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Protocol for the Process Evaluation of a Complex Intervention Delivered in Schools to Prevent Adolescent Depression: The Future Proofing Study

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Protocol for the Process Evaluation of a Complex Intervention Delivered in Schools to Prevent Adolescent Depression: The Future Proofing Study

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Abstract

Introduction: Process evaluations provide insight into how interventions are delivered across varying contexts and why interventions work in some contexts and not in others. This manuscript outlines the protocol for a process evaluation embedded in a cluster randomised trial of a digital depression prevention intervention delivered to secondary school students (The Future Proofing Study). The purpose is to describe the methods that will be used to capture process evaluation data within this trial.

Methods and Analysis: A mixed methods design will be used with data collected in the intervention arm of the Future Proofing Study. Data collection methods will include semi-structured interviews with school staff and study facilitators, automatically collected intervention usage data, and participant questionnaires (completed by school staff, school counsellors, study facilitators, and students). Information will be collected about: i) how the intervention was implemented in schools, including fidelity; ii) school contextual factors and their association with intervention reach, uptake and acceptability; iii) how school staff, study facilitators, and students and responded to delivering or completing the intervention. How these factors relate to trial effectiveness outcomes will also be assessed. Overall synthesis of the data will provide school cluster-level and individual-level process outcomes.

Ethics and Dissemination: Ethics approval obtained from the University of New South Wales. Results will be submitted for publication in peer reviewed journals and discussed at conferences. Our process evaluation will contextualise the trial findings with respect to how the intervention may have worked in some schools but not in others. This evaluation will inform the development of a model for rolling out digital interventions for the prevention of mental illness in schools.

Trial Registration: The randomised controlled trial has been prospectively registered: ACTRN12619000855123. Registered 31 May 2019,

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https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=377664&isReview=true

Keywords: Process evaluation, complex intervention, mixed methods, adolescent mental health, depression, prevention, randomised controlled trial, implementation.

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Strengths and Limitations of this Study

- This is a process evaluation embedded in a randomised clinical trial, which is critical for understanding how interventions are delivered in real world contexts.
- This protocol is the first to illustrate how to embed a process evaluation into a school-based trial of a digital depression prevention intervention, including the use of flexible and pragmatic quantitative and qualitative data collection methods.
- School context factors will be rigorously assessed and analysed for contribution to intervention reach and completion, uptake of study processes, and clinical outcomes.
- Study outcomes will guide sustainability efforts in the delivery of digital depression prevention interventions in schools.

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Introduction

Embedded in randomised controlled trials, process evaluations provide insight into reasons why interventions work in some contexts and not in others. These process evaluations can help to demystify the 'black box' of complex intervention trials by taking into account contextual factors, differences in ways the intervention is delivered, and adaptations made for intervention delivery into a particular system (1, 2). Contextual factors typically include features of the organisation or broader environment that influence the delivery of the intervention (e.g., leadership, engagement, culture, political landscape). Considering the contribution of contextual factors is necessary to aid interpretation of trial outcomes, maximise the knowledge gained from trials, identify optimal delivery processes across different settings, and inform broader dissemination efforts. In recognition of this need for process evaluations, the UK's Medical Research Council (MRC) set out a framework that emphasises the value of these evaluations in order to capture both contextual and implementation factors associated with complex interventions (3).

In line with best-practice recommendations that study protocols which pre-specify methods and approaches should be published to maintain research integrity (4), we describe a protocol for a mixed methods process evaluation embedded within a cluster randomised controlled trial (cRCT) known as the Future Proofing Study (FPS). The FPS is a large school-based trial examining whether depression can be prevented using cognitive behaviour therapy (CBT) delivered by smartphone application (5).

There has been an increase in the availability of digital mental health programs which show promise in addressing the significant disease burden associated with depression (6). Depression often first emerges during adolescence (7) and treatment alone cannot adequately reduce this burden (8). Accumulating evidence indicates that early adolescence is the ideal developmental window during which to intervene because it captures young people *before*

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the incidence of depression increases exponentially around the age of 16-17 years (9, 10). Therefore, increased efforts are being directed toward prevention approaches that are developed specifically for delivery among adolescents.

While there is evidence supporting the value and effectiveness of prevention programs in schools (11, 12), their uptake has been significantly limited by low levels of help-seeking (13) as well as practical constraints in cost and scalability. A lack of understanding about how to deliver these interventions sustainably at scale, and engage those who stand to benefit, have hampered the translation of prevention approaches into the community.

Two ways to overcome the barriers of cost and scalability of implementing adolescent depression interventions are:

- Delivering universal prevention programs in schools, and
- Using technology to deliver programs, which tends to be lower cost than traditional face-to-face methods (14).

Working with schools to deliver universal prevention programs, to every student, regardless of their risk, circumstance, or symptom profile, not only dramatically increases the potential reach of interventions, it also means that these programs can eventually be integrated into the curriculum and delivered to every student, making this approach a sustainable implementation strategy for widescale delivery and dissemination. Additionally, working with schools to deliver such programs reduces the need for young people to actively seek professional help. This is critically important - despite having a significant need, fewer than 80% of young people with mental illness seek help and receive the services they need (15, 16). The scaffolding provided by schools can be leveraged to deliver prevention programs to all students, which fits with a trend for schools to be designated the first point of contact to support youth mental health problems when they first emerge (9). Process

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evaluations such as the one described in the current paper are relatively rare, particularly those examining digital (as compared to face-to-face) interventions in school settings. In fact, we were unable to find any process evaluation descriptions in the literature that evaluate digital mental health programs in school settings. This process evaluation is an initial step towards addressing that gap.

Technology offers a promising way to deliver mental health interventions to the community. Digital mental health interventions offer two key advantages over face-to-face approaches – first, they are cheaper to access and more cost effective (17, 18), and second, they can be used to reach people across vast geographic areas. The latter is particularly important given Australia's geography, where remoteness and low population density meant that people in regional and rural areas often do not have the same level of access to mental health services as people in metropolitan areas. With more young people than ever using smartphones, mental health intervention delivered online or through applications represents an exciting avenue for reaching adolescents.

The Future Proofing Study (FPS)

The trial that is the subject of this process evaluation is the FPS. The FPS addresses barriers of reach, cost, and scalability by delivering a depression prevention program via a smartphone app to Year 8 secondary school students aged 12-13 years. This study is being conducted with approximately 200 Australian schools (up to 10,000 participants), of which half will be allocated to the intervention condition. The primary outcome is symptoms of depression. Secondary outcomes include anxiety, psychological distress and insomnia, among others. Symptom outcomes will be assessed at baseline, post-intervention, six months (primary outcome only), and then annually for five years. The primary endpoint is 12 months following baseline. More details are available from the Australian New Zealand Clinical Trials Registry (ANZCTRN12619000855123) and protocol paper (Werner-Seidler et al.,

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2020).

The intervention being delivered is known as SPARX, a CBT-based program incorporating gamification principles. The development and initial evaluation of SPARX has been documented in detail previously (19). SPARX has been tested in an Australian sample of secondary students (delivered via computer) and shown to prevent depression in the lead up to final school exams (20). The gamified intervention teaches young people about the relationship between thoughts, feelings, and behaviour. Skills learnt through SPARX include emotion identification, emotion regulation, behavioural activation (being active), recognising and challenging unhelpful thoughts, and practical problem solving. SPARX consists of seven 20-minute modules. The intervention is fully automated, and the therapeutic components are standardised. See the trial protocol for full intervention details (Werner-Seidler et al., 2020).

School Engagement and Recruitment

The FPS requires multiple levels of approval, beginning with state department and independent school body approval (NSW Department of Education; Catholic school dioceses), followed by individual school engagement. An engagement strategy for this study involves sending electronic communication material to all schools across New South Wales and in other Australian capital cities, targeting school principals and wellbeing staff to invite them to participate in this study opportunity. Schools are invited to submit expressions of interest and are subsequently followed up by the research team over the phone to explain more about the study. The schools for which the FPS is a good fit (as determined by the school) are then signed onto the study, with support from the principal, the school counsellor, and at least one other staff member (typically a teacher). In line with best practice in implementation science (21), this group of 2-3 staff members (typically not including the principal) will form the school-specific 'study implementation team'. After signing on to the study, several webinars are scheduled throughout the lead up to the study start date, so that

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school staff and parents can listen to a 15-minute study overview from the trial manager and have their questions answered.

Preparation

In preparation for in-class assessment sessions, study facilitators (volunteer research assistants) are recruited to support the study. The purpose of these facilitators is to attend schools to introduce the study to students, and ensure the technology is functioning so students can download the SPARX app and complete the baseline (and post-assessment) questionnaires. All facilitators go through an interview and screening process prior to selection, then attend a half day face-to-face training session before supporting the study in schools. This training provides an overview of the study and detailed information about their roles within schools, including a step-by-step guide to running the sessions. Discussion and practice are core components of the training.

Aims and Objectives

1. To evaluate the reach (including completion), uptake, and acceptability of the intervention (school- and student-level).
2. To understand the contribution of contextual factors (e.g., characteristics of the outer/inner setting, intervention, individuals) on:
    - School-level fidelity to the implementation strategy
    - Implementation outcomes (intervention reach, uptake, acceptability), as assessed from the perspectives of school staff, teachers and students.
3. To examine the impact of school-level variation (in implementation fidelity and outcomes) on clinical effectiveness outcomes at the school- and student-level.

The aim of this process evaluation is to understand how SPARX is implemented and delivered in schools, and to identify systematic differences and variation in delivery between clusters (individual schools). The differing ways in which schools support and deliver the

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intervention will inevitably impact its effectiveness, and this evaluation will assess these differences (3, 22). For example, degree of support from senior school leaders who would be expected to understand that participating in study activities is a priority for the school will likely impact effectiveness at the cluster level. A secondary aim is to evaluate individual-level factors likely to impact outcome. For instance, young people's openness to receiving mental health material via an app will likely impact intervention acceptability and completion. This process evaluation has been designed to capture important information from teachers, school staff and students at both the school and individual level, which may ultimately impact the effectiveness of the intervention on clinical mental health outcomes.

Findings will provide insight into factors which support and/or hinder the implementation of digital universal mental health programs in school settings. Knowledge gained from this process evaluation will help to inform the development of a model and guide for how to best deliver digital mental health programs to young people in schools.

Methods and Analysis

Design

This study uses a hybrid type 1 approach (23), with a focus on implementation process factors and outcomes in the context of an effectiveness trial. The evaluation is guided by the CFIR and RE-AIM framework (24, 25). In keeping with Nilsen's categorisation of implementation theories, models, and frameworks, these frameworks help us to understand different parts of the implementation process (26). The CFIR will be used to identify **barriers and facilitators** to intervention implementation and effectiveness (26). The CFIR is a widely used deterministic theoretical framework which has been applied in multiple settings (27), including schools (e.g., 28). The CFIR identifies five major domains, including (i) the outer setting, which includes the social, political and economic context that the organisation

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in which implementation is occurring exists; (ii) the inner setting, which includes features and characteristics of the organisation such as leadership and relative priority; (iii) the characteristics of individuals, which includes organisational staff knowledge and attitudes about the intervention and their role and identification within the wider organisation; (iv) the characteristics of the intervention itself and; (v) implementation processes, which includes the ways that the intervention will be delivered in a given context. Normalisation Process Theory will be used to provide additional insights into implementation processes (NPT; 29). NPT aims to identify and explain the implementation of new interventions and how they become integrated into routine care.

The RE-AIM framework will be used to evaluate the **implementation outcomes**, including fidelity to the implementation strategy, intervention reach, uptake, and acceptability/appropriateness (24, 30). These outcomes also map onto the framework of implementation outcomes proposed by Proctor and colleagues (31, 32). Fidelity refers to the extent to which the intervention was delivered as intended. Reach refers to the proportion of eligible participants who opened, used, and completed the intervention, as well as the proportion of students from the entire cohort of eligible students in intervention schools who consented to participate. Uptake refers to the proportion of schools that were onboarded to the study (intervention and control arms), and of school staff who were willing to support the delivery of the intervention (intervention arm only). Reach and uptake also incorporate the representativeness of the sample (school-level and individual-level). Acceptability and appropriateness refer to the perceived agreeableness or fit of the intervention. This evaluation will incorporate how the barriers and facilitators identified through the CFIR impacted the implementation outcomes, and, in turn, how these implementation outcomes impacted effectiveness outcomes.

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Logic Model

Following MRC guidance (3), the research team developed a logic model for the FPS process evaluation in a series of participatory workshops. The logic model was prospectively informed by key CFIR constructs identified in previous literature as being important in school-based studies, but also feasible and appropriate to measure within the school context in the FPS. The key constructs included the outer setting, inner setting, individual characteristics, and intervention characteristics. The logic model (Figure 1) was developed to consider the key factors (mapped to the CFIR) that would potentially impact implementation of the intervention (mapped to RE-AIM), as well as its clinical effectiveness. The process evaluation method, including the selection of dependent variables and design of surveys and semi-structured interview guides, were derived from this logic model. See Table 1 for CFIR/RE-AIM domains, key research questions, process data, and data that will be collected within each domain.

A pilot study of 8 schools conducted in 2019 was used to assess the suitability of the planned implementation strategy and process evaluation methods. We retrospectively applied our logic model to collected data to evaluate whether our methodology captured relevant constructs, and sufficient variation in these constructs. We integrated learnings from this pilot study using a dynamic feedback process to strengthen our methodology for the full-scale FPS phase. Some minor changes were made following this pilot which relate to the CFIR, including a greater emphasis on sub-constructs such as school climate (inner setting).

<INSERT FIGURE 1 HERE>

Figure 1. Logic model. The model shows that CFIR constructs including school context characteristics, school organisational characteristics, and individual characteristics, will

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influence how staff engage with the implementation strategy. The intervention itself, which includes the core cognitive-behavioural therapeutic components, is conceptualised as standardised across individuals because it is delivered digitally, follows a fixed schedule and does not incorporate tailored content. The yellow input factors are expected to vary across schools and individuals, thus influencing engagement and flexibility of the implementation strategy and in turn, implementation outcomes and student-level outcomes. The logic model and implementation plan were externally peer reviewed by an experienced and internationally recognised implementation scientist outside the team within an implementation workshop. For details on assessment of these factors, see Table 1.

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Table 1 – Process evaluation details including process data, outcome data, data type and source

CFIR and RE-AIM Constructs	Research Aim	Process or Outcome Data	Data Type and Source
Outer Setting			
School contextual characteristics	What was the broad context of the schools in which the SPARX intervention was delivered? (Aim 2)	School socio-economic index School location (metropolitan/regional)	Publicly available information (ICSEA, GPS)
Inner Setting			
School organisational characteristics	What were the characteristics of the delivery environments (schools)? (Aim 2)	School size, type, composition, funding School culture	Publicly available information (school size, type, funding) SSPICSH (assesses school culture) Interviews with school staff
	What were the barriers and facilitators that affected buy-in, delivery, and student uptake? (Aim 2)	Implementation climate, relative priority, competing demands, leadership, school counsellor availability and level of support, networks and communication, school culture and climate, school readiness for implementation	Implementation Climate measures (staff and students) Relative Priority measure Competing Demands measure Interviews with school staff Checklists completed by trial manager Other administrative data including number of staff allocated to assist with delivery and consent process, level of communication with the research team
School leadership	How supportive of delivering SPARX were school principals, deputy principals and executives? (Aim 2)	Level of support and buy in from school leaders	Interviews with school staff
Individual Characteristics			
School staff	What were the characteristics (including attitudes, beliefs, traits) of school staff supporting the delivery of the intervention? (Aim 2)	Age, gender, current employment, role etc	Demographics questionnaire
	How supportive of delivery were school staff who were involved on-the-ground? (Aim 2)	Leadership, skills, motivations, expectations, self-efficacy, expectations, time available, knowledge and beliefs about the intervention, study buy in	Implementation Leadership Scale Interviews with school staff Qualitative feedback based on informal observation
Study facilitators	How well did study facilitators attending schools support the delivery of the intervention? (Aim 2)	Age, employment Skills, self-efficacy or confidence, motivations and expectations	Demographics questionnaire Self-confidence measure Interviews with study facilitators

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Students	What were the characteristics of young people that affected intervention uptake and effectiveness? (Aim 2)	History of mental illness	Reported by Year 8 students as part of the online FPS survey
Intervention Characteristics			
SPARX	Were there any barriers to intervention use? (Aim 2 & 3)	Technical issues	Logs of technical issues sent through schools, parents and participants IT data pertaining to technical problems Informal feedback provided by schools and research staff attending schools
	What do staff think about the efficacy and advantage of using the intervention? (Aim 2)	Evidence strength and quality, relative advantage	Relative Advantages measure Anticipated Benefits measure Interviews with school staff
Implementation Processes			
Normalisation and integration	How did school staff perceive the implementation processes? (Aim 2)	Coherence, cognitive participation, and collective action	NoMAD
Implementation Outcomes			
Fidelity to the implementation strategy	To what extent was the intervention implemented as planned? (Aim 2)	School delivery of the FP program, including changes to the plan	Completed implementation checklists, emails and feedback forms Interviews with school staff
Reach	What was the extent to which those who were eligible to receive SPARX used it? (Aim 1)	Proportion of eligible participants who consented to participate; proportion who opened, used and completed the SPARX intervention Representativeness of the student sample	Administrative data about consent. Digital analytic data including usage (app downloads, installs, opens), completion rate (modules completed) and time spent using SPARX Reported by Year 8 students as part of the online FPS survey
Uptake	How many eligible schools participated in the study? Within those schools, how many staff supported the delivery of SPARX? (Aim 1)	Proportion of eligible schools that were onboarded to the study; proportion of school staff (in intervention schools) who supported SPARX Representativeness of the sample	Administrative data Publicly available information about schools and self-report demographic data from school staff
Acceptability/appropriateness	How satisfied were participants with the intervention? (Aim 1)	Acceptability/appropriateness of the intervention, expectations	Reported by Year 8 students as part of the online FPS survey Informal conversations and feedback provided by Year 8 students
		Acceptability/appropriateness of the Future Proofing program (including SPARX)	Implementation Appropriateness measure Interviews with school study staff

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	How satisfied were school staff with supporting the intervention the FP program (including SPARX)? (Aim 1)	Informal conversations and feedback provided by school staff
Across Domains		
	How might the relationship between the intervention, the staff supporting the program, and context of each school shape variation in outcomes (implementation strength metric)? (Aim 2 and 3) What key lessons emerge from this study that can be generalised to the implementation of digital mental health programs in schools more broadly?	

Note. The process data and outcomes are mapped onto Figure 2. CFIR = Consolidated Framework for Intervention Research; RE-AIM = Reach, Effectiveness, Adoption, Implementation, Maintenance; Aim = Aims outlined in the Aims and Objectives section; SSPESH = Survey of School Promotion of Emotional and Social Health; NoMAD = Normalisation Measure Development questionnaire.

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School Implementation Strategy

The school implementation strategy was developed by the study authors. The authors drew on their experience in school-based intervention delivery and integrated feedback from teachers and school staff from several completed school-based trials that delivered digital interventions to school students (20, 33). Stakeholder consultation specifically for this study involved discussions with the Department of Education, consultation with several school parent committees and consultation with both youth and parent Lived Experience Advisory Panels. This strategy was also refined following the first pilot wave involving eight intervention schools.

The school 'study implementation teams' are principally responsible for the implementation of the intervention and liaising with the research team. As described earlier, these teams typically incorporate at least one classroom teacher and one school counsellor to assist with the intervention delivery. Study facilitators also support the delivery of the SPARX intervention by attending schools for the first school session.

Implementation Strategy. During the active intervention phase, schools allocate a minimum of 4 x 20-minute school class sessions during which students complete the SPARX intervention. The additional three sessions may be completed either in class if permitted by the schools, or in the students' own time. The implementation strategy developed by the project team and stakeholders to support the completion of the SPARX intervention comprises:

- Standardised facilitator training delivered face-to-face over a half-day
- Study facilitators are present at schools to support students in downloading the SPARX app and completing the baseline assessments
- School implementation team provided with a SPARX user-guide and information booklet they can refer to during the sessions

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- Schools provide students with weekly verbal reminders in home classrooms to use the app regularly
- Schools publish brief information about the study and mental health tips in the school weekly newsletter
- Schools liaise with research team weekly to troubleshoot problems

This is the strategy being outlined to schools by the research team and adherence to this strategy will be assessed. Whether or not schools schedule more than the four mandated in-class sessions for intervention completion is flexible and can be adapted to suit the preferences of the school. Student participants receive a $20AUD voucher after the intervention period to cover any phone or data related costs incurred. See Figure 2 for details of training and delivery structure.

