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Three-arm randomised controlled trial of an m-health app and digital engagement strategy for improving treatment adherence and reducing suicidal ideation in young people: study protocol

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ABSTRACT

Introduction Youth suicidal ideation and behaviour is concerning due to its widespread prevalence, morbidity and potentially fatal consequences. Digital mental health interventions have been found to improve access to low-cost and high-quality support for a range of mental health issues, yet there are few digital interventions available for suicide prevention in young people. In addition, no studies have examined how digital engagement strategies may impact the engagement and efficacy of digital interventions in suicide prevention. The current protocol describes a three-arm parallel randomised controlled trial. A therapeutic smartphone application ('LifeBuoy'; intervention condition) will be tested against a condition that consists of the LifeBuoy application plus access to a digital engagement strategy ('LifeBuoy+engagement'; intervention condition) to determine whether the addition of the digital strategy improves app engagement metrics. To establish the efficacy of the LifeBuoy application, both of these intervention conditions will be tested against an attention-matched control condition (a placebo app).

Methods and analysis 669 young Australians aged 17–24 years who have experienced suicidal ideation in the past 30 days will be recruited by Facebook advertisement. The primary outcomes will be suicidal ideation severity and level of app engagement. Primary analyses will use an intention-to-treat approach and compare changes from baseline to 30-day, 60-day and 120-day follow-up time points relative to the control group using mixed-effect modelling. A subset of participants in the intervention groups will be interviewed on their experience with the app and engagement strategy. Qualitative data will be analysed using an inductive approach, independent of a theoretical confirmative method to identify the group themes.

Ethics and dissemination The study has been approved by the University of New South Wales Human Research Ethics Committee (HC210400). The results of the trial will be disseminated via peer-reviewed publications in scientific journals and conferences.

Trial registration number ACTRN12621001247864.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Codesign of the therapeutic smartphone application and engagement strategy.
⇒ Use of mixed methods to test for efficacy as well as exploration of qualitative insights about what components of the strategies worked for whom under what conditions.
⇒ The engagement strategy will be public, lending to possible contamination if participants in another condition inadvertently access this.
⇒ The placebo app contains a mood tracker, distraction activities and safety plan for suicidal crisis—although this allows for more convincing participant-blinding and trial safety.

INTRODUCTION

Suicidal ideation is relatively common among young people in the general population, with 12-month prevalence estimates ranging between 11.7% and 26.0% in those aged 18 or younger.[1 2] Over one-third of young people who experience suicidal ideation are estimated to plan for suicide, and of those, 60% will go onto attempt suicide.[3] In Australia, suicide is the leading cause of death among individuals aged 15–24 years.[4]

High suicide rates among young people are exacerbated by their reluctance to seek help for psychological distress and suicidal ideation. A recent review[5] reported that among 12 006 individuals with past-year suicide ideation, plans and/or attempts, less than 30% sought help from mental health services. Lower rates of help seeking were associated with being younger (specifically aged 18 years or less), being male and being of a cultural minority.[5 6] In addition, face-to

face mental health treatment services are associated with many structural (cost, accessibility, availability) and attitudinal barriers (eg, stigma) that prevent most young Australians from accessing them.[7]

It is now well established that digital mental health interventions (DMHIs; that is, treatment delivered using web-based or smartphone-based platforms) have the potential to improve access to low-cost, high-quality, high-fidelity support for a range of mental health issues, thereby addressing gaps observed in current population and health system approaches.[8] While recent meta-analytic evidence supports the effectiveness of self-guided DHMIs in mitigating suicidal ideation,[9] these solutions are rarely made widely available in communities nor offered via health systems to those in need. There are significant issues that must be addressed if we are to realise the potential of DHMIs as part of suicide prevention efforts.

At present, few DHMIs targeting suicidal ideation have been developed with or for young people and rigorously tested in scientific trials to establish safety, efficacy and acceptability. While many DMHIs currently include elements of best practice, very few provide comprehensive evidence-based care with some providing potentially harmful content for individuals at risk for suicide.[10] Of additional concern is meta-analytic evidence that indicates that engagement with digital interventions is generally poor, with over 75% of users failing to complete these interventions.[11 12] Low engagement—defined as suboptimal levels of user access and/or adherence to an intervention[13]—has been identified as one of the main reasons why the potential benefits of these interventions remain unrealised in the real world[14] with emerging evidence of the potential effect of engagement on outcomes.[15 16]

To date, engagement has been measured using a wide variety of indicators that extend beyond uptake, adherence or retention rates. These indicators are generally associated with the extent of intervention use, including: (1) the number of completed modules or activities, (2) number of features accessed and (3) number and frequency of log-ins or page views.[17] Evidence of the effectiveness of engagement strategies in the context of digital interventions is rare. To date, only one systematic review[17] has investigated the effectiveness of technology-based strategies in promoting user engagement with digital interventions. The review found that technology-based strategies—mainly email reminders, text message or telephone calls—showed modest effects in promoting engagement compared with no strategy. However, only 8 of the 14 digital interventions discussed in the review were therapeutic in nature, and many of these studies comprised small sample sizes and varied greatly in the methods employed between studies.

