Original Paper

A brief intervention to increase uptake and adherence of an online program for depression and anxiety: Protocol for the Enhancing Engagement with Psychosocial Interventions (EEPI) Randomized Controlled Trial

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Abstract

Background: There is substantial evidence that psychosocial programs delivered online can be effective in treating and preventing mental health problems. However, use of evidence-based programs in the community is currently suboptimal, and there is a lack of evidence around how to increase engagement with existing evidence-based programs. Novel approaches to increasing the acceptability of online programs such as the use of brief engagement-facilitation interventions (EFI) require evaluation.

Aims: The aims of this study are to 1) examine the effectiveness of a brief online engagement-facilitation intervention (EFI) presented prior to an online self-help mental health program (*myCompass*) in improving uptake of and adherence to that program, and 2) assess if greater uptake and/or adherence are associated with improved efficacy (greater reduction in symptoms of depression and anxiety) relative to a control condition).

Methods: A three-arm randomized controlled trial will be conducted (target sample: *N*=693 participants recruited via social media). An active online cognitive behavioral therapy (iCBT) intervention will be delivered either with (arm 1) or without (arm 2) the EFI. An attention control group (arm 3) will enable testing of the relative efficacy of the iCBT intervention. Primary outcomes are *uptake* of the intervention (initiation) and *adherence* (module completion).

Results: Findings will inform the more efficient dissemination of a range of psychosocial programs into the community, with potential for significant efficiency gains in treating common mental health problems.

Conclusions: Greater engagement with online psychosocial programs may lead to significant reductions in the burden of common mental health problems in the community.

Keywords: implementation; mental health; adherence; uptake; engagement-facilitation intervention; internet

Trial registration: Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12618001565235

Introduction

Depression and anxiety are common mental disorders, with estimated 12-month prevalence rates of 5-7% for major depressive disorder and 5-10% for anxiety disorders globally [1-3]. Despite high levels of disability and burden, only one-third of people with a mental health problem will seek help from a health professional [4]. Lower cost and intensity, evidence-based alternatives to face-to-face services, such as online mental health (E-MH) programs, are increasingly being offered to those at-risk for mental health problems or experiencing mild mental illness [5].

There is substantial evidence that psychosocial programs delivered online can be effective in treating and preventing mental health problems [6]. However, uptake of these programs in the community remains suboptimal [7 8]. Previous studies have reported that many people prefer face-to-face therapy over E-MH programs [8-10], despite viewing online programs as having advantages such as convenience [8]. This preference may be due partly to the common public view that online therapies are not as effective as face-to-face therapy [11]. This implementation gap undermines the potential for technology to overcome traditional barriers to treatment access. While there are initiatives addressing public awareness of online mental health programs (e.g., [12]) and new programs are being developed to be more consumer-centered [13], there remains a lack of evidence around how to increase engagement with existing evidence-based programs.

Barriers to use of E-MH programs

There are many reported barriers to the uptake of E-MH programs [14]. A previous study reported that 52% of the unique visitors to the MoodGYM program (N = 194,840) did not register for the program [15]. Among those community-based users who registered (N =

82,159), 49% did not engage in a single module of the program. Overall, 10% of community-based visitors to MoodGYM completed one or more modules, suggesting there may have been a considerable proportion who experienced one or more barriers to engaging with the program. Reducing these barriers to uptake by a small fraction could have large impacts on the number of individuals who receive evidence-based treatment. Studies based in primary care have similarly reported rates of uptake between 3% and 25% [16].

Some of these reported barriers are modifiable. Issues around the barrier of the 'acceptability' of E-MH programs may be influenced by a number of factors, including low expectations of program effectiveness, data security concerns, limited familiarity with E-MH programs, negative attitudes towards seeking help in general, and internet anxiety [5 6 9 14 16 17]. Poor adherence is also a common feature of E-MH programs, particularly in naturalistic settings [15 18]. Low adherence can occur for a number of reasons; some positive such as sufficient dosage for remission of symptoms, some neutral such as insufficient need for treatment (e.g., healthy users), and some negative, such as poor fit of content to needs, lack of interactivity, symptom severity, low motivation, or a lack of improvement [15 18-20].

Engagement-Facilitation Interventions (EFIs)

Challenging barriers prior to the commencement of an E-MH program is anticipated to increase engagement. This approach to increasing the acceptability of a program is labelled an acceptance-facilitation intervention (AFI) or more broadly, an engagement-facilitation intervention (EFI). EFIs contain information presented to the participant that target any potential barriers to engagement that may reduce their use of the program [16]. The use of EFIs is grounded in the Theory of Planned Behavior [21], with the aim of changing social norms around use of E-MH interventions [22]. Previous research has been mixed for

demonstrating an effect for EFIs on acceptance of online programs for pain [23 24], and mental health interventions for people with diabetes [25]. One study showed that acceptability of E-MH programs for depression increased following presentation of a video-based AFI in a primary care setting [16]. However, to our knowledge, no previous study has examined the utility of an EFI in increasing uptake of and adherence to an existing, publically available E-MH program. The current proposed three-armed randomized controlled trial (RCT) will provide a robust evaluation of both the EFI and the original online mental health program's effectiveness, while accounting for individual factors that may be associated with improved engagement.

