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Plant sterol/stanol prescription is an effective treatment strategy for managing hypercholesterolemia in outpatient clinical practice

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Abstract

Objective To determine the effectiveness of prescribing 2 g plant sterols/stanols per day as an addition to standard practice in a dietary outpatient clinic. Design A randomized parallel design of comparative 12-week interventions. Subjects/Setting Patients referred by a general practitioner to a dietary outpatient clinic for the management of hyperlipidemia were eligible. Twenty-five patients (15 women and 10 men) completed the study. Intervention Counselling regarding diet for hyperlipidemia was based on the National Cholesterol Education Program (NCEP) guidelines. The intervention group was instructed to incorporate ~25 g/day of margarine containing plant sterols/stanols, which delivered ~2 g of plant sterols/stanols. Main outcome measure Changes in diet, body weight and serum total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides. Statistical analysis performed Changes in dietary and biochemical outcomes were assessed using Student's t-test. For non-normally distributed data, Wilcoxon signed rank test was used and Mann-Whitney U tests were conducted to determine the proportion of subjects reaching defined goals. The number needed to treat (NNT) index was used to report effectiveness of the intervention. Results Five of 14 subjects in the intervention group compared to 0 of 11 in the control group achieved a reduction in serum cholesterol of $\geq$ 15% (P < .05). Using the NNT index, for each 2.8 patients counselled with routine prescription of plant sterols/stanols, one additional patient would obtain a reduction in cholesterol by $\geq$ 15% compared with conventional management. This was achieved without any detrimental effects on the dietary fatty acid profile. Application/conclusion Routine prescription of margarine containing plant sterol/stanol is an effective strategy in the management of hypercholesterolemic patients in the clinical setting.

Keywords

plant sterol, functional foods, dietary prescription, randomised dietary trial

Disciplines

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Abstract

Objective To determine the effectiveness of prescribing 2 g plant sterols/stanols per day as an addition to standard practice in a dietary outpatient clinic.

Design A randomized parallel design of comparative 12-week interventions.

Subjects/Setting Patients referred by a general practitioner to a dietary outpatient clinic for the management of hyperlipidemia were eligible. Twenty-five patients (15 women and 10 men) completed the study.

Intervention Counselling regarding diet for hyperlipidemia was based on the National Cholesterol Education Program (NCEP) guidelines. The intervention group was instructed to incorporate ~25 g/day of margarine containing plant sterols/stanols, which delivered ~2 g of plant sterols/stanols.

Main outcome measure Changes in diet, body weight and serum total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides.

Statistical analysis performed Changes in dietary and biochemical outcomes were assessed using Student's t-test. For non-normally distributed data, Wilcoxon signed rank test was used and Mann-Whitney U tests were conducted to determine the proportion of subjects reaching defined goals.

The number needed to treat (NNT) index was used to report effectiveness of the intervention.

Results Five of 14 subjects in the intervention group compared to 0 of 11 in the control group achieved a reduction in serum cholesterol of $\geq$ 15% (P < .05).   Using the NNT index, for each 2.8 patients counselled with routine prescription of plant sterols/stanols, one additional patient would obtain a reduction in cholesterol by $\geq$ 15% compared with conventional management. This was achieved without any detrimental effects on the dietary fatty acid profile.

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INTRODUCTION

Forty-one clinical trials have studied the efficacy of plant sterol esters and plant stanol esters in reducing mean total cholesterol (TC) and low-density lipoprotein cholesterol (LDL)[1]. When plant sterols/stanols are added to foods such as margarine, up to a 15% reduction in serum TC and LDL has been reported and the effect is additive with diet and drug interventions[1]. To this end the Adult Treatment Panel (ATP III) of the National Cholesterol Education Program (NCEP) recommend the addition of plant sterols (2g/day) to the diet[2]. However, all studies to date have been in controlled settings using willing volunteers and providing subjects with sterol containing products. These results are yet to be replicated in subjects who assemble the diets for themselves on a routine basis, thus determining the true effectiveness of this strategy in the clinical setting [3].

