

Moderated Online Social Therapy (MOST) In Help-Seeking Young People: A Pilot Randomised Controlled Study.

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Abstract

Background: In the context of a sharp rise in help-seeking in youth mental health, digital mental health interventions offer enormous potential to improve outcomes, facilitate access, and meet the increasing demand on mental health services. For young adults attending third level education, for example, digital mental health interventions may support help-seeking students while either waiting to attend student counselling, or to sustain gains or once a brief course of face-to-face counselling sessions have completed.

Objective: This trial investigated the feasibility of using a Moderated Online Social Therapy (MOST) intervention comprising of tailored mental health content and therapist, peer, and online community support in third-level students who recently attended a student counselling service.

Methods: We conducted a pilot randomised controlled study of third-level students who had recently completed ~4 sessions of counselling. Students were randomly assigned to the intervention or control arm at a rate of 2:1. In the intervention arm, students had access to MOST for 26 weeks and both groups were assessed at baseline, 12 weeks, and 26 weeks with effect sizes calculated between groups.

Results: A total of N = 74 were recruited, meeting the recruitment target of ~3.1 participants per semester month. Retention in the trial was 70.3% at 12 weeks, reducing to 66.2% at 26 weeks. For the intervention group, when engagement was measured in terms of participation in at least one component of the intervention, 80.9% of the intervention group engaged for 5 or more weeks of the trial (~20% of the maximum 26 weeks). Based on the effect sizes observed, the intervention arm was associated with modest gains in social function and cognitive function, and reduced clinical symptom severity at 12 weeks.

Conclusions: Based on the recruitment, retention, and engagement rates observed, a full randomised controlled trial of MOST with young adults is feasible. Moreover, the effect sizes favouring the intervention arm are consistent with previous studies, and support a full trial of MOST as a potentially beneficial support for youth mental health in further education settings.

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Original Manuscript

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Abstract

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Results: A total of $N = 74$ were recruited, meeting the recruitment target of ~3.1 participants per semester month. Retention in the trial was 70.3% at 12 weeks, reducing to 66.2% at 26 weeks. For the intervention group, when engagement was measured in terms of participation in at least one component of the intervention, 80.9% of the intervention group engaged for 5 or more weeks of the trial (~20% of the maximum 26 weeks). Based on the effect sizes observed, the intervention arm was associated with modest gains in social function and cognitive function, and reduced clinical symptom severity at 12 weeks.

Conclusions: Based on the recruitment, retention, and engagement rates observed, a full randomised controlled trial of MOST with young adults is feasible. Moreover, the effect sizes favouring the intervention arm are consistent with previous studies, and support a full trial of MOST as a potentially beneficial support for youth mental health in further education settings.

Introduction

Despite having the greatest level of need, young adults have the worst access to timely and quality mental health care¹. Both prior to - and since - the COVID-19 pandemic there is robust evidence that demand for youth mental health support significantly outstrips availability in both the healthcare and education systems². In the context of a sharp rise in help-seeking, digital health interventions (mental health supports that are delivered via web-based or mobile-based platforms) offer enormous potential to improve outcomes, to widen access, and to meet the increasing demand on mental health services.

Several meta-analyses have been conducted on digital interventions (mostly focused on Cognitive Behavioural Therapy (CBT) or 'third wave' cognitive interventions) that address depression and anxiety in young adults. An umbrella review by Harith and colleagues³ found evidence to support the use of digital interventions, but noted that effectiveness was greatly dependent on the delivery format and the mental health problem targeted. Furthermore, Harith et al.³ noted that despite young people (as 'digital natives') frequently expressing a preference for the internet as a source of seeking health-related information to address or solve health problems, engagement with and adherence to digital health interventions is often suboptimal.

One such approach to improving mental health recovery in young adults is Moderated Online Social Therapy (MOST)⁴. MOST was initially developed as a digital mental health platform to provide a low-intensity, cost-effective, and engaging approach to prolonging the benefits of specialised Early Intervention for Psychosis (EIP) services⁴, has shown benefits both in terms of return to education and employment and decreased emergency care and has shown to be cost-effective from both the healthcare sector and societal perspective⁵. MOST has since been trialled in young adults in single-arm studies of help-seeking young people aged between 16 and 25 years in Australia⁶ and the Netherlands⁷, and in young people with depression⁸, social anxiety⁹, at high risk of psychosis¹⁰, at increased risk of suicide¹¹, with borderline personality disorders¹², and in a large-scale national study of young adults in Australia¹³, with small to large benefits observed for social function and symptom severity. As a digital intervention, MOST consists of both evidence-based online therapy content supported by therapist contact, and a Facebook-style community supported and moderated by peer support workers. Evidence of the acceptability of MOST for young people has been reported in a number of studies, including in young people with social anxiety¹⁴, emerging mental health issues⁷, and psychosis¹⁵.

The design and therapeutic content of MOST is strongly influenced by self-determination theory¹⁶, an empirically supported theory of motivation, which focuses on the processes and social

environments that facilitate or hamper social functioning. In terms of engagement and adherence, MOST differs from other 'self-help' style digital interventions by providing access to therapeutic content online that is supported by access to a therapist. It is further supplemented by social supports including peer support, and an online community. Providing these face-to-face supports is likely to improve engagement, which is identified as a major barrier to the use of digital interventions^{7,17,18}.