<INSERT FIGURE 2 HERE>

Data Collection Methods and Participant Groups for Process Evaluation

There are three participant groups taking part in the process evaluation: Year 8 students, school staff members (e.g., teaching and counselling staff), and study facilitators (see Table 2). School staff members will be members who are responsible for leading the delivery of the study in their school or will be teaching staff who have a supporting role (e.g., home room teachers who provide reminders to students to complete the intervention).

Four types of data will be collected and triangulated: self-report questionnaire data, digital analytic data, administrative data, and qualitative interview data. Self-report questionnaire data specific to the process evaluation will be collected from staff and study facilitators using online survey software (Qualtrics) programmed by one of the authors (JB). These questionnaires assess demographic information, school organisational characteristics,

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individual characteristics, intervention characteristics, implementation processes and implementation outcomes. Where no available published questionnaires were identified as being suitable for this process evaluation, we adapted existing standardised measures or developed our own items (details below). Self-report questionnaire data from Year 8 students about intervention use and feedback will be collected from an online survey (details described in 5) at the post-assessment time point (after the six-week intervention stage). Digital analytic data about intervention use will be captured by the purpose-built Black Dog Institute research platform, which is being used for the broader FPS. Administrative data will be collected through a range of sources, including staff observations, and communications with the research team. Qualitative data will be collected using semi-structure interviews. All data collected will be from intervention schools only as no intervention is implemented in control schools. Student and school staff data will be collected immediately after the intervention period has been completed; facilitator data will be collected both before and after the intervention period.

Table 2. Summary of data forms provided by each of the participant groups

	Questionnaire	**Individual interview**	**Digital analytics**
Year 8 students	✓		✓
School staff	✓	✓	
Facilitators	✓	✓	

Implementation Predictors

School Organisational Characteristics (Inner Setting).

Publicly Available Information. Publicly available information will be collected about school contextual characteristics, including socio-economic level, size, location, type,

and funding.

General School Culture. School staff will complete the Survey of School Promotion of Emotional and Social Health (SSPESH; 34) and a measure of organisational culture (35). The SSPESH assesses a school's capacity to promote social and emotional wellbeing, and contains four subscales: Positive School Community, Student Social and Emotional Learning, Engaging Families, and Supporting Students Experiencing Mental Health Difficulties. Items are rated on a 4-point Likert scale from 0 (not yet in place) to 3 (completely in place) and preliminary investigations support the scale structure and criterion-related validity (34).

We adapted a 9-item questionnaire about general culture within a health care setting to use within the school setting (35). Items are rated on a 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree). Lower scores indicate a more positive working culture, which includes transparency, productive working relationships, and receptivity to feedback. Previous investigation has shown that this measure has good internal consistency, although overlaps somewhat with other sub-constructs within the inner setting (e.g., learning climate; 35).

Implementation Climate. School staff will complete a measure of implementation climate that we adapted for use in the school context (35). Items are rated on a 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree). Lower scores indicate increased staff receptivity to the program and support within the school, including rewards and recognition. This measure has acceptable internal consistency and good discriminant validity (35).

Relative Priority. School staff will complete one adapted item from the School Contextual Barriers subscale of the Perceived Attributes of the Healthy Schools Approach Scale (36). The item is rated on a 5-point scale Likert scale from 1 (strongly agree) to 5 (strongly disagree). Higher scores indicate that other activities did not interfere with implementation of the FP program.

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Competing Demands. Staff will complete 3-items, developed specifically for this study, which assess how much time they allocated, and desired to allocate, to the FP program relative to other competing workload demands on visual analogue scales (anchor by 0 = no work time, 100% = all of my work time). Higher scores indicate increased allocation of time and prioritisation of the FP program.

Individual Characteristics.

Leadership. School staff will complete the Implementation Leadership Scale (ILS; 37). The ILS is a 12-item scale that assesses leadership behaviours that support implementation of evidence-based practices. The ILS contains four subscales, and two will be included in the current study (Knowledge Leadership and Supportive Leadership). These scales assess the degree to which the staff member was knowledgeable about and offered support to the program. Items are rated on a 5-point Likert scale from 0 (very much so) to 4 (not at all) and will be re-coded such that higher scores indicate more effective implementation leadership behaviours. This measure has excellent internal validity, convergent validity, and discriminant validity (37).

Self-Efficacy and Confidence. Study facilitators will rate their level of confidence in performing 23 different tasks during school-visits on visual analogue scales, which are based on the training program they completed (anchor by 0 = not at all confident, 100 = very confident). Higher scores indicate higher levels of confidence. A similar questionnaire will be repeated following their school-visits, along with four short answer questions that assess experiences with supporting staff and students during school-visits.

Intervention Characteristics.

Relative Advantage and Evidence Strength and Quality. School staff will complete the 2-item Relative Advantages subscale and one item from the Anticipated Benefits subscale of the Perceived Attributes of the Healthy Schools Approach Scale (36). Adapted for the

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current study, items are rated on a 5-point scale Likert scale from 1 (strongly agree) to 5 (strongly disagree). Scores will be re-coded such that higher scores indicate greater perceived advantage of the FP program compared to others and greater perceived impacts on mental health, respectively.

Implementation Processes.

Normalisation and Integration into Routine Practice. School staff will complete NPT's accompanying tool, the Normalisation MeAsure Development questionnaire (NoMAD; 38). The NoMAD is a 23-item measure that assesses how professionals involved in the implementation of a complex intervention perceive implementation processes. It is a flexible measure that can be altered to more accurately describe the adoption of new interventions at the provider level. Ten items of the NoMAD will be used in this study to assess intervention buy-in from school staff, and how staff members incorporated the initiative into their standard work responsibilities. These items are grouped into three categories: coherence (i.e., making sense of an intervention), cognitive participation (i.e., working with others to support an intervention), and collective action (i.e., the type of work that people do to support an intervention). Items are rated on a 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree). Initial validation demonstrated that the NoMAD has good face validity, construct validity, and internal consistency (39).

Implementation Outcomes

Fidelity to the Implementation Strategy. Fidelity will be captured through implementation checklists, informal observations provided by staff attending schools, and communications between schools and research staff.

Reach. SPARX app usage data from students will allow for the assessment of app use (downloads, installs, and opens), completion (modules completed), and time spent using SPARX. Administrative data about the number of students in intervention schools with

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consent to participate will also be used as an indicator of reach. Self-report data about individual characteristics (e.g., gender, mental health history) will be used to gauge the representativeness of the students in the intervention schools.

Uptake. Administrative data about the proportion of schools that were onboarded to the study and the proportion of teachers who supported the intervention will be collected to provide an index of uptake by schools. Representativeness of the sample will be informed by publicly available information about school characteristics (e.g., socio-economic status, location) and self-report data about school staff characteristics (e.g., role, gender).

Appropriateness. School staff will complete the Intervention Appropriateness Measure (IAM; 40). The IAM is a pragmatic 4-item measure of the perceived fit, relevance or compatibility of an evidence-based practice for a context, person, or problem (41). Items have been adapted for this study and are rated on a 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree). Scores will be re-coded such that higher scores indicate higher levels of perceived appropriateness. The IAM demonstrated strong psychometric properties in previous research (40). School staff will also complete one adapted item from the Agency Leadership Support subscale of the Barriers and Facilitators to Implementing Survey (42). The item is rated on a 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree) and will be re-coded such that higher scores indicate greater compatibility of the FP program within a particular school.

Acceptability. Year 8 students will complete an 11-item feedback questionnaire about SPARX. The questionnaire assesses three domains, including: (i) reasons for non-adherence; (ii) intervention acceptability; and (iii) skills learnt from the intervention. Items will be quantified individually. This questionnaire has previously been used to assess the acceptability of the SPARX program in the school context (43).

Individual Interviews

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Interview guides for school staff and study facilitators were derived from the logic model, CFIR online resources (e.g., https://cfirguide.org/evaluation-design/qualitative-data/), and the broader literature investigating the delivery of interventions in school settings (44, 45; see Additional File 1 for interview guides). Interviews will provide information about both implementation predictors and outcomes. For school staff, questions focus on: motivations and expectations about the intervention and study; knowledge and beliefs about the intervention; relative advantages of the intervention; self-efficacy; barriers and facilitators affecting the delivery of the intervention, including fidelity; appropriateness and acceptability of the intervention; and recommendations for future implementation. School counsellors will also be asked questions about their experiences of managing high risk participants within the study and compatibility with existing workload. For study facilitators, questions focus on: motivations and expectations about their role; confidence and competence in supporting the delivery of SPARX in schools; the quality of their training; and perceptions about their ability to support the study as required.

The interview guides allow for flexibility in questioning and diversion in responses. Questions will primarily be open-ended, with specific prompts and follow-up questions being used as necessary to encourage respondents to elaborate on their ideas and provide examples.

Patient and Public Involvement

The Future Proofing Study was developed with key stakeholders including school personnel, school counsellors, parents, adolescents, and individuals with a lived experience of mental illness. All aspects of the study design, appropriateness of outcomes measures and consent procedures were developed in consultation with these stakeholder groups. The current process evaluation involves consultation with school staff members to understand their experience. The SPARX intervention itself was codesigned with young people. All study results will be shared directly with participants and their schools through lay summaries

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and infographics.

Procedure

Ethical approval was provided by the University of New South Wales Human Research Ethics Committee (HC180836) and NSW Government State Education Research Applications Process Approval (SERAP 2019201).

The FPS has two waves of delivery (April-June 2020; July-Sept 2020). Process evaluation data will be collected at each wave, immediately following the intervention period. Purposive sampling will be used to capture a range of diverse school settings.

School students will complete process measures at the same time as completing primary measures for the FPS. Study facilitators will provide informed consent following the compulsory face-to-face training session they attend with the research team at the Black Dog Institute. Questionnaires will be completed online.

School staff directly involved in the study will be invited to complete the questionnaire by the trial manager, following the six-week SPARX intervention period. Once school staff members open the letter of invitation, they will be able to consent to a 60-minute individual interview (completed either in person or by phone). The semi-structured interviews will be conducted with research staff who have had no previous contact with the schools during the trial, thereby minimising the risk of bias and demand effects. Face-to-face interviews will be held in a quiet room on school grounds. Phone and face-to-face interviews will be recorded and transcribed verbatim.

Data analysis

Quantitative

Questionnaire data and open-ended questions from surveys will be exported into data analytic software for analysis. Descriptive statistics will be calculated for all participant

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groups and will provide information about intervention use and its acceptability (questionnaire data from Year 8 participants), differential implementation, fidelity to the implementation strategy, school context factors within each school (questionnaire including several short answer questions from school staff), and competence and experience in schools from those facilitating the study (facilitator questionnaires). Differences between school clusters will be assessed using Analysis of Variance methods (ANOVA). Regression models will assess the on the effects of contextual factors on implementation outcomes (e.g., reach, uptake, acceptability).

Qualitative

Interviews will be digitally audio-recorded and transcribed verbatim. The transcripts will be checked for accuracy against the sound files as per best practice in transcription (46, 47). Qualitative data will then be imported into NVivo to aid in data management and analysis. Thematic analysis will be undertaken to identify, interpret and report on the repeated patterns of meaning within the data, drawing from Braun and Clark's classic six phase model (48, 49).

Initially, one coder will code a subset of the transcripts using an inductive approach, incorporating themes from the data together with topics covered in the interview guide. This subset will then be double coded by an independent coder who will develop their own coding scheme. Codes will be compared and discussed by the two coders, with refinement occurring via an interactive process until a final coding scheme is determined. A senior qualitative analysist will review the coding framework and scheme before all transcripts are coded by the first coder. Research rigor will be enhanced by a team approach to analysis, reflexive field notes, and prolonged engagement with the subject matter (50).

Triangulation of Qualitative and Quantitative Data

Triangulation involves the use of multiple approaches to address a research question.

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The combination of several approaches increases confidence in the findings and provides a more comprehensive account of the results than individual approaches would do alone (51). In this study, reliability, validity and confidence will be maximised through cross verification and exploration of differences between the outcomes of the various methods. This takes place in several ways:

- Maximising validity in analysis of qualitative data within the research team using techniques such as discussing coding, constant comparison, accounting for deviant cases, and systematic coding;
- Triangulation of school staff and research assistant interviews with results from the questionnaires, exploring and accounting for differences;
- Triangulation of self-report and interview data with publicly available information relating to school contextual characteristics (e.g., school socio-economic level and size) and school delivery of the program, including deviations to the implementation strategy.
- Mapping the perspectives of different stakeholders across the study (school staff, study facilitators).

Additional Analyses

We will generate an 'implementation strength' metric for each school and its relationship to primary and secondary trial outcomes. This is an emerging evaluation approach, used mainly in low and middle-income countries. The approach aims to understand the degree of implementation effort needed during intervention delivery to achieve desired benefits (52, 53).

The implementation strength metric will provide funders and policy makers with an objective measure to monitor effectiveness of implementation if it goes beyond this trial and becomes a sustainable approach. The metric can be used to assess whether the approach to

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implementation meets the minimum level required to prevent the onset of mental health problems in adolescents. The metric will be based on implementation inputs and contextual factors informed by the intervention logic model and process evaluation frameworks (CFIR and RE-AIM) (e.g., adoption from teachers and other staff in the school and fidelity to the intervention strategy), and will be developed with the Future Proofing research team using principal component analysis.

Discussion

This paper describes the design of a mixed methods process evaluation of a cluster randomised controlled trial, the FPS. The FPS investigates the impact of a digital cognitive-behavioural therapy intervention when delivered at scale in school settings. Digital mental health programs have tremendous potential to prevent up to 22% of depression cases and, when delivered at scale, could have population-level impacts (54). However, these programs have not been translated into practice and policy because optimal ways to scale and deliver these interventions are not yet well understood.

As an initial step to address this issue, the current process evaluation will attend to contextual and implementation factors that vary across schools and provide a lens through which to interpret trial efficacy outcomes. We expect that results will provide a richly detailed and nuanced understanding of the key factors involved in the effective delivery of digital mental health programs across different schools. We expect that results will not only contextualise our trial findings but will also be used as a model to guide the delivery of school-based interventions that focus on preventing mental illness more broadly. Findings from this process evaluation will indicate whether the approach used in the FPS trial is likely to be sustainable in the school environment going forward and, if so, the threshold level of support required in order to prevent depression and benefit student mental health.

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The prospective publication of this protocol outlines our planned methodological approach. It also serves as a road map for other researchers on a practical way of carrying out process evaluations of complex interventions in the school setting. As is the case with the delivery of interventions across different contexts, we acknowledge that our approach has inbuilt flexibility to explore the data and make provisions for unexpected implementation factors that arise.

Limitations and Strengths

There are several limitations to our process evaluation that warrant mention. First, we are not including direct observation of teachers in their role supporting the delivery of SPARX. While this would provide objective fidelity data, it requires resources beyond the scope of this project and is not representative of how the program will be sustained following the conclusion of the trial. Second, the qualitative interviewer is a member of the research team (but not the evaluation team). Care will be taken to ensure that this staff member has no contact with schools prior to the interview visit to minimise bias. However, there remains a risk that demand effects may impact the information that is shared. Third, the process evaluation process (questionnaires and interview) will undoubtedly add to the burden placed on school staff. Given that the FPS is already placing a significant burden on the time of busy school staff, this additional component might contribute to low levels of participation.

To the point of burden on schools, one of the strengths of the design is that we have undertaken a pilot phase involving eight intervention schools and have been able to refine our processes (e.g., introduce an incentive) for school staff members to participate. This process evaluation also involves the combination of qualitative and quantitative methods which will be triangulated to provide a coherent and comprehensive picture of the data. The use of the 'implementation strength' metric represents a novel approach in this field, borrowed from the low-middle income country implementation science sector. The inclusion of this approach

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will provide important information to funders and policy makers following on from this trial, indicating the level of implementation support required to prevent mental illness and improve wellbeing of adolescent school students.

Notwithstanding the limitations raised above, this process evaluation will contribute to the broader knowledge base and indicate how best to deliver digital mental health prevention programs in school settings.

Ethics and Dissemination

As noted, all procedures have received ethical approval from relevant committees. Results from this study will be published in an open access peer-reviewed journal.

Additional Files

Additional File 1 (Semi-Structured Interview Guides).docx

List of Abbreviations

FPS = Future Proofing Study

cRCT = Cluster Randomised Controlled Trial

CFIR = Consolidated Framework for Implementation Research

RE-AIM = Reach, Effectiveness, Adoption, Implementation, Maintenance framework

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Declarations

Trial status

Recruitment for the trial is underway. Data collection commences in September 2020 (delayed from April 2020 due to COVID-19).

Ethical approval and consent to participate

This study has ethical approval from the University of New South Wales Human Research Ethics Committee (HC180836; 21st January 2019) and NSW Government State Education Research Applications Process Approval (SERAP 2019201; 19th August 2019). All schools, staff, parents and participants must provide active consent to participate.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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randomised controlled trial within which this process evaluation is embedded came from an NHMRC Project Grant Awarded to Helen Christensen GNT1120646. The funding bodies had no role in any aspect of the study design or this manuscript.

Author contributions

HC and AWS conceived of the study and secured the funding. AWS and JB led the design of the process evaluation, with input from all authors, and expert guidance from RL and KB. AWS drafted the manuscript, with assistance from JB. ALC, MT, KM, RL, KL and HC have a continuing role in monitoring the conduct and outcomes of the process evaluation. All named authors contributed substantially to the approved final manuscript.

