PROTOCOL TITLE

SIBS-ONLINE: Pilot of an online program for siblings and parents of children living with chronic illness

VERSION NUMBER 2

13/11/2020

SIBS-ONLINE Protocol 2020

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## Summary

Protocol title SIBS-ONLINE: Pilot of an online program for siblings and parents of children living with chronic illness

Protocol version 1

Objectives

 We will pilot SIBS-ONLINE and answer the following research questions:

 Research question 1: Is there a change in siblings’ mental health between immediately before and immediately after participating in SIBS-ONLINE

 Research question 2: Are there changes in related outcomes such as family communication, sibling coping, parent mental health, sibling quality of life, and siblings’ disorder knowledge between immediately before and immediately after participating in SIBS-ONLINE?

 Research question 3: Is SIBS-ONLINE feasible and acceptable?

Planned sample size 30 siblings and 30 parents

Inclusion criteria Eligible participants will be adolescents aged at least 12 years and at most 18 years of age, who live with at least one brother or sister with a chronic illness who has been diagnosed ≥6 months prior to the study. One of the siblings’ parents will also be eligible to participate. Participants must be able to give informed consent and speak/read conversational English. All participants will be required to have access to the internet and a computer/smartphone/tablet with web-cam and microphone.

Study procedure The project will be conducted at the School of Women's and Children's Health at the University of New South Wales and the Sydney Children’s Hospital. Potential participants will be contacted in a number of ways: 1) our clinician-investigators will provide the contact details of eligible families they are treating; 2) investigators and research assistants will approach families on the wards and clinics of the Sydney Children’s Hospital in Randwick (including the Kids Cancer Centre, the Department of Medical Genetics, outpatient clinics, cystic fibrosis clinic, nephrology clinic, and gastrointestinal clinic) and invite them to the study; 3) potential participants will be invited to the study if they have previously opted-in to be invited to participate in our future research ; 4) advertisement flyers will be posted around the Sydney Children’s Hospital, Randwick; 5) we will advertise the study online via our social media (e.g. Twitter, blogposts etc.) and the social media of community organisations (e.g. Cystic Fibrosis Australia, Genetic Epilepsy Team Australia); and 6) we are partnering with Canteen Australia and Cystic Fibrosis Australia who will advertise the study to families using their services (advertisement at Canteen and Cystic Fibrosis Australia will include i. sharing contact details of families who have consented to be contacted about online programs with the research team; ii. advertisement flyers around the Canteen and Cystic Fibrosis Australia headquarters in Sydney; iii. online advertisement via Canteen’s and Cystic Fibrosis Australia’s social media).

The SIBS-ONLINE intervention consists of four sessions delivered via video-conferencing (e.g. Skype) by group leaders (two with only parents and two with only siblings) and two homework and feedback sessions at home. The sibling sessions will focus on discussing emotions, thoughts, and feelings about their siblings’ chronic illnesses and questions they might ask of parents. The parent sessions focus on learning about challenges common to siblings and encouraging open-exploratory communication with their children. The homework and feedback sessions will be conducted with siblings and their parents together. Clinical staff and psychosocial researchers from BSU and Canteen will be trained and act as group leaders for the parent and sibling groups.

Sample size calculations If the within-individual correlation is at least 0.80 and the within-group correlation is no larger than 0.35, then a sample size of 30 siblings provides greater than 80% power to detect a large change (0.8 standard deviations) in SDQ total difficulties score, using a two-sided test with a significance level of 0.05. We will conduct five groups with six parents and six siblings in each group.

Analysis plan SIBS-ONLINE has a single-arm pre-post design with the primary outcome being the difference in SDQ scores from pre-intervention to immediately post-intervention, reported by siblings and parents. The primary analysis will be a test of the null hypothesis that the mean difference between the paired scores is equal to zero, accounting for within-group correlation by using a repeated-measures regression model with cluster-robust standard errors. The estimated difference will be presented with a two-sided 95% confidence interval.

Duration of the Study The study will begin once ethical approval and site-specific approval has been gained and conclude in December 2023.

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# Introduction and rationale

Child chronic illness affects the family system and each family member individually [1-4]. At least 20% of children have a chronic illness, and most of these children have siblings [5]. Siblings are at-risk for ongoing mental health concerns including anxiety, depression, substance abuse, self-harm, and suicidal ideation [6]. These negative experiences can be long-term - following siblings from childhood through to adulthood [7-10]. Siblings of children with a chronic illness may also report positive experiences, such as increased empathy and closer ties with their affected brother or sister [6, 11, 12]. Further research is still needed to determine the factors related to mental health concerns among siblings, and those related to mostly positive experiences. Siblings’ caring responsibilities for their affected brother or sister may impact their emotional functioning. Caring responsibilities may include minding the child while the parents are unavailable and assisting with medical/nursing duties at home [13]. Siblings’ caring responsibilities have often been observed among adult siblings, but research with siblings of young people with epilepsy show that these responsibilities start in childhood and adolescence [14]. Our own research shows that adolescent siblings can experience anxiety about the future when they anticipate having to care for their brother or sister in adulthood, when their parents are older and less able to complete all the necessary caring tasks (manuscript under preparation).

Successful early interventions to improve sibling mental health are currently lacking. Although some sibling interventions have shown positive outcomes for siblings’ wellbeing [2] [15], recent systematic reviews have demonstrated that no intervention qualifies as either “well-established” or “probably efficacious” [16, 17]. Research also shows that interventions should focus on enhancing siblings’ coping skills, yet this has rarely been the target of sibling interventions [18].