Student mental health

In many European countries, young adults remain in some form of education until their early twenties. Based on OECD figures published in 2022, 54% of 18-24-year-olds are in some form of third level education, rising to 59% in the EU22, and up to 63% in Ireland¹⁹. According to a 2018 WHO study of ~14,000 students from across eight countries, approximately one in three screened positive for at least one common DSM-IV anxiety, mood, or substance disorder²⁰. Similarly, Sheldon et al.²¹ in a meta-analysis of third level students, reported a pooled prevalence of depression at 25% and suicide-related outcomes at 14%. Taken together, these data suggest that education settings such as universities and colleges represent a key location for the development and delivery of mental health interventions. As noted above, however, access to young adult mental health services is often limited, and particularly so in university mental health services where a student may at best have access to short-term (1-4) sessions of counselling. In this context, MOST may provide a means to supplement existing 1:1 therapy in a scalable and cost-effective manner.

The purpose of the present study was to provide information about the feasibility of conducting a randomised trial of MOST in young people who recently attended a university counselling service, along with preliminary data regarding the efficacy of MOST for the purpose of a definitive randomised controlled trial. This study was carried out as part of a funded program of research entitled 'Improving Psychosocial Supports in Youth Mental Health' (The PSYcHE programme). Given that the overarching objective of the PSYcHE program was to improve psychosocial function, our main outcome variable was social and occupational function. Furthermore, because a central hypothesis of the PSYcHE program was that cognitive function, and particularly social cognitive cognition, is an important determinant of social and occupational function in youth mental health, we also included cognitive and social cognitive performance as secondary outcome measures. In terms of clinical variables, we initially only intended to assess the feasibility of loneliness, as measured by the UCLA loneliness scale²². However, studies published soon after the start of the trial both of MOST and of other digital interventions indicated that some of the largest effects might be observed on measures of anxiety, mood and distress. Consequently, the

trial protocol was amended after six months to also test the feasibility of including measures of anxiety and depression.



Methods

Ethics, consent, and permissions

This study was approved by the Galway Clinical Research Ethics Committee, Merlin Park Hospital, Galway, Ireland (ref. CA2468). All participants provided informed written consent. The ethics application also detailed general data protection regulation (GDPR) considerations, and the proposed management of vulnerable individuals in the study. The trial was registered with ISRCTN, number 15520701.

Setting & inclusion criteria

We conducted this prospective, assessor-blind, randomised controlled pilot study at the student counselling service of the University of Galway, Ireland, which serves just over 18,000 students. We aimed to include students who attended the service with persistent mental health difficulties of at least 12 months in duration. The rationale for this was to focus on a more homogenous sample of young people seeking help for mental health difficulties rather than more transient difficulties causing distress. Inclusion criteria were being aged between 18 and 35 years of age, self-reporting mental health difficulties of longer than one year in duration, being clinically stable, and having the ability to give consent. Exclusion criteria were a history of organic impairment (including IQ < 70), history of a head injury with loss of consciousness > 5-minute duration, and substance abuse in the preceding month.

Referrals to the study were made electronically by the student counsellor towards the end of the participant's short term 1:1 counselling sessions (~4 sessions were provided). Once the referral was received, a research assistant completed the informed consent procedure, after which an initial screening was conducted. Following screening for inclusion/exclusion criteria, eligible participants were enrolled into the study and completed a baseline assessment. See **Appendix 1** for a breakdown of recruitment across the study period.

Randomisation and masking

Following baseline assessment participants were randomly allocated to their treatment group. Randomisation was implemented using *Sealed Envelope*²³ at a rate of 2:1 intervention versus control. A block design approach was taken to account for gender, with six participants per block. Research assessors (master's level psychology research assistants) were masked to group allocation. Participants were informed about their trial allocation by a research assistant who was independent from the research assessors and whose role was to 'onboard' participants onto the MOST

intervention platform. To ensure that assessors remained blind to treatment status, research assessors were asked to guess the treatment arm of the participant following each assessment. Assessors correctly guessed intervention status only 33% of the time ($\chi^2 = 1.43$; $p = 0.34$), suggesting that assessors were in fact blinded to status.

Procedures

For those randomised to the MOST arm, an onboarding process was completed, during which participants were registered with the platform and given a guided tour. MOST has been described elsewhere^{24,25}. In brief, participation in the platform consisted of (1) engaging with a therapy 'journey'; content automatically tailored for each participant based on their response to an questionnaire completed as part of the onboarding, further discussion below, (2) support with participation on the therapy journey from a therapist in the form of fortnightly ~15min video or telephone calls, (3) a community wall, see below, and (4) peer support for engagement in the community wall in the form of fortnightly ~30min video or telephone calls. Clinical and peer support workers followed established protocols provided by the MOST platform developers.

Therapy journey

This took the form of interactive online therapy modules (focusing on anxiety, social anxiety, depression, and social interaction) based on third wave CBT 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). Participants's engagement and application of this content in daily life is supported by five activity types, including *comics*, *reflective actions*, *actions*, *talking points* and *pages*. *Comics* are illustrated multipaneled narratives that bring therapeutic concepts to life via recurring characters, *reflective actions* are prompt for reflection, *actions* suggest a practical step (eg, behavioural experiment), *talking points* prompt young people and peer workers to post their thoughts and reactions to the content, and *pages* summarise each track and provide psychoeducation. Users have the option to save activities to a 'toolkit', so they have an accessible, personalised and labelled bank of strategies when needed.