Aims

1. To test whether delivery of a brief EFI increases uptake of and adherence to an online mental health program.

2. To test whether greater uptake and/or adherence are associated with improved efficacy, as indicated by greater reduction in symptoms of depression and anxiety relative to a control condition.

Methods

Trial design

A three-arm RCT will test whether an EFI increases uptake of and adherence to an online intervention targeting comorbid mental health problems. Participants will be randomly allocated to either (1) the active intervention with the EFI (*myCompass 2 + EFI*); (2) the active intervention without the EFI (*myCompass 2 Alone*); or (3) an attention control condition (*HealthWatch*) matched for time taken to complete. This will enable testing of

whether the EFI has an impact on the efficacy of the myCompass 2 program. This study protocol addresses the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist [26].

Interventions

The Engagement-Facilitation Intervention (EFI)

The pre-intervention EFI consists of brief, tailored material presented on a series of webpages to the participant after they are randomized to a condition but before they start the intervention for depression and anxiety (*myCompass 2*).

The EFI was developed using a series of four focus groups (total $n = 24$; male = 3, female = 21) with community members who had personal lived experience of depression and/or anxiety. The development of the EFI was informed by the principles of participatory design, which are particularly appropriate in implementation research that focuses on the relevance and uptake of interventions [27]. The results of the focus groups indicated that the EFI material should challenge personal barriers to engagement with psychosocial interventions by focusing on feedback about symptoms, information about the content and efficacy of the E-MH program, normalizing participation in E-MH programs, and brief information on data security. The development of the EFI was also informed by theory that emphasizes the importance of social norms in the acceptability of online psychosocial programs [16 21 22]. The EFI is very brief, and takes approximately five minutes to interact with and read. Brevity is essential to ensure that information is easily digestible and does not add a significant barrier to the time required to engage with the intervention program itself.

The EFI was delivered in a click through linear format, as part of the online platform also housing the surveys, and the control group content. The EFI includes the following components:

1. Graphical feedback about the participant's symptom levels and a written description of the benefits of participating in E-MH programs, tailored to symptom levels.
2. Written information about the efficacy of the E-MH program.
3. Written information about the content and time commitment involved with the program.
4. Two testimonials (presented in a single 1 minute video) outlining the benefits of E-MH programs to provide information and normalize participation in online self-guided therapy interventions.
5. Written information about data security.

myCompass 2

myCompass 2 is an updated version of the previously evaluated *myCompass* online program [28 29]. It is a fully automated, interactive self-help program (without therapist assistance) that is delivered for free via the Internet (see https://www.mycompass.org.au/). *myCompass 2* can be accessed on mobile phones and tablets in addition to computers. The program provides people experiencing mild to moderate symptoms of stress, anxiety and/or depression, with 24/7 access to a private, personalized and evidence-based treatment program. Evidence from two community-based trials (n = 89; n = 720) showed that the original version of the *myCompass* program was able to significantly reduce mental health symptoms and improve work and social functioning [28 29].

Similar to the original version, *myCompass 2* also contains 14 modules derived primarily from cognitive behavior therapy (CBT), with elements of problem solving therapy, interpersonal psychotherapy and positive psychology. Seven modules provide core transdiagnostic CBT, while the remaining seven are tailored to specific mental health concerns (e.g., sleep, communicating clearly) Other features include real-time self-monitoring of thoughts, feelings and behaviors (via mobile phone or computer); SMS or email self-monitoring reminders; graphical feedback about self-monitoring information; and helpful facts, mental health-care tips or motivational statements (via SMS or email). Similar to the original *myCompass* program [29], *myCompass 2* is tailored to user needs, with screening scales used to profile the participant and provide them with recommendations as to which modules would be most suitable for them. *myCompass 2* is delivered over 7 weeks to enable sufficient time to complete all of the available modules. It is expected that users will complete two modules per week for 7 weeks, although completion of fewer modules has been shown to lead to significant symptom reduction [29 30]. Each module takes 30-45 minutes to complete.

Attention control condition (HealthWatch)

The attention control condition will consist of 14 brief modules of public domain health and lifestyle information unrelated to mental health, that has been matched for time taken to complete, and has previously been shown to have high credibility (see, e.g., [31 32]. Module topics are: Keeping bones strong and healthy, The dark side of sun exposure, Fight off food poisoning, Taking supplements, Keep your kidneys healthy, Your microbes and you, Handling household burns, Cold, flu, or allergy?, Healthy heart, Allergens & irritants, Getting in straight, The power of your pancreas, Keep an eye on your eyes, Don’t toss the floss!. The program will also be delivered over 7 weeks. At the end of the 6-month trial period after all

follow-up data has been collected, the control group will be invited to use the *myCompass* 2 program.

