PROTOCOL TITLE

Community Implementation of the ‘Cascade’ (Cope, Adapt, Survive: life after CAncEr) online program for parents of child, adolescents and young adult (AYA) cancer survivors A Phase-III Trial.  
  
VERSION NUMBER 1

24/01/2020

Cascade Implementation Protocol 2020

|  |  |
| --- | --- |
| Co-ordinating Centre: | Behavioural Sciences Unit  Kids Cancer Centre  Level 1 South  Sydney Children’s Hospital  High Street Randwick NSW 2031 |

**Principal Investigator:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name: | Dr Lauren Keladaa | | | | | |
| Institution: | Behavioural Sciences Unit, School of Women's and Children's Health, UNSW | | | | | |
| Address: | Biosciences building, UNSW Sydney, NSW 2052 | | | | | |
| Contact details: | (ph) | 02 9382 3116 |  |  | (f) | 02 9382 1789 |
| Email: | l.kelada@unsw.edu.au | | | | | |

**Chief investigators**:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name: | Prof Claire Wakefield | | | | | |
| Institution: | Behavioural Sciences Unit, Kids Cancer Centre, Sydney Children’s Hospital | | | | | |
| Address: | Level 1 South, High Street, Randwick 2031, NSW Australia | | | | | |
| Contact details: | (ph) | 02 9382 3113 | (f) | 02 9382 1789 |  |  |
| Email: | [c.wakefield@unsw.edu.au](mailto:c.wakefield@unsw.edu.au) | | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name: | Dr Ursula Sansom-Daly | | | | | |
| Institution: | Behavioural Sciences Unit, Kids Cancer Centre, Sydney Children’s Hospital | | | | | |
| Address: | Level 1 South, High Street, Randwick 2031, NSW Australia | | | | | |
| Contact details: | ph | 02 9382 3114 | (f) | 02 9382 1789 |  |  |
| Email: | [ursula@unsw.edu.au](mailto:ursula@unsw.edu.au) | | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name: | Dr Kate Hetherington | | | | | |
| Institution: | Behavioural Sciences Unit, Kids Cancer Centre, Sydney Children’s Hospital | | | | | |
| Address: | Level 1 South, High Street, Randwick 2031, NSW Australia | | | | | |
| Contact details: | (ph) | 8627 8433 | (f) | 02 9382 1789 |  |  |
| Email: | [k.hetherington@unsw.edu.au](mailto:k.hetherington@unsw.edu.au) | | | | | |

**External collaborators**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name: | A/Prof Pandora Patterson | | | | | |
| Institution: | CanTeen Australia | | | | | |
| Address: | 75 King Street, Newtown, NSW 2042 | | | | | |
| Contact details: | (ph) | (02) 9007 0212 |  | (f) (02) 9557 6625 |  |  |
| Email: | [Pandora.Patterson@canteen.org.au](mailto:Pandora.Patterson@canteen.org.au) | | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name: | NAME GOES HERE | | | | | |
| Institution: | ORGANISATION GOES HERE | | | | | |
| Address: | ADDRESS GOES HERE | | | | | |
| Contact details: | (ph) | (02) 1234 5678 |  | (f) (02) 1234 5678 | (m) | 1234 567 890 |
| Email: | [EMAIL](mailto:Pandora.Patterson@canteen.org.au) GOES HERE | | | | | |

## Summary

Protocol title Community Implementation of the ‘Cascade’ (Cope, Adapt, Survive: life after CAncEr) online program for parents of child, adolescents and young adult (AYA) cancer survivors A Phase-III Trial.

Protocol version 1

Objectives Using a clinical effectiveness-implementation hybrid design: (i) To evaluate the effectiveness of the Cascade program in providing peer support, developing healthy coping skills, building resilience and reducing distress in parents of child, adolescent and young adult (AYA) cancer survivors. (ii) To evaluate the implementation of the Cascade program across national and international cancer support community organisations.

Planned sample size 69 parents of child and AYA cancer survivors recruited across various community partner sites. Approximately 20 staff members will be trained in the delivery of the Cascade program.

Inclusion criteria Parents of children and AYAs aged under 25 who have completed cancer treatment with curative intent will be eligible to participate. Eligible participants must be able to: (i) give informed consent; (ii) read English; (iii) provide the name and contact details of a trusted healthcare professional; (iv) have access to a computer/laptop/tablet with a webcam and microphone; and (v) be able to access the internet in a private location once a week for four weeks. Parents of children and AYAs who have previously relapsed (and have finished relapse treatment) will be encouraged to participate. However, parents of children and AYAs who have recently relapsed or are still in active treatment will be excluded.  
  
Staff members at the community partner sites who are registered healthcare professionals (including, but not limited to psychologists, clinical psychologists and nurses), and/or have relevant experience in the delivery of cognitive-behaviour therapy groups, and/or are a doctoral or masters student completing clinical training under the supervision of a registered health professional are eligible to be trained to deliver Cascade. These staff members (hence facilitators), and other adjunct staff members at community organisations will participate in providing qualitative data about the implementation of Cascade.

Study procedure Preparation for the study will involve implementation and planning discussions, negotiation with cancer-support providing community organisations, and training of staff and clinicians at community organisations. Following community organisations’ preparation, parents will be recruited for the Cascade study. Parent participants will receive an initial one-on-one introduction session with the group facilitator, followed by a weekly four-module online group session with a facilitator. Following this, parents will complete a one-on-one booster session with their group facilitator.  
  
The clinical effectiveness of Cascade will be assessed by online questionnaires at intake (T1), and six weeks later, after the completion of the group and booster sessions (T2). Parent participants will complete measures of demographic data, distress, emotion levels, CBT skills use, coping behaviours, perceived peer support, therapeutic alliance, and perceived benefit/burden.  
  