Community interaction

This took the form of 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 framework⁶. 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).

Those randomised to the control arm of the study continued to receive care as usual. As entry into the trial occurred at the end of engagement with the student counselling service, this meant that participants were free to seek help from usual supports (student medical services etc), but were not provided additional supports through the trial and in a majority of cases were not receiving other therapeutic intervention during the period assessed. Control participants could be onboarded to MOST following their 6-month assessment. Outcome measures, described below, were administered to participants in both groups by assessors blinded to intervention allocation at baseline, 12 weeks and 26 weeks.

Outcomes assessed.

As a pilot study, our main outcome metrics related to the feasibility of the trial, including the number of participants recruited, their engagement with the treatment, and their retention at the follow up assessment period. In addition, we also aimed to establish the feasibility of our primary and secondary outcome measures along with some indication of treatment effect estimates that might be expected for these measures to inform power calculations for a full trial.

As described at length by us previously²⁶, identifying suitable measures of social and occupational function is complex, agreeing with the adage that simple measures are accurate and accurate measures aren’t simple. As a result, for the purposes of this study we included two separate measures of social and occupational function. The first was the Social and Occupational Functioning Assessment (SOFAS)²⁷, an interviewer rated global assessment of social and occupational function. The second measure was the Time Use Survey (TUS)²⁸, an interviewer rated assessment of constructive economic activity and structured activity.

Given that improved social and functional outcomes may relate changes in cognitive and social cognitive function (a hypothesis of the broader PSYCHE program of which this MOST study formed part), two measures of cognitive and social cognitive function were included - the Weschler Logical Memory task²⁹ which is a brief measure of verbal episodic memory, and the Reading the

Mind in the Eyes Test (RMET)³⁰ which is a brief measure of social cognition, measuring theory of mind.

In terms of clinical outcomes, the UCLA Loneliness Scale²² was included as a measure of loneliness. In addition, as noted above, the trial protocol was amended after six months to also include additional clinical measures. That is, a measure of anxiety (Generalized Anxiety Disorder 7 (GAD-7)³¹ and of depression (Patient Health Questionnaire (PHQ-9)³². These were therefore available for $n = 51$ of the 74 participants, 32 in the intervention arm and 19 in the control arm.

Intervention engagement data

Engagement data were extracted from the MOST platform once participants had completed 26 weeks on the platform. Data extracted included time spent, in minutes, working through therapeutic content as well as the number of therapeutic content activities completed, community activity (posts, comments, reactions on the community wall), and texts and calls with therapists and peer support workers. The number of weeks spent engaging with the intervention was also calculated for each participant. Engagement was estimated as the combined total number of weeks that each participant logged into the MOST platform and moved beyond the homepage, and/or engaged in a call with their assigned therapist or peer support worker.

Because previous studies had measured engagement in different ways, leading to uncertainty about what engagement could be expected, we did not set an *a priori* indicator of engagement. Adapting from the adherence literature, we considered minimal engagement as $> 20\%$, partial engagement as 50% , and full engagement as $> 80\%$. For a 26 weeks trial, 20% engagement approximates to engagement for five or more weeks, and 50% as engagement for more than 12 weeks.

Statistical analysis

Formal sample size calculations were not performed for this pilot study. Instead, the target sample size was based on recruitment of an adequate sample size for a pilot study conducted for the purposes of establishing parameters for a definitive study. Previous guidance on sample size estimation for pilot studies^{33,34} has suggested a minimum of $N = 60$ as an adequate sample. A period of 36 months was initially proposed as a timeframe to recruit participants into the trial. This was based on funding, and also allowing for the fact that a majority of students were on campus for ~ 7 months of the year. As such, we sought to recruit a minimum average of $n = 3$ students per university

term month: approximately $N = 20$ students per year of the trial.

