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Efficacy of a transdiagnostic, video-based online program for reducing depression, anxiety, and suicidal ideation in adults: Protocol for a randomised controlled trial

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ABSTRACT

Background: Transdiagnostic online interventions have the potential to overcome help seeking barriers, address symptom comorbidity, and increase accessibility to evidence-based treatments. However, there is currently a lack of high quality studies examining brief transdiagnostic interventions, as well as research examining optimal methods for screening and providing members of the community with access to these interventions. This randomised controlled trial will compare a brief, video-based transdiagnostic online intervention (*FitMindKit)* to an attention matched control condition (*HealthWatch)*.

Aims: The aims of the study are to (1) examine the efficacy of *FitMindKit* in reducing depression symptoms, anxiety symptoms, suicidal ideation, and disability relative to *HealthWatch* and (2) compare uptake of the program via the Internet with uptake via general practices and pharmacies (methods used in a parallel implementation study).

Methods: A two-arm randomised controlled trial will be conducted with adults residing in the Australian Capital Territory, Australia. Participants will be recruited online via social media advertisements, screened, and randomised to receive one of two four-week programs: *FitMindKit* (12-module psychotherapeutic intervention) or *HealthWatch* (12-module program providing general health information). Participants will be assessed at baseline and 4 weeks post-baseline.

Results: Findings from the trial will provide important knowledge regarding the utility and optimal implementation of brief transdiagnostic interventions for depression and anxiety in the community.

Conclusions: This trial has strong potential to increase access to evidence-based treatments in the community by directly addressing several factors that impede this access, such as symptom comorbidity and a lack of knowledge regarding optimal implementation pathways.

Trial registration: This trial is registered with the Australian New Zealand Clinical Trials Registry (number ACTRN12618001688279).

1. Introduction

Common mental disorders such as depression and anxiety account for significant disease and disability burden worldwide [1]. Moreover, these disorders have significant personal, interpersonal, social, educational, and vocational impacts on the individuals who experience them [2–4]. Help seeking for mental health problems remains a challenge, with stigma, cost, lack of knowledge, and low perceived need for treatment commonly cited as barriers to accessing professional help [5–7]. Internet-based, self-guided mental health interventions are capable of circumventing many barriers to help seeking and have demonstrated efficacy in preventing and treating common mental disorders [8–10].

An additional complexity that can impede the effective treatment of mental health problems is the high rate of comorbidity between depression, anxiety, and other mental health problems [11]. Comorbidity has important implications for treatment as it is often associated with increased severity and chronicity of symptoms [12]. Common approaches for managing comorbidity include transdiagnostic treatment approaches and individually tailored treatments that target multiple

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disorders [13]. Transdiagnostic treatments are not disorder-specific and provide therapeutic content capable of targeting the common mechanisms that underlie multiple mental health problems (i.e., negative thinking patterns, hyperarousal, and avoidance). Thus, users of transdiagnostic treatments typically receive the same therapeutic content regardless of their specific symptoms or disorder. Conversely, tailored treatment approaches address the symptoms of multiple disorders by providing different combinations of therapeutic content based on an individual's symptom profile. Online programs are highly suited to address comorbidity via these two approaches, and recent systematic reviews suggest that both transdiagnostic and tailored e-mental health programs are effective [14,15]. However, these reviews also highlighted the need for randomised controlled trials (RCTs) comparing transdiagnostic interventions with a robust attention control condition. Many of the studies completed to date have been pilot or feasibility studies, open trials, or have employed wait-list control conditions that have not allowed intervention and control groups to be compared at follow-up [14,15].

Our research group developed *FitMindKit* [16], a transdiagnostic online program that delivers cognitive behavioural therapy and other techniques via a series of brief videos and self-directed exercises. The program is designed to be transdiagnostic, delivering therapeutic content targeting issues that are common to multiple mental disorders, such as cognitive restructuring, problem solving skills, and relaxation strategies. However, given the modularised format of *FitMindKit*, delivery of the program is also capable of being tailored to an individual's unique presentation. *FitMindKit* has been tested previously in an RCT comparing tailored and static versions of the program [16]. In this trial, there was no effect found for tailoring compared to the static version of the program, on either effectiveness or adherence. In the current RCT, we will test a simplified static version of the program, with six fewer modules (12) than in the previous trial (18), against an attention-matched control condition. This trial will be conducted in parallel with a broader implementation study examining the effectiveness of general practice and pharmacy settings for screening individuals in the community and offering them access to *FitMindKit*. Therefore, the aim of the current trial is to examine uptake of the program via an online recruitment method compared with recruitment via pharmacies and general practice settings, and to test the effectiveness of *FitMindKit* in reducing depression symptoms, anxiety symptoms, suicidal ideation, and disability.

