Phase 3 Clinical Trial Protocol

Smooth Sailing: Evaluating an online service for student wellbeing

Putting health in mind

Black Dog Institute

Contents

Title Page

Public Title: Smooth Sailing: Evaluating an online service for student wellbeing

Scientific Title: Smooth Sailing: Evaluating an online service for student wellbeing

ANZCTR Number: TBC

Date: 1st January 2018

Secondary IDs: Nil

UTN: {Blank}

Trial acronym: {Blank}

Linked study record: Nil

Health Condition: Depression, anxiety.

Condition Category: Mental health

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, Catherine King, Dr Mirjana Subotic-Kerry, Melinda Achilles, Melissa Anderson, Belinda Parker, 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.

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 Randomised Controlled trial (RCT) of an online, schools-based, mental health service called Smooth Sailing. This study will evaluate the effectiveness of Smooth Sailing in comparison to a waitlist control group.

Smooth Sailing is a service designed to screen and assess the levels of depression and anxiety among secondary high school students. Using a website, students register to the service and then complete an assessment of their mental health symptoms which consists of brief, clinically validated questionnaires. The service then allocates each student to one of five steps for which different online activities are prescribed. The school counsellor is automatically notified by the service when students are allocated to the highest steps, which indicate the most severe symptoms or if they report thoughts that they would be better off dead or harming themselves in some way. The school counsellor then follows up with these students in person.

This 12-week trial aims to evaluate the effectiveness of the Smooth Sailing service for improving help-seeking as well as reducing symptoms of depression, anxiety, and distress among secondary school students. It is hypothesised students receiving the Smooth Sailing service will report improved help-seeking, reduced distress, depression, and anxiety, when compared to the waitlist control.

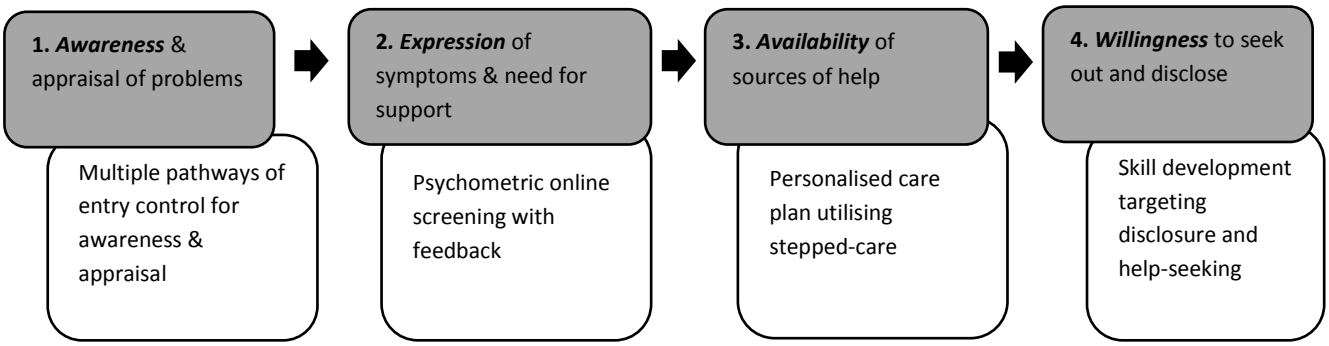
Background

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, 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.