There is a compelling need for the development and testing of effective strategies for enhancing user engagement with DHMIs. The current study has been designed to overcome challenges in the availability of effective co-designed DHMIs for young people specifically for suicidal ideation and to address gaps in our understanding of how to encourage young people to engage with them for optimised therapeutic benefit.

AIMS

Primary aims

Efficacy of the Lifebuoy app

To evaluate whether the LifeBuoy therapeutic smartphone application leads to superior reductions in suicidal ideation severity at 30-day, 60-day and 120-day post-baseline among young people relative to a control (non-therapeutic, placebo) app in a randomised trial design.

Efficacy of a digital engagement strategy

Participants will be randomised to either the LifeBuoy-only or LifeBuoy+engagement conditions to test whether a digital engagement strategy leads to higher levels of app engagement (measured by the number of modules completed, and the number and frequency of application logins) at 30-day, 60-day and 120-day post-baseline among participants with access to the LifeBuoy smartphone application.

Secondary aims

1. To determine whether the LifeBuoy app reduces incidents of suicide attempt and non-suicidal self-injury relative to the placebo attention control condition at 30-days, 60-days and 120-days.
2. To assess whether the LifeBuoy app reduces depression and anxiety symptoms relative to the placebo attention control condition at 30-days, 60-days and 120-days.
3. To examine whether the LifeBuoy app +engagement condition reduces suicidal ideation relative to the LifeBuoy-only condition at 30-days, 60-days and 120-days.

Study design

This SPIRIT-compliant protocol describes the methodology of a parallel group, three-arm randomised controlled trial design, which will employ an intervention condition ('Lifebuoy-only'), an intervention +engagement strategy condition (Lifebuoy +engagement') and a matched attentional control condition ('control'). Participants will be assessed at four time points: day 0 (baseline), day 30, day 60 and day 120.

The primary endpoint is change in suicidal ideation at 30-days relative to baseline, measured using the Suicidal Ideation Attributes Scale (SIDAS).[18] The secondary endpoint is engagement with the LifeBuoy app across time—defined as the number of modules completed and number and frequency of app logins—by participants at 30-days, 60-days and 120-days. Participant module access and module completion data will be automatically collected via the LifeBuoy app.

Setting

This is an online trial, which aims to recruit a national sample of 669 participants via social media advertisements. Trial management will take place at the Black Dog

Institute (BDI), a translational research institute located in Sydney, Australia that is affiliated with the University of New South Wales (UNSW).

Participants

Young Australians aged 17–24 years who have experienced suicidal ideation in the past 12 months will be eligible to participate. Study inclusion criteria also require that participants be living in Australia at the time of trial registration, fluent in English and own and/or have unlimited access to a smartphone (minimum iOS-V.13 and Android-V.7 versions required to run the LifeBuoy app). Individuals will be excluded from participating in the study if they have been diagnosed with psychosis or a bipolar disorder in the past 30-days because of increased risk of distress in this group.

Research team roles and responsibilities

Several committees have been established to support the overall trial governance. The Steering Committee comprises the trial lead and principal investigator (MT), the trial colead and investigator/trial manager (LM) and the coinvestigators (QW, JH, DZQG, HC and SH). This group will meet regularly and is responsible for guiding the overall trial design, intellectual contribution to the scientific quality and strategy, oversight of trial progress and compliance with good clinical research practice. The day-to-day trial leadership team will meet fortnightly (MT, LM, DZQG) and lead the operational aspects of the trial, including management of personnel responsible for the Research Register, data management and data privacy and security. A Data and Safety Monitoring Board (DSMB) has also been established, comprising three independent individuals with expertise in clinical trials, statistics and suicidality in young people. This board will meet regularly to monitor the safety and reporting of the trial.

Patient and public involvement

Public involvement in this study has been achieved through several processes. The app was initially developed using a codesign approach with young people who have a lived experience (LE) of suicide (defined as 'having experienced suicidal thoughts, survived a suicide attempt, cared for someone through suicidal crisis or been bereaved by suicide'),[19] with their perspective gathered via online surveys and focus groups. The app was then modified for the current trial, and the engagement strategy was developed, using the same codesign approach, with data collected from online survey, qualitative interview and further focus groups. The codesign of the LifeBuoy app and modifications incorporated the end user's perspectives, their priorities, experiences and preferences. An LE youth advisory panel of three members was formed 18 months prior to trial commencement. This advisory panel has been involved in refining modifications to the LifeBuoy app and engagement strategy, contributing to the engagement strategy by writing blogs from an LE perspective, and in dissemination planning for project outcomes (ie, panel members will provide oversight of study results that will be sent to participants and will be invited to coauthor manuscripts and to copresent findings at academic conferences).

