



THE EFFECTS OF LOW-CARBOHYDRATE VERSUS LOW-FAT DIETS IN OBESE/OVERWEIGHT ADULTS: ONE-YEAR FOLLOW-UP OF A RANDOMIZED TRIAL

Statistics

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ABSTRACT

A previous paper reported the six month comparison of weight loss in overweight and/or obese adults randomly assigned to either a VLCK-diet or LF-diet. To review the one year outcomes between these diets 1year follow-up of a randomized trial on 113 overweight/obese adults with a BMI>25 kg/m²; with no abnormalities were randomly selected. Participants who selected VLCK diet received counseling to restrict carbohydrate intake to <30 gram per day and those who selected LF diet received counseling to restrict caloric intake by 500 calories per day with <30% of calories from fat. Changes in weight, Body Mass Index, Body Fat, and Waist Circumference were measured at intervals of first, third, sixth and twelfth month of participants who completed the one-year follow-up. Participants on the very-low-carbohydrate diet had lost more weight loss than participants on the conventional low-fat diet at 3months, 6month and but the difference at 12months were significant. Study conclude that participants on a VLCK-diet had more favorable overall outcomes at 1year than did those on a conventional LF-diet. Weight loss was similar between groups.

KEYWORDS

Ketogenic-Diet, Low-Fat-Diet, Weight-Loss

INTRODUCTION

According to the NFHS-4 at 2015-16, the number of men (adults age 15-49 years) who are overweight/obese was 18.6% while in the NFHS-3 at 2005-06 9.3% men were overweight/obese.¹

While (26.3% men, 20.7% women) and (14.3% men, 12.6%women) were found to be overweight in urban and rural areas in India respectively during NFHS-4 in comparison to the NFHS-3.^{1,2}

According to a latest government health survey, the proportion of overweight men/women in India has doubled over the past decade; also one in five women are now overweight. The conventional dietary approach to weight management, recommended by the leading research and medical societies, is a high-carbohydrate, low-fat, energy deficit diet.³⁻⁶ Low-carbohydrate, high-protein, high fat diets have become increasingly popular, and many best-selling diet books have promoted this approach.^{7,8} Despite its longevity and popularity, no randomized trials evaluating the efficacy of the Ketogenic diet against Low Fat diets have been published.

Therefore the present work evaluated the efficacy of a Very-Low-Calorie-Ketogenic (VLCK) diet in overweight and obese adults compared to Calorie restricted Low-Fat (LF) diet after six month follow-up.

AIM:

To review the twelve month outcomes between VLCK V/S Ketogenic diets on weight loss.

METHODS

Study Type: Interventional Study

Study Design: Randomized Controlled Trial

Study Period: 1st November, 2019 to 31st October, 2020

Ethical Approval: It was taken from institutional ethics committee, GAIMS, Bhuj and written informed consent was taken from all participants with IEC no. IEC/RESCH/30/2020

Sample Collection: The participants were selected from advertisement, fitness club, awareness workshops etc. Out of total, 113 participants of whom 65 females and 48 males were selected randomly irrespective of race and religion.

All the participants were selected in the month of September-November 2019 by doing a study on prevalence of overweight and obesity among adults of Bhuj city.⁹ The selected participants were informed about the both diet programs and experiment on them.

Inclusion Criteria:

Healthy adults with BMI > 25 Kg/m² and Age > 20 years.

Exclusion Criteria:

Participants with any abnormalities like cardiac patient, diabetic patient, thyroid patient etc.

Intervention

A twelve month intervention study was implemented to test the significance of objective of the study. Consent forms were taken from all the participants after explaining both the diets and experiment on them. Then on participant's choice, they are assigned to either of both diets. Out of 113 participants, 53 chose VLCK diet and 60 chose LF calorie restricted diet.

Diet groups met in weekly counseling sessions for 4 weeks, followed by two sessions on third month, sixth month and twelfth month. Participants on the VLCK diet were instructed only to reduce carbohydrate intake to less than 20 gram per day for first three months, then every week increased carbohydrate intake up to 5 gram per day. Participants on the conventional LF diet were instructed to reduce caloric intake by 500 calories per day, with less than 30% of calories derived from saturated fat.