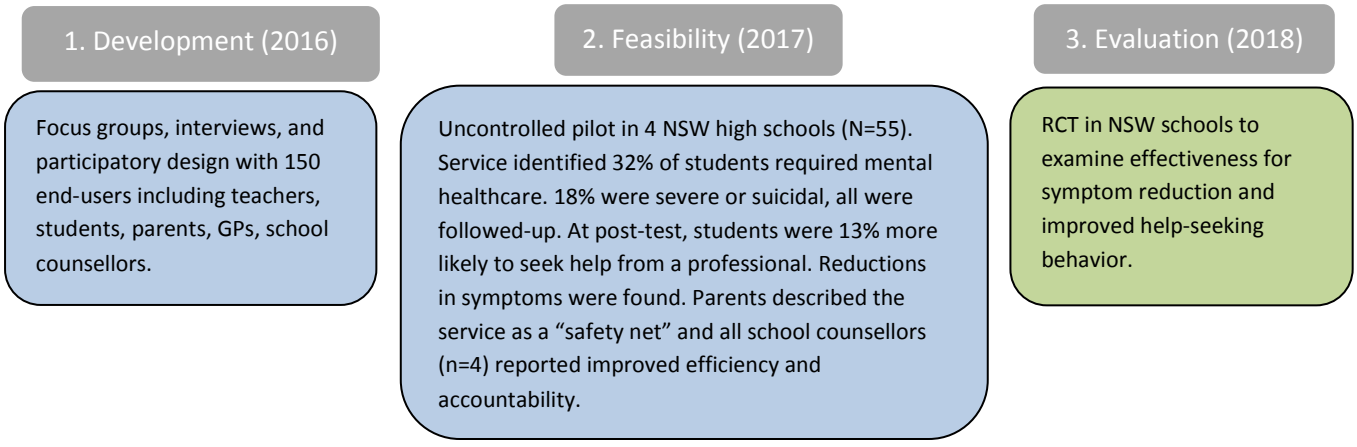
School is an ideal setting for the implementation of online stepped-care as students spend much of their daily lives in school, and it is a place of learning new skills and knowledge (Clayton, et al. 2010). However, schools currently have a fragmented approach to mental health, with some offering a school 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 service to improve help-seeking for depression and anxiety symptoms in high school students. Co-designed with students/schools/parents, the service 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 service has been named "Smooth Sailing".

Smooth Sailing is based on Rickwood et al's (2005) "Help-Seeking model" in which help-seeking is defined as a process with four key stages, as outlined below (grey squares).



Smooth Sailing as outlined above (white squares) 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 with several interacting components. This project is guided by the United Kingdom Medical Research Council's Framework for Developing and Evaluating Complex Interventions (Craig et al., 2008). To date, the development and feasibility stages have been completed. As outlined in the figure below, the next step in this process is formal evaluation, which is the premise of the current trial.



Trial Objectives and Purpose

The main objective of this trial is to evaluate the effectiveness of the Smooth Sailing online mental health service for improving help-seeking (primary outcome) as well as reducing symptoms of depression, anxiety and distress (secondary outcomes) among secondary school students.

Trial Design

Study Type

A 12-week randomised controlled trial.

Assignment

Cluster randomisation, conducted at the school level, will be employed to avoid contamination, such that schools will be randomly allocated to receive the intervention or the control condition.

Allocation/Masking/Blinding of Participants.

Randomisation will be carried out by a researcher not involved in the day-to-day conduct of the trial.

Randomisation of schools to control or intervention will be carried out according to ICH guidelines (Lewis, 1999). Schools will be allocated to a single condition (cluster design) to avoid contamination and for administrative convenience (Donner & Klar, 2000). A minimisation approach (Taves, 2010; Altman & Bland, 2005) will be used to ensure balance across conditions in terms of the Index of Community Socio-Educational Advantage (ICSEA) level (less than 1000 versus greater or equal to 1000), gender mix (co-educational versus single sex) and year level involved (year 9 students only versus multiple or other years).

Minimisation was undertaken in Stata version 14.2 using the *rct_minim* procedure (Phillip, 2017). The pool of already-available schools was sorted in a random order using the Excel 2003 data analysis random number generator and entered into the minimisation routine in ascending order using the factors specified above. Subsequent schools were assigned to an intervention arm using *rct_minim* in the order that they joined the trial and provided complete information.

Phase

Not applicable.

Type of Endpoint

Efficacy: to evaluate the intervention's effectiveness for improving help-seeking, with secondary outcomes related to symptom reductions in depression, anxiety and distress, in comparison to a waitlist control group.

Inclusion Criteria

Secondary students will be aged between 11–19 years, and currently attending high school at one of the participating 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 will be included. Participating school counsellors are required to be i) working in a participating high school for at least two days per week for the duration of the trial; ii) involved in the service; and iii) have phone and internet access for questionnaire completion and follow-up interview.

Exclusion criteria

Those not willing or able to provide informed consent will be excluded from participating.

