AYA Can-Sleep an evidence-based approach to the management of sleep disturbances in young cancer survivors

Short title: Evaluation of the AYA ‘Can-Sleep’ Program

Peter MacCallum Cancer Centre ethics

Project No: 74976 Version 4

Contents

[Project Leads 3](#_Toc71188552)

[Project Team 3](#_Toc71188553)

[Funding Source 3](#_Toc71188554)

[Project Sponsor and Collaborating Partners 4](#_Toc71188555)

[Background 4](#_Toc71188556)

[Aims 5](#_Toc71188557)

[Project design 6](#_Toc71188558)

[Phase 1: Adaption of a Self-Management Resource for AYA Cancer Survivors 6](#_Toc71188559)

[Phase 2 Implementation & Evaluation of the AYA Can-Sleep program 7](#_Toc71188560)

[Study Design 7](#_Toc71188561)

[Participants 7](#_Toc71188562)

[Clinicians 8](#_Toc71188563)

[Participant Recruitment 8](#_Toc71188564)

[Participant Screening 9](#_Toc71188565)

[Implementation 10](#_Toc71188566)

[Evaluation 16](#_Toc71188567)

[AYA Cancer Survivors Experiences 17](#_Toc71188568)

[Clinician Experiences 18](#_Toc71188569)

[Impact Measure 18](#_Toc71188570)

[Assessment of processes and procedures in the clinical setting 18](#_Toc71188571)

[Data Analysis 20](#_Toc71188572)

[Ethical Issues 21](#_Toc71188573)

[Informed Consent 21](#_Toc71188574)

[Data Storage and Privacy Issues 21](#_Toc71188575)

[Confidentiality 21](#_Toc71188576)

[References 22](#_Toc71188577)

[Appendices 24](#_Toc71188578)

## Project Leads

|  |  |
| --- | --- |
| Dr Maria FtanouHead of Clinical PsychologyPsychosocial Oncology ProgramPeter MacCallum Cancer CentreEmail: [M](about:blank)aria.Ftanou@petermac.org | Kate ThompsonProgram ManagerAdolescent & Young Adult Cancer ServicePeter MacCallum Cancer CentreEmail: [Kate.Thompson@petermac.org](about:blank) |

## Project Team

|  |  |
| --- | --- |
| Emma VaughanProject ManagerPsychosocial Oncology ProgramPeter MacCallum Cancer Centre | Ilana BergerTeam LeaderONTrac at Peter MacPeter MacCallum Cancer Centre |
| A/Prof Jeremy GoldinSleep and Respiratory PhysicianSleep MedicineThe Royal Melbourne Hospital | Prof Michael JeffordMedical Oncologist/DirectorAustralian Cancer Survivorship CentrePeter MacCallum Cancer Centre |
| Dr Joshua WileySleep researcherInstitute of Cognitive and NeuroscienceMonash University | Dr Jo Phipps-NelsonGeneral ManagerHealth Services ResearchPeter MacCallum Cancer Centre |
| A/Prof Steve EllenPsychiatristPsychosocial Oncology ProgramPeter MacCallum Cancer Centre |  |

## Funding Source

###### This project is funded by the Victorian Department of Health.

## Project Sponsor and Collaborating Partners

###### Project Sponsor: Peter MacCallum Cancer Centre

###### Collaborating Partners: The Royal Melbourne Hospital & The Royal Women’s Hospital

## Background

Each year in Victoria over 300 Adolescents and Young Adults (AYA) 15-25 years are diagnosed with cancer. Advances in cancer treatment will now see between 73-82% of these young people surviving beyond five years such that an increasing number of AYAs are living longer with the physical and psychosocial sequelae of their cancer diagnosis and its treatment [1-3]. In cancer, a person is considered to be a survivor from the point of diagnosis until the end of life [4].

Sleep problems are a significant issue experienced by up to 60% of AYA cancer survivors [5]. This includes problems initiating sleep, remaining asleep, excessive daytime sleepiness, fragmented sleep and excessive napping. Sleep problems have been associated with emotion regulation difficulties, deficits in social skills and cognition, school and work difficulties as well as higher rates of depression, anxiety and posttraumatic stress disorder (PTSD). The gold-standard treatment for insomnia is Cognitive Behaviour Therapy (CBT), CBT for insomnia is a psychological intervention that aims to change the thoughts, behaviours and emotions that interfere with sleep. CBT has been found to not only improve duration and quality of sleep but also leads to reductions in depression, anxiety and fatigue [6]. There have been very few CBT protocols developed for AYA cancer survivors.