Participants and eligibility criteria

Participants will be recruited online from the general community. To be eligible for the trial, potential participants must:

1) Have current symptoms of depression OR anxiety in the mild to moderate range (Patient Health Questionnaire-9 (PHQ-9) OR Generalized Anxiety Disorder-7 (GAD-7) score at screening of 5-14), and
2) Be aged 18 years or over and living in Australia.

Community members will be excluded from enrolling in the trial if they:

1) Have had any previous use of the *myCompass* online program.
2) Are receiving psychological therapy at screening.
3) Self-report that they have had a suicide plan in the past month.
4) Self-report that they have a diagnosis of psychosis or bipolar disorder.

Participants who are not eligible according to the above criteria will be informed following the screening and provided with relevant help-seeking resources.

Recruitment

Recruitment will be conducted through social media advertising (e.g., Facebook) to ensure a broad cross-section of the community is reached and to maintain ecological validity, as online interventions are often marketed online directly to consumers. Based on a previous RCT conducted by the lead author using a similar social media strategy [31] which recruited an

average of 2.8 participants per day, we anticipate that recruitment targets will be met within approximately 9 months for the RCT. Social media advertisements will target adults living in Australia, aged 18 years and older, who may be currently experiencing low mood or symptoms of anxiety. The advertisement will contain a link to a webpage containing information about the study. Participants who click on the advertisement will be taken to the information and consent page, where they will be invited to read information about the study and to provide their consent to participate online. It is anticipated that recruitment will commence during late 2018. The flow of participants through the study is presented in Figure 1.

Ethics approval

The ethical aspects of this research have been approved by The Australian National University Human Research Ethics Committee (ANU HREC protocol number 2018/257).

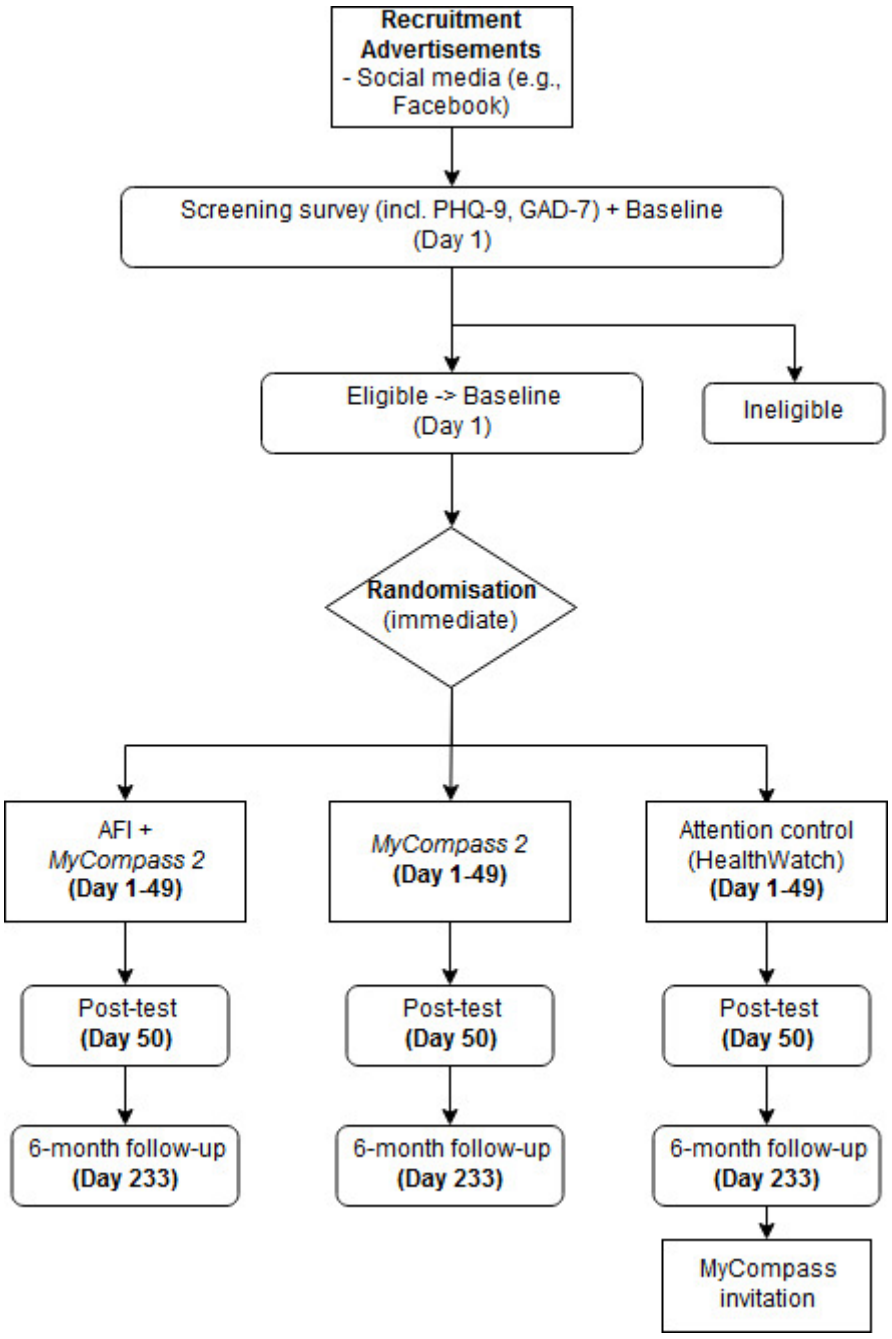

Figure 1. Trial flow chart

Hypotheses

We propose the following hypotheses:

Primary Hypotheses (Aim 1)

H1: Uptake (initiation of at least one module) will be higher in the *myCompass 2* + EFI condition relative to the *myCompass 2* Alone condition.

