Non-Drug/Device Protocol Template



# Notes to Users

**Published Date: February 2nd 2021**

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| **Why do you need a protocol?** | The protocol is essential for study conduct, review, reporting, and interpretation. |
| **Why use this template?** | This non-drug template has been modified from the SPRIRIT (**S**tandard **P**rotocol **I**tems: **R**ecommendations for **I**nterventional **T**rials). The Spirit Statement is an international initiative that aims to improve the quality of clinical trial protocols by defining an evidence-based set of items to address in a protocol.  Reference: [Chan et al., (2013) SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. *BMJ 2013; 346:e7586*](http://www.bmj.com/content/346/bmj.e7586.full?ijkey=QpAJnYI57zIwVr3&keytype=ref) |
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| protocol |
| Reboot Kids: a randomised controlled trial of a behavioural medicine intervention to prevent obesity and metabolic complications in young cancer survivors recently off treatment. |
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## **Glossary of Abbreviations & Terms**

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| **Abbreviation** | **Description (using lay language)** |
| AE | Adverse Event |
| BSU | Behavioural Sciences Unit |
| CALD | Culturally and linguistically diverse |
| CI | Coordinating Investigator |
| NHMRC | National Health and Medical Research Council |
| RCT | Randomised Controlled Trial |
| SAE | Severe Adverse Event |

## **Study Sites**

### Study Location/s

| **Site** | **Address** | **Contact Person** | **Phone** | **Email** |
| --- | --- | --- | --- | --- |
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## **Funding and Resources**

### Source/s of Funding

Cancer Council Program Grant.

## **Introduction/Background Information**

### Lay Summary

Cancer treatment can change a child’s food preferences and eating habits and the way parents and primary carers (hereon included in the term “parents”) respond to these preferences. This can make healthy eating difficult for young patients. These changes can continue for young survivors of cancer after treatment has finished (heron referred to as “survivors”). Reboot-Kids aims to help parents to understand the ways that cancer treatment can affect children’s sense of taste, food preferences and eating habits. It also aims to assist parents in identifying and implementing helpful, practical strategies to improve fruit and vegetable intake and gives evidence-based approaches to managing fussy eating. Studies have shown that nearly one-third of adult survivors of childhood cancer have metabolic syndrome. Metabolic syndrome is a collection of risk factors that place a person at greater risk of heart disease, diabetes and stroke. Some of these risk factors include abdominal obesity, high blood pressure and high blood sugars and fats (triglycerides). It is well accepted that a healthy food intake, high in fruit and vegetables reduces a person’s chance of developing metabolic syndrome.

Our study will be a randomised controlled study to assess the feasibility of the delivery of the Reboot-Kids program and the efficacy of the program to increase the vegetable intake of young childhood cancer survivors. We will have an intervention group which receives the Reboot-Kids program and a control group, which will receive the program when the trial ends. During the Reboot-Kids program, parents taking part in the program will undertake a series of telephone consultations by a suitably trained Research Officer, complemented by web-based modules that can be completed at times convenient to the participant within a fortnightly period.

There will be four telephone consultations of approximately 15-30 minutes duration, over eight weeks. The purpose of each consultation is to assess the participant’s psychological stress, address any issues the participant might have with the program, impart the educational information for the next week and, if needed, assist the participant with setting and meeting goals for improvement in family lifestyle behaviors. In addition to the telephone sessions, there are five web-based modules. The modules will provide education on healthy food choices, and guidance and practical suggestions for bringing about healthy changes. Four of the modules (1 to 4) are more detailed and involved, and include practical activities for the participant to complete. The web based modules 1 to 4 should take approximately 15 minutes to complete the core information for each module. There is extra information available to the parent and it will take approximately 15 minutes to complete, if the parent elects to view it. The time taken to do the practical activities, which are optional, is variable and dependent upon the activity and the parent themselves. The program will be delivered in a step by step guide to assist parents to think about the home environment and habits and practices around food. In order to assess the impact of the program there will also be three additional telephone interviews of approximately 30 minutes duration for the purpose of collecting diet information and a questionnaire on home environment. The diet information phone calls and questionnaires will be completed immediately before the program, at the end of the program and at a 6 month follow-up.

As parenting can be a sensitive issue for some people, there is a potential risk that some parents may feel distress during the program. The telephone interviews will be conducted by a trained interviewer with a scripted interview guide. All the information presented, both the telephone script and web-based modules have been written in an impartial tone and with a sense of suggestiveness. The participant has choice over whether to take up the suggestions or to undertake the program activities. The participant is encouraged to determine the uptake of these suggestions and activities based on their own family situation. As part of each telephone interview, the interviewer will conduct a Distress Screen. Referral information for free psychological supportive services will be provided to parents.

### Introduction

The aim of this randomised controlled trial is to:-

* evaluate the *clinical effectiveness* of the Reboot-Kids program in improving the vegetable intake of young childhood cancer survivors when delivered by a hybrid telephone consulting and web-based program method; and
* To evaluate the *implementation* of the Reboot-Kids program in its hybrid form. Factors including intervention fidelity, participant recruitment and retention, completion of program modules, and acceptability of program will be assessed.
* To evaluate the effectiveness of the Reboot-Kids program in improving parent self-efficacy to promote healthy eating habits to their young cancer survivor when delivered by a hybrid telephone consulting and web-based program method.

The Reboot-Kids program targets parents’ behavior, around issues of food habits and the home environment, to affect improvements to the dietary intake of vegetables of child cancer survivors, aged 2-12 years

Healthy eating habits are particularly important in this cohort as our research has highlighted survivors’ high risk of overweight/obesity and excessive energy intake.

A Cochrane Review [1] in 2015 by our group and a systematic review by a USA group in 2014[2] found a paucity of nutritional lifestyle intervention trials for the paediatric oncology population and, in particular, very few interventions targeting the home environment.

An earlier RCT in a pre-schooler cohort by a Newcastle research team demonstrated significant increases in food and vegetable intake following a telephone-based parent intervention, called “Healthy Habits”.[3] Based on the Newcastle study, we conducted a feasibility pilot study of a telephone based parental intervention (unpublished) and have preliminary data to support taking the program to a phase II randomised controlled trial. In addition to the telephone component, the program will be further developed to a telephone and web-based hybrid to assist in the different learning styles of participants. In light of these findings and the high prevalence of chronic metabolic conditions amongst this population, and the inherent personal and economic costs that presents, there is a need for further research on nutritional intervention in metabolic syndrome for survivors of childhood cancer.

The RCT is planned to test the hypothesis:-

*The Reboot Program is:-*

1. *Feasible to implement as a combined telephone and web-based delivered intervention to parents of young childhood cancer survivors and*
2. *Efficacious in increasing the intake of vegetable serves by survivors (who are not meeting the Dietary Guideline) by at least 20%.*
3. *Efficacious in increasing parent efficacy to promote healthy eating habits to their child and manage their child’s dietary intake.*

### Background information

Metabolic syndrome is a collection of conditions that often occur together and give increased risk of type 2 diabetes, stroke and cardiovascular disease.[4] Adult survivors of childhood cancer are at high risk of developing metabolic syndrome (prevalence is ~30%).[5, 6] Even very young survivors are at risk: one study of 3-18 year olds reported that 30% of transplant survivors, and 8% of leukaemia survivors were already affected by metabolic syndrome, compared with 0% of controls.[7] As in the general population,[8] there is a strong association between a diet high in saturated fat and sugar, and low in fruit and vegetable intake, and the metabolic syndrome in childhood cancer survivors.[6] Survivors with the metabolic syndrome are 2.2 times less likely to meet the dietary guidelines than survivors who do not have the syndrome.[5]

**The problem**

Despite the fact that a healthy diet can reduce the risk of metabolic syndrome in young survivors,[9] their health-protecting behaviour can be poor.[10, 11] Many adult survivors of childhood cancer do not meet guidelines for fruit and vegetable intake, consume excessive fat and have an inadequate calcium intake.[12, 13] We have shown that these poor dietary habits are manifesting early: we documented an excessive energy intake, and an inadequate calcium and folate intake, in young cancer survivors (<13 years of age) within five years of treatment completion.[14] Our newest data also shows that young cancer survivors have a decreased fruit and vegetable intake, as well as increased portion sizes and non-core “junk” food consumption compared with their pre-diagnosis eating habits.[15] This is concerning as poor fruit and vegetable intake in childhood is predictive of metabolic syndrome later in life.[16]

Parents of children receiving cancer treatment also report allowing their child to eat a greater amount of unhealthy food than would normally be allowed.[17] Although this is used as a means to prevent treatment-related weight loss, parents report that they continue to allow unhealthy eating habits even after treatment had finished.[15]

**Why parent-focused intervention?**

In the general population, the aetiology of children’s eating behaviour (including eating patterns, food preferences, and energy intake) is largely attributed, to parenting behaviour.[18-21] In children treated for childhood leukaemia, 80% of patients experience disrupted eating behaviour as a result of their cancer treatment (e.g. nausea, increased appetite, vomiting, food refusal, fussy eating and anger).[22] Consequently, parents often report changing their parenting strategies after diagnosis.[23] These include using lower levels of discipline (e.g. allowing their child greater control over their diet and consumption of unhealthy foods) and utilising unhealthy food as a reward or bribe to manage their child’s pain and emotional distress.[22] However food preferences and dietary habits are largely developed during early life.[24] Reduced exposure to fruit and vegetables during treatment at an early age may contribute to the development of poor dietary habits within our cohort of young survivors and greater weight gain over time. The end of treatment has also been described as a critical moment for educating cancer survivors and their families about health protective behaviours.[25] Taken together, these findings support the central role of parents as appropriate targets for dietary intervention in young survivors early off treatment. For the purposes of our study, we have defined “off treatment” as survivors who are in complete remission, and are either still of maintenance therapy, or have finished all forms of treatment.