2. Materials and methods

2.1. Study design

A two-arm RCT will be conducted with adults aged 18 years and over residing in the Australian Capital Territory (ACT), Australia. The RCT will compare the effectiveness of an online mental health program (*FitMindKit)* to a control program targeting general health (*HealthWatch)*. The RCT will be conducted in parallel with a broader e-mental health implementation trial led by the research team in the ACT, and thus the same geographical area as the implementation trial was chosen to recruit participants for the RCT in order to compare samples and study outcomes.

2.2. Participants

Fig. 1 depicts the trial flow. Participants will be recruited online via social media (paid Facebook advertisements). Facebook advertisements will target adults living in the ACT aged 18 years and older, and example text for the advertisements will include: "*Want to learn more about your mental health and wellbeing? Complete a brief survey and 4 week online program now. Participants needed for a mental health study*". A series of advertisements will be developed and used interchangeably using a range of images designed to appeal to different demographic groups. Participants will click on a link in the Facebook advertisement directing them to a webpage containing study information and questions to obtain their consent to participate.

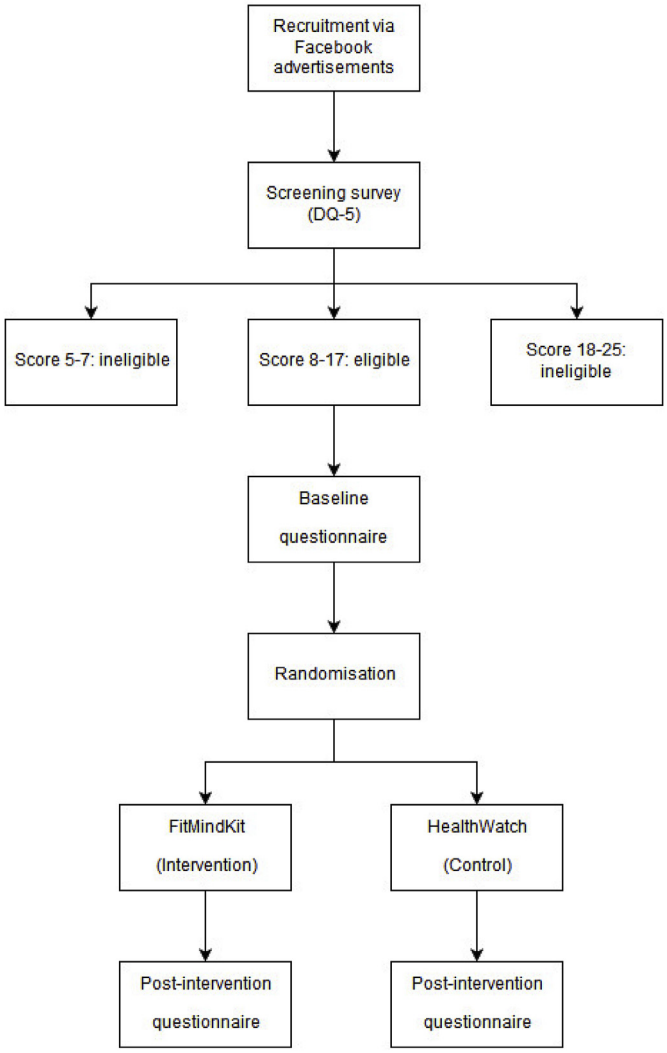

Fig. 1. Trial flow.

