Participant Information and Consent Form (Adolescents)

Title: Effects of exercise intensity in obese children and adolescents

Principal Investigator: Miss Katrin Dias
School of Human Movement Studies
The University of Queensland
Email: katrin.dias@uqconnect.edu.au
Phone: +61 7 3365 6983

Supervisor: Professor Jeff Coombes
School of Human Movement Studies
The University of Queensland
Email: jcoombes@uq.edu.au
Phone: + 61 7 3365 6767

Associate Investigator: Professor Peter Davies
Children's Nutrition Research Centre
School of Medicine
The University of Queensland
Email: ps.davies@uq.edu.au
Phone: +61 7 3365 5308

Associate Investigator: Miss Rachel Haddow
Children's Nutrition Research Centre
School of Medicine
The University of Queensland
Email: r.haddow@uq.edu.au
Phone: +61 7 3346 4937

This document has been designed to provide you with the information necessary for you to consider your son or daughter's participation in a research study. The study is investigating the effects of different intensities of exercise training on health outcomes. Please feel free to discuss your child's participation, or anything in this document you are unsure of, with your GP or specialist.

Background of Study:

Worldwide there is a growing epidemic of obesity, mainly due to an unhealthy diet and lack of exercise. Childhood obesity is associated with reduced levels of fitness, damage to blood vessels and decreased heart function. These can lead to a poor quality of life and increased risk of heart disease during adulthood.

In combination with diet interventions, exercise has been shown to be beneficial for obese individuals, however the most effective exercise prescription for children is not yet known.

Large amounts of research have shown that high intensity interval training is more beneficial than traditional continuous moderate-intensity exercise modes in adults. This study will investigate these types of training in children and adolescents.

We are specifically interested in the effects of the exercise training on the functions of the heart and blood vessels. We will be using non-invasive techniques (echocardiography) to measure these changes before, during and after the study. A small study has shown that these functions are improved with high intensity exercise in obese adolescents and this study will attempt to confirm these findings with a larger number of participants, including younger children.

Another measure we are taking is intra-abdominal fat. This refers to the fat positioned between the organs in the abdominal area. Previous research in obese women and older adults has shown that these internal fat levels decrease after a period of high intensity interval training, yet no such trials have been conducted on younger individuals.

Around 60% of obese children and adolescents present with at least one of the major cardiovascular risk factors (e.g. high blood pressure or cholesterol). We will also be measuring the effects of the exercise on changes in these risk factors.

This study will be completed with participants from both Norway and Australia, in the hope to further understand the implications of obesity at young ages. This will hopefully result in gathering more knowledge and information to help refine children's exercise prescription in the combat against childhood obesity.

Purpose of Study:

To investigate the effects of exercise intensity on intra-abdominal fat, heart and blood vessel function and cardiovascular disease risk factors in obese children and adolescents.

Access to Medical Records and Eligibility:

In order to determine eligibility of participants for inclusion in this study, medical records and data may be accessed by researchers. The research team will send a letter to your GP to request such data. This may include past medical history and recent test results such as blood analysis.

What does participation in this study involve for me and/or my child?

All participants will be required to attend a total of seventeen testing and nutrition sessions in the Exercise and Nutrition Clinic at The University of Queensland (UQ) St Lucia Campus. These sessions are additional to the twenty-four supervised exercise sessions required of participants in exercise groups. Free parking is provided outside the clinic for all study participants.

Testing visit one and two

After preliminary screening (through access of medical records) or asking you to complete a quick survey, you will be asked to attend a visit at the Exercise and Nutrition Clinic at UQ. Here, the research team will take you through details of the study, answer any questions you may have and sign the informed consent form. Some baseline measures will be taken at this first session. Participants will be required to attend three to four further testing sessions before being placed in a study group.

Participants will be randomly placed (similar to tossing a coin) in one of three groups. Two of these groups are exercise based, while one group will receive nutrition sessions only.

Testing visit three - six

Eight further testing visits will be required: four at twelve weeks and four at twelve months.

What will I and/or my child need to do during the testing visits?

During your testing visits at the School of Human Movements on the UQ St Lucia campus participants will undertake the following tests and measures over a four-hour period.

- A maximal treadmill test to determine fitness
- A resting echocardiogram (pictures of the heart using a small non-invasive probe (pen-like device) that is placed against the chest) followed by an exercising echocardiogram which will assess your child's heart response to exercise on a stationary bike
- The function of the participant's blood vessels will be measured using a small non-invasive probe (pen-like device) placed against the forearm.
- Measurement of body composition using an x-ray machine
- Have a small blood sample taken for measuring compounds that include risk factors for heart disease (e.g. cholesterol). The participant will receive an anaesthesia bandage one hour before blood collection to minimize discomfort.
- A magnetic resonance image (MRI) procedure will be performed on the participant to determine the amount of fat inside the abdominal cavity as well as determine heart function. A MRI scanner is a large magnet with a tunnel in the middle of the machine; this tunnel allows a person to lie within the magnet. To obtain a scan, the participant is required to lie still in the tunnel, on a bed within the magnet for approximately 25 minutes.
- Complete two questionnaires
- Blood pressure
- Waist circumference, height and weight

Other requirements

Participants will be given an accelerometer to wear for seven days and a diet diary to record diet for four days (one weekend day and three weekdays). This will be

required of participants at the start of the study, at twelve weeks and at twelve months.

