with youth mental health without community interventions

Acronym

EARLY

Study objectives

Community interventions improve the mental health of people aged 15-24 years old more than no interventions.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 27/01/2024, Institutional Review Board University of Emden / Leer (Constantiaplatz 4, Emden, 26723, Germany; +49 4921/807-1007 ; vp.forschung-transfer@hs-emden-leer.de), ref: 2024_EARLY_03

Study design

Multi-center community unblinded interventional study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community, Internet/virtual

Study type(s)

Other, Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Promotion of mental health and prevention of depression and anxiety.

Interventions

The study is a multi-center community unblinded interventional study. Two communities will be identified in five countries, purposively (allocation of intervention is purposively). These are the intervention communities. The two intervention communities will be matched by age distribution, gender distribution and density with two other communities. These are the control communities. Communities will not be masked.

In the intervention communities, key person groups, parent groups, and youth groups will be gathered three times. Information about relationships and their impact on mental health will be disseminated in these groups. Additionally, in the intervention communities opportunities to participate in a short mental health promotion online course will be disseminated. In the control communities, no groups are formed.

Intervention Type

Behavioural

Primary outcome measure

Current primary outcome measure as of 29/05/2025:

Resilience is measured using the Child Youth Resilience Measure (CYRM-R), Executive Functioning is measured using the Adult Executive Function Inventory (ADEXI), and Emotional regulation is measured using the Emotion Regulation Questionnaire (ERQ) at baseline (T1), mid-intervention (T2), end of intervention (T3), and (T0) follow-up

Previous primary outcome measure:

Mental health is measured using the Brief Resilience Scale (BRS) at baseline (T1), mid-intervention (T2), end of intervention (T3), and (T0) follow-up

Secondary outcome measures

Current secondary outcome measures as of 29/05/2025:

The following secondary outcome measures are assessed at baseline (T0), mid-intervention (T1), end of intervention (T2), and follow-up (T3):

1. Depression measured using the Patient Health Questionnaire-9 (PHQ-9)
 2. Anxiety measured using the Generalized Anxiety Disorder-7 (GAD-7)
 3. Stress disorder measured using the International Trauma Questionnaire (ITQ)
 4. Substance use measured using the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST – LITE)
 5. Gratitude measured using the The Gratitude Questionnaire-6, (GQ-6)
 6. Optimism measured using the Revised Life Orientation Test (LOT-R)
 7. Well-being measured using the Wellbeing Scale
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Previous secondary outcome measures:

The following secondary outcome measures are assessed at baseline (T0), mid-intervention (T1), end of intervention (T2), and follow-up (T3):

1. Depression measured using the Patient Health Questionnaire-9 for teens (PHQ-A)
2. Anxiety measured using the Generalized Anxiety Disorder-7 (GAD-7)
3. Stress disorder measured using the International Trauma Questionnaire (ITQ)
4. Substance use measured using the International Trauma Questionnaire (ITQ) and the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST – LITE)
5. Executive functioning measured using the Teenage/Adult Executive Function Inventory
6. Emotional control measured using the Emotion Regulation Questionnaire for Children and Adolescents (ERQ-CA)
7. Resilience measured using the Child Youth Resilience Measure (CYRM-R)
8. Gratitude measured using the The Gratitude Questionnaire-6, (GQ-6)
9. Optimism measured using the Revised Life Orientation Test (LOT-R)
10. Well-being measured using the Wellbeing Scale

Overall study start date

27/01/2024

Completion date

15/04/2026

Eligibility

Key inclusion criteria

1. Aged 15-24 years old
2. Proficient in the national language
3. Informed consent

Participant type(s)

Service user

Age group

Mixed

Lower age limit

15 Years

Upper age limit

24 Years

Sex

Both

Target number of participants

15000

Total final enrolment

12000

Key exclusion criteria

Not meeting the participant inclusion criteria

Date of first enrolment

15/04/2025

Date of final enrolment

15/07/2025

Locations**Countries of recruitment**

Belgium

Germany

Moldova

Poland

Portugal

Study participating centre

University of Applied Sciences Emden / Leer

Constantiaplatz 4

Emden

Germany

26423

Study participating centre

Hopital Universitaire de Bruxelles

Av. Franklin Roosevelt 50
Bruxelles
Belgium
1050

Study participating centre

Society of psychiatrists, narcologists, psychotherapists and clinical psychologists from Moldova

Str. Columna 130
Chisenau
Moldova
MD 2001

Study participating centre

Gdansk University

Jana Baszynskiego 8
Gdansk
Poland
80-309

Sponsor information

Organisation

Directorate-General Joint Research Centre

Sponsor details

European Commission, Rue de la Loi
Brussels
Belgium
1040
+3222991111
webmaster@ec.europa.eu

Sponsor type

Government

Website

http://ec.europa.eu/index_en.htm

ROR

<https://ror.org/04j5wtv36>

Funder(s)

Funder type

Government

Funder Name

Horizon 2020 Framework Programme

Alternative Name(s)

EU Framework Programme for Research and Innovation H2020, Horizon 2020, Rahmenprogramm Horizont 2020, Programa Marco Horizonte 2020, Programme-cadre Horizon 2020, Programma quadro Orizzonte 2020, Program ramowy Horyzont 2020, Horizont 2020, Horizonte 2020, Orizzonte 2020, Horyzont 2020, Horizon 2020 Framework Programme (H2020), H2020

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Publication and dissemination plan

Planned publications in peer-reviewed journals.

Intention to publish date

15/01/2027

Individual participant data (IPD) sharing plan

The datasets generated during the current study will be available upon request from Prof. Dr. Jutta Lindert (jutta.lindert@hs-emden-leer.de).

- The type of data that will be shared: raw data
- Timing for availability: July 2028
- Whether consent from participants was required and obtained: yes, informed consent will be obtained
- Comments on data anonymization: data are anonymized in line with the European data regulation laws.
- Any ethical or legal restrictions. Data transfer in line with the legal restrictions of European regulations.
- Any additional comments. No

IPD sharing plan summary

Available on request