

A four-armed randomised controlled demonstration trial of a multi-faceted dietary intervention and probiotic capsules in obese pregnant women in the Counties Manukau Health region

ACTRN12615000400561

Status	RECRUITING
Sponsor	University of Auckland
Enrollment	220 participants

Plain Language Summary

This study is testing two types of interventions for obese women in early pregnancy in South Auckland — a culturally appropriate healthy eating education program and a probiotic (beneficial bacteria) capsule. Obesity in pregnancy can increase the risk of complications, including gestational diabetes and large babies. The goal is to limit unhealthy weight gain during pregnancy and improve outcomes for mother and baby.

You may be eligible if:

- You are pregnant and between 12 weeks and 17 weeks and 6 days along
- Your pre-pregnancy BMI is 30 kg/m² or higher (obese)
- You are carrying a single baby
- You are able to provide written informed consent

You may NOT be eligible if:

- You have pre-existing diabetes or high HbA1c (50 mmol/mol or above) at your first antenatal visit
- You are currently taking probiotic supplements
- Your baby has been diagnosed with a known congenital abnormality
- You are on medications or have conditions that affect blood sugar
- You have had bariatric (weight loss) surgery
- You have severe pregnancy-related nausea and vomiting (hyperemesis)

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (4)

- Women with a BMI greater than or equal to 30 kg/m²,
- singleton pregnancy
- between 12 weeks 0 days and 17 weeks and 6 days of gestation
- able to provide informed written consent

Exclusion (6)

- pre-existing diabetes or HbA1c at booking ≥ 50 mmol/mol
- taking probiotic supplements
- known congenital abnormality
- medications or medical conditions which alter glucose metabolism
- bariatric surgery

... and 1 more (see full listing online)

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12615000400561>

Locations (1 total)

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [anzctr.org.au](https://www.anzctr.org.au). Generated by [ClinicalTrialsFinder.org](https://www.clinicaltrialsfinder.org).

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