

# WOMB project: Women, their Offspring and iMproving lifestyle for Better cardiovascular health of Both

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## Background

WOMB project is a follow-up study of the Lifestyle study, a multicenter randomized controlled trial (RCT). This study was originally set up to investigate the effects and costs of a structured lifestyle program in overweight and obese subfertile couples to prevent unnecessary treatment and improve reproductive outcome.

Compared to prompt infertility treatment, lifestyle intervention did not increase the healthy singleton live birth rate, although it increased the chance of a spontaneous conception. Furthermore, live birth rate was higher in women who lost weight.

**Aim:** In WOMB project we will go beyond the original focus on pregnancy and live birth rates and assess the effects on later health of the women (WOMB women) and their offspring (WOMB kids).

## Preconceptional Intervention

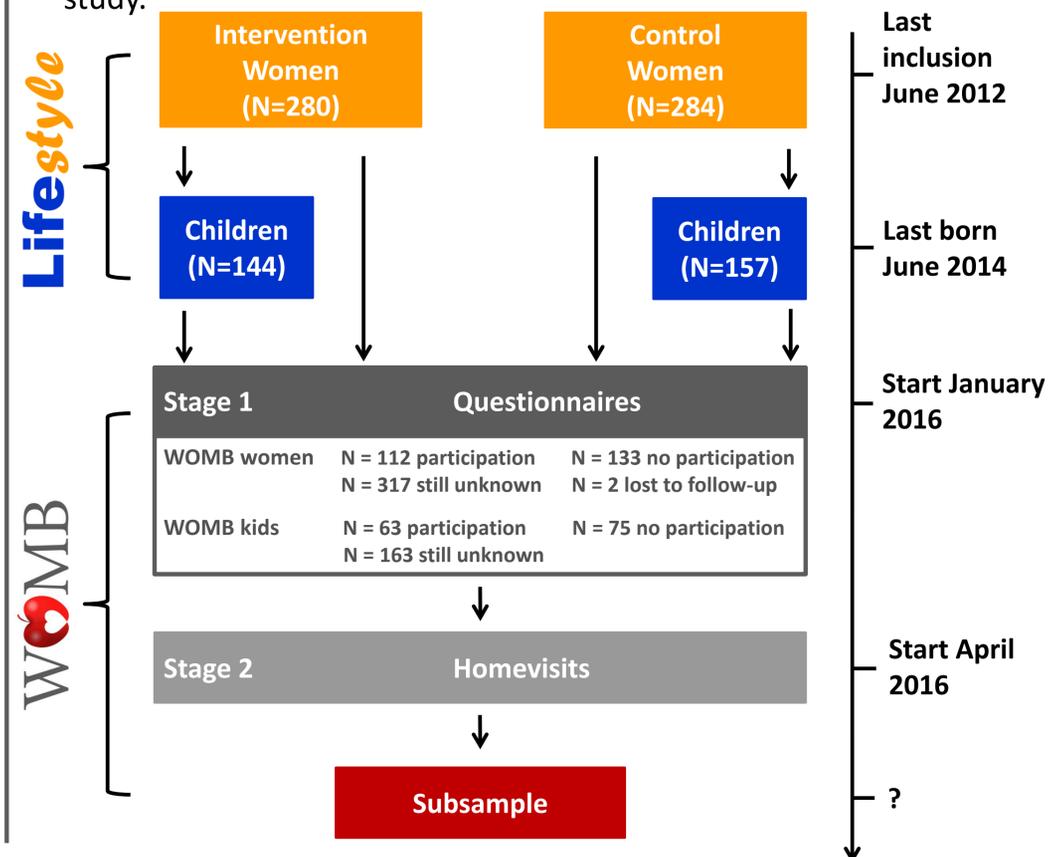
Standardized six-months structured lifestyle program program guided by trained nurse or dietician focused on:

- Change dietary pattern (reduction of  $\pm$  600 kcal/day)
- Stimulate physical activity of modest intensity (two to three times a week 30 minutes + 10.000 steps/day)
- Behavioral modification (individual counseling and formulation of goals)

## Study design

**WOMB women:** Women (N = 564) who participated in the Lifestyle study were subfertile and had a body mass index (BMI) between 29 kg/m<sup>2</sup> and 40 kg/m<sup>2</sup>. They were randomly allocated to the Lifestyle program preceding conventional fertility care or to immediate conventional fertility care.

**WOMB kids:** Population (N = 301) consists of all singletons conceived within the 24 months follow-up period of the Lifestyle study.



## Outcome measures

### WOMB women

**Primary outcome:** BMI 4 to 6 years after randomization

### Secondary outcomes:

- 1) Cardiovascular health
- 2) Reproductive health
- 3) Mental health
- 4) Physical activity
- 5) Dietary habits

### WOMB kids

**Primary outcome:** BMI at 3-5 years

### Secondary outcomes:

- 1) Cardiovascular health between 0 and 3-5 years
- 2) Growth pattern between 0 and 3-5 years
- 3) Development and behavior at 3-5 years
- 4) Lifestyle (diet, physical activity) at 3-5 years

## Analyses

To assess the effects of the intervention on later health, we will construct univariate linear regression models (**intention-to-treat and per-protocol**). In multivariate models we will adjust for relevant maternal and child characteristics.

Besides the RCT analyses also **dose-response relationships** between actual dietary intake and physical activity and the primary and secondary outcomes will be assessed.