[i]**Study Tittle:** Physical activity promotion in children and adolescents with single ventricle physiology

Protocol Number: Pro00057730

Protocol Version Date: 24 Feb 2017

Principal Investigator:

Dr. Nee Khoo MBChB, FRACP
Cardiology/Pediatrics | University of Alberta
4C2.36 Stollery Children's Hospital
Edmonton, AB T6G 2C8
Email: khoo@ualberta.ca
Phone: 780-407-3964

Collaborators:

Dr. Andrew Mackie
Dr. Michael Stickland
Dr. Pierre Boulanger
Dr. Gwen Rempel
Dr. Jennifer Conway
Mr. Peter Wood
Dr. Michael Khoury

Research Coordinator:

Rae Foshaug

List of Abbreviations

BP	Blood pressure
CHD	Congenital Heart Disease
CPET	Cardio Pulmonary Exercise Testing
ECG	Electrocardiograph
SV	Single Ventricle

Background

Children with single ventricular (SV) heart were a uniformly fatal condition prior to descriptions of surgical palliation in 1980 that results in a Fontan circulation with single ventricle physiology. In the present era, 5-year survival is 75% in multicenter studies, with some centers including the Stollery Children's Hospital reporting higher survival. Although mortality remains a challenge for this population, the research focus has shifted towards optimizing management of late complications as well as improving patient physical and mental health-related quality of life issues. Children with SV have decreased exercise tolerance and the reduction is progressive through adolescence and into adulthood. Physical factors contributing to decreased exercise tolerance in the Fontan patient include cardiovascular inefficiencies and the loss of peripheral lean muscle mass and efficiency from deconditioning. Recently, Cordina et al. has shown that an intensive exercise regiment can improve muscle strength and mass, cardiac output and exercise capacity in adults with Fontan circulation. The majority of published outcomes from exercise training in patients with congenital heart disease (CHD) have resulted in increased measured exercise capacity with no apparent negative effect. Although the link between improved exercise capacity and improved patient quality of life remains controversial, participation in an aerobic exercise regimen leads to improved health-related quality of life.

Aside from physical limitations to their exercise capacity, Fontan patient self-confidence toward physical activity is low, as is exercise participation. Studies indicate that amongst youth with CHD, low self-confidence may be a more important predictor of participation than the severity of the disease. Parental overprotection is a common finding in children with CHD with a lasting impact on patient self-confidence and anxieties toward physical activity well into adulthood. Alteration of patient and parental perception and anxieties toward participation in physical activity may improve compliance to exercise training and encourage more positive patient perceptions toward healthy lifestyle habits, including frequent physical activity participation.

Recent technological advances in remote health assessment capabilities and telehealth systems have allowed the development of medically supervised home graduated physical training for adult cardiac patient rehabilitation. The application of such technologies to pediatric congenital heart patients has not been tested. In collaboration with Prof. Boulanger at the Advanced Man Machine Interface Laboratory at the University of Alberta, a custom pediatric remote bike ergometer (MedBike) was developed. This technology provides the medical supervisor with a live-feed of patient video/audio, electrocardiograph (ECG), blood pressure (BP) and blood oximetry signals while enabling remote determination of patient work load through the bike ergometer. The long-term goal is to use this technology to improve patient exercise capacity and to positively influence patient and parental perceptions of the patient's physical ability.

Study Design: Prospective Cohort Study

Study Procedures:

Dr. Michael Khoury is a member of potential participants clinical care team. He has been added to the study team. Whenever he is available, he will perform early contact by telephone just as the clinic nurse would as described in this section. However, since he is a member of both the study team and the clinical care team there is no need for an early contact letter or permission to contact letter. This process is in adherence with section 55 (section 34) of the Health Information Act. This role will be documented on the delegation log.

