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Project SKIL: Supporting Kids in Loss

Submission date
20/03/2025

Recruitment status
No longer recruiting

Registration date
21/03/2025

Overall study status
Completed

Last Edited
04/12/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Grief is very common in children. Around two thirds of children have experienced the death of a family member or friend. Children also experience grief from other losses, e.g., death of a pet or parental divorce. While grief is normal, it can also be linked to anxiety, depression and post-traumatic stress disorder (PTSD).
Recent research has developed self-help internet intervention for grief and loss in adolescence (Project SAIL: Supporting Adolescents in Loss; www.sailgrief.org), however there are no such grief interventions available for children. This study aims to test an adapted version of Project SAIL for children aged 6-12 years (Project SKIL: Supporting Kids in Loss), to see if it works well, is acceptable, and shows early signs of effectiveness.

Who can participate?
Children aged 6–12 years who live in Australia and have a self-reported experience of grief, whether from a death (of a person or pet) or a non-death loss (such as parental divorce), can participate with permission from their parents or caregivers.

What does the study involve?
Before starting the program, children will complete a brief questionnaire and if eligible for the study, then will be randomly assigned to either the intervention group or a waitlist control group. Parents/caregivers of children in the intervention group will receive password access and weekly email reminders to help keep children on track. These reminders also include a brief suicide risk check-in. If children don't complete it, research assistants will send up to three follow-ups. Parents/caregivers of children in the waitlist control group will be informed that their child will begin the program after a four-week waiting period. The reason we have a 4-week waiting period is to be able to compare results between children who have done the intervention to those who have not, to be able to conclude whether its effective.

Four weeks after the first questionnaire, all children will receive a second questionnaire. Children in the waitlist control group will be required to complete this to receive password access to the program. This survey will ask about the child's experience with the program, including what they liked and didn't like. At this stage, children will also be invited to participate in an optional online interview with a research assistant to share more feedback.

Older children can complete the program independently, while younger ones may need support from a parent or caregiver. The program includes text, images, videos, worksheets, and interactive activities aimed at helping the child process their grief and improve their mental health. While they can work at their own pace, we recommend completing two modules per week over four weeks.

Eight weeks after the first questionnaire, all children will receive a final questionnaire. All participants will receive a $75 electronic Visa gift card, regardless of how much they complete.

What are the possible benefits and risks of participating?
It is possible that Project SKIL could be a direct benefit to the child as the aim is to teach them strategies to improve their mental health. Additionally, we hope that the results of our research can be used to inform our knowledge of how to improve treatment for grief and loss for young people experiencing grief and loss. This may benefit young people in the future.

It is possible that the topic may be distressing to the child. It is possible that they may want to get ideas about where to seek treatment or mental health support which are more extensive than provided in the online modules. Professor Sarah Egan is a highly experienced registered Clinical Psychologist and can speak to the parent/caregiver to recommend further referral processes.

Where is the study run from?
The study is managed by researchers at Curtin University (Australia). You can complete the program from home using your laptop, phone, or tablet.

When is the study starting and how long is it expected to run for?
The study will start recruitment on 1 April 2025, and is expected to run until the last participant recruitment on 30 June 2025.

Who is funding the study?
This project is funded by Telethon Channel 7 (Australia)

Who is the main contact?
Professor Sarah Egan is the lead researcher for this project. If you have any questions, please contact her at s.egan@curtin.edu.au

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A protocol for a randomised controlled trial of unguided internet cognitive behaviour therapy for grief in children

Acronym
Project SKIL

Study objectives
We hypothesise that there will be a significantly greater improvement in the intervention group in the primary outcome of anxiety, and secondary outcomes of well-being, depression, prolonged grief, and PTSD, compared to children in the wait-list control group. We predict that these improvements will be maintained at one-month post-intervention follow-up. We have set a benchmark for feasibility based on previous studies with adolescents (Egan, Munro et al., 2024), that feasibility will be demonstrated via at least 85 children aged 6-12 years recruited within a 14-week period. We also predict that feasibility will further be demonstrated via reasonable attrition, defined as 25% or less of participants who do not complete post-treatment measures.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 04/02/2025, Curtin University Human Research Ethics Committee (Kent Street, Bentley, Western Australia, Perth, 6102, Australia; +61 (08) 9266 9223; ROC-ethics@curtin.edu.au), ref: HRE2024-0722

Study design
Interventional randomized waitlist-controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
Anxiety, well-being, depression, prolonged grief, and PTSD in children who have experienced loss.

Interventions
The study consists of a randomised waitlist-controlled trial which provides children living in Australia, with a 4-week unguided, parent/carer supported ICBT for grief. Following screening, eligible children will be randomised to receive treatment either immediately or after a 4-week waiting period. Outcome measures will be completed pre- and post-intervention, and at four-week follow-up post-intervention.

Egan, Munro et al's (2024) co-designed unguided internet cognitive behaviour therapy for grief in adolescence intervention (see www.sailgrief.org), was adapted for primary school aged children in Australia, aged 6-12 years. A draft website was circulated to the Youth Advisory Committee who provided feedback on the adapted website via an initial one-hour online meeting. Further changes were made based on the Committee's suggestions - this Committee will be involved in the study throughout the research process. The adapted modules are designed to be self-directed for older children or completed with the support of a parent /caregiver for younger children. At the start of the intervention, there is an explanation of loss that normalizes different ways of grieving. Instructions on how to use the online program, along with tips for parents and carers are included. It is recommended that 2 modules per week, are completed over four weeks. Each module includes six to nine webpages with text, images, video and audio vignettes, worksheets, and interactive components.