Our own research with siblings shows there is an urgent need to improve two main aspects of siblings’ lives to help them feel more supported and better able to cope with the challenges of their brother or sisters’ illness or disability (manuscript under preparation). First, siblings need to connect with other siblings who share and understand each other’s difficulties and joys. Siblings consistently tell us that they need to know they are not alone and need the support of other siblings going through the same thing. Second, siblings need to be able to talk with their parents about how they feel in a supportive, productive way. Good family communication and support are consistent predictors of sibling wellbeing [19]. Parents, however, often report feeling overwhelmed and unsure of how to support the unaffected siblings [20]. Previous research shows that parents are concerned about treating their affected and unaffected children differently but may not have the appropriate communication and supportive skills to counteract this [20]. Poor family functioning, including conflict and resentment, is related to lack of quality parent-sibling communication [21, 22]. Parents need to be provided with tools to improve family communication – both communication regarding the affected child’s disorder and general family communication. Improving family communication may also have flow on effects for the family unit including reducing parents’ stress and improving siblings’ wellbeing.

We will therefore build upon the formative previous literature as well as our own research to develop an intervention (SIBS-ONLINE) for siblings of children with chronic illness to ensure it: 1) addresses the ongoing realities of siblings’ potential caregiving responsibilities; 2) addresses issues unique to being a sibling of a child with chronic illness; 3) allows siblings to meet and interact with other siblings; 4) improves family communication and family functioning. The original intervention (called SIBS) was developed by Prof Fjermestad and Dr Vatne and their team in Norway. We are working with consumer representatives from Canteen Australia to modify the intervention for an Australian audience. Part of the modification has been to deliver the intervention via video-conferencing. This new, updated version of the intervention for Australian families is called SIBS-ONLINE.

# Study design and procedure

## Project aims

We will pilot SIBS-ONLINE and answer the following research questions:

Research question 1: Is there a change in siblings’ mental health between immediately before and immediately after participating in SIBS-ONLINE?

Research question 2: Are there changes in related outcomes such as family communication, sibling coping, parent mental health, sibling quality of life, and siblings’ disorder knowledge between immediately before and immediately after participating in SIBS-ONLINE?

Research question 3: Is SIBS-ONLINE feasible and acceptable?

## The SIBS-ONLINE intervention

The SIBS-ONLINE intervention consists of four sessions delivered through a secure, password-protected video conferencing software on the Internet (e.g. Zoom, Skype, WebEx) by group leaders and two homework and feedback sessions at home. The homework and feedback sessions will be conducted using ‘break out rooms’ in the videoconferencing platform so that the parent-sibling dyads have privacy from the rest of the group, and so the group leader can intermittently drop-in on the conversation and provide guidance and feedback. Sessions are outlined in Table 1.

*Table 1. Overview of the SIBS-ONLINE intervention*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Day 1 – SIBLINGS (80 mins) | Day 2 – PARENTS (80 mins) | Between day 2 and 3\* | Day 3 – SIBLINGS (60 mins) | Day 4 – SIBLINGS (60 mins) | After day 4\* |
| Introduction + The illness | Homework and feedback | Emotions | Homework and feedback |
| **Aims**: Getting to know each other/ the intervention.Share thoughts about the disorder. Write question(s) to parents. | **Aims:** Provide information about the intervention**.**Learn how to listen, explore, and validate siblings’ thoughts about the disorder. | **Siblings** present their questions to parents. **Parents** Practice communication skills taught in previous sessions. **Joint goal:** A positive conversation experience. | **Aim**: Talk about emotions/ challenges. Write challenge(s) to discuss with parents. | **Aim**: Learn how to listen, explore, and validate siblings’ challenges. | **Siblings** present their challenges to parents. **Parents:** Practice communication skills taught in previous sessions. **Joint goal:** A positive conversation experience. |

\* Conducted using ‘break out rooms’ in the videoconferencing platform so that the parent-sibling dyads have privacy from the rest of the group, and so the group leader can intermittently drop-in on the conversation and provide guidance and feedback.

Fully trained staff from UNSW and Canteen will conduct the group sessions. Training will consist of two full days of learning about the intervention and role playing. These training sessions will be conducted either face-to-face or via video-conferencing and led by Prof Fjermestad and Dr Vatne. CanTeen Australia are a community organisation who offer individual and group counselling to adolescents and young adults (aged 12-25) with cancer and their families. They have world-class expertise in the provision of tailored counselling services, and have worked extensively with siblings of young people with cancer (please see: <https://www.canteen.org.au/young-people/my-brothersister-has-cancer/>).

Parents and siblings will engage in sessions with group leaders separately from each other, while homework and feedback sessions will be conducted together. The sibling sessions will focus on discussing their emotions, thoughts, and feelings about their brother or sister’s chronic illness and writing down questions they have about those illnesses for their parents. The parent sessions focus on communication training, using video examples of real sibling-parent dialogues and open-exploratory communication as basis for discussion. Parent sessions also comprise psychoeducation about sibling challenges, and introduction to cognitive-behavioural principles about emotional coping.

