Phase 2 Clinical Trial Protocol

Investigating the feasibility and acceptability of Smooth Sailing:

An online mental health service for depression and anxiety in high school students

Putting health in mind

Black Dog Institute

Contents

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Public Title: Investigating the feasibility and acceptability of Smooth Sailing: An online mental health service for depression and anxiety in high school students

Scientific Title: Investigating the feasibility and acceptability of Smooth Sailing: An online mental health service for depression and anxiety in high school students

ANZCTR Number: TBC

Date: 31st January 2017

Secondary IDs: Nil

UTN:

Trial acronym: {Blank}

Linked study record: Nil

Health Condition: Depression, anxiety, stress.

Condition Category:

Sponsor

Name: Black Dog Institute

Address: Hospital Road, Prince of Wales Hospital, Randwick, NSW 2031

Country: Australia

Type: Charities, societies, foundations

Funder

Name: HSBC Bank Australia

Address: Level 36, Tower 1, International Towers Sydney, 100 Barangaroo Avenue, Sydney NSW 2000

Country: Australia

Type: Corporate

Administration

Trial administration will be the responsibility of researchers at the Black Dog Institute, University of New South Wales.

Name and title of person authorised to amend protocol: Dr Bridianne O'Dea, Chief Investigator.

Name and title of Medical Expert: A/Professor Josephine Anderson, Clinical Services Director, Black Dog Institute.

Investigators responsible for conducting the trial: Dr Bridianne O'Dea, Professor Helen Christensen, Dr Kathleen O'Moore, Catherine King, Dr Mirjana Subotic-Kerry, Nicole Cockayne.

Name and titles of those responsible for all trial-site related medical decisions: A/Professor Josephine Anderson, Dr Bridianne O'Dea, Professor Helen Christensen, Dr Kathleen O'Moore.

Statement of Intent and Compliance

This trial will be conducted in compliance with the protocol outlined herein. This document is a protocol for a clinical research trial. The trial will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95).

Summary

Brief Summary for Lay purposes: *Short description of the primary purpose of the study, including a brief statement of the study hypothesis, intended for the lay public. Ensure that the information provided in the brief summary is consistent with study design, intervention description and study outcomes provided in the form.*

This study is a one-arm pre-post test evaluation of a schools-based mental health service. The service, titled Smooth Sailing, is designed to screen and assess the levels of depression and anxiety among secondary high school students. Using an online platform, students register to the service which assesses their mental health symptoms using brief, clinically validated questionnaires. The online platform then allocates each student to one of five "steps" for which different online activities are prescribed. The school counsellor is notified when students are found to be at the severe steps. This 6-week study aims to examine the effects of this service on help-seeking attitudes and behaviour, with secondary analyses on depression and anxiety symptoms, as well as overall acceptability of the service among students. It is hypothesised that improvements in help-seeking attitudes and behaviours will be found, with small effects on depression and anxiety symptoms.

Background

Anxiety, depression, and suicidality are prevalent among high school youth aged 12 – 17 years (Lawrence, et al, 2015). Currently, 25% of adolescents are likely to experience a mental health problem, with 1 in 8 reporting an anxiety disorder, and 1 in 16 reporting major depression. Help-seeking is low, particularly amongst males. When help-seeking does occur, finding the "right" type of help can be difficult and current mental health services for this age group are overburdened and lack capacity for mild-moderate symptoms (McGorry, et al. 2013). Alternative service models are needed to improve rates of help-seeking, reduce pressure on current systems, to prevent escalation of mental illness, and reduce the associated morbidity and mortality. It is estimated that prevention and early intervention efforts can reduce rates of mental illness by 20%.

Online stepped-care presents a viable alternative. It is based on the premise that simple, cost-effective internet interventions are offered to youth with mild-moderate symptoms, while more costly, intensive face-to-face interventions are reserved for those with more severe and persistent symptoms (van Straten, et al. 2015). Although complex, this approach is efficient, provides tailored help as required, and can prevent mental illness by detecting symptoms early. Internet interventions can be readily integrated into stepped-care as they are fully automated, acceptable to youth, preserve fidelity of care, and allow for ongoing monitoring and automated feedback. These systems can be engineered to "reach out" to youth rather than wait for them to approach.