2.3. Eligibility criteria

Participants will be assessed for eligibility based on their age and current level of psychological distress. Participants must be 18 years or older to be eligible for the trial. Psychological distress will be assessed using the Distress Questionnaire-5 (DQ5) [17], a brief screening measure that contains five items describing symptoms of common mental disorders. Participants will be asked to endorse the frequency of each item over the last 30 days on a five-point scale ranging from *never* to *always*. Scores range from 5 to 25, with scores of 5–7 indicating no/low psychological distress, 8 to 17 indicating a moderate level of psychological distress/risk of a mental disorder, and 18 to 25 indicating high risk/probable clinical symptoms of a mental disorder. The DQ5 has been shown to be highly accurate in identifying individuals who meet clinical criteria for a common mental disorder, with strong internal consistency and a unidimensional structure [17,18]. Those aged 18 years and older and who score in the moderate risk category (8–17) on the DQ5 will be eligible for the trial, as an online mental health program is likely to be the most suitable and appropriate for this group. Those in the low risk category will be provided with feedback to continue to monitor their psychological wellbeing and with help resources

to access if their symptoms change. Those in the high risk category will be provided with feedback strongly encouraging them to seek help from a health professional and contact details for face-to-face, telephone-based, and online mental health resources and services.

2.4. Procedure

Following screening, eligible participants will be invited to access the online trial portal containing trial assessments and the intervention and control programs. Participants will be required to create an account in the portal using an e-mail address and password. They will then complete the baseline questionnaire and will be subsequently randomised to the intervention or control condition using an automatic computer-generated sequence utilising a block size of six. Trial staff will not be involved in the randomisation of participants and will be blinded to the randomisation schedule. Following randomisation, participants will be informed of their allocated condition, provided with access to their assigned program, and instructed to complete the program modules at their own pace over a 4-week period. Participants will also be sent an e-mail containing details of their allocated condition and a link to the portal, as well as a weekly e-mail reminding them to engage with their allocated program. Following the 4-week period, participants will be sent an e-mail inviting them to complete the post-intervention survey. Participants will receive two reminder e-mails to complete the post-intervention survey if they have not done so after one and two weeks.

2.5. Intervention and control conditions

Participants will be blind to whether they have been randomised to the active intervention *(FitMindKit)* or the attention control program *(HealthWatch*). They will be informed that they will be randomised to one of two online programs, and will not be provided with information about which of these programs is expected to be more effective. The statistician conducting analyses of primary outcomes will also be blinded to condition allocation.

2.6. Intervention (FitMindKit)

FitMindKit consists of 18 modules including ten core modules containing therapeutic techniques based on cognitive behavioural therapy and other approaches, and an additional eight modules containing content specifically targeting anxiety, mood, alcohol/substance use, and suicidality. Twelve of the 18 *FitMindKit* modules were selected to comprise the intervention in the current trial (the 12 modules that were chosen were transdiagnostic and based on CBT principles). These include eight of the ten core modules (psychoeducation, getting help and support, cognitive reframing, problem solving, mindfulness, managing relationships, exercise and diet, and sleep hygiene), two modules targeting mood (behavioural activation and reducing rumination), one module targeting anxiety (exposure), and one module targeting suicidality (distress tolerance). Each *FitMindKit* module consists of a brief video (with an accompanying transcript available) followed by an exercise to practice the therapeutic technique described in the video. Users are introduced through the videos to a series of fictional characters who introduce the concepts and share their personal experience of one or more mental health problems (see Fig. 2). The characters and background images were designed by a graphic designer and animated with Microsoft PowerPoint.

Participants allocated to the *FitMindKit* condition will have access to the 12 modules over a period of 4 weeks and the modules are entirely self-guided. Each module takes approximately 10 min to complete (the videos range from 2 to 6 min in length). Participants will be directed to complete the module on psychoeducation first, and will then be free to choose when and in what order they complete the remaining modules during the four week period. Participants will receive one e-mail per week during the intervention period reminding them to engage with the program.

Fig. 2. Screenshot of *FitMindKit* characters.

