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Investigating the effects of community interventions to improve youth mental health

Submission date 12/03/2025	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 23/04/2025	**Overall study status** Ongoing	
Last Edited 29/05/2025	**Condition category** Mental and Behavioural Disorders	

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

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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

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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
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Study participating centre
Society of psychiatrists, narcologists, psychotherapists and clinical psychologists from Moldova
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MD 2001

Study participating centre
Gdansk University
Jana Baszynskiego 8
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Sponsor information

Organisation
Directorate-General Joint Research Centre

Sponsor details
European Commission, Rue de la Loi
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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