2006 Cholesterol challenge Study

ACTRN12606000127505

Status	RECRUITING
Phase	Phase 4
Sponsor	CSIRO Human Nutrition
Enrollment	150 participants

Plain Language Summary

This study is testing whether a structured diet and lifestyle program can lower cholesterol and reduce weight, potentially reducing the need for cholesterol-lowering medications. Participants will follow a guided program and have their cholesterol, weight, and overall heart health tracked over the study period.

You may be eligible if:
- You are between 20 and 69 years old
- Your BMI is between 27 and 40 kg/m²
- Your blood cholesterol is between 5 and 8 mmol/L
- You are not currently taking cholesterol-lowering medication
- You are generally healthy with no metabolic, kidney, or cardiovascular disease
- Your liver enzyme levels are within normal range
- You can walk independently and exercise without pain
- You have no history of heart disease

You may NOT be eligible if:
- You take medications that affect fat metabolism
- You have a family history of high cholesterol (inherited hypercholesterolaemia)
- You have type 1 diabetes
- You drink heavily (more than 21 standard drinks/week for women, 28 for men)
- You are pregnant, breastfeeding, or planning to become pregnant
- You eat out frequently (more than 5 times per week) and cannot reduce this
- You are unable to prepare meals or follow a dietary plan

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

Key Eligibility Criteria

Inclusion (1)

• Body Mass Index (BMI) >27; <40 kg/m2 (this will be calculated for you) 2. Serum cholesterol 5 – 8 mmol/L as previously assessed or identified at screening. 3. Not currently taking lipid lowering medication. 4. Be available for the duration of the study 5. Apparently healthy: no reported current or previous metabolic diseases, gastrointestinal disorders, renal or cardiovascular disease. 6. Serum liver enzymes ALAT, ASAT, y-GT and bilirubin within normal reference range at screening. 7. Walk independently and able to perform physical activity without pain 8. No history of coronary artery disease or cardiac (heart) abnormalities.

Exclusion (1)

• Reported medical treatment that may affect lipid metabolism.12. Family history of hypercholesterolemia.13. Type 1 (self reported)14. High alcohol consumption > 21 standard drinks/week (female subjects) or > 28 standard drinks/week (male subjects).15. Reported lactating, pregnant or wish to become pregnant during the study. If the volunteer becomes pregnant during the trial they will be withdrawn. The use of sterol containing products during pregnancy is not a risk for mother or baby.16. The following items if taken need to be kept stable during the study: corticosteroids, diuretics, B-blockers, fish oil supplements17. Frequent dining out (> 5X/week and unable to cease)18. Inability to prepare meals or meet diet requirements19. Extended

absences due to travel or other commitments20. Person considered by the investigator to be unwilling, unlikely or unable to comprehend or comply with the study protocol and restrictions.

Locations (1 total)

Australia