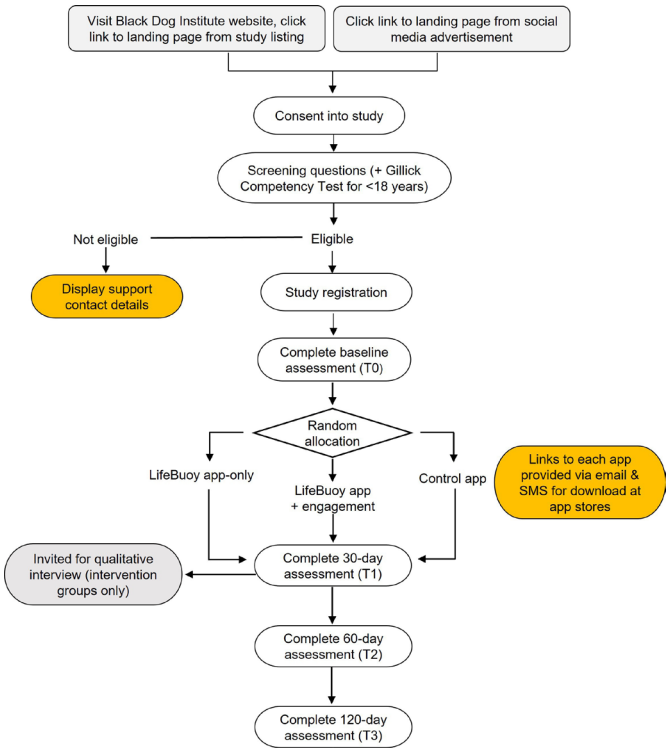

Figure 1 Study process flow.

Recruitment and procedure

A flowchart describing how an individual participant will progress through the phases of the research process is outlined in figure 1. Researchers will not have direct contact with potential participants; recruitment, consent, screening, registration and questionnaires are all scheduled and completed online.

Targeted social media advertisements will be run on BDI Facebook page in 2-week blocks, with 2-week between, until the recruitment target is met. The following parameters will be used for the Facebook advertisements for the purposes of maximising visibility to relevant users: men/women, aged 17–24 years, Australia, Interests>Additional interests, National Suicide Prevention Lifeline Suicide prevention, Beyondblue, Headspace, Lifeline (crisis support service), R U OK Day, SANE (charity).

Potential participants can indicate their interest in participating by clicking on the recruitment advertisement and following the directions to the online trial portal. Once they click on the recruitment advertisement, participants will be asked to read the Participant Information Sheet and Consent Form. After providing their consent to participate, participants will be asked to digitally sign the consent form and will then be automatedly directed to the screening survey, which will assess whether participants meet the inclusion/exclusion criteria. Participants >18 years who are eligible will be directed to

register for the study and undertake the baseline assessment. Participants who are aged 17 years will need to undertake a Gillick competence test to verify that they understand what the study is about and what is involved.[20] Participants who are deemed ineligible will be directed to a webpage thanking them for their time. This will include relevant support contact details.

In the absence of a response to completing the baseline questionnaire following registration, reminder/follow-up contact with potential participants will be undertaken by emailing and/or sending a text message. Up to two reminder invitations will also be sent out to participants over 7-days if they fail to complete subsequent post and follow-up questionnaires.

At the 30-day assessment point, participants allocated to the LifeBuoy and LifeBuoy+engagement strategy conditions will be asked whether they are interested in participating in a 45 minute interview to know more about their experience with the app—and for the LifeBuoy+engagement group only—they will be asked about which engagement strategies they used during the study and how they perceived them. Participants who consent to this will be contacted by email to arrange a time to attend an online interview (either telephone or videoconference).

Participants will be emailed e-gift vouchers (in Australian dollars) as reimbursement for their time, on completion of the 30-day ($10), 60-day ($10) and 120-day ($10) surveys to discourage trial attrition. Additionally, participants who complete qualitative interviews will be reimbursed with a $30 e-gift voucher for their time.

