

# The Fit-for-Fertility Multicenter Randomized-Controlled Trial: Improving Reproductive, Maternal and Neonatal Outcomes in Women with Obesity and Infertility

**Authors:** Gélinas M<sup>1,2</sup>, Belan M<sup>1,2</sup>, Jean-Denis F, Adamo K<sup>3</sup>, Bouzayen R<sup>4</sup>, Carranza B<sup>5</sup>, Chaillet N<sup>6</sup>, Fraser W<sup>5</sup>, Gallagher F<sup>7</sup>, Godbout A<sup>8</sup>, Greenblatt E<sup>9</sup>, Kamga-Ngande C<sup>10</sup>, Langlois MF<sup>1</sup>, Laredo S<sup>11</sup>, Lavoie K<sup>12</sup>, May-Ruchat S<sup>13</sup>, Morisset AS<sup>14</sup>, Pesant MH<sup>1</sup>, Poder T<sup>16</sup>, Sagle M<sup>16</sup>, Schuster T<sup>17</sup>, Taylor B<sup>18</sup>, Weilin K<sup>19</sup>, Baillargeon JP<sup>1,2</sup>.

## **Affiliations:**

<sup>1</sup>Department of Medicine, Division of Endocrinology, Université de Sherbrooke, Sherbrooke, Québec, Canada  
<sup>2</sup>Research Center of the Centre Hospitalier Universitaire de Sherbrooke, Sherbrooke, Québec, <sup>3</sup>School of Human Kinetics at the University of Ottawa, Ottawa, Ontario, Canada <sup>4</sup>Department of obstetrics and gynaecology of Dalhousie University, Halifax, Nova Scotia, Canada <sup>5</sup>Department of obstetrics and gynaecology of Université de Sherbrooke, Sherbrooke, Québec, Canada <sup>6</sup>Department of obstetrics and gynaecology of Université Laval, Québec, Canada <sup>7</sup>School of Nursing of Université de Sherbrooke, Sherbrooke, Québec, Canada <sup>8</sup>Department of medicine, division of endocrinology, Université de Montréal, Montréal, Québec, Canada <sup>9</sup>Mount Sinai Hospital Division of Reproductive Sciences, Toronto, Ontario, Canada <sup>10</sup>Department of obstetrics and gynaecology of Université de Montréal, Montréal, Québec, Canada <sup>11</sup>Department of Medicine, Division of Endocrinology, University of Toronto, Toronto, Ontario, Canada <sup>12</sup>Department of psychology, Université du Québec à Montréal, Montréal, Québec, Canada <sup>13</sup>Department of exercise science, Université du Québec à Trois-Rivières <sup>14</sup>Institute of Nutrition and Functional Foods, Université Laval, Quebec City, QC <sup>15</sup>Research center of the Institut universitaire de santé mentale de Montréal, Montréal, Québec, Canada <sup>16</sup>Pacific center of reproductiev medecine, Edmonton, Alberta, Canada <sup>17</sup>Department of Family Medicine, McGill University, Montréal, Que <sup>18</sup>Olive fertility center, Vancouver, British Columbia, Canada <sup>19</sup>Department of Medicine, Division of Endocrinology, Centre hospitalier universitaire Vaudois,

ClinicalTrials.gov: NCT03908099, registered on April 3<sup>rd</sup> 2019.

## **Abstract:**

### *Background:*

Moderate weight loss is recommended for women with obesity seeking medically assisted procreation (MAP) in order to improve their fertility and risks of complications during pregnancy. The general objective of this study is therefore to assess the clinical outcomes, cost-effectiveness and transferability of an interdisciplinary lifestyle intervention (the Fit-for-Fertility program) targeting women with obesity and infertility in the Canadian context.

### *Methods/Design:*

This multicenter randomized-controlled trial will recruit 616 women with infertility and obesity in seven centers. Women will be randomized either to 1) the Fit-for-Fertility program (experimental arm) alone for 6 months, and then in combination with fertility treatments if not pregnant; or 2) usual standard of care for infertility (control arm). The Fit-for-Fertility program combines individual meetings with a nutritionist and a kinesiologist, based on motivational communications, and weekly group sessions. The program is provided for 18 months or, if pregnant, up to the end of the pregnancy. The primary outcome

is the live-birth rate at 24 months. Secondary outcomes include lifestyle and anthropometric measures; fertility, pregnancy and neonatal outcomes; cost-effectiveness; and satisfaction of patients and professionals.

*Discussion:*

We expect that the Fit-for-Fertility program will increase the chance of infertility couples affected by obesity to give birth to a healthy child, and at lower costs than usual care.