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Testing whether Moderated Online Social Therapy (MOST) helps reduce distress in young people, and whether it offers good value for health services, in Europe and Australia

Submission date
28/04/2026

Recruitment status
Not yet recruiting

Registration date
29/04/2026

Overall study status
Ongoing

Last Edited
29/04/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is about helping young people who are struggling with their mental health and who are looking for support. The aim is to see if the digital health platform can help reduce psychological distress in young people. This platform is known as Moderated Online Social Therapy, or “MOST”.

Who can participate?
Young people aged 16 to 25 years who are struggling with their mental health can take part. Participants will be recruited from the Netherlands, Ireland, Spain, and Australia.

What does the study involve?
Participants will fill in questionnaires at four points over a 12-month period. Participants will be randomised to MOST or care-as-usual. Participants who are randomly allocated to the experimental condition, will have access to the MOST platform for three months in addition to care as usual. During their time on MOST they will have access to personalised, self-directed therapeutic content, they will have contact with a moderator (a coach and/or peer worker), as well as access to a moderated online community of other young people. Participants allocated to care-as-usual will continue with their usual care. Random selection helps make sure the results of the study are objective.

What are the possible benefits and risks of participating?
Taking part may help reduce psychological distress and improve mental health. There are no known health risks linked to the study.

Where is the study run from?
Included sites are Amsterdam UMC in the Netherlands, University of Galway in Ireland, Orgyen Digital in Australia and Instituto de Investigación Sanitaria Gregorio Marañón in Spain.

When is the study starting and how long is it expected to run for?
Recruitment starts in May 2026 and ends in December 2027. The final assessments will take place in December 2028.

Who is funding the study?
This study is funded by the European Commission as part of the EU Horizon project YOUTHreach (Project number: 101156514).

Who is the main contact?
If you have questions, please contact Sascha Struijs (s.y.struijs@vu.nl) or Maeve Dwan O'Reilly (maeve.dwanoreilly@universityofgalway.ie).

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Study information

Scientific Title
Comparative effectiveness and public health impact of Moderated Online Social Therapy (MOST) in young people with heightened distress: a hybrid (cost-)effectiveness implementation study in Europe and Australia

Acronym
YOUTHreach MOST

Study objectives
The primary aim of this hybrid effectiveness-implementation study is to examine, in a multi-country RCT, the effectiveness of a digital mental health platform (MOST) + CAU in reducing psychological distress at 3-month follow-up measured with the CORE-10 as primary outcome compared to CAU alone in help-seeking young people (YP) in four already operational sites (Netherlands (2 sites), Ireland (1 site) and Australia (1 site).

The secondary objectives of the multi-country RCT will be to:
1. Evaluate potential beneficial effects of the MOST platform in help seeking YPI in enhancing psychosocial functioning, overall wellbeing, and self-esteem, and reducing depression and anxiety symptoms compared with CAU at 3-month, 6-month, and 12-month follow-up

2. Establish a new site for the purposes of evaluating implementation of MOST
3. Investigate across NL, IE and AU sites the cost-effectiveness of MOST in a health economic evaluation from both societal and health system payers' perspective
4. Assess the public health impact of MOST by examining: Reach, Effectiveness, Adoption, Implementation and Maintenance (in line with the RE-AIM framework)

Ethics approval required
Ethics approval required

Ethics approval(s)
1. submitted 06/03/2026, Medisch Ethische Toetsingscommissie (Meibergdreef 9, Amsterdam, 1105 AZ, Netherlands; +31 20-4445585; metc@amsterdamumc.nl), ref: METC 2025.0950

2. submitted 19/02/2026, Comité de Ética de la Investigación con Medicamentos (CEIm) of the Hospital Gregorio Marañón (Fundación para la Investigación Biomédica, Hospital Gregorio Marañón, Pabellón de Gobierno 1st Floor, Calle Dr. Esquerdo, 46, Madrid, 28007, Spain; +34 91 370 28 24; comite.regional@salud.madrid.org), ref: 102/26

3. approved 23/05/2025, University of Galway Research Ethics Committee (University of Galway Research Ethics Committee, University of Galway, University Road, Galway, H91 TK33, Ireland; +353 91 495312; ethics@nuigalway.ie), ref: 2025.05.029

4. approved 19/06/2024, The University of Melbourne Human Research Ethics Committee (Grattan Street, Parkville, 3010, Australia; +61 383440999; HumanEthics-Enquiries@unimelb.edu.au), ref: 2024-29304-54174-2

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Psychological distress in help seeking young people

Interventions
MOST intervention

In this hybrid (cost-)effectiveness implementation study, a pragmatic, parallel-group, multi-country RCT will be conducted, in which participants will be randomly allocated using a 1:1 ratio to one of two conditions: (a) the experimental condition, in which participants receive MOST in addition to Care-As-Usual (CAU) or (b) the control condition, in which participants receive CAU alone.

