Fit-for-Fertility Multicenter Randomized Controlled Trial: Improving Reproductive, Maternal and Neonatal Outcomes in Obese and Infertile Women

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Background

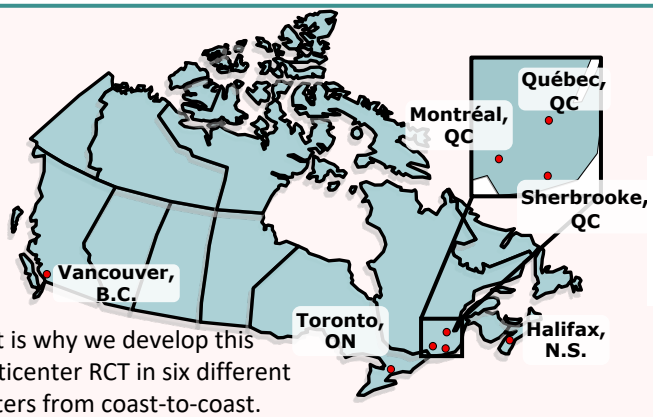
Infertility:
Inability to conceive after 12 months of regular and unprotected sexual intercourse.
It affects 15% of couples in Canada[1].

Obesity:
BMI ≥ 30 kg/m²

Obesity has been linked to:
- ↑ risk of ovulatory and menstrual disorders[1]
- ↑risk of polycystic ovary syndrome[1]
- ↓ efficiency and alter outcomes of medically assisted procreation (MAR)[1, 2]

Reversibility of the negative relation:
5-10% weight loss → ↑ woman's fertility, ↑ ovulatory frequency, ↑ pregnancy rates

Few trials done on this subject[3-6]



That is why we develop this multicenter RCT in six different centers from coast-to-coast.

Intervention

Group sessions provided by nutritionists (workshops) and kinesiologists (supervised practice of physical activity).
➢ 8 sessions in the 6 first months of the program.

Individual counseling by nutritionists and kinesiologists using motivational interview.
➢ Every 6, 8 or 12 weeks until 18 months or the end of the pregnancy.

Eligibility

Sample size: 616 women

Inclusion criterias
1. Infertility
2. Aged between 18 and 40 years; and
3. Obesity (BMI ≥ 30 kg/m² or 27 kg/m² for Asian and Latin American), or overweight for women with PCOS (BMI ≥ 27 kg/m²)

Exclusion criterias
1. Any uncontrolled medical or mental condition;
2. The only clinically indicated MAR procedure is IVF or insemination with donor;
3. Recurrent spontaneous abortions;
4. Previously diagnosed uncontrolled eating disorder or major depression;
5. A high level of depressive state;
6. Planning for or past history of bariatric surgery;
7. Engaging in another intensive lifestyle intervention;
8. Inability to understand the language of the center;
9. Poor adherence to research or evaluation.

Limitations

- Data collection done using self-reported questionnaires.
- Recall biaises due to self-reported questionnaires.
- Multicenter aspect may introduce diversity in the implementation.

Outcomes

1. Live birth rate at 24 months
2. Lifestyle and anthropometric measures
   - Fertility, pregnancy and neonatal outcomes
   - Cost-effectiveness
3. Qualitative data collected from focus groups of patients and professionals will also be analyzed.

Hypothesis

At the end of the study, we expect that the intervention will:

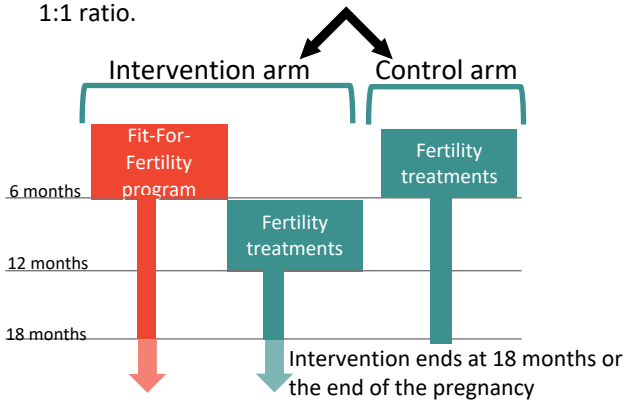
Improve the fertility of women with obesity and infertility that participated in the intervention group.

Contribute to the knowledge gaps in the effectiveness, costs and transferability of a lifestyle management program for women with obesity and infertility.

We hope that the trajectories and policies will be influenced by our results as we will inform decision-makers from Health Ministries across Canada about the outcomes of this pragmatic randomized controlled trial.

Methods/Design

Randomization by an independant statistician, stratified by center and PCOS status (yes/no). Participants will be randomized in two arms using 1:1 ratio.



Women from both groups will be evaluated every 6 months for various clinical measures.

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