School is an ideal setting for the implementation of online stepped-care as students spend much of their daily lives in school, and it is a place of learning new skills and knowledge (Clayton, et al. 2010). However, schools currently have a "scattergun" approach to mental health, with some offering a school counsellor, some offering psycho-education programs, and others not having anything at all. To improve this situation, the Black Dog Institute has been awarded funds ($517 000) to design, build, and evaluate an online mental health clinic (referred to hereon in as "the e-clinic") that targets help-seeking for depression and anxiety symptoms in high school students. Co-designed with students/schools/parents, the e-clinic delivers mental healthcare using a sophisticated internet program that triages students' mental health, delivers treatment, monitors progress and links in with the school counsellor and wellbeing team. To reduce the stigma associated with mental illness, this e-clinic service has been named "Smooth Sailing".

The theory of change underpinning Smooth Sailing is based on Rickwood et al's (2005) "Help-Seeking model" in which help-seeking is defined as an intensely personal process with four key stages:

awareness	⇨	***expression***	⇨	***availability***	⇨	***willingness***
and appraisal of problems		*of symptoms and need for support*		*of sources of help*		*to seek out and disclose to sources*

Smooth Sailing targets these stages directly by: i) Multiple pathways of entry to satisfy both internal and external awareness and appraisal; ii) Psychometric online screening with feedback; iii) Personalised program of care delivered utilising the stepped care model linking in with face-to-face services and e-support; iv) Training and skill development in disclosure, identifying trustworthy adults at home and at school, knowledge on how to start conversations about mental health and what to do if not wanting to disclose. Smooth Sailing can be described as a "complex intervention" – an intervention with several interacting components. These types of interventions present a number of unique problems for researchers, due to the difficulty in standardising the design and delivery of the intervention, their sensitivity to features of the local context (in this case, the school setting), the organisational and logistical difficulty of applying experimental methods to service design change, and the length and complexity of the causal chains linking the intervention with outcome. As such, the current study aims to evaluate the safety and efficacy (including the acceptability and feasibility) of Smooth Sailing.

Trial Objectives and Purpose

The main objectives of this trial are to:

- Evaluate the effectiveness of Smooth Sailing intervention for increasing help-seeking for depression and anxiety among high school students;
- Measure the acceptability, feasibility, and demand of this type of service model in high school settings.

Trial Design

Study Type

An uncontrolled, non-randomised, one arm pre-post interventional trial.

Assignment

Single Group such that all participants receive the same intervention throughout the study.

Masking/Blinding of Participants.

This study will be "open" (i.e. masking not used) such that all involved in the study (participant, clinician, and data analyst) are not blinded.

Phase

Not applicable.

Type of Endpoint

Efficacy/Safety: to measure the intervention's influence on help-seeking for depression, anxiety and stress; and to show that the intervention is safe under conditions of the proposed protocol.

Inclusion Criteria

Participants will be aged between 12 – 19 years and attending one of the participating high schools. Both males and females will be eligible. As well as including participants that are well, this trial will include adolescents with current depressive symptoms or any adolescents with a history of depression or anxiety. This trial will also include adolescents with current suicidality or a history of suicidality. Participants will be required to have an active email address for the duration of the trial as well as internet access either at home or at school (the school will provide internet access for the duration of the trial). Only those who provide signed written consent from their parents will be included.

Exclusion criteria

Those not willing or able to provide individual and parental consent will be excluded from participating.

Hypotheses

Those who participate in the intervention will report improvements in help-seeking, mental health knowledge, greater satisfaction with school care, and lower levels of depression and anxiety.

Selection and Withdrawal of Subjects

Recruitment, Screening & Consenting

Status: Completed

Potential participants will be identified from the high schools who consent to participating in the trial. High schools will be recruited from a shortlist of schools that have established research and educational partnerships with the Institute. This list consists of approximately 20 local and regional high schools that have previously participated in a trial or have expressed interest in participating in a research trial. These schools are based in NSW only and their postcodes include 2440 (Kempsey, NSW), 2290 (Charlestown, NSW), 2131 – 2372 (Canterbury /Bankstown), 2008 – 2036 (Eastern Suburbs), 2006 – 2372 (Inner West), 2163 – 2566 (Liverpool /Fairfield), 2020 – 2223 (St George), 2173 – 2565 (Sutherland), 2145 – 2770 (Western Sydney), 2115 – 2199 (Parramatta).