Participants allocated to the experimental condition will have access to the MOST intervention in addition to CAU. The intervention offers a platform that includes guided therapy journeys (individually selected for each participant using algorithms), professional support (from mental health moderators and youth with lived experience of mental ill-health (peer support workers), for up to 40 minutes per week, and a moderated online peer-to-peer community where participants can connect. Participants in the experimental condition can use the MOST platform plus support for 3 months, while also receiving CAU. Access to the MOST platform will span the full study duration and continue until the end of the study period. In CAU young people are free to access any supports available to them aside from MOST.

We will assess outcomes at 4 time points: at baseline, at 3-month follow-up, 6-month follow-up and 12-month follow-up. Thus, the duration of study participation for individual participants is 12 months.

Randomisation will be managed separately at each study site and stratified by gender (male, female, other) and baseline psychological distress (CORE10 score 24 or less, 25 or more). Once screening and baseline assessments have been completed, a member of the research team will randomise the participant in REDCap and communicate the allocation to the participant. The randomisation schedule and allocation records will be maintained securely within REDCap, with access limited to authorised members of the study team.

Intervention Type
Behavioural

Primary outcome(s)
1. Psychological distress measured using CORE-10 (Barkham et al., 2013) at 3-month follow-up

Key secondary outcome(s))
1. Functioning measured using Work and Social Adjustment Scale - youth version (WSAS-Y) (Jassi et al., 2020) at 3-month, 6-month, and 12-month follow-up

2. Quality of Life measured using My Life Tracker (MLT; Kwan et al., 2018) ; Co-created outcome measure (YAG, YOUTHreach consortium) at 3-month, 6-month, and 12-month follow-up

3. Depression measured using Patient Health Questionnaire-9 (PHQ-9; Kroenke et al., 2001) at 3-month, 6-month, and 12-month follow-up

4. Anxiety measured using Generalized Anxiety Disorder questionnaire-7 (GAD-7; Spitzer et al., 2006) at 3-month, 6-month, and 12-month follow-up

5. Self-esteem measured using Rosenberg Self-Esteem Scale questionnaire (RSES; Rosenberg, 1965) at 3-month, 6-month, and 12-month follow-up

6. Reach measured using Assessed by the number of individuals consenting to, participating in, initiating MOST, and dropping out during the intervention period. at 3-month, 6-month, and 12-month follow-up

7. Adoption measured using Asessed by the number and profile of sites and delivery agents trained and actively delivering MOST during the intervention period. at 3-month, 6-month, and 12-month follow-up

8. Implementation measured using Assessed by the extent to which MOST components are delivered and used as intended, using structured checklists and platform-derived usage data, the User Version of the Mobile Application Rating Scale (uMARS; Stoyanov et al., 2016), and a bespoke MOST satisfaction measure. at 3-month, 6-month, and 12-month follow-up

9. Maintenance measured using Assessed by continued use of MOST using platform-derived usage data and intended continuation of MOST use using self-report items. at 3-month, 6-month, and 12-month follow-up

10. Health economic measures measured using EQ-5D-5L (EuroQol Research Foundation, 2025; Herdman et al., 2011); Resource Use Measurement (RUM; YOUTHreach consortium)) at 3-month, 6-months, and 12-month follow-up

11. Social Media Use Measure measured using 8 items of the Compulsive internet use scale (Meerkerk et al. 2009) at 3-month, 6-month, and 12-month follow-up

12. Psychological distress measured using CORE-10 (Barkham et al., 2013) at 6-month and 12 month follow-up

13. Loneliness measured using UCLA Loneliness scale (Russel et al., 1980) at 3-month, 6-month, and 12-month follow-up

Completion date
31/12/2029

Eligibility

Key inclusion criteria
1. Age 16-25 years
2. Help seeking (e.g., attending local mental health services or seeking help for psychological distress; health service; university student counselling etc.)
3. Able and willing to consent; parental consent when applicable (e.g., in Spain for YP aged 16 and 17)
4. A score of 10 or higher on the CORE-10 questionnaire
5. Have personal and private access to a computer, smartphone or tablet.
6. Ability and willingness to nominate an emergency contact person, such as a close family member

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
25 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Insufficient command of the local language at the study center (i.e. Dutch, English, or Spanish)
2. Present with acute suicidal behavior or imminent risk of harm to self
3. If their psychiatric symptoms are due to an organic cause
4. Prior exposure to MOST intervention (e.g. ENYOY)

Date of first enrolment
04/05/2026

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
Australia

Ireland

Netherlands

Spain

Sponsor information

Organisation
European Commission

ROR
https://ror.org/00k4n6c32

Funder(s)

Funder type

Funder Name
European commission

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available