It is commonplace when determining evidence for functional foods to equate efficacy with effectiveness. Whereas efficacy aims to establish a relationship between a bioactive component and a therapeutic benefit, effectiveness goes one step further in answering the question of compliance i.e. do subjects comply with the therapy and does the therapeutic relationship hold. Whilst it may be correct

to assume that efficacy often equates to effectiveness with therapeutic drugs, with functional foods, issues relating to the belief in the benefit of use, taste, preference and price may affect intake and ultimately compliance [4, 5]. In addition, the net effect on the whole diet needs to be considered in those who select functional foods, given the importance of other dietary aspects such as restricting saturated fat and cholesterol and increasing omega-3 fatty acids, in reducing CHD risk[6]. It is therefore important in evaluating effectiveness to design trials in free-living contexts.

A clinical setting with standard practices is a useful setting for this research. However, the problem associated with recruitment in clinical trials has been acknowledged in the literature and obtaining the numbers needed to achieve statistically significant results can be problematic[7]. The Number Needed to Treat (NNT) is becoming increasingly popular as an index for reporting results of randomized controlled trials and other clinical trials[8]. The NNT represents the clinical effort that is required by treatment in order to achieve a positive outcome, compared to the expected response in a control group. This provides a useful measure of effectiveness and overcomes some of the issues of recruitment of large numbers of subjects.

To test the effectiveness of plant sterol/stanol prescription, we randomised consenting patients in an outpatient nutrition clinic to either standard practice (a low fat, low saturated fat, high fibre diet) or standard practice with the additional prescription of 25g of a plant sterol or plant stanol containing

margarine. This was a free-living trial. No food products were supplied to subjects, and the margarines prescribed were available commercially.

SUBJECTS AND METHODS

Participants and Study Design

Subjects were recruited through an established dietary outpatient clinic over an 18-month period, from February 2001 to August 2002. Subjects were included if they were aged between 30-75 years and had a fasting serum total cholesterol concentration > 5.5mmol/L. Those who were of non-English speaking background, taking lipid lowering medication for less than 3 months prior to referral or had changed dosage within the last 3-month period were excluded, along with subjects following dietary regimens for allergy or intolerance, renal disease and diabetes mellitus. Details of the study were explained to all subjects and written informed consent provided before participation in the study. The goal was to recruit 80 participants (allowing for 10 drop outs), on a sequential basis using a blocking protocol for total serum cholesterol to ensure the cholesterol levels at baseline did not differ between the groups. Within each block, the allocation to treatment or control group was random. The study was conducted on an outpatient basis over 12 weeks and no foods or supplements were provided to subjects. At baseline (week 0) and week 12 subjects filled out a 3-day food record (two week days and 1 weekend day). One week later (week 1 and 13) a detailed dietary history was conducted along with weight, waist circumference measurement and an activity questionnaire. Fasting blood samples

were collected prior to baseline ~2-3 weeks and at 12 weeks.   The human research ethics committee of the University of Wollongong and the Illawarra Area Health Service approved the study.

Treatment Conditions

Control group

Subjects were individually instructed by the same Accredited Practicing Dietitian to consume a diet low in saturated fat, consistent with the Therapeutic Lifestyle Changes dietary approach as outlined by NECP [2].   In summary, the diet aims for 25 - 30% of total calories from fat (<7% saturated fatty acids, up to 10% polyunsaturated fatty acids, and up to 20% monounsaturated fatty acids), 50 - 60% of total calories from carbohydrates, ~ 15% of total energy from protein, <200mg cholesterol/day, fibre 20 –30g/day and total energy to balanced with energy expenditure to maintain desirable body weight or prevent weight gain [2].   Sterol/stanol use was not included as part of dietary instruction, however if subjects were currently using plant sterol/stanol containing margarine they were encouraged to continue.   This was regarded as standard practice and there would be ethical implications to actively discouraging the use of these products.   Subjects were provided with information sheets offering practical suggestions and an individual diet plan.   Furthermore, all subjects were encouraged to exercise (eg 30-minute brisk walking) at least 3 sessions per week.   Counselling sessions consisted of a 1-hour session at week 1 and two 30-minute sessions at week 3 and 6.

