RESEARCH INFORMATION AND CONSENT FORM

Study title:	***Fit-for-Fertility Multicenter Randomized Controlled Trial***: Improving Reproductive, Maternal and Neonatal Outcomes in Obese and Infertile
Study number:	MP-31-2019-2802
Study funding	Canadian Institutes of health research Ferring Inc.
Principal investigator:	Jean-Patrice Baillargeon, Department of Medicine, Division of Endocrinology
Co-investigator(s):	Belina Carranza-Mamane, Department of Obstetrics and Gynecology Marie-Hélène Pesant, Department of Medicine, Division of Endocrinology

For information
From Monday through Friday, from 8 a.m. to 4 p. m.:

Dr. Jean-Patrice Baillargeon Endocrinologist	Tel.: 819-346-1110, ext. 14853 or dial "0" and ask the operator to call him on pager # 9401.
Ms. Farrah Jean-Denis, Research Coordinator	Tel.: 819-346-1110, ext. 12814 or dial "0" and ask the operator to call her on pager # 8869.

We are asking for your participation in a research study because you are currently consulting for a fertility problem. However, before agreeing to participate in this study, please take the time to carefully read, understand and consider the following information. If you accept to take part in this research study, you will be required to sign the consent form at the end of this document, and we will give you a signed copy for your records.

This information and consent form explains the purpose of this research project, its procedures, risks and inconveniences as well as the benefits, and who to contact if necessary. This document may contain words you do not understand. We invite you to ask any questions you may have to the study investigator or other people involved in

the research project and ask them to explain any words or information you do not understand.

NATURE AND OBJECTIVES OF THE RESEARCH STUDY

Obesity increases the risk of developing the polycystic ovary syndrome (PCOS), which is characterized by the absence of ovulation, but it is also associated with fertility problems even in women who ovulate. In addition, obesity reduces the effectiveness of assisted reproduction procedures, including fertility drug treatments. It has also been observed that women who become pregnant and who are obese have a higher risk of complications during pregnancy, delivery and for the newborn. However, it has been shown that a slight weight loss of about 5% of total weight can restore ovulation and improve pregnancy rates.

The purpose of this study is to evaluate the effects of a lifestyle management program on fertility, the course of pregnancy and childbirth, and the health of the newborn. We anticipate that a total of approximately 616 patients from 7 fertility clinics across Canada will participate. Of this total, approximately 53 patients will be from the *CIUSSS de l'Estrie – CHUS*.

STUDY PROCEDURES

If you accept to participate in the study, you will have 2 to 5 evaluation visits at the Research Centre of the CHUS (RC-CHUS) (Fleurimont) over a period of about 18 months.

Initial visit:

- Measurement of your height, weight, body fat percentage (with electrical bioimpedance analysis) and waistline. The use of an electrical bioimpedance analysis in standing position involves the transmission of a very light electrical current through the body tissues from the soles of the feet for a few seconds. This electrical current causes no pain and is safe for the human health.
- Measurement of your blood pressure and your resting heart rate.
- Blood sample (approximately one tablespoon, or 15 mL).
- Questionnaires to fill (approximately 1 ½ hour).
- Walking test (walking as fast as possible for 6 minutes, going back and forth for a distance of 20 meters).
- You will be given a Fitbit monitor. You will have to wear it continuously for a period of 7 consecutive days. Wearing the monitor will allow us to assess your level of physical activity and the quality of your sleep over a week.

The duration of this initial visit is approximately 2 ½ hours.

After this visit, you will be assigned randomly (like at the flip of a coin) in one of the 2 groups: the intervention group or the control group.

Intervention group:
In the days following the initial visit, a second appointment will be scheduled for a one-hour meeting with the nutritionist and kinesiologist (30 minutes with each) to begin the lifestyle modification program. You will have an individualized follow-up with these professionals every 6 weeks (30 minutes with each) at the RC-CHUS or the first 6 months, then every 8 weeks for the next 6 months and every 12 weeks for the last 6 months or until delivery. During these visits, you will also be asked to fill out a short questionnaire concerning the costs that these meetings imply for you. In order to offer you more support, the nutritionist or kinesiologist will also follow up with you by phone or email between your appointments at the RC-CHUS. With your agreement and solely for the purpose of evaluating the intervention proposed in this research project, the individual meetings of the intervention program will be recorded.

Participants in the intervention group will also have a group session once a week where different nutrition topics are discussed (8 topics, 45-minutes each), in addition to sessions where physical activities are practiced (8 different physical activities). You will be required to attend all 8 different sessions at the CHUS at Hotel-Dieu, within the first 6 months of your participation. For the remaining duration of the project, up to 18 months or as long as there are no contraindications during pregnancy, you are encouraged to continue your participation in the physical activity sessions, which last 45 minutes.

