Lawson Clinical Research Services
Victoria Hospital
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Canada

Letter of Information

Title: **FOR HEALTH: A Family-ORiented Healthy Eating, Activity and Lifestyle Training with Hands-on experience – A Feasibility Trial**

Investigators: Principal Investigators: Dr. Dirk E. Bock, M.D.
Dr. Piotr Wilk, PhD

The pronouns 'you' and 'your' should be read as referring to the participant rather than the parent/guardian/next of kin who is signing the consent form for the participant.

The purpose of this letter is to provide you with the information you need to make an informed decision on whether or not to participate in this research study. This letter is for you to keep. It is important for you to understand why the study is being conducted and what it will involve. Please take the time to read this carefully and feel free to ask questions if anything is unclear or there are any words or phrases you do not understand.

Study Purpose

You are being invited to participate in a research study investigating the effects of a novel family-centred, community-based, multidisciplinary program for preschool children with weight issues and their families/caregivers.

The prevalence of childhood obesity in Canada has increased five-fold over the previous 15 years, with 26% of all Canadian children aged 2-17 years being overweight or obese and 9% being obese. In 2006, 12.4% of U.S. children aged 2-5 were obese. Significant health risks are linked to obesity in children and adults, such as heart disease, high blood pressure, high cholesterol, diabetes, liver and gall bladder disease, respiratory problems including asthma, orthopaedic issues, as well as some cancers. Current scientific evidence sees the family as critically important for the outcomes of overweight and obese preschool children, and caregivers are seen as "agents of change" in the treatment of their obese children. Thus, any successful obesity intervention for young children must target and engage the whole family, not just the child. Also, recent systematic reviews on the effectiveness of weight management interventions in children concluded that multidisciplinary behavioural interventions are safe in children aged 4 to 18 years and can be effective in reducing overweight. However, very little data on the effectiveness of weight management interventions for children under 7 is available.

Therefore, this pilot research project aims to address the significant knowledge gap on effective family-centred interventions for overweight and obese preschool children.

"FOR HEALTH" aims to support participating families in developing a healthy lifestyle within their daily routines by providing hands-on experiences to increase nutritional knowledge, physical activity levels, and self-esteem. Establishing a healthier lifestyle will decrease the rate of weight gain and lead to a healthier weight (assessed by calculating BMI z-score from measured height and weight), and reduce the risk of developing obesity-related diseases.

About 32 young children 2 years 9 months - 6 years of age with unhealthy weights (defined as a body mass index greater than or equal to the 85th percentile on their growth chart) will be enrolled in this study. The research will contribute to the creation of evidence-based strategies effective in addressing unhealthy weights and lifestyles in young children. The larger research goal on which this study is based on is to reduce the burden of childhood overweight and obesity and, by sharing the knowledge gained through this research, to enable other health care practitioners to implement effective lifestyle management strategies for young children with unhealthy weights and their families.

The FOR HEALTH program is funded through the Translational Research Grant provided by the Children's Health Research Institute and the Department of Paediatrics, Children's Hospital, London Health Sciences Centre, Western University, and through Lawson Health Research Institute, London, Ontario, Canada.

Participation

Participation in this study is voluntary. **You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your current or future care**. You have the right to be given all important information about your treatment, the study and what you will be asked to do. You should only agree to take part if you feel happy that you know enough about it. If during the course of this study new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the investigators.

You have been referred to this program because your weight has been identified to be at a level high enough to put you at risk for a variety of diseases linked to unhealthy weights, mainly those mentioned above. Research has shown that without sufficient lifestyle changes the majority of obese children (up to 77%) will become obese adults. Therefore, you have been referred to this program to help you and your family to acquire the tools needed to develop a healthier lifestyle and weight early in life in order to reduce the health risks mentioned above.

You are eligible to participate in this study if at least one parent/caregiver agrees to: attend all the program sessions with you, to complete the study questionnaires (see below) at the required time points, and to provide a *refundable* fee. The regular amount of the deposit is $50.00. *A reduced fee will be offered to families with financial restraints.* The fee will be refunded in full at the end of the program if at least 80% of the program sessions were attended, or in case any life event that would make it too difficult or impossible to continue with the intervention.

- If you have chronic conditions other than well-controlled asthma, e.g. of the lungs, heart, liver, kidney, immune system, or with regards to development, please let the research assistant know as this will likely exclude you from the study.

- Please report any over-the-counter or prescription medication you might be taking, since some medications might limit your ability to participate in the study. The investigators would have to determine if it is appropriate for you to participate in this study.
- If you are participating in any other weight-related treatment or any other research study at this time, please inform the study investigator right away, since this might exclude you from participating.

Study Procedure

The FOR HEALTH program offers healthy eating, activity and lifestyle counseling by a dietitian, and a fitness specialist, complemented by a psychologist or senior psychology student. A paediatrician will be available at some of the sessions, a social worker will be available if needed.-The program will be held at the **YMCA London, Centre Branch, 382 Waterloo Street**. Free parking and free child care will be available for participants. Participating families will also receive a free 6-month YMCA membership while enrolled in the study.

FOR HEALTH consists of an intensive 4-month phase with 6 weekly and 6 bi-weekly sessions (1 introduction, 9 group and 2 individual sessions). This is followed by a 2-month maintenance phase with one group session per month, and two follow-up visits 3 and 6 months after the maintenance phase (see session description below for details).

