1. **What is the research study about?**

You are invited to take part in this research study. The purpose of this study is to evaluate the clinical effectiveness of an online psychological intervention for parents of children, adolescents and young adult (AYA) cancer survivors, when delivered in community settings. We would ultimately like to use this information to improve this service for parents of adolescent and young adult cancer survivors. You have been invited to participate in this study because you are a parent of a young cancer survivor (aged up to 25 years), who has just finished their cancer treatment.

1. **Who is conducting this research?**

This research is being conducted by the research team at the Discipline of Paediatrics, Faculty of Medicine, UNSW, in conjunction with the Behavioural Sciences Unit, Kids Cancer Centre, Sydney Children’s Hospital, and in partnership with [insert name of community organisation]. This study is carried out by the following researchers:

Principal Investigator: Dr Lauren Kelada

Address: Level 1, Biological Sciences Building, UNSW

Telephone no.: +61 (2) 9382 3116

Fax no.: +61 (2) 9382 1789

Co-Investigator: Prof Claire Wakefield

Address: Kids Cancer Centre (KCC), Level 1, Sydney Children’s Hospital

Telephone no.: +61 (2) 9382 3113

Fax no.: +61 (2) 9382 1789

Co-Investigator: Dr Ursula Sansom-Daly

Address: Kids Cancer Centre (KCC), Level 1, Sydney Children’s Hospital

Telephone no.: +61 (2) 9382-3114

Fax no.: +61 (2) 9382 1789

Co-Investigator: Dr Kate Hetherington

Address: Level 1, Biological Sciences Building, UNSW

Telephone no.: +61 (2) 9382 3114

Fax no.: +61 (2) 9382 1789

Co-Investigator: Ms Brittany McGill

Address: Level 1, Biological Sciences Building, UNSW

Telephone no.: +61 (2) 9385 9870

Fax no.: +61 (2) 9382 1789

This research is being funded by a Cancer Council NSW Program Grant PG16-02 with the support of the Estate of Late Harry McPaul, awarded to Co-Investigator Prof Claire Wakefield.

1. **Inclusion/Exclusion Criteria**

Before you decide to participate in this research study, we need to ensure that it is ok for you to take part. The research study is looking recruit people who meet the following criteria:

* They are parents of children and AYAs aged under 25 who have completed cancer treatment with curative intent
* They can read English
* They are able to provide the name and contact details of a trusted health professional, such as their local general practitioner
* They have access to a computer/laptop/tablet with a webcam and microphone
* They can access 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 to be able to participate in the intervention;

Participants who meet the following criteria will be **excluded** from the study:

* They are the parent of a child who is in palliative care
* They are experiencing severe depression and/or suicidal intent
* They report that they are currently undergoing treatment for Schizophrenia, or are currently experiencing a psychotic episode
* They report substance abuse

If it is the case that you are not eligible to participate in this study, but would still like to receive support, we strongly encourage you to contact a local general practitioner (or other healthcare professional) Otherwise, you can get into contact with [community organisation][Include phone/web counselling line details], where the counselling team will be able to get you into contact with further support services.

1. **Do I have to take part in this research study?**

Participation in any research study is voluntary. If you do not want to take part, you do not have to. If you decide you want to take part in the research study, you will be asked to:

* Read the information carefully (ask questions if necessary);
* If you would like to participate, complete the online consent form, and;
* Save a copy of this information statement for your records.

1. **What does participation in this research require, and are there any risks involved?**

If you decide to take part in the research study, we will ask you to:

* Complete a brief telephone intake call with a member of the counselling team at [INSERT COMMUNITY ORG] to confirm your eligibility, obtain your consumer details, assess your risk, and to obtain the details of your trusted healthcare professional or support- person.
  + Your eligibility to participate in the program will be determined based on your responses to some questions about your mental wellbeing and your child’s history of cancer. If you are not eligible to participate in Cascade, we will be able to recommend other options for support provided by [COMMUNITY ORGANISATION], or other services.
  + The details of your trusted healthcare professional or support person will only be used in the case where the research team at [COMMUNITY ORGANISATION] is sufficiently concerned about your wellbeing. If the research team does believe that your wellbeing becomes endangered during the course of the study, we will use these details to contact your healthcare professional or support person as a means of safeguarding your wellbeing We will not use this contact in any other way, as a safeguard for your confidentiality.
* Complete a ~20 minute one-on-one online introduction session with the group facilitator in order to better understand the software program, allow the facilitator to build rapport, and provide an opportunity for you to set personalised goals for the program.
* Participate in 4x weekly 90 minute sessions delivered online and facilitated by an eligible staff member based on the community organisation. The online sessions will be delivered using a video conferencing software on the Internet (e.g., WebEx, by Cisco, Skype), allowing participants to see one another while communicating. Each 90 minute sessions includes both psychological skills and cancer related content and applying CBT techniques to the key domains of concern.
* Complete a ~20 minute one-on-one booster session with your group facilitator to review and consolidate skills learnt across the program, and discuss how to apply these skills to any new challenges that may have arisen during the course of the program.
* Complete two questionnaires; once at the start of the study, and again after the one-on-one booster session at the end of the study. The questionnaires will ask you about your emotions, and your responses to the cancer experience. Each questionnaire should take approximately 15 minutes to complete.

In exchange for your participation in this study, after you complete the second questionnaire, we will provide you with a $50 AUD gift voucher of your choice via post or email.

Although we hope that participating in Cascade will help you gain specific coping skills to manage symptoms of distress, it is possible that during the study your distress levels increase in the short term. If this happens, your group facilitator will privately telephone you to discuss your concerns. They will discuss steps to ensure your safety such as reminding you of the contact details for Lifeline (13 11 14) and other emergency services. These numbers are always available for you to call if you are very distressed. More services can be found listed below. If you experience discomfort or feelings of distress while participating in the research and you require support, you can stop participating at any time. Lastly, you can talk to your local GP or other health care professional that you trust, like your hospital social worker.

**Beyond Blue (AUS)** offers information on mental health including symptom checklists, a directory of mental health professionals in Australia and online communities.

<http://www.beyondblue.org.au>

T: 1300 22 46 36

**The Black Dog Institute** provides information on depression and Bipolar Disorder – specifically looking at causes, treatments, symptoms, getting help and current research findings.

[www.blackdoginstitute.org.au](http://www.blackdoginstitute.org.au)

**Lifeline** provides access to crisis support, suicide prevention and mental health support services. [www.lifeline.org.au](http://www.lifeline.org.au)

T: 13 11 14

**SANE Australia** has mental health-related information, links and online help for people affected by mental illness, their families and friends.

[www.sane.org](http://www.sane.org)

If at any stage during the study, you become distressed or require additional support from someone not involved in the research please call:

**Contact for feelings of distress [FILL IN DEPENDING ON COMMUNITY ORG]**

|  |  |
| --- | --- |
| **Name/Organisation** | [INSERT name/organisation] |
| **Position** | [INSERT position title] |
| **Telephone** | [INSERT work telephone number] |
| **Email** | [INSERT work email address] |

1. **What will happen to information about me?**

Submission of the online questionnaire is an indication of your consent. By clicking the ‘I agree to participate’ button you are providing your permission for the research team to collect and use information about you for the research study. You are free to withdraw from the research at any time. If you withdraw from the research, or are otherwise excluded from the study, we will destroy any information that has already been collected.

Any information that we collect from you will be stored online in a secure OneDrive folder, and on secure UNSW Sydney servers. Only personnel directly involved with the Cascade research project will have access to this information.

The research team will store the data collected from you for this research project for a minimum of 15 years after the publication of the research results. The information about you will be stored in a re-identifiable format where any identifiers such as your name, address, date of birth, and uncommon medical diagnoses will be replaced with a unique code.

You will be asked to provide your consent for the research team to share or use the information collected from you in future research that:

* Will be specific to the aims of this research;
* Will be an extension of, or closely related to, the original project; or is in the same general area of research.

Your information will only be shared in a format that will not identify you.

1. **How and when will I find out what the results of the research study are?**

The results and findings from this study will be published in relevant academic journals and presented at academic conferences, in order for other health professionals and researchers to learn about the findings. Additionally, the progress of this study will be reported in a quarterly newsletter that will be distributed to key stakeholders in the Cascade research project All Information will be published in a way that will not identify you.

If you would like to receive a copy of the results you can let the research team know by inserting your email or mailing address in the consent form and checking the appropriate box below. We will only use these details to send you the results of the research.

1. **What if I want to withdraw from the research study?**

If you do consent to participate, you may withdraw at any time. You can do so by completing the ‘Withdrawal of Consent Form’ – the link to which is provided in the email you received. Alternatively, you can contact the research team by phone or email and tell them you no longer want to participate. If you decide to leave the research study, the researchers will destroy any information that has already been collected that has yet to be disseminated, and no additional information will be collected from you. Your decision not to participate or to withdraw from the study, will not affect your relationship with UNSW Sydney, Cancer Council NSW, or [INSERT OTHER COMMUNITY ORGANISATIONS].

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a compliant about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the [**UNSW Privacy Management Plan**](https://www.legal.unsw.edu.au/compliance/privacyhome.html).

**What if I have a complaint or any concerns about the research study?**

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

**Complaints Contact**

|  |  |
| --- | --- |
| **Position** | Human Research Ethics Coordinator |
| **Telephone** | + 61 2 9385 6222 |
| **Email** | [humanethics@unsw.edu.au](mailto:humanethics@unsw.edu.au) |
| **HC Reference Number** | HC190880 |

1. **What should I do if I have further questions about my involvement in the research study?**

The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:

**Research Team Contact**

|  |  |
| --- | --- |
| **Name** | Gadiel Michael Dumlao |
| **Position** | Research Associate |
| **Telephone** | +61 (2) 9382 3120 |
| **Email** | g.dumlao@unsw.edu.au |

**Chief Investigator**

|  |  |
| --- | --- |
| **Name** | Lauren Kelada |
| **Position** | Post-Doctoral Fellow |
| **Telephone** | +61 (2) 9382 3116 |
| **Email** | l.kelada@unsw.edu.au |

**Consent Form – Participant providing own consent**

**Declaration by the participant**

By filling in and completing the form below:

* I understand I am being asked to provide consent to participate in this research study;
* I have read the Participant Information Sheet, or it has been provided to me in a language that I understand;
* I provide my consent for the information collected about me to be used as described in section 7 of this document.
* I understand that if necessary, I can ask questions and the research team will respond to my questions.
* I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
* A copy of the participant information statement and consent form was provided to me via email.
* I understand that the results of the research will be made available on the [insert school/faculty/organisation] website.
* I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only.
* I am providing my contact details to allow the research team to send me reimbursement.
* I provide my consent for the information collected about me to made available to other researchers as described at section 7 of this document.
* I provide my consent for my name and contact details to be retained in a register so I can be contacted about other research projects in the future.
* I understand that my nominated trusted healthcare professional/support person’s contact details may be used to contact them in the case where the Cascade research team has sufficient concerns about my wellbeing.

**Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |
| --- |
| **I agree, start questionnaire** |

**Form for Withdrawal of Participation**

I wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales, Cancer Council NSW, or [INSERT OTHER COMMUNITY ORGS].

* I am withdrawing my consent and I would like any identifiable information collected about me which I have provided for the purpose of this research study withdrawn.
* I am withdrawing my consent and I understand that any information already published and/or not linked to my identity cannot be withdrawn from the research.

**Participant Name**

|  |  |
| --- | --- |
| Name of Participant  (please type) |  |
| Date |  |

|  |
| --- |
| **Submit withdrawal of consent** |