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Author information

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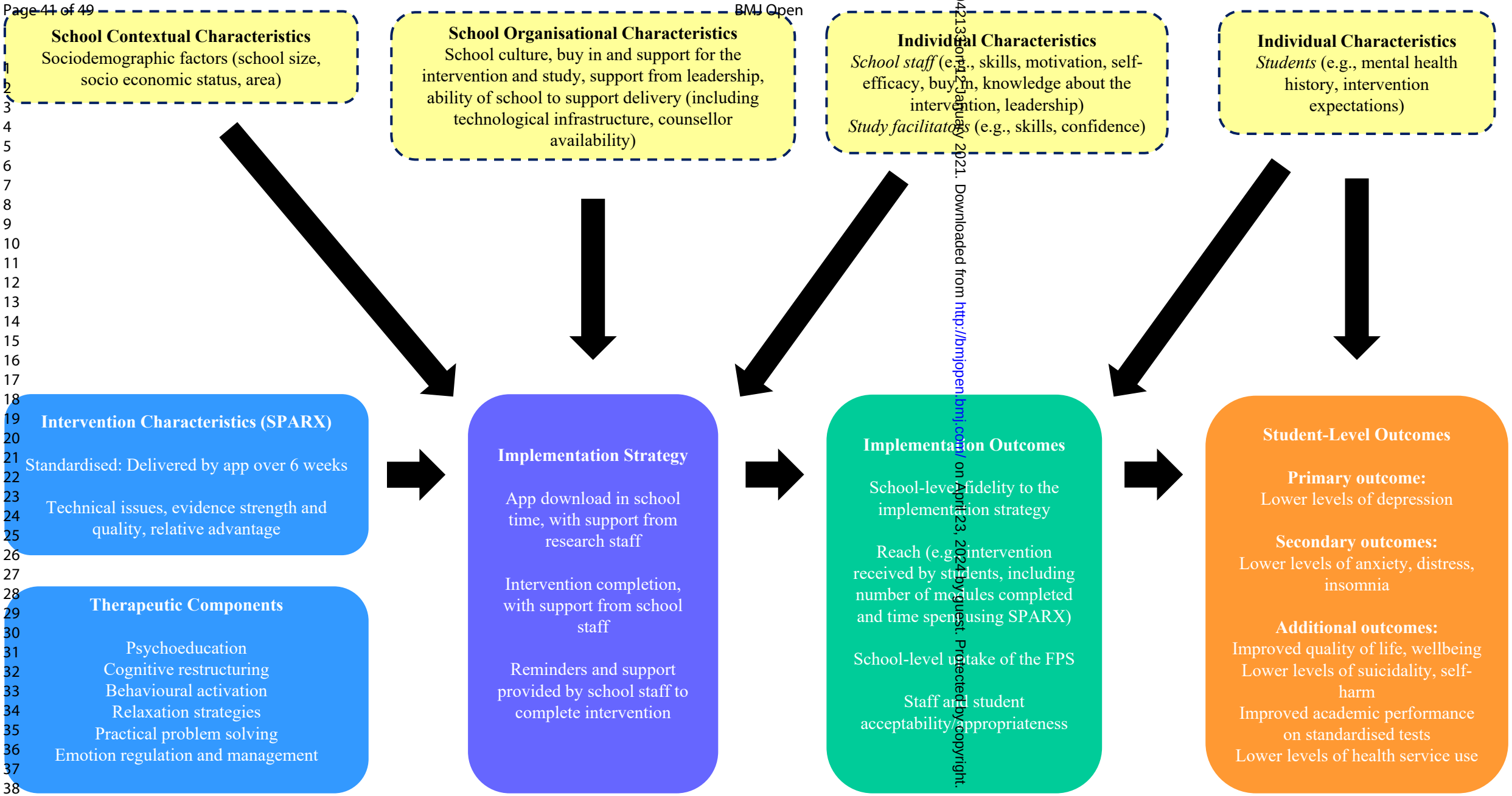

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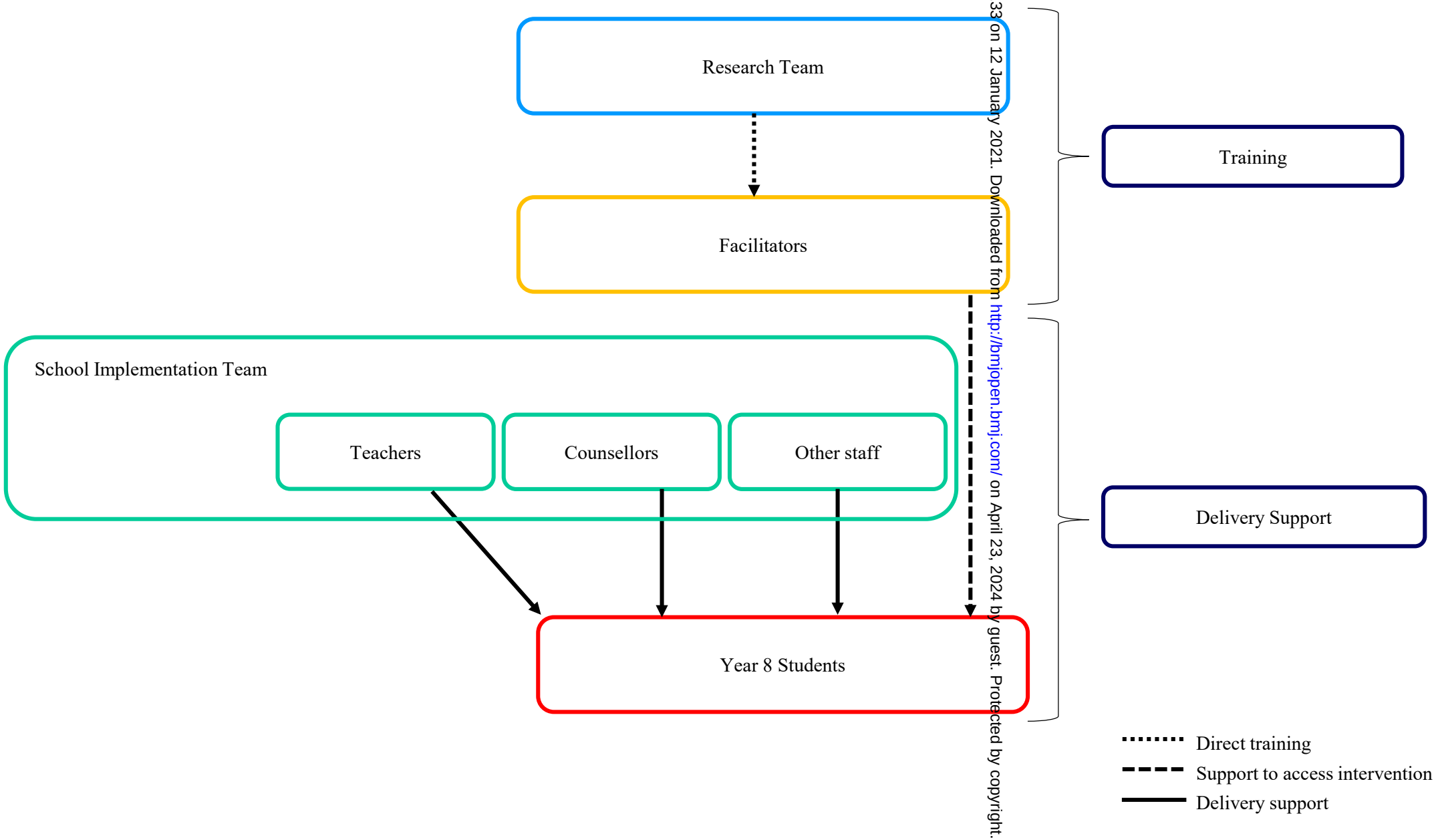

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Additional File 1
Semi-Structured Interview Guides
School Staff

INTRODUCTION: *Thank you for agreeing to take part in this interview. I appreciate your time.*

I am interested in hearing your thoughts and experiences of the Future Proofing program in your school. For this interview, the FP program includes the intervention app (SPARX) and everything else that was done to support the program in your school. I hope to use this information to work out what works in different schools and how to best provide support.

I will ask you a few questions about your experiences. This is chance for you to reflect and offer feedback on how we could improve. The interview will last up to one hour. It will be recorded, and your responses will be transcribed to ensure we accurately reflect your words. All personal information will be removed so that your answers are non-identifiable and confidential. Nothing you personally say will be shared with anyone on the FP team that you have been liaising with or with other staff at your school. You can choose to not answer any questions.

Do you have any questions before we get started?

General Opening Questions:

1. How did you first get involved in teaching/counselling/psychology?
2. Could you tell me about the core values and ethos of your school?
3. To the best of your knowledge, what mental health programs or initiatives has your school implemented to care for students besides the FP program?

Specific Questions:

4. Overall, how would you describe your experience with the FP program in your school?
5. What was your role in delivering or supporting the FP program in your school?
    a. Leader/driver, decision-maker, consent/recruitment, peripheral support

CFIR DOMAIN: INDIVIDUAL CHARACTERISTICS

Personal attributes (e.g., motivations, expectations, capacity, values)

6. Why were you motivated to take on this role?
    a. How did you come on board with the program?
7. Why do you think your school decided to support this program?
    a. To what extent do you think there was a need for a mental health program like FP in you school (*Tension for change)*?
8. What were your expectations about the FP program prior to coming on board?
    a. How were your expectations met (or not met)? What went differently to what you expected? What surprised you?
    b. What were your expectations about the apps?

Knowledge and beliefs about the intervention

9. How much do you know about SPARX, the intervention? E.g., principles, rationale, content?

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Self-efficacy

10. How confident were you in your ability to lead/support/make decisions about the FP program?
    a. What personal qualities do you think helped you to do that?

CFIR DOMAIN: OUTER SETTING

Relative Advantage

11. How did SPARX compare to other mental health programs that your school has supported or delivered?

CFIR DOMAIN: INNER SETTING

School contextual factors – Barriers and Facilitators

12. What factors influenced your ability to deliver/support the FP program in your school?
    a. What else helped or hindered your ability?
    b. Enquire into school-specific factors and program-specific factors e.g., What parts of the program were easy for you to do or support (e.g., the consent process, organising rooms, weekly team meetings)? OR What aspects of your school made it difficult for you to support the program?
    c. What factors got in the way of students completing the mental health app/s?
    d. Were you (or others) able to overcome any barriers? How did you manage to do this?

School contextual factors – Leadership

13. Tell me about the involvement of your school executive in the FP program.
    a. What role did this person have (e.g., principal/vice principal)? Did you meet regularly with this person or provide updates to them?
14. How do you think the school executive saw this initiative?

Readiness for implementation

15. How would you describe the readiness of your school to take on the FP program?
    a. What was the preparation phase like for you/other key staff?

IMPLEMENTATION METRICS

Appropriateness and Acceptability

16. How does the FP program align with your school's approach toward student mental health?
17. How suited is the FP program to address depression prevention in your school?
18. How well does an app delivering therapy work to prevent depression in your students?
19. How do you feel about using technology to deliver psychological interventions in your school?
    a. What worked well about this and what did not?
    b. Do you think SPARX met the student's mental health needs? In what way?
20. What were the by-products of the intervention that you didn't expect?
    a. What parts of the program do/do not suit your school?

***ADDITIONAL QUESTIONS FOR SCHOOL COUNSELLORS ONLY*

21. What was your experience with responding to students identified as needing follow-up during the FP program?
    a. Was there anything that could have been done to make this experience better for you and the student?
22. What do you think of the FP risk protocol?

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KEY LEARNING AND FUTURE IMPLEMENTATION

23. What parts of the FP program, if any, could be made more attractive to your school to increase uptake or support?
    a. In what ways could we make these parts more attractive?
24. To what extent do you think that the FP program could be integrated into your school's existing mental health strategy?
25. What advice would you give another school contemplating taking on the FP program?
26. What's been your major learning or insight from your school's involvement in the FP program?

Closing

27. Is there anything else you would like to add?

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Volunteer Research Assistants (Study Facilitators)

INTRODUCTION: *Thank you for offering to take part in this interview. I appreciate your time.*

I am interested in your thoughts about and experiences with supporting the FP program as a Research Assistant Volunteer. I hope to use this information to work out what works in different schools and how we can help volunteers to best provide support.

I will ask you a few questions about your experiences. This is chance for you to reflect and offer feedback on how we could improve. The interview will last up to one hour. It will be recorded and your responses will be transcribed to ensure we accurately reflect your words. All personal information will be removed so that your answers are non-identifiable and confidential. Nothing you personally say will be shared with the volunteer team or the Black Dog Institute more generally, so it will not affect your relationship with them. You can choose to not answer any questions.

Do you have any questions before we get started?

General Opening Questions:

1. What schools have you visited so far?
2. Roughly how many school visits have you attended?

Specific Questions:

CFIR DOMAIN: INDIVIDUAL CHARACTERISTICS

Personal attributes (e.g., motivation and expectations)

3. Why were you motivated you to volunteer?
4. What were your expectations coming on board with the FP program?
    a. How were your expectations met (or not met)?
    b. What went differently to what you expected? What surprised you?

Perceptions of Training

5. What are your overall impressions of the training you received?
    a. How helpful and appropriate was the training?
    b. What parts were the most useful?
    c. What was missing from the training?

CFIR DOMAIN: INNER SETTING

School visits – Barriers/Facilitators

6. What was your experience with completing the school visits?
7. Did anything unexpected happen during the school visits?
    a. If so, what?
    b. How did you manage this?
    c. How well do you think you managed this?
8. In general, how was the FP program received by school staff during visits?
9. To what extent was it useful having a volunteer partner/s at the visits?
    a. Were there any other benefits/disadvantages?

School contextual factors - Barriers/Facilitators

10. What factors influenced your ability to assist students and teachers at the school-visits?
    a. Were these common across all the visits or specific to a particular visit?
    b. What aspects of the school made it difficult to support the program?

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c. What else helped or hindered your ability? (e.g., research platform/app specific factors)
d. How did you overcome these barriers?
e. Were there any noticeable differences between different schools? If so, what were they?

KEY LEARNING AND FUTURE IMPLEMENTATION

11. What advice would you give a school contemplating taking on the FP program?
12. What advice would you give to others who are thinking about volunteering?
13. What parts of the FP program could be made more attractive to volunteers to increase uptake or support?
14. What's been your major learning or insight from taking part in the volunteer program?

Closing

15. Is there anything else you would like to add?

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Standards for Reporting Implementation Studies: the StaRI checklist for completion

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	1-2	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	2-3	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	**3**	5	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	**4**	9-11	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	8	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).
Aims and objectives	**5**	9	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	10	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	**7**	11-13	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	13	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	8	The population targeted by the intervention and any eligibility criteria.
Description	**9**	14	A description of the implementation strategy	8	A description of the intervention

Sub-groups	**10**	N/A	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	19	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	N/A	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	15	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	N/A	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	7	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	21-22	Methods of analysis (with reasons for that choice)		
Sub-group analyses	**16**	23	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Results					
Characteristics	**17**	N/A	Proportion recruited and characteristics of the recipient population for the implementation strategy	N/A	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	N/A	Primary and other outcome(s) of the implementation strategy	N/A	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	N/A	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	N/A	Representativeness and outcomes of subgroups including those recruited to specific research tasks		

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Fidelity/ adaptation	**22**	N/A	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	N/A	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	N/A	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	N/A	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	24-25	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	N/A	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	N/A	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	27	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

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Protocol for the Process Evaluation of a Complex Intervention Delivered in Schools to Prevent Adolescent Depression: The Future Proofing Study

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Protocol for the Process Evaluation of a Complex Intervention Delivered in Schools to Prevent Adolescent Depression: The Future Proofing Study

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Abstract

Introduction: Process evaluations provide insight into how interventions are delivered across varying contexts and why interventions work in some contexts and not in others. This manuscript outlines the protocol for a process evaluation embedded in a cluster randomised trial of a digital depression prevention intervention delivered to secondary school students (The Future Proofing Study). The purpose is to describe the methods that will be used to capture process evaluation data within this trial.

Methods and Analysis: A mixed methods design will be used with data collected in the intervention arm of the Future Proofing Study. Data collection methods will include semi-structured interviews with school staff and study facilitators, automatically collected intervention usage data, and participant questionnaires (completed by school staff, school counsellors, study facilitators, and students). Information will be collected about: i) how the intervention was implemented in schools, including fidelity; ii) school contextual factors and their association with intervention reach, uptake and acceptability; iii) how school staff, study facilitators, and students and responded to delivering or completing the intervention. How these factors relate to trial effectiveness outcomes will also be assessed. Overall synthesis of the data will provide school cluster-level and individual-level process outcomes.

Ethics and Dissemination: Ethics approval obtained from the University of New South Wales. Results will be submitted for publication in peer reviewed journals and discussed at conferences. Our process evaluation will contextualise the trial findings with respect to how the intervention may have worked in some schools but not in others. This evaluation will inform the development of a model for rolling out digital interventions for the prevention of mental illness in schools.

Trial Registration: The randomised controlled trial has been prospectively registered: ACTRN12619000855123. Registered 31 May 2019,

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https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=377664&isReview=true

Keywords: Process evaluation, complex intervention, mixed methods, adolescent mental health, depression, prevention, randomised controlled trial, implementation.

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Strengths and Limitations of this Study

- This protocol is the first to illustrate how to embed a process evaluation into a school-based randomised controlled trial of a digital depression prevention intervention.
- Flexible and pragmatic quantitative and qualitative data collection methods will be used to balance research rigor with feasibility within the school delivery context.
- Process data from a range of key stakeholders will be collected, including school staff, study facilitators, and students.
- To minimise burden on schools, fidelity data from teachers and in-depth qualitative data from students will not be collected.
- The methodology and study processes were pilot tested to ensure appropriateness within the school context.

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Introduction

Embedded in randomised controlled trials, process evaluations provide insight into reasons why interventions work in some contexts and not in others. These process evaluations can help to demystify the 'black box' of complex intervention trials by taking into account contextual factors, differences in ways the intervention is delivered, and adaptations made for intervention delivery into a particular system (1, 2). Contextual factors typically include features of the organisation or broader environment that influence the delivery of the intervention (e.g., leadership, engagement, culture, political landscape). Considering the contribution of contextual factors is necessary to aid interpretation of trial outcomes, maximise the knowledge gained from trials, identify optimal delivery processes across different settings, and inform broader dissemination efforts. In recognition of this need for process evaluations, the UK's Medical Research Council (MRC) set out a framework that emphasises the value of these evaluations in order to capture both contextual and implementation factors associated with complex interventions (3).

In line with best-practice recommendations that study protocols that pre-specify methods and approaches should be published to maintain research integrity (4), we describe a protocol for a mixed methods process evaluation embedded within a cluster randomised controlled trial (cRCT) known as the Future Proofing Study (FPS). The FPS is a large school-based trial examining whether depression can be prevented using cognitive behaviour therapy (CBT) delivered by smartphone application (5).

There has been an increase in the availability of digital mental health programs which show promise in addressing the significant disease burden associated with depression (6). Depression often first emerges during adolescence (7) and treatment alone cannot adequately reduce this burden (8). Accumulating evidence indicates that early adolescence is the ideal developmental window during which to intervene because it captures young people *before*

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the incidence of depression increases exponentially around the age of 16-17 years (9, 10). Therefore, increased efforts are being directed toward prevention approaches that are developed specifically for delivery among adolescents.

While there is evidence supporting the value and effectiveness of prevention programs in schools (11, 12), their uptake has been significantly limited by low levels of help-seeking (13) as well as practical constraints in cost and scalability. A lack of understanding about how to deliver these interventions sustainably at scale, and engage those who stand to benefit, have hampered the translation of prevention approaches into the community.

Two ways to overcome the barriers of cost and scalability of implementing adolescent depression interventions are:

- Delivering universal prevention programs in schools, and
- Using technology to deliver programs, which tends to be lower cost than traditional face-to-face methods (14).

Working with schools to deliver universal prevention programs, to every student, regardless of their risk, circumstance, or symptom profile, not only dramatically increases the potential reach of interventions, it also means that these programs can eventually be integrated into the curriculum and delivered to every student, making this approach a sustainable implementation strategy for widescale delivery and dissemination. Additionally, working with schools to deliver such programs reduces the need for young people to actively seek professional help. This is critically important - despite having a significant need, fewer than 80% of young people with mental illness seek help and receive the services they need (15, 16). The scaffolding provided by schools can be leveraged to deliver prevention programs to all students, which fits with a trend for schools to be designated the first point of contact to support youth mental health problems when they first emerge (9). Process

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evaluations of face-to-face mental health programs have been documented, some of which have been delivered in school settings (e.g., 17). However, we were unable to find any process evaluation descriptions in the literature that evaluate *digital mental health programs* in school settings. Conducting process evaluations specific to digital methods of delivery are important because the contextual barriers and facilitators, as well as concerns around fidelity of the intervention, are likely to have unique characteristics. For example, facilitator or training in intervention delivery will be different in supporting the use of an automated program relative to a face-to-face program. This process evaluation is an initial step towards addressing that gap.

Technology offers a promising way to deliver mental health interventions to the community. Digital mental health interventions offer two key advantages over face-to-face approaches – first, they are cheaper to access and more cost effective (18, 19), and second, they can be used to reach people across vast geographic areas. The latter is particularly important given Australia's geography, where remoteness and low population density meant that people in regional and rural areas often do not have the same level of access to mental health services as people in metropolitan areas. With more young people than ever using smartphones, mental health intervention delivered online or through applications represents an exciting avenue for reaching adolescents.

The Future Proofing Study (FPS)

The trial that is the subject of this process evaluation is the FPS. The FPS addresses barriers of reach, cost, and scalability by delivering a depression prevention program via a smartphone app to Year 8 secondary school students aged 12-13 years. This study is being conducted with approximately 200 Australian schools (up to 10,000 participants), of which half will be allocated to the intervention condition. The primary outcome is symptoms of depression. Secondary outcomes include anxiety, psychological distress and insomnia, among

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others. Symptom outcomes will be assessed at baseline, post-intervention, six months (primary outcome only), and then annually for five years. The primary endpoint is 12 months following baseline. More details are available from the Australian New Zealand Clinical Trials Registry (ANZCTRN12619000855123) and protocol paper (5).

The intervention being delivered is known as SPARX, a CBT-based program incorporating gamification principles. The development and initial evaluation of SPARX has been documented in detail previously (20). SPARX has been tested in an Australian sample of secondary students (delivered via computer) and shown to prevent depression in the lead up to final school exams (21). The gamified intervention teaches young people about the relationship between thoughts, feelings, and behaviour. Skills learnt through SPARX include emotion identification, emotion regulation, behavioural activation (being active), recognising and challenging unhelpful thoughts, and practical problem solving. SPARX consists of seven 20-minute modules. The intervention is fully automated, and the therapeutic components are standardised. See the trial protocol for full intervention details (5).