A clinic nurse will be put on the delegation log to cover Dr. Khoury during any absence. For that reason the early contact letter and permission to contact letter will be maintained on this ethics approval. Whenever the clinic nurse covers for Dr. Khoury's early contact role, the early contact letter and permission to contact letter will be used to adhere with section 55 (section 34) of the Health Information Act. This role will be documented on the delegation log. Potential participants will be identified by clinic nurses/physician who will be made aware of the inclusion criteria. Clinic nurses will ask potential participants if they would be willing to be approached by a study investigator. If so, a clinic nurse will contact a member of the study team. Recruitment will be achieved by approaching eligible patients in the clinic by a member of the study team that is not the most responsible physician (research coordinator) to prevent undue pressure.

Given that 10 healthy adult participants will be recruited from the study team for stage 1, we will take additional steps to prevent undue pressure. The study team will be been made aware eligibility. Interested persons have been asked to contact the study coordinator. The study coordinator will complete the consenting process. The study PI/team will be available for further discussion. It will be clearly stated that participation is completely voluntary and that the participant may withdraw consent at any point without it impacting their role/credit in this study, their employment or future medical care.

Study will be performed in two stages.

Stage 1 (pre study): To calibrate Medbike with reference standard cardiopulmonary exercise test (CPET), and to determine patient tolerance to maintenance of exercise intensity to varying workload in children with Fontan for planning of optimal exercise regimen.

Stage 1A: The program has two retrospective calibration samples already that will be used. Consent will not be obtained given that the data is anonymized and medical records/other identifying information will not be obtained. We will also recruit 10 healthy adult participants prospectively to calibrate the MedBike. VO2 and CPET will be set at a constant workload between 25W and 125W. Exercise will be repeated after 2 hours of rest on the Medbike with the same setting and VO2 measures. This visit will take 3 hours to complete.

Stage 1B: We will recruit 10 patients with Fontan physiology to undergo a baseline standard CPET. Consistent with standard guidelines (ATS/ACCP statement on cardiopulmonary exercise testing, Am J Respir Crit Care med 2003; 167:211-277), exercise workload will be increased progressively such that peak oxygen consumption is achieved in 8-12 minutes. Oxygen consumption, CO2 production, ventilation, arterial saturation (SpO2) and blood pressure will be monitored throughout each exercise test.

Stage 1B will be completed in two visits.

- Visit 1: Participants will perform a standard CPET and VO2 will be measured. This visit will take 1 hour to complete. From the results of this baseline CPET, a high-intensity interval training (HIIT) program will be designed for the subjects (described below).
- Visit 2: Participants will perform the designed HIIT program using the MedBike. This will consist of a 5-minute warm up at 30% of the subject's peak power output (based on results of the baseline CPET study). There will then be 7 bouts of high-intensity interval bursts. Each burst will consist of 2-minutes at 70-90% of peak power output and a 1-minute rest at 40-50% of peak power output. The subjects will then end with a 5-minute cool down at 30% peak power output. An exercise physiologist will be present and will make changes to the interval bursts based on the subject's perceived difficulty and workload. The program is 30-minutes in total. We anticipate

that Visit 2 will take approximately 1-hour to complete with set-up, orientation, and sizing of the MedBike to the subject. In the room with the subject will be an exercise physiologist/technician capable of troubleshooting issues with the MedBike and associated devices for data collection. There will also always be a supervising physician with training in Pediatric Advanced Life Support (PALS), who will continuously monitor the subject's vital signs and the subject's overall clinical status. A 5-10 minute questionnaire will be administered. The purpose of this short questionnaire is to learn a bit more about the participants experience using our video-game tele-medicine exercise bike, the MedBike.

Stage 1B will provide insights as to the feasibility and logistics regarding HIIT programs in the pediatric Fontan patients. This will provide critical information for the invesitgators as they transition to Stage 2.

Stage 2 (HIIT exercise program): We will evaluate the safety and efficacy of an 8-week, 3 times per week supervised HIIT exercise program in patients with SV physiology.

We aim to recruit 15 subjects with Fontan physiology for Stage 2. Fontan subjects who participated in Stage 1B will invited to continue to Stage 2. If they choose to continue with the HIIT exercise program, Visit 2 of Stage 1B will serve as their first session. Two MedBike exercise ergometers (one pediatric size and one adult size bike) will be housed in the University of Alberta Hospital Rehabilitation Unit with tele-health links to a remote workstation in a separate room. The patients will exercise in a room adjacent to the supervisor workstation with no direct visual or audio contact except for the video/audio feed. This is to help simulate the real-world applicability of having the MedBike at a remote location (such as the subject's home). The HIIT program described above will be applied. The exercise physiologist will again have the ability to modify the program based on the perceived difficulty or ease of it, noting changes that were made. Again, a medical personnel with training in Pediatric Advanced Life Support certification will be present supervising the sessions.

All eligible patients will undergo full cardio pulmonary exercise testing (CPET) and anthropometry assessment of lean muscle mass prior to exercise training and at the end of the training period. For subjects who participated in Stage 1 of the study, their Stage 1 CPET will serve as their initial study. We will document any adverse effects from the 240 training sessions during the study.

Exercise sessions will be based on standardized guidelines for aerobic exercise (ACSM's guidelines for exercise testing and prescription 2013). Heart rate, blood pressure, oxygen saturation and rating of perceived exertion will be monitored during each session.

Any adverse events such as profound desaturation (oxygen saturations fall of > 10% points for greater than 1 min, chest pain and ECG changes consistent with ischemia (ST depression or elevation in 2 consecutive leads), reducing blood pressure during exercise >20mmHg, development of tachyarrhythmia (atrial or ventricular) and any bike injury, will result in immediate stoppage of exercise regimen and evaluation by the onsite medical personal, if necessary pediatric cardiology consultation.

The impact of the exercise program on patient and parental perceptions of the patient's physical capacity will be evaluated using qualitative methods, as well as health related quality of life questionnaires. Patient and parents will be interviewed prior to, and at the end of, the exercise training as to their perceptions of the influence of physical activity in the presence of complex CHD.

Primary outcome: Exercise capacity assessed as the change in max VO2 pre- vs. post- completion of the HIIT exercise program. Hypothesis- we will observe an increased in VO2 max of 15%.

Secondary outcomes: a)Patient and parental perception of a CHD patient's safety and limitations while performing physical activity through a successful physical rehabilitation program; b) adverse events (safety profile of exercise program).

Inclusion Criteria:

Stage 1A – Retrospective calibration records, prospectively recruited healthy adults 18+

Stage 1B: SV patients with Fontan circulation age 10 - 18 years.

Stage 2 - SV patients with Fontan circulation age 10 - 18

Exclusion Criteria: Patients with cardiac arrhythmias, persistent low resting oxygen saturation of < 85%, severe ventricular dysfunction on the most recent clinical echocardiogram, patients with reports of chest pain on exertion, and those in whom their cardiologist has restricted their exercise for any reason.

Statistical Plan

Sample Size

Stage 1A:
Two retrospective samples will be included. Ten healthy adults will be recruited prospectively.

Stage 1B:
10 patients with Fontan physiology.

Stage 2:
To detect a clinically relevant change of 15% in max VO2 with power of 0.8, alpha of 0.05 and effect size of 1.08 with the an anticipated mean peak VO2 28.2 ml/kg/min +/- 6.1, the calculated sample size is 9. We will recruit 15 Fontan patients in anticipation of up to 30% failure to complete study exercise regimen.

Statistical Methods:

All data will be reported as median with ranges. Comparison between pre and post exercise training data will be tested using paired Wilcoxon signed rank sum. Significance is present when $p<0.05$.

The Research Team:

This research will be lead by Dr. Khoo, who is a proven investigator with 25 peer- reviewed publications in the last 5 years. The co-investigators include Dr. Conway, a heart failure specialist and Dr. Mackie, the team lead of the Division's Single Ventricle Outcomes Team that is supported by a WCHRI- funded fulltime research coordinator. This team is also supported by the Department of Pediatrics and AHS, with 3 funded Clinical Research Fellows attached to the Division. Our collaborators Prof. Boulanger, Dr. Stickland and Dr. Rempel are recognized experts in their respective fields of computing science, exercise physiology and qualitative research of family outcomes related to SV, all with extensive success in their research endeavor.

Anticipated Outcomes and Impact:

We anticipate improved patient CPET performance and a potential increase in measured total lean muscle mass after completing the exercise regimen. We do not anticipate any significant adverse effect from participation in the training sessions thus confirming its safety profile. As we have already performed prototype testing of the custom remote ergometer bike during design and assembly, we do not anticipate any major equipment performance issue or failure. The qualitative research findings will help explain our quantitative findings as we will elicit detailed descriptions of experiences, attitudes, and emotions related to physical activity in children and adolescents with life-limiting/complex CHD. We expect improved health-related quality of life scores in both patient and parental report post exercise training. The impact of a successful exercise training program in pediatrics has immediate benefits in promoting physical activities in children with SV which is currently reduced and likely to continue to decline with increasing age. Exercise training promotes self-confidence and perceived improvement in quality of life. It has the potential to promote a lifetime habit of regular physical activities that is likely to positively impact on a child's long-term cardiovascular and mental health.

Future direction and Knowledge Translation:

We will disseminate our findings through national and international presentations and publications in peer reviewed scientific journals. We will use our findings to support and guide the formation of a Pediatric Cardiac Exercise Rehabilitation Program in Alberta through establishing a guiding committee to engage stakeholders in the Western Canadian Children's Heart Network, nurses, cardiologists, general pediatricians, and organizations such as the Canadian Pediatric Cardiology Association, the Canadian Pediatric Society, and the Canadian Nurses Association, health care administrators and program and policy development personnel at the local and provincial levels. At a local level, we will use the results of the study to lobby charitable foundations, Alberta Health Services, other local funding agencies and government to support the establishment of an Edmonton Pediatric Cardiac Exercise Rehabilitation Program for immediate implementation. We will link with The Children's Heart Society to disseminate our results through their social media outlets and newsletter. In addition to the immediate clinical impact for patients with SV, the findings from the study will spawn subsequent research initiatives for promotion and improvement of physical fitness in other pediatric congenital heart lesions and non-cardiac pediatric conditions with an increased life-time burden of cardiovascular risk such as patients with diabetes, obesity and other chronic disease.

References:

1) Atallah J, Dinu IA, Joffe AR, Robertson CM, Sauve RS, Dyck JD, Ross DB, Rebeyka IM, Western Canadian Complex Pediatric Therapies Follow-Up group. Two-Year survival and mental and psychomotor outcomes after the Norwood procedure: an analysis of the modified Blalock-Taussig shunt and right ventricular-to-pulmonary artery shunt surgical eras. Circulation 2008; 118:1410-8
2) Möller P, Weitz M, Jensen KO, Dubowy KO, Furck AK, Scheewe J, Kramer HH, Uebing A. Exercise capacity of a contemporary cohort of children with hypoplastic left heart syndrome after staged palliation. Eur J Cardio-thoracic Surg 2009; 36: 980-985
3) Giardini A, Hager A, Pace Napoleone C, Pichhio FM, Natural history of exercise capacity after Fontan operation: a longitudinal study. Ann Thorac Surg 2008; 85: 818-821
4) Jenkins PC, Chinnock RE, Jenkins KJ, Mahle WT, Mulla N, Sharkey AM, Flanagan MF Decreased exercise performance with age in children with hypoplastic left heart syndrome. J Pediatr. 2008 Apr; 152: 507-12.
5) Goldberg DJ, Avitabile CM, McBride MG, Paridon SM. Exercise capacity in the Fontan circulation. Cardiol Young. 2013 Dec;23(6):824-30
6) Cordina RL, O'Meagher S, Karmali A, Rae CL, Liess C, Kemp GJ, Puranik R, Singh N, Celermajer DS. Resistance training improves cardiac output, exercise capacity and tolerance to positive airway pressure in Fontan physiology. Int J Cardiol. 2013 Sep 30;168(2):780-8
7) Duppen N, Takken T, Hopman MTE, ten Harkel ADJ, Dulfer K, Utens EMWJ, Helbing WA. Systematic review of the effects pf physical exercise training programmes in children and young adults with congenital heart disease. Int J Cardiol 2013; 168:1779-1787
8) Idorn L, Jensen AS, Juul K, Overgaard D, Nielsen NP, Sorensen K, Reimers JI, Sondergaard L. Quality of life and cognitive function in Fontan patients, a population-based study. Int J Cardiol 2013; 168: 3230-5
9) Dulfer K, Duppen N, Kuipers IM, Schokking M, van Domburg RT, Verhulst FC, Helbing WA, Utens EM. Aerobic exercise influences quality of life of children and youngsters with congenital heart disease: a randomized controlled trial. J Adolesc Health. 2014;55(1):65-72
10) Bar-Mor, G., Bar-Tal, Y., Krulik, T., & Zeevi, B. (2000). Self- efficacy and physical activity in adolescents with trivial, mild, or moderate congenital cardiac malformations. Cardiol Young 2000; 10: 561-566
11) Rebrouck Y, Mertens L. Physical performance and physical activity in grown-up congenital heart disease. Eur J Cardiovasc Prev Rehabil 2005; 12: 498-502
12) Moola F, Fusco C, Kirsh JA. The perceptions of caregivers towards physical activity and health in youth with congenital heart disease. Qual Health Res 2011;21:278
13) Ong L, Nolan RP, Irvine J, Kovacs AH. Parental overprotection and heart-focused anxiety in adults with congenital heart disease. Int J Behav Med 2011;18:260-267
14) Kraal JJ, Peek N, Marle MEvdA, Kemps HMC. Effects and cost of homebase training with telemonitoring guidance in low to moderate risk patients entering cardiac rehabilitation: The FIT@Home study. BMC Cardiovacular Disorders 2013; 13: 82
15) Hebert A, Mikkelsen UR, Thilen U, Idorn L, Jensen AS, Nagy E, Hanseus K, Sorensen KE, Sondergaard L. Bosentan improves exercise capacity in adolescents and adults after Fontan Operation: the TEMPO (Treatment with Endotheline Receptor Antagonist in Fontan Patients, a Randomized, Placebo-Controlled, Double Blind Study measuring Peak Oxygen Consumption) study. Circulation 2014; 130(23): 2021-2030

ii

ADULT CONSENT FORM

Title of Study: Physical Activity Promotion in Children and Adolescents with Single Ventricle Physiology

Principal Investigator: Dr. Nee Khoo, 780-407-3355

Research/Study Coordinator: Rae Foshaug, 780-407-7499

If you are the patient, please note that where it states 'child' it is referring to you rather than your parent/guardian or legal representative.

Why am I being asked to take part in this research study?

You and your child are being asked to participate in this research study because we would like to learn more about a group of heart conditions called single ventricle physiology (SV). We will be asking children with SV to participate. We will be including about 35 patients in this study.

Before you make a decision one of the researchers will go over this form with you. You are encouraged to ask questions if you feel anything needs to be made clearer. You will be given a copy of this form for your records.

What is the reason for doing the study?

We found that children with SV have lower exercise ability. But the way children and their parents feel about exercise might be a better predictor of the child's exercise ability rather than their physical limitations.

We have developed a graduated exercise program for children with SV. The purpose of this study is to test this exercise program and measure the feelings of the child and their parent toward exercise before and after this exercise program.

What will I be asked to do?

If you join this study you and your child will be asked to:

Your child has already participated in Stage 1B of the study which involved determining patient tolerance to varying exercise intensities and workloads. We are now inviting your child to participate in Stage 2. Stage 2 involves completing the graduated exercise program.

Stage 2:

Your child will complete a standard test for heart and lung function called a CPET while exercising on a bike once before they participate in the graduated exercise program and once after they complete the program. Each visit will take 1 hour to complete.

Only children with SV heart conditions will participate in a graduated exercise program on the MedBike. The MedBike is equipped with telehealth links to a remote and portable workstation in the University of Alberta Hospital. The MedBike will be installed in your home before your child begins the graduated exercise program. Members of the MedBike team at the University of Alberta will be responsible for installation, set-up, and training with regards to participant use of the MedBike. Installation, set-up, and training will occur at a time that is most convenient for you.