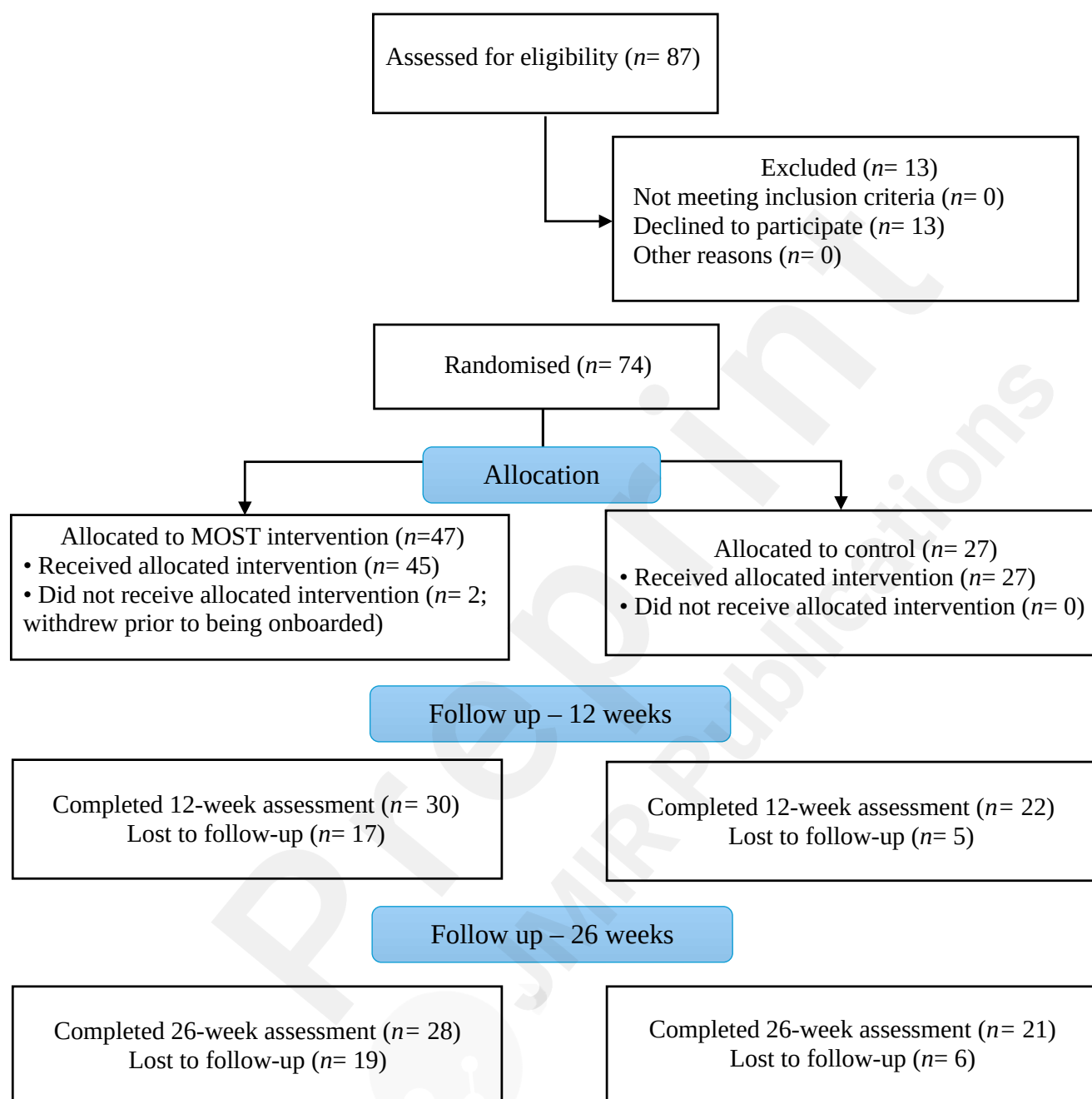
To assess differences between groups, analyses of covariance (ANCOVAs) were carried out to obtain adjusted mean differences between groups with a 95% confidence interval (CI), while accounting for baseline variables. Effect sizes were also calculated by taking the β coefficients of the treatment arm from the ANCOVAs and dividing them by the pooled baseline standard deviation (SD) for each measure respectively. The analysis plan did not include reporting of p values; this was based on recommendations that, as pilot studies are not fully powered, interpretation of results should be done with caution and the analysis should be designed to inform future trials rather than hypothesis testing.³⁵ All analyses were completed at the end of the last follow-up assessments and were based on the intention-to-treat population. Analyses were carried out between the intervention and control groups as well as between participants who engaged for 5 or more weeks (minimum threshold for engagement) and the control participants. Analyses was conducted using SPSS v27.

Results

Recruitment and sample description

Recruitment

Our initial target was to recruit $N = 60$ participants over a 36-month period, representing a recruitment rate of 20 participants per year. We expected that most of the recruitment would occur during the seven months of term time, such that we would be required to recruit ~ 3.3 participants per month of term (semester) time (~ 1.67 participants per calendar month) to achieve this target. The actual number of participants recruited was $N = 74$ over the 44 months (extended by 8 months due to the COVID pandemic) between April 2021 and December 2024 (See **Figure 1** for Consolidated Standards of Reporting Trials (CONSORT) participant flow chart³⁶). In terms of the university semester, this equates to ~ 3.1 participants recruited for each month of term time or ~ 1.68 participants per calendar month (see **Appendix 1** for recruitment numbers by month).

Figure 1*Participant recruitment and retention***Sample description**

A demographic and clinical description of the sample is provided in **Table 1**. The sample had a mean age of 22 years and 72% identified as female. Sixty eight percent of the sample lived in shared accommodation while 24% continued to live at home. Predictably for a sample recruited from a student cohort, all but two participants were in full or part time education at the time of baseline assessment, with those two participants having just left education since initial contact.

In term of duration of mental health difficulties, reflecting the inclusion criteria of experiencing difficulties for at least 12 months, participants subjectively reported duration of difficulties as ranging from 12 months to 165 months (13.8 years) in the intervention arm and 12-192 months (16 years) in the control arm. The most commonly self-reported difficulties were anxiety (45%), mood (23%), academic difficulties (15%), and relationship difficulties (7%). In terms of alcohol use (measured by the Alcohol Use Disorders Identification Test (AUDIT)³⁷), 59.5% were classified as 'low risk', 29.7% as 'low risk' or 'increasing risk' and 6.8% as 'possibly dependent' on alcohol. In terms of drug use, (measured by the Drug Use Disorders Identification Test (DUDIT)³⁸) all participants were estimated as 'probably not' substance dependent and none as probably heavily dependent.