**What type of parent-focused intervention?**

Social learning theory posits that children learn new behaviour by direct observation of others’ behaviours.[26] Parents are particularly powerful, providing frequent opportunities for observation from the child. Informed by social cognitive theory, parent-focused nutritional interventions assist the parent to role model healthy eating habits, as well as acting as a source of authority.[27-31] Intervention research by Wyse et al provides strong empirical support for involving parents to improve children’s nutritional outcomes. Using a social cognitive model, Wyse and colleagues developed “Healthy Habits”, a brief, 4-week, telephone-based parent intervention to increase fruit and vegetable consumption within a sample of Australian children.[32] Parent-modifiable factors included increasing the availability and accessibility of fruit and vegetables in the home, role modelling eating fruit and vegetables and providing supportive family eating routines (e.g. eating meals without the television on, enforcing family rules and setting limits on how and when food should be offered). Parents also received training and resources to overcome barriers to effective nutritional modelling (barriers can include a lack of nutrition knowledge and limited knowledge about meal preparation and managing fussy eating). In testing “Healthy Habits” in the pilot study, there was a significant increase in children’s fruit and vegetable intake at 2 months (post-intervention) for the group receiving the Healthy Habits program compared to the group not receiving the program, suggesting the intervention was effective. As previously mentioned, this effect was reproduced in the Healthy Habits RCT and at the 6 month post-intervention follow-up, though with a lower significance.[3] Before the intervention, 32% of children in the pilot study did not meet the Australian recommended intake of fruit and vegetables and following the intervention, this decreased to 18%. The intervention was also considered by the research group to be cost effective to deliver[33] and highly feasible and acceptable to parents, with all parents who started the intervention completing all four telephone sessions.[32]

**How to deliver effective parent-focused interventions?**

Childhood cancer patients are often from remote areas with follow-up medical treatment provided by local tertiary services. Nearly 40% of survivors treated at the SCHN travel from rural and regional areas of NSW (Children’s Hospital at Westmead, CHW, n.d.). On average, families receiving treatment at Sydney Children’s Hospital (SCH) live 239km away.[34] A telephone and web-based delivered intervention would reduce barriers to access, resulting from geographical distance, and provide a feasible and acceptable means for delivering specialised nutritional support to survivors and their families treated at the SCHN and other sites.

Telephone and web-based interventions represent a potentially feasible and acceptable means to provide tailored nutritional support to parents of young cancer survivors Australia-wide. As reported above, “Healthy Habits”, the telephone parent-targeted, fruit and vegetable intervention was successfully trialed was shown to be feasible, acceptable to the participants and effective in changing children’s dietary habits. Preliminary results from our Reboot-Kids pilot study are showing a trend for increase in vegetable intake. (Ethics: HREC/15/SCHN/395). In an African-American population, web delivered information about healthy eating for families was readily taken up by parents, with an 86% log on rate.[35]

A systematic review of meta-analyses of RCTs utilising internet delivered self-guided health interventions identified that the successful interventions were those that used multiple layers of targeted approaches.[36] Our delivery method will therefore be a hybrid of telephone consultations and web-based modules that re-inforce the key messages delivered in each. A meta-analysis of web-based delivered health interventions, which included interventions targeting adult diet and child behaviours, were found to be efficacious.[37] While this study is targeting child dietary changes, it is the parents receiving the web-based program and the results of the meta-analysis are still applicable.

**The intervention**

We have developed a novel intervention, Reboot-Kids, to meet the needs of families of survivors who are concerned about their survivor’s dietary intake. The Reboot-Kids program is evidence-based and theoretically grounded on the Health Belief Model.[26] Reboot-Kids RCT will be partly delivered via telephone consultation by a dietitian, or trained care provider, and supplemented with web-based education and goal setting guidance. It incorporates four fortnightly 30-minute telephone consultations with one parent, for the purpose of education, recapping the previous week’s content and assessing progress. The telephone consultation will follow a script as set out in the Reboot-Kids Interventional Manual. The telephone consultation will be followed by a web-based education module; and goal and strategy setting activities. The Reboot-Kids program contains evidence-based educational information about survivors’ taste and smell function;[38] food preferences and dietary intake; and uses parent quotes to normalise experiences.[23] Table 1 outlines the Reboot-Kids program content.

The program builds on an already tested intervention, “Healthy Habits” that has successfully increased fruit and vegetable intake in a cohort of Australian children. Despite Reboot-Kids being a relatively ‘low dose’ intervention, we are confident that Reboot-Kids will create real change into the long term: “Healthy Habits” achieved significant effects even 12 months post-intervention.[33]

Our pilot study of Reboot-Kids has, to date, 10 consented parents. Of those consented, five parents have completed the Reboot-Kids program and two of those have had the 6-month follow-up Booster consultation. The Reboot-Kids program was highly acceptable to those parents who have completed the evaluation questionnaire (n=3). Evaluation of participant perception was conducted using a likert scale for statements around knowledge gained, usefulness of program, amount and type of content in the program, the telephone consultation – duration and suitability of method. All three parents responded favourably to all statements with the exception of one participant neither agreeing, or disagreeing, with less than four telephone sessions being preferable. Comments on the program included “I learned new strategies that I will continue to use”; “I really enjoyed the program”; “It is very beneficial to be taught new strategies and have the facilitator remind me of them from week to week”; and “found Lauren's suggestions really helpful for our family” (Lauren being the telephone consultant). There were no unfavourable comments.

In addition to the participant perception data, data was collected regarding the timing of the telephone consultations. Repeatedly, the scheduled time for the telephone consultation had to be delayed and the telephone consultations on average ran 15 days overdue (range 6-62). As a result, the RCT will have telephone consultations fortnightly instead of weekly.

Data is also being collected to assess the feasibility of the program. Analysis of the telephone consultations for all parents for the duration of the program to date (22 consultations in total) show the time of the consultation with a mean of 54.7 minutes (range 24-87). The first telephone consultation out of the four consultations in the program is of the longest duration with a mean of 70.7 minutes (range 63-87).

As mentioned previously, the Reboot-Kids RCT will be a hybrid of telephone consultations and web-based modules. The educational content will be delivered briefly over the telephone with key messages being the focus. The web-based modules will cover the content in more detail (referred to in the app as core information) and provide options for the parent to also view “extra info”, along with explanatory pop-up boxes as needed. Goal setting and associated strategies will be delivered as largely web-based, however, if a parent needs guidance the consultant can provide that over the telephone.

There are a number of reasons to change from a telephone only delivery method to a hybrid method and that is to meet the requirement of a multi-layer approach, for which the benefits were discussed earlier; to utilize the audio-visual technology for visual and/or audio presentation to suit the parent’s needs; give flexibility of time and convenience as to when the parent can complete the program during the fortnight period; the ability for the program content to be completed in smaller, pieces of information at a time if this suits the parent; and to readily supplement the program content with links to relevant supporting websites. It is also anticipated that shorter telephone consultations, will be easier to schedule due to the lower time demand and also reduce the number of re-schedules needed for consultations with the parent “running out of time” as a factor seen in the pilot study.(Ethics: HREC/15/SCHN/395).

Another reason to include web-based content, is to reduce the number of telephone consultants required to resource the RCT. Using the pilot data above for an average consultation time of 54.7 minutes, the RCT would require 109.4 hours of telephone consultation time. This equates to one person working full time every minute of the working week for more than 3 weeks on the telephone.

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| **Table 1: Reboot-Kids Program Content** | | |  |
| **MODULE** | **CONTENT** | **OBJECTIVE** | **CANCER RELEVANT CONTENT** |
| **Getting ready** | **Why is healthy eating important for children**  **after cancer treatment?**   * Importance of starting early * Importance of fruit and vegetables for children after cancer treatment | * Pre-reading by parent to elicit motivation for change and prepare for goal setting. | * Importance of supporting healthy eating habits and regular physical activity after cancer treatment. * Common experiences of children and parents during and after cancer treatment (e.g. food aversions, poor fruit and vegetable intake, altered taste perceptions, physical inactivity and parent overprotectiveness) * End of cancer treatment as the most difficult time for families * Addressing challenges - effects of cancer treatment on re-establishing a normal routine including children’s fatigue, fussy eating, inconsistent discipline, misbehaviour, and overprotectiveness. |
| **Why is healthy eating difficult for children**  **after cancer treatment?**   * Treatment side effects * Parenting styles * Steroid treatment * Less exposure to healthy foods |
| **Eating habits after cancer treatment survey**   * Children’s eating habits before, during and after cancer treatment * Children’s vegetable intake after cancer treatment |
| **Module 1** | **Goal setting** | * Setting SMART goals[39] to achieve by the end of the Reboot Program |  |
| **What is healthy eating?**   * 2015 Healthy Eating Pyramid * What is a serve of vegetables? * What is a serve of fruit? * What is a serve of grains, meat, dairy? * Putting the five ‘core’ food groups all together * What is a ‘non-core’ food? * What is a serve of discretionary food? * Fat, salt and sugar * How to read nutrition information panels | * Promote mastery by normalising concerns/fears * Increase awareness of children’s screen time habits * Understanding the Australian Guide to Healthy Eating and portion sizes * Information about the type and quantity of food that children should be eating * Identify ‘sometimes’ food * Introduce the ‘food diary’ * Identify different methods for increasing children’s fruit and vegetable intake |  |
| **Does your child meet the Dietary Guidelines for fruit and vegetables**? |
| **Activity: Keeping a vegetable providing diary** | * To assist the parent in increasing the number of opportunities the child is exposed to, and offered, fruit and vegetables. |  |
| **Strategies**   * Identifying strategies learnt in Module 1 that can be used to meet goal(s) * Planning steps and resources needed to do so. | * To assist the parent in meeting the practical requirements for the strategies needed to achieve the program goal(s). |  |
| **Module 2** | **The Home Food Environment (HELPS Guide)[40]**   * Establishing rules * Location of meal * Distraction of television | * Barriers to introducing change - establishing rules & dealing with change. * Tips for structuring family mealtimes * Providing praise and positive reinforcement * Brainstorm effective non-food rewards * Review strategies for creating a healthy home environment * Review screen time goals | * Addressing challenges for families establishing change after cancer - parent guilt and/or overprotectiveness, misbehaviour resulting from absence of discipline and/or routine during treatment. |
| **Activity: Fridge magnets and ready to eat chopped vegetables** | * To ensure provision of accessible fruit and vegetables for easy consumption and to engage the child through the use of pictorial fridge magnets to indicate what is available in the fridge. |  |
| **Activity: Meal Planning** | * Introduce meal planning - up-skill the parent in planning so as to assist in the provision (opportunity) for fruit and vegetable consumption by the child. |  |
| **Strategies**   * Identifying strategies learnt in Module 2 that can be used to meet goal(s) * Planning steps and resources needed | * Plan for the week ahead - assist the parent in meeting the practical requirements for the additional strategies needed to achieve the program goal(s). |  |
| **Module 3** | **Encouraging Children to Eat Vegetables**   * P’s and C’s Framework[41] * Meal and mealtime strategies * Role Modelling | * Assist the parent in having a clearly defined role in the feeding process and equip the parent with skills to manage the child’s behavior at mealtimes. * Practical strategies for promoting fruit and vegetables to children, including planning and providing choices. * Tips on making food exciting and interesting * Preparing for misbehaviour * Discussion of unhelpful strategies, including what to try and avoid. * Rationale for role modelling |  |
| **Strategies**   * Identifying strategies learnt in Module 3 that can be used to meet goal(s) * Planning steps and resources needed | * To assist the parent in meeting the practical requirements for the additional strategies needed to achieve the program goal(s). |  |
| **Module 4** | **Review and future planning** | * To revise key topics of the Reboot Program. * Introduce strategies for shopping with children * Assist the parent in acknowledging any healthy eating behavior changes made; positive feedback. * Plan for the future -support the planning process for continued positive changes. | * Address any cancer related fears and or concerns. |
| **Strategies**   * Identifying barriers * Produce strategies to overcome barriers. | * For the parent to identify barriers and produce solutions for those barriers to avoid behavior relapse. |  |
| **Goal evaluation** | * To encourage maintenance (or work towards) goal(s) achievement. |  |

**Why do this study?**

Despite the fact that a healthy diet could lessen the risk of late morbidity and mortality, young cancer survivors still have poor intake of fruits and vegetables, which is likely to persist into adulthood. Although interventions to increase fruit and vegetable intake have been successfully tested in healthy Australian children,[3] there is no research on their effectiveness in cancer survivors. The Reboot-Kids Program addresses this gap by providing parents of survivors with skills-based training to target poor fruit and vegetable intake, and fussy eating behaviour. These feeding issues are common in this population,[15] and yet still to be systematically reviewed. Innovative cancer-specific modifications have been made to the original Healthy habits intervention and have been tested in the Reboot-Kids pilot study. Cancer specific information on how cancer treatment may affect children’s dietary intake (poor fruit and vegetable intake and taste dysfunctions), parenting styles (laxness around unhealthy eating) and survivors’ vulnerability to late effects (cardiovascular disease, overweight and obesity) is therefore included in the Reboot-Kids program.

A systematic review conducted last year on lifestyle behaviour interventions delivered using technology for children, adolescent and young adult cancer survivors found very few technology based interventions have been developed and there were no nutrition interventions, using technology, published.[42] There is a need to fill this gap, particularly when web-based and computer based interventions for healthy behaviours have had successful uptake and retention rates.[43]

The Reboot-Kids RCT will include a web-based application that can assist the parent in guided decision making for goal and strategies setting, complemented by educational content and resources. It is up to the individual parent as to how much of the web-based content they wish to utilise. The parent will complete a web-based module following a telephone consultation with a suitably trained research officer. The program has significant implications for survivors. We anticipate that higher consumption of fruit and vegetables and reduced screen time amongst survivors will support the development of healthy long-term lifestyle habits, which can significantly reduce the risk of chronic disease later in life.

The prevalence of metabolic syndrome amongst this cohort, the community and personal costs associated with metabolic syndrome, along with the previously mentioned paucity of nutritional intervention trials for this cohort, warrants the phase II RCT.

## **Study Objectives**

### Research Question

How feasible is it to deliver the Reboot-Kids nutrition intervention as a hybrid telephone/web-based program and does it improve vegetable consumption in survivors aged 2 to 12 years (who are not meeting the Dietary Guideline) compared to survivors not receiving any intervention (control group), six months after commencing the program?

### Primary Objectives

1. To evaluate the process of delivering the Reboot-KIDS intervention to parents as a hybrid telephone/web-based program

### Secondary Objectives

1. To assess the efficacy of improving the total intake of fruit and vegetables consumed by young survivors as a result of their parent undertaking a behaviour influencing program to bring about measureable changes in fruit consumption
2. To assess the changes in the home environment – availability and accessibility of fruit and vegetables, parent role modelling, family meals, food preparation and practices, screen time – that bring about the improvement in fruit and vegetable consumption.
3. To assess any change to a survivor’s health as indicated by Body Mass Index (BMI).
4. To assess any change in parent self-reported self-efficacy to promote healthy foods to their child.
5. To assess the efficacy of improving young survivors’ fruit and vegetable intake patterns (variety/frequency) In the previous week (diet quality).

### Outcome Measures

The Australian Government and the National Health and Medical Research Council (NHMRC) have guidelines for recommended daily serves of vegetables and fruit. The number of serves vary depending upon the child’s age and for the oldest two age groups, by gender. Refer to Table 2 for the recommended daily serves. Due to the recommended number of serves differing by age and gender groups, measured daily serves will be converted to a percentage of the recommended daily serves.

**Table 2: NHMRC Australian Dietary Guidelines – Recommended daily serves of Fruit**

**and Vegetables**[44]

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Age/  Gender | 2-3 years | 4-8 years | 9-11 years | | 12-13 years | |
| Girls | Boys | Girls | Boys |
| Vegetable | 2½ | 4½ | 5 | 5½ | 5 | 5½ |
| Fruit | 1 | 1½ | 2 | 2 | 2 | 2 |

**Primary Outcome Measures**

Program evaluation data to assess feasibility of the program will be collected at the end of completion of the program (T1). Table 4 sets out the timing for data collection times.

* Initial response rate

Program process - Web-based content

* Number of parents who complete each module.
* Number of parents who complete the activities set during the module.
* The average number of minutes taken to complete each module.
* Proportion of each module content was completed – All/All of Main part/Some of main part/All goal setting and activities/part goal setting and activities.

Program process - Telephone-based content

* Number of times a parent re-schedules a telephone interview.
* If parent found telephone session useful.
* The average call length.
* Number of parent drop outs during the program (Goal: < 20%)
* Proportion of each module content completed –All/Most/Half/Little.

**Secondary Outcome Measures**

Fruit and vegetable consumption data, home food environment data and child’s weight and height will be collected at T0, T1 and T2 as shown in Table 4 and will be reported by the parent using validated tools. The methods of data collection are discussed in detail in section 6.5 Study Methodology.

Vegetable consumption

* Survivor’s percentage of daily serves of vegetables consumed, as reported by their parent, as a proportion of the recommended daily serves. Measured at T0, T1, T2

Fruit consumption

* Survivor’s percentage of daily serves of fruit consumed, as reported by their parent, as a proportion of the recommended daily serves. Measured at T0, T1, T2
* Home food environment score.
* Child’s height and weight.

Survivor diet quality

Children’s total fruit and vegetable diet quality score, using the fruit and vegetable subscale of the Children’s Dietary Questionnaire. Measured at T0, T1 and T2.

Parent self-efficacy

* Parents’ ratings of perceived self-efficacy to manage their child’s eating habits on 10 5-point Likert scales. We will create a total self-efficacy score by summing parent responses to all 10-items. Measured at T0, T1 and T2.

## 6. Study Design

### 6.1 Study design diagram

**Recruitment Stream 1**

Potential participants will be identified through each sites paediatric cancer database and sent a text-message study invitation, including a link to a study video and an online parent information form.

**Recruitment Stream 2**

Treating oncologists will identify eligible participants from the weekly outpatient oncology clinic attendance lists, provided by the Trial Coordinator. Participants identified as eligible will be approached at the outpatient oncology clinic to invite them to participate in the study.

**Recruitment Stream 3**

The study will be advertised in the outpatient clinic, at relevant cancer support organisations, and through paid advertisements on Facebook.

**Recruitment Non-respondents**

Trial coordinator will telephone non-respondents to the invitation 2-weeks after receiving the text-message invitation

**Stage 1 Baseline Assessment (T0)**

Consented participants to do:

1. Distress Screen. If score greater than/equal to 7 or change of greater than/equal to 3, refer to support as per distress process.
2. Three-Pass 24 Hour Dietary Recall
3. Fruit and Vegetable Intake questionnaire
4. Children’s Dietary Questionnaire
5. Reboot Socio-Demographic Questionnaire
6. Home Environment Questionnaire
7. Healthy Cooking Questionnaire
8. Screen Time Questionnaire
9. Parent self-efficacy items

**Randomisation and Allocation**

Participants randomised to intervention or control group within sites

**Stage 2 Reboot Intervention**

1. Consented participants will receive email with a link to web-based program and a temporary logon password.
2. Participants will undertake the Reboot-Kids Program of telephone consultations and web-based modules over 10-weks.

**Stage 2 Reboot Control**

1. No intervention
2. Participants allocated to control group will be on a 6 month wait list for Reboot-Kids Program.

**Stage 3 Post-Test Assessment (T1)**

**Upon completion of Module 4, all participants will undertake:**

1. *Distress Screen*. If score greater than/equal to 7 or change of greater than/equal to 3, refer to support as per distress process.
2. *Three-Pass 24 Hour Dietary Recall*
3. Fruit and Vegetable Intake questionnaire
4. *Home Environment Questionnaire*
5. *Children’s Dietary Questionnaire*
6. *Parent self-efficacy items*

**Stage 4 Follow-Up Assessment (T2)**

**Six months after completion of module 4, all participants will undertake**

1. Distress screen
2. Three-Pass 24 Hour Dietary Recall
3. Fruit and Vegetable Intake Questionnaire
4. Home Environment Questionnaire
5. *Children’s Dietary Questionnaire*
6. *Parent self-efficacy items*

**Stage 5 Reboot Control**

1. After the completion of follow-up assessment, control group participants will receive an email invitation to do the Reboot-Kids program
2. Participants accepting the invitation will be provided with the program.

### 6.2 Study type & design schedule

**Type of study**

The study is a Phase II prospective parallel cohort randomized controlled trial.

**Design elements**

The cohort is a parent-child dyad where the child is a childhood cancer survivor aged 2 to 12 years who have completed treatment of their cancer and are not yet attending high school. The intervention is a hybrid of telephone interview and web-based application, targeted at the survivor’s parent. Parents will be recruited as participants to give a sample size of 40 receiving the intervention immediately and 40 serving as waitlist controls. The waitlist controls will serve as a comparison to the intervention group to measure differences between the two groups for changes in survivor’s vegetable consumption over the intervention period and at the six-month follow-up. Both the intervention and control group will receive the same questionnaires and diet history recall at the same time points. The only exception to this will be that the control group will not receive the program evaluation questionnaire. The wait-list group will wait for 6 months after which time they will be offered the Reboot-Kids Program. A similar phase II intervention study for survivors’ using a web, text and telephone counselling method for weight management, successfully demonstrated efficacy of the intervention with a sample size of 38 survivors (3 drop outs) who were randomised equally to an intervention or control arm.[45]

**Multi-centre**

The study is a multi-site randomised controlled trial being conducted at 4 sites across Australia.

**How design will achieve aims and objectives**

A multi-site trial is required to attain the numbers required, whereby randomisation will be stratified by site. Parents of survivors who are patients from hospitals allocated to the intervention group will receive the Reboot Program immediately once pre-test measures are collected. Parents of survivors who are patients from hospitals allocated to the control group will commence the program after a 6 month wait. As the intervention (treatment) will be delivered from the one site, BSU, Kids Cancer Centre, Randwick, via telephone/webex calls and web-based application there will be no treatment imbalance across recruitment sites.

### 6.3 Data to be collected

Participants will be invited to complete two questionnaires at each assessment time-point, including baseline (T0), immediately following the completion of the program, identified as the completion of the fourth online module (T1) and 6-months from baseline (T2). Participant data will be collected using two tools including: (1) a single telephone-based 24-hour dietary recall and, (2) an online Reboot Kids Questionnaire. The online Reboot Kids Questionnaire will collect data on multiple constructs, as described in sections 5.1 to 5.6

The Reboot Kids questionnaire will be identical at each assessment point (T0, T1 and T2), except for the demographic, home cooking and program evaluation items. This trial does not aim to assess changes in participants demographic and treatment history and usual home cooking habits from pre-to-post. Therefore, data on demographic and usual home cooking habits will only be assessedat baseline or the T0 Reboot Kids Questionnaire T0. As program evaluation can only occur after participants have completed the program, data regarding the acceptability and usability of the hybrid telephone/web-based delivery of the Reboot Kids program will only be collected duringthe post-intervention assessment schedule or T1 Reboot Kids Questionnaire.

* *Fruit and vegetable consumption and diet quality*

Quantitative data on the survivor’s fruit and vegetable consumption, including the variety of fruit and vegetables consumed in the previous 7-days will be collected using the Three-pass 24hr Dietary Recall, which is completed over the telephone and the fruit and vegetable subscale of the Children’s Dietary Questionnaire, which is completed online.

* *Parental self-efficacy for promoting healthy eating to their children*

Quantitative data on parent reported confidence over the next year to provide fruit and vegetables to their child throughout the day, role model eating fruit and vegetables themselves and say ‘no’ to children’s demands for non-core foods.

* *Usual Home Cooking Habits*

Data on participant’s usual cooking habits will be collected through administration of the Healthy Cooking Score Questionnaire, which includes questions on frequency of home cooked meals, methods of cooking, fat, herbs/spices, and condiments used. Items were developed based on a previously published framework of healthy cooking behavior, which have been shown to be relevant to childhood cancer survivor families.[46, 47]

* 5*Home Food Environment*

Data on the home environment will be collected through administration of the Home Environment Questionnaire (HEQ), which includes questions about parent role modelling, including TV time and family meals, food provision and accessibility. The HEQ was developed and successfully trialed by Wyse et al in the Healthy Habits study of fruit and vegetable intake of Australian children.[48] The HEQ questions are questions either developed specifically for the Healthy Habits study or are validated items taken from the 1995 National Nutrition Survey[49] or the Healthy Home Survey.[50] Using an adapted questionnaire developed by Jago et al, screen viewing time data for all screens, including mobile devices will be collected.[51]

* *Demographics and treatment history*

Information on age, sex, ethnicity, first language, income range, height and weight, education, employment status of the parent, as well as the survivor’s cancer diagnosis, treatment and family structure will be collected via a Demographic Questionnaire.

As a safety measure, this questionnaire also includes an emotional thermometer (ET) to assess parent distress and emotional state within the past week of completing the questionnaire.[52] The ET is discussed in detail under Section 6.5 Study Methodology – Procedures list. The questionnaire, including the ET questions, takes about three minutes to complete.

* Program evaluation questionnaire to evaluate the acceptability and usability of the hybrid telephone/web-based delivery of the Program.
* Web-based Captured Data

In addition to the two intervention surveys, this trial will also collect data on participant use of the study website. This data will be collected using participants’ responses the online learning modules and will not be included in the assessment schedule.

During the Reboot Kids program, the online modules will invite parent participants to answer questions e about their prior knowledge of dietary guidelines, fruit and vegetable availability and accessibility for their child, family habits with meal times, television habits during meal times, and meal planning practices. In addition, we will invite participants to record their responses to several optional items, including their program goals, perceivedbarriers to achieving their goals and preferred program strategies (multiple strategies are offered) for improving their child’s fruit and vegetable intake. Participantswill formulate these goals and strategies based on the needs of theirtheir household and family, and will therefore differ slightly between participating families. The responses will be stored as data to be revisited during the different program modules and will be built upon as the parent’s knowledge and experience grows. The web-based captured data, which can be re-identified, will be kept for future studies.

As part of the web-based program, the parent can enter available times that they can be telephoned for the RebootKids program telephone consultations.

### 6. 4Method of data collection

A mortality check will be made, with the relevant State’s registry of deaths, regarding the survivor and their parent as a potential participant for recruitment. The process and timing of this data collection is detailed in section 7.1 Recruitment Procedure and Diagram 1.

Once the parent has consented they will be contacted by the trial co-ordinator to organise a time within the next week for a *Three-pass 24hr Dietary Recall* to be conducted over the phone and to confirm the parent’s email address. The Trial Co-ordinator will then send an email containing a link to the T0 Reboot Kids questionnaire questionnaires Following this call, a research officer will contact the parent at the designated time to conduct, firstly a Distress Screen and then depending up on the Distress Screen result, a *Three-pass 24hr Dietary Recall*.

Upon completion of the T0 single 24-hour dietary call and Reboot Kids Questionnaire, the Trial Co-ordinator will send the parent a link to the Reboot Kids Program, using the parent’s unique study identification number (Participant ID) as the username, along with a provided password, which the parent can change after the initial login. Upon completion of Module 4 of the web-based application, a link will automatically take the parent to the questionnaires for the post-test assessment. A link to Questionnaires for the 6-month follow-up assessment will be emailed. Table 4 below shows the study components and timing of those.

The nature of the data collected from the web-based program will consist of both data input by the parent during the use of the program, as well as monitoring data captured to measure the use and usability of the program. Data from the web-based program will be stored on the University of New South Wales (UNSW) Engineering Faculty’s server. Data from the online questionnaires will be captured by UNSW REDCapSurvey Service, provided by UNSW IT. Data will then be exported from UNSW IT serverand stored on a locked server on the UNSW One Drive for the School of Women’s and Children’s Health. . To identify each participant in the REDCap survey program, a ‘participant randomisation form’ was specifically designed for this study. The ‘participant randomisaiton form’ is a unique form for each participant, which is completed by the study coordinator. The form includes two participant ‘identifier’ fields; 1) the participant’s study ID number (allocated in sequential order, based on the date of informed consent) and 2) the participant’s email address. As the participant’s ID and email address are coded as ‘identifiers’, REDCap will automatically use the participant’s email address to send the participant’s survey invitations at each assessment timepoint and the participant’s ID number to link survey responses together, in the study database. In addition to the recording two key participant identifier’s (study ID number and email address), the form includes’ a ‘randomisation button’, which allows the study coordinator to randomly allocate the participant into either the intervention or the waitlist control condition (using an electronically generated randomization list uploaded into the software’s randomization schedule field). As the ‘participant randomisation form’ will be used for procedural steps only (not for data collection), this form is not viewed by the participant and is only accessible to the study coordinator, using the Reboot Kids REDCap username and password.

Data from the *Three-pass 24hr Dietary Recall* will be entered into **FoodWorks** version 8, Xyris Software (Australia) Pty Ltd by a qualified dietitian with the data stored on the SCHN server. All data will be identified with a Participant ID which can only be re-identified by accessing a master participant file held on the SCHN server. The master participant file held at SCHN will hold data for parents from all participating hospitals.

### 6.5 Specify the time frame for each component

The study participant recruitment will commence in March 2018 and finish in March 2019.

Table 3: Study schedule

|  |  |  |
| --- | --- | --- |
| **Component** | **Start date** | **End date** |
| Protocol development and web application development | February 2017 | November 2017 |
| Site recruitment and agreements | April 2017 | June 2017 |
| Trial ethics and governance | June 2017 | November 2017 |
| Site set-up: assignment of Site-coordinator ± other study personal, data management, communication, SOPs, licenses. | December 2017 | February 2018 |
| Participant recruitment | September/October 2019 | September/October 2020 |
| Intervention and data collection | October 2019 | June 2021 |
| Follow-up | April 2020 | December 2021 |
| Analysis | December 2021 | February 2022 |

It is expected that ethics approval will be granted by mid-late 2018. Development of the web based program and modification of the Reboot-Kids Interventional Manual was completed in November 2017. Recruitment will be open for 12 months, following ethics approval with each site identifying and screening potential parents - a process that will take approximately 10 to 30 person hours initially, followed by ongoing monitoring for new cases. Intervention delivery will begin in late November 2018, continuing for approximately 2 years to November2020. Follow-up (6-month) data collection will commence May 2019 and complete by end May 2021. Analysis will be completed by mid 2021.

As the intervention does not require face to face delivery due to it being a telephone/web-based intervention, there will be no need for site visits.

1. **Home visits**

Not applicable as a telephone/web-based intervention.

1. **Contingency plans**

Access to computer and internet check

During the initial telephone interview there will be a check that the parent still meets the eligibility criteria of access to the internet. Internet access and a suitable computer set-up is a requirement to participate in RebootKids and includes access to a computer, laptop and/or tablet. Parents without access to appropriate equipment will be able to borrow a laptop or tablet and/or wireless internet connection device for the duration of the study, provided by the lead RebootKids research team from the BSU. The parent will also be made aware both in the information and consent forms, and at the initial intake interview, that this equipment is solely to be used for the purposes of participating in Reboot-Kids and that further, the equipment must be returned at the study’s completion. The parent participant will also agree to these conditions of use in the consent form signed at the start of the study.

An email response to the initial email sent will be required as confirmation the parent has functioning internet access.

If during a telephone interview a parent appears at imminent risk of significant distress, the research officer will immediately contact Professor Claire Wakefield and the research team to co-ordinate crisis care through the participating hospital’s social worker. In the event that a social worker is unavailable for assistance, the parent’s GP will be contacted and/or the local community mental health team. The research officer will encourage the parent to call the Lifeline crisis hotline or emergency services in the interim.

If following the conduct of a distress screening, which will be a standard part of a telephone interview, a parent is found to score a 7 or higher, Professor Claire Wakefield will be notified with the case being discussed and a subsequent plan made. Free supportive services will be provided to all parents in need.

1. **Student project**

The development of the web-based program for delivery is being completed by two students from the University of New South Wales, Faculty of Engineering, School of Computer Science and Engineering, as part of their undergraduate degree course, under the supervision of Professor Nigel Lovell, Scientia Professor, Graduate School of Biomedical Engineering.

1. **Study Components**

**Table 4: Study Assessments and Procedures**

|  |  | **Screening** |
| --- | --- | --- |
| **Assessment/**  **Procedure** | **Pre-baseline** | **Baseline T0** | **Getting ready** | **Module 1** | **Module 2** | **Module 3** | **Module 4** | **Post-test T1** | **Follow-up T2** |
| **Completed by end of:** | **-1** | **0** | **1** | **3** | **5** | **7** | **9** | **11** | **26** |
| **SCREENING** | **Clinical and demographic data** | **x** |  |  |  |  |  |  |  |  |  |
| **Mortality check** | **x** |  |  |  |  |  |  |  |  |  |
| **Consult CNC/treating Oncologist** | **x** |  |  |  |  |  |  |  |  |  |
| **Informed Consent** | **x** |  |  |  |  |  |  |  |  |  |
| **Set-up initial contact** |  | **x** |  |  |  |  |  |  |  |  |
| **Distress screen** | **x** |  |  |  |  |  |  |  | **x** |  |
|  |  |  | **x** |  |  |  |  |  |  | **x** | **x** |
|  | **Reboot Kids Questionnaire (online)** |  |  | **x** |  |  |  |  |  | **x** | **x** |
|  | **Three pass 24hr Diet Recall (telephone)** |  |  | **x** |  |  |  |  |  | **x** | **x** |
| **INTERVENTION** | **Telephone/WebEx consultation \*** |  |  |  |  | **x** | **x** | **x** | **x** |  |  |
| **Online education and online goal work** |  |  |  | **x** | **x** | **x** | **x** | **x** |  |  |
| **Goal setting/revisiting** |  |  |  | **x** | **x** | **x** |  | **x** |  |  |
| **Parent activity**  **(non-mandatory)** |  |  |  |  | **x** | **x** | **x** |  |  |  |

**\* Telephone/Webex consultations for modules 1 to 4, take place a couple of days prior to the commencement of the week they are marked in.**

### 6.6 standard care and additional to standard care

Presently, there is no standard nutrition care for this cohort post cancer treatment.

### 6.7 Randomisation

Randomisation will be simple randomization at each site. Parents will be randomly allocated to either: the Reboot Kids Program or a wait-list control group, using an electronic randomiser implemented by independent personnel at theBehavioural Sciences Unit, School of Women’s and Children’s Health, UNSW. The Site Co-ordinator will recruit and submit consented parent details to the Trial Co-ordinator for randomised assignment to a trial arm.

### 6.8 Study methodology

1. *Emotion Thermometer*

The Emotion thermometers are a validated tool to assess parents’ levels of distress and have been successfully used in many previous studies by our team. The emotion thermometers tool is an adaptation of the Distress Thermometer (DT), originally developed and validated for the evaluation of distress (and anxiety and depression) in cancer.[52] This measure comprises four predictor domains (distress, anxiety, depression, anger) and one outcome domain (need for help). Each domain is rated on a 0 to 10 point Likert scale in a visual thermometer. The tool was found to take about 45 seconds for most patients for complete.[53] The Emotion Thermometers have been validated in an Australian sample by Andrews et al, 2008.[54]

1. *Dietary intake (3-Pass 24 Hour Dietary Recall - 20 minutes)*

A research officer with appropriate training (an accredited practicing dietitian), will contact the parent to administer a parent proxy *Three-Pass 24 Hour Dietary Recall*. This method consists of a structured interview in which the parent is asked to list everything the child ate or drank during the previous day. The *Three-Pass 24 Hour Dietary Recall* has one of the highest validation standards for dietary assessment methods. For examining the effect of an intervention and determining the difference between two groups in mean usual intake change, the National Cancer Institute recommends the use of the *Three-Pass 24 Hour Dietary Recall* and one administration of it on the sample in each time point is valid.[55] The methodology involves a ‘3 pass method’ and comprises of three distinct probing sessions (or passes). The first pass will obtain a list of foods; the second pass adds detailed descriptions of foods consumed, and the third pass reviews for missing items. This methodology has no written literacy requirements, does not allow the participant to alter food intake behaviour and can allow for the participant to report all foods consumed.[56] The *Three-Pass 24 Hour Dietary Recall* provides an estimate of actual dietary intake including the brand, ingredients and portion size.[56] This measure has been validated in survivors[57]*.* The *Three-Pass 24 Hour Dietary Recall* will measure daily serves of vegetables and daily serves of fruit, including fruit juice/drinks, food energy, nutrients and non-nutrient food components consumed by the child in order to assess dietary behaviours.

1. Reboot Kids Questionnaire Measures

* Diet quality (Fruit and Vegetable Subscale, The Children’s Dietary Questionnaire, CDQ)

Section A assesses the variety of fruit and vege-

tables consumed in the previous seven days using

tick boxes against a list of commonly consumed

fruits and vegetables (19 and 25, respectively).

Section B assesses on a 6-point Likert scale (0, 1,

2, 3, 4, 5 times), frequency of intake in the

previous 24 hours of fruit juice/drink, water, milk

(separated for full cream and reduced fat), cheese/

cheese spreads, yoghurt/custard (separated for full

cream and reduced fat), fruit and vegetables, and

variety of fruit and vegetables. Section C focuses on

foods recommended to ‘eat sometimes or in small

amounts’ (i.e., high in energy/sugar/fat/salt) that are

known to be frequently consumed by children

(1,3,4). Frequency of intake in the last seven days

of 13 items, including soft drink/cordial, sweet

biscuits, confectionery and ‘takeaway’ was assessed

using a 7-point Likert scale (0, 1, 2, 3, 4, 5, 6

times). Two additional questions in section C

assessed the number of days in the last week fruit

and vegetables were eaten using a 7-point Likert

scale (0, 1, 2, 3, 4, 5, 6 days)

The fruit and vegetable subscale of the CDQ62,63 assesses the variety of fruit and vegetables consumed in the previous seven days using tick boxes against a list of 19 commonly consumed fruits and 24 commonly consumed vegetables. The number of tick boxes are summed to create a total score, where a higher score indicates a greater variety of vegetables consumed in the previous week, reflecting better diet quality.

* Parent self-efficacy in managing their young survivors’ dietary intake.

Current evidence suggests that parental self-efficacy or confidence around promoting healthy foods to their child is important in facilitating improvements in children’s dietary intake. As there were no existing measures of self-efficacy specific to parent behaviour, we modified existing measures of parental self-efficacy to measure parents’ confidence to promote healthy eating habits to their child using 10 questions e.g., “How confident are you that you can provide vegetables on at least three occasions throughout the day?” Items reflected parent confidence to provide a variety of vegetables to their child every week, provide fruit to their child on at least two occasions throughout the day, manage their child’s eating habits, role-model eating vegetables themselves, encourage their child to participate in food preparation, prepare fruit/vegetables in an appealing way for children, prepare ready-to-eat vegetables for their child and respond to children’s food refusal and demands for non-core foods. All items will be scored on a five-point Likert scale from 1 (not at all confident) to 5 (extremely confident) and averaged to produce a total parent self-efficacy score, before and after, program participation.*UsualCooking Habits* CCS are at high risk of several chronic conditions including secondary cancers that may be influenced by home cooking behaviours. Eating foods prepared in the home from basic ingredients, as opposed to eating out, has been linked to increased intake of fruits, vegetables and whole grains. The Healthy Cooking Questionnaire is a tool which will measure the healthfulness of food preparations. It is based on two main sets of healthy cooking behaviours – one based on meat products, and another based on vegetables and grains.[58]

* *Home Food Environment (HEQ)*

Factors such as parent modelling, screen time, family meals, food availability and accessibility have all been shown to be important factors in influencing a child’s fruit and vegetable intake.

The home food environment will be assessed using a measure successfully trialed in a previous study of fruit and vegetable intake of Australian children.[59] In this previous study of fruit and vegetable intake, it was demonstrated that parent fruit and vegetable intake; and parents provision of fruit and vegetables, mediated the effectiveness of the intervention measured at 2 and 12 months post-intervention. It is recommended that future home based interventions target these variables to increase children’s fruit and vegetable consumption.[59] In line with past literature, the current home environment measure will ask parents to report the number of occasions that parents consumed fruit and vegetables in front of their children on the previous day, and provided fruits and vegetables to their child on the previous day. In adult cancer survivors, a greater amount of screen time (television viewing) is associated with increased risk of mortality by contributing to physical inactivity.[60]

* *Screen-time*

National screen time data has demonstrated children in NSW are exceeding the recommended limit of 2-hours of screen time each day, which is placing them at risk of insulin resistance and low cardio-respiratory fitness. This places young cancer survivors in NSW at additional risk for future adverse health outcomes Participant’s will be asked to answer a questionnaire about their child’s screen-time habits. Questions will be asked about TV, computer, game console, iPad, tablet and smartphone device usage, both on weekdays and weekends. Jago et al state, “the assessment of TV viewing using parental response to a single question has been shown to correlate moderately (r=0.60) with 10 days’ of TV diaries among young children”. Studies have shown that children who spend longer in front of screens are more likely to be overweight or obese and that vegetable servings per day decrease with increased TV viewing by children.

* *Anthropometry*Parents will measure their child’s height and weight at baseline (T0), (T1) and six-month follow-up (T2).
* *Program evaluation*

1. *Delivery method*

The evaluation of the delivery method of the telephone/web-based hybrid program model will be determined by assessing the time taken to complete telephone sessions and the difficulty in organising and executing planned telephone sessions. Log on data will capture the time duration parents are logged on to the web-based modules and the portion of the module completed for the assigned period. Parents will also complete a post-intervention evaluation questionnaire upon completion of the last module (time=T1). The evaluation questionnaire will include a question as to whether the parent considered they achieved or almost achieved their program goal.

* *Consultant fidelity ratings and working alliance*

Telephone consulting sessions will be audio-recorded with consent. Audio-recording will be undertaken to promote treatment fidelity and to ensure adherence to the protocol.[61] At the beginning of the first intervention telephone call, participants will be asked verbally if they consent to being audio-recorded during each telephone session. Participants will informed that they have the option to decline consent and that this will not affect their participation in the study in any way.

## **7. Study Population**

### 7.1 Recruitment Procedure

The parents of survivors aged 2 to 12 years, who have completed treatment of their cancer and are not yet attending high school, will be recruited. All recruitment criterion are listed below.

Two recruitment streams will be used; A) Standard mail-out and Text-Message (SMS) and B) Face-to-face engagement at clinic visits, both of which are based on standard operating procedures at the Behavioural Sciences Unit, Kids Cancer Centre and have been tested in our pilot study. This recruitment process will be replicated at each participating site as appropriate to the clinical setting.

**Stream A**

Potential parents will be selected using the site specific hospital or oncology unit patient (child) database. The Site Co-ordinator will search the database for patients treated within the last 5 years and currently aged between 2 and 12 years. Date of birth, date of diagnosis, treatment type, vital status (e.g. “alive”) and alerts (e.g. family stress, difficulty coping) will be used to determine eligibility. If eligible, patient and parent names, diagnosis, time off treatment and treating team names of the consultant oncologist, dietitian and clinical nurse consultant (CNC) will be collected. The Site Co-ordinator will then contact one of the members of the treating team, to whom the patient and parent are well known, to review for eligibility and to remove patients that meet any of the exclusion criteria. In line with standard operating procedures at the BSU, the names of any eligible survivors approved by their treatment team, who have been off treatment for more than 12 months, will be sent to the relevant State’s registry office of births, deaths, and marriages (BDM) for final review. Refer to Diagram 1. Following confirmation of survival from BDM, the Site Coordinator, will forward eligible parents an invitation to participate in the study through a mailed or SMS personalized invitation from the local site’s cancer centre medical director, explaining the purpose of the project, why they have been chosen and what participation involves, a link to a brief informational study video, as well as a link to an online parent information and consent sheet (PICS). Parents can choose to participate by completingthe online PICS . The Site Co-ordinator will maintain a database of contacted and consenting parents and will also collect consenting parents mailing address and contact phone number from the respective databases and forward in a password protected file to the Trial Co-ordinator at the Behavioural Sciences Unit. Where local sites are willing to release patient contact details prior to the parents consenting to participate, the Site Co-ordinator will forward the details to the Trial Co-ordinator in a password protected file. The Trial Co-ordinator will be responsible for contacting the relevant State’s BDM and acquiring consent from parents, in line with the standard operating practices of the BSU, utilising an SMS-basedpersonalised invitation from the local sites medical director as above.

**Stream B**

The Site co-ordinator will check the weekly attendance lists for the outpatient oncology long-term follow-up for potential parents. Patients off this list will be screened as per Stream A up until the BDM check. Parents of patients deemed eligible will be approached at the clinic by the Site co-ordinator, to invite them to participate in the study. To reduce any undue burden to participate, the Site co-ordinator will explain that neither they nor the study are associated with their treatment team and that participation is completely voluntarily and declining to participate will not affect their child’s treatment at the hospital in any way. Interested eligible parents will be given the option to view the study video and the online PICS in clinic or to read and complete the online parent PICS at home. Parents who opt to view the study video and read the online information and consent from home, will be invited to provide their email address. The study coordinator will then email parents a link to the study video and the online information and consent form. .

Ideally, eligible parents should be able to take as much time as they want to read the study information package and consider whether or not to participate.

**Stream C**

A study flyer will also be displayed in the waiting area for post-treatment (outpatient) clinics. The study flyer will contain basic information about the study, eligibility, a link to the online parent information opt-in form, and contact information for the study coordinator. Patients interested in participating in the study will be able to contact the study coordinatior via phone or email to obtain further information about the study and request (if desired) a study package. Eligibility for the study will be confirmed verbally over the phone by the study coordinator prior to mailing the study package.

We will also advertise the study through cancer support organisations, such as CanTeen, Redkite and the Leukaemia Foundation. For these “sites”, advertisements will be placed in the organisation’s newsletters, via their social media and on their websites. Participants will be able to express their interest in participating in the study by contacting the research team directly or registering their interest, including their name and preferred contact information, using an online information opt-in form. After they have contacted the research team, potential participants will be sent an invitation pack providing further information about the study (using the same methodology as participants recruited through the hospital system, except that the letter will come from the research team, rather than their oncologist). Should potential participants decide not to participate in the study after receiving the invitation pack, they will be able to opt out of the study at any time.

The Reboot team will use the paid advertising services on Facebook to reach parents of childhood cancer survivors who access Facebook. The targeted advertising features will be used to ‘promote’ the study to parents who access content related to childhood cancer on Facebook. Parents will be able to use the contact information displayed on the ad should they wish to contact the research team.

*Follow-up of Non-respondents*

Non-responders from both Stream A and B will be followed up two weeks after having been given or mailed the invitation to participate in the study, should a participant not return their questionnaire within the two weeks. A research officer will either telephone or send an SMS message to enquire whether they received the invitation package and assess whether they were interested in participating. Any person who cannot be reached after 3 failed attempts will be deemed non-contactable.

Diagram 1: Process detail for recruitment through hospital sites

The site co-ordinator will select potential participants from their hospital or unit database and use Powerchart to check eligibility.

These clinician approved names will be sent to the registry of Births Deaths and Marriages (BDM) in the relevant State in order to determine the vital status of each child, so as to avoid inappropriately contacting bereaved families.

Once the final list has been returned from BDM, the list will be sent for electronic matching software (MacroMatch) to cross-check the hospital’s list of survivors with the electronic white pages using Sensis Data Solutions.

**RECRUITMENT**

**(Through hospital sites):**

These lists of names will be sent to the potential participants’ oncologist/CNC who will remove from the list any families who they are aware do meet one any of the exclusion criteria.

### 7.2 Inclusion Criteria

Eligible parents must be able to:

* Give informed consent
* Read English. Culturally and linguistically diverse backgrounds cannot be included with the current resourcing for this study. It is hoped to include CALD in the next phase.
* 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
* Access a telephone or Skype for the intervention telephone sessions.
* Access a computer or tablet for the intervention web-based modules. To ensure equity of access, these can be provided to a family who do not have these devices and:
  + “Have a child who is a cancer survivor aged between 2 and 12 years who is considered “off treatment” (i.e. survivors who are in complete remission, and are either still on maintenance therapy, or have finished all forms of treatment)”

### 7.3 Exclusion Criteria

Parents will be excluded from the study if they:

* Have a child who is currently on active treatment, has relapsed, is in palliative care, or who is deceased.
* Have severe depression/suicidal ideation, as determined by clinical experience of the treating oncologist and or dietitian or CNC.
* Have a child who is still receiving supplementary feeding (i.e. Enteral or parental nutrition)
* Have a child who is meeting the Australian Dietary Guidelines (for their age) for fruits and vegetables, as measured by the 3 Pass 24 Hour Diet Recall.
* Are unable to access a telephone or the web based application.

### 7.4 Consent

Potential parents will be given a Participant Information Statement and Individual Consent form with a letter of invitation from the local site’s cancer centre medical director. The Participant will be invited to contact the Trial Co-ordinator for more information and/or any of the Principal Investigators if they have concerns – contact details will be on the Information sheet.

## 8. Participant Safety and Withdrawal

### 8.1 Risk Management and Safety

Parenting can be stressful and some parents may be particularly sensitive to issues around parenting. As this study will ask participant’s to reflect on some of their home environment practices and parental habits they might find it a difficult process. Both the web-based presentation and the interview session are suggestive in nature and uses non-judgmental language. Parents are not required or pressured to undertake any of the activities or actions. Only suggestions and support that have worked for other parents are provided. An example from the program of a communication with the parent is “That’s ok, we only provide you with suggestions that have worked for other families. You don’t have to try every suggestion.”

In order to ensure all parents have access to support from the commencement of the study, they will be informed both in writing (Section 7 of the participant information and consent form) and verbally (during the initial contact telephone call) of steps they can take if they feel distressed. Parents suffering distress will be advised to contact any of the Site Co-ordinators, the Trial Co-ordinator, their General Practitioner, Social Worker, the Co-ordinating Investigator or Principal Investigators. The Co-ordinating Investigator is Professor Claire Wakefield who is also a registered psychologist. Additionally, parents will be provided with the Lifeline 24 hour helpline number. The contact details for all these supports will be on the Participant Information Statement.

All applicants who opt-in to participate must also provide contact details for their GP or another health professional, who the research team will only contact if we are sufficiently concerned about the participant (this is explained to parents 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 parents’ confidentiality

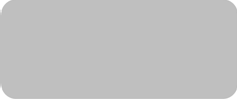
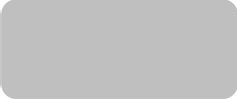
Parents will be asked to complete an emotional thermometer assessment at baseline and at the beginning of each weekly intervention session, via the telephone and at follow-up.

In line with previous studies conducted by our team, a participant will be deemed ‘distressed’ if they score above 7 on any of the thermometers. Furthermore, if a participant’s scores increase by three points from one session to the following session, they will also be deemed ‘distressed’. Any deterioration in mood or elevated distress reported on these measures will trigger the research officer to inquire about the parents’ current psychological supports, that is, if they are linked with a social worker, GP, or psychologist. If the individual does not have current mental health support, the research officer will advise the participant of Lifeline’s number and recommend they contact them while they inform the Trial Co-ordinator and the Co-ordinating Investigator, who will develop and document a management plan.

In the unlikely case that the participant appears at imminent risk of harm, the Trial coordinator will immediately contact the Co-ordinating Investigator and the research team to co-ordinate crisis care through the local site’s social worker or the parents’ GP or the local community mental health team. The research officer should encourage the participant to call the Lifeline crisis hotline or emergency services. Refer to Diagram 2.

As participation in this intervention is completely voluntary it is expected that families of young survivors, seeking additional support, will consent to receive information on how to improve survivor’s dietary intake and sedentary behaviours. As this information can reduce the risk of future mortality, the risk of possible discomfort to parents does not appear to outweigh the likely benefit of this research.

Diagram 2: Process for distressed parents participating



Participant ≥7 on Emotion

Thermometer

Participant ≥3 unit change on Emotion

Emotion Thermometer

Advise participant to call Lifeline or mental health worker

Advise Trial coordinator and/or Coordinating Investigator

Participant at imminent risk

Participant at risk

Coordinating investigator and team to co-ordinate crisis care

Trial coordinator, coordinating investigator and site investigator to develop and document a case management plan.



### 8.2 Adverse Event Reporting

It is unlikely that a participant will suffer an adverse event as a direct cause of this study’s intervention. Regardless of causal effect or not, should a participant suffer an AE or an SAE, the event will be reported to the CI for a determination to be made as to cause and a record of the event will be made in the Case Report File as per the SCHN Policy, *'Safety Reporting for Clinical Trials'* (Document No. 2012-9061).

### 8.3 Handling of Withdrawals

A participant is free to withdraw from the trial at any time, by either verbally advising or emailing the Site Investigator or by submission of a *Withdraw Consent Form*. At the time of withdrawal, if the participant requests that their data not be included in the analysis, this will be respected. Where the participant offers a reason for withdrawal the Site Investigator will record this. If participants wish to withdraw from the study, we will still ask them to continue with the study assessments, if they are able or willing to. The participant will be offered free psychological support services in connection with their social worker, GP or mental health case worker and in cases where this is taken up, the Co-ordinating Investigator will be advised. The participant will also be offered the option of support follow-up in 2 weeks.

### 8.4 Replacements

Where parents withdraw they will not be replaced as the sample size will have an in-built buffer to account for withdrawals.

## 9. Statistical Methods

### 9.1 Sample Size Estimation & Justification

Sample size was calculated for the primary outcome of feasibility, as measured by the average number of modules completed by participants allocated to the Reboot-Kids program. A group of equal size will be recruited to the waitlist arm in order to provide preliminary data on the efficacy outcomes of fruit and vegetable consumption to inform a potential phase III study.

### 9.2 Power Calculations

If the average rate of module completion in the Reboot-Kids program is 50% (2 out of 4 modules) or lower, the program may be considered to be infeasible. If the modules are assumed to be independent within and between participants,40 participants in the Reboot-Kids program represents a sample of 160 modules. If the true average rate of module completion is at least 60% (2.4 out of 4 modules), we will have greater than 80% power to reject the null hypothesis that the rate is 50% or lower, with a one-sided significance level of 5%.[70]

A study of 40 participants also allows estimation of the proportion of participants who complete more than two modules with a 95% confidence interval of maximum width ±15%, and provide 80% power at 5% one-sided significance to detect an increase in this proportion above 50% if the true rate is 70% or higher.

Pilot data showed that the mean time to completion of a module was 55 minutes, with a standard deviation of 10. With 40 participants, the confidence interval around the mean time would have a width of 6.2 minutes.

### 9.3 Statistical Methods To Be Undertaken

Participant demographic, family and clinical characteristics and study outcomes will be presented in randomised treatment groups and overall using standard descriptive statistics: frequencies and percentages for categorical variables and mean, standard deviation and range or median, interquartile range and range for continuous variables.

The primary analysis will include all participants allocated to the Reboot-Kids program. The average rate of module completion will be estimated and presented with a one-sided 95% confidence interval based on the binomial distribution. If this confidence interval includes a rate of 50%, we cannot reject the null hypothesis that the program is infeasible.

Summary statistics for the other feasibility outcomes will also be calculated for participants in the Reboot-Kids program, and presented with 95% confidence intervals as appropriate.

Based on pilot data, the planned sample size will not have sufficient power for a formal comparison of changes in fruit and vegetable consumption between the intervention and waitlist groups, and hence analysis of these outcomes will focus on descriptive statistics that will inform the design of a potential phase III study examining the efficacy of the Reboot-Kids program.

## 10. Storage of Blood and Tissue Samples

### 10.1 Details of where samples will be stored, and the type of consent for future use of samples

There will be no human tissue collected as part of this study.

# **11. Data Security & Handling**

### 11.1 Details of where records will be kept & How long will they be stored

Consent forms and re-identifiable hand-recorded 24hr dietary recall data and notes from telephone follow-up will be stored as hard copy files in a locked filing cabinet, in a locked office of the SCH. Consent forms collected at sites other than SCH will be scanned and forwarded to the Trial co-ordinator. Originals will be held by the local site for 6 months and along with confirmation of receipt of the scanned document, the original will be destroyed. The data from the hand recorded *Three-pass 24hr Dietary Recall* will be entered into **FoodWorks** version 8, Xyris Software (Australia) Pty Ltd by a qualified dietitian, with the FoodWorks data stored in a password protected file, on the hospital drive. The master participant file for participant identification, via the participant ID, will be password protected and kept on the SCH research drive. Data collected from use of the web-based program will be stored on the University of New South Wales Engineering Faculty’s server. It will be identified by the User ID. Data from the online questionnaires will be captured by Qualtrics Online Survey Service, supported by University of New South Wales (UNSW) IT. Data will be exported from Qualtrics online platform and downloaded to a secure Sydney Children's Hospital (SCH) server.

All the data held, will not be accessible to any individual other than the research team members. All data collected will be stored for a minimum of 15years or until the youngest participants turns 25 (whichever is the longest), in line with SCHN Clinical Trials Policy (Document number 2014-9108).

### 11.2 Confidentiality and Security

Master files for participant re-identification will be password protected and held on research-specific secured, hospital drives. Data and questionnaire files will also be stored on secure hospital drives and only accessible to the designated research team members. Any patient information emailed between contributing sites will be sent in a password protected file with the password conveyed by separate communication means. Hand written data collected from the *Three-pass 24hr Dietary Recall* and telephone sessions will be stored as hard copy files in a locked filing cabinet in offices of the BSU until scanned and stored digitally (original hard copies will then destroyed following Good Clinical Practice Guidelines). Consent forms will be stored digitally on a restricted UNSW server and password protected and destroyed following Good Clinical Practice Guidelines. The *Three-pass 24hr Dietary Recall* will have some identification to enable the research officer to contact and interview the participant. The research officer will have the participant’s first name, the survivor’s first name and a telephone number.

### 11.3 Ancillary data

Telephone sessions will be recorded on a hand held digital recording device. The data from the device will be downloaded as an MP3 or other suitable audio file and secured on the hospital research drive. The record on the hand held device will be deleted as soon as successfully downloaded. Downloads should take place within a week of recording.

# **12. Appendix**

**List of Attachments included:**

|  |  |  |
| --- | --- | --- |
| **Document Name** | **Version Number** | **Date (e.g., 18 January 2012)** |
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| **Document Name** | **Version Number** | **Date (e.g., 18 January 2012)** |
| CV Annabel Liang | 1 |  |
| Reboot RCT Online Participant Information/Registration form | 1 |  |
| Reboot web-based application (Beta version)  Online login https://rebootkids.ihealthe.org/  User: admin Password: admin123 |  |  |
| Reboot study video script |  |  |
| Reboot study text-message invitation script |  |  |

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