Intervention group

The intervention diet was identical to the control diet in all but one aspect. All subjects on the intervention diet were instructed to consumer 25g (5 teaspoons) of either Flora's *Pro-active*® or Meadow Lea's *Logicol*™ margarine (these were the only plant sterol and plant stanol containing products respectively on the Australian market at the time of the study). The information sheets and diet plans explicitly stated these products and the amount to be consumed each day. Subjects were instructed to modify their fat intake to accommodate the sterol/stanol dosing and encouraged to consume additional carotenoid containing vegetables to prevent a possible decrease in plasma carotenoids as a result of the sterol/stanol intake [9]. This message was the focus of each follow-up clinic visit.

Dietary Measurement

A dietary history (DH) interview was conducted by the same dietitian (CP) at baseline and at 12 weeks. The DH method lends itself well to clinical practice where it provides clinicians with and opportunity to subjectively examine meal patterns and provide dietary advice while the patient is still present [10]. Furthermore the utility of this method has been demonstrated in a number of sample groups, including short-term intervention studies [11,12,13]. The approach taken was a narrative style DH interview (open-ended) described in detail elsewhere[11]. In summary, the meal based diet history interview noted the types, amounts and frequency of consumption of all foods consumed routinely within a 3-month reference time. The interview was completed with a food frequency checklist of major food categories,

snack and drink items (including alcohol), and sources of omega 3 fatty acids (fish, nuts, soy foods), as well as questions on food preparation practices. The same assessor was the interventionist in this study; therefore the DH was not blinded. Subjects were also required to keep an estimated 3-day food record (FR) (two weekdays and one weekend day) after the collection of the DH. Forms were provided along with instructions on how to estimate food portion sizes using standard kitchen measuring equipment. Food records were checked for missing values and clarification.

Anthropometric Measurement

Weight and height was recorded at each interview using calibrated balance scales and a wall mounted stadiometer. All subjects were clothed (light shirt). Height was measured to the nearest 0.5cm and weight to the nearest 0.1kg. Waist and hip circumferences were measured at each time point. Waist circumference was measured using a standard cloth measuring tape (units in centimetres and inches); with measurements made halfway between the lower border of the ribs, and the iliac crest in a horizontal plane. Hip circumference was measured at the widest point over the buttocks. For each circumference, measurements were recorded to the nearest 0.5 cm. Activity level was obtained from a self-reported description of usual activity, including details of number of sessions a week of activity, the duration of each session and the intensity of each activity.

Biochemical Measurement

In keeping with standard clinical practice, a trained phlebotomist at accredited pathology laboratories within the Illawarra region (Southern IML Pathology) drew blood samples from subjects after an overnight fast. Subsequently, samples were analysed for concentrations of total cholesterol, HDL cholesterol, LDL cholesterol, and triacylglycerol. The pathology laboratories were fully accredited with the National Association of Testing Authorities (NATA) and the Royal College of Pathologists of Australasia (RCPA), which is a mandatory requirement for pathology laboratories in Australia.

Analysis and Statistics

Dietary data were analysed with Foodworks nutrient analysis software package (Professional Version 3.1, Xyris Sortware, Highgate Hill, Brisbane Australia), which is based on the Australian Nutrient Database (AUSNUT 2000, Department of Human Services and Health, Canberra).

The required sample calculation of $n = 80$ was based on detecting a difference in TC between the groups of 10% at 80% power. A Bland Altman plot [14] was prepared to determine possible bias between actual and recalled total fat (%kcal) with the two dietary assessment methods. As described by Bland and Altman [14] the average of the reported fat intake in the DH and the FR (x axis) are plotted against the difference between the DH and FR recorded fat intake (y axis). The limits of agreement were set at 2 SD of the difference above and below the mean. Comparing the reported intake using the DH and FR using Pearson's correlation coefficient assessed the validity of sterol/stanol intake.

Changes between week 0 and week 12 were studied for all variables. Dietary data and baseline

measurements were assessed using a two-factor analysis of variance with diet and sex as fixed factors.