In a recent study by Zhou et al. (2020) a CBT program called SHUTi AYA was delivered via the internet to AYA cancer survivors [7]. It consisted of six sessions based on the fundamental strategies from CBT for insomnia, and was tailored to the AYA population. They found improvements in AYA’s insomnia, daytime sleepiness, fatigue, quality of life, and these improvements were maintained up to 2 months post follow up. For AYA cancer survivors in Victoria (and Australia) there are no such targeted programs aimed at identifying and addressing sleep difficulties.

The Victorian Cancer Survivorship Program (VCSPII) recently funded Peter MacCallum Cancer Centre to implement Can-Sleep*,* a stepped care program (see previously approved project 17\_83L) to address sleep difficulties in adult cancer survivors. This was the first Australian health service project of its kind. The program consisted of 3 steps; screening, self-management interventions and group CBT. It allowed for the early identification of sleep problems, increased access to evidence-based sleep treatment and resulted in significant reductions in sleep difficulties. The Can-Sleep program was found to be both acceptable to clinicians and survivors, and feasible to deliver. Can-Sleep is now standard of care at Peter MacCallum Cancer Centre.

At present, there is no systematic and routine screening of sleep difficulties and no established referral pathway for AYA cancer survivors. Sleep difficulties in AYA cancer survivors are identified in an ad hoc manner, identified late or are dismissed as a normal part of developmental age. With the support of relevant experts including AYA clinicians, psycho-oncology experts, sleep experts and most importantly young people, we will redesign our approach to the identification, intervention and management of sleep difficulties in AYA cancer survivors.

Our project team has partnered with the Victorian & Tasmanian Youth Cancer Action Board (YCAB) in the adaption of the Can-Sleep stepped care program to treat sleep difficulties in AYA cancer survivors. YCAB is a 12-member board of young people who have had a diagnosis of cancer between the ages of 15 and 25 years. They are broadly representative of the diversity of young people and have received treatment across the paediatric/adult, metro/regional, public/private healthcare sectors. YCAB aims to support young people to have a voice and play an active role in shaping the services young people access, informing policy and influencing research priorities relevant to them and have a strong track record in the co-design and development of resources for young people in the area.

## Aims

The overall aim of this project is to evaluate the implementation of the AYA Can-Sleep Program to identify and treat sleep difficulties in AYA cancer survivors. The specific objectives of this project are to:

1. Improve the identification of sleep difficulties in AYA cancer survivor population;
2. Assess the severity of sleep difficulties in the AYA cancer survivor population;
3. Develop a self-management resource for AYA cancer survivors with sleep difficulties;
4. Improve access for AYA cancer survivors to evidence-based sleep interventions;
5. Improve the knowledge of both tertiary and community clinicians in how to best manage sleep problems in AYA cancer survivors.

The project will specifically aim to answer the following questions:

1. Is screening for sleep difficulties feasible and acceptable to AYA survivors and clinicians?
2. Is the self-management resource acceptable, relevant and useful to AYA cancer survivors?
3. Are the individual CBT sessions acceptable and useful for AYA cancer survivors?
4. Is the AYA Can-Sleep Program a feasible and acceptable model of care to deliver in an Adolescent & Young Adult Cancer Service?

## Project design

This 18-month project uses implementation and health services evaluation methodology with a mixed-methods approach to evaluate an AYA Can-Sleep Program to identify and treat sleep difficulties in AYA cancer survivors. The current project involves 2 phases:

* **Phase 1**: Adaption of a self-management resource for AYA cancer survivors which is already under way.
* **Phase 2:** Implementation and evaluation of the AYA Can-Sleep Program

## Phase 1: Adaption of a Self-Management Resource for AYA Cancer Survivors

The Project team have partnered with YCAB to adapt the Can-Sleep booklet titled: “Can-Sleep Making night-time sleep problems go away” for the AYA population. Developed initially for the adult population, by adults, the purpose of adapting the resource is to ensure it is more engaging, satisfying, and acceptable to young people. An initial face to face workshop with YCAB conducted on the 24th April 2021. Participants were provided with pre-reading materials including a copy of the current Can-Sleep resource and questions/reflections to prepare for workshop discussions. The workshop commenced with revisiting the rationale behind the development of targeted sleep intervention for AYA cancer survivors. It then explored participant’s experiences with sleep related challenges both during and following treatment completion. This was followed by a brainstorming exercise to gather suggestions regarding content, style and design of the booklet.