Table 1: Demographic and clinical description of sample at baseline assessment

	Intervention Group (n = 47)		Control Group (n = 27)	
	M	SD	M	SD
Age	22.77	6.12	22.56	3.71
Gender (M: F: GF: Other)	12:32:1:2	-	5:21:00:1	-
Current education status:				
Not in education	1	2.10%	1	3.70%
Part time	2	4.30%	3	11.10%
Full time	44	93.60%	23	85.20%
Accommodation:				
Lives with parents	13	28%	5	19%
Lives with others	30	64%	20	74%
Lives alone	1	2%	1	4%
Presenting problem (self-report):				
Anxiety (n/%)	20	43%	13	48%
Mood (n/%)	10	21%	7	26%
Academic (n/%)	6	13%	5	19%
Relational (n/%)	4	9%	1	4%
Behavioural (n/%)	3	6%	0	0%
Other (n/%)	4	9%	1	4%
Duration of difficulties (months):	44.45	40.66	52.33	44.83
Clinical Measures				
GAD-7	11.12	4.77	11.63	4.93
UCLA	47.96	11.3	48.04	10.33
PHQ-9	12.32	5.06	13.63	5.11
Risk of alcohol and drug dependency				
AUDIT	45	7.29 (6.38)	27	7 (4.53)
DUDIT	46	2.26 (4.62)	27	2.67 (4.53)

Predicted general cognitive ability

TOPF

104.16

8.72

104.93

6.63

Abbreviations: GAD-7, Generalized Anxiety Disorder 7; UCLA, UCLA Loneliness Scale; PHQ-9, Patient Health Questionnaire; AUDIT, Alcohol Use Disorders Identification Test; DUDIT, Drug Use Disorders Identification Test, TOPF, Test of Premorbid Functioning.

In terms of randomisation, which was set at 2:1 intervention to control, $n = 47$ of the $N = 74$ participants (63.5%) were assigned to the intervention arm of the study. No randomization errors were identified during the trial period.

Rates of retention and engagement

Retention

This was defined as the percentage of participants who completed outcomes measures at 12 and 26 weeks. Our initial target for retention was 75% at 12 and 26 weeks, with a threshold target of 70% required to proceed to a full RCT without amendment of the study. In terms of actual retention rates in the study, 12 week assessments were collected for $n = 52$ of the 74 participants (70.3%), representing $n = 30$ (64%) of the 47 intervention participants and $n = 22$ (78%) of the $n = 27$ participants in the control arm. Twenty-six-week assessments was available for $n = 49$ participants (66.2%). This represented $n = 28$ (59.6%) of the intervention group and $n = 21$ (77.8%) of the control group. In summary, this reflects an overall drop-out rate of 29.7% at 12-week follow-up, increasing marginally to 33.8% at 26 weeks.

Rates of engagement

As described above, engagement was captured in terms of discreet activities on MOST (see **Appendix 2**) and then categorised in terms of number of weeks of engagement in the intervention. Participants were categorised according to their level of engagement using the following thresholds: minimal engagement = >5 weeks; 20% of the intervention period, partial engagement = >12 weeks; 50% of the intervention period, and full engagement = >21 weeks; 80% of the intervention period. We observed that $n = 38$ participants in the intervention arm (81%) engaged with the program for 5 or more weeks. $N = 39$ (83%) were engaged in the first 12 weeks, and. $N = 35$ (74%) continued to engage beyond 12 weeks (see **Appendix 3**). Finally, to allow comparison with other studies of MOST and other digital interventions, engagement was also recorded and summarised in terms of min/max, median and mean for total activity time, number of therapy journey activities completed, community posts made/commented on/reacted to, and numbers of calls with the therapist and/or peer

support worker. These are provided in **Appendix 2**.

Outcome measures

Table 2 shows the group means and standard deviations, adjusted mean differences for the SOFAS, and the effect sizes for those differences between the intervention group and the control group. **Table 3** shows the same descriptive values for participants from the intervention group who had a minimum of 20% engagement on MOST, compared to the control group.

Primary outcome measures

Social and occupational functioning

No difficulties were encountered in administering the SOFAS. In terms of group comparisons, there was small effect on SOFAS scores at 12 weeks for those allocated to MOST ($d = -0.28$), with an equivalent effect size observed when only those who engaged for more than 5 of the 26 weeks (i.e. $> 20\%$) were included in the intervention arm. Of note, there was no evidence of an effect of MOST on the SOFAS when measured at 26 weeks for either the full intervention group or for those who were at least minimally engaged.

Two issues emerged in the administration of the TUS. The first of these was COVID-19 related. Across the first 18 months of the recruitment period, time use was significantly altered by restrictions imposed due to the pandemic. The second was the issue of tracking activity over six months when students' activity differed significantly depending on when they were in college during the semester, or during the holiday period between semesters. Consequently, the changes in TUS scores were problematic to interpret in terms of the size of the effect of the intervention.