The effect of dietary intervention was assessed using paired Student's *t*-tests when comparing the

change in variables (dietary, anthropometric and biochemical data) between groups. For

non-normally distributed data, Wilcoxon signed ranks test was used for within group comparisons, and

Mann-Whitney *U* test were conducted to determine the proportion of subjects reaching dietary and

biochemical goals between the groups. Changes in clinical outcomes were analysed with an intention

to treat model-using analysis of variance i.e. subjects were included in the analysis whether or not they

consumed the prescribed dose of plant sterol/stanol. The relationship between plant sterol intake and

serum cholesterol was determined using Pearson's correlation coefficient. The number needed to treat

(NNT) index as described elsewhere was used to report effectiveness of the intervention [8]. The NNT

was calculated using the proportions of subjects on the control or experimental treatment who achieve a

total cholesterol reduction of $\geq$ 15%. NNT is defined as[8]:

$$\text{NNT} = \frac{1}{\pi_1 - \pi_2}$$

Here π_1 and π_2 are defined as the proportions of subjects on the control or experimental treatment

(respectively) that experience the defined outcome.

A *P* - value less than .05 were considered to be statistically significant. SPSS for Windows (version

10.0, 1999, Chicago, IL) was used for all statistical analyses.

RESULTS

Subject demographics

During the 18-month time course of the study forty-two participants met the eligibility criteria, 32

agreed to participate producing a group randomisation of 15 control and 17 intervention subjects.

Twenty-five subjects (15 women, 10 men) completed the study producing a group randomisation of 11

control and 14 intervention subjects.   One subject withdrew after a myocardial infarct, another subject

was hospitalised for psychiatric illness and was unable to complete the final assessment phase, the

clinic lost contact with another subject, and four withdrew after the initial assessment.   Baseline

characteristics of all subjects admitted to the study are shown in Table 1.   The groups did not differ in

terms of age, sex, body mass index, level activity, waist:hip ratio, medication use, or serum lipid levels.

[INSERT Tab 1]

Dietary data

Using the Bland-Altman plot there was no relationship between the average of the reported fat intake

using DH and FR with the difference between the two methods (Figure 1).   All but one value was

within the 2 SD confidence limits as recommended by Bland and Altman[14] indicating that there was no systematic bias. Strong correlations were found between the DH and FR method (r = 0.782, *P*<.001) for plant sterol/stanol consumption. Results of the dietary analyses using DH data are reported in Table 2. Overall, nutrient intakes were not significantly different between the two groups at baseline and at the end of the study (12 weeks). However, the change in protein was higher in the intervention group (22%) compared to the control group (5%) as well as the change in alcohol intake (-7g/day, 2g/day in the intervention and control group respectively). The average intake of plant sterols/stanols increased by 1.3g/day in the intervention group and reduced by 0.3g/day in the control group (*P*<.05), and 20% achieved the goal intake of ≥ 2g/day compared to none in the control (*P*<.05). After the intervention period, 43% (*P*<.05) of the intervention subjects achieved a polyunsaturated fat intake within the NCEP Step 1 diet recommendations (≥ 7%kcal) whereas none achieved this goal in the control. There were no other differences between the groups in achieving the NCEP recommendations (Table 3).

 [INSERT Fig 1]

 [INSERT Tab 2]

 [INSERT Tab 3]

Serum lipids in response to treatment

Total cholesterol, plasma triacylglycerol, HDL cholesterol and LDL cholesterol concentrations did not

differ significantly over time or between groups.   Concentrations of plasma lipids at the beginning and end of the trial are shown in Table 4.   After the 12-week intervention the reductions in total cholesterol and LDL cholesterol were more than double in the intervention group compared to the control group, but these differences did not reach statistical significance.   There was a strong inverse relationship between 12-week dietary sterol/stanol intake and change in serum cholesterol (r = -.62; P = .001) and serum LDL cholesterol (r = -.58; P = .019).

[INSERT Tab 4]

Clinical indexes

At the completion of the 12-week study 5 of 14 subjects in the intervention group achieved $\geq$ 15% change in total cholesterol compared to 0 of 11 in the control (P <.05).   No other significant changes were observed between the groups.   Both groups showed a mean weight change of < 1.0 kg and there were no significant differences in body weight from the baseline to the end of the study.   The NNT was calculated to be 2.8.