Hypotheses

The primary hypothesis is that, compared to students in the control group, those who participate in the Smooth Sailing service will report improved levels of help-seeking. The secondary hypothesis is that compared to students in the control group, those who participate in the Smooth Sailing service will report reduced levels of distress, depression, and anxiety.

Selection and Withdrawal of Subjects

Recruitment, Screening & Consenting

Status: Completed

Recruitment of schools: This study will recruit schools through direct contact with the School Principal, School Counsellor, or Head of Wellbeing. Initial contact will be made via email from the Chief Investigator to high schools that have established research and educational partnerships with the Institute. This list consists of approximately 90 local and regional high schools that have previously participated in a trial or have expressed interest in participating in a research trial conducted by the Black Dog Institute. To ensure that the sample size is achieved, this study will also recruit other high schools through advertisements placed in various Black Dog Institute newsletter and electronic direct mailouts, social media channels, and associated mailing lists including the Schools Link Newsletters and the Department of Education networks.

Expressions of Interest will be followed up with an email from a member of the research team. This email will outline the study requirements and will include a copy of the Letter to Principal, Overview of the Service, Brief Trial Protocol, Recruitment Flyer, and relevant ethics approvals letter. The team will schedule a phone call to answer additional questions and provide further information if requested. Schools will be asked to provide a signed 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 again briefed on the study and the study protocol.

Recruitment of students: After the school principal has given consent for the school to participate in the study, the school will be randomly allocated to the intervention group or the waitlist control. Schools will then be posted the appropriate Student Participant

Information Forms for distribution among students by a school staff member. Interested students will be asked to sign the Participant Information and Consent Form (PICF) on the day of baseline assessment.

Recruitment of school counsellors: School counsellors from the participating schools will be given a copy of the School Counsellor PICF (Appendix I) as part of the school recruitment process. Interested school counsellors will be asked to contact the research team to participate.

Screening

NA

Consent

Schools: Consent to participate at the school level is demonstrated by a signed letter of support from either the school counsellor, school principal, or equivalent.

Students: Individual student consent will be given by a signed copy of the Student Participant Information and Consent Form (PICFs – Intervention and Control, see Appendices G and H) and completion of a Gillick Competency Test (Appendix M). This test consists of questions to confirm that students understand the study requirements. An opt-out consent process is employed for parental consent. Students are strongly encouraged to discuss the study with their parents. The school will also notify the parents via their usual best methods of communication (e.g., newsletter or email) and provide their parents with the study information. Parents will have 14 days from trial start date to contact the school and notify them that they do not wish for their child to participate.

Students from Sydney Catholic Schools: Students from participating schools in the Sydney Catholic Diocese are required to obtain signed parental consent in addition to providing personal consent. This is a requirement of research conducted in Sydney Catholic Schools. The Participant Information and Consent Forms for Sydney Catholic Schools (PICFs – Intervention and Control, see Appendices S and T) will be distributed to students to take home and obtain their parents' signatures. Students and their parents will be required to sign the same form to indicate consent. On the day of the baseline visit, PICFs will be checked by the researchers to ensure both forms of consent have been provided before allowing students to participate in the study.

Withdrawal of consent: The Participant Information Statement and Consent Form (PICF) 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. Participants or parents of participants wishing to withdraw from the study can do so by emailing the study (smoothsailing@blackdog.org.au) and providing either their first name and last name, or unique ID code. No reasons need to be given. All data will then be removed from the study and e-health platform.

Trial Procedure

For all students: After participation of each school is confirmed, a member of the research team will arrange a visit to conduct the baseline assessment. This will be completed online, during class time, using a computer/mobile/ or tablet device. Registration is estimated to take no more than 30 minutes. A research team member and school staff member (e.g., teacher or school counsellor) will be present to answer any questions and offer assistance. On day 43 and day 85, a member of the research team will return to the school to collect the 6-week and 12-week endpoint measures (respectively) using the same procedure for baseline.

