Participant Information Sheet – Parent/Guardian

Title
The alternate day fasting diet in adolescents with obesity: a randomised controlled trial

Short Title
Fast Track to Health

Principal Investigator
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The Children’s Hospital at Westmead

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Part 1: What does my child’s participation involve?

1. Introduction
Thank you for taking the time to read this Information Sheet. This is an invitation for your child to take part in the Fast Track to Health study (known as Fast Track) because he/she is above a healthy weight.

Please read this sheet carefully. Ask questions about anything you do not understand or want to know more about. Before deciding whether or not to allow your child to take part, you may want to talk to them about it or with a relative, friend or local doctor.

Participation in this study is voluntary. If you do not want your child to take part, they do not have to.

If you agree to have your child participate in this study, you will be asked to sign the Consent Form. By signing it you are telling us that you:

- Understand what you have read
- Consent for your child to take part in the study
- Consent for your child to have the tests and treatments that are described
- Consent to the use of your child’s personal and health information as described
You will be given a copy of this Information Sheet and Consent Form to keep.

2. What is the purpose of this study?
This study looks at the effect of two different dietary patterns on health and wellbeing, weight loss and risk factors for heart disease and diabetes in young people. The dietary patterns being compared are an intermittent fast style eating pattern called Modified Alternate Day Fasting, and a Reduced Calorie diet. We do not know which dietary pattern may be the most effective at reducing weight and improving risk factors for heart disease and diabetes. We aim to test this, and also to understand which aspects of each dietary pattern are acceptable to young people. It may be that both dietary patterns are effective. Finding this out is important so we can provide more choice to help treat young people with weight concerns in the future.

Approximately 180 participants are expected to take part in Fast Track. The study has been funded by the National Health and Medical Research Council (NHMRC) of Australia. It will take place at The Children’s Hospital at Westmead and at the Be Active Sleep Eat (BASE) facility at Monash University and Monash Children’s Hospital.

3. What does participation in this research involve and what does my child have to do?
If your child takes part in this study, they will be randomised to follow one of two dietary patterns. Randomisation is like tossing a coin to determine the dietary pattern. For both diets, a dietitian will provide you and your child with a meal plan, detailed information and support to help him/her follow their plan and ensure that it is nutritionally adequate. It is not possible for participants to choose the dietary pattern. Nor will there be the opportunity to change diets under the supervision of the investigators at the end of the study.

Modified Alternate Day Fasting dietary pattern
This is a very low energy diet that is followed for 3 days per week (approximately ¼ of normal daily energy needs or 600-700 calories/day) and then a standard healthy diet for 4 days per week.

Reduced Calorie dietary pattern
This is a moderately low energy diet with higher fibre foods and is consistent with the Australian Dietary Guidelines.

Who can participate in the study?
Young people aged 13-17 years who are well above a healthy weight are eligible to participate.

How long will the study go for?
The study is 12 months long and there will be about 10-13 visits with the study team.

Fast Track involves three phases:

Phase 1: Everyone will follow a Very Low Energy Diet to kick-start weight loss. This means having 3-4 meal replacements, such as shakes, soups or bars, plus a small meal each day for 4 weeks. Meal replacements will be provided free of charge in phase 1. This study will use Optifast meal replacements, which have been shown to be a safe and effective way of achieving weight loss. Optifast has been used for weight management in clinical practice for a number of years. If your child has a food allergy, it is still possible for them to complete Phase 1. Please let the study dietitian know, and they will provide appropriate guidance regarding allergen free alternatives.

Phase 2: Your child will be randomised to the Modified Alternate Day Fasting dietary pattern, or the Reduced Calorie dietary pattern.
Phase 3: Everyone will continue to follow their meal plans with support from the dietitian.

**Phase 1 - Jumpstart (weeks 0-4)**
- Everyone will follow a Very Low Energy Diet
- This involves having 3-4 meal replacements PLUS one low carbohydrate meal each day
- All meal replacements are provided for free
- Weekly visits with the dietitian

**Phase 2 - Intensive Intervention (weeks 5-16)**
- Young people will be given either a Modified Alternate Day Fasting plan OR Reduced Calorie plan
- Contact with the dietitian every 2-4 weeks

**Phase 3 - Step-down diet intervention (weeks 17-52)**
- Everybody continues to follow the eating plan they have been given
- Continued support from dietitian

For the first 4 weeks of the study, you will have weekly contact with the dietitian. Then every 3-4 weeks during phase 2, and every 2-3 months during phase 3. Some of these meetings may be via Skype, Facetime or on the phone. Most visits will take about 30 minutes. Meetings during weeks 1-4 will also include a small blood test using a finger prick meter to see how well participants are following the Very Low Energy Diet. If your child is following the Modified Alternate Day Fasting (MADF) plan, they will also be asked to provide a small blood sample via a finger prick meter at week 16 and week 52. This is to see how well participants have followed the MADF plan.

