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Online social support for third level students - A pilot feasibility trial of the PSYCHE-MOST intervention.

Submission date	Recruitment status	[ ] Prospectively registered
19/04/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/07/2024	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/07/2024	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

In many European countries, a significant portion of young adults engage in some form of education until their early twenties. A 2017 study conducted by the World Health Organization (WHO) involving approximately 14,000 students across eight countries, including Northern Ireland, revealed that around one in three individuals exhibited symptoms indicative of at least one common mental disorder as defined by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR), such as anxiety, mood disorders, or substance-related disorders.

With a noticeable increase in individuals seeking help for mental health concerns in recent times, digital health interventions—mental health support delivered through web-based or mobile-based platforms—hold significant promise in enhancing outcomes, broadening access, and addressing the growing demand for mental health services.

One such approach aimed at enhancing mental health recovery among young adults is Moderated Online Social Therapy (MOST), as proposed by Alvarez-Jimenez and colleagues in 2021. Initially developed as a digital mental health platform available via both web interface and dedicated app, MOST offers a low-intensity, cost-effective, and engaging method to sustain the benefits of specialized Early Intervention for Psychosis (EIP) services. Studies have shown its effectiveness in facilitating return to education and employment while reducing the need for emergency care. It has also undergone a trial involving young individuals aged 12 to 25 who sought help for mental health issues.

MOST comprises evidence-based online therapy content supplemented by therapist interaction, alongside a community feature resembling a Facebook-style platform, supported and moderated by peer support workers.

The objective of the current study is twofold: firstly, to assess the feasibility and acceptability of MOST among individuals who recently accessed a university counseling service, and secondly, to provide preliminary data on the effectiveness of MOST, laying the groundwork for a definitive randomized controlled trial.

Who can participate?
Adults aged 18 - 35 years, self reporting mental health difficulties of longer than one year in duration.

What does the study involve?
The study involves participating in a 26 week online digital intervention that consists of a therapy journey supported by fortnightly contact with a clinician, and an online social community supported by fortnightly contact with peer support workers.

What are the possible benefits and risks of participating?
The potential benefits are to wellbeing (e.g. reduction of clinical symptoms of anxiety/low mood) and improvement of social function. No risks have been identified to date with participation. In addition, participants complete an assessment battery at baseline, 3months and 6 months.

Where is the study run from?
University of Galway (Ireland)

When is the study starting and how long is it expected to run for?
September 2019 to December 2025

Who is funding the study?
Health Research Board (Ireland)

Who is the main contact?
Prof Gary Donohoe, gary.donohoe@universityofgalway.ie

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
RL-2020-007

Study information

Scientific Title
Improving Psychosocial Supports in youth mental health (PSYCHE) - A pilot feasibility randomised controlled trial of Moderated Online Social Therapy (MOST) for improving social function in third level students

Acronym
PSYCHE-MOST

Study objectives
The trial explores the feasibility and acceptability of delivering MOST to help-seeking university students who have recently attended student counselling for the purposes of improving social function. The main study hypothesis is that (a) it will be possible to recruit n=60 and retain a majority of these at follow up.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/10/2020, Galway University Hospital Clinical Research Ethics Committee (Room 2, 2nd Floor, HR building, Merlin Park, Galway, H91N973, Ireland; +353 - 91 - 731990; colette.collins@hse.ie), ref: CA2468

Study design
Interventional pilot feasibility single center randomized controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mental health difficulties in third level students

Interventions

This trial is a pilot randomised controlled study recruiting young adults aged 18-35 years from a university student counselling service. The trial explores the feasibility, acceptability, and effectiveness of delivering MOST to participants who attended student counselling.

MOST (The intervention being assessed) consists of
(1) Interactive online therapy modules based on third wave cognitive behavioural therapy and primarily targeting social functioning by e.g., fostering self-efficacy (identifying personal strengths based on the strengths-based framework), positive emotions and subjective well-being (e.g., practicing mindfulness and self-compassion), or positive connections with others (e. g., focusing on empathy skills). Completing this therapy journey is supported by clinicians available by telephone/video chat on a for fortnightly basis.
(2) An online social network or 'Café' to foster social support. Participants are encouraged to communicate with one another and with peer and expert moderators. This is moderated by clinicians and led by 'peer-support workers' with lived experience and informed by the evidence-based problem-solving framework.
A further feature of MOST is an online group function to enable users to nominate issues (e.g., 'how to break through shyness and make new friends?'), which are discussed in moderated groups through structured phases (e.g., brainstorming, pros and cons and wrap-up).

The intervention is 26 weeks duration. The follow up periods are 3 and 6 months post baseline. Randomisation is based on the sealed envelope online tool.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility outcomes:
Rates of recruitment and retention recorded using patient records at baseline, 3 months (12 weeks) and 6 months (26 weeks).

Key secondary outcome(s))
Measured at baseline, 3 months (12 weeks) and 6 months (26 weeks) based on interview with the participant:

Demographic/Clinical measures:
1. Assessment interview (Demographic and clinical info)
2. DUDIT (Drug use)
3. AUDIT (Alcohol use)
4. Generalised Anxiety Disorder Assessment (GAD-7)
5. Patient Health Questionnaire (PHQ-9)
6. Time Use Survey
7. Social and Occupational Functioning Assessment Scale (SOFAS)
8. UCLA Loneliness scale

Cognition measures:
9. Reading the Eyes in the Mind
10. Test of premorbid functioning (TOPF)
11. Logical Memory (WMS)

Completion date
30/12/2025

Eligibility

Key inclusion criteria
1. Aged between 18 and 35 years of age,
2. Clinically stable and having the ability to give consent.
3. Self-reporting mental health difficulties of longer than one year in duration.

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
35 years

Sex
All

Key exclusion criteria
1. History of organic impairment (including IQ <70), or history of a head injury with loss of consciousness > 5-minute duration,
2. Drug or alcohol dependent.

Date of first enrolment
01/04/2021

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Ireland

Study participating centre
University of Galway Student counselling center
University Road
Galway
Ireland
H91TK33

Sponsor information

Organisation
Ollscoil na Gaillimhe – University of Galway

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)
Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the study PI, Prof Gary Donohoe, gary.donohoe@universityofgalway.ie

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes