

# Online social support for early psychosis - A pilot feasibility trial of the PSYCHE-MOST intervention.

<b>Submission date</b> 09/08/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/12/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Protocol
<b>Last Edited</b> 05/12/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

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). Initially developed as a digital mental health platform available via both a web interface and a dedicated app, MOST offers a low-intensity, cost-effective, and engaging method to sustain or augment 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 years old 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 are currently attending an EIP service, and secondly, to provide preliminary data on the effectiveness of MOST, laying the groundwork for a definitive randomized controlled trial.

### Who can participate?

Patients aged between 18 and 35 years old who are clinically stable, able to give consent and self-reporting mental health difficulties of longer than one year in duration

### What does the study involve?

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 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 in duration with follow-ups at 3 and 6 months.

What are the possible benefits and risks of participating?

Possible benefits include (1) a reduction in clinical symptoms of anxiety and low mood, (2) opportunities to receive support from an online therapist while completing a CBT-informed online therapy intervention, and (3) opportunities to receive peer support from a peer support worker.

Possible risks include (1) distress caused by participating in the assessment, which asks questions about early childhood adversity and clinical symptom severity, and (2) low-level distress caused by participating in an online intervention that may not meet the psychological needs of the individual.

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?

Dr Gary Donohoe, gary.donohoe@universityofgalway.ie

### **Study website**

<https://www.universityofgalway.ie/psyche/>

## **Contact information**

### **Type(s)**

Public, Scientific, Principal Investigator

### **Contact name**

Prof Gary Donohoe

### **ORCID ID**

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### **Contact details**

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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 early psychosis

### Acronym

PSYCHE-MOST-EIP

### Study objectives

The trial explores the feasibility and acceptability of delivering MOST to individuals who are currently attending early intervention for psychosis services in Ireland. The main study hypothesis is that (a) it will be possible to recruit n=30 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 multi-center randomized controlled study

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

## **Study setting(s)**

Community

## **Study type(s)**

Treatment

## **Participant information sheet**

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

## **Health condition(s) or problem(s) studied**

Psychosis

## **Interventions**

This trial is a pilot randomised controlled study recruiting patients attending an early intervention for psychosis service in Ireland. The trial explores the feasibility, acceptability, and effectiveness of delivering MOST to participants who attended the EIP service.

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 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 control group receives treatment as usual, defined as continuing to receive any care that they were receiving prior to the intervention.

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 measure**

Feasibility outcomes: Rates of recruitment and retention measured using data recorded in patient records at baseline, 3 months (12 weeks) and 6 months (26 weeks)

## **Secondary outcome measures**

The following secondary outcome measures will be measured during interviews with the participant at baseline, 3 months (12 weeks) and 6 months (26 weeks):

#### Demographic/Clinical measures:

1. Data on age, sex, living situation, educational experience, and employment history measured using and assessment Interview
2. Drug use measured using the Drug Use Disorders Identification Test (DUDIT)
3. Alcohol use measured using the Alcohol Use Disorders Identification Test (AUDIT)
4. Severity of positive and negative symptoms in psychosis measured using the Scale for the Assessment of Positive Symptoms (SAPS) and the Scale for the Assessment of Negative Symptoms (SANS)
5. Anxiety symptoms measured using the Generalized Anxiety Disorder Assessment (GAD-7)
6. Depressive symptoms measured using the Patient Health Questionnaire (PHQ-9)
7. Self-care capability measured using the Independent Living Scale
8. Time spent on various daily activities measured using the Time Use Survey
9. Social and occupational functions measured using the Social and Occupational Functioning Assessment Scale (SOFAS)
10. Social and occupational function measured using the Global Assessment of Functioning (GAF)
11. Occupational functioning, social functioning, and symptom severity measured using the Mental Illness Research, Education, and the Clinical Center version of the Global Assessment of Functioning (MIRECC GAF)
12. Loneliness measured using the UCLA Loneliness Scale

#### Cognition measures:

1. Theory of mind measured using Reading the Eyes in the Mind
2. Emotion recognition measured using the Cambridge Neuropsychological Test Automated Battery - Emotional Recognition Task (CANTAB ERT)
3. General cognitive ability prior to illness measured using the Test of Premorbid Functioning (TOPF)
4. Verbal episodic memory measured using the Weschler Memory Scale (WMS) Logical Memory Test
5. Visuospatial abstract reasoning measured using the Weschler Matrix Reasoning
6. Verbal abstract reasoning measured using the Weschler Similarities
7. Visuospatial working memory measured using the Cambridge Neuropsychological Test Automated Battery Spatial Working Memory Test (CANTAB SWM)

#### Overall study start date

01/09/2019

#### Completion date

30/12/2025

## Eligibility

#### Key inclusion criteria

1. Aged between 18 and 35 years old
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)

Patient

#### Age group

Adult

**Lower age limit**

18 Years

**Upper age limit**

35 Years

**Sex**

Both

**Target number of participants**

30

**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**

**Sligo/Leitrim EIP center**

Dublin road

Sligo

Ireland

F91 X92V

**Study participating centre**

**Galway Adult Mental Health Service**

University Hospital Galway

Galway

Ireland

H91YR71

**Sponsor information**

**Organisation**

Ollscoil na Gaillimhe – University of Galway

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<https://www.universityofgalway.ie>

**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**

Local government

**Location**

Ireland

**Results and Publications****Publication and dissemination plan**

Planned publication in a high-impact journal

**Intention to publish date**

01/12/2026

**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](mailto:gary.donohoe@universityofgalway.ie)

**IPD sharing plan summary**

Available on request