Schools are initially emailed a study invitation from the chief investigator using a standard letter attachment. This email consists of an overview of the study, and a brief protocol (adapted from this document). The schools are invited to participate in a follow-up phone call to answer any additional questions. Once this is complete, consenting schools are asked to sign and date a letter of support which is then returned to the Chief Investigator. This is then forwarded to the governing ethics bodies. Once a school's participation has been secured, the school counsellor is briefed on the study and the study protocol is explained by the trial manager. The school then selects a class group of approximately 30 students based on teacher co-operation and general study suitability (e.g., in terms of school demands such as exams, curriculum studies, other research study participation). Due to the inclusion/exclusion criteria, there is no need for screening of these participants. Once the class is selected, one or more members of the research team will visit the school during the first two weeks of the school term to oversee the baseline assessment. Participant Information and Consent will be disseminated ahead of this time via mail, so that students have adequate time to seek parental consent before the baseline assessments. To avoid coercion, students are asked to sign their forms outside of school time. Final participants are those who return their personal consent forms along with parental permission.

Withdrawal

The Participant Information Statement and Consent Form informs potential participants that participation is completely voluntary, and that they are free to withdraw from the study at any time, without penalty and without having to give a reason. The Parent/Guardian Information Statement and Consent Form also informs parents/guardians that participation is completely voluntary, and that they are free to withdraw their consent and/or permission for their child to participate at any time, without penalty and without having to give a reason. Participants wishing to withdraw from the study can do so by contacting the trial manager and providing either their first name and last name, or unique ID code. No reasons need to be given.

Trial Procedure

Once parental consent is collected, the research team will visit the school to supervise participants' registration to the intervention (i.e. day one). The registration process will be completed online, during class time, using a computer/mobile/ or tablet device. Registration is estimated to take no more than 20-30 minutes. Although registration is completed privately by the student, a researcher or trained school staff member will be present to answer any questions and offer assistance. Baseline measures will be collected during this online registration process. Once all students have registered and completed the baseline assessment, a list of student names, alongside their trial identification numbers, will be given to the school counsellor. This will be used when the school counsellor is required to follow-up with a student as the email alerts do not contain student names (only the trial identification numbers). Throughout the trial, students will be able to use the intervention at their own leisure, either in or out of school time. Participants will also receive two optional monitoring questionnaires which are delivered via email (with SMS reminder) at day 15 and day 29. At day 43, a researcher will return to the school to collect the final endpoint measures using the same procedure for registration.

Treatment of Subjects

Intervention

Name: Smooth Sailing (Arm 1). Intervention codes: Early detection/screening and Treatment (other) (behavioural intervention)

Smooth Sailing is an online mental health service designed and administered by the Black Dog Institute. It is based on the principles of "stepped care" such that the intensity of the recommended interventions is matched to individuals' symptom severity and individuals "step up" if they have not responded to treatment after a set period of time. Exposure to Smooth Sailing involves:

1. Registration & Mental Health Assessment. In class time, participants are given a slip of paper with the service URL and their unique identification code. They then use a school or personal internet device to visit this website and undertake registration. Before registration commences, participants are asked to complete the Gillick Competency measure which consists of X questions to further confirm their understanding of the service and study requirements. Upon correct completion of this, participants are invited to create a personal profile (name, date of birth, email address, mobile phone number, and gender, history of mental health issues, and use of the internet for mental health information). Once a personal profile is created, four questionnaires were used to measure the presence of depression, anxiety, help-seeking attitudes and behaviours (see Appendix B in Attachments section of ANZCTR record). This takes approximately 30 minutes to complete.

2. Step allocation. Based on the answers inputted during registration, Smooth Sailing allocates each participant to one of five "steps". This is automatic and based on a clinical algorithm which accounts for the severity levels of the anxiety and depression symptoms as reported by the participant on the Generalised Anxiety Disorder Scale (GAD-7) and the Patient Health Questionnaire (PHQ-9). Each "step" matches a severity level and was based on clinical practice guidelines. The step allocations were: Nil/minimal (Step 0), Mild (Step 1),

Moderate (Step 2), Moderately Severe (Step 3), and Severe (Step 4). Please see Table 1 for more detail.