Secondary outcome measures

Cognitive and social cognitive assessment

As widely used cognitive measures, no difficulties were observed in administering either the Logical Memory task or the RMET. A small effect was observed on the RMET task at 12 weeks for both the intervention group (-0.23) and when only those who had at least minimally engaged were assessed (-0.21). No effect was observed on the declarative memory scale at 12 weeks. While a small effect at 26 weeks was observed in the full group, this was not consistent between the full and $> 20\%$ engaged group.

Clinical functioning

As already noted, the trial protocol was amended after six months to also include the GAD-7 and PHQ9, which were therefore available for $n = 51$ of the 74 participants, $n = 32$ in the intervention arm and $n = 19$ in the control arm. Across the clinical measures, small to medium effects in favour of the intervention arm were observed at 12 weeks, with effect sizes of $d = -0.5$ for the GAD7, $d = -0.34$ for the PHQ9 and $d = -0.31$ for the loneliness scale. Comparable effect sizes were observed in the full intervention arm and when only those with $> 20\%$ engagement were used in the comparison. Again, as with other effect sizes favouring the intervention arm, these effects were not observed at 26 weeks.

Table 2: Comparison of outcome data for full sample

					Adjusted Mean	Effect Size
					Difference (95% CI)	(d)
		Intervention	Control			
		n	M(SD)	n	M(SD)	
Primary outcome measures						
Social and occupational Function						
SOFAS						
0 weeks	47	79.38 (8.26)	27	77.89 (8.86)	-	-
12 weeks	29	81.48 (9.83)	22	78.45 (10.82)	-2.36 (-8 to 3.27)	-0.28
26 weeks	24	82.79 (10.26)	21	83.52 (7.7)	1.08 (-4.09 to 6.25)	0.13
TUS Constructive economic activity						
0 weeks	47	43.77 (19.13)	27	45.3 (29.52)	-	-
12 weeks	30	36.42 (15.26)	22	48.32 (32.04)	10.86 (-1.66 to 23.37)	0.47
26 weeks	28	38.18 (19.52)	21	42.85 (14.91)	4.36 (-6.06 to 14.78)	0.19
TUS Structured activity						
0 weeks	47	53.62 (19.33)	27	53.67 (28.23)	-	-
12 weeks	30	46.23 (16.08)	22	59.63 (31.38)	12.74 (0.66 to 24.83)	0.56
26 weeks	28	47.91 (21.43)	21	52.49 (16.09)	4.13 (-7.08 to 15.34)	0.18
Secondary outcome measures						
Cognitive and social cognitive function						
RMET						
0 weeks	47	27.19 (4.3)	27	27.11 (3.48)	-	-
12 weeks	30	27.1 (4.36)	22	25 (4.16)	-0.93 (-2.67 to 0.81)	-0.23
26 weeks	28	28.21 (4.3)	21	27.48 (3.49)	-0.11 (-1.98 to 1.76)	-0.03
Logical Memory						
0 weeks	47	9.38 (2.89)	27	8.78 (3.06)	-	-
12 weeks	17	8.82 (2.7)	16	8.81 (2.4)	0.02 (-1.34 to 1.38)	0.01
26 weeks	28	9.54 (2.91)	21	8.86 (3.29)	-0.69 (-2.12 to 0.75)	-0.23
Clinical measures						
UCLA Loneliness						
0 weeks	46	47.96 (11.3)	26	48.04 (10.33)	-	-
12 weeks	30	45.23 (13)	22	44.14 (12.73)	-3.43 (-9.55 to 2.69)	-0.31

26 weeks	28	40.14 (13.23)	21	42.48 (12.38)	-1.44 (-7.64 to 4.77)	-0.13
PHQ-9						
0 weeks	31	12.32 (5.06)	19	13.63 (5.11)	-	-
12 weeks	20	10 (6.1)	19	10.05 (4.89)	-1.72 (-5.46 to 2.02)	-0.34
26 weeks	21	8.9 (5.8)	18	9.83 (3.7)	0.54 (-2.92 to 4)	0.11
GAD-7						
0 weeks	32	11.12 (4.77)	19	11.63 (4.93)	-	-
12 weeks	20	9.6 (6.2)	19	9.32 (4.77)	-2.36 (-5.58 to 0.85)	-0.50
26 weeks	21	8.1 (5.32)	18	8.28 (5.07)	1.08 (-2.64 to 4.81)	0.23

Abbreviations: SOFAS, Social and Occupational Functioning Assessment; TUS, Time Use Survey; RMET, Reading the Mind in the Eyes Test, Logical Memory, Weschler Logical Memory task; UCLA, Loneliness Scale; PHQ-9, Patient Health Questionnaire; GAD-7, Generalized Anxiety Disorder 7.

