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# Randomization to a low-carbohydrate diet advice improves health related quality of life compared with a low-fat diet at similar weight-loss in Type 2 diabetes mellitus<sup>☆,☆☆</sup>

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## ABSTRACT

**Aims:** To compare the effects on health-related quality of life (HRQoL) of a 2-year intervention with a low-fat diet (LFD) or a low-carbohydrate diet (LCD) based on four group-meetings to achieve compliance. To describe different aspects of taking part in the intervention following the LFD or LCD.

**Methods:** Prospective, randomized trial of 61 adults with Type 2 diabetes mellitus. The SF-36 questionnaire was used at baseline, 6, 12 and 24 months. Patients on LFD aimed for 55–60 energy percent (E%) and those on LCD for 20 E% from carbohydrates. The patients were interviewed about their experiences of the intervention.

**Results:** Mean body-mass-index was  $32.7 \pm 5.4$  kg/m<sup>2</sup> at baseline. Weight-loss did not differ between groups and was maximal at 6 months, LFD:  $-3.99 \pm 4.1$  kg, LCD:  $-4.31 \pm 3.6$  kg ( $p < 0.001$  within groups). There was an increase in the physical component score of SF-36 from 44.1 (10.0) to 46.7 (10.5) at 12 months in the LCD group ( $p < 0.009$ ) while no change occurred in the LFD group ( $p < 0.03$  between groups). At 12 months the physical function, bodily pain and general health scores improved within the LCD group ( $p$  values 0.042–0.009) while there was no change within the LFD group.

**Conclusions:** Weight-changes did not differ between the diet groups while improvements in HRQoL only occurred after one year during treatment with LCD. No changes of HRQoL occurred in the LFD group in spite of a similar reduction in body weight.

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Abbreviations: SF-36, Short Form 36; LCD, low-carbohydrate diet; LFD, low-fat diet; HRQoL, health-related quality of life; PCS, physical component score; MCS, mental component score.

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## 1. Introduction

Several studies have shown that both individuals with obesity [1–3] and Type 2 diabetes [4,5] have lowered health-related quality of life (HRQoL) in comparison with normal-weight individuals. There is also an inverse relationship between degree of obesity measured with BMI and HRQoL [6]. Both the physical component score (PCS) and mental component score (MCS) of the Short Form 36 (SF-36) show lower values in obesity, which indicates lower HRQoL, but the difference is more prominent in the PCS [7]. In the Australian Diabetes, Obesity and Lifestyle study [8] obesity at baseline was related to a decreased HRQoL, when followed during 5 years, and low HRQoL was also a predictor of weight gain during the follow-up period. While the scores are lower for patients who have developed diabetic complications [9], a lowered score can also be found in patients with newly diagnosed diabetes without any diabetes-related complications [10] which shows that it is not only a result of such complications. The relationship is dual as low scores on the SF-36 have been found to predict the risk of later development of Type 2 diabetes, cardiovascular disease and mortality [11]. In the study by Williams et al., low PCS on the SF-36 was related to further increase in cardiovascular mortality in patients with diabetes and a similar association was found for the MCS. There are thus interactions between HRQoL and both Type 2 diabetes and obesity.

Intentional weight-loss in both obesity and in Type 2 diabetes leads to improvements in cardiovascular risk factors, and has also been found to improve HRQoL [12,13]. In the SHIELD study improvement of quality of life was found in the participants with Type 2 diabetes who had lost weight during the last 12 months compared with respondents reporting weight gain [14]. Also weight reduction by gastric bypass, Roux-en-Y gastric bypass surgery, has been shown to improve HRQoL when followed up after 2 years postoperatively [15,16].

Some studies have prospectively compared the effect of different diet regimens in patients with Type 2 diabetes mellitus, with the main focus being change of body weight and of cardiovascular risk factors. There are very few reports on HRQoL in such comparative studies. In a study Brinkworth et al. compared the effects on Profile of Mood States, Beck Depression Inventory, and Spielberger State Anxiety Inventory score in overweight or obese participants randomized to low-fat or low-carbohydrate diet, and found greater improvement of psychological mood in the low fat group [17]. However, diabetes was an exclusion criterion in the study by Brinkworth et al.

We performed a randomized study confined to patients with Type 2 diabetes mellitus to compare glycaemic control and also of weight-loss and cardiovascular risk factors of a low-carbohydrate diet with that of a traditional low-fat diet. The results on body weight, glycaemic control and other cardiovascular risk factors have been previously reported [18]. In contrast to most previous studies, the patients randomized to the low-carbohydrate diet were not advised to avoid saturated fat. The interventions were based on four group meetings with duration of 60 min each for the first year and no further group meetings during the remaining 12 months were

given. Both reduction of energy intake and changes of the macronutrient composition might, by not well-known mechanisms, affect HRQoL [19]. In these further analyses of our study, the aim was to compare effects on health-related quality of life during a low-carbohydrate diet compared with a traditional low-fat diet in patients with Type 2 diabetes mellitus. A second aim was to describe different aspects from taking part of the intervention following the low-fat or low-carbohydrate diet.

## 2. Materials and methods

The methods have been described before [18]. In short patients with Type 2 diabetes were included in the study, which was conducted at two primary health care centres in southeast Sweden. The patients were randomized either to a low-carbohydrate diet or to a traditional low-fat diet, both with a caloric content of 1600 kcal for women or 1800 kcal for men. Randomization was not stratified, and was based on drawing blinded ballots. The low-carbohydrate diet had an energy content where 50 E% was fat, 20 E% carbohydrates and 30 E% protein. The low-fat diet had a nutrient composition that was similar to what is traditionally recommended for treatment of Type 2 diabetes in Sweden with 30 E% fat (less than 10 E% saturated fat), 55–60 E% carbohydrates and 10–15 E% protein. No information was given to change the level of physical activity of the participants.

Investigations of anthropometrics and laboratory tests were performed at baseline and at 6, 12 and 24 months, and patients were also asked to fill-out questionnaires on health-related quality of life (SF-36) at these time-points. Diet records were also performed at these 4 visits with one additional recording at 3 months.

The generic Short Form-36 (SF-36) questionnaire designed to measure individuals HRQoL in clinical practice, research, health policy evaluations and general population surveys was used. The 36 item questionnaire comprise eight health domains; physical functioning (PF, 10 items), role limitations due to physical problems (RP, 4 items), bodily pain (BP, 2 items), general health (GH, 5 items), vitality (VT, 4 items), social function (SF, 2 items), role limitations due to emotional problems (RE, 3 items), and mental health (MH, 5 items) and one single item rating health status over one year [20]. Each domain is separately scored and transformed in values between 0 and 100 where a higher score indicates higher HRQoL. The combined Physical component score (PCS) and Mental component score (MCS) were calculated. Both reliability and validity has been extensively evaluated under Swedish conditions [21]. No imputation of data was done in the case of a missing questionnaire.

The participants were interviewed following a semi-structured interview guide with eight questions regarding different aspects of taking part of the intervention following the low-fat or low-carbohydrate diet. The answers were written down by the interviewer during the interview and the text was analyzed using conventional content analysis following Hsieh and Shannon [22]. At 12 months, but not at other time points, they also answered 3 VAS-scales about appetite and satiety.

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