During the first 6 months of the program, you must agree to receive no fertility treatments, including fertility medications. After this period, if you are not pregnant, you will be seen by your fertility specialist and received required interventions according to standard fertility care.

Control group:
From the beginning of the project, you will consult your fertility specialist and receive standard fertility care.

For both groups:
<u>Evaluation visits at 6 months, 12 months and the final visit at 18 months if no pregnancy:</u>
You must be fasting for the 12 hours preceding those visits. During those visits you will go through the same tests as the initial visit. The visits should last about 2 hours.

If you become pregnant, 2 visits are planned:
<u>1st pregnancy visit (if no evaluation visit during the last month) and final pregnancy visit between 24 and 28 weeks of pregnancy:</u>
You must be fasting for the 12 hours preceding those visits. During those visits you will go through the same tests as the initial visit, except for the walk test that will not be done at the final pregnancy visit. The visits should last about 2 hours.

Please refer to the calendar at the end of the present document for a global view of the tests and procedures realized during the research project.

In addition to these visits, we will consult your personal health records to gather information regarding the fertility treatments used, the progress of your pregnancy, your delivery and your baby. In order to obtain general health information on your baby, we will access his or her personal health records. We will also be able to assess some of the components of your health-related costs based on your hospital visits as described in your record. In case we need information from your personal health records in a hospital other than the CHUS, we will have you sign an access request.

At the end of the project, some patients from the control and the intervention groups will be invited to participate in a focus group. These patients will be selected according to a list of criteria. The following topics will be discussed: satisfaction and perceptions of the care received and the impact of the program on quality of live. To ensure accurate data collection, the discussion will be recorded. All records will be destroyed after transcription.

PARTICIPANT'S COOPERATION

We ask your collaboration to inform us as soon as possible in case of a pregnancy. For the participants in the intervention group, we ask that you attend all individual appointments in the lifestyle program and the 8 group sessions, and to notify us as soon as possible if you are unable to attend one of your appointments.

RISKS AND INCONVENIENCES THAT MAY ARISE FROM THE SUBJECT'S PARTICIPATION IN THE RESEARCH STUDY

Your participation in this study involves minimal risk. The risks associated with having blood samples taken are: mild pain, dizziness, fainting, bruising, bleeding, and in rare cases, blood clots and infection.

For the participants in the intervention group, exercise demonstrations will be done under the supervision of a kinesiologist. The risk of injury is very low since the exercise will be done in a way to provide a gradual effort and respect your abilities. However, you may feel muscle aches the day after the activity, but these will be only be short-lived.

Travel is required for participation in the lifestyle program: approximately 10 meetings for the individual follow-ups and at least 8 group sessions.

RISKS OF INFORMATION DISCLOSURE

For the participants in the intervention group, you may feel some discomfort with the recording of the individual meetings with the kinesiologist and the nutritionist. In such a case, you will be free to ask that the recording be stopped.

For the participants in the control and intervention groups who will take part in the focus group, the facilitation will be designed and carried out in such a way as to make you as

comfortable as possible, in particular by reminding everyone their right to be different. Furthermore, you are in no obligation to answer any questions. If you feel uncomfortable, you may share it with the facilitator in private or in front of the group. The facilitator will take the time to listen to you and see what can reassure you.

BENEFITS RESULTING FROM YOUR PARTICIPATION IN THE RESEARCH STUDY

There may be a personal benefit to you from your participation in this research project, but we cannot guarantee it. Furthermore, the ensuing information from this research project could contribute to the advancement of knowledge in the field of infertility.

VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW

Your participation in this research project is voluntary. You are therefore free to refuse to participate. You may also withdraw from the project at any time, without giving any reason, by informing the research team.

Your decision not to participate in the study, or to withdraw this research project, will bear no consequences on your relationship with the research team.

Unless you inform us otherwise, if you withdraw or are withdrawn from the study, the information and material already collected during the study will still be stored, analysed or used to ensure scientific integrity of the study.

Any new knowledge acquired during the course of the project that could have an impact on your decision to continue participating in this research project will be communicated to you as soon as possible.

CONFIDENTIALITY

Collection - Reason for which personal information is requested.
During your participation in this research project, the study investigator and his/her study staff will collect and record information about you in a study file. They will only collect information required to meet the scientific goals of this study.

Collection – What personal information will be collected
The study file may include information from your medical chart regarding your past and present state of health, your lifestyle, as well as the results of tests, exams, and procedures that you will undergo during this research project. Your research file could also contain other information, such as your name, sex, date of birth and ethnic origin.