School Engagement and Recruitment

The FPS requires multiple levels of approval, beginning with state department and independent school body approval (NSW Department of Education; Catholic school dioceses), followed by individual school engagement. An engagement strategy for this study involves sending electronic communication material to all schools across New South Wales and in other Australian capital cities, targeting school principals and wellbeing staff to invite them to participate in this study opportunity. Schools are invited to submit expressions of interest and are subsequently followed up by the research team over the phone to explain more about the study. The schools for which the FPS is a good fit (as determined by the school) are then signed onto the study, with support from the principal, the school counsellor, and at least one other staff member (typically a teacher). In line with best practice in

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implementation science (22), this group of 2-3 staff members (typically not including the principal) will form the school-specific 'study implementation team'. After signing on to the study, several webinars are scheduled throughout the lead up to the study start date, so that school staff and parents can listen to a 15-minute study overview from the trial manager and have their questions answered.

Preparation

In preparation for in-class assessment sessions, study facilitators (volunteer research assistants) are recruited to support the study. The purpose of these facilitators is to attend schools to introduce the study to students, and ensure the technology is functioning so students can download the SPARX app and complete the baseline (and post-assessment) questionnaires. All facilitators go through an interview and screening process prior to selection, then attend a half day face-to-face training session before supporting the study in schools. This training provides an overview of the study and detailed information about their roles within schools, including a step-by-step guide to running the sessions. Discussion and practice are core components of the training.

Aims and Objectives

We adapted the MRC framework for complex interventions to focus on effectiveness of an evidence-based intervention *within a specific context of delivery* (i.e., schools). Overall, the objective of this process evaluation is to understand how SPARX is implemented and delivered in schools, and to identify systematic differences and variation in delivery. Specifically, the aims are:

1. To evaluate the reach (including completion), uptake and acceptability of the intervention (school- and student-level).
2. To understand the contribution of contextual factors (e.g., characteristics of the outer/inner setting, intervention, individuals) on:

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- School-level fidelity to the implementation strategy. For example, different schools will likely provide different levels of study support based on available resourcing.
- Implementation outcomes (intervention reach, uptake, acceptability), as assessed from the perspectives of school staff, teachers, and students. For example, young people's openness to receiving mental health material via an app will likely impact intervention acceptability and completion.

3. To examine the impact of school-level variation (in implementation fidelity and outcomes) on clinical effectiveness outcomes at the school- and student-level. School-level clinical effectiveness is defined as changes in clinical outcomes (e.g., self-reported depression) for different schools. The differing ways in which schools support and deliver the intervention will inevitably impact its effectiveness, and this evaluation will assess these differences (3, 23). For example, degree of support from senior school leaders who would be expected to understand that participating in study activities is a priority for the school will likely impact effectiveness at the cluster level.

This process evaluation has been designed to capture important information from teachers, school staff and students at both the school and individual level, which may ultimately impact the effectiveness of the intervention on clinical mental health outcomes for students. Findings will provide insight into factors which support and/or hinder the implementation of digital universal mental health programs in school settings. Knowledge gained from this process evaluation will help to inform the development of a model and guide for how to best deliver digital mental health programs to young people in schools.

Methods and Analysis

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Design

This study uses a hybrid type 1 approach (24), with a focus on implementation process factors and outcomes in the context of an effectiveness trial. The evaluation is guided by the CFIR and RE-AIM framework (25, 26). In keeping with Nilsen's categorisation of implementation theories, models, and frameworks, these frameworks help us to understand different parts of the implementation process (27). The CFIR will be used to identify **barriers and facilitators** to intervention implementation and effectiveness (27). The CFIR is a widely used deterministic theoretical framework which has been applied in multiple settings (28), including schools (e.g., 29). The CFIR identifies five major domains, including (i) the outer setting, which includes the social, political and economic context that the organisation in which implementation is occurring exists; (ii) the inner setting, which includes features and characteristics of the organisation such as leadership and relative priority; (iii) the characteristics of individuals, which includes organisational staff knowledge and attitudes about the intervention and their role and identification within the wider organisation; (iv) the characteristics of the intervention itself and; (v) implementation processes, which includes the ways that the intervention will be delivered in a given context (including fidelity to the implementation strategy). Normalisation Process Theory will be used to provide additional insights into implementation processes (NPT; 30). NPT aims to identify and explain the implementation of new interventions and how they become integrated into routine care.

The RE-AIM framework will be used to evaluate the **implementation outcomes**, including intervention reach, uptake, and acceptability/appropriateness (25, 31). These outcomes also map onto the framework of implementation outcomes proposed by Proctor and colleagues (32, 33). Reach refers to the proportion of eligible participants who opened, used, and completed the intervention, as well as the proportion of students from the entire cohort of eligible students in intervention schools who consented to participate. Uptake refers to the

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proportion of schools that were onboarded to the study (intervention and control arms), and of school staff who were willing to support the delivery of the intervention (intervention arm only). Reach and uptake also incorporate the representativeness of the sample (school-level and individual-level). Acceptability and appropriateness refer to the perceived agreeableness or fit of the intervention. This evaluation will incorporate how the barriers and facilitators identified through the CFIR impacted the implementation outcomes, and, in turn, how these implementation outcomes impacted effectiveness outcomes.

Logic Model

Following MRC guidance (3), the research team developed a logic model for the FPS process evaluation in a series of participatory workshops. The logic model was prospectively informed by key CFIR constructs identified in previous literature as being important in school-based studies, but also feasible and appropriate to measure within the school context in the FPS. The key constructs included the outer setting, inner setting, individual characteristics, and intervention characteristics. The logic model (Figure 1) was developed to consider the key factors (mapped to the CFIR) that would potentially impact implementation of the intervention (mapped to RE-AIM), as well as its clinical effectiveness. The process evaluation method, including the selection of dependent variables and design of surveys and semi-structured interview guides, were derived from this logic model. See Table 1 for CFIR/RE-AIM domains, key research questions, process data, and data that will be collected within each domain.

A pilot study of 8 schools conducted in 2019 was used to assess the suitability of the planned implementation strategy and process evaluation methods. We retrospectively applied our logic model to collected data to evaluate whether our methodology captured relevant constructs, and sufficient variation in these constructs. We integrated learnings from this pilot

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study using a dynamic feedback process to strengthen our methodology for the full-scale FPS phase. Some minor changes were made following this pilot which relate to the CFIR, including a greater emphasis on sub-constructs such as school climate (inner setting).

<INSERT FIGURE 1 HERE>

Figure 1. Logic model. The model shows that CFIR constructs including school context characteristics, school organisational characteristics, and individual characteristics, will influence how staff engage with the implementation strategy. The intervention itself, which includes the core cognitive-behavioural therapeutic components, is conceptualised as standardised across individuals because it is delivered digitally, follows a fixed schedule and does not incorporate tailored content. The yellow input factors are expected to vary across schools and individuals, thus influencing engagement and flexibility of the implementation strategy and in turn, implementation outcomes and student-level outcomes. The logic model and implementation plan were externally peer reviewed by an experienced and internationally recognised implementation scientist outside the team within an implementation workshop. For details on assessment of these factors, see Table 1.

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Table 1 – Process evaluation details including process data, outcome data, data type and source

CFIR and RE-AIM Constructs	Research Aim	Process or Outcome Data	Data Type and Source
Outer Setting			
School contextual characteristics	What was the broad context of the schools in which the SPARX intervention was delivered? (Aim 2)	School socio-economic index School location (metropolitan/regional)	Publicly available information (ICSEA, GPS)
Inner Setting			
School organisational characteristics	What were the characteristics of the delivery environments (schools)? (Aim 2)	School size, type, composition, funding School culture	Publicly available information (school size, type, funding) SSPOSH (assesses school culture) Interviews with school staff
	What were the barriers and facilitators that affected buy-in, delivery, and student uptake? (Aim 2)	Implementation climate, relative priority, competing demands, leadership, school counsellor availability and level of support, networks and communication, school culture and climate, school readiness for implementation	Implementation Climate measures (staff and students) Relative Priority measure Competing Demands measure Interviews with school staff Checklists completed by trial manager Other administrative data including number of staff allocated to assist with delivery and consent process, level of communication with the research team
School leadership	How supportive of delivering SPARX were school principals, deputy principals and executives? (Aim 2)	Level of support and buy in from school leaders	Interviews with school staff
Individual Characteristics			
School staff	What were the characteristics (including attitudes, beliefs, traits) of school staff supporting the delivery of the intervention? (Aim 2)	Age, gender, current employment, role etc	Demographics questionnaire
	How supportive of delivery were school staff who were involved on-the-ground? (Aim 2)	Leadership, skills, motivations, expectations, self-efficacy, expectations, time available, knowledge and beliefs about the intervention, study buy in	Implementation Leadership Scale Interviews with school staff and study facilitators
Study facilitators	How well did study facilitators attending schools support the delivery of the intervention? (Aim 2)	Age, employment Skills, self-efficacy or confidence, motivations and expectations	Demographics questionnaire Self-confidence measure Interviews with study facilitators

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Students	What were the characteristics of young people that affected intervention uptake and effectiveness? (Aim 2)	History of mental illness	Reported by Year 8 students as part of the online FPS survey
Intervention Characteristics			
SPARX	Were there any barriers to intervention use? (Aim 2 & 3)	Technical issues	Logs of technical issues sent through schools, parents and participants IT data pertaining to technical problems Informal feedback provided by schools and research staff attending schools
	What do staff think about the efficacy and advantage of using the intervention? (Aim 2)	Evidence strength and quality, relative advantage	Relative Advantages measure Anticipated Benefits measure Interviews with school staff
Implementation Processes			
Normalisation and integration	How did school staff perceive the implementation processes? (Aim 2)	Coherence, cognitive participation, and collective action	NoMAD
Fidelity to the implementation strategy	To what extent was the intervention implemented as planned? (Aim 2)	School delivery of the FP program, including changes to the plan	Completed implementation checklists, emails and feedback forms Interviews with school staff
Implementation Outcomes			
Reach	What was the extent to which those who were eligible to receive SPARX used it? (Aim 1)	Proportion of eligible participants who consented to participate; proportion who opened, used and completed the SPARX intervention Representativeness of the student sample	Administrative data about consent. Digital analytic data including usage (app downloads, installs, opens), completion rate (number of modules completed) and time spent using SPARX Reported by Year 8 students as part of the online FPS survey
Uptake	How many eligible schools participated in the study? Within those schools, how many staff supported the delivery of SPARX? (Aim 1)	Proportion of eligible schools that were onboarded to the study; proportion of school staff (in intervention schools) who supported SPARX Representativeness of the sample	Administrative data Publicly available information about schools and self-report demographic data from school staff
Acceptability/appropriateness	How satisfied were participants with the intervention? (Aim 1)	Acceptability/appropriateness of the intervention, expectations	Reported by Year 8 students as part of the online FPS survey Informal conversations and feedback provided by Year 8 students
		Acceptability/appropriateness of the Future Proofing program (including SPARX)	Implementation Appropriateness measure Interviews with school study staff

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	How satisfied were school staff with supporting the intervention the FP program (including SPARX)? (Aim 1)	Informal conversations and feedback provided by school staff
Across Domains		
	How might the relationship between the intervention, the staff supporting the program, and context of each school shape variation in outcomes (implementation strength metric)? (Aim 2 and 3) What key lessons emerge from this study that can be generalised to the implementation of digital mental health programs in schools more broadly?	

Note. The process data and outcomes are mapped onto Figure 2. CFIR = Consolidated Framework for Intervention Research; RE-AIM = Reach, Effectiveness, Adoption, Implementation, Maintenance; Aim = Aims outlined in the Aims and Objectives section; SSPESH = Survey of School Promotion of Emotional and Social Health; NoMAD = Normalisation Measure Development questionnaire.

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School Implementation Strategy

The school implementation strategy was developed by the study authors. The authors drew on their experience in school-based intervention delivery and integrated feedback from teachers and school staff from several completed school-based trials that delivered digital interventions to school students (21, 34). Stakeholder consultation specifically for this study involved discussions with the Department of Education, consultation with several school parent committees and consultation with both youth and parent Lived Experience Advisory Panels. This strategy was also refined following the first pilot wave involving eight intervention schools.

The school 'study implementation teams' are principally responsible for the implementation of the intervention and liaising with the research team. As described earlier, these teams typically incorporate at least one classroom teacher and one school counsellor to assist with the intervention delivery. Study facilitators also support the delivery of the SPARX intervention by attending schools for the first school session.

Implementation Strategy. During the active intervention phase, schools allocate a minimum of 4 x 20-minute school class sessions during which students complete the SPARX intervention. The additional three sessions may be completed either in class if permitted by the schools, or in the students' own time. The implementation strategy developed by the project team and stakeholders to support the completion of the SPARX intervention comprises:

- Standardised facilitator training delivered face-to-face over a half-day
- Study facilitators are present at schools to support students in downloading the SPARX app and completing the baseline assessments
- School implementation team provided with a SPARX user-guide and information booklet they can refer to during the sessions

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- Schools provide students with weekly verbal reminders in home classrooms to use the app regularly
- Schools publish brief information about the study and mental health tips in the school weekly newsletter
- Schools liaise with research team weekly to troubleshoot problems

This is the strategy being outlined to schools by the research team and adherence to this strategy will be assessed. Whether or not schools schedule more than the four mandated in-class sessions for intervention completion is flexible and can be adapted to suit the preferences of the school. Student participants receive a $20AUD voucher after the intervention period to cover any phone or data related costs incurred. See Figure 2 for details of training and delivery structure.

<INSERT FIGURE 2 HERE>

Data Collection Methods and Participant Groups for Process Evaluation

There are three participant groups taking part in the process evaluation: Year 8 students, school staff members (e.g., teaching and counselling staff), and study facilitators (see Table 2). School staff members will be members who are responsible for leading the delivery of the study in their school or will be teaching staff who have a supporting role (e.g., home room teachers who provide reminders to students to complete the intervention).

Four types of data will be collected and triangulated: self-report questionnaire data, digital analytic data, administrative data, and qualitative interview data. Self-report questionnaire data specific to the process evaluation will be collected from staff and study facilitators using online survey software (Qualtrics) programmed by one of the authors (JB). These questionnaires assess demographic information, school organisational characteristics,

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individual characteristics, intervention characteristics, implementation processes and implementation outcomes. Where no available published questionnaires were identified as being suitable for this process evaluation, we adapted existing standardised measures or developed our own items (details below). Self-report questionnaire data from Year 8 students about intervention use and feedback will be collected from an online survey (details described in 5). Digital analytic data about intervention use will be captured by the purpose-built Black Dog Institute research platform, which is being used for the broader FPS. Administrative data will be collected through a range of sources, including communications with the research team. Qualitative data will be collected using semi-structure interviews. All data collected will be from intervention schools only as no intervention is implemented in control schools. Student and school staff data will be collected immediately after the intervention period has been completed (i.e., after the six-week intervention stage); facilitator data will be collected both before and after the intervention period.

Table 2. Summary of data forms (and collection point) provided by each of the participant groups

	Questionnaire	**Individual interview**	**Digital analytics**
Year 8 students	✓ (post-intervention)		✓ (ongoing)
School staff	✓ (post-intervention)	✓ (post-intervention)	
Facilitators	✓ (before first school visit and after final post-intervention visit)	✓ (after final school post-intervention visit)	

Implementation Predictors

School Organisational Characteristics (Inner Setting).

Publicly Available Information. Publicly available information will be collected

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about school contextual characteristics, including socio-economic level, size, location, type, and funding.

General School Culture. School staff will complete the Survey of School Promotion of Emotional and Social Health (SSPESH; 35) and a measure of organisational culture (36). The SSPESH assesses a school's capacity to promote social and emotional wellbeing, and contains four subscales: Positive School Community, Student Social and Emotional Learning, Engaging Families, and Supporting Students Experiencing Mental Health Difficulties. Items are rated on a 4-point Likert scale from 0 (not yet in place) to 3 (completely in place) and preliminary investigations support the scale structure and criterion-related validity (35).

We adapted a 9-item questionnaire about general culture within a health care setting to use within the school setting (36). Items are rated on a 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree). Lower scores indicate a more positive working culture, which includes transparency, productive working relationships, and receptivity to feedback. Previous investigation has shown that this measure has good internal consistency, although overlaps somewhat with other sub-constructs within the inner setting (e.g., learning climate; 35).

Implementation Climate. School staff will complete a measure of implementation climate that we adapted for use in the school context (36). Items are rated on a 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree). Lower scores indicate increased staff receptivity to the program and support within the school, including rewards and recognition. This measure has acceptable internal consistency and good discriminant validity (36).

Relative Priority. School staff will complete one adapted item from the School Contextual Barriers subscale of the Perceived Attributes of the Healthy Schools Approach Scale (37). The item is rated on a 5-point scale Likert scale from 1 (strongly agree) to 5 (strongly disagree). Higher scores indicate that other activities did not interfere with

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implementation of the FP program.

Competing Demands. Staff will complete 3-items, developed specifically for this study, which assess how much time they allocated, and desired to allocate, to the FP program relative to other competing workload demands on visual analogue scales (anchor by 0 = no work time, 100% = all of my work time). Higher scores indicate increased allocation of time and prioritisation of the FP program.

Individual Characteristics.

Leadership. School staff will complete the Implementation Leadership Scale (ILS; 38). The ILS is a 12-item scale that assesses leadership behaviours that support implementation of evidence-based practices. The ILS contains four subscales, and two will be included in the current study (Knowledge Leadership and Supportive Leadership). These scales assess the degree to which the staff member was knowledgeable about and offered support to the program. Items are rated on a 5-point Likert scale from 0 (very much so) to 4 (not at all) and will be re-coded such that higher scores indicate more effective implementation leadership behaviours. This measure has excellent internal validity, convergent validity, and discriminant validity (38).

Self-Efficacy and Confidence. Study facilitators will rate their level of confidence in performing 23 different tasks during school-visits on visual analogue scales, which are based on the training program they completed (anchor by 0 = not at all confident, 100 = very confident). Higher scores indicate higher levels of confidence. A similar questionnaire will be repeated following their school-visits, along with four short answer questions that assess experiences with supporting staff and students during school-visits.

Intervention Characteristics.

Relative Advantage and Evidence Strength and Quality. School staff will complete the 2-item Relative Advantages subscale and one item from the Anticipated Benefits subscale

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of the Perceived Attributes of the Healthy Schools Approach Scale (37). Adapted for the current study, items are rated on a 5-point scale Likert scale from 1 (strongly agree) to 5 (strongly disagree). Scores will be re-coded such that higher scores indicate greater perceived advantage of the FP program compared to others and greater perceived impacts on mental health, respectively.

Implementation Processes.

Normalisation and Integration into Routine Practice. School staff will complete NPT's accompanying tool, the Normalisation MeAsure Development questionnaire (NoMAD; 39). The NoMAD is a 23-item measure that assesses how professionals involved in the implementation of a complex intervention perceive implementation processes. It is a flexible measure that can be altered to more accurately describe the adoption of new interventions at the provider level. Ten items of the NoMAD will be used in this study to assess intervention buy-in from school staff, and how staff members incorporated the initiative into their standard work responsibilities. These items are grouped into three categories: coherence (i.e., making sense of an intervention), cognitive participation (i.e., working with others to support an intervention), and collective action (i.e., the type of work that people do to support an intervention). Items are rated on a 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree). Initial validation demonstrated that the NoMAD has good face validity, construct validity, and internal consistency (40).

Fidelity to the Implementation Strategy. Fidelity will be captured through implementation checklists, communications between schools and research staff, and interviews with school staff.

Implementation Outcomes

Reach. SPARX app usage data from students will allow for the assessment of app use (downloads, installs, and opens), completion (number of modules completed, out of a total of

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seven), and time spent using SPARX. Administrative data about the number of students in intervention schools with consent to participate will also be used as an indicator of reach. Self-report data about individual characteristics (e.g., gender, mental health history) will be used to gauge the representativeness of the students in the intervention schools.

Uptake. Administrative data about the proportion of schools that were onboarded to the study and the proportion of teachers who supported the intervention will be collected to provide an index of uptake by schools. Representativeness of the sample will be informed by publicly available information about school characteristics (e.g., socio-economic status, location) and self-report data about school staff characteristics (e.g., role, gender).

Appropriateness. School staff will complete the Intervention Appropriateness Measure (IAM; 41). The IAM is a pragmatic 4-item measure of the perceived fit, relevance, or compatibility of an evidence-based practice for a context, person, or problem (42). Items have been adapted for this study and are rated on a 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree). Scores will be re-coded such that higher scores indicate higher levels of perceived appropriateness. The IAM demonstrated strong psychometric properties in previous research (41). School staff will also complete one adapted item from the Agency Leadership Support subscale of the Barriers and Facilitators to Implementing Survey (43). The item is rated on a 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree) and will be re-coded such that higher scores indicate greater compatibility of the FP program within a particular school.