H2: Greater adherence will be observed (i.e., higher number of modules completed) in the *myCompass 2* + EFI condition relative to *myCompass 2* Alone.

Secondary Hypotheses (Aim 2)

H3: Efficacy (reduction in symptoms of depression and anxiety) will be higher in the two active *myCompass 2* intervention conditions than the *HealthWatch* attention control condition at post-test and 6-month follow-up.

H4: Efficacy will be higher in the *myCompass 2* + EFI condition than the *myCompass 2* Alone condition at post-test and follow-up, and this difference will be mediated by adherence to the program.

Exploratory Hypotheses

H5: Adherence, uptake and efficacy will be moderated by a range of sociodemographic and psychological characteristics including gender, age, cultural/linguistic background, education, social support, symptoms of depression and anxiety, acceptability of psychosocial online programs, attitudes toward professional psychological treatment, familiarity and use of technology, stigma and mental health literacy.

H6: Secondary indices of efficacy (reductions in suicidality, distress and disability; increases in acceptability of internet-based psychosocial interventions and quality of life) will be

highest in *myCompass 2* + EFI, followed by *myCompass 2* Alone, which will outperform the *HealthWatch* attention control condition.

Outcomes and data analysis

Primary outcomes

Uptake (H1) will be assessed as the number of individuals who access at least one therapeutic module of the program. Rates of uptake in *myCompass 2* + EFI will be compared to uptake in the *myCompass 2* Alone condition, based on a chi-square test, as complete data on uptake will be available for all individuals randomized to the active conditions. Online usage data is automatically collected by the *myCompass 2* program for each user. Adherence (H2) will be based on the number of modules completed of *myCompass 2* by the post-test survey. Adherence is a complex outcome, as individuals may discontinue a program for many reasons, such as receiving adequate dosage, lack of engagement, low motivation for change, or low need (few symptoms) [15]. We have chosen the definition of number of modules completed as it captures the dosage of therapeutic content received. We will explore secondary indices of adherence (e.g., percentage of users completing one/half/all modules) for consistency of outcomes, and examine self-reported reasons for non-adherence. To test the effect of the EFI on adherence, module completion in *myCompass 2* + EFI will be compared to module completion in the *myCompass 2* Alone condition using a Mann-Whitney test, based on usage data as above.

Secondary outcomes

Efficacy (H3, H4) will be assessed on the basis of reduced symptoms of depression (PHQ-9, [33]) and generalized anxiety (GAD-7, [34]) at post-test and 6-month follow-up.

Comparisons of efficacy will be made between participants in each of the active intervention conditions and those in the attention control condition.

Secondary efficacy outcomes (H6) will also be examined, including effects on acceptability of internet-based psychosocial interventions [16], general psychological distress using the Distress Questionnaire-5 (DQ5, [35]), suicidal ideation using the Psychiatric Symptom Frequency (PSF) scale [36]), disability/days out of role, and quality of life (EUROHIS-QOL 8; [37]).

Analysis of the relative efficacy of the *myCompass 2 + EFI* condition to the *myCompass 2* Alone condition (H4) will be conducted with respect to change over time (pre-test to post-test and pre-test to follow-up) relative to the control condition. Intention-to-treat analyses will be conducted using mixed model repeated measures analyses, conservatively estimated using unstructured covariance matrices. These models incorporate all available data, including participants with missing data points, under the missing-at-random assumption without using biased techniques such as last observation carried forward [38]. These models also account for within-individual variability in testing observed effects.

Predictors of these outcomes (uptake, adherence and efficacy; H5) will be assessed at baseline and include gender, age, cultural/linguistic background, education, self-reported history of psychological treatment and diagnosed mental illness, symptoms of depression and anxiety (PHQ-9, [33]; GAD-7, [34]), social support (Schuster Social Support Scale [39]), personality profile (Big 5 – Mini-IPIP [40]), acceptability of internet-based psychosocial programs [16], perceptions of online therapy (brief PCTQ-P, [41]), attitudes toward professional psychological treatment (ATSPPH-SF, [42 43]), and depression stigma and literacy [44].

Analyses for H5 will be published separately to the main analyses, and involve logistic regression models for uptake and negative binomial regression models for adherence (accounting for inflated zeros and skewness of module completion), accounting for intervention condition. In addition, growth mixture models will be used to model response to the intervention (efficacy), classifying participants into multiple latent classes based on their patterns of symptom change over time. Predictors of class membership will then be tested using multinomial logistic regression models to ascertain which characteristics are associated with response to the intervention, adjusting for intervention condition.