For students in the intervention group: Smooth Sailing will produce a personalised suite of online activities that the student can do to improve their mental health. This is to be used either during allocated weekly class time or at their own leisure. Participants will also receive four monitoring questionnaires which are delivered via email (with SMS reminder) at 14-day intervals (i.e. day 15, day 29, day 57 and day 71). Once all students have completed the baseline assessment, a link to a secure online portal will be issued to the school counsellor. The school counsellor will be able to log into this system to identify which students require follow-up. An automated email reminder alert to check the portal will also be sent to the school counsellor and research team for each student that requires follow-up. No identifiable information will be contained in the email.

For school counsellors in the intervention group: At baseline school counsellors will be asked to complete a questionnaire, and at the final 12-week assessment, they will be asked to repeat this questionnaire. Additionally, school counsellors will be invited to participate in a short in-person or phone interview to discuss their experiences in the study.

Treatment of Subjects

Intervention

Brief 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 will step up if they have not responded to treatment after a set period of time. Smooth Sailing involves:

1. **Registration & Baseline Assessment.** In class time, participants are given a slip of paper with the service URL and their unique identification code. Using a school or personal internet device, students visit this website and undertake registration. Before registration

commences, participants are also asked to complete the Gillick Competency Test. Upon correct completion of this, participants are invited to create a personal profile (name, age, email address, mobile phone number, gender, history of mental health issues, and use of the internet for mental health information). Once a personal profile is created, a series of questionnaires will be used to measure the presence of depression, anxiety, and help-seeking attitudes/ behaviours (see Table 4). This will take 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 is based on Clinical Practice Guidelines for Adolescent Depression. The step allocations are: 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 is allocated to Step 3 or 4 or reports thoughts that they would be better off dead or harming themselves in some way triggers an electronic notification alert, which is automatically sent to the school counsellor for further investigation. This allows the school counsellor to facilitate a face-to-face session to provide the student with counselling, or them refer on to external services. The online psychoeducation consists of five modules on i) general mental health, ii) depression, iii) anxiety, iv) seeking help for yourself, v) 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, and 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 CBT programs: i) MoodGym (Australian National University) and ii) The BRAVE Program (University of Queensland). MoodGym is an interactive self-help, online program 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. At four timepoints in the study (Day 15, Day 29, Day 57 and Day 71) participants receive an automated 4-item monitoring questionnaire to assess how they are doing. This consists of the PHQ-2 and GAD-2 and will be delivered via email or SMS. Students are then reminded to use the program, with no symptom feedback given.

5. Six-week Reassessment (6-week follow-up): At Day 43, researchers revisit the schools, where participants are asked to log into the service using the same URL and unique ID codes and are delivered the follow-up questionnaires. The results of these questionnaires are used to determine whether a participant had responded to care or needs 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 6 weeks of their baseline allocation, they would be "stepped up" to the next level of care. See Table 3 below for the stepping matrix. The matrix was designed such that a participant would not be stepped down, instead will either remain at the same step or step up.

6. 12-week Reassessment (Post-test/ final endpoint): At Day 85, researchers revisit the schools. Participants again log into the service using the same URL and unique ID codes and are delivered the final endpoint questionnaires. School Counsellors will receive the same types of automated alerts as scheduled in baseline assessment when a student rates their symptoms to be severe or indicative of self-harm or thoughts of dying.

Throughout the trial, participating students will use Smooth Sailing at pre-test (for registration and baseline measure collection), at 6-weeks (for reassessment) and at 12-weeks (for final endpoint). Any students who could not access the website at 6-weeks or 12-weeks due to IT issues will be given a paper copy of questionnaires to complete and the research team will input that data electronically into the dataset. Researchers will use a paper scoring method to calculate participants' step at these timepoints and will inform the school counsellor verbally if the student required follow-up. The online portal will be immediately updated once the research team had entered the data by hand.

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 psychoeducation.** 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 psychoeducation 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	**Support from the school counsellor in addition to self-directed online cognitive behavioural therapy (CBT) and the online psychoeducation material.** This support will be offered face-to-face by a school counsellor. In the current study, any participant who reports moderately severe 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	**Face-to-face support from the school counsellor, in addition to self-directed online cognitive behavioural therapy (CBT) and the online psychoeducation material.** In the current study, any participant who reports severe 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.