Table 3: Comparison of outcome data between participants who engaged for a minimum of 5 weeks and control participants

	Intervention - >5 weeks engagement*		Control		Adjusted Mean Difference (95% CI)	Effect Size (d)
	n	M(SD)	n	M(SD)		
Primary outcome measures						
Social and occupational Function						
SOFAS						
0 weeks	38	79.5 (8.3)	27	77.89 (8.86)	-	-
12 weeks	27	81.22 (10.05)	22	78.45 (10.82)	-2.16 (-7.96 to 3.64)	-0.25
26 weeks	22	81.82 (10.15)	21	83.52 (7.7)	1.91 (-3.34 to 7.16)	0.22
TUS Constructive economic activity						
0 weeks	38	46.27 (19.91)	27	45.3 (29.52)	-	-
12 weeks	28	35.6 (15.41)	22	48.32 (32.04)	11.76 (-1.12 to 24.64)	0.49
26 weeks	26	37.36 (20.04)	21	42.85 (14.91)	5.18 (-5.56 to 15.92)	0.21
TUS Structured activity						
0 weeks	38	55.74 (19.82)	27	53.67 (28.23)	-	-
12 weeks	28	45.7 (16.36)	22	59.63 (31.38)	13.24 (0.73 to 25.75)	0.56
26 weeks	26	46.58 (21.41)	21	52.49 (16.09)	5.41 (-5.89 to 16.72)	0.23
Secondary outcome measures						
Cognitive and social cognitive function						
RMET						
0 weeks	38	27.39 (4.48)	27	27.11 (3.48)	-	-
12 weeks	28	27.21 (4.48)	22	25 (4.16)	-0.87 (-2.66 to 0.93)	-0.21
26 weeks	26	28.08 (4.35)	21	27.48 (3.49)	0.13 (-1.79 to 2.04)	0.03
Logical Memory						
0 weeks	38	9.39 (3.12)	27	8.78 (3.06)	-	-
12 weeks	16	8.75 (2.77)	16	8.81 (2.4)	0.1 (-1.29 to 1.5)	0.03
26 weeks	26	9.58 (2.97)	21	8.86 (3.29)	-0.7 (-2.18 to 0.78)	-0.23
Clinical measures						
UCLA Loneliness						

	0 weeks	37	48.41 (11.72)	26	48.04 (10.33)	-	-
	12 weeks	28	46.32 (12.67)	22	44.14 (12.73)	-4.4 (-10.51 to 1.72)	-0.40
	26 weeks	26	40.54 (13.47)	21	42.48 (12.38)	-1.23 (-7.58 to 5.11)	-0.11
PHQ-9							
	0 weeks	25	12.88 (5.15)	19	13.63 (5.11)	-	-
	12 weeks	19	10.32 (6.09)	19	10.05 (4.89)	-2.23 (-5.94 to 1.47)	-0.44
	26 weeks	19	9.05 (6.07)	18	9.83 (3.7)	0.38 (-3.29 to 4.05)	0.07
GAD-7							
	0 weeks	26	11.58 (4.47)	19	11.63 (4.93)	-	-
	12 weeks	19	9.53 (6.38)	19	9.32 (4.77)	-2.13 (-5.32 to 1.06)	-0.47
	26 weeks	19	8.37 (5.47)	18	8.28 (5.07)	1.1 (-2.83 to 5.03)	0.24

Abbreviations: SOFAS, Social and Occupational Functioning Assessment; TUS, Time Use Survey; RMET, Reading the Mind in the Eyes Test, Logical Memory, Weschler Logical Memory task; UCLA, Loneliness Scale; PHQ-9, Patient Health Questionnaire; GAD-7, Generalized Anxiety Disorder 7.

Discussion

This trial investigates the feasibility of conducting a randomised control trial of a moderated online intervention in a university setting. The intervention included online tailored mental health content with support from a therapist and peer-to-peer social mentoring and networking with the aim of improving mental health and social functioning. Based on recruitment at a single site, we achieved our recruitment target of 1.67 participants per month (~3.1 participants per semester month). Retention in the trial was 70.3% at 12 weeks, reducing to 66.2% at 26 weeks. For the intervention group, when engagement was measured in terms of participation in at least one component of the intervention (therapy journey, therapist contact, community wall participation or peer support contact), 80.85% of the intervention group engaged for 5 or more weeks of the trial (equivalent to at least 20% of the maximum 26 weeks for which the intervention was available to participants).

While the study was not adequately powered to test for differences between intervention and control groups, calculation of effects sizes associated with mean differences between the intervention group and the control arm indicated a small benefit favouring the intervention group ($d = 0.28$) for the SOFAS measure of social and occupational functioning (but not the TUS). Similar small effects were observed for the secondary cognitive variables of memory function and social cognitive function. Finally, slightly larger (positive) effects were observed on the clinical measures available (GAD-7 $d = -0.5$, PHQ9 $d = -0.34$ and $d = -0.31$ for the loneliness scale). Across each of these primary and secondary measures, the effect sizes observed at 12 weeks were similar when either the full intervention group or only those with at least minimal engagement (5 or more weeks) compared to the control group. However, these effect sizes reduced to less than $d = 0.1$ at 26 weeks.

Progression to a full trial

As noted above, rates of recruitment were as originally planned, and no difficulties were encountered with randomization procedures and completion of outcome measures (except for the TUS, discussed further below). Retention rates in the trial of 70.3% at 12 weeks were marginally lower than the criteria of 75%, indicating that $n = 4$ fewer participants were retained than expected. Our criteria of 75% was based on Alvarez-Jimenez et al.'s original study⁴ in patients with early psychosis. As such, this may have been unrealistic for a student population given that previous studies of MOST in a similar sample reported a retention rate of 59%⁷.