The Workshop was held for approximately 2hrs in duration and in the Youth Cancer Centre, a comfortable and age appropriate environment at Peter MacCallum Cancer Centre. The Workshop was facilitated by the ONTrac at Peter Mac Victorian Adolescent & Young Adult Youth Participation Coordinator who holds extensive experience in the co-design of AYA resources with young people and the AYA Can-Sleep Project Manager. The workshop was audio recorded to enable the accurate detailing of discussions with outcomes summarised into a document, shared with participants and will be continue to be used as a reference point throughout the design process.

Safety and wellbeing was attended to by including regular breaks, availability of snacks, and sensitivity to participant’s emotional health and discussion/disclosures of sensitive information that may cause distress. A senior social worker was available onsite for the duration of the workshop.

A pilot of the resource is now in the process of being developed and iterative engagement with YCAB will help to refine the document as it is being developed. A second workshop will be held once the pilot resource has been fully developed to obtain formal feedback about content. This workshop will also discuss design options for the resource

## Phase 2 Implementation & Evaluation of the AYA Can-Sleep program

### Study Design

Phase 2 of the study design uses implementation and health services evaluation methodology with a mixed-methods approach to evaluate the AYA Can-Sleep Program.

### Participants

Eighty AYA cancer survivors will be screened across a fifteen week period commencing July 2021 from Peter MacCallum Cancer Centre and Royal Women’s Hospital outpatient clinics.

#### Inclusion criteria

* Aged 16 - 25 years
* A histologically confirmed diagnosis of cancer
* Able to read and write English
* Able to give informed consent

As the study is low risk, AYA cancer survivors 16 years and above who meet the inclusion criteria will be assumed to have sufficient maturity to understand the relevant information and to give their own consent to participate in the study.

It is anticipated that the study population will be heterogeneous in nature and we will be unable to draw conclusions about the experience of specific subgroups. This project is exploratory in nature and will provide an initial evaluation of the feasibility of AYA Can-Sleep program.

### Clinicians

All clinical staff working with AYA cancer survivors in the Adolescent & Young Adult Cancer Service, multidisciplinary tumour streams, and Royal Women’s Hospital will be invited to participate in the evaluation component of the project. These clinical staff may include oncologists (adult & paediatric), nurses, psychosocial oncology staff and allied health staff.

### Participant Recruitment

Weekly screening through EPIC of all AYA attending outpatient appointments at Peter Mac and Royal Women’s Hospital will be undertaken by a member of the project team. AYA cancer survivors who meet the eligibility criteria will be approached by a member of the AYA team or project team and be verbally informed of the project and invited to take part in the AYA Can-Sleep Program and the evaluation.

All AYA cancer survivors who are interested in the project will be provided with the participant information and consent form (PICF) (Appendix A) and an opportunity to ask any questions related to the study. Participation is voluntary and AYA cancer survivors will be assured that a decision to decline participation will not impact on their care or treatment..

For AYA cancer survivors who wish to consider their involvement, or complete their forms online, an online link will be sent through the secure REDCap survey where they will first complete an online copy of the PICF, followed by the screening measures and Evaluation Survey A (Appendix B). AYA cancer survivors who do not return the surveys within 2 weeks of receiving them will be followed up with one phone call/voicemail and one email reminder. Those who still do not return the forms will be considered to have declined involvement and have no further contact from the project team.

A record of AYA cancer survivors who have been approached for the study will be recorded on the Project Specific Case Report Form (CRF-A: Eligibility and Consent Checklist) (Appendix C) and entered in to the secure REDCap database. AYA cancer survivors who decline to participate in the study will be asked if they consent to their reasons for declining, patient information (age, sex, diagnosis, treatment received), and site they were approached at being recorded on the CRF. This will allow for differences between consenters and decliners to be examined. This will also ensure that AYA cancer survivors are not approached more than once.

#### Withdrawal Criteria

AYA cancer survivors who do not continue with the AYA Can-Sleep follow-up intervention or will be asked if they consent to completing follow-up measures, evaluation, and for any of their existing data to be included in analyses. If consent is not given for the latter, their data will be erased from the database at the completion of the study and any electronic or paper records pertaining to their involvement will be destroyed except medical notes that have been committed to the electronic system.

A record of AYA cancer survivors who have withdrawn from the study will be recorded on the Project Specific Case Report Form (CRF-B: Patient data) (Appendix C) and maintained on the secure REDCap database until the completion of the study. This is to ensure that these AYA cancer survivors are not approached again by the project team. AYA cancer survivors will be unable to withdraw their data after the completion of the study as their data may have already been used in analyses.