2.7. Control (HealthWatch)

The *HealthWatch* program includes 12 modules containing general health information not specific to mental health, with the length of each module designed to be approximately equivalent to the length of a *FitMindKit* module. The modules are text-based and contain information on the following topics: bone health, sun exposure, food poisoning, dietary supplements, kidney health, microbes, household burns, respiratory viruses, heart health, allergens, posture, and pancreas health. Participants allocated to the *HealthWatch* condition will have access to these modules over a 4-week period and can complete them in any order they choose. Participants will also receive a weekly e-mail reminding them to login and access the program. The control condition is not designed to be therapeutic, but rather to match for the attention that participants receive in the active intervention condition. Participants will be informed prior to providing consent that they will be randomised to one of two programs, and that one targets mental health and the other targets general health. The HealthWatch program has previously been shown to have comparable or better adherence than active treatment conditions [16,19].

2.8. Measures

Participants will complete a baseline assessment prior to randomisation and intervention allocation, and a post-intervention assessment following the 4-week intervention period. Assessments include: demographic characteristics (administered at baseline only), symptoms of depression, anxiety, panic, and social anxiety disorder, as well as suicidal ideation, disability (days out of role), and program satisfaction (administered post-intervention only).

The following demographic characteristics will be assessed: *gender* (male, female, other), *age* (18–25, 26–35, 36–45, 46–55, 56–65, 66+), *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 *language spoken at home* (English only, English and another language, another language only).

The PHQ-9 will be used to assess the frequency of DSM-IV symptoms of Major Depression [20]. This scale consists of nine items rated on a four-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 to 27, with higher scores indicating higher symptom severity. The PHQ-9 has sound sensitivity and specificity for detecting major depression in both clinical and general population samples and has been shown to

detect change over time [21].

The GAD-7 will be used to assess symptoms of Generalised Anxiety Disorder according to DSM-IV and DSM-5 diagnostic criteria [22]. The seven items from the scale are rated on the same four-point scale as the PHQ-9, and summed scores on the GAD-7 range from 0 to 21, with higher scores indicating greater symptom severity. Studies have demonstrated that the GAD-7 has good psychometric properties in general population samples [21,23].

Symptoms of panic and social anxiety disorders will be measured by the four-item Panic Disorder Screener and the four-item Social Anxiety Disorder Screener, respectively [24–26]. These scales have been developed and validated using Australian community-based samples, and they assess the frequency of panic symptoms (e.g., "I had a sudden unexpected period of intense fear, anxiety or discomfort") and social anxiety symptoms (e.g., "I felt nervous during social situations") in the past 30 days. Items are rated on a five-point scale ranging from *never* to *always*. Both screeners have demonstrated good convergent and divergent validity relative to clinical criteria, with strong internal consistency [24].

Suicidal ideation will be measured using the Suicidal Ideation Attributes Scale (SIDAS) [27]. The SIDAS contains five items assessing frequency of suicidal ideation (e.g. "In the past month, how often have you had thoughts about suicide?"), controllability of suicidal thoughts (e.g. "In the past month, how much control have you had over these thoughts?"), closeness to suicide attempt (e.g. "In the past month, how close have you come to making a suicide attempt?"), distress associated with suicidal thoughts (e.g. "In the past month, to what extent have you felt tormented by thoughts about suicide?"), and functioning (e.g. "In the past month, how much have thoughts about suicide interfered with your ability to carry out daily activities, such as work, household tasks or social activities?"). Items are rated on a 10-point scale, and scores range from 0 to 50, with scores over 21 indicating high risk of suicidal behaviour. The SIDAS has demonstrated high internal consistency and good convergent validity [27].

Two items will be used to measure the extent of disability and disruption felt by participants due to mental health problems [28]. Participants will be asked to indicate: "How many days out of the past 30 were you totally unable to work or carry out your normal activities due to mental health problems?" and "How many days out of the last 30 were you able to work or carry out your normal activities but had to cut back on what you did or did not get as much done as usual due to mental health problems?". These items have been used previously in a large, community-based epidemiological study of mental disorders in the United States [28,29].

Satisfaction will be assessed using a seven-item scale assessing how much the participant: (1) enjoyed the program, (2) found it helpful, (3) understood the content, (4) found it interesting, (5) would use it in the future, (6) would recommend it to others, and (7) learnt new skills from the program [16]. Each item is rated on a 10-point scale ranging from *completely disagree* (1) to *completely agree* (10).