3. Delivery of tailored program. After step allocation, Smooth Sailing delivers a program of content that is tailored to each step. Steps 0 and 1 receive online psychoeducation. Step 2 receive online psychoeducation + online self-directed Cognitive Behavioural Therapy (CBT). Steps 3 and 4 receive online psychoeducation + online self-directed CBT + additional support from the School Counsellor. Any participant who was allocated to Step 3 or 4 triggered an electronic notification alert which was automatically sent to the school counsellor for further investigation. This allowed the school counsellor to facilitate a face-to-face session within 48 hours to provide the counselling or refer on to external services. The online psychoeducation consists of five modules on i) general mental health, ii) depression, iii) anxiety, iiii) seeking help for yourself, iv) seeking help for a friend. Each of these modules contains information about definitions of mental health terms, signs and symptoms, causes of mental health problems, what to do if needing help, and strategies and tips for what a young person can do immediately. Each module is complemented by animations and illustrations to depict key messages as well as hyperlinks to other credible youth mental health services and websites including Headspace, Reachout, Kids Helpline. This content was created specifically for this service, and was reviewed by clinicians. It is designed to be self-directed, such that the youth can read and return to it whenever they wish. The online CBT module consists of a single webpage that outlines two evidence-based self-directed online cognitive behavioural therapy programs: i) MoodGym (Australian National University) and ii) Brave Online (University of Queensland). MoodGym is an interactive self-help book which helps to learn and practise skills for managing symptoms of depression and anxiety. It consists of five modules alongside questionnaires, summaries and a personal workbook. BRAVE was developed for children and teenagers who experience Separation Anxiety Disorder, Social Phobia, Specific Phobia and Generalised Anxiety Disorder. This program helps young people to learn new ways to manage their anxiety and fears. It consists of 10 sessions and is effective for reducing social worries, anxiety about separating from loved ones, fears of specific objects or situation, worries about friendships, school performance or other everyday worries. Please see Table 2 for more detail.

4. Monitoring and Feedback. At two points in the study (Day 15 and Day 22) participants received an automated 18-item “monitoring questionnaire” to assess how they were doing. This consisted of the Goldberg Depression and Anxiety Scales and was delivered via email or SMS. An automated thank you message was received alongside a reminder to use the program if participants completed this questionnaire.

5. Reassessment (Post-test/endpoint): At Day 43, researchers revisited the schools. Participants again logged onto the service using the same URL and unique ID codes and were delivered the final endpoint questionnaires. In theory, the results of these questionnaires would be used to determine whether a participant had responded to care or needed to be “stepped up”. In accordance with the Clinical Practice Guidelines for the Treatment of Depression in Young Adults, if a participant has not responded to their care within 43 days of their baseline allocation, they would be “stepped up” to the next level of care. See Table 3 below for the stepping matrix at 43 days. The matrix was designed such that a participant would not be stepped down, instead will either remain at the same step or step up. However, as the current trial ceased at 43 days, no stepping occurred during this trial. Instead, this trial was

designed to provide the clinical data necessary to determine whether the steps are feasible for future trials.

Throughout the trial, participants will be obligated to use Smooth Sailing at pre-test (for registration and baseline measure collection) and again at post-test (for reassessment and final endpoint collection) only. Completion of the monitoring questionnaires and use of the other components is entirely voluntary, and will be a measured as part of the study.

Table 1. Step Allocation Criteria

Step	Severity Level	Criteria
Step 0 &	Nil, minimal	PHQ9 (0 - 4) & GAD7 (0 - 4)
Step 1	Mild	PHQ9 (5 - 9) & GAD7 (0 - 9) OR PHQ9 (0 – 9) & GAD7 (5 – 9)
Step 2	Moderate	PHQ9: (0-14) & GAD7: (10-14) OR PHQ9: (10-14) & GAD7: (0-14)
Step 3	Moderately Severe	PHQ9: (0-19) & GAD7:(15-19) OR PHQ9: (15-19) & GAD7: (0-19)
Step 4	Severe	PHQ9: (0-27) & GAD7: (20-21) OR PHQ9: (20-27) & GAD7: (0-21)

Table 2. Care delivered at each step

Step	Severity Level	Care provided
Step 0 and 1	Nil, minimal, mild	Online psycho-education: This consists of written text, videos, and activities created by Black Dog Institute researchers. It also includes URL links to other psycho-education material published by reputable Australian mental health organisations including headspace, Reachout, beyondblue and SANE Australia. It is estimated that 60% of participants will be allocated to this step at baseline.
Step 2	Moderate	Self-directed online cognitive behavioural therapy (CBT) in addition to the online psycho-education material. The online CBT programs that will be offered by Smooth Sailing are evidence-based, produced by Australian university research groups, and free to access. The programs include MoodGym (Australian National University), and Brave Online (University of Queensland). It is estimated that up to 25% of participants will be allocated to this step at baseline.
Step 3	Moderately Severe	Self-directed online cognitive behavioural therapy (CBT) in addition to the online psycho-education material and additional support from the school counsellor. This support will be offered face-to-face by a school counsellor. In the current study, any participant who reports moderate symptoms will trigger an electronic notification alert which will be automatically sent to the school counsellor or head teacher for further investigation. This will allow the school counsellor to facilitate a face-to-face session to provide the