Trial delivery

The trial will be delivered using the digital infrastructure of the Black Dog Institute, Sydney, Australia. The infrastructure enables computer-generated random allocation, and automatic assessments, intervention materials and reminders to be delivered seamlessly to participants using a single login.

Data collection

Eligible participants will be asked to provide an e-mail address and complete a baseline questionnaire. Following completion of the baseline questionnaire, participants will be randomized to one of the three conditions, using computer-based randomization stratified on symptom severity (as measured by the DQ5 [35] at baseline), age, and gender (permuted block randomization, block size of 6 within each stratum) to ensure balance across conditions using a computerized randomization algorithm embedded into the trial portal. The intervention period will run for 7 weeks during which time participants will be able to access their assigned program as much or as little as they like. Participants will receive an automated weekly reminder e-mail to encourage them to engage with the active intervention website

(Conditions 1 and 2) or the attention control website (Condition 3). Assessments will occur at baseline, post-intervention, and at 6 months post-intervention. Participants will receive a reminder to complete the questionnaire if they have not done so after 1 and 2 weeks. The trial will be effectively double-blinded. Participants will be blinded to whether they are receiving the active intervention or the attention control intervention – they will only be informed that they will be randomized to receive one of three programs: (1) strategies for challenging unhelpful thoughts and behaviors, (2) education about online interventions plus program (1), or (3) general health and lifestyle information. They will not be provided with information about which of these interventions is expected to be the most effective. The statistician performing the analyses will be blinded to condition allocation. Assessments will also be blinded, as they are entirely based on self-report. Table 1 presents the measures for the trial and the assessment time points.

Table 1. Assessment time points

Construct	Measure	Screening	Baseline	Post-survey	Follow-up survey
Depression symptoms	*PHQ-9*	X		X	X
Anxiety symptoms	*GAD-7*	X		X	X
Gender	--		X		
Age	--		X		
Language spoken at home	--		X		
Education	--		X		
Employment status			X		
Region/area of residence			X		
Social support	*Schuster Social Support Scale*		X		
Personality inventory	*Big 5 (mini-IPIP)*		X		
Acceptability of internet-based psychosocial programs	*UTAU*		X	X	X
Perceptions of online therapy	*Brief PCTQ-P*		X		
Attitudes toward professional psychological treatment	*ATSPPH-SF*		X		
History of psychological treatment	*Self-report*		X		
History of diagnosed mental illness	*Self-report*		X		
Depression stigma	*DSS- Personal stigma scale*		X		
Depression literacy	*D-Lit*		X		

General psychological distress	*DQ5*	X	X	X
Suicidal ideation	*PSF*	X		X
Disability/days out of role	--	X	X	X
Quality of life	*EURO-HIS 8*	X	X	X

Measures

Demographic characteristics and history of mental illness/psychological treatment

The following demographic characteristics will be assessed: gender (male, female other), age (18-25, 26-35, 36-45, 46-55, 56-65, 66+), language spoken at home (English only, English and another language, another language only), level of education (primary school, some secondary school/year 10 equivalent, year 12, Certificate Level I-IV, Diploma/Associate degree, Bachelor degree, Graduate Diploma/Graduate Certificate, Masters degree, Doctoral degree), employment status (full-time, part-time/casual, unemployed, not working due to studying/maternity leave, retirement, etc.), and region/area of residence (metropolitan area, regional area, rural/remote area). History of mental illness and psychological treatment will be assessed by the following items developed by the researchers: "Have you ever in your life been diagnosed with any of the following disorders:" (list of 10 possible disorders provided, with an option to list an 'other' mental disorder if not on the list) and "Have you ever in your life participated in psychological treatment for any psychological problem (e.g., with a psychologist, psychiatrist, counsellor, mental health nurse, general practitioner etc.)?" (Yes/No)

Depression symptoms

Depression symptoms will be assessed using the PHQ-9 [33]. This scale consists of 9 items assessing the frequency of DSM-IV symptoms of Major Depression in the past two weeks. Items are rated on a 4-point scale ranging from *not at all* to *nearly every day*, and item scores

are summed to produce an overall severity score ranging from 0-27, with higher scores indicating higher symptom severity. The PHQ-9 has good sensitivity and specificity for detecting major depression in both clinical and general population samples and has been shown to detect change over time [45].

Anxiety symptoms

Anxiety symptoms will be measured by the GAD-7, a scale comprising seven items that correspond to DSM-IV and DSM-5 criteria for generalized anxiety disorder [34]. Items are rated on the same 4-point scale as the PHQ-9, and summed scores on the GAD-7 range from 0-21, with higher scores indicating greater symptom severity. Studies have demonstrated that the GAD-7 has good psychometric properties in general population samples, with accuracy against clinical diagnosis [45 46].

Social support

The Schuster Social Support scale will be used to measure the quality of the participants' important social relationships [39]. The scale contains 15 items in total, with three 5-item subscales assessing the extent of supportive and negative social interactions with a respondent's family, friends, and spouse. Only the family and friend subscales (10 items in total) will be used in this study. Items are rated on a 4-point scale ranging from *often* to *never*. Example items include: "[How often do your friends] make you feel cared for?" and "[How often do your family] criticize you?" This scale has shown adequate reliability in a community-based sample [39].

Personality

Personality characteristics will be assessed using the Mini-IPIP, a 20-item version of the larger International Personality Item Pool [40]. The scale contains 4 items assessing each of the Big Five personality traits: *Extraversion* (example item: "I am the life of the party"), *Agreeableness* (example item: "I sympathize with others' feelings"), *Conscientiousness* (example item: "I get chores done right away"), *Neuroticism* (example item: "I have frequent mood swings"), and *Intellect/Imagination/Openness* (example item: "I have a vivid imagination"). Respondents are asked to rate the personal accuracy of each item on a 5-point scale ranging from *very inaccurate* to *very accurate*. The scale shows acceptable internal consistency, and convergent, discriminant, and criterion-related validity [40].

Acceptability of internet-based psychosocial programs

Acceptability of internet-based programs will be assessed using items developed and/or compiled by Ebert and colleagues, based on the Unified Theory of Acceptance and Use of Technology (UTAUT) [16]. Ebert and colleagues developed four items to measure acceptance, each rated on a 5-point scale ranging from *totally disagree* to *totally agree*. An example item is: "If I was suffering from psychological strain such as enduring lowered mood, loss of interest and lowered energy, sleeping problems, rumination, loss of joy in life…I could imagine trying out an Internet-based intervention for mental health problems". Scores are summed (range = 4-20), with higher scores indicating higher acceptance. These items were demonstrated by Ebert and colleagues to have acceptable internal consistency [16]. Ebert and colleagues also developed eight further scales to measure additional constructs for facilitators and barriers of acceptance. We selected the following three scales for this study: *performance expectancy* (4 items drawn from Wilson and Lankton [47] and Schomerus and colleagues [48], example item: "Using an Internet-based training would reduce my mental health problems"), *effort expectancy* (3 items, also drawn from [47] and

[48], example item: “Using an Internet-based depression intervention would be an easy task for me”), and *concerns regarding data security* (2 items, developed by Ebert and colleagues, example item: “When participating in an online-training I would trust, that all information I disclose would be treated in strict confidence”. These items are rated on the same 5-point scale described above.

Perceptions of online therapy

Perceptions of online therapy will be assessed using 12 items from the original 39-item Perceptions of Computerized Therapy Questionnaire-Patient Version (PCTQ-P) [41]. The number of items was reduced in order to minimize respondent burden, and items were excluded on the basis of factor loadings, balanced with the need to retain sufficient variability within subscales of the measure. The measure contains five subscales designed to measure different characteristics that have been shown to influence adoption of online therapy: *relative advantage* (example item: “I like that computerized therapy is anonymous”), *compatibility* (example item: “I have a positive attitude about computerized therapy”), *complexity* (example item: “It is easy to use computerized therapy”), *observability* (example item: “I have heard of computerized therapy before now”), and *future use intentions* (example item: “I plan to use computerized therapy in the future”). Items are rated on a 7-point scale ranging *strongly agree* to *strongly disagree*. Strong reliability has been demonstrated for total and subscale scores of the overall PCTQ-P [41].

Attitudes towards professional psychological treatment

The attitudes of respondents to seeking professional psychological treatment will be measured using five items from the short form of the Attitudes Towards Seeking Professional Psychological Help scale (ATSPPH-SF [43]) with updated language and wording [42]. Based

on factor loadings from previous research conducted by the current study author on the original ATSPPH-SF scale, many items (particularly reverse-scored items) did not load very well on a single factor. Thus, for simplicity the reverse coded items were removed, with the remaining five items retained (1, 3, 5, 6, 7). This scale asks respondents to agree with statements about psychological treatment using a 4-point Likert scale (0=Disagree, 3=Agree). Scores range from 0-30, with higher scores indicating more positive attitudes towards seeking professional help. Example items include "If I was having personal or emotional problems, the first thing I would do is seek professional help", and "A person with an emotional problem is not likely to solve it alone; he or she is likely to solve it with professional help". The 10-item short-form scale has demonstrated sound psychometric properties in previous research [42 43 49].

Depression stigma

The Personal Stigma Subscale of the Depression Stigma Scale (DSS-PSS, [50]) will measure the personal stigma respondents have experienced in relation to their own attitudes towards depression. Items include "People with depression could snap out of it if they wanted", "Depression is not a real medical illness", "If I had depression, I would not tell anyone". Respondents are asked to indicate their level of agreement with each of 9 statements about depression using a 5-point Likert scale (0=strongly disagree, 4=strongly agree). Higher scores indicate higher levels of personal stigma about depression. The DSS-PSS has demonstrated good internal consistency, test-retest reliability, and convergent validity [50].