Statistical Analysis

Data was compiled in M.S.Excel 2007. The primary end point was weight loss at six months and weight maintenance at twelve months. Given an anticipated dropout rate of 25 percent, we set the Enrollment target at 113 subjects. By twelve months, 75 subjects remained in the study (34 in the very-low-carbohydrate-ketogenic group and 41 in the low-fat group). The level of significance was set at 0.05 for all statistical tests. Descriptive statistics (mean, standard deviation, etc.) were calculated for all dependent measures such as body weight, energy and macronutrient intake, etc. The primary outcome was a comparison of body weight during weight loss at 6 months and weight maintenance at twelve months for the two treatment conditions student's t tests and repeated measures ANOVA were used to detect differences in the change in body weight and change in anthropometry variables over time of one year.

RESULTS

Participants

A total of 113 participants met the inclusion criteria and initiated the study. The participants were healthy adults (48 men and 65 women), middle-aged, and overweight/obese.

At baseline, 53 participants were assigned to the very-low-carbohydrate (VLCK) diet group and 60 participants were assigned to the low fat (LF) diet group. There were no statistical differences.

Between the very-low-carbohydrate and low fat group at baseline for age, weight, waist circumference. However Body Mass Index (BMI) found statistically significant between the very-low-carbohydrate and low fat group at baseline.

Table 1: Reasons For The Withdrawal From The Study

Reasons	Base to 3 Months	3 to 6 Months	6 to 12 Months	Total
Lack of Attendance	1/2	2/3	2/1	5/6
Unable to Comply with a VLCK Diet During Weight Loss being vegetarian	1/0	0/0	3/0	4/0
Disliked Record Keeping or Other Components of the Program	0/0	0/1	0/1	0/2
Injury	0/0	0/0	0/1	0/1
Monetary Conflict	2/0	1/2	1/1	4/3
Pregnant	0/0	1/2	0/0	1/2
Work Conflicts	0/1	1/0	0/0	1/1
Family conflicts	2/1	2/1	0/1	4/3
Moved from Area (Migration)	0/0	0/0	0/1	0/1
Total Dropouts	6/4	7/9	6/6	19/

VCLK/LF: Very Low Carbohydrate Ketogenic/Low Fat

Table-1 shows that by the end of twelve months total 75 participants have completed the intervention study (19/53 participants dropped out from VLCK-Diet group and 19/60 participants dropped out from LF-diet group). By the end of twelve months 34 and 41 participants had completed weight loss intervention on VLCK and LF diets respectively.

The baseline characteristics of the study participants. Among 53(46.9%) participants in the VLCK diet group, 21 were male and 32 were female with mean age 39.86 years[SD,10.30], mean weight was 82.20 kg [SD,11.78], mean waist circumference was 100.55 cm[SD,8.36] with mean BMI 30.82 kg/m² [SD,3.05]. Among 60(53.1%) participants in the LF diet group, 27 were male and 33 were female with mean age 41.45 years[SD,9.98], mean weight was 86.34 kg [SD,13.49], mean waist circumference was 99.82 cm[SD,8.86] with mean BMI 32.13 kg/m² [SD,3.38]. Body Mass Index of the participants of both the groups was found statistically significant. (p<0.05)

Table 2: Nutrient Composition Of The Different Diets

Variable	VLCK Diet		LF Diet	
	n	Mean(SD)	N	Mean(SD)
Total Energy,kcal				
Baseline	53	2274.4(333.8)	60	2368.75(316.9)
3month	47	1079.9(251.3)	56	1455.0(156.2)
6month	40	1320.4(272.0)#	47	1142.8(268.8)#
12month	34	1380.6(104.9)\$	41	1656.1(210.0)\$
Total Carbohydrates,g				
Baseline	53	200.7(26.3)	60	197.7(29.3)
3month	47	45.9(4.8)**	54	155.5(31.5)**
6month	40	52.3(7.6)#	45	151.7(31.4)#
12month	34	89.9(35.4)\$	41	160.6(21.3)\$
Dietary-Fiber,g				
Baseline	53	23.1(4.3)	60	21.8(4.6)
3month	47	21.5(2.4)	54	21.9(2.0)
6month	40	19.3(3.3)	45	20.2(3.3)
12month	34	26.6(18.2)	41	21.5(4.3)
Net-Carbohydrates,g				
Baseline	53	200.7(26.3)	60	197.7(29.3)
3month	47	13.5(3.1)**	54	133.6(31.7)**
6month	40	33.0(6.8)#	45	131.4(3.9)#
12month	34	63.2(17.4)\$	41	139.1(22.1)\$
Fat,g				
Baseline	53	70.1(18.3)	60	70.8(19.0)
3month	47	84.0(19.5)**	54	38.7(9.2)**
6month	40	95.4(19.7)#	45	38.1(9.0)#
12month	34	89.7(8.6)\$	41	64.9(10.8)\$
Protein,g				
Baseline	53	40.50(14.02)	60	45.32(14.25)
3month	47	67.49(15.70)	54	69.7(16.5)
6month	40	82.5(17.0)#	45	68.6(16.1)#
12month	34	62.1(15.7)\$	41	82.8(10.5)\$