Your child will complete the graduated exercise program in the convenience of their home with tele-health link that includes a live video and audio feed to the supervisor workstation at the University of Alberta. Each

session will take 1 hour and your child will complete 3 sessions each week for 8 weeks. We ask that you be available to supervise your child while they are exercising on the MedBike.
You and your child will complete a quality of life questionnaire before and after the 8 week exercise program. This will take about 20 minutes to complete.

You and child will participate in an interview before and after the 8 week exercise program. These interviews will be voice recorded. This will take about 30 minutes of your time.

Give us permission to review your child's cardiology records for information about his/her heart. This includes the name of your child's heart condition, cardiac operations or procedures, cardiac medications, cardiology clinic notes, and inpatient notes for cardiac problems. We will NOT review medical records that are not related to your child's heart condition. All information will be kept strictly confidential.

What are the risks and discomforts?

The risks and discomforts for this study are minimal. Your child may feel tired from the exercise. Each exercise session will be supervised remotely by a member of the MedBike team, and exercise physiologist, and by medical personnel capable of reading ECG data to minimize the risk or injury. If you or your family has any concerns during this study, please feel free to contact the principal investigator, Dr. Nee Khoo, or the study coordinator, Rae Foshaug.

It is not possible to know all of the risks that may happen in a study, but the researchers have taken all reasonable safeguards to minimize any known risks to a study participant. If we find out anything new during the course of this research which may change your willingness to be in the study, we will tell you about these findings.

What are the benefits to me?

There are no direct benefits to you or your child from participating in this research study. However, your child's exercise capacity may improve. Also, you and your child's feelings towards exercise may improve. However, you may not get any benefit from being in this research study.

Do I have to take part in the study?

Being in this study is your choice. If you decide to be in the study, you can change your mind and stop being in the study at any time, and it will in no way affect the care or treatment that you are entitled to. If you decide to quit before the study is over, we will keep the data collected about you and your child up until that time unless you ask us not to, but we will not collect any further data.

Will I be paid to be in the research?

You will be provided with parking passes in order to attend both CPET testing sessions. Your child will receive a $25 gift card of his/her choice to Walmart, Chapters Indigo, or iTunes at the end of Stage 2 to acknowledge the time and commitment to participating in the exercise sessions.

Will my information be kept private?

During the study we will be collecting data about you and your child. We will do everything we can to make sure that this data is kept private. No data relating to this study that includes you or your child's name will be released outside of the researcher's office or published by the researchers. Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your information is kept private

The investigator or their study staff may need to look at your child's personal health records or at those kept by other health care providers that you may have seen in the past (i.e., your cardiologist). Any personal health information that we get from these records will be only what is needed for the study.

During research studies it is important that the data we get is accurate. For this reason your child's health data, including your name, may be looked at by people from:

the University of Alberta, HREB, and Health Canada.

By signing this Consent Form you are saying it is okay for the study team to collect, use and disclose information about your child from your personal health records as described above.

After the study is done, we will still need to securely store your child's health data that was collected as part of the study. At the University of Alberta, we keep data stored for a minimum of 5 years after the end of the study.

If you leave the study, we will not collect new health information about you, but we will need to keep the data that we have collected if it is already included in our analysis of the results of the study.

What if I have questions?

If you have any questions about the research now or later, please contact **Dr. Nee Khoo at 780-407-3355 or the study coordinator at 780-407-7499.**

If you have any questions regarding your rights as a research participant, you may contact the Health Research Ethics Board at 780-492-2615. This office has no affiliation with the study investigators.