Data/information storage - Protection
All the information collected will remain confidential to the extent provided by law. You will only be identified by a code number. The key to the code linking your name to your study file will be kept by the doctor in charge of this research study.
To ensure your safety, your participation in this research study will be mentioned in your medical chart. Consequently, any person or company to whom you give access to your medical file will have access to that information.

Duration of data storage

The research data will be kept during 25 years by the investigator in charge of the research study.

Dissemination of results

Results of the research could be published or discussed during scientific meetings, but it will be impossible to identify you.

Right of access for monitoring and safety

For monitoring, control, protection and safety, your study file could be examined by persons mandated by the institution or the Research Ethics Board. These individuals observe confidentiality policies.

You have the right to access your study file in order to verify the information gathered, and to have it corrected if necessary.

COMPENSATION

As compensation for the costs incurred as a result of your participation in the research project, you will receive an amount of 20$ per evaluation visit. If you withdraw or are withdrawn from the study before its completion (or if your participation is ended), the compensation will be proportional to the duration of your participation.

Your parking fees related to your evaluation visits will be covered using a prepaid code that we will be given for each of your research evaluation visits. This does not include the visits associated to the intervention program for the participants in this group.

FUNDING

This project is funded mainly by the Canadian Institutes of Health Research, an agency of the Government of Canada responsible for investing in health research. This project also benefits of the support of private companies, but no amount is intended to cover salaries or advantages for the research team. All the financial support is dedicated to the realization of the study.

IN CASE OF PREJUDICE

Should you suffer any harm as a result of your participation in the research project, you will receive all the care and services required by your health condition.

By agreeing to participate in this research project, you do not waive any of your legal rights nor do you release the researcher responsible for this research project and the establishment of their civil and professional responsibilities

CONTACT PERSONS

If you have any questions or problems related to the research study or if you wish to withdraw from the research project, you can contact the physician in charge or a person from the research team. Please refer to the box on page 1.

If you have any questions about your rights as a participant in this research study or if you have any complaints, you can contact the *CIUSSS de l'Estrie – CHUS'* Office of Complaints and Quality of Services at plaintes.ciussse-chus@ssss.gouv.qc.ca or at the following number: 1-866-917-7903.

MONITORING OF ETHICAL ASPECTS OF THE STUDY

The Research Ethics Board of the *CIUSSS de l'Estrie – CHUS* approved this study and is in charge of its monitoring for the participating institutions of the Québec Health and Social Services Network.

If you wish to contact a member of that board, you can reach the Research Ethics Support Services of the *CIUSSS de l'Estrie - CHUS* at ethique.chus@ssss.gouv.qc.ca or at the following number: 819-346-1110, ext. 12856.

FOLLOW-UP STUDIES

In the event that future research projects following or similar to the current project are conducted, would you agree to be contacted by a member of the research team to offer you a new participation? Of course, during this call, you would be entirely free to accept or refuse to participate.

☐ YES ☐ NO

CONSENT

I have reviewed the *Information and Consent Form*. The research project and this information and consent form have been explained to me. My questions were answered and I was given the time to decide. Upon reflection, I consent to participate in this research study project under the conditions stated above.

I authorize the research team to access my medical records.

I accept that the individual meetings for the purpose of the intervention program will be recorded.

☐ YES ☐ NO

Participant's name (block letters)	*Participant's signature*	*Date*

I explained the research project and this Information and Consent Form to the participant and answered her questions.

Name of the person who obtained consent (block letters)	*Signature of the person who obtained consent*	*Date*

Version October 08, 2020

CALENDAR FOR RESEARCH AND INTERVENTION VISITS

Boxes marked with an X indicated tests and data collected at each visit:

	Initial visit	6-month visit	12-month visit	18-month visit (final visit)	Intervention sessions[2]	Weekly Group Workshops (8 weeks)[2]
Physical examination (weight, height, blood pressure and pulse)	x	x	x	x	x	
Blood test	x	x	x	x		
Questionnaires	x	x	x	x	x	x
Fitbit journal	x	x	x	x		
6-minutes walk test	x	x	x	x		
Nutritionist and kinesiologist					x	x

For women who become pregnant during the study:

	First pregnancy visit[1]	24-28 weeks (final visit)	Intervention sessions[2]
Physical examination (weight, height, blood pressure and heartrate)	x	x	x
Blood test	x	x	
Questionnaires	x	x	x
Fitbit journal	x	x	
6-minutes walk test	x		
Nutritionist and kinesiologist			x

[1] Only if the last research visit > 1 month.
[2] For participants in the intervention group only.