The success of program implementation will be evaluated in terms of data collected from community counselling staff, management staff, and internal research/support staff (e.g. IT). Data will be collected on participant responsiveness (uptake rates, session adherence, attrition), technical issues, intervention fidelity (treatment manual adherence), and financial sustainability (time, personnel and resource costs). Community facilitators will complete a brief questionnaire and interview with the Cascade study team at three time points (before, during and at the completion of the implementation at their associated community organisation) to assess staff perception of the program, confidence in delivery, and perceived barriers/facilitators to implementation.

Sample size calculations A sample of N=69 will provide >80% power to detect a small effect size (d≥0.3) of the Cascade intervention on the primary variable of emotion regulation which consists of two independent factors (significance level of 0.025 for each factor, two tailed). Assuming a response rate of 50% and an attrition rate of 20% (based on previous research by our group), we will need to assess approximately 173 parents of child and AYA cancer survivors for eligibility.

Analysis plan The Cascade implementation study has a single-arm pre-post design, with emotion regulation as the primary clinical efficacy outcome. To evaluate this, we will use a paired-samples t-test to compare participant scores on the ERQ before and after the Cascade intervention. Additional tests will be performed to elucidate any secondary outcomes.

Additionally qualitative data exploring challenges and impacts of implementation will be collected from various staff at community organisations.

Duration of the Study Three years from initial consultation with community organisations to analysis of data and publication.

Contents

[Cascade Implementation Protocol 2019 2](#_Toc30699857)

[Summary 3](#_Toc30699858)

[1. Introduction and rationale 6](#_Toc30699859)

[2. Project Aims 6](#_Toc30699860)

[3. Project Duration 7](#_Toc30699861)

[4. Number of community organisations 7](#_Toc30699862)

[5. Selection criteria 7](#_Toc30699863)

[5.1. Inclusion criteria 7](#_Toc30699864)

[5.1.1. Parent participants 7](#_Toc30699865)

[5.1.2. Community organisation staff 7](#_Toc30699866)

[5.2. Exclusion criteria 8](#_Toc30699867)

[5.2.1. Parent participants 8](#_Toc30699868)

[5.2.2. Community organisation staff 8](#_Toc30699869)

[5.3. Withdrawal procedure 8](#_Toc30699870)

[6. Study design and procedure 9](#_Toc30699871)

[6.1. Design rationale 9](#_Toc30699872)

[6.2. The Cascade intervention 9](#_Toc30699873)

[6.3. Procedure 12](#_Toc30699874)

[6.3.1. Advertising and recruitment 12](#_Toc30699875)

[6.3.2. Consent 12](#_Toc30699876)

[6.3.3. Intake 12](#_Toc30699877)

[6.3.4. Introduction session 12](#_Toc30699878)

[6.3.5. Treatment 12](#_Toc30699879)

[6.3.6. Booster session 12](#_Toc30699880)

[6.4. Outcome measures 14](#_Toc30699881)

[6.4.1. Assessment of program efficacy 14](#_Toc30699882)

[6.4.2. Assessment of program implementation 15](#_Toc30699883)

[6.5. Study procedure risks 16](#_Toc30699884)

[7. Statistical considerations 17](#_Toc30699885)

[7.1. Sample size calculation 17](#_Toc30699886)

[7.2. Analysis plan 17](#_Toc30699887)

[8. Regulatory considerations 18](#_Toc30699888)

[8.1. Compliance with regulatory guidelines 18](#_Toc30699889)

[8.2. Ethical review 18](#_Toc30699890)

# Introduction and rationale

Each year, more than 1200 parents/carers are told that their child has cancer, Australia’s leading cause of disease-related child death(1). From diagnosis, parents support their child through debilitating treatment for months/years, whilst grappling with the possible death of their child (2). The treatment period is intense, with a primary focus on survival*.* Due to improved multimodal therapies, most children survive cancer(3). It is often only when treatment ends that parents process the experience, at the very time when hospital-based psychosocial support is diminished(4). Despite the positive aspects of treatment completion, this is a vulnerable time for parents, who can experience **worsening QoL, anxiety, depression, helplessness and loneliness (5, 6)**. Parents living in rural/remote areas are most at risk of these poor outcomes (5). Left untreated, this distress can last years.

There is strong evidence that skills-based interventions lead to positive psychosocial outcomes(7).Parent-targeted interventions are also feasible and acceptable in the cancer context (7), however, few interventions have been rigorously evaluated. Many are also implemented face-to-face, which creates inequity between rural and metropolitan families as a result of differences in accessibility (8). Consequently, no efficacious and equitable program currently exists to provide support for Australian parents at the recognised crisis (9) of cancer treatment completion. This is a clear gap given that a) parental distress is prevalent; b) skills-based support is effective; and c) parental functioning directly impacts all family members. Evidence-based interventions provided to parents during this ‘coming off treatment’ phase is an opportunity to prevent long-term mental health problems. To respond to this need, our team developed and evaluated a theoretically grounded online intervention, ‘Cascade’ [‘Cope, Adapt, Survive: Life after cancer’], to teach adaptive coping skills to promote resilience for parents in the early phases of their child’s survivorship. The program is preventative, promoting resilience and mental health in the long-term by equipping parents with evidence-based skills early. The program involves four weekly group sessions with 3-5 participants per group, led by a facilitator, and delivered using online videoconferencing software.

