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P-627 Pregnancy Rate and Outcomes Following a Randomized Controlled Three-component Lifestyle Intervention in Women with PCOS

A. Dietz de Loos¹, G. Jiskoot¹, Y. Louwers¹, A. Beerthuizen², J. Busschbach², J. Laven¹

¹Erasmus University Medical Center, Department of Obstetrics and Gynaecology - Division Of Reproductive Endocrinology and Infertility, Rotterdam, The Netherlands
²Erasmus University Medical Center, Department of Psychiatry - section Medical Psychology and Psychotherapy, Rotterdam, The Netherlands

Study question: What is the impact of a three-component lifestyle intervention on the pregnancy rate, time to pregnancy and pregnancy complications in women with polycystic ovary syndrome?

Summary answer: A non-significant positive trend in pregnancy outcomes was demonstrated in favor of the lifestyle intervention groups, in line with the weight loss achieved per group.

What is known already: PCOS (polycystic ovary syndrome) is associated with overweight and obesity. Women with PCOS and overweight or obesity...
present with more pronounced reproductive derangements. Moreover, when pregnant, pregnancy complications such as gestational diabetes, hypertensive disorders and preterm birth seem to be more prevalent in this population. The first line treatment for women with PCOS and overweight or obesity is a multi-component lifestyle intervention. Data on pregnancy outcomes after multi-component lifestyle interventions in women with PCOS are scarce.

**Study design, size, duration:** The present study is a one-year randomized controlled trial to investigate the effect of a three-component (cognitive behavioral therapy, healthy diet and physical therapy) lifestyle intervention (LSI) with or without Short Message Service (SMS) on pregnancy leading to live birth, pregnancy complications and outcomes within 24 months after the start of the lifestyle intervention compared to care as usual (CAU).

**Participants/materials, setting, methods:** Women diagnosed with PCOS according to the Rotterdam 2003 criteria and a BMI above 25 kg/m² were included. A total of 183 participants were randomly assigned to three groups: 1) three-component lifestyle intervention with SMS (SMS+); 2) three-component lifestyle intervention without SMS (SMS-); 3) care as usual (CAU). Encourage to lose weight autonomously (control group). Pregnancy and neonatal outcomes were collected from the Dutch Bureau of Statistics (CBS) combined with the Dutch Perinatal registry (Perined).

**Main results and the role of chance:** Within 24 months after the start of the intervention the pregnancy rate leading to live birth was 41.7% (25/60) within SMS+, 38.1% (24/63) within SMS- and 38.3% (23/60) within CAU. This was non-significant between the groups. Mean time to pregnancy for SMS+ was 18.3 months, 19.1 months for SMS- and 19.4 months for CAU (p = 0.775). Gestational diabetes (LSI: 8.2% vs CAU: 21.7%, p = 0.133), hypertensive disorders (LSI: 8.2% vs CAU: 13.0%, p = 0.673) and preterm birth (LSI: 12.2% vs CAU: 17.4%, p = 0.716) rates were all lower in the LSI groups (SMS+ and SMS- combined) compared to CAU.

**Limitations, reasons for caution:** Although significantly less than the LSI groups, even the CAU group achieved weight loss, which may give an underestimation of the effect of the lifestyle intervention with regard to pregnancy outcomes.

**Wider implications of the findings:** Weight loss overall seems to have a positive effect on pregnancy outcomes, and multi-component lifestyle interventions are needed to achieve weight loss.

**Trial registration number:** NTR2450