The face to face appointments at the beginning of the study, week 4, week 16 and week 52 will be longer. The first appointment will take about 3 and a half hours and the appointment at weeks 4, 16 and 52 will take about 3 hours. At these visits, your child’s height, weight and waist circumference will be measured. A number of other tests including a fasting blood test, blood pressure measurement, and body composition analysis, as well as a review with the dietitian will be completed. We will ask your child to answer questionnaires related to dietary intake, sleep, physical activity, and psycho-behavioural aspects including quality of life, self-esteem and eating behaviours. These will take about 35-45 minutes to complete. At the beginning of the study, week 12 and week 36 your child will be asked to complete a separate electronic diet recall questionnaire. This will ask participants about their food and drink intake in the previous 24 hours. The questionnaire is online and will take about 30 minutes to complete. It can be completed by your child at home in their own time on a computer, smart phone or iPad or before their appointment with the dietitian. The data entered into this questionnaire is not stored in Australia, however only the research team will be able to identify who has completed the questionnaire. That is, the data will be stored without your child’s name, but with a study number only.

Throughout the study, your child will also receive regular support from the dietitian via his/her choice of SMS text message, email or phone calls. Additionally, weekly text messages will be sent as part of the Fast Track Study. These have been created to promote participation and increase motivation during the study.
Your child will be asked to provide a mobile number (either your child’s or your number). Your child’s name and nominated mobile number will be stored on a secure online text messaging account held by The Children’s Hospital at Westmead. This account is routinely used by the hospital to communicate with patients. Only authorized members of the research team will be able to access this account. There will be an opportunity for your child to opt out of receiving these weekly messages at the beginning of the study if they choose.

Your child will also have the option of joining a private Facebook group. This has been created to provide useful information to your children, such as recipes and school holiday activities. However, it is not compulsory to join the Facebook group.

As the parent or carer, you will be asked to complete two questionnaires at:
   a. The start of the study, this will ask for general information, medical and family history
   b. 4 weeks, 16 weeks and 26 weeks into the study, these will ask how the diet is affecting aspects of your child’s and family’s quality of life.
Each questionnaire will take approximately 10 minutes to complete.

Screening assessment
Before your child is enrolled into the Fast Track study, they will be asked to complete a brief screening appointment. This is to ensure it is safe for your child to take part in the study. Screening should take about 20 minutes and may take place on the same day as your child’s first appointment. The following assessments will take place:

- **Screening Questionnaires**: Your child will be asked to answer questions related to eating behaviours (e.g. binge eating) and wellbeing (e.g. depression). These will take approximately 10 minutes to complete.
- **Blood Sugar Levels**: Your child will be asked to provide a small blood sample using a finger prick meter to measure their blood sugar levels.
- **Clinical Assessment**: All participants will be seen by a doctor before enrolment. If you have been referred to this study by a doctor, this assessment may have already taken place. Otherwise, one of the Fast Track study doctors will complete a brief medical assessment. This will take approximately 5-10 minutes.

During the study, your child will complete the following:

1. **Height weight and waist circumference measurements.**

2. **Body composition**: Will be measured by Dual energy X ray absorptiometry (DXA) and Bioelectric Impedance Analysis (BIA). The DXA scan is non-invasive, painless and measures the amount of body fat compared to muscle in the body. Two X ray beams are passed through the body to give an image of soft tissue on the computer. This involves your child lying still on a table for about 10 minutes while the scan is performed and exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 to 3 millisieverts (mSv) each year. The effective dose from this study is 0.006 mSv. At this dose, no harmful effects of radiation have been shown and the risk is minor. The BIA is like stepping on a weighing scale and it will not cause any discomfort.

3. **Blood test (fasting)**: Approximately 20mL of blood (about 4 teaspoons) from a vein in your child’s arm will be collected in the morning at baseline and weeks 16 and 52. This can be painful and bruising can occur. However, a local anaesthetic can be used to numb the area. Blood samples are being collected to test for markers related to overweight, type 2 diabetes and heart disease. An additional optional blood sample of 10mL (2 teaspoons) may be collected and stored for testing for
a range of metabolites and hormones relating to overweight at a later date. If you do not wish for this additional sample to be collected, please let the study co-ordinator know.

4. **Blood pressure**: Will be measured using a cuff placed around your child’s upper arm. The cuff expands when air is pumped into it and your child will feel some pressure on their arm for less than 20 seconds. The cuff automatically deflates after your child’s blood pressure has been measured.

5. **Dietitian review**: A dietitian will explain the diet at each visit, and answer any questions or issues you or your child may have. The dietitian will also review your child’s diet through a food history. This will involve asking what your child has eaten on the previous day.

6. **Questionnaires**: Your child will be asked to answer a number of questionnaires related to diet, sleep, physical activity, and psycho-behavioural aspects including quality of life, self-esteem and eating behaviours. The questionnaires can be filled out the on an iPad during visits or in their own time at home. They will take about 30 – 40 minutes to complete.

### Appointment Summary

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<tr>
<th></th>
<th>Start of study</th>
<th>Weeks 1-3</th>
<th>Week 4</th>
<th>Weeks 5-15</th>
<th>Week 16</th>
<th>Weeks 17-51</th>
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<td>3 hours</td>
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### Additional Costs

There are no additional costs associated with participating in this study, nor will you or your child be paid. During phase 1 of the study, your child will be given meal replacements **free of charge**. We will not provide food for the rest of the study.

If your child is following the **Modified Alternate Day Fasting** plan in Phase 2 and 3, they will have the option to use meal replacements on **fasting** days. The cost of these **will not** be covered. The cost per meal replacement is about $4.

### Reimbursement

You will be compensated for travel costs to and from the study site, with a parking voucher and petrol vouchers.

4. **What are the alternatives to participation?**
Your child does not have to participate in this study to receive help with their weight. If you do not want your child to take part in this study, or if they are not eligible, the study doctor or dietitian will talk with you and your child about other options or refer you to your child’s local GP for care.

5. What if I withdraw my child from this study?
If your child withdraws from the study, the study team will not collect additional personal information. However, information already collected will be kept to ensure the results of the study can be measured properly. You should be aware that data collected up to the time of withdrawal will form part of the study results.

6. What are the possible benefits of taking part?
The support your child receives from the dietitian may help him/her manage their weight and your child’s risk factors for heart disease and diabetes will improve.

7. What are the possible risks and disadvantages of taking part?
We do not expect any side effects or risks associated with this study. If the study makes your child feel upset, you or your child may stop the study at any time. You will be provided with information and contacts your child can talk to, if that is what they want to do.

Part 2: How is the study being conducted?

8. What will happen to information about your child?
Information collected from your child during the study (including their name, date of birth and your nominated email contact) will be stored in a secure web application called REDCap. This system is managed by the University of Sydney and will be used by researchers to analyse the information we collect during the study. Information about your child’s participation in this study may be noted in their health records. Group results may be discussed at conferences or published; however, no child will be identifiable. The study team will send you a newsletter with the overall results of the study when it has finished. However, due to the length of the study, it may be some time before the team is able to do this.

All information collected during the study that can identify your child will be treated confidential in accordance with Australian privacy laws and stored for a period of 15 years. This information will only be accessible to study investigators. After 15 years, computer files will be deleted and paper files will be shredded. The additional blood samples collected during the study will be securely stored at The Children’s Hospital at Westmead. Your child’s samples will be identified by name and date of birth. To protect your child’s privacy and confidentiality, only authorised research investigators will be able to access them. They will be kept for future studies on metabolites and hormones relating to overweight. Additional blood samples will be held for up to 10 years after which they will be destroyed.

The study will be conducted in accordance with recognised international quality standards, the International Conference on Harmonisation – Good Clinical Practice (ICH-GCP) guidelines. According to these guidelines, the accuracy of information recorded must be checked against original information (for example, your child’s medical records, laboratory test results etc.). By signing the Consent Form, you are giving your permission for the researchers to access your child’s medical records.

9. Who has reviewed this study?
This project has been approved by Sydney Children’s Hospitals Network Human Research Ethics Committee. If you have any concerns about the conduct of this study, please do not hesitate to contact the Executive Officer at the Ethics Committee (02 9845 3066) and quote approval number HREC/17/SCHN/164.
This project has also been authorised to be conducted at The Children’s Hospital at Westmead. If you have any concerns about the conduct of this study at this site please do not hesitate to contact the Research Governance Officer on (02) 9845 3011.

If you have any questions about your child’s diet or appointments, please do not hesitate to discuss them with the investigators listed below at:

<table>
<thead>
<tr>
<th>Contact</th>
<th>Phone Number</th>
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<tbody>
<tr>
<td>Ms Katharine Aldwell</td>
<td>(02) 9845 3146</td>
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<tr>
<td>Ms Hiba Jebeile</td>
<td>(02) 9845 3119</td>
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</tbody>
</table>

This Information Sheet is for you to keep. We will also give you a copy of the signed consent form.
Title: The alternate day fasting diet in adolescents with obesity: a randomised controlled trial

Short Title: Fast Track to Health

Principal Investigator: Prof Louise Baur, Weight Management Services, The Children’s Hospital at Westmead; The University of Sydney. 02 9845 1906

Associate Investigator(s):
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  - Ms Alicia Grunseit, 02 9845 2225
  - Ms Kerryn Chisholm, 02 9845 2225

Location: The Children’s Hospital at Westmead

Contact: Ms Katharine Aldwell
Email: schn-chw-fasttrack@health.nsw.gov.au
Ph: 0438 458 405 or 02 9845 3146

Declaration by Parent/Guardian

I have read and understand the Participant Information Sheet.

- I understand the purposes, procedures and risks of the study described in the Information Sheet.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to my child participating in this study as described and understand that I am free to withdraw them at any time during the study without affecting their future health care.
- I understand that I will be given a signed copy of this document to keep.

I consent for my child’s blood sample to be collected and stored for testing of metabolites and hormones relating to overweight at a later date □ Yes □ No
I would like to be informed of any clinically significant results identified from future analyses of my child’s blood sample □ Yes □ No

I consent for my child to receive weekly text messages and for my child’s name and nominated mobile number to be stored by the study team □ Yes □ No

Name of Child (please print): ______________________________

Signature of Child (if applicable): ______________________________

Name of Parent/Guardian (please print) ______________________________

Signature of Parent/Guardian: ___________________________ Date: ______________