Each group’s first session will involve an introduction to the intervention and the other participants in their respective groups. For siblings, the first sessions will also focus on sharing thoughts about their brother/sisters’ illness and writing any question(s) they have for their parents. For parents, the first session will overview and provide information about the intervention as well as exercises which will encourage parents to listen, explore, and validate the siblings’ thoughts about the disorder.

After each group has had their first session, a joint session will be conducted by the parents and siblings at home. The joint sessions will incorporate integrated sibling-parent dialogues in which siblings present their questions and, in turn, parents practise communication skills learned in initial session. Group leaders will intermittently join these conversations, and provide each parent with personalized feedback on their communication skills.

After the joint session, parents and siblings will reconvene in their groups for one more separate session. Siblings will focus on challenging emotions and feelings they have about their brother/sisters’ illness and writing them down to express to their parents. Parents will focus on listening, exploring, and validating emotional challenges. A second joint session will then be held where the siblings present their challenges to the parents who further practise their learned communication skills.

Each group has two group leaders. In SIBS-ONLINE, the same two group leaders will run the sibling and parent groups. Group leaders will 1) be an employee or student of either UNSW or Canteen; 2) hold at least a Bachelor’s degree in psychology or social work, with work experience with mental health; and 3) be trained by the lead investigator to run the groups. Group leaders, in addition running the SIBS-ONLINE groups, will be involved in collecting research data through the completion of templates after each group session (see Section ‘2.6 Outcome measures’ for details).

# Study population

## Inclusion criteria for sibling participants

* Young people aged between 12 and 18 years old (inclusive);
* Currently living with a brother or sister who has been diagnosed with a chronic illness at least 6 months prior;
* Able to give informed consent; and
* Able to speak/read conversational English
* Must have access to a computer/smartphone/tablet and Internet connection

We will include siblings of children with various chronic illnesses, including cancer, developmental disability, cystic fibrosis, kidney diseases, gastrointestinal disorders, and genetic neurological disorders. We aim to recruit across a wide range of chronic illnesses, to determine if SIBS-ONLINE has a broad, trans-diagnostic appeal. Research indicates that the issues facing siblings are similar across a range of various chronic illnesses [17, 23].

### Inclusion criteria for parent participants

* One parent/guardian of each participating sibling will also participate
* Must be parent/guardian to at least one child diagnosed with a with a chronic illness at least 6 months prior, who lives at home
* Able to give informed consent
* Able to speak/read conversational English
* Must have access to a computer/smartphone/tablet and Internet connection

### Exclusion criteria for sibling and parent participants

Parents and siblings will be not be eligible to participate if:

* They possess insufficient English language skills to complete and understand the core aims of the study, and to be able to participate in the group sessions
* They display cognitive impairment which may limit their ability to provide reliable questionnaire responses
* They have a child/sibling with a chronic illness who was diagnosed less than 6 months prior to the study
* If the child with the chronic illness is terminal and believed to be imminently dying, or has died
* They indicate serious suicidal intent and/or have a suicidal plan

All participants who require practical assistance with completing the questionnaires or interviews will be offered appropriate supports where possible (e.g. large font size questionnaire; a researcher to read the questions aloud to assist participants with vision impairment). A researcher or parent will be allowed to assist young people to complete their questionnaire if needed. While we acknowledge that having a researcher/parent assist in the completion of the sibling’s questionnaire may influence the sibling’s answers, we would prefer to allow siblings to still share their experiences should they wish to do so. Any help received will be recorded on the sibling’s questionnaire.

Figure 1 shows a flowchart for how participants will progress through the study.

Participants express interest in participating to study team via recruitment pathways (see **2.5.2 Advertising and recruitment**).

Study team conduct an intake call with family to discuss participation in the study and gain consent to send out study information and questionnaires.

If consent is obtained, parents and siblings are sent separate Participant Information and Consent Forms and their first questionnaire.

After questionnaires are received, participants begin SIBS-ONLINE Intervention.

After Intervention has finished, participants complete two post-Intervention questionnaires: one immediately after and another three months later.

*Figure 1. SIBS-ONLINE participation flowchart*

### The research team

The study investigators include trained psychosocial researchers, clinicians, nurses and social workers who will recruit and consent participants using the process below. Clinicians will not consent the potential participants if they have a clinical relationship with the family. Research assistants from the study’s research team will help with recruitment, consenting participants and data collection. Members of the research team may also act as group leaders for the intervention, given they meet the required inclusion criteria (see Section ‘2.2. The SIBS-ONLINE intervention’).

## Procedure

### Enrolment procedure

Overview of procedure

1. Contact parent participants, or parent/sibling dyads either in-person, over the phone, or via email.
2. Obtain consent from parents and siblings

3. Parents and siblings will either complete baseline questionnaires in hardcopy form or online using the secure, password-protected Qualtrics platform.

4. Parents and siblings participate in SIBS-ONLINE.

5. Parents and siblings will either complete follow-up questionnaires in hardcopy form or online using the Qualtrics platform.

### Recruitment and advertising

Six methods will be used to contact and recruit potential participants:

Our clinician-investigators will provide the contact details of eligible families they are treating. Where possible, the study investigators from the participating sites (i.e. the Kids Cancer Centre, the Department of Clinical Genetics, outpatient clinics, cystic fibrosis clinic, Department of Nephrology, gastrointestinal clinic and Tumbatin clinic of the Sydney Children’s Hospital, Randwick) will identify families who have consented to be contacted by research staff about participation in research or participation in psycho-social interventions, and collect their contact details from their clinics’ database. Investigators and research assistants will then call, email or mail parents as an initial intake discussion. Where only a phone number has been recorded, an investigator or research assistant will call the parents, introduce the study, obtain further contact details, and provide letters of invitation that direct participants to an online consent form.

