Transtheoretical model-based dietary interventions in primary care: a review of the evidence in diabetes

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CRD summary
The authors concluded that there was insufficient evidence to decide on the benefits of stage-based transtheoretical models of primary care dietary interventions for people with diabetes or an increased risk of diabetes. There were some limitations, such as a lack of defined primary outcomes, but overall the review was well conducted and the authors’ conclusions are likely to be reliable.

Authors’ objectives
To evaluate stage-based transtheoretical models of primary care dietary interventions in people with diabetes or an elevated risk of diabetes.

Searching
The Cochrane Central Register of Controlled Trials (CENTRAL), CINAHL, MEDLINE (from inception), PsycINFO, and EMBASE were searched for articles from 1983 to November 2005 unless otherwise stated. Some details of the search strategy were reported and only published studies were included. No language restrictions were applied, but articles that were not in English were excluded. Reference lists of included studies and reviews were also screened.

Study selection
Randomised controlled trials (RCTs) that compared a transtheoretical model-based dietary counseling intervention with a control intervention in adults diagnosed with type 2 diabetes or with an elevated risk of diabetes were eligible for inclusion; the risk factors for diabetes were specified. Transtheoretical models propose that people at different stages have differing counseling needs. Active interventions were defined as verbal advice, written materials, or computerised counseling. Trials had to be conducted in a primary care setting and have a minimum follow-up of six months.

The review assessed a variety of dietary-related outcomes including: total energy intake; total fat intake; saturated, monosaturated, and unsaturated fat intake; weight and various measures of weight; body mass index (BMI); systolic and diastolic blood pressure; blood pressure; waist circumference; and lipids. The distribution and movement across stages of change were assessed, as were the short-term outcomes (six to eight months) and long-term ones (12 to 24 months).

The included trials were mainly of patients with elevated cardiovascular risk factors; one trial included patients with an elevated BMI or waist-to-hip measurement. Most patients were middle-aged or older adults; some trials included mostly women. They evaluated different types, intensities, and providers of counseling and used different intensities within trials. Some focused on dietary counseling, while others included exercise and smoking counseling. All trials used usual care as the control, but the providers of this care varied. The duration of follow-up ranged from four to 24 months.

Three reviewers independently selected trials and resolved disagreements through discussion.

Assessment of study quality
Validity was assessed using a modified version of the published and validated Quality Assessment Tool for Quantitative Studies. This assessed selection bias, allocation bias, confounders, blinding, methods of data collection, withdrawals and drop-outs, analysis, and intervention integrity. A total quality score was calculated, for each trial, as the median score on the eight criteria.

An unstated number of reviewers independently assessed trial quality and resolved disagreements by consensus.

Data extraction
For each trial the statistical significance of treatment differences were reported for each outcome of interest.
Two reviewers assembled the data into tables, but no other details of the data extraction process were reported.

**Methods of synthesis**
The trials were combined in a narrative synthesis, in which the level of evidence for each outcome was graded, using a hierarchy of evidence, based on population characteristics, intervention, controls, and quality. The evidence was classified as strong, moderate, limited, conflicting, or no evidence from RCTs.

**Results of the review**
Five trials (reported in seven papers) were included (n=2,429) and their sample sizes ranged from 143 to 883. Two trials were considered to be of moderate quality and three were considered to be weak. The flaws included the potential for selection and allocation bias, incomplete reporting of trial details, and inadequate blinding. In most of the trials, not all patients automatically received dietary counselling.

**Short-term outcomes:** The authors stated that three trials assessed these outcomes, but there were two unique trials reported in three papers. There was limited evidence that transtheoretical models were more effective than usual care for: total energy intake, total fat intake, saturated fat intake, monounsaturated fat intake, weight, and movement across stage of change (one RCT). There was limited evidence of no difference between treatment and control for: unsaturated fat intake, diastolic and systolic blood pressure, waist circumference, and waist-to-hip measurement (one RCT).

**Long-term outcomes:** The authors stated that five trials assessed these outcomes, but there were four unique trials reported in five papers. There was limited evidence that transtheoretical models were more effective than usual care for: total fat intake (two RCTs), monounsaturated fat intake (one RCT), and systolic blood pressure (one RCT). There was limited evidence of no difference between treatment and control for: total energy intake (two RCTs), saturated fat intake, unsaturated fat intake, BMI (two RCTs), diastolic blood pressure, blood pressure, waist circumference, and waist-to-hip measurement (two RCTs), early weight loss and regain, and distribution across stage of change (unless otherwise stated, one RCT). There was moderate evidence of no treatment difference for weight and lipid values (three RCTs). The evidence for movement across stage of change was conflicting (three RCTs).

**Authors' conclusions**
There was insufficient data to draw conclusions on the benefits of stage-based transtheoretical models of primary care dietary interventions in people with diabetes or an increased risk of diabetes.

**CRD commentary**
The review question was clearly stated and the inclusion criteria were appropriately defined for the study design, intervention and participants. The inclusion criteria for outcomes were not defined and a wide variety of outcomes were assessed, which increased the possibility of random significant differences. Several relevant sources were searched, but no attempts were made to reduce publication and language bias. It was not clear why the last search date was 2005 when the review was not published until 2009. Methods were used to minimise reviewer errors and bias in trial selection and data extraction. Only RCTs were included, their validity was assessed, and the results were reported. In view of the differences between trials, a narrative synthesis that considered the level of evidence was appropriate.

There were some limitations, such as a lack of defined primary outcomes, but overall the review was well conducted and the authors’ conclusions are likely to be reliable.

**Implications of the review for practice and research**

**Practice:** The authors did not state any implications for practice.

**Research:** The authors stated that more high-quality trials of stage-based dietary counselling for diabetes patients were required. Future trials should use standardised protocols and assess both the effects of the intervention and the training and education given to providers. Critical appraisal tools should be developed to assess the interventions. Provider training should be assessed for multiple levels of behaviour change outcomes and the process of the counselling sessions should be evaluated. If the authors intend to publish further results, this should be stated in the initial publication.
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