Outcome measures used

From the point of view of measurement of outcomes, our primary outcome was social and occupational functioning. Social and occupational function is difficult to measure accurately at the best of times²⁶. Additionally, our study coincided with the COVID-19 pandemic, which significantly impacted on social and occupational function and time use for many participants during the study. Furthermore, given the student experience of moving between the routine of term time and the social and occupational upheaval associated with the winter and summer breaks, intervention related changes in functioning were difficult to track accurately. While observer-rated measurement using the SOFAS was able to detect the same level of effects as observed on cognitive and clinical measures, time use did not appear to be a sensitive or reliable measure of change in function. On this basis, other measures of social function might be considered to index change in this domain in a future trial.

Among the measures recorded in the study, the largest effect observed was on the GAD-7, a measure of generalized anxiety ($d = -0.5$). While this was not a primary outcome measure in the trial, measures of anxiety (and mood) are the measures most closely related to the therapy content of MOST given that much of the MOST therapy journeys focus on either anxiety, social anxiety or mood¹³. It might be expected therefore that the largest effects might be observed on these more proximal outcome measures.

A noticeable difference in the effect sizes can be observed across timepoints; with some benefits associated with participating in the intervention arm at 12 weeks, not appearing at 26 weeks. In the Alvarez-Jimenez et al.⁴ psychosis sample, no difference in social functioning was apparent between groups at follow-up, whereas a difference in the odds of enrolling in education or finding employment was observed. Given the near full college enrolment in our sample (as a study of students), we were obviously unlikely to see the same educational/occupational benefits. In the Van Doorn et al.⁷ study, the significant difference in social and occupational function as measured by the SOFAS, did persist at 26 weeks. However, that study represented a single group design investigating changes within the intervention group over time, as opposed to between group differences. In the present study, it is unlikely that these difference between 12 and 26 weeks are explained by engagement attrition, as most of the attrition occurred in the initial couple of weeks, with 83% engaged for at least five weeks and 74% engaged beyond 12 weeks. Instead, the reduced effect at 26 weeks appears to have reflected the improved scores of the control group at 26 weeks, as indexed by the SOFAS, the social cognitive, and clinical measures.

Strengths and limitations

The purpose of a pilot study is to identify potential difficulties and avoid these prior to commencing a full trial. In terms of strengths, several aspects of the methodology for evaluating the use of MOST in a young adult student sample were supported in this study, including the feasibility of recruitment and retention, randomisation, and a majority of the assessments used at each timepoint. In terms of the weaknesses of our methodology, we have already noted the difficulty with measuring social and occupational function. Specifically, that the Time Use Survey might not be a suitable measure for use in a student population. We have also noted that the largest effect sizes for MOST are likely to be observed on clinical outcome measures that relate more directly to the intervention.

We also note that the dropout rate was slightly higher in the intervention arm compared to the control arm. This is likely to reflect, in part, the time demands of participating in the various components of MOST. One unanswered question following this study is how long students should be expected to participate. As will be noted from **Appendix 3**, there were clearly significant differences between participants in terms of their interest/willingness to remain involved across the 26 weeks that MOST was offered. While as noted, the vast majority remained active for more than five weeks, the median number of months of involvement was five months ($M = 4.32$, $SD = 1.95$). This information should inform expectations for involvement in the full trial.

Conclusion

Based on the recruitment, retention, and engagement rates observed, this pilot feasibility study provides evidence for the feasibility of a full randomised control trial of MOST with a young adult population. Moreover, the effect sizes favouring the intervention arm are consistent with previous studies, suggesting that MOST may be a potentially beneficial support for youth mental health in the context of further education. This study also highlights important factors that need to be addressed in a full study, such as including measures of anxiety and depression as potentially primary outcome variables, of selecting sensitive measures of social function, and of ensuring sustained engagement in the intervention.

Declarations

Ethical approval

This study was approved by the Galway Clinical Research Ethics Committee, Merlin Park Hospital, Galway, Ireland (ref. CA2468).

Availability of data and materials

The full protocol in addition to datasets and statistical code generated during the current study will be available from the corresponding author on reasonable request.

Competing Interests

Author MA was involved with development of the MOST program. However, they are not involved with supervising any of the assessment procedures or data analysis.

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Role of the funding source

The funder of the study (the Health Research Board, Ireland) had no role in study design, data collection, data analysis, data interpretation, or writing of the report. GD had full access to all the data in the study and had final responsibility for the decision to submit for publication

Authors' contributions

GD & JmcC originated the conception and design of the study. GD, MDOR, SH, EF, TB, and CH led the trial, and GD, MDOR, and SH completed the analysis and interpretation of data. All authors reviewed and approved the manuscript.

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Supplementary Files

Multimedia Appendixes

Recruitment figures per month across the study period.

URL: <http://asset.jmir.pub/assets/12a19f636874d05088870618b7ba19f3.docx>

Summary of engagement on MOST.

URL: <http://asset.jmir.pub/assets/75ca7ad90319fc39236eb7264411fd63.docx>

Engagement on MOST by month.

URL: <http://asset.jmir.pub/assets/dd448e0ac8b737c68abbcbb89b05774a.docx>