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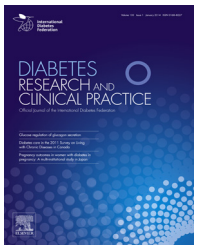

Randomization to a low-carbohydrate diet advice improves health related quality of life compared with a low-fat diet at similar weight-loss in Type 2 diabetes mellitus☆,☆☆

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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 ± 5.4 kg/m^2 at baseline. Weight-loss did not differ between groups and was maximal at 6 months, LFD: -3.99 ± 4.1 kg, LCD: -4.31 ± 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.

☆ Trial registry number: NCT01005498 at ClinicalTrials.gov.
☆☆ This study has been presented as an abstract at EASD 24 September 2013, Barcelona, Spain.

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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.

2.1. Statistics

Statistical calculations were done with PASW 20.0 software (SPSS Inc., Chicago, IL, USA). Linear correlations were calculated, as stated in the text. Comparisons within and between groups were done with Student's paired and unpaired 2-tailed *t*-test or in the case of questionnaires by Wilcoxon and Mann–Whitney tests. Mean (SD) is given unless otherwise stated. Statistical significance was considered to be present at the 5% level ($p \leq 0.05$). ANOVA with repeated measures was used for calculations of the changes during the total study duration.

2.2. Ethics

The study was approved by the Regional Ethics Committee of Linköping and performed in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participating subjects. The study was registered with trial number NCT01005498 at ClinicalTrials.gov.

3. Results

3.1. Total study population

The study population and the flow chart of the study have been previously described in detail [18]. In total 61 patients entered the study, and at baseline the SF-36 questionnaires were completed by 30 patients in the low-fat group and by 30 patients in the low-carbohydrate group. The questionnaire was answered by 22 patients at 6 months, 28 patients at 12 months and 29 patients at 24 months in the LFD group, while the corresponding figures for the LCD group were 23, 27 and 25, respectively.

The mean age in the low-fat group was 62.7 ± 11 years and there were 13 men and 18 women having a diabetes-duration of 8.8 ± 6.2 years. Corresponding figures for the low-carbohydrate group were 61.2 ± 9.5 years, 14 men and 16 women and a known diabetes-duration of 9.8 ± 5.5 years. Age, gender composition and known duration of diabetes did not differ between the groups (all $p > 0.05$).

Among the patients who answered the SF-36 questionnaire body weight in the LFD group was 98.8 ± 21.6 kg at baseline, 93.7 ± 19.3 kg at 6 months, 92.9 ± 18.7 kg at 12 months and 95.0 ± 21.5 kg at 24 months. Corresponding figures for the LCD group were 91.4 ± 18.9 kg, 84.8 ± 18.6 kg, 88.4 ± 19.3 kg and 85.2 ± 16.1 kg. There were no differences in weight reduction between these groups (at 6 months: LFD group: −4.5 ± 4.5 kg, LCD group: −4.5 ± 3.6 kg, $p = 0.99$, at 12 months: LFD group: −3.4 ± 4.3 kg, LCD group: −3.1 ± 4.1 kg, $p = 0.84$, at 24 months LFD group: −3.4 ± 4.5 kg, LCD group: −3.2 ± 4.3 kg, $p = 0.85$). Weight reduction within either group was significant between baseline and the same time points ($p < 0.001$).

The results of HRQoL are described in Table 1. There was no difference in baseline values in any of the domains between the low-fat and low carbohydrate groups. The low-carbohydrate showed improvements in the Physical function, Bodily Pain, General Health and Vitality domains of the SF-36 at 12 months compared to baseline (p values 0.042–0.009). In contrast to this, no change was observed in the low-fat group at any time during the study. The change from baseline to 12 months showed improvements in Bodily Pain and General Health in the low-carbohydrate group in comparison with the low-fat group ($p = 0.017$ and 0.022, respectively). At 12 months there was also an improvement in the combined Physical Component Score (PCS) in the low-carbohydrate group compared to baseline ($p = 0.009$) and also compared to the low-fat group ($p = 0.028$) (Fig. 1). We also recalculated the results based on the patients who were judged to be fully compliant with the prescribed diet by the criteria of intake of fat > 40 E% together with carbohydrates < 40 E% for the LCD and fat < 40 E% together with carbohydrates > 40 E% for the LFD, and this did not change the main results (data not shown).