Intervention

LifeBuoy

LifeBuoy is a DHMI; a smartphone application developed by researchers at the BDI. It is a fully automated, self-guided programme theoretically grounded in dialectical behaviour therapy (DBT) and acceptance and commitment therapy (ACT). The first version of LifeBuoy was evaluated in a trial which commenced in May 2020, with the main outcome analysis showing that it did lead to greater reductions in the severity of suicidal ideation in the intervention group, relative to the control group, at postintervention—and these gains were maintained at 3-month postintervention follow up.[21] The version of Lifebuoy being tested in this current trial has undergone further refinements based on quantitative survey and qualitative feedback from trial participants, and in partnership with a youth LE advisory panel, recruited specifically for this purpose. These refinements also align with the current evidence base for what are considered characteristics of high-efficacy DHMIs.[22]

The app contains seven learning modules (outlined in table 1) that are based on DBT and ACT and incorporates core components (distress tolerance, emotion regulation, core mindfulness skills, values) through interactive learning exercises to help young people develop strategies and problem-solving skills for managing suicide thoughts. It is estimated that each module will take approximately 10 or more minutes to complete. Participants will be directed to each module linearly and unlocking a new module will require completion of the previous one (this also is the gamification of the app, as islands 'light up' or become technicolour when complete). Once modules are unlocked, participants can reaccess them at any time. Participants in the trial can use the app as often or as little as desired.

The app also includes 'self-monitoring' and 'toolbox' features. The self-monitoring feature allows users to track their mood and time spent in self-care behaviours. If the user selects a negative mood, they are directed towards their safety plan, crisis contact numbers and self-soothing/distracting activities. The toolbox provides users easy access to some distress tolerance tools, additional information and distraction strategies.

Participants will download the LifeBuoy app from the App Store or Google Play onto their personal smartphones. Once the app is downloaded, it will not require internet connection; internet connectivity will only be required to upload usage and adherence data to UNSW servers. Participants will have access to the app—to complete seven modules—until the final participant has completed the final assessment, at which point the apps will be deactivated for all participants.

LifeBuoy-C

For our control condition, we developed an app which retained the structure and look of the LifeBuoy app (ie, users were presented with seven modules), but which included content that was not based on a manualised therapeutic approach. In each module, users were provided with written content about topics that peripherally relate to mental health, including stress, confidence and the importance of goals; no interactive tools or resources were built in or provided via the app. LifeBuoy-C was used to control for a potential digital placebo effect seen in a trial of smartphone interventions.[23] The control intervention was designed to provide information for young people that matched the intervention in terms of duration and attention without providing any proven therapeutic content. As with LifeBuoy, each module will take 10 or more minutes to complete. Users will have access to the mood tracker and toolbox functions, but the toolbox will not include distress tolerance tools, only two distraction activities. Participants who received the control app will be informed that they were in the control condition at the conclusion of their final (120-day) assessment and provided a link to the intervention app, with access enabled for 30-days.

LifeBuoy digital engagement strategy

In addition to the LifeBuoy app, this study will trial a multicomponent digital engagement strategy aimed at increasing the use and therapeutic benefit of the LifeBuoy app. The strategy has been developed in consultation with the youth LE project advisory group. The engagement strategy will be comprised of three components:

Table 1 LifeBuoy app contents and therapeutic strategy

App module	1	2	3	4	5	6	7
General content*	**Psychoeducation**	**Distress tolerance 1**	**Distress tolerance 2**	**Core mindfulness**	**Emotion regulation 1**	**Emotion regulation 2**	**Values**
Specific topics	Psychoeducation on suicidal ideation and dissociation; how to recognise dissociation; grounding techniques; suicide-related quiz	Psychoeducation on breathing; tips for calm breathing practice; visualisation tool for practice	Temperature, intense exercise, paced breathing, and paired muscle relaxation (TIPP); self-soothing with relaxing audio tracks; and a distraction game	Information about mindfulness; three mindfulness meditation audio tracks	Self-care checklist (PLEASE skills); activity to identify well-being contributors vs expenditures; activity to identify where to focus efforts and reduce worry	Psychoeducation about emotions; emotional awareness scenario quiz; guidance on rational thinking	Identification of and satisfaction with personal values; value-based goal setting
Therapeutic goal	Foster self-compassion via education, validation and normalisation	Relaxation and lowering baseline anxiety via education and interactive practice	Effective distress management via lowering physiological arousal and practice of soothing and distraction activities	Improved cognitive presence and focus (and less emotional intensity) via mindfulness meditation practice	Reduced vulnerability to 'emotion mind', enhanced self-care, self-knowledge and autonomy via reflection and examined locus of control	Improved emotion regulation via education, awareness practice, and cognitive restructuring	Greater self-knowledge and increased agency via meaningful goal setting that aligns with personal values

*Content and activities based on dialectical behaviour therapy (DBT) and acceptance and commitment therapy (ACT).