Nutrition sessions

All participants (and a family member) will receive ten sessions with a dietitian. The dietitian will provide you with advice on healthy eating. These sessions will be every second week for three months and then once every two months for nine months. These sessions will last 20-30 minutes and will be scheduled on the same day as an exercise training session.

Sleep and Screen Time Surveys

All participants will be asked to fill out a survey asking questions about screen time, on 3 different occasions throughout the research period, during their nutrition sessions. One parent/guardian (who accompanies the participant to their nutrition session) will be asked to fill out a survey about the sleeping patterns of the participant. This will also occur on 3 separate occasions throughout the research period.

Exercise sessions

Participants placed in either of the two exercise groups will be required to exercise three times per week for twelve months. During the first three months, two of these sessions will be supervised in the Exercise and Nutrition Clinic at The University of Queensland (UQ) St Lucia Campus and the other exercise session per week can be done at home. Therefore participants allocated to an exercise group will have a total of twenty-four exercise visits to the clinic during the twelve months. This is additional to the seventeen testing sessions that are applicable to all three groups. During the next nine months all the exercise training will be done at home.

1. **The High Intensity Group – will complete 4x4 minute intervals in each training session**

Participants randomised to the high intensity interval training (HIIT) group perform a 10-minute warm up at 60% of maximal heart rate (HR_{max}). For the intervals, participants will either walk, run or cycle at 85-95% of their maximal heart rate at intervals of 4 x 4 minutes, with 3 minute active breaks (~60% of HR_{max}) between intervals. Exercise sessions will be followed by a 5 minute cool-down period. Total exercise time will be approximately 40 minutes.

2. **The Moderate Intensity Group – will complete continuous moderate intensity exercise**

Participants randomised to the moderate intensity exercise (MICT) group will walk, run or cycle continuously at 70% HR_{max} for approximately 44 minutes to equalize the energy expenditure performed by the HIIT. Exercise sessions will be followed by a 5 minute cool-down period. Total exercise time will be approximately 50 minutes.

3. **The Control Group – will not be prescribed any exercise, however they will attend nutrition sessions with an accredited dietician**

Participants randomised to an exercise group will be asked to fill out a training booklet for the one unsupervised session every week. Instructions on how to do this will be provided.

Risks involved with the study:

Exercise:

Obesity is associated with an increased risk of cardiovascular disease so there is a small risk of a cardiac event occurring during exercise. However because all participants will have undergone an echocardiogram and an exercise stress test any underlying cardiac abnormalities (the major causes of cardiac events during exercise) will almost certainly be detected prior to the commencement of training. Supervising Exercise Physiologists are well trained to recognise and prevent any early signs and symptoms of a cardiac event occurring.

Risk of injury:

As with any exercise, there is a risk of injury. Possible injuries may include muscular strains or sprains. All necessary measures will be taken to prevent and/or reduce chances of this occurring. This includes correct fitting of equipment (if using a stationary bike), use of harness for maximal treadmill test, and adequate warm up and cool down. If little to no exercise has been performed prior to participation in this study, muscle soreness is to be expected. However, this is a temporary discomfort and will disappear over a few days. Furthermore, this soreness will occur less as the exercise sessions continue.

Brachial artery dilation test:

The arm may feel slightly uncomfortable while the blood pressure cuff is inflated. The arm may develop a “pins and needles” feeling. This is similar to a “dead arm” that you may get when you lie on your arm. This feeling only lasts a short time.

Blood analysis:

Obtaining a sample may be more difficult in some people than others due to blood vessel size variation. Other risks may include excessive bleeding, fainting or light-headedness, hematoma or infection

Dual x-ray absorptiometry:

An x-ray scan is used to determine body composition and involves emission of a very small amount of radiation. However, approximate dosage received from one scan is around 0.001 mSv which equates to 3 hours of natural background radiation and the corresponding risk is extremely low.

Psychological discomfort:

Participants who are assigned to exercise groups and have previously participated in little to no exercise may encounter some psychological discomfort in their efforts to complete challenging physical tasks. Experienced exercise physiologists will monitor

all testing and exercise sessions and communication with participants, as well as assessment of physiological measures (such as heart rate and blood pressure) will ensure participants are as comfortable as possible.

