

T4DM: *Improving outcomes for people with type 2 diabetes*

Results show the importance of weight loss (achieved by healthy eating and exercise) for preventing diabetes or even reversing newly diagnosed Type 2 diabetes. Treatment with testosterone had only a small but significant additional benefit.

EXPERTISE

CTC were the trial's coordinating and statistical centre, providing expertise in trial design and conduct. CTC led a program of media recruitment strategies, and managed an innovative, semi-automated centralized screening process. CTC is leading work on how body composition changes impact the testosterone effect and developing a clinical risk score.

Trial snapshot

Start date: 2013
End date: 2019



1,007
participants from six centres in Australian capital cities

Collaborators:

University of Adelaide, University of Western Australia, University of Melbourne, Sydney Local Health District, ANZAC Research Institute, Metro South Hospital and Health Service

BACKGROUND

Men who are overweight or obese frequently have low serum testosterone concentrations, which are associated with increased risk of type 2 diabetes.

STUDY OVERVIEW

T4DM aimed to determine whether testosterone treatment prevents progression to or reverses early type 2 diabetes, beyond the effects of a community-based lifestyle programme.

T4DM was a large, multi-centre, phase III, double-blind, placebo-controlled two-year trial of testosterone therapy combined with a lifestyle intervention (Weight Watchers®) compared to the lifestyle intervention alone for the prevention of Type 2 diabetes.

The trial was run through six centres in Australian capital cities. Recruitment to the study closed in February 2017 with 1007 participants enrolled. Follow-up was completed in May 2019.

KEY FINDINGS

- The proportion of men with diabetes at two years in the testosterone group was significantly lower than in the placebo group. Importantly, the effect of the testosterone did not depend on the blood concentration of testosterone measured when they first entered the study - that is, it did not depend on having a low or normal testosterone concentration.
- Results show the importance of weight loss (achieved by healthy eating and exercise) for preventing diabetes or even reversing newly diagnosed Type 2 diabetes. Treatment with testosterone had only a small but significant additional benefit.