Acceptability. Year 8 students will complete an 11-item feedback questionnaire about SPARX. The questionnaire assesses three domains, including: (i) reasons for non-adherence; (ii) intervention acceptability; and (iii) skills learnt from the intervention. Items will be quantified individually. This questionnaire has previously been used to assess the acceptability of the SPARX program in the school context (44).

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Individual Interviews

Interview guides for school staff and study facilitators were derived from the logic model, CFIR online resources (e.g., https://cfirguide.org/evaluation-design/qualitative-data/), and the broader literature investigating the delivery of interventions in school settings (45, 46; see Additional File 1 for interview guides). Interviews will provide information about both implementation predictors and outcomes. For school staff, questions focus on: motivations and expectations about the intervention and study **processes more broadly**; knowledge and beliefs about the intervention; relative advantages of the intervention; self-efficacy; barriers and facilitators affecting the delivery of the intervention, including fidelity; appropriateness and acceptability of the intervention; and recommendations for future implementation. School counsellors will also be asked questions about their experiences of managing high risk participants within the study and compatibility with existing workload. For study facilitators, questions focus on: motivations and expectations about their role; confidence and competence in supporting the delivery of SPARX in schools; the quality of their training; and perceptions about their ability to support the study as required.

The interview guides allow for flexibility in questioning and diversion in responses. Questions will primarily be open-ended, with specific prompts and follow-up questions being used as necessary to encourage respondents to elaborate on their ideas and provide examples.

Patient and Public Involvement

The Future Proofing Study was developed with key stakeholders including school personnel, school counsellors, parents, adolescents, and individuals with a lived experience of mental illness. All aspects of the study design, appropriateness of outcomes measures and consent procedures were developed in consultation with these stakeholder groups. The current process evaluation involves consultation with school staff members to understand their experience. The SPARX intervention itself was codesigned with young people. All

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study results will be shared directly with participants and their schools through lay summaries and infographics.

Procedure

Ethical approval was provided by the University of New South Wales Human Research Ethics Committee (HC180836) and NSW Government State Education Research Applications Process Approval (SERAP 2019201).

The FPS has two waves of delivery (October-December 2020; April-July 2021). Process evaluation data will be collected at each wave. All school students will complete relevant survey questions at the same time as completing primary measures for the FPS. All study facilitators will be asked to provide informed consent for their data to be used for research purposes following the compulsory face-to-face training session they attend with the research team at the Black Dog Institute. Data provided by facilitators will be from two surveys, one completed immediately following the training and another completed after their final school visit. All school staff from intervention schools (on average, three from each school, estimated number of intervention schools = 100) who were directly involved in the study will be invited to complete one survey following the six-week SPARX intervention period. All surveys will be completed online.

After completing their respective online questionnaires, all school staff and study facilitators will be given the option to participate in a 60-minute individual interview (completed either in person or remotely). Purposive sampling will be used to capture a range of diverse school settings and experiences. Face-to-face interviews will be held in a quiet room on school grounds or at the Black Dog Institute. Virtual interviews, which may be required due to COVID-19 restrictions, will also be conducted. All interviews will be audio-recorded and transcribed verbatim. All contact with study facilitators and school staff, including the semi-structured interviews, will be made by research staff who have had no

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previous contact with them during the trial. This independence minimises the risk of bias and demand effects.

Data analysis

Quantitative

Questionnaire data and open-ended questions from surveys will be exported into data analytic software for analysis. Descriptive statistics will be calculated for all participant groups and will provide information about intervention use and its acceptability (questionnaire data from Year 8 participants), differential implementation, fidelity to the implementation strategy, school context factors within each school (questionnaire including several short answer questions from school staff), and competence and experience in schools from those facilitating the study (facilitator questionnaires). Differences between school clusters will be assessed using Analysis of Variance methods (ANOVA). Regression models will assess the on the effects of contextual factors on implementation outcomes (e.g., reach, uptake, acceptability).

Qualitative

Interviews will be digitally audio-recorded and transcribed verbatim. The transcripts will be checked for accuracy against the sound files as per best practice in transcription (47, 48). Qualitative data will then be imported into NVivo to aid in data management and analysis. Thematic analysis will be undertaken to identify, interpret and report on the repeated patterns of meaning within the data, drawing from Braun and Clark's classic six phase model (49, 50). An iterative and reflexive approach will be used to analyse the data, incorporating themes from the data together with topics covered in the interview guide. Two coders will independently engage in a familiarisation phase before generating codes and initial themes for a subset of the data. These codes and themes will be reviewed and

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discussed by the two coders, with refinement occurring via an interactive process. A senior qualitative analysist will also review the first-stage coding framework and scheme before all transcripts are coded by the first coder. Refinement will continue to occur via an interactive process until final codes and themes are realised and defined across the whole data set. Research rigor will be enhanced by a team approach to analysis, reflexive field notes, and prolonged engagement with the subject matter (51).

Triangulation of Qualitative and Quantitative Data

Triangulation involves the use of multiple approaches to address a research question. The combination of several approaches increases confidence in the findings and provides a more comprehensive account of the results than individual approaches would do alone (52). In this study, reliability, validity and confidence will be maximised through cross verification and exploration of differences between the outcomes of the various methods. This takes place in several ways:

- Maximising validity in analysis of qualitative data within the research team using techniques such as discussing coding, constant comparison, accounting for deviant cases, and systematic coding;
- Triangulation of school staff and research assistant interviews with results from the questionnaires, exploring and accounting for differences;
- Triangulation of self-report and interview data with publicly available information relating to school contextual characteristics (e.g., school socio-economic level and size) and school delivery of the program, including deviations to the implementation strategy.
- Mapping the perspectives of different stakeholders across the study (school staff, study facilitators).

Additional Analyses

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We will generate an 'implementation strength' metric for each school and its relationship to primary and secondary trial outcomes. This is an emerging evaluation approach, used mainly in low and middle-income countries. The approach aims to understand the degree of implementation effort needed during intervention delivery to achieve desired benefits (53, 54).

The implementation strength metric will provide funders and policy makers with an objective measure to monitor effectiveness of implementation if it goes beyond this trial and becomes a sustainable approach. The metric can be used to assess whether the approach to implementation meets the minimum level required to prevent the onset of mental health problems in adolescents. The metric will be based on implementation inputs and contextual factors informed by the intervention logic model and process evaluation frameworks (CFIR and RE-AIM) (e.g., adoption from teachers and other staff in the school and fidelity to the intervention strategy), and will be developed with the Future Proofing research team using principal component analysis.

Discussion

This paper describes the design of a mixed methods process evaluation of a cluster randomised controlled trial, the FPS. The FPS investigates the impact of a digital cognitive-behavioural therapy intervention when delivered at scale in school settings. Digital mental health programs have tremendous potential to prevent up to 22% of depression cases and, when delivered at scale, could have population-level impacts (55). However, these programs have not been translated into practice and policy because optimal ways to scale and deliver these interventions are not yet well understood.

As an initial step to address this issue, the current process evaluation will attend to contextual and implementation factors that vary across schools and provide a lens through

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which to interpret trial efficacy outcomes. We expect that results will provide a richly detailed and nuanced understanding of the key factors involved in the effective delivery of digital mental health programs across different schools. We expect that results will not only contextualise our trial findings but will also be used as a model to guide the delivery of school-based interventions that focus on preventing mental illness more broadly. Findings from this process evaluation will indicate whether the approach used in the FPS trial is likely to be sustainable in the school environment going forward and, if so, the threshold level of support required in order to prevent depression and benefit student mental health.

The prospective publication of this protocol outlines our planned methodological approach. It also serves as a road map for other researchers on a practical way of carrying out process evaluations of complex interventions in the school setting. As is the case with the delivery of interventions across different contexts, we acknowledge that our approach has inbuilt flexibility to explore the data and make provisions for unexpected implementation factors that arise.

Limitations and Strengths

There are several limitations to our process evaluation that warrant mention. First, we are not including direct observation of teachers in their role supporting the delivery of SPARX. While this would provide objective fidelity data, it requires resources beyond the scope of this project and is not representative of how the program will be sustained following the conclusion of the trial. Second, given the complexity of the study and high demand placed on students (e.g., engaging with the study apps and completing the online surveys at multiple time points over five years), we are not collecting in-depth qualitative data by way of interviews. Instead, we collect information about students' perceptions of the intervention (e.g., acceptability) through short self-report questions in the online survey. Second, the qualitative interviewer is a member of the research team (but not the evaluation team). Care

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will be taken to ensure that this staff member has no contact with schools prior to the interview visit to minimise bias. However, there remains a risk that demand effects may impact the information that is shared. Third, the process evaluation process (questionnaires and interview) will undoubtedly add to the burden placed on school staff. Given that the FPS is already placing a significant burden on the time of busy school staff, this additional component might contribute to low levels of participation.

To the point of burden on schools, one of the strengths of the design is that we have undertaken a pilot phase involving eight intervention schools and have been able to refine our processes (e.g., introduce an incentive) for school staff members to participate. This process evaluation also involves the combination of qualitative and quantitative methods which will be triangulated to provide a coherent and comprehensive picture of the data. The use of the 'implementation strength' metric represents a novel approach in this field, borrowed from the low-middle income country implementation science sector. The inclusion of this approach will provide important information to funders and policy makers following on from this trial, indicating the level of implementation support required to prevent mental illness and improve wellbeing of adolescent school students.

Notwithstanding the limitations raised above, this process evaluation will contribute to the broader knowledge base and indicate how best to deliver digital mental health prevention programs in school settings.

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Ethics and Dissemination

As noted, all procedures have received ethical approval from relevant committees. Results from this study will be published in an open access peer-reviewed journal.

Additional Files

Additional File 1 (Semi-Structured Interview Guides).docx

List of Abbreviations

FPS = Future Proofing Study

cRCT = Cluster Randomised Controlled Trial

CFIR = Consolidated Framework for Implementation Research

RE-AIM = Reach, Effectiveness, Adoption, Implementation, Maintenance framework

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Declarations

Trial status

Recruitment for the trial is underway. Data collection commences in **October** 2020 (delayed from April 2020 due to COVID-19).

Ethical approval and consent to participate

This study has ethical approval from the University of New South Wales Human Research Ethics Committee (HC180836; 21st January 2019) and NSW Government State Education Research Applications Process Approval (SERAP 2019201; 19th August 2019). All schools, staff, parents and participants must provide active consent to participate.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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randomised controlled trial within which this process evaluation is embedded came from an NHMRC Project Grant Awarded to Helen Christensen GNT1120646. The funding bodies had no role in any aspect of the study design or this manuscript.

Author contributions

HC and AWS conceived of the study and secured the funding. AWS and JRB led the design of the process evaluation, with input from all authors (including KH, IZ, PJB), and expert guidance from RL and KB. AWS drafted the manuscript, with assistance from JRB. ALC, MT, KM, RL, KB and HC have a continuing role in monitoring the conduct and outcomes of the process evaluation. All named authors contributed substantially to the approved final manuscript.

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Author information

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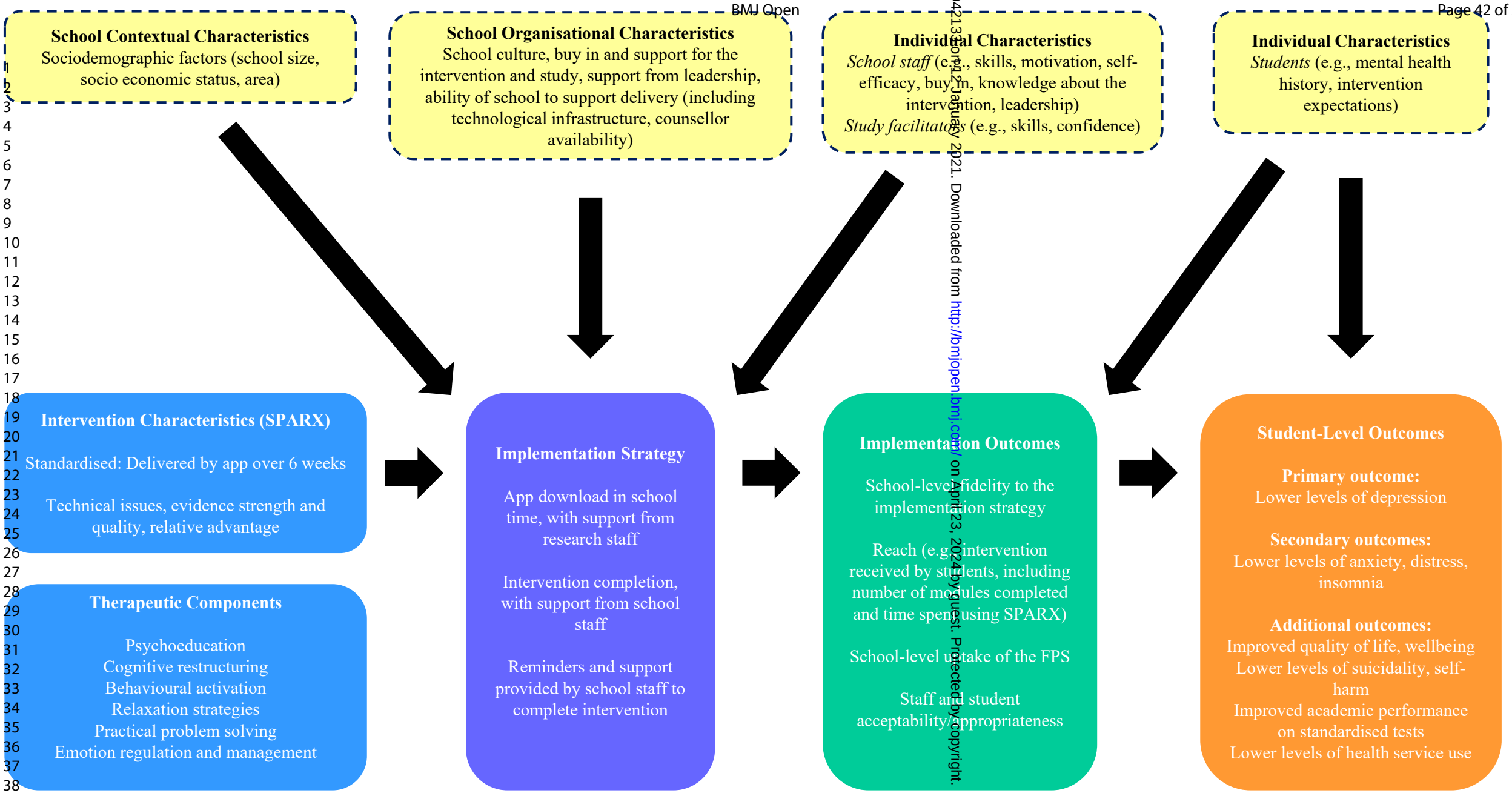

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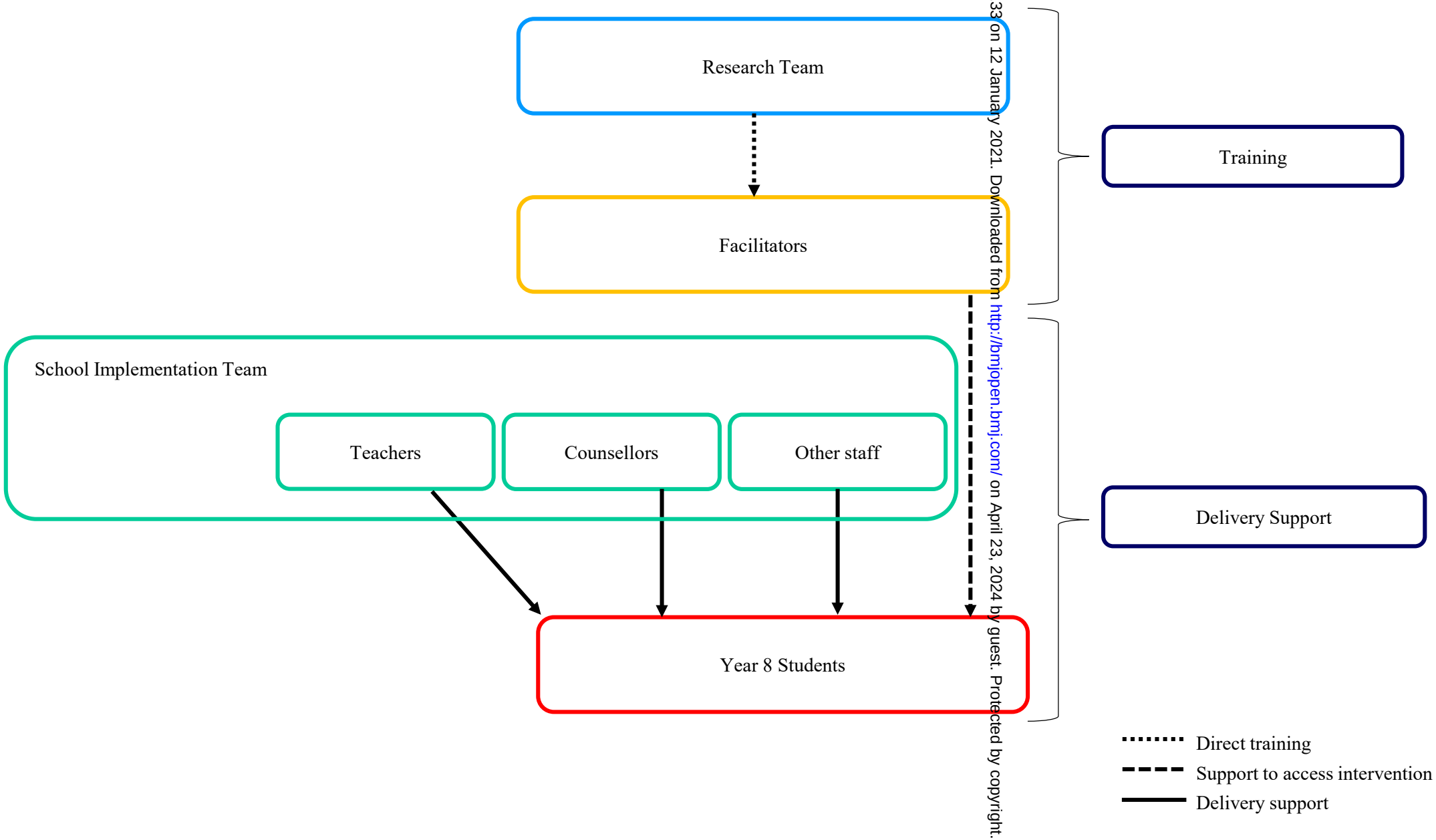

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Additional File 1
Semi-Structured Interview Guides
School Staff

INTRODUCTION: *Thank you for agreeing to take part in this interview. I appreciate your time.*

I am interested in hearing your thoughts and experiences of the Future Proofing program in your school. For this interview, the FP program includes the intervention app (SPARX) and everything else that was done to support the program in your school. I hope to use this information to work out what works in different schools and how to best provide support.

I will ask you a few questions about your experiences. This is chance for you to reflect and offer feedback on how we could improve. The interview will last up to one hour. It will be recorded, and your responses will be transcribed to ensure we accurately reflect your words. All personal information will be removed so that your answers are non-identifiable and confidential. Nothing you personally say will be shared with anyone on the FP team that you have been liaising with or with other staff at your school. You can choose to not answer any questions.

Do you have any questions before we get started?

General Opening Questions:

1. How did you first get involved in teaching/counselling/psychology?
2. Could you tell me about the core values and ethos of your school?
3. To the best of your knowledge, what mental health programs or initiatives has your school implemented to care for students besides the FP program?

Specific Questions:

4. Overall, how would you describe your experience with the FP program in your school?
5. What was your role in delivering or supporting the FP program in your school?
    a. Leader/driver, decision-maker, consent/recruitment, peripheral support

CFIR DOMAIN: INDIVIDUAL CHARACTERISTICS

Personal attributes (e.g., motivations, expectations, capacity, values)

6. Why were you motivated to take on this role?
    a. How did you come on board with the program?
7. Why do you think your school decided to support this program?
    a. To what extent do you think there was a need for a mental health program like FP in you school (*Tension for change)*?
8. What were your expectations about the FP program prior to coming on board?
    a. How were your expectations met (or not met)? What went differently to what you expected? What surprised you?
    b. What were your expectations about the apps?