Investigators and research assistants will approach families on the wards and clinics of the Sydney Children’s Hospital in Randwick (including the Kids Cancer Centre, the Department of Clinical Genetics, outpatient clinics, cystic fibrosis clinic, Department of Nephrology, gastrointestinal clinic and Tumbatin clinic) and invite them to the study. Investigators will ensure that potential participants understand that they are under no obligation to provide consent on the spot, but can do so if they wish.

Potential participants will be invited to the study if they have previously opted-in to be invited to participate in future research through one of our previous studies. In our previous studies on siblings (*SibStars*) and genetic epilepsy, parents and siblings completed questionnaires. At the end of the questionnaires, participants were asked to indicate whether they would be willing to participate in any future research about families and chronic illnesses, and if ‘yes’, left a phone number and/or email address to be contacted on. We will now contact the participants who indicated they would like to be contacted for future research.

Advertisement flyers will be posted around the Sydney Children’s Hospital, Randwick to advertise and provide a brief, simple overview of the study. Tear-away tabs will include the study email address (SIBS-ONLINE@unsw.edu.au) and a URL/QR code for the online information sheet. Our research team will contact the family thereafter for an initial intake discussion.

We will advertise the study online via our social media (e.g. Twitter, blogposts etc.) and the social media of community organisations (e.g. Cystic Fibrosis Australia). In these posts we will provide a link to online letters of information, and contact details for the study team (SIBS-ONLINE@unsw.edu.au) . Our research team will contact the family thereafter for an initial intake discussion

We are partnering with Canteen Australia and Cystic Fibrosis Australia who will advertise the study to families using their services (advertisement at Canteen and Cystic Fibrosis Australia will include i). sharing contact details of families who have consented to be contacted about online programs with the research team; ii). advertisement flyers around the Canteen and Cystic Fibrosis Australia headquarters in Sydney (the same advertisement flyers used around Sydney Children’s Hospital, described in point 4); iii). online advertisement via Canteen’s and Cystic Fibrosis Australia’s social media) (the same online posts we will use, described in point 5). An initial intake discussion will be conducted thereafter.

All potential participating families will be contacted for an initial intake discussion. This might take place in person or over the phone/email, depending on which pathway they are recruited through. In the initial intake discussion, the investigator or research assistant will:

- Introduce and explain the study to parents (and siblings if they are present),

- Answer any questions the families have,

- Assess their preferred method and location of completing the consent forms and questionnaire (online or paper, at home or on the hospital ward),

- Provide hardcopies of parental consent forms, information sheets and questionnaires (if families indicate they are interested in the study and would like hardcopies) OR obtain a postal or email address so researchers can send all documents at a later date

Researchers will ask parents to provide their own phone number/ email address if they have not already provided them. We will only contact the sibling directly if the parent provides their contact information on their behalf and with the child’s consent. Otherwise, we will only directly contact the parent who will pass on information to the sibling.

Upon confirming the parents’ and siblings’ inclusion in the study, we will mail, email or text the information sheet, parental and sibling consent forms, and the parent and sibling questionnaires. Where an email or mailing address has been recorded, we will mail or email the information sheet, parental consent form and pre-intervention questionnaires to parents (or links to the questionnaires). Where possible, we will mail questionnaires to families in two separate envelopes – one for the parent and one for the sibling. Where appropriate consent has been given (as per previous paragraph), we will email/text questionnaires to parents and siblings separately. In other cases we will ask the parents who provide parental consent to give the sibling questionnaire(s) to their eligible children. We will also include an ‘opt-out’ card with the rest of the study materials – participants will be encouraged to return this via reply-pain envelope if they do not wish to participate, or to click this box online, or email the chief investigator so that the study investigators will not contact them further.
We will follow the same procedure to send post-intervention questionnaires to parents and siblings.

***Hardcopy questionnaires*.** Where parents and siblings have chosen to receive their questionnaires by mail, sibling and parent questionnaires will be sent separately and with separate reply-paid envelopes. A researcher will mail a study information pack containing:

* An information sheet (parent and child version);
* The consent form;
* The questionnaire
* An ‘opt-out’ card’ and
* A reply-paid envelope

***Online questionnaires*.** The online questionnaires will be administered through Qualtrics, an online survey instrument available through the University of New South Wales. Qualtrics is a secure, password-protected program that allows participants access to the online questionnaires only through a personal email invitation from the study coordinator. Surveys can be completed using any internet enabled device (including tablets, iPads and smart phones). The online questionnaires will administer the identical items to the paper questionnaire using an easy-to-use standard survey template in Qualtrics.

If separate emails/mobile numbers for parents and siblings have been provided to the researchers, we will then email/text a link to the pre-intervention questionnaire to parents and siblings separately. If only one contact detail has been provided, we will provide separate links to the parent and sibling questionnaires within the one email/text. Links will direct participants to an information sheet and consent form and the questionnaire.