In multiple linear regression analyses using change in PCS as dependent variable and changes in BMI and HbA1c as independent variables, the change in PCS remained associated with the change in BMI in the LFD group at 6 and 12 months ($\beta = -0.872$, $p = 0.001$, respectively $\beta = -0.679$, $p < 0.0005$) and the change in HbA1c in the LFD group at 6 months ($\beta = 0^{\cdot}496$, $p = 0.028$). There were no associations in changes in the LCD group in the same analyses. There were no associations between regain of body weight from 6 to 12 months and changes of SF-36 variables during the same period (data not shown). Changes in Mental Component Score (MCS) showed no associations to changes in BMI and HbA1c in linear regression analysis at 6 and 12 months, for both groups.

The VAS scale ''I will succeed/not succeed with this diet'' showed similar results 6.5 (2.6) in the low fat group and 7.4 (2.7) in the low carbohydrate group at 12 months ($p = 0.95$). The VAS scale ''I am often hungry/satisfied'' showed similar results 6.6 (2.7) in the low fat group and 7.2 (2.7) in the low carbohydrate group ($p = 0.81$). The VAS scale ''I have craving for food/not craving for food'' also showed similar results 6.4 (3.1) in the low fat group and 6.2 (3.4) in the low carbohydrate group ($p = 0.38$).

3.2. Interview

Each transcript was read from beginning to end several times and key words or phrases were highlighted and coded. Four categories emerged during this process that describes different aspects of taking part in the intervention.

3.3. Big and small changes

Participants in both diet-groups did not find the necessary changes very burdensome. In the low-fat group it was common to have been eating quite similar before taking part of the study. When eating out it could be hard to follow the diet strictly.

The participants that found the changes difficult were only found in the low carbohydrate-diet group, and potatoes were mentioned as hard to restrain from as well as change from low-fat to high fat products. Participants in this group also found it difficult to substitute pasta and potatoes as well as cookies and snacks within the diet provided. It was hard to eat so much fatty products.

Table 1 – SF-36 at baseline, 6, 12 and 24 months in 30 patients with Type 2 diabetes during treatment with low fat diet and in 30 patients with Type 2 diabetes during treatment with low carbohydrate diet (means (SD); Wilcoxon signed rank test and Mann–Whitney *U* test). The questionnaire was answered by 22 patients at 6 months, 28 patients at 12 months and 29 patients at 24 months in the low fat group while the corresponding figures for the low carbohydrate group were 23, 27 and 25, respectively.

SF-36 domains	Diet	baseline	6 months	*P* value 0–6	12 months	*P* value 0–12	24 months	*P* value 0–24	P-value between groups 0 and 6	P-value between groups 0 and 12	*P* value between groups 0 and 24	Friedman's 2-way analysis of variance
Physical	Low fat	79.8 (20.0)	84.5 (12.1)	0.65	83.8 (15.7)	0.10	81.6 (17.7)	0.62	0.48	0.27	0.38	0.49
function	Low carb	77.7 (19.3)	79.4 (15.6)	0.15	83.6 (18.2)	**0.009**	78.7 (19.7)	0.12				**0.004**
Role	Low fat	78.1 (35.9)	84.5 (26.8)	0.55	87.5 (27.6)	0.34	67.8 (42.7)	0.13	0.68	0.89	0.87	**0.042**
Physical	Low carb	79.5 (29.7)	70.5 (39.1)	0.78	78.7 (33.0)	0.64	66.3 (43.7)	0.13				0.60
Bodily Pain	Low fat	69.3 (27.1)	66.2 (22.3)	0.49	65.7 (26.5)	0.59	61.6 (28.34)	0.11	0.85	**0.017**	0.12	0.12
	Low carb	61.0 (23.0)	61.0 (25.0)	0.95	71.4 (22.1)	**0.021**	60.6 (25.6)	0.72				**0.031**
General	Low fat	62.5 (21.1)	67.7 (18.2)	0.41	63.3 (18.4)	0.46	66.1 (23.4)	0.51	0.85	**0.022**	0.88	0.40
Health	Low carb	63.2 (22.3)	63.5 (25.6)	0.29	70.7 (22.7)	**0.031**	63.8 (26.7)	0.55				**0.031**
Vitality	Low fat	65.0 (20.3)	71.0 (17.4)	0.66	66.9 (22.9)	0.83	67.8 (23.9)	0.49	0.39	0.12	0.75	0.87
	Low carb	62.2 (19.9)	65.5 (22.4)	0.16	69.8 (19.3)	**0.042**	61.2 (23.9)	0.92				0.09
Social	Low fat	91.7 (14.8)	93.2 (18.0)	0.57	93.8 (15.4)	0.54	88.3 (20.3)	0.18	0.94	0.96	0.69	0.73
Function	Low carb	90.8 (15.7)	87.0 (23.7)	0.72	92.1 (15.2)	0.34	88.0 (19.9)	0.39				0.41
Role	Low fat	83.3 (33.6)	90.5 (26.1)	0.71	91.7 (26.6)	0.10	85.1 (34.0)	0.86	0.50	0.67	0.73	0.67
Emotional	Low carb	90.8 (17.6)	78.8 (35.0)	0.20	91.4 (21.9)	0.73	93.9 (19.6)	0.91				0.06
Mental	Low fat	83.3 (15.8)	84.5(17.0)	0.80	83.7 (17.4)	0.57	82.3 (16.9)	0.78	0.40	0.93	0.59	0.14
Health	Low carb	80.1 (13.4)	81.6 (17.)	0.28	83.2 (10.6)	0.54	81.0 (10.7)	0.78				0.35
PCS	Low fat	45.3 (10.5)	45.8 (8.2)	0.88	45.9 (8.9)	0.86	43.6 (10.5)	0.17	0.23	**0.028**	0.44	0.35
	Low carb	44.1 (10.0)	43.2 (12.4)	0.10	46.7 (10.5)	**0.009**	41.4 (14.0)	0.77				**0.011**
MCS	Low fat	51.7 (9.8)	53.5 (10.1)	0.50	52.8 (9.5)	0.64	52.0 (9.4)	0.91	0.43	0.64	0.58	0.28
	Low carb	51.7 (7.2)	50.0 (13.0)	0.33	52.6 (5.3)	0.23	53.1 (4.2)	0.48				0.66

Bold values denotes significance ($p < 0.05$). If you find this helpful, please, include this in the legend to the figure.