Knowledge and beliefs about the intervention

9. How much do you know about SPARX, the intervention? E.g., principles, rationale, content?

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Self-efficacy

10. How confident were you in your ability to lead/support/make decisions about the FP program?
    a. What personal qualities do you think helped you to do that?

CFIR DOMAIN: OUTER SETTING

Relative Advantage

11. How did SPARX compare to other mental health programs that your school has supported or delivered?

CFIR DOMAIN: INNER SETTING

School contextual factors – Barriers and Facilitators

12. What factors influenced your ability to deliver/support the FP program in your school?
    a. What else helped or hindered your ability?
    b. Enquire into school-specific factors and program-specific factors e.g., What parts of the program were easy for you to do or support (e.g., the consent process, organising rooms, weekly team meetings)? OR What aspects of your school made it difficult for you to support the program?
    c. What factors got in the way of students completing the mental health app/s?
    d. Were you (or others) able to overcome any barriers? How did you manage to do this?

School contextual factors – Leadership

13. Tell me about the involvement of your school executive in the FP program.
    a. What role did this person have (e.g., principal/vice principal)? Did you meet regularly with this person or provide updates to them?
14. How do you think the school executive saw this initiative?

Readiness for implementation

15. How would you describe the readiness of your school to take on the FP program?
    a. What was the preparation phase like for you/other key staff?

IMPLEMENTATION METRICS

Appropriateness and Acceptability

16. How does the FP program align with your school's approach toward student mental health?
17. How suited is the FP program to address depression prevention in your school?
18. How well does an app delivering therapy work to prevent depression in your students?
19. How do you feel about using technology to deliver psychological interventions in your school?
    a. What worked well about this and what did not?
    b. Do you think SPARX met the student's mental health needs? In what way?
20. What were the by-products of the intervention that you didn't expect?
    a. What parts of the program do/do not suit your school?

***ADDITIONAL QUESTIONS FOR SCHOOL COUNSELLORS ONLY*

21. What was your experience with responding to students identified as needing follow-up during the FP program?
    a. Was there anything that could have been done to make this experience better for you and the student?
22. What do you think of the FP risk protocol?

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KEY LEARNING AND FUTURE IMPLEMENTATION

23. What parts of the FP program, if any, could be made more attractive to your school to increase uptake or support?
    a. In what ways could we make these parts more attractive?
24. To what extent do you think that the FP program could be integrated into your school's existing mental health strategy?
25. What advice would you give another school contemplating taking on the FP program?
26. What's been your major learning or insight from your school's involvement in the FP program?

Closing

27. Is there anything else you would like to add?

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Volunteer Research Assistants (Study Facilitators)

INTRODUCTION: *Thank you for offering to take part in this interview. I appreciate your time.*

I am interested in your thoughts about and experiences with supporting the FP program as a Research Assistant Volunteer. I hope to use this information to work out what works in different schools and how we can help volunteers to best provide support.

I will ask you a few questions about your experiences. This is chance for you to reflect and offer feedback on how we could improve. The interview will last up to one hour. It will be recorded and your responses will be transcribed to ensure we accurately reflect your words. All personal information will be removed so that your answers are non-identifiable and confidential. Nothing you personally say will be shared with the volunteer team or the Black Dog Institute more generally, so it will not affect your relationship with them. You can choose to not answer any questions.

Do you have any questions before we get started?

General Opening Questions:

1. What schools have you visited so far?
2. Roughly how many school visits have you attended?

Specific Questions:

CFIR DOMAIN: INDIVIDUAL CHARACTERISTICS

Personal attributes (e.g., motivation and expectations)

3. Why were you motivated you to volunteer?
4. What were your expectations coming on board with the FP program?
    a. How were your expectations met (or not met)?
    b. What went differently to what you expected? What surprised you?

Perceptions of Training

5. What are your overall impressions of the training you received?
    a. How helpful and appropriate was the training?
    b. What parts were the most useful?
    c. What was missing from the training?

CFIR DOMAIN: INNER SETTING

School visits – Barriers/Facilitators

6. What was your experience with completing the school visits?
7. Did anything unexpected happen during the school visits?
    a. If so, what?
    b. How did you manage this?
    c. How well do you think you managed this?
8. In general, how was the FP program received by school staff during visits?
9. To what extent was it useful having a volunteer partner/s at the visits?
    a. Were there any other benefits/disadvantages?

School contextual factors - Barriers/Facilitators

10. What factors influenced your ability to assist students and teachers at the school-visits?
    a. Were these common across all the visits or specific to a particular visit?
    b. What aspects of the school made it difficult to support the program?

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c. What else helped or hindered your ability? (e.g., research platform/app specific factors)
d. How did you overcome these barriers?
e. Were there any noticeable differences between different schools? If so, what were they?

KEY LEARNING AND FUTURE IMPLEMENTATION

11. What advice would you give a school contemplating taking on the FP program?
12. What advice would you give to others who are thinking about volunteering?
13. What parts of the FP program could be made more attractive to volunteers to increase uptake or support?
14. What's been your major learning or insight from taking part in the volunteer program?

Closing

15. Is there anything else you would like to add?

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Standards for Reporting Implementation Studies: the StaRI checklist for completion

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	1-2	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	2-3	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	**3**	5	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	**4**	9-11	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	8	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).
Aims and objectives	**5**	9	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	11	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons.		
Context	**7**	11-13	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	8	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	8	The population targeted by the intervention and any eligibility criteria.
Description	**9**	17	A description of the implementation strategy	8	A description of the intervention

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Sub-groups	**10**	N/A	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	18	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	N/A	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	14	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	N/A	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	7	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	26-28	Methods of analysis (with reasons for that choice)		
Sub-group analyses	**16**	26-28	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Results					
Characteristics	**17**	N/A	Proportion recruited and characteristics of the recipient population for the implementation strategy	N/A	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	N/A	Primary and other outcome(s) of the implementation strategy	N/A	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	N/A	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	N/A	Representativeness and outcomes of subgroups including those recruited to specific research tasks		

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Fidelity/ adaptation	**22**	N/A	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	N/A	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	N/A	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	N/A	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	28-30	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	N/A	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	N/A	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	31-33	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

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BMJ Open

Protocol for the Process Evaluation of a Complex Intervention Delivered in Schools to Prevent Adolescent Depression: The Future Proofing Study

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Protocol for the Process Evaluation of a Complex Intervention Delivered in Schools to Prevent Adolescent Depression: The Future Proofing Study

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Abstract

Introduction: Process evaluations provide insight into how interventions are delivered across varying contexts and why interventions work in some contexts and not in others. This manuscript outlines the protocol for a process evaluation embedded in a cluster randomised trial of a digital depression prevention intervention delivered to secondary school students (The Future Proofing Study). The purpose is to describe the methods that will be used to capture process evaluation data within this trial.

Methods and Analysis: Using a hybrid type 1 design, a mixed methods approach will be used with data collected in the intervention arm of the Future Proofing Study. Data collection methods will include semi-structured interviews with school staff and study facilitators, automatically collected intervention usage data, and participant questionnaires (completed by school staff, school counsellors, study facilitators, and students). Information will be collected about: i) how the intervention was implemented in schools, including fidelity; ii) school contextual factors and their association with intervention reach, uptake and acceptability; iii) how school staff, study facilitators, and students and responded to delivering or completing the intervention. How these factors relate to trial effectiveness outcomes will also be assessed. Overall synthesis of the data will provide school cluster-level and individual-level process outcomes.

Ethics and Dissemination: Ethics approval was obtained from the University of New South Wales Human Research Ethics Committee (HC180836; 21st January 2019) and the NSW Government State Education Research Applications Process (SERAP 2019201; 19th August 2019). Results will be submitted for publication in peer reviewed journals and discussed at conferences. Our process evaluation will contextualise the trial findings with respect to how the intervention may have worked in some schools but not in others. This evaluation will inform the development of a model for rolling out digital interventions for the prevention of

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mental illness in schools.

Trial Registration: The randomised controlled trial has been prospectively registered: ACTRN12619000855123. Registered 31 May 2019, https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=377664&isReview=true

Keywords: Process evaluation, complex intervention, mixed methods, adolescent mental health, depression, prevention, randomised controlled trial, implementation.

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Strengths and Limitations of this Study

- The methodology of this embedded process evaluation is underpinned by implementation frameworks and logic modelling.
- Flexible and pragmatic quantitative and qualitative data collection methods will be used to balance research rigor with feasibility within the school delivery context.
- Process data from a range of key stakeholders will be collected, including school staff, study facilitators, and students.
- To minimise burden on schools, fidelity data from teachers and in-depth qualitative data from students will not be collected.
- The methodology and study processes were pilot tested to ensure appropriateness within the school context.

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Introduction

Embedded in randomised controlled trials, process evaluations provide insight into reasons why interventions work in some contexts and not in others. These process evaluations can help to demystify the 'black box' of complex intervention trials by taking into account contextual factors, differences in ways the intervention is delivered, and adaptations made for intervention delivery into a particular system (1, 2). Contextual factors typically include features of the organisation or broader environment that influence the delivery of the intervention (e.g., leadership, engagement, culture, political landscape). Considering the contribution of contextual factors is necessary to aid interpretation of trial outcomes, maximise the knowledge gained from trials, identify optimal delivery processes across different settings, and inform broader dissemination efforts. In recognition of this need for process evaluations, the UK's Medical Research Council (MRC) set out a framework that emphasises the value of these evaluations in order to capture both contextual and implementation factors associated with complex interventions (3).

In line with best-practice recommendations that study protocols that pre-specify methods and approaches should be published to maintain research integrity (4), we describe a protocol for a mixed methods process evaluation embedded within a cluster randomised controlled trial (cRCT) known as the Future Proofing Study (FPS). The FPS is a large school-based trial examining whether depression can be prevented using cognitive behaviour therapy (CBT) delivered by smartphone application (5).

There has been an increase in the availability of digital mental health programs which show promise in addressing the significant disease burden associated with depression (6). Depression often first emerges during adolescence (7) and treatment alone cannot adequately reduce this burden (8). Accumulating evidence indicates that early adolescence is the ideal developmental window during which to intervene because it captures young people *before*

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the incidence of depression increases exponentially around the age of 16-17 years (9, 10). Therefore, increased efforts are being directed toward prevention approaches that are developed specifically for delivery among adolescents.

While there is evidence supporting the value and effectiveness of prevention programs in schools (11, 12), their uptake has been significantly limited by low levels of help-seeking (13) as well as practical constraints in cost and scalability. A lack of understanding about how to deliver these interventions sustainably at scale, and engage those who stand to benefit, have hampered the translation of prevention approaches into the community.

Two ways to overcome the barriers of cost and scalability of implementing adolescent depression interventions are:

- Delivering universal prevention programs in schools, and
- Using technology to deliver programs, which tends to be lower cost than traditional face-to-face methods (14).

Working with schools to deliver universal prevention programs, to every student, regardless of their risk, circumstance, or symptom profile, not only dramatically increases the potential reach of interventions, it also means that these programs can eventually be integrated into the curriculum and delivered to every student, making this approach a sustainable implementation strategy for widescale delivery and dissemination. Additionally, working with schools to deliver such programs reduces the need for young people to actively seek professional help. This is critically important - despite having a significant need, fewer than 80% of young people with mental illness seek help and receive the services they need (15, 16). The scaffolding provided by schools can be leveraged to deliver prevention programs to all students, which fits with a trend for schools to be designated the first point of contact to support youth mental health problems when they first emerge (9). Process

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evaluations of face-to-face mental health programs have been documented, some of which have been delivered in school settings (e.g., 17). However, we were unable to find any process evaluation descriptions in the literature that evaluate *digital mental health programs* in school settings. Conducting process evaluations specific to digital methods of delivery are important because the contextual barriers and facilitators, as well as concerns around fidelity of the intervention, are likely to have unique characteristics. For example, facilitator or training in intervention delivery will be different in supporting the use of an automated program relative to a face-to-face program. This process evaluation is an initial step towards addressing that gap.

Technology offers a promising way to deliver mental health interventions to the community. Digital mental health interventions offer two key advantages over face-to-face approaches – first, they are cheaper to access and more cost effective (18, 19), and second, they can be used to reach people across vast geographic areas. The latter is particularly important given Australia's geography, where remoteness and low population density meant that people in regional and rural areas often do not have the same level of access to mental health services as people in metropolitan areas. With more young people than ever using smartphones, mental health intervention delivered online or through applications represents an exciting avenue for reaching adolescents.

The Future Proofing Study (FPS)

The trial that is the subject of this process evaluation is the FPS. The FPS addresses barriers of reach, cost, and scalability by delivering a depression prevention program via a smartphone app to Year 8 secondary school students aged 12-13 years. This study is being conducted with approximately 200 Australian schools (up to 10,000 participants), of which half will be allocated to the intervention condition. The primary outcome is symptoms of depression. Secondary outcomes include anxiety, psychological distress and insomnia, among

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others. Symptom outcomes will be assessed at baseline, post-intervention, six months (primary outcome only), and then annually for five years. The primary endpoint is 12 months following baseline. More details are available from the Australian New Zealand Clinical Trials Registry (ANZCTRN12619000855123) and protocol paper (5).

The intervention being delivered is known as SPARX, a CBT-based program incorporating gamification principles. The development and initial evaluation of SPARX has been documented in detail previously (20). SPARX has been tested in an Australian sample of secondary students (delivered via computer) and shown to prevent depression in the lead up to final school exams (21). The gamified intervention teaches young people about the relationship between thoughts, feelings, and behaviour. Skills learnt through SPARX include emotion identification, emotion regulation, behavioural activation (being active), recognising and challenging unhelpful thoughts, and practical problem solving. SPARX consists of seven 20-minute modules. The intervention is fully automated, and the therapeutic components are standardised. See the trial protocol for full intervention details (5).

School Engagement and Recruitment

The FPS requires multiple levels of approval, beginning with state department and independent school body approval (NSW Department of Education; Catholic school dioceses), followed by individual school engagement. An engagement strategy for this study involves sending electronic communication material to all schools across New South Wales and in other Australian capital cities, targeting school principals and wellbeing staff to invite them to participate in this study opportunity. Schools are invited to submit expressions of interest and are subsequently followed up by the research team over the phone to explain more about the study. The schools for which the FPS is a good fit (as determined by the school) are then signed onto the study, with support from the principal, the school counsellor, and at least one other staff member (typically a teacher). In line with best practice in

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implementation science (22), this group of 2-3 staff members (typically not including the principal) will form the school-specific 'study implementation team'. After signing on to the study, several webinars are scheduled throughout the lead up to the study start date, so that school staff and parents can listen to a 15-minute study overview from the trial manager and have their questions answered.

Preparation

In preparation for in-class assessment sessions, study facilitators (volunteer research assistants) are recruited to support the study. The purpose of these facilitators is to attend schools to introduce the study to students, and ensure the technology is functioning so students can download the SPARX app and complete the baseline (and post-assessment) questionnaires. All facilitators go through an interview and screening process prior to selection, then attend a half day face-to-face training session before supporting the study in schools. This training provides an overview of the study and detailed information about their roles within schools, including a step-by-step guide to running the sessions. Discussion and practice are core components of the training.

Aims and Objectives

We adapted the MRC framework for complex interventions to focus on effectiveness of an evidence-based intervention *within a specific context of delivery* (i.e., schools). Overall, the objective of this process evaluation is to understand how SPARX is implemented and delivered in schools, and to identify systematic differences and variation in delivery. Specifically, the aims are:

1. To evaluate the reach (including completion), uptake and acceptability of the intervention (school- and student-level).
2. To understand the contribution of contextual factors (e.g., characteristics of the outer/inner setting, intervention, individuals) on:

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- School-level fidelity to the implementation strategy. For example, different schools will likely provide different levels of study support based on available resourcing.
- Implementation outcomes (intervention reach, uptake, acceptability), as assessed from the perspectives of school staff, teachers, and students. For example, young people's openness to receiving mental health material via an app will likely impact intervention acceptability and completion.

3. To examine the impact of school-level variation (in implementation fidelity and outcomes) on clinical effectiveness outcomes at the school- and student-level. School-level clinical effectiveness is defined as changes in clinical outcomes (e.g., self-reported depression) for different schools. The differing ways in which schools support and deliver the intervention will inevitably impact its effectiveness, and this evaluation will assess these differences (3, 23). For example, degree of support from senior school leaders who would be expected to understand that participating in study activities is a priority for the school will likely impact effectiveness at the cluster level.

This process evaluation has been designed to capture important information from teachers, school staff and students at both the school and individual level, which may ultimately impact the effectiveness of the intervention on clinical mental health outcomes for students. Findings will provide insight into factors which support and/or hinder the implementation of digital universal mental health programs in school settings. Knowledge gained from this process evaluation will help to inform the development of a model and guide for how to best deliver digital mental health programs to young people in schools.

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Methods and Analysis

Design

This study uses a hybrid type 1 approach (24), with a focus on implementation process factors and outcomes in the context of an effectiveness trial. The evaluation is guided by the CFIR and RE-AIM framework (25, 26). In keeping with Nilsen's categorisation of implementation theories, models, and frameworks, these frameworks help us to understand different parts of the implementation process (27). The CFIR will be used to identify **barriers and facilitators** to intervention implementation and effectiveness (27). The CFIR is a widely used deterministic theoretical framework which has been applied in multiple settings (28), including schools (e.g., 29). The CFIR identifies five major domains, including (i) the outer setting, which includes the social, political and economic context that the organisation in which implementation is occurring exists; (ii) the inner setting, which includes features and characteristics of the organisation such as leadership and relative priority; (iii) the characteristics of individuals, which includes organisational staff knowledge and attitudes about the intervention and their role and identification within the wider organisation; (iv) the characteristics of the intervention itself and; (v) implementation processes, which includes the ways that the intervention will be delivered in a given context (including fidelity to the implementation strategy). Normalisation Process Theory will be used to provide additional insights into implementation processes (NPT; 30). NPT aims to identify and explain the implementation of new interventions and how they become integrated into routine care.

The RE-AIM framework will be used to evaluate the **implementation outcomes**, including intervention reach, uptake, and acceptability/appropriateness (25, 31). These outcomes also map onto the framework of implementation outcomes proposed by Proctor and colleagues (32, 33). Reach refers to the proportion of eligible participants who opened, used, and completed the intervention, as well as the proportion of students from the entire cohort of

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eligible students in intervention schools who consented to participate. Uptake refers to the proportion of schools that were onboarded to the study (intervention and control arms), and of school staff who were willing to support the delivery of the intervention (intervention arm only). Reach and uptake also incorporate the representativeness of the sample (school-level and individual-level). Acceptability and appropriateness refer to the perceived agreeableness or fit of the intervention. This evaluation will incorporate how the barriers and facilitators identified through the CFIR impacted the implementation outcomes, and, in turn, how these implementation outcomes impacted effectiveness outcomes.

Logic Model

Following MRC guidance (3), the research team developed a logic model for the FPS process evaluation in a series of participatory workshops. The logic model was prospectively informed by key CFIR constructs identified in previous literature as being important in school-based studies, but also feasible and appropriate to measure within the school context in the FPS. The key constructs included the outer setting, inner setting, individual characteristics, and intervention characteristics. The logic model (Figure 1) was developed to consider the key factors (mapped to the CFIR) that would potentially impact implementation of the intervention (mapped to RE-AIM), as well as its clinical effectiveness. The process evaluation method, including the selection of dependent variables and design of surveys and semi-structured interview guides, were derived from this logic model. See Table 1 for CFIR/RE-AIM domains, key research questions, process data, and data that will be collected within each domain.

A pilot study of 8 schools conducted in 2019 was used to assess the suitability of the planned implementation strategy and process evaluation methods. We retrospectively applied our logic model to collected data to evaluate whether our methodology captured relevant

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constructs, and sufficient variation in these constructs. We integrated learnings from this pilot study using a dynamic feedback process to strengthen our methodology for the full-scale FPS phase. Some minor changes were made following this pilot which relate to the CFIR, including a greater emphasis on sub-constructs such as school climate (inner setting).