### Consent

An intake call will be conducted with the family to discuss participation in the study, assess whether they meet any exclusion criteria (e.g. suicidal intent – see 2.3.3 Exclusion Criteria), and gain consent to send out information and questionnaires. Informed written consent will be obtained from a parent/guardian by investigators and research assistants (who do not have a clinical relationship with the chronically ill child) for sibling participation (if siblings are aged under 18 years, upon obtaining informed parental consent, siblings will be given an age appropriate Information Form. Siblings under the age of 18 (who have the requisite maturity to understand the study requirements) will be asked to counter-sign the parental consent form to indicate their own consent to participate in the study. Siblings aged 18 years will sign their own consent for, without the need for parent/guardian consent. Parents will indicate consent for their own participation by signing their consent form. Participants will also be provided with ‘opt-out’ cards if they do not wish to participate, so the investigators know to not contact them further.

Parents/guardians and siblings will be assured that their decision to participate will not in any way affect their or their child’s/sibling’s current or future clinical management and that they would be free to withdraw from the study at any time. The investigators and research assistants who are consenting the participants will explain to parents and siblings that they do not need to give a reason if they do not wish to participate, but if they would like to share a reason for why they do not wish to participate, then this information would be useful to us. Investigators will attempt to gather the age, gender and postcode of the ill child for families who choose not to participate, so that we can assess response bias.

### Opt-out and withdrawal procedure

***Opt-out:*** Participants will be able to opt-out of the study irrespective of which questionnaire format they pick. If they choose online, families may ‘opt-out’ by following the links online or by emailing one of the study’s investigators (please see the ‘opt-out’ card attached). They may also opt-out during a follow-up call conducted if we do not hear from the families within 2-4 weeks. An investigator or research assistant will call to ask whether they have received the invitation package and whether there are any unresolved questions. If the participant is not available, they will receive a second follow-up call within 1 week. Participants are informed about this procedure on the information sheet. If the family selected hardcopy questionnaires, they may return their opt-out card in the reply-paid envelope. They may also opt-out via emailing the study investigators or during follow-up calls as above.

This information sheet will provide all participants with an appropriate plain language explanation about the nature of the data that will be collected, the purpose of collecting it, and the procedure to decline participation in accordance with the National Statement on Ethical Conduct in Human Research (2007) (Updated May 2015) by the Australian Government National Health and Medical Research Council (NHMRC).

***Withdrawal:*** If parents and siblings initially consent to participating, they can withdraw from SIBS-ONLINE at any time without consequence from the lead study team or community organisation. Each participant will receive a ‘withdrawal of consent’ form when they receive the consent form and information sheet, which they can email to the lead investigator at any time.

If a participant’s reason for withdrawal relates to a serious adverse event as a result of SIBS-ONLINE, the investigators will report the circumstances of the event to the Sydney Children’s Hospital Network (SCHN) HREC, in addition to any jurisdiction or community organisation specific policies and registries..

In cases where a participant who is later excluded from or withdraws from the study, we will consult the participant as to whether they would like to have their individual data removed from the study. If they elect to have their individual data removed, it will be deleted from all locations. However, given that the current study is a group program, the group leader’s session notes may exist that contain information about the excluded participant in addition to information about still-eligible participants. . If an outgoing participant elects to have their data removed, copies of group data will be created where any information from the excluded/withdrawing participant is expunged, and the original group data will be destroyed.

## Outcome measures

Table 2 shows the scales included in 1) the sibling questionnaires, 2) the parent questionnaires, and 3) the group leader notes, and at which timepoint the participants will complete each scale.

Using the standard ‘rule of thumb’ that participants will take 10 seconds per question, we estimate that the parent questionnaire will take 15-20 minutes to complete, and the sibling questionnaire will take 20-25 minutes to complete.

Table 2. *Overview of measures before (Tpre ) and after (Tpost, T3m) SIBS-ONLINE*

|  |
| --- |
| Description (title)**, rater** and*time* |
| **Primary outcome** |
| Mental health (Strengths and Difficulties Questionnaire, total difficulties score) **S/P***Tpre, Tpost,T3m* |
| **Secondary outcomes**  |
| Family communication (Parent-Child Communication Scale) **S/P** *T*pre*,Tpost,T3m* |
| Quality of life (PedsQL) **S/P** *Tpre,T3m* |
| Distress *(Emotion Thermometers)* **S/P** *T*pre*,Tpost,T3m*Adaption (Negative Adjustment Scale) **S** *Tpre,T3m* |
| Coping (Kidcope) **S** *Tpre,T3m*Sibling disorder knowledge (Sibling Knowledge Interview-written version) **S** *Tpre,T3m* |
| **Control- and predictor variables**  |
| Socio-demographics, **S/P** *Tpre*Disorder information (Purposely designed questions) **P** *Tpre* |
| Parent mental health (K10) **P** *Tpre, Tpost, T3m* |
| Medical record information re: ND: Clinical severity/impairment ratings. **M** *Tpre* |
| **Feasibility, acceptability, and manual adherence during intervention** *(completed after each group session)* |
| Feasibility **G**Acceptability **S/P/G** *T*pre*,Tpost,T3m*Competence and Adherence Scale for Cognitive Behavioral Therapy **G** |

*Note*. S = siblings; P = parents; G = group leader; M = medical records. Tpre = Pre-intervention. Tpost = After intervention. T3m = 3 months after intervention.