2.9. Ethics approval

The ethical aspects of this research have been approved by The Australian National University Human Research Ethics Committee (ANU HREC protocol number 2017/911).

2.10. Hypotheses

It is hypothesised that: i) the active intervention condition (*FitMindKit)* will be associated with significant reductions in depression symptoms, anxiety symptoms, suicidal ideation, and days out of role, relative to the attention control condition; and ii) the online recruitment method utilised in the current trial will be associated with greater uptake (number of participants screened and enrolled in the online programs) compared with recruitment via general practices and pharmacies.

2.11. Data analysis

The primary outcome (reduction in PHQ-9 depression symptoms) and secondary outcomes (reductions in symptoms of generalised anxiety, panic, and social anxiety, reductions in suicidal ideation and days out of role) will be assessed using mixed model repeated measures ANOVA (MMRM [30]) to account for missing data and to include all available data for participants in the trial. This approach provides an intention-to-treat analysis to compare the intervention and control groups, yielding unbiased estimates of intervention effects. An unstructured variance-covariance matrix will be assumed and degrees of freedom (df) estimated with Satterthwaite's correction. In MMRM, the critical test of the effectiveness of the intervention is the two-way interaction between time and condition. Three-way interaction effects between time, condition, and moderator will be used to examine whether the intervention was more effective in specific groups on the basis of factors such as gender, age group or severity of symptoms.

2.12. Sample size and power analysis

The target sample size is 750, based on detecting a moderate effect size of Cohen's d = 0.3 at post-test with 90% power, assuming up to 40% attrition from the trial. A larger sample would enable examination of moderation effects and greater power to detect changes in clinical cut-offs for less common mental disorders such as panic disorder. We anticipated that the study would require 19,000 individuals to click on the screening survey link to reach the recruitment target. This estimate was based on the assumption that 40% of all respondents to the screening survey would meet criteria for the study and 75% of these would consent to participate in the trial based on previous studies [19,31]. In addition, based on similar recruitment methodology [19], it was assumed that 90% of individuals who clicked on the screening survey link would not proceed to complete the screening survey.

3. Discussion

The high rate of comorbidity between common mental disorders represents a significant challenge for help seeking and treatment. Internet-based mental health interventions are ideally suited to address comorbidity, but few studies to date have employed rigorous methods or examined these interventions against robust comparators. Additionally, the potential public health impact of online interventions is limited without knowledge regarding the optimal pathways for screening and providing the community with access to these programs. This trial investigates the efficacy of a brief, transdiagnostic online mental health program relative to a robust, attention matched control condition, and examines program uptake and adherence in a community-based sample recruited online.

3.1. Limitations and risks

Potential limitations and risks associated with the trial include difficulties meeting participant recruitment targets, the potential for low rates of engagement with the intervention, and generalisability of the findings given the restricted geographical area targeted for recruitment. The research team has successfully recruited large samples using similar online recruitment methods with similar populations in previous studies [16 19]. To foster engagement, *FitMindKit* has been designed to be as brief as possible in order to minimise burden on participants, while still providing enough therapeutic dosage to create symptom change. Weekly reminder e-mails are also designed to encourage ongoing use of the intervention. Finally, while it is acknowledged that participants recruited from the ACT may not be broadly representative of the entire Australian population or of other populations, this recruitment strategy

enables important and novel comparisons to be made between different implementation pathways (online vs. general practice vs. pharmacy) for online mental health programs.

4. Conclusion

This trial will provide important knowledge regarding the utility of a brief, transdiagnostic online intervention in reducing common mental health problems among members of the community. Averting the burden associated with depression and anxiety disorders is an important public health priority, and interventions such as *FitMindKit* have the potential to be implemented on a large scale, at low cost, and with low burden on the user. Moreover, determining optimal pathways for implementing these interventions is critical in combatting the substantial barriers faced by the field in translating research evidence into practice. Translational research that simultaneously examines uptake and efficacy using robust, yet ecologically valid methods has high potential to provide greater numbers of people in the community with access to much-needed, evidence-based interventions.

Contributions

PJB and ALC designed the study and obtained the project funding, LF drafted the manuscript, AG assisted with drafting the manuscript. All authors approved the final manuscript.

Conflicts of interest

None declared.

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