Depression literacy

The level of literacy for depression will be measured using the short form of the Depression Literacy questionnaire (D-LIT, [44]); an 11-item scale with high internal consistency and

test-retest reliability. Items ask respondents to indicate true/false/don't know in relation to statements about the nature, detection, symptoms, and treatment of depression. Example items include "People with depression often speak in a rambling and disjointed way", "Depression does not affect your memory and concentration", and "Clinical psychologists can prescribe antidepressants". Scores range from 0-11, each correct response scores 1 point, with higher scores indicating higher depression literacy [44].

General psychological distress

The Distress Questionnaire-5 (DQ5, [35]) will measure general psychological distress. Five items ask respondents to indicate the frequency with which they have experienced a range of distressing situations, thoughts, and feelings over the previous 30 days using a 5-point Likert scale (1=Never, 2=Rarely, 3=Sometimes, 4=Often, 5=Always). Example items include: "My worries overwhelmed me". "I felt hopeless", and "I found social situations upsetting" [35]. Total scores range from 5-25, with higher scores indicating more severe levels of psychological distress. The DQ5 has demonstrated high internal consistency and external validity, low response burden, and high sensitivity and specificity for identifying caseness for psychiatric disorder using a cutoff of 11 [35 51].

Suicidal ideation

Suicidal ideation will be measured using the five suicide-specific items from the Psychiatric Symptom Frequency Scale (PSF [36]). These items measure both suicidal ideation and suicidal behavior in the previous 12 months, using items covering thoughts, plans, and attempts in relation to suicide. Participants indicate yes/no to indicate whether any of these aspects of suicide ideation or behavior have been present in the previous 6 months, with

higher scores indicating higher severity of suicidal ideation and actions. The suicide items of the PSF have demonstrated high internal reliability and validity [36].

Disability/days out of role

Disability and days out of role will be assessed by two open-ended questions, the first assessing days out of role: “In the last 30 days, how many days were you totally unable to work, study, or manage your day-to-day activities because of emotional problems (such as feeling depressed or anxious)?” and the second assessing disability “Aside from those days, in the last 30 days, how many days were you able to work, study, or manage your day-to-day activities but had to cut back on what you did or did not get as much done as usual because of emotional problems?”.

Quality of life

Quality of life will be assessed using the EUROHIS-QOL 8-item index (EUROHIS-8; [37]). The EUROHIS-8 is composed of eight items designed to measure the psychological, physical, social, and environmental aspects of quality of life. Example items include: “How would you rate your quality of life?” and “How satisfied are you with your ability to perform your daily activities?” Responses are scored on a 5-point scale, with response categories ranging from *very dissatisfied* to *very satisfied*, *very poor* to *very good*, and *not at all* to *completely*. Item responses are summed, producing a total score ranging from 0 to 32, with higher scores indicating higher quality of life. Studies have demonstrated sound internal consistency for the EUROHIS-8 in multiple samples [37 52].

Power and recruitment

For primary hypothesis H1, to detect increases in uptake from 50% to 65% (a conservative baseline based on previous research [53]), with conservative increase based on previous work by Ebert et al. [16] with 90% power requires a sample of 231 per condition (with $\alpha = .05$). To detect increases in adherence (H2), assuming a small effect of $f = 0.19$ (the estimated median effect from previous research [53]) between active conditions requires a sample of 111 per condition.

For secondary hypotheses (H3-4), a sample of 110 per condition is required to find a small effect size of $f = 0.18$ (based on a previous study by Proudfoot et al. [29]) between active conditions relative to control over the three assessment time points (baseline, post, and 6 month follow-up) with 90% power ($\alpha = .05$, $r = 0.5$ between repeated measures). Allowing for up to 30% attrition from post-test assessments indicates a target sample of 158 per condition will be required. Based on the largest estimate of N required ($n = 231$ per condition), we aim to recruit a sample of $N = 693$.

Incentives

Small incentives in the form of online (e-) gift cards will be given to all participants for completion of each assessment conducted online, irrespective of condition and irrespective of their level of engagement with the intervention. One e-gift card ($15) will be given on completion of the post-test survey and another ($25) at completion of the follow-up survey. These incentives are compensation for the participant's time to fill in each survey, and will assist in maximizing the data available to test efficacy outcomes. Only participants who complete the survey at each assessment will receive the e-gift card. Participants will be emailed an e-gift card following the completion of each survey.

Quality assurance and monitoring

The project manager will work closely and have regular contact with other members of the research team to monitor the progress of the project. The project manager will also have regular contact with the IT staff at the Black Dog Institute to ensure that the online trial delivery platform is performing as expected. Screening and program uptake will be monitored closely.

Ethical concerns

Ethical concerns relevant to the present study relate predominantly to the use of internet-based interventions. These include the online storage of data, managing privacy of personal information, obtaining consent to participate, providing opportunities to exit the study, and ensuring any distressed participants in the study are provided with appropriate assistance. These issues are addressed below.