Partnerships with the community sector provide opportunities for the widespread dissemination of mental health interventions. Recent psycho-oncology reviews have demonstrated that despite an increase in intervention studies, there is a serious lack of implementation/dissemination studies, with <6% of existing interventions being implemented in practice(10). This means that early-phase work continues to suffer from what is seen in many sciences- an up to 17 year lag between research and practice. Numerous non-government community organisations provide vital support to families after cancer, including Cancer Council NSW, CanTeen, Camp Quality, Leukaemia Foundation, and Redkite. These organisations are increasingly providing a platform for broader education around psychological concerns post-treatment, as well as directly addressing survivors’ and families’ concerns through the provision of resources and interventions (11). Transitioning the delivery of efficacious e-mental health models of care to the community sector will reduce the burden on the health system sector while enabling service provision to be dispersed across stakeholders.Initial results from pilot and randomised control trials of Cascade indicate that the intervention is acceptable to AYAs with cancer, and feasible to deliver. Of particular importance, data indicate that the web-based video conferencing technology is workable from both a technical and clinical perspective (12).

# Project Aims

This project has dual aims;

1. To evaluate the clinical effectiveness of the Cascade program in improving emotion regulation and coping, and reducing the distress of parents of child, adolescents and young adult (AYA) cancer survivors when delivered in a community setting.
2. To evaluate the implementation of the Cascade program in community setting(s). Factors including intervention fidelity, participant recruitment and retention, reach/organisational uptake, and financial sustainability will be assessed.

Given these aims, we hypothesise that;

1. Cascade will produce positive mental health outcomes, observed as increased emotion regulation, increased feelings of peer support, increased performance of CBT-based behaviours, and increased coping behaviours in parents of AYA cancer survivors;
2. The Cascade intervention is feasible to deliver in community settings when considered from a financial, technical, and intervention fidelity perspective.

# Project Duration

As of November 2019, we have already commenced discussions with a number of community organisations that have expressed interest in implementing the Cascade intervention. We expect that active recruitment of parent participants will commence in January 2020, and expect to publish study results in December 2023. Therefore, we anticipate the duration of this study to be approximately 36 months.

# Number of community organisations

As of January 2020, ethics approval for a catch-all form of the Cascade protocol is being sought from the UNSW HREC. As opportunities for collaboration arise from ongoing negotiations with community organisations, we will seek approval for with UNSW HREC for revised versions of our initial ethics approval, in addition to approval from jurisdiction-specific HRECs.

# Selection criteria

As per sample size calculations (additional detail in **Section 7.1**), we are aiming for a sample size of N=69. Assuming a similar attrition rate to the Phase II Cascade trial, we plan to approach a total of ~179 parents of children and AYA’s who have completed cancer treatment in order to reach this sample size. We anticipate that ~20 staff members from community partner sites will be trained to deliver the Cascade intervention over the whole trial.

## Inclusion criteria

### Parent participants

Eligible participants will be parents of children and AYAs aged under 25 who have completed cancer treatment with curative intent. Both parents of each child will be able to participate, however, if both parents opt in, they will be placed in different groups to allow greater confidentiality within the group and to ensure that any groups have only a single representative from each family. If a parent’s child relapses during the course of the program the parent will be excluded and receive at least one one-on-one session with their facilitator and a referral to the social worker at their child’s treatment centre for coordination of further psychological support.

Eligible parent participants must be able to:

* Give informed consent;
* Read English;
* Provide the name and contact details of a trusted health professional, such as their local general practitioner or the social worker at their treating centre;
* Have access to a computer/laptop/tablet with a webcam and microphone;
* Access the Internet in a private location (that is, where they will feel comfortable discussing issues related to their child’s cancer) once a week for 4 weeks.

### Community organisation staff

Community organisation staff members will be eligible to participate (i.e. be trained in and evaluate Cascade) if they:

* Are a registered healthcare professional (including but not limited to psychologists, clinical psychologists, and nurses); and/OR
* Have prior experience in the delivery of a cognitive-behaviour therapy group treatment program; and/OR
* Are determined by the community organisation as having sufficient experience to deliver the program; and/OR
* Are a doctoral or master’s student completing clinical training under the supervision of a registered health professional.

## Exclusion criteria

### Parent participants

Exclusion criteria include:

* Any parent with insufficient English language skills.
* Any parent of a child who is currently on active treatment, has relapsed, or is in palliative care.
* Any parent with severe depression and/or suicidal intent or plan, as determined in the initial intake interview, or by the clinical experience of the psychologist or by the participant’s responses to the first questionnaire. Participants who report at the initial intake interview that they are currently experiencing serious suicidal intent (with or without a defined plan) will be excluded with appropriate referral options provided. Further, parents who score ≥ 30 on the Kessler Psychological Distress Scale (K10) will be telephoned and assessed further to determine whether or not their score is indicative of a ‘severe’ mental health disorder and to assess their suicidal risk. If further assessment indicates a parent is experiencing a ‘severe’ mental health disorder and/or suicidal risk they will be excluded and provided with appropriate referral options.
* Any parent who reports that they who reports that they are currently undergoing treatment for Schizophrenia, or who is judged to be currently experiencing a psychotic episode, based on clinical judgment at the initial interview.
* Any parent who reports substance abuse.

All parents who are excluded from the program for any reason will have a one-on-one session with the study psychologist, if desired, to develop an appropriate referral plan.

### 5.2.2. Community organisation staff

Staff will be ineligible to be trained to deliver Cascade if they are:

* Not a registered healthcare professional; AND
* Have insufficient experience with the delivery of cognitive-behavioural therapy interventions.

## Withdrawal procedure

Parents can withdraw from the Cascade program at any time without consequence from the lead study team or community organisation. If the reason for withdrawal relates to participants requiring alternative or more intensive support this will be coordinated by the clinical team at the community site. See **Study Procedure Risks 6.5** for more information.

If a participant’s reason for withdrawal relates to a serious adverse event as a result of the Cascade intervention, the lead study team will report the circumstances of the event to the UNSW HREC, in addition to any jurisdiction-specific registries and trial sponsors.

Individual data obtained from a participant who is later excluded from or withdraws from the study will be deleted from all locations. However, given that Cascade is a group program, the facilitator’s group session notes may exist that contain information about the excluded participant in addition to information about still-eligible participants. To ensure that excluded/withdrawing participants’ privacy is respected, copies of this data will be created where any information from the excluded/withdrawing participant is expunged, and the original data will be destroyed.

Additionally, if a participant elects to withdraw from the study, they will be asked to review the extent of contact that they have with the community organisation in future. Participants will be able to express if they would no longer like to be targeted by marketing materials from the community organisation, in which case they will be placed on a no-contact list.

# Study design and procedure

## Design rationale

Randomised control trials (RCTs) are the most scientifically rigorous research designs to determine intervention efficacy. However, complex study designs may interrupt the progress of the implementation of programs into non-research settings. Therefore, the design of this study is grounded in an Implementation-Effectiveness Hybrid Type 2 design (13). This type of design allows the simultaneous evaluation of the clinical effectiveness of an intervention and the implementation process, to allow for rapid translation while still providing valuable information on the clinical effectiveness of the Cascade intervention.

Our choice in design is motivated by the need for advancement in both the development and implementation of cancer aftercare interventions(14). In other words, there is a level of “implementation momentum”(13) within the healthcare system and literature that justifies a rapid and routine uptake of an accessible program for parents of child and AYA cancer survivors.

The clinical effectiveness portion of the study will consist of an assessment of the effect of the Cascade intervention on perceived peer support, amongst other mental health outcomes. Cascade’s effectiveness will be evaluated through a non-randomised controlled pre-post design; that is, we will assess key outcomes before (at baseline) and after the consumers’ participation in the Cascade intervention. The implementation portion of the study will consist of a comprehensive qualitative assessment of Cascade’s impact on community counselling staff from a financial, technical, and subjective point of view.

The study design and procedure aims to fulfil the three major aims of implementation science (15):

**Describing and or guiding the process of translating research into practice:**

- Implementation planning began in early 2020 and will continue throughout the trial. This will involve meetings with implementation science experts and community organisations. Ongoing development of the Cascade study procedure will result in rapid translation from theoretical intervention to practical solution. Detailed records will be kept of this process so as to describe the implementation process for the purpose of dissemination into the implementation research literature.

**Understanding and/or explaining what influences implementation outcomes.**

- Individual and group interviews with consumers and stakeholders throughout the implementation process (before, during, and after running Cascade groups) will provide insight into perceived barriers and facilitators to successful implementation. Findings from a qualitative analysis of these interviews will contribute to the following aim;

**Evaluating the implementation.**

See **section 6.4 ‘Outcome measures’** below.

## The Cascade intervention

The Cascade intervention takes the format of a weekly four-module online group session delivered by a trained facilitator based in the community organisation. The Cascade intervention will be offered alongside other existing support and counselling services (both online and face-to-face) embedded within the community organisation. Consumers’ engagement with other support services within the community organisation will not exclude their participation in Cascade, unless deemed appropriate by community staff. Each group will comprise a facilitator based in the community organisation and 3-6 parents of children with mixed diagnoses, ages and genders. Sessions will be delivered through a secure, password-protected video conferencing software on the Internet. Participants will also receive a written manual summarising the weekly home practice activities.

The first ten to fifteen minutes of each session involves informal discussion such as discussing everyone’s week and reviewing the home practice exercises. This 15 minutes is provided as a buffer to allow any late-comers to join, as well as to ensure that any delays caused by technical difficulties do not impede in the delivery of the session’s content.

The remainder of the session is devoted to psychoeducation by the facilitator, peer discussion, and group-based modelling and practice of the week’s skill. An effort is made in each module to relate the skills or ‘psychological content’ to group members’ experiences, both cancer-related and non-cancer-related. This is critical to ensuring the relevance of the skills to the parents’ lives and to assist them to see how they might be able to apply to them.

**Table 1: Cascade session content**

|  |  |  |  |
| --- | --- | --- | --- |
| **Module** | **Module title** | **Psychological objectives/skills** | **Cancer relevant content** |
| a) PSYCHO-EDUCATION and HEALTH (behavioural activation) | “What just happened to us??” | ●Program engagement  ●Value of learning coping skills  ●Normalising concerns/fears  ●Importance of building structure and positive events back into life | *Common experiences of parents during & after their child’s cancer. What ‘survivor’, ‘cure’ and ‘getting back to normal’ means. Regaining balance after cancer: employment, finances, healthy lifestyle, stress management.* |
| b) APPRAISAL (unhelpful thinking styles) | “How has cancer changed the way I think?” | ●‘ABC model’(16)- impact of thoughts on feelings/responses to difficult situations  ● Use of cognitive challenging to manage unhelpful thoughts | *Thoughts and feelings after cancer: ongoing worries about child’s health, family finances, relationships* |
| c) MINDFULNESS AND DISENGAGEMENT | “Out of your head and back into life” | ●Use of acceptance and mindfulness strategies to manage ‘bigger’ existential thoughts and worries | *Existential thoughts about death and dying, fear of recurrence, distressing memories* |
| d) SOCIAL SUPPORT (assertiveness) | “Looking forward” | ●Identify difficulties in relationships and communication ‘traps’  ●Use of assertiveness skills and cognitive challenging to move toward valued relationship goals | *Reconnecting with friends and partner; how to talk about cancer. Skills to navigate difficult family/social situations post-cancer.* |
| e) BOOSTER SESSION |  | ●Recap goals, progress made so far ●Problem solve challenges | *How has life after cancer changed? Skills refresher. New goals.* |

## Procedure

See Figure 1 for additional detail on participant flow throughout the course of the Cascade intervention.

### Advertising and recruitment

The Cascade program will be advertised on various platforms; for example, on the official website or Facebook page of the community organisation and via targeted emails to consumers. Interested consumers will be mailed or emailed an information package. Referrals may also be received from counselling staff within the community organisation and staff from other relevant clinical services around Australia.

### Consent

Informed consent will be obtained from all participants prior to participation in the program. Consent will be obtained in the form of a completed online consent form delivered via Qualtrics.

### Intake

Parent participants will complete a brief telephone intake call with a facilitator at the community site. The purpose of the intake call is to confirm eligibility, obtain consumer details, assess risk, and obtain the details of a trusted healthcare professional and of another support-person if relevant

### Introduction session

After group allocation parent participants will complete a one-on-one online video-call introduction session with the group facilitator. This will take approximately 20 minutes. The purpose of this session is to introduce participants to the software program, allow the facilitator to build rapport, and provide an opportunity for the facilitator to communicate confidentiality and privacy guidelines to the parent participants. This session will also provide an opportunity for the participant to set personalised goals for the program.

### Treatment

Following the introductory session, parents will complete four weekly online group sessions, with each focussing on a specific module. Each 90-minute module focusses on applying CBT techniques to areas of concern specific to parents of child and AYA cancer survivors as identified by our extensive pilot work(12). Module content is outlined comprehensively in **TABLE 1.** Tailored supportive counselling(17) is used in all Cascade sessions, and involves empathic listening to normalise the range of parent experiences and promote peer discussion/support. Home practice is encouraged for parent participants, with practice exercises and examples in the provided manual.

### Booster session

One week after the end of Module 4, parent participants will complete a one-on-one booster session with their group facilitator to review and consolidate skills learnt across the program, receive additional input from the facilitator and discuss how to apply these skills to new challenges that may have arisen since finishing their program. The facilitator will also follow up with the goal outlined by the parent participant in the initial introduction session. Participants will complete a second questionnaire (Q2) one to four weeks after completion of the booster session. The booster session will take 10-60 minutes.

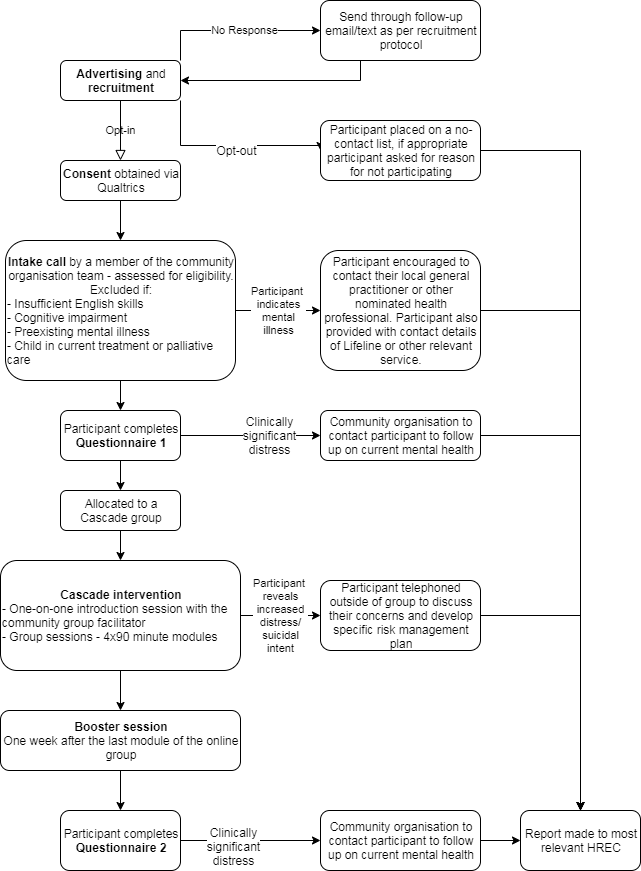
****

Figure 1. Flow of parent participants through the Cascade implementation study.

## Outcome measures

### Assessment of program efficacy

Parent participants will complete a battery of validated measures to assess coping and intervention outcomes at two time points – at baseline (T1), and after completion of the intervention (T2). See details below.

**Questionnaire 1 only**

1. **Consent for use of quotes**

Question requesting use of unidentified quotes from questionnaire responses to provide further insight into program strengths and barriers to use.

1. **Demographic data**

Information on age, sex, education, employment status, family structure, cancer diagnosis, and treatment regimen will be collected using standardized items.

**Questionnaire 1 and 2**

1. **Emotion Regulation Questionnaire (ERQ)**The ERQ is a brief 10-item scale designed to measure respondents’ tendency to regulate their emotions. Emotion regulation “strategies” are divided into two subsets: Cognitive Reappraisal, where individuals construe a situation in a way that alters its emotional impact; and Expressive Suppression, whereby individuals suppress ongoing emotion-expressive behaviour.Participants respond on a seven-point Likert scale (1-7, with 1 representing strongly disagree, and 7 representing strongly agree) (18).
2. **Coping Self-Efficacy Scale (CSES)**

The CSES is a 13-item measure of respondents’ self-percieved ability to cope effectively with life challenges. This measure has been validated as a means of assessing changes in coping over the course of an intervention.7 Coping behaviours are divided into three subsets: Use problem focussed coping, stop unpleasant emotions and thoughts, and get support from friends and family. Participants respond on an 11-point Likert scale (0-10), where 0 represents ‘cannot do at all’, 5 represents ‘moderately certain can do’, and 10 represents ‘certain can do’ (19).