Table 3. Step Allocations

Step at 43 days	Step at Baseline	0	1	2	3	4
		Step at 85 days				
0 (Minimal)		0	1	2	3	4
1 (Mild)		1	1	2	3	4
2 (Moderate)		2	2	3	3	4
3 (Moderately severe)		3	3	3	4	4
4 (Severe)		4	4	4	4	4

During the trial assessments, 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 is at step 3 and 4 (i.e. moderately-severe to severe depression/anxiety) or reports suicidal ideation throughout the study.

Comparator:

Control - Waitlist. Schools that are allocated into the control condition will be placed on a waitlist to receive the Smooth Sailing program after the trial data collection has been completed and analysed. As such, students from control schools will receive treatment as usual during the initial 12-week study period. This means they will still be able to access the school counsellor when needed and permitted to participate in any mental health education or activities initiated by the school. During this time, students from control schools will complete a series of questionnaires at baseline, 6- and 12-week follow-up. Upon completion of the study period, control schools will be given the option to implement the Smooth Sailing program in their school. If the school goes ahead, students from control schools will be able to register to the Smooth Sailing service. Once consent is obtained, students in the control condition will be asked to visit the control website to complete the screening assessment. At 6-weeks and 12-weeks, students will be asked to complete another set of online questionnaires during class time. Access to the service will cease after 12 weeks.

Assessment of Efficacy

Outcome Measures

Table 4 provides a basic overview of the outcome measures.

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

	Measure(s)	Day 1	Day 15	Day 29	Day 43	Day 57	Day 71	Day 85
ALL	Demographics	X						
	General Help-Seeking Questionnaire (GHSQ)	X						X
	Brief Barriers to Help-seeking (BASH-B)	X						X
	Mental Health Literacy & Stigma Scale	X						X
	Mental Health History	X			X			X
	DQ5	X			X			X
	CES-DC	X			X			X
	GAD-7	X			X			X
	Actual Help-seeking Questionnaire (AHSQ)	X			X			X
Intervention only								
	PHQ-9	X			X			X
	PHQ2 + GAD2		X	X		X	X	
	Satisfaction Questionnaire							X

Pre-test/Baseline Assessment

On Day 1 (Baseline), all participants will complete:

- Demographics questionnaire;
- Distress Questionnaire-5 (DQ5);
- Centre for Epidemiologic Studies Depression Scale – Child version (CES-DC);
- Generalised Anxiety Disorder Questionnaire (GAD-7);
- General Help-Seeking Questionnaire (GHSQ);
- Actual Help-Seeking Questionnaire (AHSQ);
- Barriers to Seeking Help (BASH-Brief);
- Mental Health Literacy and Stigma Scale.

Participants allocated to the Intervention arm will also complete:

- Patient Health Questionnaire (PHQ-9).

Check-in/Monitoring (14-day intervals)

At four timepoints in the study (Day 15, Day 29, Day 57 and Day 71) participants in the Intervention arm will complete:

- Patient Health Questionnaire 2 (PHQ-2);

- Generalised Anxiety Disorder Questionnaire (GAD-2).

6-week Follow-up

At day 43, all participants will complete the:

- Mental health information questionnaire;
- Distress Questionnaire-5 (DQ5);
- Centre for Epidemiologic Studies Depression Scale – Child version (CES-DC);
- Generalised Anxiety Disorder Questionnaire (GAD-7);
- Actual Help-Seeking Questionnaire (AHSQ).

Participants allocated to the Intervention arm will also complete:

- Patient Health Questionnaire (PHQ-9).

Final endpoint Assessment (12-week Follow-up)

At Day 85, all participants will complete:

- Mental health information questionnaire;
- Distress Questionnaire-5 (DQ5);
- Centre for Epidemiologic Studies Depression Scale – Child version (CES-DC);
- Generalised Anxiety Disorder Questionnaire (GAD-7);
- General Help-Seeking Questionnaire (GHSQ);
- Actual Help-Seeking Questionnaire (AHSQ);
- Barriers to Seeking Help (BASH-Brief);
- Mental Health Literacy and Stigma Scale.