Sibling questionnaire

**Demographics**

Demographic questions. Demographic questions will collect the following information:

• Age

• Date of birth

• Gender

• Whether they identify as Aboriginal and/or Torres Strait Islander (Aboriginal; Torres Strait Islander; not Aboriginal or Torres Strait Islander)

• Country of birth

• Mother’s country of birth

• Father’s country of birth

• Who they live with (mum; dad; siblings; step mum; step dad; and/or other)

• Number of siblings

• Sex of sibling with a chronic illness

• Age of sibling with a chronic illness

• Their sibling’s diagnosis (Cancer; Cystic Fibrosis; Cerebral Palsy; Diabetes; Arthritis; Irritable Bowel Syndrome; Intestinal failure; Tuberous Sclerosis; Kidney Disease; Epilepsy; Other)

• Whether or not the study has been beneficial/burdensome so far

**Mental health - Strengths and Difficulties Questionnaire**

Our primary measure is the Strengths and Difficulties Questionnaire (SDQ), a 25 item measure of mental health that can be administered to siblings as a self-rated questionnaire to siblings, as well as to parents as a proxy report [24]. We will use the total difficulties score as our primary outcome measure, which measures sibling mental health. Siblings and parents endorse items on a 3-point Likert scale (not true, somewhat true, certainly true). This measure is well validated in both English and Norwegian-speaking populations [25, 26] and has demonstrated a good level of internal consistency in a pilot trial of this intervention, (Cronbach’s alpha >0.7 for siblings, mothers, and fathers [27]).

**Quality of life – PedsQL**

The PedsQL is a widely-validated measure of health-related quality of life in both healthy and ill children and adolescents [28]. The PedsQL is available in self- and parent proxy report versions – the most relevant version is for ages 13-18. Participants respond on a 0-4 Likert scale to a total of 23 items. These items can be broken up into four subscales (Physical, emotional, social, and school functioning), and two summary scores (physical and psychosocial health summary score). The measure is modular –subscales can be used in various combinations. The PedsQL is a feasible and valid tool for cancer and chronic disease. The PedsQL has been validated in English-speaking populations [28].

**Family communication - Parent-child communication scale**

The parent-child communication scale (PCCS) is a measure of perceived openness to communication [29]. There are two versions of the PCCS – a parent report and a child report. For both scales, participants respond on a 5-point Likert scale (almost never, once in a while, sometimes, often, almost always). The child report version is 10 items long and can be broken up into two subscales (parent communication and child communication). The child report version of this scale has been reported to be satisfactorily reliable. The parent communication subscale of this measure delivered has been demonstrated to be satisfactorily reliable for English speakers (Cronbach’s alpha of 0.56-0.75; [30]).

**Sibling adaptation - Negative Adjustment Scale**

The Negative Adjustment Scale (NAS) is a measure of emotional adjustment for siblings of children with chronic diseases. The NAS can be used for both parents and siblings of children with chronic illnesses [31]. This scale was originally developed from the Sibling Perception Questionnaire (SPQ), which was designed to measure school-aged siblings’ responses to childhood cancer [32]. The NAS was developed from the SPQ by combining the interpersonal, intrapersonal, and fear subscales of the SPQ into a composite scale and replacing the word “cancer” with generic terms (such as “problem”).

The NAS consists of 18 items; participants respond to questions on a 4-point Likert Scale (never - a lot). When delivered to siblings, the NAS demonstrates satisfactory reliability in English-speaking populations (Cronbach’s alpha = 0.79; [31]). When delivered to parents, the NAS demonstrates satisfactory reliability for English-speakers (Cronbach’s alpha of 0.74; [31])

**Sibling disorder knowledge - Sibling knowledge interview**

The Sibling Knowledge Interview is a structured interview and scoring system for assessing siblings’ knowledge of their brother/sister’s disorder in terms of name and explanation. Siblings are asked to name the disorder, and responses are coded 1-3 (from “does not know” to “accurate and specific term”). Siblings are then asked to explain child’s disorder in terms of characteristics, symptoms, and treatment – responses are coded 1-5 (from “no understanding” to “accurate understanding”). Sibling responses are recorded and coded by multiple coders who are blind to participants’ identity. The SKI in this form has been used to assess sibling knowledge of disorder in other intervention studies [31] [27]. Additionally, a later version of the SKI asks siblings their understanding of the aetiology of the child’s disability [33]. Siblings provide up to three reasons for how the child came to have the disability, which are then coded into one of six categories (medical, religious, congenital, accident-related, nonspecific, and unknown). In the current study, these questions will be presented within the questionnaire and siblings will be given space to write/type their responses.

**Coping – Kidcope**

The Kidcope is a brief, reliable, and valid self-report measure of coping that is available in forms for children aged 7-12 and adolescents aged 13-18. The version for children aged 7-12 has 15 items, with 1-2 items per coping strategy, and the adolescent version has 10 items, with 1 item per strategy. For both versions, participants respond to questions asking whether or not they use the strategy (i.e., frequency, scored yes/no for children or rated on a Likert scale for adolescents), and how much the strategy helps (i.e., efficacy, scored on a 3 or 5 point Likert scale for children and adolescents, respectively)[34, 35].

**Distress - Emotion Thermometers**

Emotion Thermometers Tool © is a measure which comprises four predictor domains (distress, anxiety, depression, anger) and one outcome domain (need for help). Each domain is rated on a 10-point visual thermometer scale. Each scale has been validated in an Australian sample [36] and used extensively by our team previously [37, 38]. We will receive formal approval to administer this scale from the scale developer, Professor Alex Mitchell, University of Leicester prior to the study commencement.