Initial introduction visit, will take approximately 60 minutes

• Program eligibility will be assessed, all questions you might have about the program will be discussed and the study consent form will be signed. This will make you a study participant.

• Your and your parent(s)/caregiver(s) height and weight will be taken.

• Parent(s)/caregiver(s) will be asked to complete two questionnaires (*Physical Activity, Quality of Life;* this will take approximately 15 minutes to complete), and to record all food items that you will consume over the following 3 days on a form (*3-day food record*).

Group Sessions (9 during months 1-4, 2 during months 5-6), 90 minutes each

Each group session will consist of three components: (1) a 60-minute group educational session for parents, and at the same time (2) 60-minutes of active playtime with various age-appropriate activities for children, mainly supervised and led by qualified YMCA staff.

Educational sessions will include skill training and practical activities revolving around healthy food choices (understanding food labels, meals planning and preparation, healthy snacks, portion size, etc.), healthy, active versus a sedentary lifestyle (screen time, active play time, family sports, fitness activities, etc.), and behavioural aspects (role models, eating habits, not using food as reward or punishment, parenting styles, etc.).

Guided, supervised physical activities will include swimming, ball and other active group games.

(3) For the last 30 minutes of each session parents will join their children for parent-child activities related to the previously discussed topics. Group sessions will also allow participants to meet other parents and share their experiences.

Individual Sessions (2 sessions during months 1-4, 45 min. each)
The two individual sessions will provide a platform to discuss individual- and family-specific questions, support needs, challenges in implementing a change towards a healthier lifestyle, as well as previously set and future goals.

Measurements and questionnaires
The above mentioned measurements (weight, height) and questionnaires will be repeated at 4 and 6 months, as well as at the 3- and 6-month follow-up (9 and 12 months after program start).

Risks and discomforts
There are no known risks associated with the healthy lifestyle intervention provided with this program. However, while children will be supervised by trained, experienced staff during active, age-appropriate playtime, a potential small risk for play-related accidents remains.

Benefits
Participating families will receive a free 6-month YMCA membership while enrolled in the study. While there is no guarantee that you may benefit further from participating in this study, there may be significant direct benefits for you and your family. You might acquire valuable knowledge around important aspects of leading a healthier lifestyle and how to implement lifestyle changes in your family. Also, you might achieve a healthier weight and an increase in quality of life. Furthermore, other family members (especially if also overweight or obese) might benefit as well from the knowledge and experience gained through the program.
In addition, your participation in and the results of this this research will contribute to the creation of evidence-based knowledge on strategies effective in addressing the overweight and obesity epidemic in young children and their families. By sharing the knowledge gained through this research, other health care practitioners may be enabled to implement effective lifestyle management strategies for young children with unhealthy weights and their families in their areas as well.

Alternatives to Study participation
An alternative to the intervention described above is not to participate in the study and to continue on just as you do now.

Confidentiality
Your confidentiality will be maintained except where release of information is required by law. By signing the Consent Form you agree that the referring physician may share with the study coordinator, and personnel involved in the study those parts of the information contained in your clinic records which might be relevant to the study, and that other information collected during the study may also be shared with those involved in conducting and analyzing the study, and with the referring physician.

Your confidentiality will be respected and protected. No information that discloses your identity will be released or published. Published reports or presentations will refer to grouped data and not to any identifiable individuals. However, the original signed research

consent form and the data which will follow will be included in your health record. All data collected for this study is kept secure, private and confidential as per current health information legislation and data protection practices. All data stored in the research database is made anonymous by removing personal identifiers to protect your identity. However, it is important to note that the researchers need to be able to contact you about program-related issues and results. In order for them to be able to do so, a code in the research database will allow the research team to look up your contact information in a second and especially protected database ("Master List"), which will be accessible only by the core team members, and which will be stored separately from the research database, and will also be subject to the same aforementioned legislation. Your study-related records will be kept for a period of 7 years.

Representatives of the Western University Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research.

On the consent form below you will be asked whether or not you agree to be contacted in the future on participating in any other future research project.

Contact for Further Information

Thank you for taking the time to read the information about this study. If you have any questions or concerns now or at any time about the study, your safety please ask your study doctor, the study staff, or the contact person indicated below.

FOR HEALTH Study coordinator: Wendy Madarasz, phone (519) 685-8500, ext. 56816.

E-Mail: ForHealth@lhsc.on.ca

Follow us on Facebook: https://www.facebook.com/pages/For-Health-Program/185319061619205?id=185319061619205&sk=info

If you have questions about your rights as a research participant please call Dr. David Hill, Scientific Director, c/o Lawson Health Research Institute at (519) 667-6649.

Consent Form

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Sponsor: Department of Paediatrics, Children's Hospital, London Health Sciences Centre, Western University, London, Ontario, Canada.

Investigators: Principal Investigators: - Dr. Dirk E. Bock, MD
- Piotr Wilk, PhD

I have read the Letter of Information, have had the nature of the study explained to me and I agree/I agree for my child to participate. All questions have been answered to my satisfaction. I will receive a copy of the Letter of Information and signed Consent Form.

_____
Patient's Name (printed)

_____ _____
Printed Name and Signature of Parent / Legal guardian Date

_____ _____
Person Obtaining Consent (printed name and signature) Date

Optional:
I agree that a member of the research team may contact me at a later date to ask if I may be interested to participate in a future research project (PLEASE INITIAL):

No_____ Yes_____