Data storage and privacy

We will ensure the privacy of online data through password protected computers, and a secure portal for online data collection and delivery of the EFI and the E-MH program (*myCompass 2*). Participant survey data will be assigned an identification code, and stored separately from personal information (e-mail addresses). Informed consent will be provided through an information web page. The online consent process will require participants to answer a question indicating that they wish to consent to participate in the study. Participants who do not consent can close the webpage and will not proceed any further. Participants who complete the screening measures and are not eligible to proceed will be provided with a webpage thanking them for their interest in the study and offering help-seeking information.

Participant withdrawal and distress

Participants will be informed at each assessment point that they can withdraw from the study at any time. If a participant requests to have their data removed from the study, the principal investigator will action this request. Any participants who contact the research team in distress will be followed-up by a registered psychologist, who will provide support and referral to other services as necessary, including general practitioners, and crisis support services (e.g., Lifeline). Participants will also be encouraged throughout their participation in the project to seek help if they are experiencing any distress, with contact information for appropriate resources provided repeatedly. Participants who endorse anything other than "not at all" to the question "*Thoughts that you would be better off dead, or of hurting yourself*" on the PHQ-9, or endorse any item on the PSF will be provided with referral information to contact Australian telephone crisis services (i.e., Lifeline, and the Suicide Call Back Service).

Informed consent

All participants will be provided with a participant information sheet they can print out or save when invited to take part in the study. Informed consent will be provided via a web page. The online consent process will require participants to answer a question indicating that they have read and understood the participant information sheet and provide consent to participate in the study.

Data management

All data files and databases will be stored for at least 5 years from the time of all publications. The data will be stored on a secure server with access restricted to authorized

personnel (the project team and IT support staff responsible for managing the server). Email addresses and data will be stored separately.

Dissemination

Results of the research will be submitted for publication in relevant academic journals and mental health conferences. Results will also be summarized on the lead researcher's university website. A plain language summary will be provided to participants who request additional information.

Discussion

The current protocol describes a randomized controlled trial of an Engagement-Facilitation Intervention designed to increase uptake and adherence to an online intervention. There are many existing online psychosocial interventions that are effective for reducing symptoms of mental and physical health problems. However, their impact is stymied by poor engagement: uptake is low and adherence is suboptimal. If the current brief EFI is shown to increase uptake and adherence, the resultant elevated rates of community members benefiting from use of a broad spectrum of evidence-based treatments may have a considerable effect on the health of the population. The EFI model is readily transferable to a range of health and social programs, with potential for significant impact in increasing the dissemination of such interventions.

Limitations and risks

There are several potential limitations or risks associated with the current study. Firstly, there is the potential for not meeting recruitment targets as stated and the trial remaining underpowered. However, as discussed, this scenario is unlikely given previous studies we

have conducted using similar populations and recruitment methods. In addition, the use of incentives for assessments and the availability of usage data for all participants will further mitigate against this possibility. A further limitation is that we are not prescribing the pace for the completion of the *myCompass 2* program; therefore participants may complete any or all parts of the program during a less than apt timeframe (e.g., all during the first or last week of the study). However, this is also a strength of the current study as it enables the study to maintain ecological validity and will provide valuable data on how the intervention is used in a real world setting. Assumptions around adherence to the intervention may be inaccurate. However, to account for a broad range of adherence levels, the power calculations assume 50% adherence in the control group – lower or higher rates of adherence would increase power to detect a 15% difference in adherence for the intervention groups. Finally, the elements of the EFI were selected through a systematic process that accounted for existing empirical findings around uptake and adherence, along with qualitative data collected from focus groups with individuals with lived experience of anxiety or depression. Nevertheless, other elements might be more persuasive in changing usage of such interventions, and the design of the EFI may also influence its impact.

Conclusion

This research has potential to have a significant impact on uptake and adherence, not only for online mental health programs, but psychosocial interventions more broadly. In particular, if the EFI is shown to be effective in increasing uptake of the intervention, potential implications at a population level are considerable. For example, if broadly implemented, a 15% increase in the number of Australians using evidence-based interventions may result in up to 600,000 additional individuals benefiting from e-mental health programs for anxiety or depression each year. The potential in countries with lower uptake of these interventions is

even greater. This model of engagement, if effective, is readily transferrable to other types of interventions and could be adopted immediately for a broad range of online and face-to-face psychological and social programs. There are effective psychosocial programs to reduce or manage the symptoms of an increasing number of mental and physical health problems. Even a small increase in the uptake of these programs across the community could potentially have an immense public health impact, with more individuals accessing evidence-based treatments and accessing more efficient tools to manage their symptoms.

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Contributions

PJB led the design of the study and contributed to the drafting of the manuscript. AG assisted with drafting the manuscript. All authors approved of the final manuscript.

Conflicts of Interest

None declared.

Abbreviations

AFI – Acceptance-Facilitation Intervention

ANU – The Australian National University

CBT – Cognitive Behavioural Therapy

EFI – Engagement Facilitation Intervention

E-MH program – e-mental health program

iCBT – internet-based Cognitive Behavioural Therapy

RCT – Randomized controlled trial

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