If an AYA cancer survivor is withdrawn from the study intervention due to clinical decision making by the therapist involved, the rational for this will be recorded on the Project Specific CRF-B and maintained on the secure REDCap database.

### Participant Screening

#### Demographics

Demographic and clinical characteristics will be collected by the Project Manager from the AYA cancer survivor’s medical record after they have consented to the project. Data collected will include:

* Age
* Sex
* Diagnosis
* Treatment received

The data will be recorded on a designated Project Specific Case Report Form (CRF-B) and maintained on the secure REDCap database.

#### Screening Measures

A number of validated outcome measures will be used to screen AYA cancer survivors throughout AYA Can-Sleep Program.

1. **The Insomnia Severity Index (ISI**) [8]. The ISI is a 7-items self-report measure that assesses the severity of sleep difficulties. It assesses problems falling asleep, maintaining sleep and early morning awakening. It also assesses satisfaction with current sleep, noticeability of sleep problem to others, worry about sleep, and the interference of sleep problems with daily functioning. The items on the ISI are rated on a Likert scale and summed to obtain a total score, ranging from 0-28, higher scores represent greater insomnia difficulties. A cut off of ≥ 8 indicates sleep difficulties [8-10]. It has good internal consistency reliability (alpha = 0.83), test-retest reliability of 0.79 and has been validated in AYA cancer survivors [9].
2. **The Epworth Sleepiness Scale (ESS) [11]**. The ESS asks participants to rate the probability of falling asleep on a scale of increasing probability from 0 to 3 for eight different situations that most people engage in during their daily lives. Scores of ≥11 will be interpreted as clinically significant, as scores from 11-24 represent increasing levels of excessive daytime sleepiness. The ESS has good internal consistency reliability (alpha = 0.89), and 2-week test-retest reliability of (0.82) in both the adult and AYA populations [12].
3. **STOP-BANG** [13]. STOP-BANG is an eight item self-report questionnaire that assesses the presence of risk factors for obstructive sleep apnoea (OSA). Items are dichotomous (yes/no) and total scores range from 0 to 8, with higher scores indicating higher risk of OSA. Scores of 5 to 8 are classified as high risk of moderate to severe OSA. STOP-BANG has demonstrated adequate sensitivity of up to 96% to detect OSA [14].
4. **Restless Leg Screening Scale (RLSS).** The RLSS is a purpose built self-report measure comprising of five dichotomous items (yes/no) which reflect the diagnostic criteria for Restless Leg Syndrome in DSM-V. Where all five items are rated as ‘yes’, the AYA cancer survivor is considered at risk of Restless Leg Syndrome.

#### Other Measures

**Daily Sleep Diary**. The Daily Sleep Diary asks questions about sleep the night before, including sleep timing, time taken to fall asleep, sleepiness at bedtime, awakenings during the night, and naps.

A copy of these measures are held as Appendix D*.*

### Implementation

The AYA Can-Sleep Program is comprised of:

1. Screening and referral for an underlying sleep problem;

2. Follow-up care involving any one or more of the following three intervention

* 1. Treatment at the Royal Melbourne Hospital Sleep Medicine Service
  2. Self-Management Intervention (CBT-SM)
  3. Individual CBT

These are explained in detail below and Figure 1 demonstrates how AYA cancer survivors will be referred to each part of the AYA Can-Sleep program.

#### Initial Screening and Referral

A member of the AYA team or project team will screen all participating AYA cancer survivors for insomnia using the ISI and ESS. Participants with scores of <8 on ISI and score of <11 ESS will receive no follow up or treatment. Participants who are identified as having sleep difficulties (scores of ISI ≥ 8 and/or ESS ≥ 11) will be asked to complete questionnaires for obstructive sleep apnoea and restless legs syndrome using the STOP-BANG and the RLSS. Participants who score ≤4 on the STOP-BANG and <5 on the RLSS will be referred into the 5 week Self-Management Intervention (CBT-SM) as outlined below.

Participants who score high on the STOP-BANG (≥ 5) or the RLSS (i.e. yes to all questions) will be referred to the Department of Respiratory and Sleep Medicine (DRSM) at the Royal Melbourne, facilitated by members of the AYA team/project team. The project team will be notified of the clinical outcome post follow up care with the DRSM. A consultation with the participant, DRSM and the project team will then take place and if clinically appropriate, the AYA will be rescreened and referred into the 5 week Self-Management Intervention (CBT-SM) or Individual CBT if sleep difficulties are ongoing (scores of ISI ≥ 8 and/or ESS ≥ 11).

#### Self-Management Intervention (CBT-SM)

Participants referred to the Self-Management Intervention (CBT-SM) will be provided with the AYA adapted CBT-SM booklet as described in Phase 1. A member of the AYA team or project team will provide CBT-SM booklet to the AYA cancer survivor, and provide instructions for the use of the resource.

The CBT-SM booklet will likely include:

* Practical advice on how to establish good sleep hygiene habits and use relaxation techniques to promote sleep.
* Strategies to manage common worries and cognitions that interfere with sleep.
* Strategies to manage common cancer treatment side effects that interfere with sleep including pain and unpleasant night time sensations including nausea, hot flushes, rash, and symptoms of peripheral neuropathy.

Approximately three weeks post receiving the CBT-SM booklet, members of the project team will make contact with AYA cancer survivors (via text, email or phone) to arrange a suitable time for a telephone call (Follow up 1). The aim of this call is to answer any questions the AYA cancer survivor might have and resolve any problems that may have arisen. For AYA cancer survivors who do not respond to the initial contact a reminder text message and email will be sent. As AYA cancer survivors may be busy with school, work and other commitments, the project team will be flexible in how they make contact for Follow up 1.

Two weeks after Follow up 1 is completed, AYA cancer survivors will be re-screened using the ISI and ESS (Follow up 2). Rescreening will be conducted by a member of the project team. For participants with scores of ISI ≥ 8 and/or ESS ≥ 11 following CBT-SM, it will be assumed that their sleep difficulties have improved and they will receive no further treatment. If participants have ongoing sleep difficulties (i.e. scores of ≥ 8 on the ISI and/or ≥ 11 on the ESS) they will be referred for individual CBT. If the participant is unable to attend individual CBT they will be referred back to community support services and/or their GP for follow-up.

As discussed above, the project team will be flexible in how they make contact with AYA cancer survivors for Follow up 2, using a schedule of phone, text message and email reminders. Participants who prefer not to complete these measures over the phone, will receive an email link to complete them online through the secure REDCap survey. Participants who do not return the measures within 2 weeks of receiving them will be called, texted and/or emailed up to three times (at 2 week intervals) to remind them to return the measures.

#### Individual CBT

Participants who continue to score ≥ 8 on the ISI and/or ≥ 11 on the ESS after completing the CBT-SM, will be invited to attend 4 structured individual CBT sessions. The individual CBT sessions will be approximately 50-60 minutes in duration, with a psychologist. The individual CBT sessions will include all the information provided in the CBT-SM resource but will also provide an opportunity to identify and remove barriers to change. The content of the individual CBT sessions has been modelled on CBT insomnia programs that have been efficacious in the adult cancer population [15] and the AYA cancer survivor population [16]. The session structure is outlined in Table 1 below:

**Table 1**

*Session Structure of Individual CBT*

|  |  |
| --- | --- |
| Session | Content |
| 1 | Conduct a thorough evaluation of sleep history.Further education around sleep hygiene.To introduce rationale for sleep restriction and stimulus control and address any potential barriers.Discuss cancer-related late effects, including medications, that impact sleep function.Instruct on completion of sleep diary. |
| 2 | Review of sleep diary.Instruct on calculation of sleep efficiency.Schedule sleep-wake schedule based on sleep diary.Introduce arousal and how this affects sleep.Discuss counter arousal methods.Discuss with family members (if relevant) the intervention rationale and sleep objectives. |
| 3 | Review of sleep diary.Discuss sleep expansion.Explore participant’s beliefs about sleep.Identify and address cognitive factors that impact adherence and sleep function.Troubleshoot adherence challenges. |
| 4 | Review progress and alter treatment as required.Discuss sleep-related cognitive arousal.Review of goals.Create a relapse prevention plan (if appropriate).Review of follow up options. |

The intervention will address symptoms that are specific to AYA cancer survivors. Sleep diaries will be completed throughout the course of individual therapy, so that sleep restriction recommendations can be tailored for each participant. In the week after the fourth session, participants will be re-screened using the ISI and ESS. Participants with ongoing sleep difficulties (score ≥ 8 on the ISI) will have a treatment planning discussion of further needs and treatment options which may include referrals to; the Department of Respiratory and Sleep Medicine, a psychiatrist, further individual therapy, peer supports or community services. Treatment plans and outcomes will be communicated with the participant’s GP and/or primary care team.

*Figure 1.* Implementation Procedures.