<INSERT FIGURE 1 HERE>

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Table 1 – Process evaluation details including process data, outcome data, data type and source

CFIR and RE-AIM Constructs	Research Aim	Process or Outcome Data	Data Type and Source
Outer Setting			
School contextual characteristics	What was the broad context of the schools in which the SPARX intervention was delivered? (Aim 2)	School socio-economic index School location (metropolitan/regional)	Publicly available information (ICSEA, GPS)
Inner Setting			
School organisational characteristics	What were the characteristics of the delivery environments (schools)? (Aim 2)	School size, type, composition, funding School culture	Publicly available information (school size, type, funding) SSPASH (assesses school culture) Interviews with school staff
	What were the barriers and facilitators that affected buy-in, delivery, and student uptake? (Aim 2)	Implementation climate, relative priority, competing demands, leadership, school counsellor availability and level of support, networks and communication, school culture and climate, school readiness for implementation	Implementation Climate measures (staff and students) Relative Priority measure Competing Demands measure Interviews with school staff Checklists completed by trial manager Other administrative data including number of staff allocated to assist with delivery and consent process, level of communication with the research team
School leadership	How supportive of delivering SPARX were school principals, deputy principals and executives? (Aim 2)	Level of support and buy in from school leaders	Interviews with school staff
Individual Characteristics			
School staff	What were the characteristics (including attitudes, beliefs, traits) of school staff supporting the delivery of the intervention? (Aim 2)	Age, gender, current employment, role etc	Demographics questionnaire
	How supportive of delivery were school staff who were involved on-the-ground? (Aim 2)	Leadership, skills, motivations, expectations, self-efficacy, expectations, time available, knowledge and beliefs about the intervention, study buy in	Implementation Leadership Scale Interviews with school staff and study facilitators
Study facilitators	How well did study facilitators attending schools support the delivery of the intervention? (Aim 2)	Age, employment Skills, self-efficacy or confidence, motivations and expectations	Demographics questionnaire Self-confidence measure Interviews with study facilitators

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Students	What were the characteristics of young people that affected intervention uptake and effectiveness? (Aim 2)	History of mental illness	Reported by Year 8 students as part of the online FPS survey
Intervention Characteristics			
SPARX	Were there any barriers to intervention use? (Aim 2 and 3)	Technical issues	Logs of technical issues sent through schools, parents and participants IT data pertaining to technical problems Informal feedback provided by schools and research staff attending schools
	What do staff think about the efficacy and advantage of using the intervention? (Aim 2)	Evidence strength and quality, relative advantage	Relative Advantages measure Anticipated Benefits measure Interviews with school staff
Implementation Processes			
Normalisation and integration	How did school staff perceive the implementation processes? (Aim 2)	Coherence, cognitive participation, and collective action	NoMAD
Fidelity to the implementation strategy	To what extent was the intervention implemented as planned? (Aim 2)	School delivery of the FP program, including changes to the plan	Completed implementation checklists, emails and feedback forms Interviews with school staff
Implementation Outcomes			
Reach	What was the extent to which those who were eligible to receive SPARX used it? (Aim 1)	Proportion of eligible participants who consented to participate; proportion who opened, used and completed the SPARX intervention Representativeness of the student sample	Administrative data about consent. Digital analytic data including usage (app downloads, installs, opens), completion rate (number of modules completed) and time spent using SPARX Reported by Year 8 students as part of the online FPS survey
Uptake	How many eligible schools participated in the study? Within those schools, how many staff supported the delivery of SPARX? (Aim 1)	Proportion of eligible schools that were onboarded to the study; proportion of school staff (in intervention schools) who supported SPARX Representativeness of the sample	Administrative data Publicly available information about schools and self-report demographic data from school staff
Acceptability/appropriateness	How satisfied were participants with the intervention? (Aim 1)	Acceptability/appropriateness of the intervention, expectations	Reported by Year 8 students as part of the online FPS survey Informal conversations and feedback provided by Year 8 students
		Acceptability/appropriateness of the Future Proofing program (including SPARX)	Implementation Appropriateness measure Interviews with school study staff

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	How satisfied were school staff with supporting the intervention the FP program (including SPARX)? (Aim 1)	Informal conversations and feedback provided by school staff
Across Domains		
	How might the relationship between the intervention, the staff supporting the program, and context of each school shape variation in outcomes (implementation strength metric)? (Aim 2 and 3) How might the school-level variation (in implementation fidelity and outcomes) affect clinical effectiveness outcomes (e.g., self-reported depression)? (Aim 3) What key lessons emerge from this study that can be generalised to the implementation of digital mental health programs in schools more broadly?	

Note. The process data and outcomes are mapped onto Figure 2. CFIR = Consolidated Framework for Intervention Research; RE-AIM = Reach, Effectiveness, Adoption, Implementation, Maintenance; Aim = Aims outlined in the Aims and Objectives section; SSPESH = Survey of School Promotion of Emotional and Social Health; NoMAD = Normalisation Measure Development questionnaire.

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School Implementation Strategy

The school implementation strategy was developed by the study authors. The authors drew on their experience in school-based intervention delivery and integrated feedback from teachers and school staff from several completed school-based trials that delivered digital interventions to school students (21, 34). Stakeholder consultation specifically for this study involved discussions with the Department of Education, consultation with several school parent committees and consultation with both youth and parent Lived Experience Advisory Panels. This strategy was also refined following the first pilot wave involving eight intervention schools.

The school 'study implementation teams' are principally responsible for the implementation of the intervention and liaising with the research team. As described earlier, these teams typically incorporate at least one classroom teacher and one school counsellor to assist with the intervention delivery. Study facilitators also support the delivery of the SPARX intervention by attending schools for the first school session.

Implementation Strategy. During the active intervention phase, schools allocate a minimum of 4 x 20-minute school class sessions during which students complete the SPARX intervention. The additional three sessions may be completed either in class if permitted by the schools, or in the students' own time. The implementation strategy developed by the project team and stakeholders to support the completion of the SPARX intervention comprises:

- Standardised facilitator training delivered face-to-face over a half-day
- Study facilitators are present at schools to support students in downloading the SPARX app and completing the baseline assessments
- School implementation team provided with a SPARX user-guide and information booklet they can refer to during the sessions

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- Schools provide students with weekly verbal reminders in home classrooms to use the app regularly
- Schools publish brief information about the study and mental health tips in the school weekly newsletter
- Schools liaise with research team weekly to troubleshoot problems

This is the strategy being outlined to schools by the research team and adherence to this strategy will be assessed. Whether or not schools schedule more than the four mandated in-class sessions for intervention completion is flexible and can be adapted to suit the preferences of the school. Student participants receive a $20AUD voucher after the intervention period to cover any phone or data related costs incurred. See Figure 2 for details of training and delivery structure.

<INSERT FIGURE 2 HERE>

Data Collection Methods and Participant Groups for Process Evaluation

There are three participant groups taking part in the process evaluation: Year 8 students, school staff members (e.g., teaching and counselling staff), and study facilitators (see Table 2). School staff members will be members who are responsible for leading the delivery of the study in their school or will be teaching staff who have a supporting role (e.g., home room teachers who provide reminders to students to complete the intervention).

Four types of data will be collected and triangulated: self-report questionnaire data, digital analytic data, administrative data, and qualitative interview data. Self-report questionnaire data specific to the process evaluation will be collected from staff and study facilitators using online survey software (Qualtrics) programmed by one of the authors (JB). These questionnaires assess demographic information, school organisational characteristics,

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individual characteristics, intervention characteristics, implementation processes and implementation outcomes. Where no available published questionnaires were identified as being suitable for this process evaluation, we adapted existing standardised measures or developed our own items (details below). Self-report questionnaire data from Year 8 students about intervention use and feedback will be collected from an online survey (details described in 5). Digital analytic data about intervention use will be captured by the purpose-built Black Dog Institute research platform, which is being used for the broader FPS. Administrative data will be collected through a range of sources, including communications with the research team. Qualitative data will be collected using semi-structure interviews. All data collected will be from intervention schools only as no intervention is implemented in control schools. Student and school staff data will be collected immediately after the intervention period has been completed (i.e., after the six-week intervention stage); facilitator data will be collected both before and after the intervention period.

Table 2. Summary of data forms (and collection point) provided by each of the participant groups

Participant group	Questionnaire	Individual interview	Digital analytics
Year 8 students	✓ (post-intervention)		✓ (ongoing)
School staff	✓ (post-intervention)	✓ (post-intervention)	
Facilitators	✓ (before first school visit and after final post-intervention visit)	✓ (after final school post-intervention visit)	

Implementation Predictors

School Organisational Characteristics (Inner Setting).

Publicly Available Information. Publicly available information will be collected about school contextual characteristics, including socio-economic level, size, location, type, and funding.

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General School Culture. School staff will complete the Survey of School Promotion of Emotional and Social Health (SSPESH; 35) and a measure of organisational culture (36). The SSPESH assesses a school's capacity to promote social and emotional wellbeing, and contains four subscales: Positive School Community, Student Social and Emotional Learning, Engaging Families, and Supporting Students Experiencing Mental Health Difficulties. Items are rated on a 4-point Likert scale from 0 (not yet in place) to 3 (completely in place) and preliminary investigations support the scale structure and criterion-related validity (35).

We adapted a 9-item questionnaire about general culture within a health care setting to use within the school setting (36). Items are rated on a 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree). Lower scores indicate a more positive working culture, which includes transparency, productive working relationships, and receptivity to feedback. Previous investigation has shown that this measure has good internal consistency, although overlaps somewhat with other sub-constructs within the inner setting (e.g., learning climate; 35).

Implementation Climate. School staff will complete a measure of implementation climate that we adapted for use in the school context (36). Items are rated on a 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree). Lower scores indicate increased staff receptivity to the program and support within the school, including rewards and recognition. This measure has acceptable internal consistency and good discriminant validity (36).

Relative Priority. School staff will complete one adapted item from the School Contextual Barriers subscale of the Perceived Attributes of the Healthy Schools Approach Scale (37). The item is rated on a 5-point scale Likert scale from 1 (strongly agree) to 5 (strongly disagree). Higher scores indicate that other activities did not interfere with implementation of the FP program.

Competing Demands. Staff will complete 3-items, developed specifically for this

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study, which assess how much time they allocated, and desired to allocate, to the FP program relative to other competing workload demands on visual analogue scales (anchor by 0 = no work time, 100% = all of my work time). Higher scores indicate increased allocation of time and prioritisation of the FP program.

Individual Characteristics.

Leadership. School staff will complete the Implementation Leadership Scale (ILS; 38). The ILS is a 12-item scale that assesses leadership behaviours that support implementation of evidence-based practices. The ILS contains four subscales, and two will be included in the current study (Knowledge Leadership and Supportive Leadership). These scales assess the degree to which the staff member was knowledgeable about and offered support to the program. Items are rated on a 5-point Likert scale from 0 (very much so) to 4 (not at all) and will be re-coded such that higher scores indicate more effective implementation leadership behaviours. This measure has excellent internal validity, convergent validity, and discriminant validity (38).

Self-Efficacy and Confidence. Study facilitators will rate their level of confidence in performing 23 different tasks during school-visits on visual analogue scales, which are based on the training program they completed (anchor by 0 = not at all confident, 100 = very confident). Higher scores indicate higher levels of confidence. A similar questionnaire will be repeated following their school-visits, along with four short answer questions that assess experiences with supporting staff and students during school-visits.

Intervention Characteristics.

Relative Advantage and Evidence Strength and Quality. School staff will complete the 2-item Relative Advantages subscale and one item from the Anticipated Benefits subscale of the Perceived Attributes of the Healthy Schools Approach Scale (37). Adapted for the current study, items are rated on a 5-point scale Likert scale from 1 (strongly agree) to 5

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(strongly disagree). Scores will be re-coded such that higher scores indicate greater perceived advantage of the FP program compared to others and greater perceived impacts on mental health, respectively.

Implementation Processes.

Normalisation and Integration into Routine Practice. School staff will complete NPT's accompanying tool, the Normalisation MeAsure Development questionnaire (NoMAD; 39). The NoMAD is a 23-item measure that assesses how professionals involved in the implementation of a complex intervention perceive implementation processes. It is a flexible measure that can be altered to more accurately describe the adoption of new interventions at the provider level. Ten items of the NoMAD will be used in this study to assess intervention buy-in from school staff, and how staff members incorporated the initiative into their standard work responsibilities. These items are grouped into three categories: coherence (i.e., making sense of an intervention), cognitive participation (i.e., working with others to support an intervention), and collective action (i.e., the type of work that people do to support an intervention). Items are rated on a 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree). Initial validation demonstrated that the NoMAD has good face validity, construct validity, and internal consistency (40).

Fidelity to the Implementation Strategy. Fidelity will be captured through implementation checklists, communications between schools and research staff, and interviews with school staff.

Implementation Outcomes

Reach. SPARX app usage data from students will allow for the assessment of app use (downloads, installs, and opens), completion (number of modules completed, out of a total of seven), and time spent using SPARX. Administrative data about the number of students in intervention schools with consent to participate will also be used as an indicator of reach.

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Self-report data about individual characteristics (e.g., gender, mental health history) will be used to gauge the representativeness of the students in the intervention schools.

Uptake. Administrative data about the proportion of schools that were onboarded to the study and the proportion of teachers who supported the intervention will be collected to provide an index of uptake by schools. Representativeness of the sample will be informed by publicly available information about school characteristics (e.g., socio-economic status, location) and self-report data about school staff characteristics (e.g., role, gender).

Appropriateness. School staff will complete the Intervention Appropriateness Measure (IAM; 41). The IAM is a pragmatic 4-item measure of the perceived fit, relevance, or compatibility of an evidence-based practice for a context, person, or problem (42). Items have been adapted for this study and are rated on a 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree). Scores will be re-coded such that higher scores indicate higher levels of perceived appropriateness. The IAM demonstrated strong psychometric properties in previous research (41). School staff will also complete one adapted item from the Agency Leadership Support subscale of the Barriers and Facilitators to Implementing Survey (43). The item is rated on a 5-point Likert scale from 1 (strongly agree) to 5 (strongly disagree) and will be re-coded such that higher scores indicate greater compatibility of the FP program within a particular school.

Acceptability. Year 8 students will complete an 11-item feedback questionnaire about SPARX. The questionnaire assesses three domains, including: (i) reasons for non-adherence; (ii) intervention acceptability; and (iii) skills learnt from the intervention. Items will be quantified individually. This questionnaire has previously been used to assess the acceptability of the SPARX program in the school context (44).

Individual Interviews

Interview guides for school staff and study facilitators were derived from the logic

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model, CFIR online resources (e.g., https://cfirguide.org/evaluation-design/qualitative-data/), and the broader literature investigating the delivery of interventions in school settings (45, 46; see Additional File 1 for interview guides). Interviews will provide information about both implementation predictors and outcomes. For school staff, questions focus on: motivations and expectations about the intervention and study processes more broadly; knowledge and beliefs about the intervention; relative advantages of the intervention; self-efficacy; barriers and facilitators affecting the delivery of the intervention, including fidelity; appropriateness and acceptability of the intervention; and recommendations for future implementation. School counsellors will also be asked questions about their experiences of managing high risk participants within the study and compatibility with existing workload. For study facilitators, questions focus on: motivations and expectations about their role; confidence and competence in supporting the delivery of SPARX in schools; the quality of their training; and perceptions about their ability to support the study as required.

The interview guides allow for flexibility in questioning and diversion in responses. Questions will primarily be open-ended, with specific prompts and follow-up questions being used as necessary to encourage respondents to elaborate on their ideas and provide examples.

Patient and Public Involvement

The Future Proofing Study was developed with key stakeholders including school personnel, school counsellors, parents, adolescents, and individuals with a lived experience of mental illness. All aspects of the study design, appropriateness of outcomes measures and consent procedures were developed in consultation with these stakeholder groups. The current process evaluation involves consultation with school staff members to understand their experience. The SPARX intervention itself was codesigned with young people. All study results will be shared directly with participants and their schools through lay summaries and infographics.

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Procedure

The FPS has three waves of delivery (October-December 2020; April-July 2021; July-September 2021). Process evaluation data will be collected at each wave. All school students will complete relevant survey questions at the same time as completing primary measures for the FPS. All study facilitators will be asked to provide informed consent for their data to be used for research purposes following the compulsory face-to-face training session they attend with the research team at the Black Dog Institute. Data provided by facilitators will be from two surveys, one completed immediately following the training and another completed after their final school visit. All school staff from intervention schools (on average, three from each school, estimated number of intervention schools = 100) who were directly involved in the study will be invited to complete one survey following the six-week SPARX intervention period. All surveys will be completed online.

After completing their respective online questionnaires, all school staff and study facilitators will be given the option to participate in a 60-minute individual interview (completed either in person or remotely). Purposive sampling will be used to capture a range of diverse school settings and experiences. Face-to-face interviews will be held in a quiet room on school grounds or at the Black Dog Institute. Virtual interviews, which may be required due to COVID-19 restrictions, will also be conducted. All interviews will be audio-recorded and transcribed verbatim. All contact with study facilitators and school staff, including the semi-structured interviews, will be made by research staff who have had no previous contact with them during the trial. This independence minimises the risk of bias and demand effects.

Data analysis Plan

Quantitative. Survey questionnaire data (from approximately 100 schools) will be

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exported into data analytic software for analysis. Descriptive statistics will be calculated for all participant groups and will provide information about intervention use and its acceptability (questionnaire data from Year 8 participants), differential implementation, fidelity to the implementation strategy, school context factors within each school (questionnaire including several short answer questions from school staff), and competence and experience in schools from those facilitating the study (facilitator questionnaires). Differences between school clusters will be assessed using Analysis of Variance methods (ANOVA). Regression models will assess the on the effects of contextual factors on implementation outcomes (e.g., reach, uptake, acceptability).

Qualitative. Interviews will be digitally audio-recorded and transcribed verbatim. The transcripts will be checked for accuracy against the sound files as per best practice in transcription (47, 48). Qualitative data will then be imported into NVivo to aid in data management and analysis. Thematic analysis will be undertaken to identify, interpret and report on the repeated patterns of meaning within the data, drawing from Braun and Clark's classic six phase model (49, 50). An iterative and reflexive approach will be used to analyse the data, incorporating themes from the data together with topics covered in the interview guide. Two coders will independently engage in a familiarisation phase before generating codes and initial themes for a subset of the data. These codes and themes will be reviewed and discussed by the two coders, with refinement occurring via an interactive process. A senior qualitative analysist will also review the first-stage coding framework and scheme before all transcripts are coded by the first coder. Refinement will continue to occur via an interactive process until final codes and themes are realised and defined across the whole data set. Research rigor will be enhanced by a team approach to analysis, reflexive field notes, and prolonged engagement with the subject matter (51).

Triangulation of Qualitative and Quantitative Data. Triangulation involves the use

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of multiple approaches to address a research question. The combination of several approaches increases confidence in the findings and provides a more comprehensive account of the results than individual approaches would do alone (52). In this study, reliability, validity and confidence will be maximised through cross verification and exploration of differences between the outcomes of the various methods. This takes place in several ways:

- Maximising validity in analysis of qualitative data within the research team using techniques such as discussing coding, constant comparison, accounting for deviant cases, and systematic coding;
- Triangulation of school staff and research assistant interviews with results from the questionnaires, exploring and accounting for differences;
- Triangulation of self-report and interview data with publicly available information relating to school contextual characteristics (e.g., school socio-economic level and size) and school delivery of the program, including deviations to the implementation strategy.
- Mapping the perspectives of different stakeholders across the study (school staff, study facilitators).

Additional Analyses. We will generate an 'implementation strength' metric for each school and its relationship to primary and secondary trial outcomes. This is an emerging evaluation approach, used mainly in low and middle-income countries. The approach aims to understand the degree of implementation effort needed during intervention delivery to achieve desired benefits (53, 54).

The implementation strength metric will provide funders and policy makers with an objective measure to monitor effectiveness of implementation if it goes beyond this trial and becomes a sustainable approach. The metric can be used to assess whether the approach to implementation meets the minimum level required to prevent the onset of mental health

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problems in adolescents. The metric will be based on implementation inputs and contextual factors informed by the intervention logic model and process evaluation frameworks (CFIR and RE-AIM) (e.g., adoption from teachers and other staff in the school and fidelity to the intervention strategy), and will be developed with the Future Proofing research team using principal component analysis.

Ethics and Dissemination

Ethics approval was obtained from the University of New South Wales Human Research Ethics Committee (HC180836; 21st January 2019) and the NSW Government State Education Research Applications Process (SERAP 2019201; 19th August 2019). Results will be submitted for publication in peer reviewed journals and discussed at conferences. Our process evaluation will contextualise the trial findings with respect to how the intervention may have worked in some schools but not in others. This evaluation will inform the development of a model for rolling out digital interventions for the prevention of mental illness in schools.

