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

Submission date
09/08/2024

Recruitment status
No longer recruiting

Registration date
05/12/2024

Overall study status
Ongoing

Last Edited
05/12/2024

Condition category
Mental and Behavioural Disorders

[ ] 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
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

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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
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Sponsor information

Organisation
Ollscoil na Gaillimhe – University of Galway

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Sponsor type
University/education

Website
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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

IPD sharing plan summary
Available on request