

## The Diabetes Excess Weight Loss (DEWL) Trial: a randomised controlled trial of high-protein versus high-carbohydrate diets over 2 years in type 2 diabetes

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### Abstract

**Aims/hypothesis** To compare the effectiveness of low-fat high-protein and low-fat high-carbohydrate dietary advice on weight loss, using group-based interventions, among overweight people with type 2 diabetes.

**Electronic supplementary material** The online version of this article (doi:10.1007/s00125-012-2461-0) contains peer-reviewed but unedited supplementary material, which is available to authorised users.

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**Study design** Multicentre parallel (1:1) design, blinded randomised controlled trial.

**Methods** Individuals with type 2 diabetes aged 30–75 years and a BMI >27 kg/m<sup>2</sup> were randomised, by an independent statistician using sequentially numbered sealed envelopes, to be prescribed either a low-fat high-protein (30% of energy as protein, 40% as carbohydrate, 30% as fat) or a low-fat high-carbohydrate (15% of energy as protein, 55% as carbohydrate, 30% as fat) diet. Participants attended 18 group sessions over 12 months. Primary outcomes were change in weight and waist circumference assessed at baseline, 6 and 12 months. Secondary outcomes were body fatness, glycaemic control, lipid profile, blood pressure and renal function. A further assessment was undertaken 12 months after the intervention. Research assessors remained blinded to group allocation throughout. Intention-to-treat analysis was performed.

**Results** A total of 419 participants were enrolled (mean±SD age 58±9.5 years, BMI 36.6±6.5 kg/m<sup>2</sup> and HbA<sub>1c</sub> 8.1±1.2% (65 mmol/mol)). The study was completed by 70% (294/419). No differences between groups were found in change in weight or waist circumference during the intervention phase or the 12-month follow-up. Both groups had lost weight (2–3 kg,  $p<0.001$ ) and reduced their waist circumference (2–3 cm,  $p<0.001$ ) by 12 months and largely maintained this weight loss for the following 12 months. By 6 months, the difference in self-reported dietary protein between groups was small (1.1% total energy;  $p<0.001$ ). No significant differences between groups were found in secondary outcomes: body fatness, HbA<sub>1c</sub>, lipids, blood pressure and renal function. There were no important adverse effects.

**Conclusions/interpretation** In a 'real-world' setting, prescription of an energy-reduced low-fat diet, with either increased protein or carbohydrate, results in similar modest losses in weight and waist circumference over 2 years.