**Acceptability**

Two items will be included in post-intervention questionnaires to assess the extent to which participating in the intervention was beneficial or burdensome. Participants will be asked to rate on a 5-point scale the extent to which they found participating in the program has been burdensome (1= “Not at all” to 5= “Very much”) or beneficial (same 5-point rating scale).

Parent questionnaire

**Demographics**

Simple check-box and open-ended questions will gather information on the following:

• Parents’ date of birth

• Parents’ sex

• Country of birth

• Whether they identify as Aboriginal and/or Torres Strait Islander (Aboriginal; Torres Strait Islander; not Aboriginal or Torres Strait Islander)

• Marital status (Never married or never defacto; Currently married or defacto; Divorced/separated/previous defacto; Widowed)

• Postcode

• Religion (No religion; Christian; Buddhism; Islam; Hindu; Other religion)

• First language

• Highest level of education (Year 10 or below; Certificate/diploma; Year 12; University degree; Apprenticeship; Post-graduate degree)

• Current employment status

• Annual household income

• Whether they have private health insurance

• Whether they are receiving financial support from someone else (No; Government / organisation; Parent, spouse or partner)

• Ages and genders of all children

• Whether or not the study has been beneficial/burdensome so far.

• Medical history of the child with a chronic illness. (This data will be cross-checked with hospital medical records where possible).

**Parent mental health – Kessler Psychological Distress Scale**

The Kessler Psychological Distress Scale (K10) [39] measures distress. Participants indicate how often over the previous 30 days they experienced each of the 10 items (e.g. ‘Nervous’, ‘Hopeless’, ‘So depressed that nothing could cheer you up’. Participants rate each item on a 5-point Likert scale from 1 (all of the time) to 5 (none of the time). Higher scores indicate higher distress. The K10 has strong predictive validity for clinically relevant distress, and can be compared to population norms [39, 40].

**Family communication - Parent-child communication scale**

The parent report version of PCCS is 20 items long and can be broken up into four subscales (Parent communication, parent restricted topics, child empathy/listening, child emotional expression). Each of these subscales has been demonstrated to be reliable in both normative and high-risk control samples of English speakers (alpha of 0.55 to 0.73, depending on group and subscale; [41]).

**Disorder information**

Purposely designed questions will inquire about the child’s chronic illness including the date of diagnosis, cause, severity etc. We will match these questions to the questions asked in the siblings in The Sibling Knowledge Interview, as a way to validate siblings’ answers (please see parent questionnaire timepoint 1 for details).

**Acceptability**

As above for sibling measures.

Group leader notes

To gather data on the feasibility and acceptability of SIBS-ONLINE the group leaders will complete templates after each group to assess the following:

**Feasibility**

* Recruitment rates;
* Number of days to group commencement;
* Amount of time for session commencement;
* Proportion of eligible, interested families who had technological equipment and internet access required to participate;
* Number, type and description of technological difficulties experienced across sessions and described in group leaders’ notes. An indication from 1 to 10 how disruptive these technological difficulties were.
* Number of rescheduled group sessions and group sessions scheduled outside office hours.

**Acceptability**

* Opt‐in rate [total eligible and consenting families/all families approached];
* Enrolment rate [total families who consented/all eligible families];
* Retention rate;
* Participant engagement [total group sessions attended];
* Completion rates for between‐session homework.

**Group cohesion**

* Group leaders will assess their level of comfort running the group and their clinical impression of how cohesively the group operated Leaders will answer questions across six domains: rapport, openness, mutual trust, peer-to-peer discussion, motivation, and engagement (all on 10-point scales with higher scores indicating more favourable assessments). These items were developed for use in an implementation study of an online support program for adolescent and young adult cancer survivors [42].

**Manual adherence during intervention**

* The Competence and Adherence Scale for Cognitive Behavioural Therapy (CAS-CBT) is an 11-item scale developed to measure adherence to treatment protocol and facilitator competency in manualized CBT treatment for youth[43]. In its original format, trained raters assessed video recordings of either individual or group sessions of a CBT program for youth with anxiety disorders. In the present study, SIBS-ONLINE group leaders will complete a template at the end of each session where they will rate themselves for each CAS-CBT item on a 0-6 scale (“none” to “thorough” for adherence, “poor” to “excellent” for skills). The psychometric properties of the CAS-CBT have been demonstrated on a Norwegian sample – the CAS-CBT has a high level of internal consistency (Cronbach’s alpha of 0.87), and a high level of within-rater stability (r=>0.89)[43].

## Study procedure risks

The SIBS-ONLINE intervention teaches parents and siblings skills in effectively communicating and exploring difficult feelings, thoughts, and topics related to their siblings’ chronic illness. It is possible that participating in the study may encourage upsetting/distressing memories and thoughts about the health of the participant’s brother or sister. This might cause some short-term distress. Our priority is to support any participants feeling distressed during study activities.

Any risk issues will be managed by the SIBS-ONLINE research team at Behavioural Sciences Unit (BSU), Sydney Children’s Hospital or at Canteen Australia, depending on which site is running the group. The BSU is comprised of several psychosocial researchers who are experienced in the handling of adolescent and parental distress in the context of chronic illness. Moreover, Canteen comprises numerous qualified and experienced counsellors who have frequently worked with vulnerable and distress adolescent, young adults and parents.