		counselling or refer on to external services. It is estimated that between 10-15% of participants will be allocated to this step at baseline.
Step 4	Severe	Self-directed online cognitive behavioural therapy (CBT) in addition to the online psycho-education material and additional support from the school counsellor. In the current study, any participant who reports moderate symptoms will trigger an electronic notification alert which will be automatically sent to the school counsellor or head teacher for further investigation. This will allow the school counsellor to facilitate a face-to-face session to provide the counselling or refer on to external services. It is estimated that 5% of participants will be allocated to this step at baseline.

Throughout the trial, the school counsellor will be physically located within the school that the participant attends. He or she has a background in counselling or psychology and is present at the school at least two days per week. The school counsellor will provide clinical support to any participant that reports moderately severe or severe depression/anxiety scores, or reports suicidal ideation throughout the study. See Assessment of Efficacy for details on how service use, adherence, and satisfaction will be measured.

Table 3. Step Allocations at Day 43 based on Step at Baseline

Step at 43 days	Step at Baseline 1	2	3	4
1	1	2	3	4
2	2	3	3	4
3	3	3	4	4
4	4	4	4	4

Comparator: No control group as it is an uncontrolled trial.

Assessment of Efficacy

Outcome Measures

Table 4 provides a basic overview of the outcome measures, with more detail provided in in Appendix B.

Table 4. Outcome measures, instruments, and time of administration

Target group	Outcome	Measure(s)	Timing
Students	Demographics	Personal Information/Demographics	Pre only
	Depression	PHQ-9	Pre and post
	Anxiety	GAD-7	Pre and post

	Help-seeking	General Help-Seeking Behavior Questionnaire, Actual Help-seeking Behaviour Questionnaire	Pre and post
	Service Satisfaction	Purpose Built Service Satisfaction Questionnaire for Students	Post only

Pre-test/Baseline Assessment

During the registration process, participants will complete the online battery of questionnaires including the: Demographics questionnaire; Patient Health Questionnaire (PHQ-9); Generalised Anxiety Disorder Questionnaire (GAD-7); the General Help Seeking Behaviour Questionnaire and Actual Help-seeking Behaviour Questionnaire. This will be conducted under the supervision of a researcher and teacher/school counsellor, during class time.

Post-test/Final endpoint Assessment

At day 43, participants will return to the website to complete the online battery of questionnaires including the: Patient Health Questionnaire (PHQ-9); Generalised Anxiety Disorder Questionnaire (GAD-7); the General Help Seeking Behaviour Questionnaire and Actual Help-seeking Behaviour Questionnaire and the Satisfaction Questionnaire for Students Acceptability and demand measured by: The number of youth and parents who consented to the study; The number of modules completed; The number of students who reported using the online CBT programs; The number of students who completed the fortnightly check-in questionnaires;

Assessment of Safety

Outcomes Advisory Group

An Outcomes Advisory Group has been established to provide specific monitoring, governance, and reporting of adverse events and trial safety. This group consists of the trial manager, the lead investigators, and the medical expert. This team meets every two weeks, and on an as-needed basis, to monitor the safety of the trial. A data safety monitoring board will not be utilised in the current study. This decision was made on the basis of two key factors:

1. The current study targets a non-clinical population, and does not target a high risk sample.
2. The research platform used in the trial has an alert system which provides timely feedback to research personnel, so that distressed participants can be identified and attended to straight away. Once identified, school counsellors will be made aware of the distressed participant, so that they may provide immediate and, if necessary, ongoing assistance. This procedure ensures the highest level of care for participants, as school counsellors are appropriately trained, familiar, accessible, and available to assist should such a scenario eventuate.

Duty of Care and Risk Management Protocol for Risk of Significant Harm

The following Duty of Care and Risk Management Protocol will be used if a research participant self-identifies or self-reports as being at “risk of significant harm” during the study.