## 

## Evaluation

We are using the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework to evaluate the acceptability, feasibility and effectiveness of the AYA Can-Sleep Program from the perspective of both young people and clinicians. The RE-AIM framework consists of five dimensions (1). ‘Reach’ is the proportion of the target population that participated in the intervention. ‘Effectiveness’ is the impact of an intervention on individual outcomes. ‘Adoption’ is the number, percentage and representativeness of participating settings and providers. ‘Implementation’ is the extent the intervention was implemented as intended in the real world. The final dimension is ‘Maintenance’, which refers to the extent that a program is sustained over time (1).

The Participants Experiences Surveys and the Staff Engagement Survey, as well as data collected on our Project Specific CRF’s will be analysed using the RE-AIM framework. We will seek to understand areas of success, identify areas for improvement and contribute to the evidence-base regarding screening and treating sleep difficulties in AYA cancer survivors. The evaluation will aim to answer the following questions:

1. Is screening for sleep difficulties feasible and acceptable to AYA survivors and clinicians?
2. Is the self-management resource acceptable, relevant and useful to AYA cancer survivors?
3. Are the individual CBT sessions acceptable and useful for AYA cancer survivors?
4. Is the AYA Can-Sleep Program a feasible and acceptable model of care to deliver in an Adolescent & Young Adult Cancer Service?

### AYA Cancer Survivors Experiences

AYA cancer survivor reported appropriateness and acceptability will be collected by two surveys designated Evaluation Survey A and Evaluation Survey B.

#### Evaluation Survey A – (Participants Experiences Survey – Screening Questionnaires)

Every AYA cancer survivor screened for sleep difficulties will be asked to complete Evaluation Survey A (Appendix B). The survey has been purpose built to assess how well the reasons and procedure for completing the AYA Can-Sleep Program screening questionnaires were explained, how easy the screening questionnaires were to understand and complete, and whether the completion time was acceptable or too long.

AYA cancer survivors who do not receive a referral to the AYA Can-Sleep intervention or who decline the interventions will still be asked to complete Evaluation Survey A. This information will help the team assess whether there are any differences between AYA cancer survivors who participate in the intervention and those that do not (i.e., sampling biases) that may impact the generalisability of our results and the feasibility of this model of care. The survey takes no more than 5 minutes to complete and each AYA cancer survivor will complete this survey only once.

#### Evaluation Survey B - (Participant Experiences Survey – Post Follow-Up Care)

AYA Cancer Survivors will be asked to complete Evaluation Survey B (Appendix E) within 2 weeks of completing the follow-up care they receive: after completing the Self-Management Intervention, and after the series of individual CBT sessions (x 4). AYA cancer survivors will be sent an online link through the secure REDCap survey where they can complete the survey.

The survey has been designed to determine what barriers have prevented seeking help for sleep problems in the past, what the most useful/helpful and least useful/helpful aspects of their follow-up care were, and whether AYA cancer survivors experienced any subjective changes in their sleep following the intervention they received. Survey completion time is approximately 10 minutes. Participants who do not return the surveys within 2 weeks of receiving them will be followed up using a schedule of text message, phone, and email reminders to minimise missing data.

### Clinician Experiences

Towards the end of the evaluation period, clinicians in the Adolescent & Young Adult Cancer Service,multidisciplinary tumour streams, and Royal Women’s Hospital who have participated in the AYA Can-Sleep Program will be sent a link to the Staff Engagement Survey via email (please see Appendix F). The aim of the survey is to elicit information about positive and negative experiences with the AYA Can-Sleep Program, to identify the feasibility and ability to integrate the program in to routine practice and any improvements that may need to be made.Survey completion time is approximately 20 minutes.

### Impact Measure

The impact of the AYA Can-Sleep Program will be evaluated on the basis of the number of AYA cancer survivors who report clinically meaningful changes (improvements) in sleep quality as measured by changes in their ISI collected at screening, post the Self-Management Intervention, and post individual CBT. Based on previous studies in cancer [17-19] and clinical judgement, we defined clinically meaningful changes for the ISI at 3 or more, a change of 3 represents approximately half a standard deviation on the ISI, or about half a “category” shift based on common cut offs.

During individual CBT, participants will also be asked to complete a sleep diary in the two weeks prior to their first session and throughout the duration of the individual CBT program as part of the model of care. Data from sleep diaries will also be used for the program evaluation to measure program compliance and efficacy.