*pvalue <0.05:Significant difference between VLCK-diet and LF-diet at baseline

**pvalue <0.05:Significant difference between VLCK-diet and LF-diet at 3months

#pvalue <0.05:Significant difference between VLCK-diet and LF-diet at 6months

\$pvalue <0.05:Significant difference between VLCK-diet and L- diet at 12months

Table-2 shows the nutrient composition of both the diets VLCK-diet and calorie restricted LF-diet over different time periods. As compared with the subjects on the low-fat diet, subjects on the VLCK diet reported a significantly greater decrease in caloric intake, a significantly greater reduction in the percentage of calories from carbohydrates and a significantly greater increase in the percentage of calories from protein and fat(P<0.05).

Table 3: Change In Anthropometry Variable

Variable	VLCK Diet		LF Diet	
	n	Mean(SD)	n	Mean(SD)
Weight,kg				
Baseline	53(100)	82.8(11.8)	60(100)	86.3(13.5)
3month	47(88.7)	75.1(11.9)**	54(90)	82.0(13.8)**
6month	40(75.5)	68.1(11.3)	45(75)	79.5(13.5)
12month	34(64.2)	66.3(11.6)	41(68.3)	78.4(14.1)
Waist-Circumference,cm				
Baseline	53(100)	100.6(8.4)	60(100)	99.8(8.9)
3month	47(88.7)	98.1(8.5)	54(90)	97.6(8.6)
6month	40(75.5)	95.4(8.4)#	45(75)	97.1(8.7)#
12month	34(64.2)	95.1(8.8)	41(68.3)	96.1(8.2)
Body-Mass-Index(BMI),kg/m²				
Baseline	53(100)	30.8(3.1)*	60(100)	32.1(3.4)*
3month	47(88.7)	27.9(2.7)**	54(90)	30.2(3.1)**
6month	40(75.5)	24.9(2.5)#	45(75)	29.0(2.9)#
12month	34(64.2)	24.4(2.5)\$	41(68.3)	28.3(2.8)\$
Basal-Metabolic-Rate(BMR)				
Baseline	53(100)	1621.3(249.2)	60(100)	1683.3(272.7)
3month	47(88.7)	1579.9(251.3)	54(90)	1661.7(275.6)
6month	40(75.5)	1454.9(319.5)#	45(75)	1642.8(268.7)#
12month	34(64.2)	1487.6(222.2)\$	41(68.3)	1639.7(273.1)\$

*pvalue <0.05:Significant difference between VLCK-diet and LF-diet at baseline

**pvalue <0.05:Significant difference between VLCK-diet and LF-diet at 3months

#pvalue <0.05:Significant difference between VLCK-diet and LF-diet at 6months

\$pvalue <0.05:Significant difference between VLCK-diet and L- diet at 12months

Table-3 shows the change in the body weight(Kg), Body-Mass-Index(BMI)(Kg/m²), and Waist-Circumference(cm) over the periods of 12month by VLCK diet and LF calorie restricted diet. It was observed that participants on VLCK diet reduce significantly more body weight, BMI and waist circumference with respect to participants on calorie restricted LF diet(p<0.05).

DISCUSSION

A total of 103 participants completed 3months of the study (47 of VLCK-diet and 56 of LF-diet), 87 participants completed 6 months (40 of VLCK-diet and 47 of LF-diet) and by the end of twelve months total 75 participants have completed the intervention study (19/53 participants dropped out from VLCK-Diet-group,19/60 from LF-diet-group). By the end of twelve months 34 and 41 participants had completed weight loss intervention on VLCK and LF diets respectively.