1. An Instagram account that will deliver brief, visual content that aligns to the strategies and educational information within the app itself. Instagram posts will be uploaded at least once a week throughout the duration of the study, up till 30-days after recruitment of the final study participant. The Instagram account will be public, with comments disabled, as public access allows users to view content anonymously (otherwise they will need to register to view the account, which may be perceived as a barrier to engagement). While a public account may mean other trial participants have the potential to see this account, it will not be actively advertised to them to minimise this risk.
2. An online blog, primarily written by clinicians that will provide in-depth therapeutic information and advice for maintaining mental health and strategies to deal with suicidal distress. LE youth advisors will also contribute to this blog, writing about their LE of mental health issues and/or suicidal ideation. New articles will be posted once a fortnight throughout the duration of the study, again, up to 30-days following the recruitment of the final participant.
3. Emails that will be sent out fortnightly to participants with links to strategies 1 and 2 to remind them to visit them. The emails will also include a link to a short two-item survey asking participants if they have accessed the Instagram account and/or blog within the previous fortnight.

This strategy was derived using a bottom-up approach, which involved gathering information and perspectives from young people with an LE of suicide. The sources of data include: (1) qualitative interview feedback from participants in the first LifeBuoy trial, (2) data from a broad online survey of 260 mental health app users in Australia (3) and input from a youth LE project advisory group.

MEASURES

The administration schedule for each of the self-report assessment measures described in this section is presented in table 2.

Primary outcome measures

Suicidal ideation will be measured using SIDAS.[18] Respondents rate five items relating to suicidal ideation symptoms in the past 30-days on a 11-point scale (0–10). The scale provides a total score ranging from 0 to 50, with a

Table 2 Survey measures and administration schedule

Measure	Baseline (day 0)	Survey 2 (day 30)	Survey 3 (day 60)	Survey 4 (day 120)	Outcome
Suicidal ideation (SIDAS)*	✓	✓	✓	✓	Primary
Engagement†	In-app data will be collected continuously				Primary
Self-harm behaviour		✓	✓	✓	Secondary
Depression (PHQ-9)‡	✓	✓	✓	✓	Secondary
Anxiety (GAD-7)§	✓	✓	✓	✓	Secondary
Demographics	✓				Exploratory
Social phobia (mini-SPIN)¶	✓	✓	✓	✓	Exploratory
Substance use (TAPS-1)**	✓	✓	✓	✓	Exploratory
Substance use and suicide	✓	✓		✓	Exploratory
Impulsiveness (BIS-Brief)††	✓				Exploratory
Daily stressors (BDSS)‡‡	✓	✓	✓	✓	Exploratory
Use expectations	✓				Exploratory
App rating (uMARS)§§		✓			Exploratory
Engagement strategy		✓	✓		Exploratory

*Suicidal Ideation Attributes Scale.
†Defined as the number of modules completed, the number and frequency of app logins, and the total time spent on the app.
‡Patient Health Questionnaire Depression Scale.
§Generalised Anxiety Disorder-7 Scale.
¶Social Phobia Inventory (mini).
**Tobacco, Alcohol, Prescription medications and other Substance (screener).
††The Barratt Impulsiveness Scale (brief).
‡‡Brief Daily Stressors Screening tool.
§§Mobile App Rating Scale user version.
BDSS, Brief Daily Stressors Screening tool; BIS-Brief, brief version of The Barratt Impulsiveness Scale; GAD-7, Generalised Anxiety Disorder-7 Scale; mini-SPIN, Social Phobia Inventory; PHQ-9, Patient Health Questionnaire Depression Scale; SIDAS, Suicidal Ideation Attributes Scale; TAPS, Tobacco, Alcohol, Prescription medications, and other Substance; uMARS, Mobile App Rating Scale user version.

higher score indicating greater suicidal ideation severity. Negatively worded items are reversed scored and scores of 21 or greater indicate a high risk for suicidal behaviour (attempt). The scale has demonstrated excellent internal consistency (α=0.91).[18]

Engagement will be measured continuously using in-app data (ie, not administered via self-report survey). This data will include a count of the number of modules completed, the number and frequency of app log-ins and the total time spent on the app among participants with access to the LifeBuoy smartphone application.

Secondary measures

Self-harm behaviour

This will be assessed with two items created for this study to monitor safety during the trial: (1) 'since the last LifeBuoy study survey, how many times have you made an attempt to kill yourself in which you had some intent to die?' (free numerical response). If the participant selects once or more, two follow-up questions will be asked (a) 'how many suicide attempts were made in the past 30-days' (free numerical response) and (b) to indicate the severity of the most severe attempt since the last LifeBuoy survey (no care was needed, I attended the hospital, but without injury and left without being admitted, I attended the hospital with injury but left without being admitted, I was admitted to hospital without injury or I was admitted to hospital with injury); (2) 'since the last LifeBuoy study survey, how many times have you injured yourself on purpose without suicidal intent (ie, intentional, self-inflicted damage to the surface of the body but with no intent to die)?' (free numerical response). If the participant selects once or more, two follow-up questions will be asked (a) 'How many times did you self-injure in the past 30-days' (free numerical response) and (b) to indicate the severity of the most severe injury since the last LifeBuoy survey, with the following response options: no medical care was needed, I treated the injury myself, I attended a medical clinic or hospital and left without being admitted or I was admitted to hospital. If any self-harm is reported during the trial an additional question will be asked, 'Do you think that participating in this study or using this app has contributed to any recent distress leading you to self-harm?'.