1. **Modified Cancer Peer Support Scale (CaPSS)**

The CaPSS is a brief 11 item scale originally designed to measure the quality of peer support experienced by adolescents living with cancer. We will use a version of the scale modified with permission to assess the quality of peer support experienced by parents of adolescents and young adults living with cancer. To this end, the original questionnaire will be modified with the sentence stem “When I think about my interactions with parents of young people who have been diagnosed with cancer I feel…” Participants respond on a five-point Likert scale (i.e. none of the time, a little of the time, some of the time, most of the time, and all of the time) (20).

1. **Kessler Psychological Distress Scale**

The K10 is a widely used, 10-item assessment of psychological distress recommended as an Australian Federal Government mental health measure.Participants respond on a five-point Likert scale (i.e. None of the time, a little of the time, some of the time, most of the time, all of the time) (21).

1. **Emotion thermometers**

Participants respond on an 11 point Likert scale (0-10) presented in a visual thermometer format (22).

1. **Cognitive-behavioural therapy skills acquisition and use:**

Ten purposively designed items that assess participants’ self-efficacy using a number of cognitive and/or behavioural coping skills, and whether they have used these skills since finishing their online group. Items question participants on their performance of CBT-related skills/activity. For each item, participants indicate whether they feel like they could complete the skill/activity (yes/no), and whether they actually performed the skill/activity (not at all/a little/a lot).

1. **Brief Cope**

A shortened version of the COPE scale, designed to assess several responses known to be relevant to effective and ineffective coping.3 Participants respond to 18 items on a four-point Likert scale (i.e. I haven’t been doing this at all/I’ve been doing this a little bit/I’ve been doing this a medium amount/I’ve been doing this a lot)(23) .

1. **Benefit/Burden items**

Two items to assess the extent to which parent participants found the program beneficial or burdensome. Participants respond on a five-point Likert scale (i.e. not at all, a little bit, somewhat, quite a bit, very much).

1. **Participant goals/expectations**A series of free-response items where participants outline their personal goals and expectations for the Cascade program.

**Questionnaire 2 only**

1. **Working Alliance Inventory – Short Revised (WAI-SR)**

The WAI-SR is a 12-item scale that will be included to assess participants’ therapeutic alliance with their online facilitator. We will use a version of the WAI-SR modified to exclude items on the goal subscale, for a total of eight items. Participants respond on a five-point Likert scale (i.e. seldom, sometimes, fairly often, very often, and always)(24) .

1. **Changes to health/mental health status:**

We purposively developed items to assess any changes to participants’ health/mental health status over the last three months. Parents could endorse as many of the following as are relevant to their family over the last three months: ‘my child has experienced worsening of their health’, ‘I have experienced worsening of my health’, ‘my child has experienced worsening of their psychological wellbeing’, ‘I have experienced worsening of my psychological wellbeing’, and ‘my family has experienced an additional significant stressor’.

1. **Open ended questions:**

We will include open-ended questionnaires to obtain qualitative feedback from participants.

1. **Would you recommend the program to other parents of childhood cancer survivors?**

Question asking participants if they would recommend the program to other parents of child, adolescent, or young adult cancer survivors. Participants respond on a five-point Likert scale (extremely unlikely, unlikely, neither likely nor unlikely, likely, extremely likely).

### Assessment of program implementation

1. **Impact of training/program delivery on community counselling staff**

Community counselling staff will complete a brief questionnaire and face-to-face/phone interview with the Recapture Life research team at three time points (before, during and at the completion of the trial), to assess staff perception of the program, confidence in program delivery, and perceived barriers/facilitators to implementation.

1. **Participant responsiveness**

Data will be collected on program uptake rates, session attendance, and attrition rates.

1. **Technical issues**

Technical issues will be documented in session log completed by community counselling staff after every session. Staff will report factors such as number of technical glitches (relating to audio-visual functioning, internet speed, WebEx program functioning), perceived impact of technical difficulties on the session.

1. **Intervention fidelity**

Staff will be required to document their adherence to the treatment manual at each session. If deviations from the treatment manual occurred, staff will be asked to make a note of the reasons for deviation (e.g. not enough time).

1. **Financial sustainability**

Financial sustainability will be evaluated in terms of time (staff time spent preparing for sessions, time spent waiting for participants to log-in, time spent on participant follow-up), and resource costs (e.g. dongle costs, costs of WebEx subscription).

## Study procedure risks

The Cascade protocol teaches parent participants specific coping skills which they can use to manage symptoms of distress – we anticipate that parents will experience a reduction in symptoms of distress and an increase in their quality of life. In teaching these skills, and discussing issues related to cancer, however, it is possible that for some participants their distress levels will increase in the short term. Our priority is to support participants to stay safe. In the Recapture Life Phase II randomised controlled trial no serious adverse events occurred that were required to be reported to the ethics committee, demonstrating the rigour of our safety management protocol. We have considered potential for harm when delivering group-based psychosocial interventions online, and procedures for appropriate risk management in-depth, recently publishing about this in a national psychological journal (25) as well as undertaking a review of international best-practice guidelines for the delivery of videoconferencing-based interventions (26).