The percentage of participants who had dropped out of the study at 3,6 and 12months was higher in the group following the LF-diet (4(6.67%), 9(15%), 6 (10%) respectively) than in the group following the VLCK-diet (6(11.32%), 7(13.2%), 6(11.32%) respectively), but these differences were not statistically significant.

Overall, 75(66.37%) of participants completed the twelve-month full study, however 87(77%) of participants completed the six-month study and 103(91.15%) of those who completed the three-month assessment completed the full study.

During the weight loss period (1-6months) both groups lost significant amounts of body weight. The VLCK-diet group decreased body weight by $20.4 \pm 6.2\text{kg}$ (19%) and the LF-diet $19.1 \pm 5.4\text{kg}$ (18%); the difference between groups was not statistically significant. While in the weight maintenance period (6-12months), the weight of VLCK-diet group body was $66.3 \pm 14.6\text{kg}$ and the LF-diet $78.4 \pm 11.14\text{kg}$; the difference between groups was not statistically significant.

In the statistical analysis in which base-line values were carried forward in the case of missing values, the group on the VLCK-diet had lost significantly more weight than the group on the LF-Calorie-restricted-diet at 3months, 6months and 12months ($p < 0.05$) (Table 3).

Waist circumference and BMI were not statistically different between or within groups at any time period. However between the groups VLCK-diet and LF-diet Waist-circumference and BMI were statistically different at 6months and 12months.

Comparison of energy and macronutrient intake data during weight loss intervention trial showed that the VLCK-diet-group consumed significantly more grams of protein, fat, and percentage of total energy intake from protein and fat compared to the LF-diet-group. The low fat group consumed significantly more total energy, grams of carbohydrate and fiber and a greater percentage of total energy intake from carbohydrate compared to the VLCK-diet-group. After adjusting for baseline, total energy intake and protein intake were no longer significantly different between groups during weight loss (Table 2).

CONCLUSION

Present study focused a significant difference in the current literature by comparing body weight in participants on either a very low carbohydrate ketogenic (VLCK) diet or low-fat-calorie-restricted (LF) diet during a 6month weight loss period and another 6month period for weight maintenance. The primary finding of this study was that a VLCK-diet and LF-diet are comparable for body weight reduction over 6 months; however, there was significant variation in weight change within each group. And by the end of 12 months those who were following a VLCK-diet reduce more weight and maintain the reduction significantly well as compared to those who were following LF-calorie-restricted diet. Therefore this study conclude that VLCK-diet found a better diet to reduce body-weight as well as reduces inches by fat reduction than the conventional calorie restricted LF-diet.

RECOMMENDATION

However ketogenic diet provides better results than low fat diet, further more long term research is require at least of one year follow up to make the conclusions. Because being high protein intake in a Very-Low-Carbohydrate-Ketogenic (VLCK)-diet, this diet is more suitable for non-vegetarians than pure vegetarians, due to having less protein food options in vegetarian food sources.

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REFERENCES

- 1) International Institute for Population Sciences (IIPS). National Family Health Survey (NFHS-4), India, Mumbai: IIPS. 2015-16; pp. 01.
- 2) "National Family Health Survey, 2005-06" (2007) (<http://www.measuredhs.com/publications/publication-frind3-dhs-final-reports.cfm>).
- 3) Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults — the Evidence Report. *Obes Res* 1998;6:Suppl 2:51S-209S. [Erratum, *Obes Res* 1998;6:464.]
- 4) Thomas PR, ed. Weighing the options: criteria for evaluating weight-management programs. Washington, D.C.: National Academy Press, 1995.
- 5) Position of the American Dietetic Association: weight management. *J Am Diet Assoc* 1997;97:71-4.
- 6) Krauss RM, Deckelbaum RJ, Ernst N, et al. Dietary guidelines for healthy American adults: a statement for health professionals from the National Committee, American Heart Association. *Circulation* 1996;94:1795-800.
- 7) Steward HL, Bethea MC, Andrews SS, Balart LA. Sugar busters! New York: Ballantine Publishing, 1995.
- 8) Eades MR, Eades MD. Protein power. New York: Bantam Books, 1999.
- 9) Maitri Hathi, Dr. Rupesh Mehta, Himanshu Nagar. Prevalence of overweight and obesity and its association with lifestyle among adult population of Bhuj city, Gujarat. *Global Journal for Research Analysis*. Volume-9/ Issue-5/May-2020. Print ISSN No. 2277-8160/DOI:10.36106/gjra