Risk management for participants will be executed on an ongoing basis throughout the course of the study. A distress management protocol is outlined below.

## Distress management protocol

We will provide a leaflet (in hardcopy or PDF) to all participants which will provide information where they can go to seek further help and information. We have made separate leaflets for parents and young people (see attached).

All appropriate steps will be taken to ensure that bereaved parents and bereaved siblings, and parents and siblings of children with a terminal illness or are receiving palliative care are not contacted to participate in the study.

### At recruitment

Parents or siblings who indicate early that they are currently experiencing serious suicidal intent and/or have a suicidal plan will not be eligible to participate. They will be strongly encouraged to contact their local general practitioner (GP) or other nominated health professional (such as their hospital social worker). These participants will also be provided with the contact details of Lifeline and urged to call these numbers if they feel they are at immediate risk of harm. We will notify parents if we identify that siblings are currently experiencing serious suicidal intent and/or have a suicidal plan.

All participants will be informed both in writing (on the information and consent form) and verbally (in the initial intake interview) of steps they can take if they feel emotionally distressed during the intervention and questionnaire activities, including the contact details of the community counselling team, the importance of contacting their own GP, and contact details of emergency services.

We will obtain contact details for a trusted healthcare professional (e.g. family GP) to contact in the case where we identify suicidality. Parents will be asked to nominate a healthcare professional and their best contact details on the Participant Information Sheet and Consent Form. Healthcare professionals will be contacted only in the event of the participating parent or sibling indicating serious suicidal intent and/or possessing a suicidal plan at any stage throughout the study.

### During the pilot

It is possible that during the pilot, a participant comes to reveal an increase in distress, and/or suicidal or self-harm risk to a family member. This will not be discussed in-depth during a group intervention session but rather if such an issue is raised, the participant will be telephoned privately by a member of the research team experienced in psychosocial risk and distress management to further discuss their concerns. This telephone call will take place within 24 hours of determining that a participant is at risk of harm. In addition, where a participant reports suicidal intention or plan, we will immediately contact their trusted healthcare professional (parents will provide HCP contact details on the PISC).

### During completion of questionnaires

Questionnaires assessing symptoms of depression, anxiety and stress via Emotion Thermometers will be completed prior to and after participating in SIBS-ONLINE. Participants who rate their distress as ≥8 out of 10 will be contacted separately by the group leader to further assess their current mood and level of risk and appropriate referrals.

# Statistical considerations

#  Sample size calculation

The statistical power of a comparison of paired samples depends on the within-individual correlation over time. A study in Dutch 10-to-14 year-olds estimated a correlation coefficient of 0.87 (95% 0.80–0.91) [44] in the self-reported SDQ total difficulties score over an interval of 2 months. The lower bound of this confidence interval may be considered as a conservative estimate of the correlation that we would expect to see over the much shorter duration of SIBS-ONLINE.

We will pilot SIBS-ONLINE with N=30 families (30 siblings and 30 of their parents), conducting five groups with six participants in each group. Given that the changes within each group will not be independent, the power also depends on the intra-group correlation.

If the within-individual correlation is at least 0.80 and the within-group correlation is no larger than 0.35 (as evidenced in the evaluation of the original Norwegian SIBS intervention for siblings of children with chronic illness [45]), then a sample size of 30 siblings provides greater than 80% power to detect a large change (0.8 standard deviations) in SDQ total difficulties score, using a two-sided test with a significance level of 0.05.

There is a possibility that multiple siblings, or multiple parents from a family of a child with a chronic illness will want to participate. If this case arises, any data from those participants will be potentially correlated, reducing the effective sample size. For each family that contributes multiple siblings or parents, the target sample size will be increased to ensure that there are at least 30 independent individuals.

## Analysis plan

SIBS-ONLINE has a single-arm pre-post design with the primary outcome being the difference in SDQ scores from pre-intervention to immediately post-intervention, reported by siblings and parents. The primary analysis will be a test of the null hypothesis that the mean difference between the paired scores is equal to zero, accounting for within-group correlation by using a repeated-measures regression model with cluster-robust standard errors. The estimated difference will be presented with a two-sided 95% confidence interval.

Analyses of secondary outcomes will be performed in a similar manner, as appropriate for the specific outcome.

In the case where multiple siblings or parents from the same family are included in the study, statistical tests that account for this additional non-independence will be used.

Analyses will be conducted in SPSS.

## Data storage

Participant information and data will be held securely at Sydney Children’s Hospital Randwick and UNSW. All hard copy data will be locked in a filing cabinet, whilst electronic databases and information will be password protected and only accessible by the study team. At the completion of the research project, all identifying information will be removed from data sets. Any re-identifiable information will be confidentially disposed of 15 years from publication/study completion or after the youngest child participant turns 18. Ethical applications for any future research activities during this time will be applied for as necessary. Paper-based documents will be shredded, and all electronic files deleted, at the specified time.

# Project Duration

The study will begin once ethical approval and site-specific approval has been gained and will conclude in December 2023.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **2020** | **2021** | **2022** | **2023** |
| **Process** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** |
| Ethics and site-specific approval |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Recruitment |  |  |  |  |  |  |  |  |  |  |  |  |  |
| SIB-ONLINE intervention sessions conducted  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Analysis |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Manuscript write-up |  |  |  |  |  |  |  |  |  |  |  |  |  |

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