Depressive symptoms will be measured using the Patient Health Questionnaire Depression Scale.[24] This scale consists of 9 items rated on a 4-point scale, ranging from 0 (not at all) to 3 (nearly every day). Higher scores indicate the presence of more depressive symptoms, and the maximum total score is 27. The scale has demonstrated good internal consistency (α>0.80).[25]

Anxiety symptoms will be measured using the Generalised Anxiety Disorder-7 Scale (GAD-7).[24] The GAD-7 consists of 7 self-reported items rated on a 4-point scale (0=not at all to 3=nearly every day), with a total score ranging from 0 to 21 and higher scores indicating more severe anxiety symptoms. The scale has demonstrated good internal consistency (α>0.80).[25]

Exploratory measures

Demographic information

This will measure age, sex, gender identity, sexual orientation, residential state or territory and area (ie, metropolitan or rural/remote), language spoken at home, who they live with at home, relationship status, highest level of education completed, employment status and whether they have ever been diagnosed with mental illness and when. Information related to their service use is also collected, such as whether they have ever seen a mental health professional for a mental health problem, the number of separate mental health professionals over their lifetime, whether they are currently receiving treatment (pharmacotherapy and/or talking therapy) for a mental health issue, how many sessions they have had with any current mental health professional and the longest duration they have stayed with a mental health professional.

History of self-harm thoughts and behaviours, and severity, will also be measured using four items created for this study. These items will include (1) 'How many times have you made an attempt to kill yourself in which you had some intent to die?' where a response of one time or more will prompt follow-up questions, 'Have you attempted suicide in the past 12-months?' (yes/no) and 'How many suicide attempts were made in the past 30-days' (free numerical text), with a severity question matching that in 'self-harm behaviours'; (2) 'For how long now have you been experiencing suicidal thoughts?' (3 months or less, up to 12-months, more than 12-months, more than 2 years, more than 5 years); (3) 'At what age did you first experience suicidal thoughts?' (free numerical response) and (4) "Have you ever injured yourself on purpose without suicidal intent (ie, intentional, self-inflicted damage to the surface of the body with no intent to die)?' where a response of one time or more will prompt follow-up questions, 'How many times have you injured yourself on purpose in the past 12-months?' (free numerical response) and 'How many times have you injured yourself on purpose in the past 30-days?" (free numerical response), with a severity question matching that in 'self-harm behaviours'.

Social phobia will be measured with the Social Phobia Inventory (mini-SPIN).[26] The mini-SPIN consists of three self-reported items rated on a 5-point scale, ranging from 0 (not at all) to 4 (extremely). Total scores range from 0 to 12, with higher scores indicating more severe social phobia symptoms. The scale has demonstrated strong internal consistency (α=0.85).[27]

Substance use

This will be measured using the TAPS-1, which is the screening component of the Tobacco, Alcohol, Prescription medications and other Substance (TAPS).[28] The TAPS-1 inquires about past 12-month frequency of tobacco, alcohol, illicit drugs and non-medical use of prescription drugs use. We will modify this screener to assess use in the past 30-days. Four items are rated on a 5-point scale, ranging from 1 (I did not use) to 5 (daily).

Total scores range from 4 to 20, with higher scores indicating more problematic substance use. The TAPS-1 can be used as a standalone screener to identify unhealthy substance use.[29]

Substance use and suicide

This will be assessed by asking, 'Have you ever used substances to cope with suicidal thoughts' (yes/no). If the respondent selects 'yes', they will be asked to indicate which substance(s) from a drop down menu, including alcohol, cigarettes, illicit substances and non-illicit substances (ie, prescribed medication or over-the-counter medicine).

Impulsiveness will be measured using the brief version of the Barratt Impulsiveness Scale (BIS-Brief).[30] The BIS-Brief consists of 8 self-reported items rated on a 4-point scale ranging from 1 (rarely/never) to 4 (almost always/always), with a total score ranging from 8 to 32 and higher scores reflecting greater impulsiveness. Four items are negatively worded and reverse-scored.