ADULT CONSENT

Title of Study: Physical activity promotion in children and adolescents with single ventricle physiology

Principal Investigator(s):	Dr. Nee Khoo	Phone Number(s): 780-407-3355
Study Coordinator:	Rae Foshaug	Phone Number(s): 780-407-7499

1. Do you understand that your child has been asked to be in a research study? ☐ Yes ☐ No
2. Have you read and received a copy of the attached Information Sheet? ☐ Yes ☐ No
3. Do you understand the benefits and risks involved in your child taking part in this research study? ☐ Yes ☐ No
4. Have you had an opportunity to ask questions and discuss this study? ☐ Yes ☐ No
5. Do you understand that you and/or your child are free to leave the study at any time, without having to give a reason and without affecting your future medical care? ☐ Yes ☐ No
6. Has the issue of confidentiality been explained to you? ☐ Yes ☐ No
7. Do you understand who will have access to your child's study records, (including personally identifiable health information? ☐ Yes ☐ No

Stage 2:

8. I agree for my child _____to take part in this study. ☐ Yes ☐ No
9. Do you understand that YOU have been asked to be in a research study? ☐ Yes ☐ No
10. I _____agree to take part in this study. ☐ Yes ☐ No

_____	_____	_____
Signature	Printed Name	Date

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

_____	_____	_____
Signature of Designee	Printed Name of Designee	Date

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH PARTICIPANT

CHILD ASSENT FORM

Physical Activity Promotion in Children and Adolescents with Single Ventricle Physiology

Principal Investigator: Dr. Nee Khoo, 780-407-1103
Research Coordinator: Rae Foshaug, 780-407-7499

You and your parent(s) are being asked to take part in a research study because we would like your help to understand a heart condition. We are asking children with this heart condition to be part of this study.

The treatment for this heart condition has gotten a lot better. But children with this heart condition still have a lower ability to exercise. Also, the feelings of children and their parents about exercise needs to be better.

We have created an exercise program for children with this heart condition. We want to learn if this program can help children's ability to exercise. Also we want to understand the feelings of children and parents about exercise before and after the program.

What will you have to do? If you and your parent(s) agree then you will do the following:

You will come to the hospital for several visits.

Stage 1:
- You've already completed this stage of the study.

Stage 2:
- Only children with the heart condition will be asked to do stage 2.
- You'll visit the hospital twice so we can test your heart and lungs before and after you do the exercise program.
- In your home, you will exercise 3 times a week for one hour. This will happen for a total of 8 weeks.
- You and your parent will answer a questionnaire. This will take about 20 minutes to finish.
- You and your parent will be asked questions before and after the exercise program. We will take voice recordings of this visit. This will take about 30 minutes to finish.
- We will look at your chart for information about your heart.

Will it hurt? Some kids might feel tired from exercise but we will be there the whole time to make sure you are exercising safely to lower the risk of getting hurt. If you or your parents have any concerns you can contact Dr. Khoo at 780-407-1103 or Rae Foshaug at 780-407-7499.

Will it help? There is no direct benefit to you but you might get better at exercising and it may make you and your parents feel better about your exercise ability. Also, your help in this study might teach doctors, nurses and other children with your heart condition.

What will you get for being in the study?
If you decide to be in this study, we would like to thank you for your time with a $25 gift card of your choice to Walmart, Chapters Indigo, or iTunes at the end of Stage 2. Even if you choose to withdraw before the study is finished, you will still get a portion of this gift card.

Can you quit? You are allowed to say no if you don't want to take part in this study. If you say yes and then change your mind later, you can quit. No one will be frustrated with you if you decide you don't want to do this, or if you decide to stop part way through. You should tell your mom or dad, or the doctor or nurse that you want to quit.

Who will know? No one except your parents and the doctor will know you're taking part in the study unless you want to tell them. Your name and your chart won't be seen by anyone except the doctors and study staff during the study.

Your signature: We would like you to sign this form to show that you agree to take part. Your mom or dad will be asked to sign another form agreeing for you to take part in the study.

Do you have more questions? You can ask your mom or dad about anything you don't understand. You can also talk to Dr. Khoo. His phone number is 780-407-1103. Or you can talk to Rae Foshaug. Her phone number is 780-407-7499.

I agree to take part in this study.

_____	_____
<signature of research participant>	<date and time>
_____	_____
<signature of investigator/designee>	<date and time>