Participants allocated to the Intervention arm will also complete:

- Patient Health Questionnaire (PHQ-9);
- Service Satisfaction Questionnaire.

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 a medical expert. This team meets monthly, 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 regard 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 depressive 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 a 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.
- 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 (e.g., let the researcher or the teacher know immediately by putting their hand up or asking to be excused). This researcher will have a valid Working with Children Check (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 a member of the research team 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 them 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

Table 5 outlines a series of possible adverse events that may be captured by the assessments within this study among the Intervention group only. These events will be monitored by the number of email triggers sent by the service during the study period.

Table 5. 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 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.
"Moderately severe" or "severe" anxiety at baseline	A Generalised Anxiety Disorder (GAD-7) baseline score of 15 or above.	
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.

The "Responding to risk of harm" document provides a more detailed outline for decision making regarding risk of harm in the current trial.

Table 6 outlines additional adverse events during the trial which are not captured by the assessments and our action.

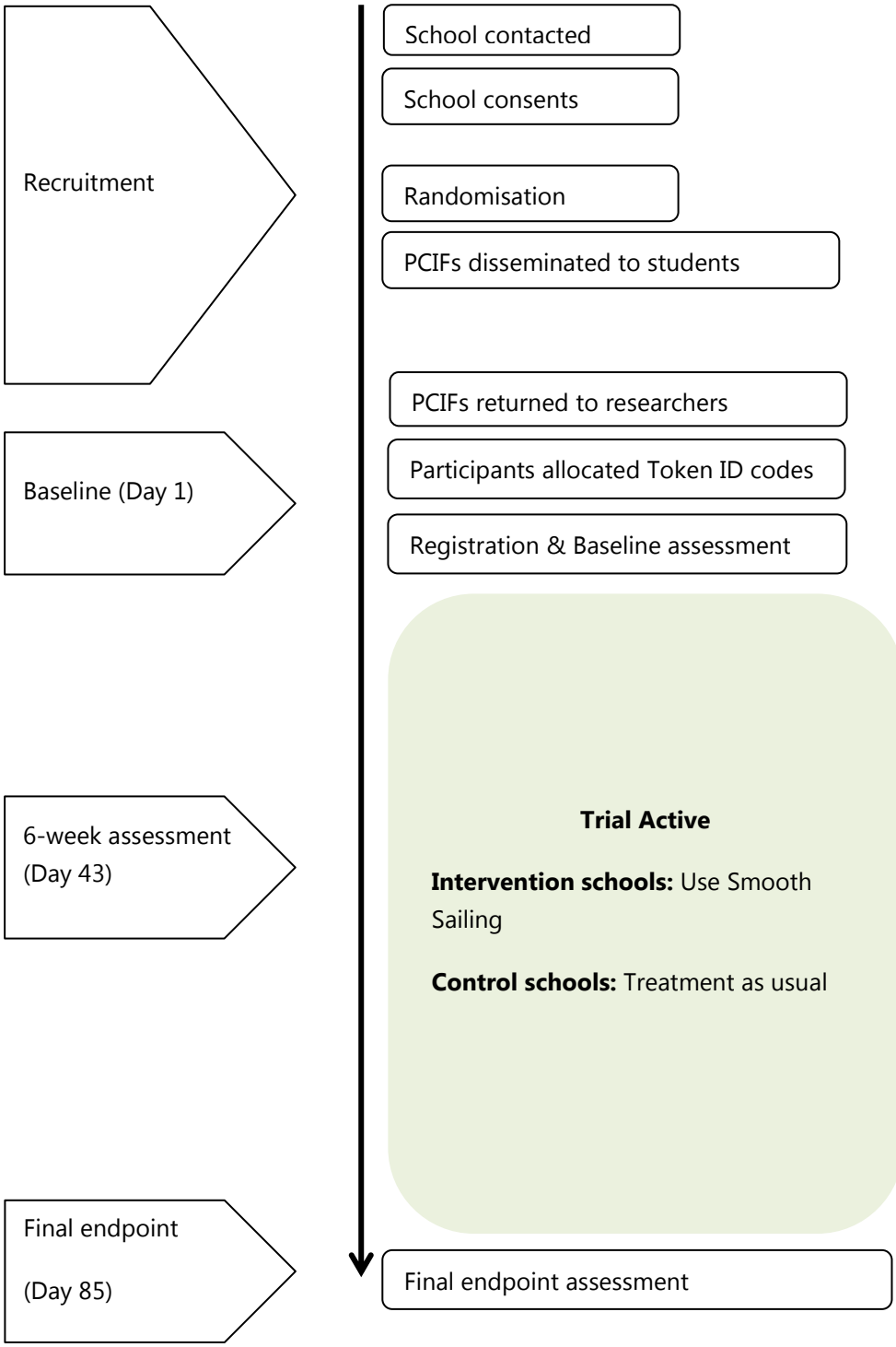
Table 6. Additional Adverse Events

Event	Assessment/Criteria	Action
Participant reports elevated suicide risk to school	School Counsellor is notified and assesses 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 at 6 and 12-week follow-up points. The research team will report to the Outcomes Advisory Group at 2-week intervals on the total number of alert emails being sent.
Participant reports depressed mood to school		
Participant reports anxiety to school		
Risk of significant harm as identified by school contact		

Statistics

The target sample size is 1600 participants. This calculation was based on detecting an effect size of 0.20, which is similar to that obtained in prior school-based depression intervention programs. Power was set at 0.8, $\alpha = 0.05$ (two-tailed) and correlation of 0.5 assumed between baseline and endpoint scores. To allow for possible clustering effects, a design effect was calculated assuming an Intra-Class Correlation (ICC) of 0.02 and an average school size of 300 students. This estimate was derived from previous Australian school-based studies. The estimated sample size also accommodates for a 20% attrition rate based on previous school-based trials. To achieve the desired sample size, 16 schools will be selected for study inclusion, based on approximately 100 participating students per school.