Daily stressors were measured using the Brief Daily Stressors Screening tool (BDSS).[31] The BDSS asks respondents to rate their subjective degree of stress from 10 daily stressors in eight distinct life domains over the past 12-months, on a 5-point scale, ranging from 0 (not at all) to 4 (very much). Total scores range from 0 to 40, with higher scores indicating a greater degree of stress. The scale has demonstrated acceptable internal consistency (α=0.79).[31] This scale will be modified to assess daily stressors in the past 30-days rather than 12-months, which has demonstrated acceptable test–retest reliability over a 1-month interval.[31]

Use expectations will be measured using six items created for this study, including: 'How satisfied have you been with face-to-face treatment overall', with response options ranging from very dissatisfied (1) to very satisfied (5); 'Are you looking for alternative mental health treatment to face-to-face therapy' (yes/no) and if yes 'why?' with free-text response option; 'Do you prefer face-to-face mental health treatment over digital treatment (eg, via computer or app)?' (yes/no); 'If you are currently in face-to-face treatment, how are you expecting to use this app?' (free-text response); and 'What motivated you to participate in this study?' (free-text response).

App rating will be measured using the Mobile App Rating Scale user version (uMARS).[32] The uMARS comprises 20 items rated on a 5-point scale (1=lower scores/negative perceptions and 5=higher scores/positive perceptions) for classifying and assessing the quality of mHealth apps. The scale includes four objective quality subscales—engagement, functionality, aesthetics and information quality—and one subjective quality subscale. One further subscale, consisting of 6 items, measure users' perceived impact of the evaluated app. The scale has demonstrated excellent internal consistency (α=0.90).[32]

Engagement strategy

This will be assessed by asking participants the total number of Instagram posts and blog articles they viewed during the study and to rate how much they strongly agreed (10) to strongly disagreed (0) with 10 statements, such as whether they found the Instagram posts visually appealing, informative and interesting. These 10 statements will be repeated for the blog articles. Participants will also be asked to provide free-text responses to which aspect(s) of the Instagram posts and blog articles they liked, did not like and why, as well as how these strategies may have helped them engage with LifeBuoy.

Qualitative measures

The semistructured interviews will include questions about each participant's experience with the app, and where appropriate, with the digital engagement strategy. Questions will focus on understanding what participants found appealing, helpful, encouraging and motivating as well as what they found unappealing, unhelpful or unnecessary. Participants will also reflect on why they thought certain engagement strategies did, or did not, work to encourage them to use the LifeBuoy app and will be asked for feedback on any improvements that could be made to the content, design or delivery method of the engagement strategies. The interviews will be audio recorded and transcribed for analysis.

Safety procedure

A strict safety protocol will be followed given our participant eligibility criteria. A linked directory of six major Australian crisis helplines (eg, LifeLine, Suicide Call Back Service) will be included in each app, enabling participants to connect directly to these services. In addition, if participants in any condition score 21 or greater on the SIDAS[18] at any of the assessment occasions, or report a suicide attempt during the trial or non-suicidal self injury that requires medical care during the trial, the research team will be alerted via email. At the same time, the participant will be sent an email or text flagging their risk and asked whether they want to be contacted by the team's clinical psychologist. If the participant returns a 'yes' response, they will be contacted by phone within 72 hours. All adverse events will be recorded and reported to the ethics committee and our DSMB. The DSMB will convene to review aggregate subject data related to safety, attrition, withdrawals, data integrity and overall conduct of the trial, at 2-weeks following each major assessment period and if any serious adverse events are recorded. Participants may be withdrawn from the study if they experience a serious adverse event that is attributable to a study intervention or procedure or means they can no longer participate in the study (assessed by 'self-harm behaviour' requiring hospitalisation). Participants may also self-withdraw consent to take part. Participants that are withdrawn from the study will not be replaced.

Sample size

The plan is to enrol 669 subjects to this trial. Sample size calculations were based on the primary aims. For aim 1, to detect an expected minimum effect size of d=0.45 between the LifeBuoy intervention and the control condition on the primary measure of suicidal ideation (SIDAS), determined from the prior LifeBuoy trial (paper in review), with α=0.01, power=0.95 and assuming a 0.50 correlation between repeated measures, 112 subjects are needed in each condition. As a three-arm trial, with a 1:1:1 allocation, this means N=336 subjects are required to detect this effect. In addition, assuming an attrition rate of 25% in each group at our 30-day assessment based on the previous trial of LifeBuoy, 450 participants are needed (150 in each arm, rounded up). This sample size is sufficient to detect the expected effects associated with primary aim 1. For aim 2, our recent systematic review of the engagement literature yielded three studies which were similar in design and population to our study.[33–35] The effect sizes in these studies varied from d=0.04 to 0.53 reflecting a difference in user engagement when comparing a digital intervention only and the same digital intervention with an engagement strategy. Given the small number of studies, there is insufficient information to assume that effect sizes are normally distributed. Thus, the median effect size among the three studies (d=0.38) was used as a benchmark. To detect an effect size of d=0.38 for primary aim 2 (alpha 0.01, power 0.95, assuming a 0.50 correlation between repeated measures, and 25% attrition), 223 participants are needed in each arm (rounded up). With a 1:1:1 allocation, this means N=669 subjects are required. Therefore, the larger sample size of 669 participants will be chosen to meet requirements of both primary aims. Qualitative interviews with 40 young people from the LifeBuoy and LifeBuoy+engagement group (minimum of 20 participants from the latter) will be recruited at the 30-day assessment time point, in which they will be asked whether they are interested to take part in an interview about their experience of the app and engagement strategy. This sample size will be large enough to reach saturation of qualitative themes.