Defining "risk of significant harm"
This document will use the definition of "risk of significant harm" as outlined in the NSW Children and Young Person (Care and Protection) Act 1998 and this definition will be applied across all schools in involved in the study. Under the act, a risk of significant harm involves serious threats to safety, welfare, and wellbeing of a child for any of the following reasons:

- The basic physical or psychological needs of the child or young person are not being met (neglect);
- The parents or caregivers have not arranged necessary medical care (unwilling or unable to do so);
- Risk of physical or sexual abuse or ill-treatment (physical or sexual abuse);
- Parent or caregiver's behaviour towards the child causes or risks psychological harm (emotional abuse);
- Incidents of domestic violence and as a consequence a child is at risk of serious physical or psychological harm (domestic or family violence).
- Students may also be at risk of harming themselves or others, such as reported suicidal thoughts/plans/behaviours, or thoughts/plans/behaviours in regards to hurting someone else.

The NSW Department of Education has established a policy titled "Protecting and Supporting Children and Young People Policy" which is enforced in all NSW schools and clearly sets out the roles and responsibilities of staff in relation to child protection including training, reporting on safety, and supporting children and young people, as well as monitoring, evaluation and reporting requirements.

Procedure for responding to risk of significant harm within this Trial
Within the Smooth Sailing service, the pre-test and post-test assessments include the Patient Health Questionnaire (PHQ-9). This questionnaire is used to assess the presence of depression symptoms and has one item assessing suicidal risk (item 9). This item reads *"Over the past two weeks, have you had any thoughts that you would be better off dead or of hurting yourself in some* way". A participant is able to answer either 'not at all' (0); 'several days' (1), 'more than half the days' (2) or 'nearly every day' (3). The battery also includes the General Anxiety Disorder Questionnaire (GAD-7) which is used to screen for the presence of general anxiety symptoms. Both the PHQ-9 and GAD-7 are standardised psychological screening measures and as such, may provide an objective measure of anxiety, depression, and suicide risk if completed truthfully. However, further assessment from a trained mental health professional is required for the extent of an individual's risk to be fully determined. As such, the most appropriate response to elevated scores is to notify a trained mental health professional so that they can follow up with the participant. This is a commonly accepted protocol for mental health research studies. In the context of this study, the trained mental health professional will be the School Counsellor.

Given the sensitive nature of the questionnaires, students must be provided with adequate supervision for completion. In the current study, any student participating in the trial will be subject to the following supervisory conditions:

- Students will only be able to complete the questionnaires during class time, under the supervision of the researcher, school counsellor and/or class teacher. This will ensure that the student has adequate supervision, and if an alert is triggered, the school

counsellor will be able to make timely contact. This will also ensure that the research team will be able to monitor the impacts of this questionnaire more precisely. Any student who cannot attend school for the class period in which the baseline and follow-up questionnaires are to be completed will not be able to participate in the study.

- A trained mental health researcher from the Black Dog Institute will be present at the school during class time for the completion of the baseline and follow-up questionnaires. This researcher will supervise students during their completion of the questions, and monitor for distress. This researcher will verbally explain the process and provide instructions for what a student should do if feeling distressed (a. Let the researcher or the teacher know immediately by putting their hand up or asking to be excused). This researcher will have a valid WWCC which is included in the application.
- The school counsellor will also be onsite at the school and available for immediate contact for any students who require this during the completion of the baseline and follow-up questionnaires.
- A private breakout space (i.e. a classroom or school counsellor's office) will be made available should any student require private support.
- If a student reports that they are moderately severe or severely depressed/anxious during the baseline or follow-up questionnaires, then the school counsellor will be notified using the procedures outlined below under "Procedure for Responding to Risk of Significant Harm". The trial manager will also be notified and will follow-up with the school counsellor within 48 hours to ensure that the school counsellor is responding to the alert. Please note that the Trial Manager will be onsite for the completion of the baseline and follow-up questionnaires, and will therefore be able to check notifications immediately while participants are in the room. This allows for a swift response.
- To further support the school counsellor, a list of resources will be provided to the before the study commences, outlining additional adolescent mental health services that are available in their local area for referral. The Smooth Sailing Clinical Advisory Group (which consists of Child and Adolescent Psychiatrist and a Clinical Psychologist located at the Black Dog Institute) will also be available to provide any clinical support to the school counsellors wherever it is requested via telephone and email. This will ensure that the school counsellor feels adequately supported throughout the study, and increases the clinical capacity available to the students.

Summary of Potential Adverse Events

The table below outlines a series of possible adverse events that may be captured by the assessments within this study. These events will be monitored by the number of email triggers sent by the service during the study period.