### Assessment of processes and procedures in the clinical setting

A number of measures outlined in the table below will be used to evaluate appropriateness and acceptability of the AYA Can-Sleep Program. A Project Specific Case Report Form (CRF-B) will be used by the project team to assess follow-up. The project team, using CRF-B will collect the following:

**Table 2**

*Data collection methods for assessing the appropriateness and acceptability of the AYA Can-Sleep Program*

|  |  |  |  |
| --- | --- | --- | --- |
| Data | Variables | Collection method | Collection place / time |
| Screening | # AYA’s initially screened | Project specific CRF-B | Collected in clinics during screening. |
|  | # AYA’s rescreened after receiving follow-up care | Project specific CRF-B | Collected during rescreening. |
| Referral rates/uptake | # AYA’s referred to each component of follow-up care (Sleep Unit/CBT-SM/Individual CBT) | Project specific CRF-B | Collected during the referral process. |
|  | # AYA’s that accepted referrals for follow-up care | Project specific CRF-B | Collected from the referral/intervention processes. |
| AYA’s adherence to therapy | # Weeks completed CBT-SM# Sessions of Individual CBT | Project specific CRF-B | Collected during Self-Management Intervention follow up phone calls or Individual CBT. |
| Evaluation participation | # AYA’s who completed evaluation# Clinicians who completed surveys | Project specific CRF-BClinician survey data extracted from REDCap | Collected at screening and at subsequent end of follow-up care. |

#### AYA Team and Project Team Time

Time and costing data for implementing new program and delivery of intervention will be based on the number of minutes or hours spent per task costed according to role of the staff member (AYA clinician or project team member). An outline of the variables collected is detailed in Table 3 below, and this data will be collected on the Project Specific CRF (CRF-B).

Table 1

*Time and Costing of AYA Can-Sleep Project*

| Activity | Variables | Data collected |
| --- | --- | --- |
| Screening | AYA Clinician/Project team member time including explaining screening tools to AYA’s, scoring tools, triaging AYA’s. | Role (e.g. psychologist, AYA clinician)Time in minutes |
| Referrals | AYA Clinician/Project team member time:Arrangement / writing of referral to RMH Sleep StudyArrangement / writing of referral to CBT-SMArrangement of referral to individual CBT | Role (e.g. AYA clinician, psychologist, administrator)Time taken on task |
| Intervention delivery: Self-Management Intervention | AYA Clinician/Project team member time:Delivery of one-on-one introductory session (AYA’s receipt of resource)Follow-up at three weeksRescreeningFollow-up care discussion at end of intervention, including re-screening. | Role (e.g. AYA clinician, psychologist, administrator)Time in minutes |
| Intervention delivery: Individual CBT sessions | Project team member time:Time for individual session deliveryTime spent outside of sessionsFollow-up at end of intervention, including rescreening time | Role (e.g. psychologist, administrator)Time in minutes |

## Data Analysis

Data analysis of the quantitative data that are collected through the participant and clinician surveys, and Project Specific CRFs will be descriptive (means/SD or frequency/percentage as appropriate). The impact of the program will be assessed by counting the number of participants who show improvement in the screening measures from pre- to post-intervention as determined by pre-specified clinical cut-offs for each measure. Quantitative data will be analysed using SPSS (version 24).

Qualitative responses will be analysed using thematic analysis with a focus on understanding participants’ experiences within and the different stepped interventions. To analyse free text content analysis will be undertaken. Data from free text responses will be coded to encapsulate the key idea of the response. Once coded the data will be sorted to examine the frequency of responses and the content of the responses.

## Ethical Issues

This project will be conducted according to the NHMRC National Statement on Ethical Conduct in Human Research (2007 and updates) and the World Medical Association of Helsinki (2013 and updates) [17].

### Informed Consent

The members of the Project team will assure AYA cancer survivors that participation is entirely voluntary and that they may stop their involvement in the evaluation project at any time. It will be thoroughly explained that their decision will not impact on their care or relationship with the hospital.

### Data Storage and Privacy Issues

A unique study identification number system will be used for data collected for this project. This system involves keeping a ‘key’ that specifies and links the AYA cancer survivor’s personal identifying information (e.g. names, URNs) with their corresponding study identification number (e.g. PT01/ PT02 etc.). The key will be kept electronically (in a password protected excel spread sheet) separate from all hardcopy and softcopy data collected on a Peter Mac server. Any identifying information will be entered into the REDCap database to maintain contact with participants only, and will not be used in data analysis. Any identifying information will be permanently deleted from the REDCap database at the conclusion of the project and will not be disclosed during any analysis, publications, or dissemination.