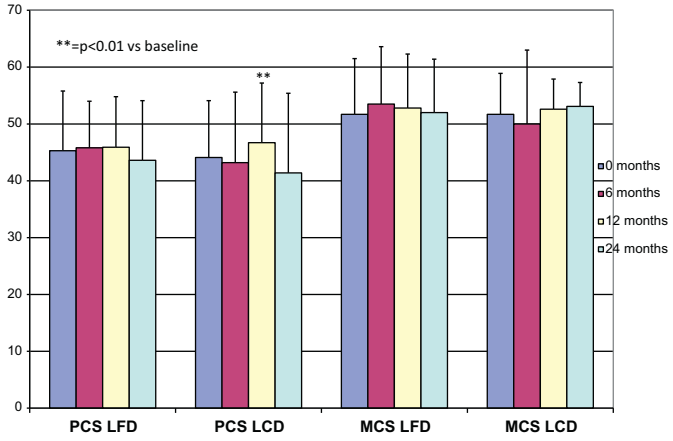

Fig. 1 – Physical component score (PCS) and mental component score (MCS) of SF-36 at baseline, 6, 12 and 24 months in 30 patients with Type 2 diabetes during treatment with low fat diet (LFD) and in 30 patients with Type 2 diabetes during treatment with low carbohydrate diet (LCD) (means (SD); Wilcoxon signed rank test and Mann–Whitney *U* test). The questionnaire was answered by 22 patients at 6 months, 28 patients at 12 months and 29 patients at 24 months in the low fat group while the corresponding figures for the low carbohydrate group were 23, 27 and 25, respectively.

Participants in both diet-groups found the recipes provided to be ''dull'' and wanted a more varied food selection. They also felt guilty when not strictly following the diet.

3.4. *Gains*

Both diet-groups mentioned expected gains in health with their diet.

In the low-fat group the diet was described as easy to follow, tasty and cheap in price.

The low-carbohydrate group described that they felt less hungry and were less prone to sweets.

3.5. *Strategies*

Both diet-groups mentioned difficulties when eating in other people's homes or when going to restaurants and during holidays. Strategies mentioned were to eat very little of the food not allowed. During Christmas it was easy to find alternatives to eat.

3.6. *Support*

Both diet-groups mentioned that it was supportive if the whole family could follow the same diet. In the low-carbohydrate group the families sometimes choose to prepare two different meals at a time.

4. Discussion

In obesity, with or without coexisting Type 2 diabetes mellitus, intentional reduction of body weight is considered to improve health-related quality of life [1,3,4] and it was therefore of interest that no such effect could be found according to SF-36 after 6 months which was the time when the reduction of body weight in both diet groups was maximal in the present study. Later, after 12 months, improvements of HRQoL were found only in the low carbohydrate group. The improvements related to physical function and to vitality and general health, while the domains relating to mental health showed no change. In the SF-36, a difference of five points in an individual domain or 2–3 points in PCS or MCS are considered clinically significant [23,24]. The changes of these subscales and of PCS that were found in our study are thus considered to be clinically significant. A lowered energy intake of 1600 kcal for women and 1800 kcal for men was prescribed for both study groups, but the main focus in the study was the comparison of a diet with a low carbohydrate intake with a low fat diet, which is the traditional diet recommended for treatment of Type 2 diabetes mellitus. In recent years there has been increased interest in the use of low-carbohydrate diets in the treatment of diabetes, but we are not aware of any previous study that has addressed the effects on HRQoL measured by SF-36 in patients with Type 2 diabetes mellitus randomized to a low-carbohydrate diet.

In obese subjects, lower values of the scales of the SF-36 relating to physical function than in normal weight and overweight individuals are found [7], and it is therefore likely to see an improvement in these scales during an intervention. There are different possible mechanisms for the improvements of these during the study including reduction of body weight in the patients, who had a mean BMI of 32 when entering the study, improvement of glycaemic control, but also the change of macronutrients *per se*. Our finding that there was no change in SF-36 after 6 months, when reduction of body weight was maximal in both groups, argues against this being only an effect of weight reduction. A limitation of our study is that not all patients filled out the questionnaire at this time while the answering frequency was good at 12 months. This makes the 6 months results more uncertain. Another limitation is that a few patients were not fully compliant with their diets throughout the study but calculations excluding these patients showed similar SF-36 results. Furthermore the

magnitude of weight reduction was similar in both groups, but the improvement in HRQoL occurred only in the LCD group. In the LFD group associations were found between changes of PCS and both changes of BMI and HbA1c, while no such associations were found in the LCD group which might suggest that other factors, possibly the diet *per se*, might have been of importance for the improvements found in PCS in the LCD group.