All psychosocial risk issues will be managed by the clinical team at the community site in direct consultation with the lead Cascade research/clinical team based at the Behavioural Sciences Unit (BSU), Sydney Children’s Hospital. The BSU research team is comprised of several registered clinical psychologists/psychologists experienced in the management of AYA mental health. Throughout the trial each community site’s clinical team will be provided with regular supervision by the lead clinical team from the Sydney Children’s Hospital. It is important to note that the community team will likely have organisation-specific protocols in place for managing and reporting risk of harm which may overlap with the risk management plan detailed below. Discussions will take place between the community team and lead Cascade research team to streamline risk management plans.

Risk management for parent participants will be executed on an ongoing basis throughout the course of the study. If at any stage there are signs of clinically significant distress (as judged by the group facilitator or community organisation staff member managing intake), the group facilitator/intake officer will engage in a risk management procedure dependent on the parent participant’s progress in the Cascade study:

**At Recruitment:**

Parents who indicate early that they are currently experiencing serious suicidal intent and/or have a suicidal plan will not be eligible to participate, and 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.

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 trial, including the contact details of the community counselling team, the importance of contacting their own GP, and contact details of emergency services. All applicants who opt-in to participate must also provide contact details for their GP or another health professional, who the community team/research team will only contact if we are sufficiently concerned about the participant (this is explained to participants verbally, and in the Participant Information Sheet; see attachments). We will not contact GPs or other health professionals as a standard protocol otherwise, in order to safeguard participants’ confidentiality.

**During the Trial:**

It is possible that in the course of the trial, 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 an intervention session but rather if such an issue is raised, the participant will be telephoned privately by the group facilitator to further discuss their concerns. This telephone call will take place ideally within 48 hours of determining that a participant is at risk of harm, and within a week at the very most.

**During Completion of Questionnaires:**

Questionnaires assessing symptoms of depression, anxiety and stress, as well as aspects of cancer-related QoL, will be completed prior to participating in Cascade and one week after the completion of the online booster session. Any deterioration in mood or elevated distress reported on these measures will trigger protocols involving contacting the participant to discuss their emotional state (See Appendix 1), and a meeting between the community team and the lead research team to develop and document a management plan. Documentation will be sent to the relevant HREC as it becomes available.

Regular meetings will take place between the community site team and the lead research team at the Sydney Children’s Hospital to discuss the progress of each participant and of the overall trial. Dr Lauren Kelada (CI) will monitor overall progress weekly and will take overall responsibility for this trial. All adverse events will be promptly reported to the HREC.

# Statistical considerations

## Sample size calculation

The total target sample size is N=69 parents of child and AYA cancer survivors over our recruitment period. We anticipate that a total of 173 participants will need to be approached (accounting for a response rate of 50% and an attrition rate of 20%, based on previous research by our team.)

We will use the Emotion Regulation Questionnaire (ERQ) as a measure of our primary therapeutic outcome – parent use of emotion regulation strategies. The ERQ is a well-established measure consisting of questions that test two independent factors; reappraisal and suppression. Both factors have an estimated test-retest reliability of r=0.69 across 3 months(19).

Although the time between Q1 and Q2 of the Cascade is likely to be 1.5 months as opposed to 3 months, we have elected to use r=0.69 as a conservative estimate of the within-individual correlation over the shorter time period. Using a paired t-test with a two-sided significance level of 0.025 separately for each emotion regulation factor, a sample size of N=69 provides >80% power to detect a small change (d=0.3) over the time of the Cascade intervention. The significance level of 0.025 for each test controls the overall type I error rate associated with performing statistical comparisons on the two independent measures at 5%.

We estimate that N=20 community staff from community partner sites will be trained to deliver the Cascade program over the whole trial.

## Analysis plan

The Cascade implementation study has a single-arm pre-post design, with emotion regulation as the primary clinical efficacy outcome. To evaluate this, we will use a paired-samples t-test to compare participant scores on the ERQ before and after the Cascade intervention. Paired-samples t-tests will similarly be used to examine changes in participant outcomes on the CSES, CaPSS, K-10, emotionality (emotion thermometers), coping, and perceived benefit/burden items. McNemar’s test will be used to examine changes in participant CBT skills acquisition and use. Additionally, linear regression models will be used to evaluate whether any secondary outcomes (including working alliance and changes to health/mental health) are associated with change to parent participants’ ERQ scores. Finally, thematic analysis will be performed on participants’ responses to open-ended goal questions.

To evaluate the feasibility of the intervention, a combination of qualitative and quantitative measures will be used. Descriptive statistics will be used to characterise factors such as recruitment rates, technical issues per session, time to login, and adherence rates. Thematic analysis will be used on data from session notes to evaluate intervention fidelity. Thematic analysis will also be used to examine organisational factors within community organisations contributing to and hindering successful program implementation. Additionally, an economic analysis will be performed to compare the cost of delivery of the Cascade program by community organisations to the cost of delivery by traditional healthcare outlets.

Quantitative analyses will include all registered participants, and will employ multiple imputation techniques to account for missing data points (27). A significance level of 5% will be used for all hypothesis tests. A detailed analysis plan will be for all quantitative outcomes will be finalised prior to beginning analysis.

# Regulatory considerations

## Compliance with regulatory guidelines

This study will be conducted in compliance with the:

* National Health and Medical Research Council National Statement on Ethical Conduct in Human Research;
* Guidelines under Section 95 of the Privacy Act 1988
* Australian Code for the Responsible Conduct of Research;
* Declaration of Helsinki.

## Ethical review

Prior to the commencement of the study, the protocol, Informed Consent form, information sheet will be submitted to the Sydney Children’s Hospital Network Human Research Ethics Committee (HREC).