Table 1. Potential Adverse Events

Event	Assessment/Criteria	Action
"Moderately severe" or "severe" depression at baseline	A Patient Health Questionnaire-9 (PHQ-9) baseline score of 15 or above.	An automatic email alert will be sent to the nominated school counsellor and a member of the research team. The school counsellor will be notified to follow-up with the participant using normal school protocols, including any mandatory reporting requirements. The trial manager will also re-contact the school counsellor within 48
"Moderately severe" or "severe" anxiety at baseline	A Generalised Anxiety Disorder (GAD-7) baseline score of 15 or above.	

		hours to confirm that the email notification was received and is being acted upon. The research team will report to the outcomes advisory group at 2-week intervals on the total number of alerts.
Suicidal ideation at baseline	A score greater than or equal to one on the PHQ-9 item 9.	As above. In addition, a pop-up alert is shown to the participant which states the following: *"Thanks for letting us know. We think it'd be great if you could tell a trusted adult about how you have been feeling. If you're not up to talking to someone you know, try Kids Helpline on 1800 55 1800 (it's not just for kids!) or Lifeline 13 11 14. Smooth Sailing will let your School Counsellor know that it's been tough for you lately. Your School Counsellor will touch base with you in the next few days, just to see if there is anything they can do to help. Don't worry - this is all done very privately. In the meantime, keep using Smooth Sailing - we're here to help!"*In addition, the participant will automatically receive access to the Smooth Sailing program which includes a range of psycho-education, help-seeking resources, and online therapy programs, which are evidence-based. Participants have access to this program for the duration of the trial.

Please see the supplementary material "Responding to risk of harm" document for a more detailed outline and flowcharts for decision making regarding risk of harm in the current trial.

Table 2 outlines additional adverse events during the trial which are not captured by the assessments and our action.

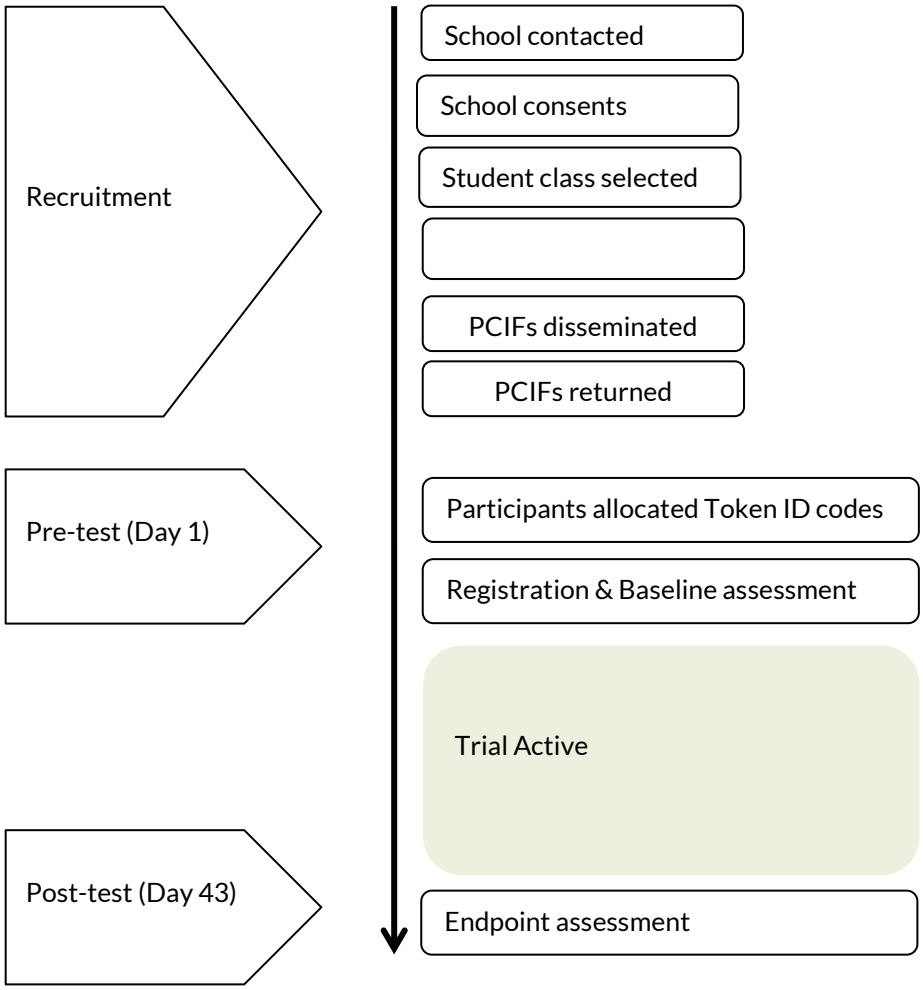
Table 2. Additional Adverse Events

Event	Assessment/Criteria	Action
Participant reports elevated suicide risk to school	School Counsellor is notified and assessed participant's risk using normal school protocols.	Normal school protocols (as outlined by the Protecting and Supporting Children and Young People Policy) are followed. School Counsellor to report these events to the trial manager via phone call or email. The trial manager asks school counsellor about any adverse events upon 6 week follow-up The research team will report to the Outcomes Advisory Group at 2-week intervals on the total number of trigger emails being sent.
Participant reports depressed mood to school		
Participant reports anxiety to school		
Risk of significant harm as identified by school contact		

Statistics

Although this study is an uncontrolled acceptability trial, we will be examining differences pre and post-test. A recent systematic review of help-seeking interventions (Gulliver et al 2012) reports an effect size of d = 0.12 – 0.53 for psycho-education interventions. As such, our sample size calculations are based on using an alpha of 0.05 and effect size of 0.50. As guided by Cohen (1992), 64 participants are needed to demonstrate this effect. Given that 40% are likely to drop out, we will target 106 participants for recruitment.

Trial Flow


Recruitment
Pre-test (Day 1)
Post-test (Day 43)
School contacted
School consents
Student class selected
PCIFs disseminated
PCIFs returned
Participants allocated Token ID codes
Registration & Baseline assessment
Trial Active
Endpoint assessment

Trial Schedule

Date	Task
September 2016	Submit UNSW HREC protocol
October 2016	Submit NSW Education SERAP protocol
December 2016	School recruitment
January 2017	Confirm school involvement
February 2017	Register clinical trial protocol
February 2017	Pre-test measures
March 2017	Trial Active
June 2017	Post-test

Ethics

Approved: UNSW HREC

Name: University of New South Wales Human Research Ethics

Address: UNSW, High St, Randwick

Country: Australia

Submit date: 31.08.2016

Approval date:06.10.2016

Approval ID: HC16724

Dissemination of Results & Publication Policy

How will research results be reported to the participants? When signing consent, participants will be asked if they would like to be emailed a 1 page summary (in the form of an infographic) of the research results upon completion of the study. This will be sent out to all participants who select this option. A summary of the results will also be published on the Black Dog Institute website.

How will research results be reported to other academics? The results of this study will be analysed and published in relevant academic journals. Results will also be presented at relevant academic conferences.

How will research results be reported to other stakeholders? To ensure that research results are easily understood, we will construct a one-page infographic that easily conveys the key findings of the study. This will be emailed to all stakeholders upon completion of the study. We will also offer short face-to-face presentations (where possible) to present the key findings to schools, including parent and staff presentations. A summary of the results will also be published on the Black Dog Institute website.

How will participant confidentiality be maintained? In all reports, participants will not be individually identifiable. Numerical data will be presented at the aggregate level. Any qualitative data reported will use the non-identifiable code allocated to it.

Data Handling, Storage, Access, and Record Keeping

Handling, Storage and Access

A unique identification number will be allocated to each participant. Names will only be linked to IDs for the purposes of duty of care reporting. All data files linking personal information (such as participants' names) to ID numbers will be stored separately from raw research data. Responses will be identified by the unique user ID only. All self-report data collected during the study will be stored in password protected files on secure servers at the University of New South Wales, with data files only accessible to authorised study personnel. Biological data will be labelled with participant ID only and securely stored in locations with restricted access. Smooth Sailing program complies with strict privacy and security and guidelines. Participants will create their own password-protected accounts and passwords must be supplied in order to access and submit personal data.

Record Keeping

In accordance with clinical trial protocols, all data obtained in the current study will be stored securely for a minimum of 15 years.

Analysis

Data will be collected using the Black Dog Institute e-health platform. Participant data will then be exported to SPSS statistical software for analyses. Statistical analyses will be performed using SPSS 21.0 (SPSS Inc., Chicago, Il, USA). The primary outcome measures will be analysed using mixed modelling which is similar to repeated-measures analysis. This type of analysis will determine any significant differences in the scores reported at time 1 (pre) and then at time 2 (post). The primary hypothesis will be evaluated by differences in pre and post scores on help-seeking questionnaires. Secondary hypotheses will be evaluated by descriptive analyses of the acceptability and feasibility questionnaires.