In this study no scale specifically addressing anxiety and depression was used, but we could not find support for that the low carbohydrate diet caused deterioration of the mental scores of SF-36. The MCS was unchanged in both study groups at all times evaluated. As mentioned Brinkworth et al. [17] studied the effect of a LCD and a LFD for one year on quality of life, but they did not include SF-36. They reported short-term results up to 8 weeks showing very rapid, already after 2 weeks, and similar improvements in mood for both groups [25]. When the patients were followed for a longer period, up to one year, some of the scores returned towards baseline in the LCD group, and a significant difference emerged compared with the LFD group [17]. These results might seem contradictory to our results but there are major differences between this study and ours. A major difference was that a very low carbohydrate diet aiming at only 4% of the energy intake consisting of carbohydrates was used while we prescribed a more moderate carbohydrate restriction to 20 E% and reached 26–31 E% according to the diet registrations. Another difference was that in their study obese participants were included but diabetes was an exclusion criterion. Also the reduction of body weight was greater, almost 14 kg at the termination of the study, which might have been a consequence of more intense lifestyle treatment regimen. From the results of our study it can be concluded that aiming for more moderate reduction of carbohydrates is feasible in patients with Type 2 diabetes in routine primary care, and has no adverse effects on the mental aspects of HRQoL. This is also in agreement with a study by Davis et al. [26] who found a tendency towards improvement of the anxiety and worry items of the Diabetes-39 questionnaire during a diet intervention in Type 2 diabetes. There are very few studies of short duration that have compared the effects of different diets on HRQoL and mood in obesity. Yancy et al. [27] found that treatment with a low carbohydrate diet improved the MCS in SF-36 in overweight volunteers. In a small 3-week study d'Anci et al. found worse performance on memory-based tasks and less confusion during a low-carbohydrate diet compared with a low-fat diet. The study was performed in overweight or obese women. In our study we did not measure acute effects on HRQoL, but in contrast found no changes in any of the groups in SF-36 after 6 months, which might suggest that longer treatment is necessary to obtain improvements of HRQoL.

In the LookAHEAD study, changes of depressive symptoms were evaluated at baseline and after one year with the Beck Depressive Inventory [12]. The lifestyle intervention in the patients who had Type 2 diabetes was based on a low fat diet in combination with increased physical activity. It was concluded that intentional weight loss was not associated with the precipitation of depressive symptoms, but instead appeared to protect against this occurrence.

The interview suggests that both study groups made relevant changes of their previous diet to follow the prescribed diet during the study. In general, they did not find these changes difficult but the need to reduce intake of potatoes which is a main carbohydrate-rich ingredient of Swedish diet (It is eaten in average 0.7 times a day according to a survey presented by the National Food Agency) was pointed out as troublesome by the LCD group. Reduction of carbohydrate intake when changing to a very low carbohydrate diet has been described as troublesome [28] and even the moderate reduction of carbohydrates in our study caused some problems when changing from low-fat to high-fat products, as well as substitute cookies and snacks. A wish for more varied food recipes was pronounced by both groups.

Both study groups mentioned hopes that their diet would incur health benefits and felt guilty when not strictly adhering to it. Benefits for the low fat diet was that it was tasty and cheap in price while feeling less hungry and easier to avoid sweets were mentioned in the low carbohydrate group, but it should be noted that the questions based on VAS-scales, that were administered only at 12 months, showed no difference between the study groups on satiety and hunger. Both study groups mentioned difficulties following the diet when socializing with others *i.e.* during holidays or eating out. Eating only small amounts of "forbidden" food items were mentioned as a way to handle these situations. When eating at their own home it was more convenient if the whole family could eat the same food. When implementing and sustaining dietary change social relationships within and without the household has an impact on compliance. It seems important to involve the family in these changes [29].

In conclusion, 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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Conflict of interest

The authors declare that there is no conflict of interest associated with this manuscript.

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