Discussion

This paper describes the design of a mixed methods process evaluation of a cluster randomised controlled trial, the FPS. The FPS investigates the impact of a digital cognitive-behavioural therapy intervention when delivered at scale in school settings. Digital mental health programs have tremendous potential to prevent up to 22% of depression cases and, when delivered at scale, could have population-level impacts (55). However, these programs have not been translated into practice and policy because optimal ways to scale and deliver these interventions are not yet well understood.

As an initial step to address this issue, the current process evaluation will attend to

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contextual and implementation factors that vary across schools and provide a lens through which to interpret trial efficacy outcomes. We expect that results will provide a richly detailed and nuanced understanding of the key factors involved in the effective delivery of digital mental health programs across different schools. We expect that results will not only contextualise our trial findings but will also be used as a model to guide the delivery of school-based interventions that focus on preventing mental illness more broadly. Findings from this process evaluation will indicate whether the approach used in the FPS trial is likely to be sustainable in the school environment going forward and, if so, the threshold level of support required in order to prevent depression and benefit student mental health.

The prospective publication of this protocol outlines our planned methodological approach. It also serves as a road map for other researchers on a practical way of carrying out process evaluations of complex interventions in the school setting. As is the case with the delivery of interventions across different contexts, we acknowledge that our approach has inbuilt flexibility to explore the data and make provisions for unexpected implementation factors that arise.

Limitations and Strengths

There are several limitations to our process evaluation that warrant mention. First, we are not including direct observation of teachers in their role supporting the delivery of SPARX. While this would provide objective fidelity data, it requires resources beyond the scope of this project and is not representative of how the program will be sustained following the conclusion of the trial. Second, given the complexity of the study and high demand placed on students (e.g., engaging with the study apps and completing the online surveys at multiple time points over five years), we are not collecting in-depth qualitative data by way of interviews. Instead, we collect information about students' perceptions of the intervention (e.g., acceptability) through short self-report questions in the online survey. Second, the

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qualitative interviewer is a member of the research team (but not the evaluation team). Care will be taken to ensure that this staff member has no contact with schools prior to the interview visit to minimise bias. However, there remains a risk that demand effects may impact the information that is shared. Third, the process evaluation process (questionnaires and interview) will undoubtedly add to the burden placed on school staff. Given that the FPS is already placing a significant burden on the time of busy school staff, this additional component might contribute to low levels of participation.

To the point of burden on schools, one of the strengths of the design is that we have undertaken a pilot phase involving eight intervention schools and have been able to refine our processes (e.g., introduce an incentive) for school staff members to participate. This process evaluation also involves the combination of qualitative and quantitative methods which will be triangulated to provide a coherent and comprehensive picture of the data. The use of the 'implementation strength' metric represents a novel approach in this field, borrowed from the low-middle income country implementation science sector. The inclusion of this approach will provide important information to funders and policy makers following on from this trial, indicating the level of implementation support required to prevent mental illness and improve wellbeing of adolescent school students.

Notwithstanding the limitations raised above, this process evaluation will contribute to the broader knowledge base and indicate how best to deliver digital mental health prevention programs in school settings.

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Additional Files

Additional File 1 (Semi-Structured Interview Guides).docx

List of Abbreviations

FPS = Future Proofing Study

cRCT = Cluster Randomised Controlled Trial

CFIR = Consolidated Framework for Implementation Research

RE-AIM = Reach, Effectiveness, Adoption, Implementation, Maintenance framework

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Declarations

Authors' Contributions

HC and AW-S conceived of the study and secured the funding. AW-S and JRB led the design of the process evaluation, with input from all authors (including KH, IZ, PJB), and expert guidance from RL and KB. AW-S drafted the manuscript, with assistance from JRB. ALC, MT, KM, RL, KB and HC have a continuing role in monitoring the conduct and outcomes of the process evaluation. All named authors contributed substantially to the approved final manuscript.

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Competing Interests Statement

The authors declare that they have no competing interests.

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feedback on this project.

Trial Status

Recruitment for the trial is underway. Data collection commences in **October** 2020 (delayed from April 2020 due to COVID-19).

Consent to Participate

All schools, staff, parents, and participants must provide active consent to participate.

Consent for Publication

Not applicable.

Availability of Data and Materials

Not applicable.

Author information

Not applicable.

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Figure Legends

Figure 1. Logic model. The model shows that CFIR constructs including school context characteristics, school organisational characteristics, and individual characteristics, will influence how staff engage with the implementation strategy. The intervention itself, which includes the core cognitive-behavioural therapeutic components, is conceptualised as standardised across individuals because it is delivered digitally, follows a fixed schedule and does not incorporate tailored content. The yellow input factors are expected to vary across schools and individuals, thus influencing engagement and flexibility of the implementation strategy and in turn, implementation outcomes and student-level outcomes. The logic model and implementation plan were externally peer reviewed by an experienced and internationally recognised implementation scientist outside the team within an implementation workshop. For details on assessment of these factors, see Table 1.

Figure 2. Details of implementation strategy training and delivery structure.

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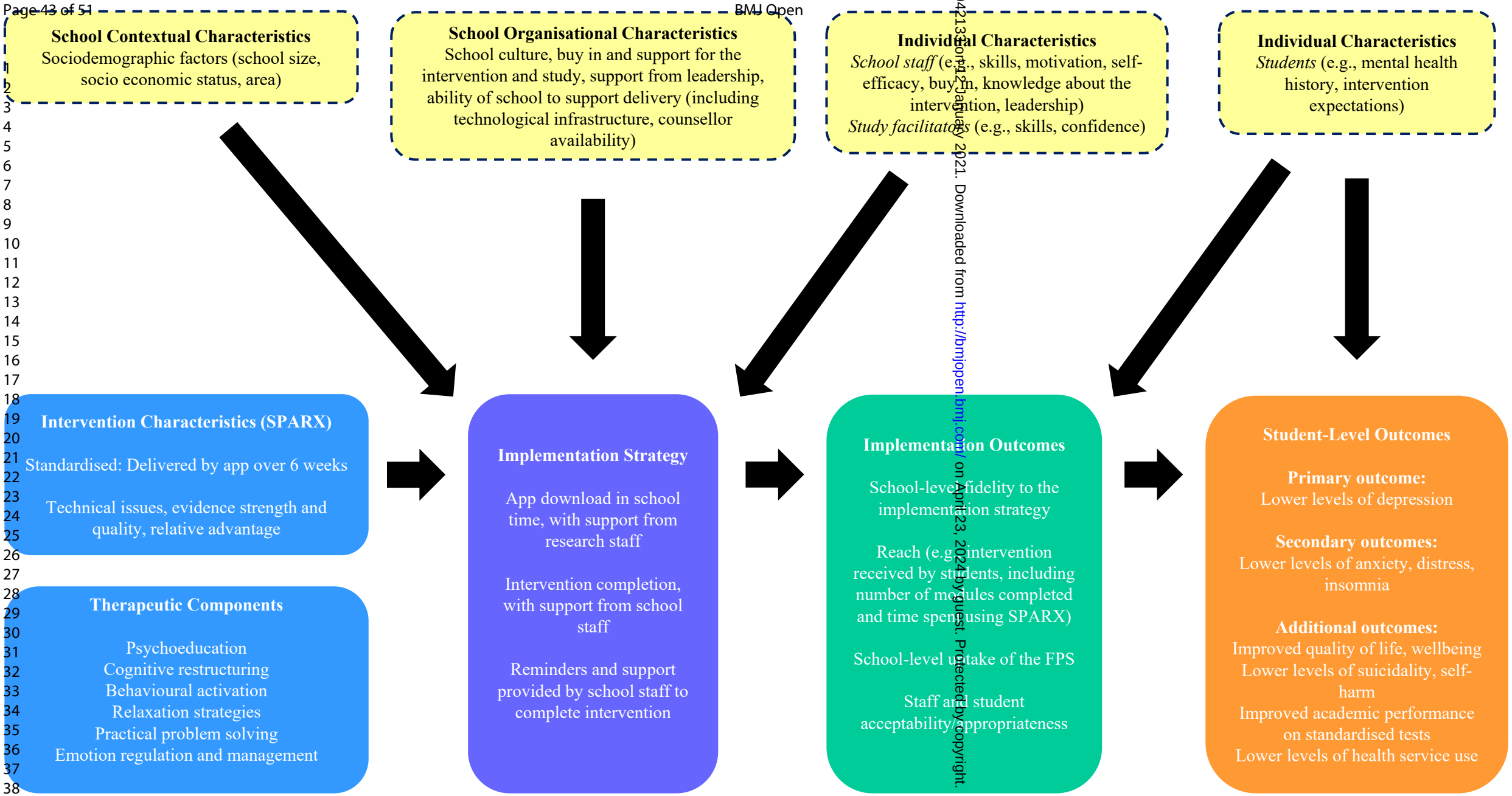

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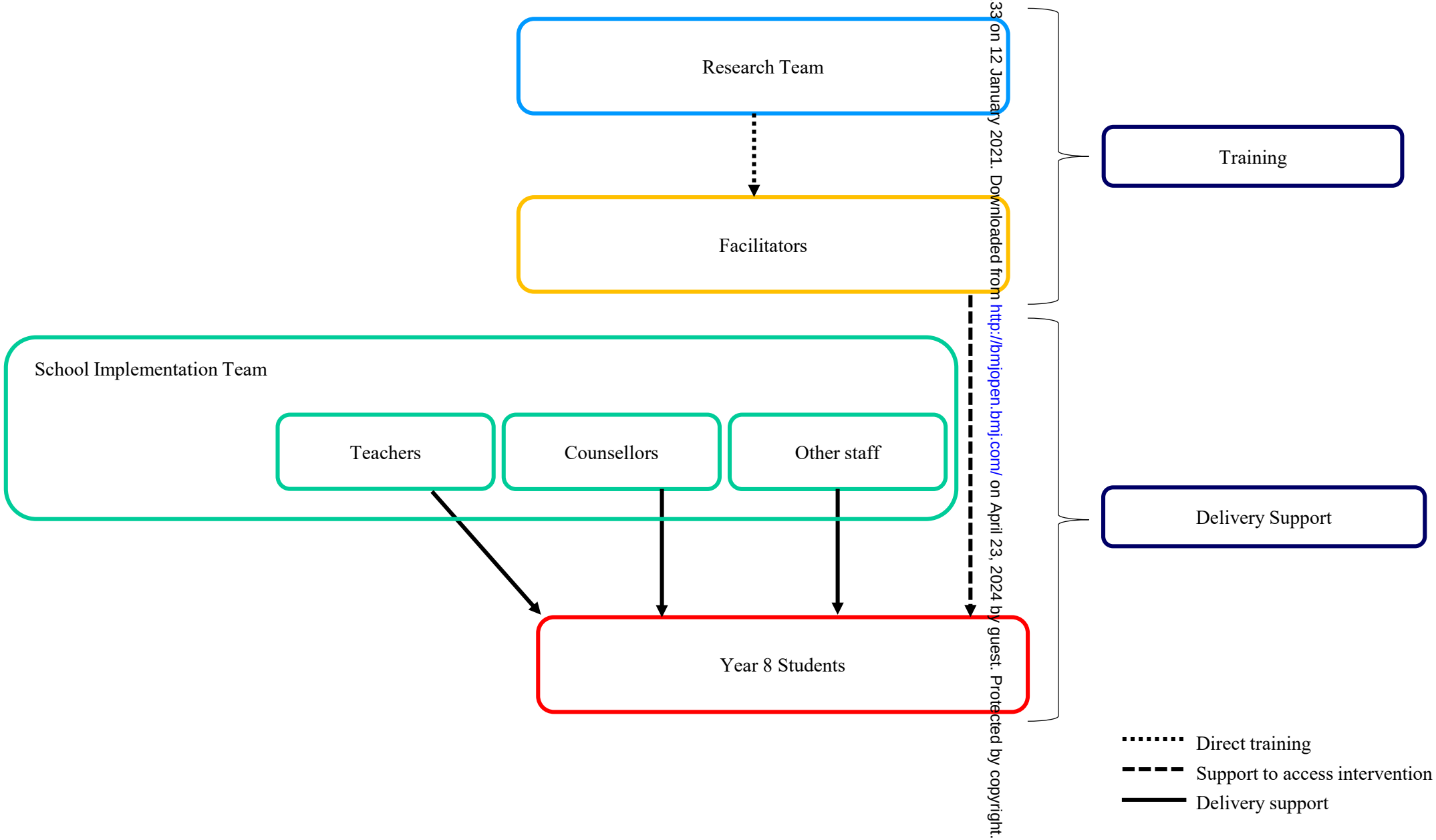

Additional File 1
Semi-Structured Interview Guides
School Staff

INTRODUCTION: *Thank you for agreeing to take part in this interview. I appreciate your time.*

I am interested in hearing your thoughts and experiences of the Future Proofing program in your school. For this interview, the FP program includes the intervention app (SPARX) and everything else that was done to support the program in your school. I hope to use this information to work out what works in different schools and how to best provide support.

I will ask you a few questions about your experiences. This is chance for you to reflect and offer feedback on how we could improve. The interview will last up to one hour. It will be recorded, and your responses will be transcribed to ensure we accurately reflect your words. All personal information will be removed so that your answers are non-identifiable and confidential. Nothing you personally say will be shared with anyone on the FP team that you have been liaising with or with other staff at your school. You can choose to not answer any questions.

Do you have any questions before we get started?

General Opening Questions:

1. How did you first get involved in teaching/counselling/psychology?
2. Could you tell me about the core values and ethos of your school?
3. To the best of your knowledge, what mental health programs or initiatives has your school implemented to care for students besides the FP program?

Specific Questions:

4. Overall, how would you describe your experience with the FP program in your school?
5. What was your role in delivering or supporting the FP program in your school?
    a. Leader/driver, decision-maker, consent/recruitment, peripheral support

CFIR DOMAIN: INDIVIDUAL CHARACTERISTICS

Personal attributes (e.g., motivations, expectations, capacity, values)

6. Why were you motivated to take on this role?
    a. How did you come on board with the program?
7. Why do you think your school decided to support this program?
    a. To what extent do you think there was a need for a mental health program like FP in you school (*Tension for change)*?
8. What were your expectations about the FP program prior to coming on board?
    a. How were your expectations met (or not met)? What went differently to what you expected? What surprised you?
    b. What were your expectations about the apps?

Knowledge and beliefs about the intervention

9. How much do you know about SPARX, the intervention? E.g., principles, rationale, content?

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Self-efficacy

10. How confident were you in your ability to lead/support/make decisions about the FP program?
    a. What personal qualities do you think helped you to do that?

CFIR DOMAIN: OUTER SETTING

Relative Advantage

11. How did SPARX compare to other mental health programs that your school has supported or delivered?

CFIR DOMAIN: INNER SETTING

School contextual factors – Barriers and Facilitators

12. What factors influenced your ability to deliver/support the FP program in your school?
    a. What else helped or hindered your ability?
    b. Enquire into school-specific factors and program-specific factors e.g., What parts of the program were easy for you to do or support (e.g., the consent process, organising rooms, weekly team meetings)? OR What aspects of your school made it difficult for you to support the program?
    c. What factors got in the way of students completing the mental health app/s?
    d. Were you (or others) able to overcome any barriers? How did you manage to do this?

School contextual factors – Leadership

13. Tell me about the involvement of your school executive in the FP program.
    a. What role did this person have (e.g., principal/vice principal)? Did you meet regularly with this person or provide updates to them?
14. How do you think the school executive saw this initiative?

Readiness for implementation

15. How would you describe the readiness of your school to take on the FP program?
    a. What was the preparation phase like for you/other key staff?

IMPLEMENTATION METRICS

Appropriateness and Acceptability

16. How does the FP program align with your school's approach toward student mental health?
17. How suited is the FP program to address depression prevention in your school?
18. How well does an app delivering therapy work to prevent depression in your students?
19. How do you feel about using technology to deliver psychological interventions in your school?
    a. What worked well about this and what did not?
    b. Do you think SPARX met the student's mental health needs? In what way?
20. What were the by-products of the intervention that you didn't expect?
    a. What parts of the program do/do not suit your school?

***ADDITIONAL QUESTIONS FOR SCHOOL COUNSELLORS ONLY*

21. What was your experience with responding to students identified as needing follow-up during the FP program?
    a. Was there anything that could have been done to make this experience better for you and the student?
22. What do you think of the FP risk protocol?

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KEY LEARNING AND FUTURE IMPLEMENTATION

23. What parts of the FP program, if any, could be made more attractive to your school to increase uptake or support?
    a. In what ways could we make these parts more attractive?
24. To what extent do you think that the FP program could be integrated into your school's existing mental health strategy?
25. What advice would you give another school contemplating taking on the FP program?
26. What's been your major learning or insight from your school's involvement in the FP program?

Closing

27. Is there anything else you would like to add?

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Volunteer Research Assistants (Study Facilitators)

INTRODUCTION: *Thank you for offering to take part in this interview. I appreciate your time.*

I am interested in your thoughts about and experiences with supporting the FP program as a Research Assistant Volunteer. I hope to use this information to work out what works in different schools and how we can help volunteers to best provide support.

I will ask you a few questions about your experiences. This is chance for you to reflect and offer feedback on how we could improve. The interview will last up to one hour. It will be recorded and your responses will be transcribed to ensure we accurately reflect your words. All personal information will be removed so that your answers are non-identifiable and confidential. Nothing you personally say will be shared with the volunteer team or the Black Dog Institute more generally, so it will not affect your relationship with them. You can choose to not answer any questions.

Do you have any questions before we get started?

General Opening Questions:

1. What schools have you visited so far?
2. Roughly how many school visits have you attended?

Specific Questions:

CFIR DOMAIN: INDIVIDUAL CHARACTERISTICS

Personal attributes (e.g., motivation and expectations)

3. Why were you motivated you to volunteer?
4. What were your expectations coming on board with the FP program?
    a. How were your expectations met (or not met)?
    b. What went differently to what you expected? What surprised you?

Perceptions of Training

5. What are your overall impressions of the training you received?
    a. How helpful and appropriate was the training?
    b. What parts were the most useful?
    c. What was missing from the training?

CFIR DOMAIN: INNER SETTING

School visits – Barriers/Facilitators

6. What was your experience with completing the school visits?
7. Did anything unexpected happen during the school visits?
    a. If so, what?
    b. How did you manage this?
    c. How well do you think you managed this?
8. In general, how was the FP program received by school staff during visits?
9. To what extent was it useful having a volunteer partner/s at the visits?
    a. Were there any other benefits/disadvantages?

School contextual factors - Barriers/Facilitators

10. What factors influenced your ability to assist students and teachers at the school-visits?
    a. Were these common across all the visits or specific to a particular visit?
    b. What aspects of the school made it difficult to support the program?

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c. What else helped or hindered your ability? (e.g., research platform/app specific factors)
d. How did you overcome these barriers?
e. Were there any noticeable differences between different schools? If so, what were they?

KEY LEARNING AND FUTURE IMPLEMENTATION

11. What advice would you give a school contemplating taking on the FP program?
12. What advice would you give to others who are thinking about volunteering?
13. What parts of the FP program could be made more attractive to volunteers to increase uptake or support?
14. What's been your major learning or insight from taking part in the volunteer program?

Closing

15. Is there anything else you would like to add?

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Standards for Reporting Implementation Studies: the StaRI checklist for completion

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	1-2	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	2-3	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	**3**	5	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	**4**	9-11	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	8	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).
Aims and objectives	**5**	9	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	11	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	**7**	11-13	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	8	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	8	The population targeted by the intervention and any eligibility criteria.
Description	**9**	17	A description of the implementation strategy	8	A description of the intervention

Sub-groups	**10**	N/A	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	18	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	N/A	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	14	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	N/A	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	7	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	26-28	Methods of analysis (with reasons for that choice)		
Sub-group analyses	**16**	26-28	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Results					
Characteristics	**17**	N/A	Proportion recruited and characteristics of the recipient population for the implementation strategy	N/A	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	N/A	Primary and other outcome(s) of the implementation strategy	N/A	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	N/A	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	N/A	Representativeness and outcomes of subgroups including those recruited to specific research tasks		

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Fidelity/ adaptation	**22**	N/A	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	N/A	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	N/A	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	N/A	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	28-30	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	N/A	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	N/A	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	31-33	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

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