During the course of the study, the investigator will submit to the HREC the following:

* Amendments to the protocol,
* serious and unexpected adverse events and the outcome,
* specific site updates as agreed to by the investigator and respective HREC, and
* any additional information (e.g., unexpected serious adverse events reported by other sites, amendments to the Investigator Brochure, and administrative changes to the protocol).

At the end of the study, the Investigator will inform the HREC in writing that the study has ended and no further activities regarding this protocol will be conducted at the site.

# References

1. Australian Institute of H, Welfare. Cancer survival and prevalence in Australia: period estimates from 1982 to 2010. Asia Pac J Clin Oncol. 2013;9(1):29-39.

2. Valdimarsdottir U, Kreicbergs U, Hauksdottir A, Hunt H, Onelov E, Henter JI, et al. Parents' intellectual and emotional awareness of their child's impending death to cancer: a population-based long-term follow-up study. Lancet Oncol. 2007;8(8):706-14.

3. Wakefield CE, McLoone JK, Butow P, Lenthen K, Cohn RJ. Parental adjustment to the completion of their child's cancer treatment. Pediatric blood & cancer. 2011;56(4):524-31.

4. Wijnberg-Williams BJ, Kamps WA, Klip EC, Hoekstra-Weebers JE. Psychological adjustment of parents of pediatric cancer patients revisited: five years later. Psychooncology. 2006;15(1):1-8.

5. Aitken TJ, Hathaway G. Long distance related stressors and coping behaviors in parents of children with cancer. J Pediatr Oncol Nurs. 1993;10(1):3-12.

6. Maurice-Stam H, Oort FJ, Last BF, Grootenhuis MA. Emotional functioning of parents of children with cancer: the first five years of continuous remission after the end of treatment. Psychooncology. 2008;17(5):448-59.

7. Meyler E, Guerin S, Kiernan G, Breatnach F. Review of family-based psychosocial interventions for childhood cancer. J Pediatr Psychol. 2010;35(10):1116-32.

8. Morley B, Pirkis J, Naccarella L, Kohn F, Blashki G, Burgess P. Improving access to and outcomes from mental health care in rural Australia. Aust J Rural Health. 2007;15(5):304-12.

9. Arnold EM. The cessation of cancer treatment as a crisis. Soc Work Health Care. 1999;29(2):21-38.

10. Bryant J, Boyes A, Jones K, Sanson-Fisher R, Carey M, Fry R. Examining and addressing evidence-practice gaps in cancer care: a systematic review. Implementation Science. 2014;9(1):37.

11. Patterson P, McDonald FE, Orchard P. A new Australian online and phone mental health support service for young people living with cancer. Australasian Psychiatry. 2014;22(2):165-9.

12. Wakefield CE, Sansom-Daly UM, McGill BC, Ellis SJ, Doolan EL, Robertson EG, et al. Acceptability and feasibility of an e-mental health intervention for parents of childhood cancer survivors: "Cascade". Support Care Cancer. 2016;24(6):2685-94.

13. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Medical care. 2012;50(3):217.

14. Wakefield C, McLoone J, Butow P, Lenthen K, Cohn R. Support after the completion of cancer treatment: perspectives of A ustralian adolescents and their families. European journal of cancer care. 2013;22(4):530-9.

15. Nilsen P. Making sense of implementation theories, models and frameworks. Implementation science. 2015;10(1):53.

16. Butler AC, Chapman JE, Forman EM, Beck AT. The empirical status of cognitive-behavioral therapy: A review of meta-analyses. Clinical Psychology Review. 2006;26(1):17-31.

17. Geldard K, Geldard D. Counselling adolescents: The proactive approach for young people: Sage; 2009.

18. Gross JJ, John OP. Individual differences in two emotion regulation processes: implications for affect, relationships, and well-being. J Pers Soc Psychol. 2003;85(2):348-62.

19. Chesney MA, Neilands TB, Chambers DB, Taylor JM, Folkman S. A validity and reliability study of the coping self-efficacy scale. Br J Health Psychol. 2006;11(Pt 3):421-37.

20. Patterson P, McDonald F, Tindle R, Kelly‐Dalgety E, Zebrack B, Costa D. The development and preliminary evaluation of the cancer peer support scale in adolescents living with cancer. Psycho‐Oncology. 2018;27(12):2865-8.

21. Kessler RC, Andrews G, Colpe LJ, Hiripi E, Mroczek DK, Normand SL, et al. Short screening scales to monitor population prevalences and trends in non-specific psychological distress. Psychol Med. 2002;32(6):959-76.

22. Mitchell AJ, Baker-Glenn EA, Granger L, Symonds P. Can the Distress Thermometer be improved by additional mood domains? Part I. Initial validation of the Emotion Thermometers tool. Psychooncology. 2010;19(2):125-33.

23. Carver CS. You want to measure coping but your protocol's too long: consider the brief COPE. Int J Behav Med. 1997;4(1):92-100.

24. Munder T, Wilmers F, Leonhart R, Linster HW, Barth J. Working Alliance Inventory-Short Revised (WAI-SR): psychometric properties in outpatients and inpatients. Clin Psychol Psychother. 2010;17(3):231-9.

25. Sansom‐Daly UM, Wakefield CE, McGill BC, Patterson P. Ethical and clinical challenges delivering group‐based cognitive‐behavioural therapy to adolescents and young adults with cancer using videoconferencing technology. Australian Psychologist. 2015;50(4):271-8.

26. Sansom-Daly UM, Wakefield CE, McGill BC, Wilson HL, Patterson P. Consensus among international ethical guidelines for the provision of videoconferencing-based mental health treatments. JMIR mental health. 2016;3(2):e17.

27. Schafer JL, Graham JW. Missing data: our view of the state of the art. Psychol Methods. 2002;7(2):147-77.