Trial Flow


Recruitment
Baseline (Day 1)
6-week assessment (Day 43)
Final endpoint (Day 85)
School contacted
School consents
Randomisation
PCIFs disseminated to students
PCIFs returned to researchers
Participants allocated Token ID codes
Registration & Baseline assessment
Trial Active
Intervention schools: Use Smooth Sailing
Control schools: Treatment as usual
Final endpoint assessment

Trial Schedule

Date	Task
October 2017	Submit UNSW HREC protocol
November 2017	Submit NSW Education SERAP protocol Register clinical trial protocol
December 2017	School recruitment
January 2018	Confirm school involvement
February to April 2018	Baseline assessments
March to June 2018	Trial Active
30th June 2018	Endpoint assessments completed
July to September 2018	Data analysis
December 2018	Trial complete

Ethics

Ethical body (1): UNSW HREC

Name: University of New South Wales Human Research Ethics

Address: UNSW, High St, Randwick, NSW, 2031

Country: Australia

Submit date: 18.10.2017

Approval date: 24.11.2017

Approval ID: HC17910

Ethical body (2): SERAP

Name: State Education Research Applications Process (SERAP)

Address: School Policy and Information Management (SERAP), NSW Department of Education, Locked Bag 53, Darlinghurst NSW 1300

Country: Australia

Submit date: 31/10/2017

Approval date: 10/01/2018

Approval ID: SERAP 2016471

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. A final report will also be submitted to the funding body.

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

Smooth Sailing is hosted on the Faculty of Medicine, UNSW, servers. These are encrypted servers with data backups occurring daily.

At baseline, participants will create their own password-protected accounts within Smooth Sailing. 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 as part of the School Counsellor login portal. School Counsellors will use a password to log into the portal to easily identify which students require follow-up.

For research analysis purpose, 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 with data files only accessible to authorised study personnel. Smooth Sailing program complies with strict privacy and security and guidelines and is underwritten by the Institute's Privacy Policy which can be found here https://www.blackdoginstitute.org.au/privacy

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 outcome measures will be analysed using mixed modelling with intention to treat. This type of analysis will determine any significant differences in the scores reported at time 1 (baseline) and at time 2 (6-week) and time 3 (12-week post). The primary hypothesis will be evaluated by differences in pre and post scores on help-seeking questionnaires, with secondary hypotheses relating to depression, anxiety, and distress symptoms.