At the conclusion of data analysis, the REDCap project will be archived on the REDCap platform. Other data will be stored in password-protected folders on Peter Mac's secure servers. Only members of the Project team will have access to this data, in accordance with the National Statement on Ethical Conduct in Human Research 2007 and the Australian Code for Responsible Conduct of Research 2018. Hardcopy data will be stored in locked filing cabinets within Peter Mac Department of Psychosocial Oncology. Five years after publication or dissemination of project outcomes, hard-copy and electronic data will be destroyed.

### Confidentiality

It is not expected that participating in this project will pose any risks of harm to participants. If any disclosures of risks to safety (e.g., suicidal ideation) occur during any stages of the project, standard clinical processes will be followed including safety planning with the participant, and when needed advising an appropriate support person such as a member of the participant’s treating team and/or a family member. This limit to confidentiality is included in the PICF.

References

1. Bélanger, L.J., et al., *Physical activity and health-related quality of life in young adult cancer survivors: a Canadian provincial survey.* Journal of Cancer Survivorship, 2011. **5**(1): p. 44-53.

2. Clinton-McHarg, T., et al., *Measuring the psychosocial health of adolescent and young adult (AYA) cancer survivors: a critical review.* Health and quality of life outcomes, 2010. **8**(1): p. 1-13.

3. Tai, E., et al., *Health status of adolescent and young adult cancer survivors.* Cancer, 2012. **118**(19): p. 4884-4891.

4. Marzorati, C., S. Riva, and G. Pravettoni, *Who is a cancer survivor? A systematic review of published definitions.* Journal of Cancer Education, 2017. **32**(2): p. 228-237.

5. Health, A.I.o., *Australia's health 2012: the thirteenth biennial health report of the Australian Institute of Health and Welfare*. 2012: AIHW.

6. Trauer, J.M., et al., *Cognitive behavioral therapy for chronic insomnia: a systematic review and meta-analysis.* Annals of internal medicine, 2015. **163**(3): p. 191-204.

7. Zhou, E.S. and C.J. Recklitis, *Internet‐delivered insomnia intervention improves sleep and quality of life for adolescent and young adult cancer survivors.* Pediatric blood & cancer, 2020. **67**(9): p. e28506.

8. Morin, C.M., *Insomnia: Psychological assessment and management*. 1993: Guilford press.

9. Michaud, A.L., et al., *Validation of the Insomnia Severity Index (ISI) for identifying insomnia in young adult cancer survivors: comparison with a structured clinical diagnostic interview of the DSM-5 (SCID-5).* Sleep Medicine, 2021. **81**: p. 80-85.

10. Savard, M.H., et al., *Empirical validation of the Insomnia Severity Index in cancer patients.* Psycho‐Oncology: Journal of the Psychological, Social and Behavioral Dimensions of Cancer, 2005. **14**(6): p. 429-441.

11. Johns, M.W., *A new method for measuring daytime sleepiness: the Epworth sleepiness scale.* sleep, 1991. **14**(6): p. 540-545.

12. Takegami, M., et al., *Development of a Japanese version of the Epworth Sleepiness Scale (JESS) based on item response theory.* Sleep medicine, 2009. **10**(5): p. 556-565.

13. Chung, F., H.R. Abdullah, and P. Liao, *STOP-Bang questionnaire: a practical approach to screen for obstructive sleep apnea.* Chest, 2016. **149**(3): p. 631-638.

14. Nagappa, M., et al., *Validation of the STOP-Bang questionnaire as a screening tool for obstructive sleep apnea among different populations: a systematic review and meta-analysis.* PloS one, 2015. **10**(12): p. e0143697.

15. Zhou, E.S., A.H. Partridge, and C.J. Recklitis, *A pilot trial of brief group cognitive‐behavioral treatment for insomnia in an adult cancer survivorship program.* Psycho‐oncology, 2017. **26**(6): p. 843-848.

16. Glasgow, R.E., T.M. Vogt, and S.M. Boles, *Evaluating the public health impact of health promotion interventions: the RE-AIM framework.* American journal of public health, 1999. **89**(9): p. 1322-1327.

17. Johnson, J.A., et al., *A systematic review and meta-analysis of randomized controlled trials of cognitive behavior therapy for insomnia (CBT-I) in cancer survivors.* Sleep medicine reviews, 2016. **27**: p. 20-28.

18. Dozeman, E., et al., *Guided web-based intervention for insomnia targeting breast cancer patients: Feasibility and effect.* Internet interventions, 2017. **9**: p. 1-6.

19. Zachariae, R., et al., *Efficacy of internet-delivered cognitive-behavioral therapy for insomnia–a systematic review and meta-analysis of randomized controlled trials.* Sleep medicine reviews, 2016. **30**: p. 1-10.