Randomisation and blinding

Participants will be randomised with a 1:1:1 allocation using a block design (three participants per block). Randomisation will be carried out using the BDI's Research Engine, which employs a centrally administered computerised random number generator. In this way, group allocation is performed independently of all members of the research team. All study assessments will be via electronic self-report. There are no outcome assessors and so the risk of differential treatment of those in the intervention and control is minimised. No explicit communication of the randomisation outcome will be made to participants. The analyst for the quantitative outcomes of the trial will be blinded to condition allocation.

Data collection and management

All research data collected in this trial will be stored using a unique participant ID code. A list of identifiable participant information associated with each ID code will be stored separately from the research data. Coded survey outcome data will be stored securely on the BDI online research platform. Data will be exported into appropriate statistical software for analysis. The data manager will be responsible for extracting and securely transferring data to the research team. Only researchers whose analyses require access to the specific data set collected from each survey will be able to access those data. DSMB members may request unblinded data if there is a rationale (eg, unexpected adverse events, aggregate data indicates self-harm above the rates expected from this group) and will make the final decision to terminate the trial if necessary.

ANALYSIS

Quantitative data

Mixed models repeated measure analyses, with maximum likelihood estimation and an appropriate covariance structure, will be used to evaluate longitudinal changes in suicidal ideation and secondary mental health outcomes between the LifeBuoy and attentional control arms. Where required, generalised linear mixed models with an appropriate link function will be used for the analysis of categorial variables. The mixed model approach incorporates all available data, including participants with missing follow-up data points, under the missing-at-random assumption. Analyses will, therefore accord with the intention-to-treat principle.

A similar analytical approach will be used to evaluate engagement metrics (ie, number of modules completed; number and frequency of app logins) and suicidal ideation between the LifeBuoy only and LifeBuoy+engagement strategy arms.

Qualitative data

Qualitative feedback on users' perceived acceptability of the LifeBuoy app and engagement strategy will be examined through semistructured interviews with a subset of participants (n=40 in total) and questionnaires in the survey. The interview data will be analysed using a framework analysis approach.[36] An inductive approach, independent of a theoretical confirmative method, will be used to identify and group themes. The researchers will then refine the themes and determine the final coding framework. Discrepancies will be resolved by a third researcher to ensure reliability of the process.

ETHICS AND DISSEMINATION

This trial has obtained ethics approval from the University of New South Wales Human Research Ethics Committee (UNSW HREC, HC210400). Participants will be informed that any information collected during the trial—including in-app data—will be used for research purposes only and

stored in accordance with this protocol. All trial findings will be presented at the aggregate level. A summary of the findings using lay language will be communicated to participants who opted in during the consent process to receive this information. This summary will be emailed at the completion of the study (expected in 2023). The results of the trial will also be disseminated via peer-reviewed publications in scientific journals, as a PhD thesis, and in conference presentations.

Trial status

Participant recruitment and baseline data collection for this trial will begin in April 2022. The trial has been prospectively registered with the Australian New Zealand Clinical Trials Registry. Important protocol modifications will be communicated to UNSW HREC and ANZCTR. Protocol V.1.4, February 2022.

DISCUSSION

This protocol describes a novel, doubled-blind three-arm randomised controlled trial, which aims to test the efficacy of the LifeBuoy app in reducing suicide ideation across time and examine the efficacy of a digital engagement strategy on app engagement across time. This research will answer important questions about the acceptability and efficacy of digital health interventions and how to encourage young people to use them to optimise the therapeutic benefits. This evidence will be important in driving decisions about how (and whether) to scale up these interventions. This study is particularly relevant to young people given their pervasive use of mobile technology, while currently no mobile apps that attempt to reduce suicidal ideation are available. Smartphone app-based self-guided psychological treatments for suicidal thoughts have the potential to increase treatment access and reduce obstacles in help seeking by providing accessible, anonymous and timely support, which can then potentially reduce suicide risks.

Contributors MT was responsible for conceptualising the study, methodological design and acquisition of funding for the study to take place; LM prepared the manuscript and contributed to the design of the study, and selection of assessment measures; DZQG assisted with drafting the original research protocol that formed the framework for this manuscript, contributed to selection of assessment measures and critically revised the manuscript; QW contributed to writing the statistical analyses, conducted the power analysis and critical revision of the manuscript; JH, SH and HC provided intellectual contribution to design of the study and critical revision of the manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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