Issues related to participation in the study:

If you think your child develops any side effects that are related to the study you should immediately contact Professor Jeff Coombes, 0417 166 358.

If your child has a study-related illness, the investigator and the study staff will make sure that they receive necessary treatment. The University of Queensland provides indemnity insurance coverage for all potential damage or loss that may be sustained as a result of negligence carried out in the course of performing this activity.

Benefits:

This study will answer a number of questions relating to the effects of high intensity exercise training in individuals who suffer from childhood obesity. By investigating the best type of exercise we will be able to better treat and improve the lifestyles of children and adolescents with obesity. If this study is shown to improve health it may be used as a model for standard exercise prescription for children and adolescents who are obese.

Confidentiality:

Personal information gained from the study such as fat mass, fitness and cardiovascular measures will be recorded but not easily identified to any one individual. Once all the measures are completed and the study outcome is verified, subject data will be de-identified and filed in a locked cabinet within the supervisor's office. To ensure longevity of the data, results will also be kept in a password locked computer with access granted only to the primary investigators. Data will be kept for a minimum of 5 years at the university before being destroyed.

Access to Results:

When the study has finished you will provided with all of your child's results. You will also be given the opportunity to ask any questions regarding the results and anything else to do with the study in a de-briefing session.

Reimbursement:

There is no money available to pay you for your involvement in the study.

Ethical considerations:

This study has been reviewed and approved by the Ethics Committee of The University of Queensland. Should you wish to discuss the study with someone not directly involved, in particular in relation to matters concerning study policies,

information about conduct of the study or your child's rights as a participant, or should you wish to make independent complaint, you can contact either:

The Ethics Officer

Research and Innovation Division

Cumbrae Stewart Building (72)

The University of Queensland

Phone (07) 3365 3924

Email: humanethics@research.uq.edu.au

If you wish to discuss this study with someone directly involved in this research you are free to discuss your participation with the principal investigator-

Miss Katrin Dias on +61 7 3365 6983

PARTICIPATION IS ENTIRELY VOLUNTARY AND PARTICIPANTS ARE FREE TO WITHDRAW FROM THIS STUDY AT ANY TIME WITHOUT PENALTY.

Consent Form – Parent/ Guardian

Title: Effects of exercise intensity in children and adolescents

The investigators of this study conform to the principles governing the ethical conduct of research, and will protect the safety, interests and well being of subjects at all times. This form, the information sheet has been given to you in the interest of your own protection. They contain an outline of procedures and possible risks involved.

Declaration by Parent/Guardian

1. I have read the Participant Information Sheet for this study and am aware of the risks involved.
2. I have had an opportunity to ask questions and I am satisfied with the answers I have received.
3. I given permission for the child's doctors, other health professionals, hospitals or laboratories to release information to The University of Queensland concerning the participant for the purpose of this research project. I understand that such information will remain confidential.
4. I acknowledge that participation in this study involves the child undergoing a series of tests of fitness, heart and blood vessel function, blood tests, body composition x-ray and magnetic resonance imaging for measuring intra abdominal fat. In addition he/she will be required to attend dietary counselling sessions and potentially exercise training sessions.
5. I freely agree to the child participating in this research project as described and understand that I am free to withdraw the child at any time during the research project without any prejudice from the University of Queensland.
6. I am aware of my responsibilities as the parent/guardian for the child and I understand that I will be assisting the child in meeting their responsibilities whilst they are participating in this study.
7. I understand that the data provided to the researchers is confidential and can be identifiable only to the primary investigators even if the study is published.
8. I understand that, if I decide to discontinue the child's study participation, the child and I may be asked to attend follow-up visits to allow collection of information regarding the participant's health status.
9. I understand that I will be given a signed copy of this document to keep.

I agree that my child can participate in the procedures outlined in the patient information sheet for the study: **Effects of exercise intensity in children and adolescents.**

Name of Child (please print) _____

Signature of Child _____ Date _____

Name of Parent/Guardian (please print) _____

Signature of Parent/Guardian _____ Date _____

Consent Form – Participant

Title: Effects of exercise intensity in children and adolescents

The research team will make sure you are safe at all times and will look after you. This information is for you to read and ask any questions before you sign.

Declaration by Participant

1. I have read the Participant Information Sheet for this study and am aware of all the tests involved. This includes fitness tests, tests of your heart and blood vessels, blood tests, an x-ray and a stomach scan.
2. I understand that I need to attend an exercise program, talk to a nutritionist about healthy eating.
3. I have asked my questions and they have been answered.
4. I want to participate in this project and know that I can stop participating at any time. I understand that if I do stop participating, I might be asked to come back for another testing session.

I agree that my child can participate in the procedures outlined in the patient information sheet for the study: **Effects of exercise intensity in children and adolescents.**

Name of Participant (please print) _____

Signature of Participant _____ Date _____