The study will be advertised on social media and through organisations that provide camps for grieving families. Consent forms with written information about the study will be administered to interested families. Active assent is sought by informing children and their parent/carer of the study and the voluntary nature of their participation. Participants will be reimbursed AUD$75 via a Visa gift card voucher regardless of whether they complete all measures at each timepoint or the intervention.

Registration will be online on the study website. The website will contain a digital participant information sheet, and a consent button for parents/carers. The parent or carer and child's contact information as well as demographic information including age, and country of residence will be collected. Children living in Australia aged 6-12 years will be able to complete pre-intervention measures and brief questions on treatment status. The CSS screener will be administered to assess suicide risk, if a child scores four or higher, they will be prompted to complete the full measure. A team member will then contact the child's parent/carer via email to provide mental health referral options. The child will be provided with access to the intervention to not exclude them, but the parent/carer will be informed that they will not be included in the trial.
Following this, simple randomisation using a computerised sequence generation will be used to allocate eligible children into the intervention or waitlist control group. Parents/carers of children in the intervention group will be emailed password access to the online intervention. It will be suggested to parents/carers that children complete two modules per week, over four weeks. Weekly email reminders will be sent to parents/carers to prompt them to complete the recommended modules. These email reminders will include a link to the intervention website and a prompt to complete a weekly suicide risk assessment (i.e., CSS). Research assistants will send three email and text reminders if participants do not complete the weekly CSS.

The online intervention is set up with a module completion question at the end of each module. Children can move between different modules and go back to completed modules. To ensure participant information is protected, no data will be stored on the intervention website and participants will be advised to download completed worksheets they wish to save.

A research assistant will email participant's parent/carer with reminders with the intervention link to complete questionnaires at baseline and four- and eight-weeks post baseline assessment. Adverse effects of the intervention will be monitored as per the ICBT for grief intervention for adolescents (see Egan, Munro et al., 2024; Egan, Pauley-Gadd et al., 2024) intervention through the examination of clinical significance and the Reliable Change Index (RCI; Jacobson & Truax, 1991). As in the adolescent study (Egan, Munro et al., 2024; Egan, Pauley-Gadd et al., 2024) a score of below 1.96 will be used to indicate the possibility of no change or a potential negative effect of the intervention in which case a research assistant will email the parent/carer instructing them to attend their general practitioner to access a referral to a mental health professional for their child. Contact information of emergency helplines will also be included. Data on negative outcomes will be included in the trial study outcome paper and will also be reported to the Curtin University Human Research Ethics committee for any adverse outcomes.

Intervention Type
Behavioural

Primary outcome(s)
Anxiety is measured using the Revised Children's Anxiety and Depression Scale (RCADS) – 11 item version (Radez et al., 2021) at baseline, then four-weeks, and eight-weeks.

Key secondary outcome(s))
1. Depression is measured using the Revised Children's Anxiety and Depression Scale (RCADS) – 11 item version (Radez et al., 2021) at baseline, then four-weeks, and eight-weeks
2. Prolonged grief will be measured the Inventory of Prolonged Grief for Children (IPG-C; Spuij et al., 2012) at baseline, four-weeks, and eight weeks. As per the study of ICBT-G-A (Egan, Pauley-Gadd et al., 2024) an additional question to capture non-bereavement related loss will be added to measure with the following question 'Have you lost someone significant to you? If no, please describe the nature of your loss (e.g., death of a pet, parents' divorce)' with an open text response box
3. PTSD symptoms will be measured using the Children's Revised Impact of Events Scale (CRIES; Perrin et al., 2005) at baseline, four-weeks, and eight-weeks. Following the ICBT-G-A trial (Egan, Pauley-Gadd et al., 2024) to make sure the child is answering the measure in relation to the loss they have identified and not another trauma, at the start of the CRIES additional instructions to complete the questionnaire 'regarding the loss which you just described' will be included
4. Wellbeing will be measured using the WHO-5 Well-Being Index (Bech et al., 2003) at baseline, four-weeks, and eight-weeks

Completion date
14/10/2025

Eligibility

Key inclusion criteria
1. Self-reported experience of grief connected with death (person or pet) or non-death losses (e. g., parental divorce)
2. Children aged 6 to 12 years

3. Living in Australia
4. Children whose parents/carer provide informed consent

Participant type(s)
Healthy volunteer, Resident, Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
12 years

Sex
All

Total final enrolment
96

Key exclusion criteria
1. Children with an elevated risk of suicide as measured by the Columbia Suicide Screening Questionnaire (Posner et al., 2011)

Date of first enrolment
01/04/2025

Date of final enrolment
19/08/2025

Locations

Countries of recruitment
Australia

Study participating centre
Curtin University
Kent Street, Bentley, Western Australia
Perth
Australia
6000

Sponsor information

Organisation
Curtin University

ROR
https://ror.org/02n415q13

Funder(s)

Funder type
Charity

Funder Name
Telethon Channel 7

Results and Publications

Individual participant data (IPD) sharing plan
The data is available on request from Professor Sarah Egan.
s.egan@curtin.edu.au

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes