

Project Description

# Section 1: Overview

**1.1.**  Project Title: **A** **pilot feasibility trial of web-based mindfulness program for adolescent and young people with cancer**

**1.2.** Project Acronym or short title (if applicable):

**1.3.** Version Number:

**1.4** Does this project already have funding logged with the Grants Services team? School of Nursing and Midwifery Partnership Grant project number P00027828

Project ID: **65164** (**School of Nursing and Midwifery’s cost centre 20341.65164)**

# Section 2: Western Sydney University School or Institute approval

**2.1.** Which Institute/School/Centre will be administering this project? Western Sydney University and Canteen

**2.2.** If your Institute/School/Centre has a requirement that human research projects are reviewed or agreed to before an ethics application comes to the ethics committee, has this occurred?

 [ ]  Yes [x]  No [ ]  NA

# Section 3: Project Team Named in the HREA

# (Provide names only. Additional details should be included in HREA Q1.9)

**3.1.** Chief Investigator / Principal Supervisor: Dr. Sheeja Perumbil Pathrose

**3.2.** Chief Student (if applicable):N/A

**3.3.** Other Investigators/Supervisors: A/Prof Lucie Ramjan, Dr. Pandora Patterson, Prof Yenna Salamonson, Dr. Fiona McDonald, A/Prof Bronwyn Everett, Prof Jane Ussher and Gina Biegel

**3.4.** Other Students:

**3.5.** Role/s yet to be assigned: Research Assistant

**3.6:** Will students be added to this project in the future? If yes, what level of study will they be enrolled in, and what will their role/s be on the project? N/A

# Section 4: Background (Limit to 500 words for all of section 4. Overly long entries will be returned to the researcher for editing.)

**4.1.** Literature Review (include citation details):

 Every day, 2-3 adolescents and young adults aged 14–29 years are diagnosed with cancer in Australia (1). There is a need for these young people to continually re-adjust to different phases of the cancer journey (diagnosis/treatment/post treatment), in addition to their age specific identity crisis (2, 3). Post-traumatic stress, anxiety, depression, and poor quality of life are common in young people with cancer and substantially contribute to the burden of disease (4, 5). Unmet psychosocial needs have a cumulative impact on disease burden and therefore cost-effective interventions targeting this population are warranted (6, 7). Preventive and promotive mental health interventions have been shown to improve psychosocial functioning and resilience in young people (7-9). However, studies reveal inadequacy of mental health services among this unique sub-population (10-12). Mindfulness-based programs (MBI) have demonstrated benefits for adults with chronic illness and are becoming increasingly popular among children and young people (7, 13, 14). Although the evidence base for the utility of MBI in adolescents with chronic illness is growing, there are limited mindfulness resources available to meet the needs of young people with cancer (7, 14).

**4.2.** Rationale/Justification (i.e. how the research will fill any gaps, contribute to the field of research or contribute to existing or improved practice):

Traditional approaches of in-person, multi week mindfulness programs have limited accessibility and low compliance, however web-based mindfulness programs are reported to be feasible and accessible, 15-and an effective alternative to face- to-face delivery (7). The research team identified the need to tailor the mindfulness program to address cancer specific needs (7, 15). Therefore, the team designed a web- based mindfulness program with feedback from young people, care givers, healthcare providers and parents through a user-centered approach (manuscript in preparation). The results from our previous pilot study identified that the current web-based platform limited accessibility being hosted on an offshore platform. This project aims to transfer the program onto a more user-friendly and accessible platform. Any program should be examined for usefulness, acceptability, and feasibility among young people with cancer. Therefore, a pilot feasibility trial of the improved web-based mindfulness program with this population needs to be undertaken. This study seeks to explore the acceptability, feasibility, and usefulness of a web-based program for young cancer patients. It is anticipated that providing the program online will increase its accessibility and appeal to young cancer patients who may find attending group-based activities at structured times and locations challenging due to the physical challenges associated with cancer, its treatment, and side-effects. Additionally, this pilot study will provide the necessary information to develop a larger scale, comprehensive randomised controlled trial.

**4.3.** Research questions/aims/objectives/hypothesis:

This proposed study has two main objectives; (1) To examine the feasibility of conducting larger scale, comprehensive randomised controlled trial among young people with cancer (aged 15-30 years) including recruitment, retention, and satisfaction rates; and (2) to identify the potential for change through measurement of psychosocial outcomes including mindfulness, stress, and quality of life.

**4.4.** Expected Outcomes:

 Age and cancer specific mindfulness intervention may assist young people manage challenges and therefore potentially prevent long term adverse effects on psychological wellbeing. The young people with cancer in large would potentially benefit with this intervention assisting with dealing with stress related to cancer and treatment.

# Section 5: Sites and Methodology (Limit to 250 words for all of section 5)

**5.1.** List the *specific* sites based on your answers to HREA Q1.4. (e.g. *which* Universities, workplaces, schools or public places?):

 Online

**5.2.** The HREA lists the following methodological approach(es). Refer HREA Q1.17.

**5.2.1** Delete the options which are not applicable

Intervention

Clinical Trial

Survey

**5.2.2** Explain why you selected these methodologies:

 It is a web-based mindfulness intervention study evaluating the feasibility of conducting larger scale RCT. Online recruitment and delivery of intervention is chosen based on the evidence to reach to young people with cancer.

# Section 6: Active Participant Details (YOU MUST copy questions 6.2. to 6.14 as a table for every participant group. Delete this Section if you are only collecting/using pre-existing data.

**6.1.** How many participant groups will be in this project?Examples of participant groups include teachers, students and parents. (You will need 1 table for each group.)

|  |  |
| --- | --- |
| **6.2 Participation Group Number (eg 1, 2 etc)** | 20 |
| **6.3 Group name** | Young people (15-30 years) diagnosed with cancer |
| **6.4 Characteristics of the group that are relevant to the aims of the project** | Young people between the ages of 15-30 years who have or have had a diagnosis of cancer will take part in this study. The age range proposed for this study falls between the range proposed by the National Cancer Institute’s progress review group (Australian Institute of Health and welfare, 2011).Young people diagnosed with cancer have been found to have higher levels of emotional distress compared to their peers. Web-based mindfulness-based programs has been found to be a convenient, inexpensive, effective program to cope with stress among children and adults, however adolescents and young people with cancer have not been adequately studied. |
| **6.5 Inclusion criteria** | Young people between the ages of 15-30 years who have or have had a diagnosis of cancer will be included in the study.  |
| **6.6 Exclusion criteria** |  |
| **6.7 Expected number and age of participants** | 20 young people between the ages of 15-30 years  |
| **6.8 Sample size and statistical power issues** | As the primary aim of this pilot feasibility trial is to examine feasibility and refine aspects of the research approach; a formal sample size calculation is not warranted. 20 young people will be randomized for the medium effect size of 0.5 (21) to either a study group or a waitlist control group using a computer-generated randomization procedure. |
| **6.9 Describe what these participants will be asked to do** | Prospective participants will gain access to the survey which will include the participant information sheet and first set of baseline measures. Completion and submission of the questionnaires will be deemed as implied consent to participate in the research. On completion, participants in the study group will be given access to the web-based mindfulness program by an email and participants in a waitlist control group will receive access on completion of the post- survey (after 6 weeks). A weekly reminder through Qualtrics will be sent to the to engage in the program. After the 6 weeks both groups will complete the post-test questionnaires of the same quantitative measures and in addition study group receives a post program survey with open-ended questions to assess the feasibility of the mindfulness program.  |
| **6.10 Follow up plans** |  |
| **6.11 Recruitment**How will you identify and recruit participants? Include whether screening takes place before or after consent; who will initially approach the participants; how participants will receive the recruitment documentation; how much time a participant will have to consider participation.**Will participants be offered any form of reimbursement?**This can be written in conjunction with question 2.1.1 of the HREA. | Study will adopt following recruitment options.* Targeted emails and SMS to young people registered with Canteen
* Distribution of flyers and conveying the project during face-to-face meetings/ camps conducted by Canteen
* A web page in canteen website with pop up option introducing the project with link to the Qualtrics survey.
* A dedicated Twitter feed (Twitter, Inc., San Francisco, USA) targeting young people: short tweets will have the link to the Qualtrics survey. Will encourage people to retweet the messages to their followers.
* A dedicated Facebook group page (Facebook, Inc., California, USA) will be created with same content and will be linked to the Twitter feed
* Snowballing: Participants will be encouraged to share the study link to others

No screening will take place and recruitment will be open to all young people aged 15-30 years diagnosed with cancer. The prospective participants will be invited by an email or will make contact for further information about the study which will be provided in the form of a Participant Information Sheet (PIS). There is no face-to-face interaction in this study as the survey of measures and program is fully online. Participants will take approximately 15 minutes to complete the baseline survey and the program would require at least one hour per week for 6 weeks. Post program response may take 15-20 minutes to complete. Participants will receive a gift card worth $50 for their time to complete the online surveys and in reimbursement for internet usage. |
| **6.12 Consent type**If you are seeking a waiver of consent for the use of pre-existing data, you must complete Section 11 of this form.  | [ ]  Written [ ]  Verbal [x]  Implied [ ]  Waiver [ ]  Opt-out [ ]  Assent  |
| **6.13 Summary of consent process** The summary can be adapted from Question 2.2.1 of the HREA. | The prospective participants will attend to the Qualtrics survey advertised in social media or through targeted emails. Survey will contain Participant Information Sheet (PIS). Completion and submission of the survey will be deemed as implied consent to participate in the research.  |
| **6.14 Summary of project risks**(do not respond with N/A or ‘none’)The summary can be a condensed version of information included in question 2.3.1 of the HREA. This section should relate to risks to this group of participants. | We anticipate that participation in this study should not cause undue distress. However, a list of free counselling services will be provided in the PIS, should completion of any of the study questionnaires cause distress.  |

# Section 8: Data

**8.1.** What is the scope of consent you will seek for this project? – relates to HREA 2.2.2.1

[ ]  **Specific consent** should be selected when consent is restricted to the specific project under consideration.

 If seeking specific consent, what is the ethically justifiable reason for this approach? (see section 3.1.50 of the National Statement on Ethical Conduct in Human Research):

[x]  **Extended consent** should be selected when there is intention to use data or tissue in future research projects (This refers to extended, closely related, ongoing projects or projects in the same general area of research). This also includes permission to enter original data or tissue into a data/tissue bank.

[ ]  **Unspecified consent** should be selected when there will be a need to use data or tissue in any future research. This also includes permission to enter original data or tissue into a data/tissue bank and needs to be clearly outlined to participants.

**8.2.** For prospective data collection, what information are you going to collect/gather?

* ***Demographic variables*** include time invariant (age, date of birth, gender, age at diagnosis) and time-variant (employment/school status, relationship/marital status,) information.
* ***Feasibility outcomes measures:***
	+ Assessing recruitment feasibility: Recruitment feasibility will be examined through detailed tracking of recruitment processes, including number of targeted emails sent, number of views, retweets and shares.
	+ Assessing retention and participation: Retention rate will be estimated by number of participants completing post-program measures. Participation data will be collected from traffic source analysis performed using Google Analytics (http://www.google.com/analytics), an integral feature of Google.
	+ Assessing participant satisfaction: This will include a satisfaction survey consisting of five items, including ease of navigation, meaningfulness, usefulness in improving general well-being, ability to gain mindful awareness, and whether the web-based platform is challenging with a 4-point Likert-scale response ranging from agree completely to disagree with an option for open-ended response text.
* ***Self-reported psychosocial outcomes***
	+ Mindful Attention Awareness Scales (MAAS): MAAS adult version will be used for participants between the ages of 18-30 years which has 15 items and adolescent version with 14 items will be used for participants between the ages of 15-17 years to explore self-report measure of trait mindfulness. Tool demonstrates good Internal reliability of (α = .82–.84 for MAAS-Adolescent version and good internal reliability (α = .86) for adult version.
	+ Quality of life. The single-item Ladder of Life, used to measure general life satisfaction. The scale asks participants to rate their QOL on a 10-point Likert scale (1 = worst imaginable–10 = perfect).
	+ Patient Health Questionnaire-2 (PHQ-2) will be used to assess the depression symptoms during the past 7 days. Each item on the measure is rated on a 4-point scale (0=Not at all; 1=several days; 2=More than half the days; and 3=nearly every day). The total score can range from 0 to 27, with higher scores indicating greater severity of depression.
	+ Kessler Psychological Distress Scale (K10). This scale measures psychological distress over the previous month and has been shown to be useful in capturing general distress and predictive distress in an Australian sample (n = 2967) of young people. The K10 has high internal consistency (a = 0.93).

**8.3.** How will you measure, manipulate and/or analyse the information that you collect/gather? When relevant include matching and sampling strategies, accounting for potential bias, confounding factors and missing information. Providing just the name of the software program is not enough information.

* Social media influence will be calculated using the ‘Klout Score’. Klout (Klout Inc, San Francisco, US) is a free online social media analytics tool used to rank users according to their online social influence by means of their proprietary Klout Score. This is a numerical value between 1 and 100, measured using access- and analysis related metrics from linked social media accounts in the preceding 90 days. These may include follower counts, retweets and the influence of the users who retweet your own messages.
* Frequencies will be used to examine the retention rate of post-test completion in study group and waitlist control group and google analytics data including time spent in each module and in activities.
* Paired t tests will be conducted to examine pre-post differences in the psychosocial outcomes of interest, and Cohen’s d effect sizes and confidence intervals will be calculated to examine the effect size of any changes in mindfulness, quality of life, stress and depressive symptoms.

**8.4**. Are any Data Linkages planned or anticipated? If yes, please describe. See [Guidance sheet](https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics/useful_resources) for more information.

Yes, pre and post-test questionnaires will need to be matched at two points so we will request DOB, Age, Postcode, Diagnosis Date/Age at the start of both sets of questionnaires.

Section 9: Results, Outcomes and Future Plans

**9.1.** Will the results or findings of the research, e.g. a summary of the findings, be returned to participants?

[x]  No, the result of the study will be published in the peer reviewed journal articles as aggregate data and a link to the published paper will be made available on the Canteen website.

**What are your plans for the following activities?**

**9.2.** Dissemination and publication of project outcomes (e.g. thesis, journals, Research Direct)

We will disseminate our data through peer-reviewed publications and presentations at professional conferences and meetings.

**9.3.** Other potential uses of the data at the end of the project: The findings from this project will form data for future larger studies should funding be available.

**9.4.** Sharing and/or future use of data and/or follow up research:N/A

**9.5.** Anticipated secondary use of data:N/A

**9.6.** Summarise the arrangements regarding intellectual property (individual, community, organisational, commercial) and copyright related to the data ownership and outputs of the research.

The copy right of the content and IP of the mindfulness program is owned by this project team. Coordinating PI will be responsible for maintaining the utmost confidentiality of the collected data. Data will be decoded for analysis and participants will be given pseudonym. Internet Protocol addresses will not be collected through Qualtrics. Email and mobile number are collected; however, this information will be removed before data analysis. Data will be analysed and only the aggregate data will be published or made available for future research.

Conflicts of Interest

Have you disclosed any financial or non-financial interests at Q1.10 in the HREA which relate to a conflict *other than* a HREA Committee Member i.e. research-related commercial activity, Western Sydney staff members?

[x]  No → continue to Attachment Checklist

[ ]  Yes → please ensure that any conflicts of interest are recorded on the University’s

 [Conflict of Interest Register](https://erm.protecht.com.au/wsu/worms/client/app/anonymousWidget.html?widget=AnonymousRegisterEntry&appId=1121&tablename=table_137120)

Attachment Checklist

The file names should reflect the contents of the document. Document formats should usually be Word or PDF.

**Mandatory Attachments**

[x]  Project Description on WSU template <https://www.westernsydney.edu.au/research/forms>

[ ]  HREA form <https://hrea.gov.au/>

☐ WSU Data Management Plan (mandatory as per the University’s Research Data Management Plan and Element 4 of the National Statement) <https://researchdirect.westernsydney.edu.au/>

☐ For projects which have chosen extended or unspecified as the scope of consent, the tailored sheet ‘Explanation of extended and unspecified consent’ must be attached to the Participant Information Sheet so that the participant is informed about what these terms mean and how their data may be used <https://www.westernsydney.edu.au/research/forms>

**Other possible attachments**

The attachments required will depend on the project. Below are the most usual attachments.

* Participant information sheet(s) - Western Sydney template at <https://www.westernsydney.edu.au/research/forms>
* Participant consent form(s) - Western Sydney template at <https://www.westernsydney.edu.au/research/forms>
* Recruitment text/script/flyer
* An age appropriate dialogue text for children’s assent
* Copies of the documents you will use to collect the data eg survey, interview questions
* An e-mail confirming you have completed the Confirmation of Candidature (MPhil, PhD) or Presentation of Proposal (MRes) process
* Permission to access participants or a site or an existing dataset

Clinical Trials – Continue to Section 10 below

Requesting a Waiver of Consent – Continue to Section 11 below

**This project description forms one part of your ethics application. It can either be uploaded to the online HREA system, or attached when you email your application to the ethics team.**

# Attachment A. Section 10 – Clinical Trial

**Delete this section if not applicable or you will be supplying a clinical trial protocol instead. If completing this section you also need to have completed Sections 1-10.**

**10.1.** Is this research a Clinical Trial? [x]  Yes [ ]  No

The WHO defines a clinical trial as “any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.”

<http://www.who.int/topics/clinical_trials/en>

 The National Statement says:

*3.1.7 For any research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes, researchers must register the project as a clinical trial on a publicly accessible register complying with international standards (see information on the International Clinical Trials Registry Platform (ICTRP) on the World Health Organisation website) before the recruitment of the first participant.*

**10.2.** Will you register this trial on a publicly available register? [x]  Yes [ ]  No

If no, why not?

**10.3.** Will the research require registration with the Therapeutic Goods Administration? [ ]  Yes [x]  No

For information on how to register a clinical trial under the Western Sydney TGA account contact the human ethics team [humanethics@westernsydney.edu.au](file:///%5C%5Cad.uws.edu.au%5Cdfshare%5CREDI%5CEthics%5CHuman%20Ethics%202019%5CPlanning%5CProject%20description%5Chumanethics%40westernsydney.edu.au)

**10.4.** Will the trial seek registration under the CTN/CTX scheme? [x]  Yes [ ]  No

**References**

1. Australian Institute of Health and welfare. Cancer in adolescents and young adults in Australia 2018 [Available from: https://www.aihw.gov.au/getmedia/ed22109b-ab23-4273-8d23-7949a8922ea2/aihw-can- 110.pdf.aspx?inline=true.

2. Kim B, Patterson P, White K. Developmental considerations of young people with cancer transitioning to adulthood. European journal of cancer care. 2018;27(6):e12836-n/a.

3. Kim B, White K, Patterson P. Understanding the experiences of adolescents and young adults with cancer: A meta-synthesis. European Journal of Oncology Nursing. 2016;24:39-53.

4. Husson O, Zebrack B, Block R, Embry L, Aguilar C, Hayes-Lattin B, et al. Posttraumatic growth and well-being among adolescents and young adults (AYAs) with cancer: a longitudinal study. Supportive Care In Cancer: Official Journal Of The Multinational Association Of Supportive Care In Cancer.

5. CanTeen Australia. The economic cost of cancer in adolescents and young adults. 2018.

6. Barnett M, McDonnell G, DeRosa A, Schuler T, Philip E, Peterson L, et al. Psychosocial outcomes and interventions among cancer survivors diagnosed during adolescence and young adulthood (AYA): a systematic review. Journal of cancer survivorship : research and practice. 2016;10(5):814-31.

7. Pathrose SP, Everett B, Patterson P, Ussher J, Salamonson Y, McDonald F, et al. Mindfulness- Based Programs for Young People With Cancer: An Integrative Literature Review. Cancer Nursing. 2020;Publish Ahead of Print.

8. Van der Gucht K, Takano K, Labarque V, Vandenabeele K, Nolf N, Kuylen S, et al. A Mindfulness- Based Program for Adolescents and Young Adults After Cancer Treatment: Effects on Quality of Life, Emotional Distress, and Cognitive Vulnerability. Journal of Adolescent & Young Adult Oncology. 2017;6(2):307-17.

9. Malboeuf-Hurtubise C, Achille M, Muise L, Beauregard-Lacroix R, Vadnais M, Lacourse É. A Mindfulness-Based Meditation Pilot Study: Lessons Learned on Acceptability and Feasibility in Adolescents with Cancer. Journal of Child and Family Studies. 2016;25(4):1168-77.

10. Zebrack BJ, Block R, Hayes-Lattin B, Embry L, Aguilar C, Meeske KA, et al. Psychosocial service use and unmet need among recently diagnosed adolescent and young adult cancer patients. Cancer. 2013;119(1):201-14.

11. Medlow S, Patterson P. Determining research priorities for adolescent and young adult cancer in Australia. European Journal of Cancer Care. 2015;24(4):590-9.

12. Phillips CR, Davis LL. Psychosocial Interventions for Adolescents and Young Adults with Cancer. Seminars in oncology nursing. 2015;31(3):242-50.

13. Victorson D, Murphy K, Benedict C, Horowitz B, Maletich C, Cordero E, et al. A randomized pilot study of mindfulness-based stress reduction in a young adult cancer sample: Feasibility, acceptability, and changes in patient reported outcomes. Psycho-oncology. 2020.

14. Eysenbach G, Warner E, Siembida E, Bhatlekar S, Donovan E, Martin SR, et al. A Mobile-Based Mindfulness and Social Support Program for Adolescents and Young Adults With Sarcoma: Development and Pilot Testing. JMIR Mhealth Uhealth. 2019;7(3).

15. Sheeja Perumbil Pathrose PP, Jane Ussher, Bronwyn Everett, Yenna Salamonson, Fiona McDonald, Gina

M. Biegel, Steven He, and Lucie Ramjan. Feasibility, Acceptability, and Psychosocial Outcomes of a Mindfulness-Based Interactive e-Book for Young People with Cancer. Journal of Adolescent and Young Adult Oncology. 2021;0(0)