DISCUSSION

This present study is the first, to our knowledge, investigating the utility of using plant sterol/stanol enriched margarine in a free-living clinical context. While evidence-based nutrition recommendations attempt to translate research data into nutrition care[15], research in clinical settings are paramount, as the applicability of controlled studies to the general community is often questioned[16]. For example, in the effective management of hyperlipidemia there are a number of dietary approaches that can achieve moderate results; these include reducing the saturated fat in the diet, increasing omega-3 polyunsaturated diet and increasing dietary fibre[17]. It is important that the introduction of novel dietary strategies do not adversely affect the dietary profile.

In conjunction with dietary advice consistent with the NCEP guidelines, we found that the inclusion of ~1.5-2g/d of plant sterol in margarine did not adversely affect the dietary fat or plasma lipid profiles (Tables 2 and 4). Of particular interest was the increase in the proportion of fats coming from polyunsaturated fat in the intervention group. Intervention trials have shown that visible fats (such as margarine and nuts) are often excluded from the diet in preference to hidden fats that are often saturated [18]. The net effect is an decrease in the P:S ratio. There is increasing evidence of the importance of polyunsaturated fats as an important dietary component in reducing the risk of CVD and the need to increase the P:S ratio is of importance[19]. A serendipitous result of prescribing a daily dose

of plant sterol/stanol enriched margarine was the delivery of extra omega-3 polyunsaturated fatty acids. As plant sterols/stanols have an additive effect with other dietary modifications[20], prescribing enriched margarine is an effective strategy to achieve both of these targets.

Our dietary assessment measures had some limitations. In our pursuit of designing a study resembling 'real life' conditions there was a trade off by un-blinding the DH, as the assessor was also the interventionist. The impact of this on our interpretation of results is marginal as we demonstrated strong agreement between the DH and FR methods for dietary fats and sterol/stanols indicating relative validity.

Although compliance to the dietary regimen is a key component of determining effectiveness, the ability to show the therapeutic benefit is also important. The mean percent reduction in total cholesterol and LDL cholesterol in the intervention group was ~11% and ~12% respectively compared to ~5% and ~4% in the control group. This difference however was not statistically significant either within groups or between groups over time, probably because our final sample size was significantly smaller (n=25) compared to our original sample size power calculations (n=80). The study was underpowered to reject the null hypothesis that is, there was not have enough evidence to say there was a significant difference between the groups.

Our results show that dietary prescription of plant sterol/stanol margarines in conjunction with the NECP guidelines for the management of blood lipids resulted in an intake of 1.3g sterol/day, whereas in the control group plant sterols reduced their intake by 0.4g/day. Although studies have shown that 2g/day of plant sterol is the therapeutic optimal dose, the response curve is linear suggesting that an intake of around 1.5g/day is still clinically useful and the levels achieved would be predicted to achieve a change of ~10% in total serum cholesterol and LDL cholesterol[20].

A significant limitation to clinical practice in the dietary management of hyperlipidemia is that despite studies in controlled environments achieving up to 15% reductions in total cholesterol, results in a free-living context have at best have shown a 5% reduction [21]. We observed that 5 of 11 (36%) in the intervention group achieved a reduction in serum cholesterol levels $\geq$ 15% compared to none in the control. This has an important clinical implication, which can be summarised using the NNT statistic. Using this index we can predict that if clinicians routinely prescribe 2g/day of plant sterol/stanol margarine, then for every 2.8 patients given this advice an extra patient will achieve a cholesterol reducing effect $\geq$ 15%, compared to a more conventional approach to dietary therapy. However, these results can only be viewed as preliminary at this stage as the small sample size makes generalizing beyond the bounds of this clinical context inappropriate. Further research is required in this area which would involve a larger sample, drawn over multiple clinical sites before conclusive evidence can be provided.

CONCLUSION/APPLICATIONS

What we have known for many years regarding the efficacy of plant sterol/stanol enriched food products in the management of hyperlipidemia can now be extrapolated into a free-living, context. Plant sterol/stanol margarines provide a useful and significant adjunct to medical nutrition therapy. However, while these results may be relevant when considering other functional ingredients added to margarine, the value of other functional foods on the dietary profile would need studies specifically designed to examine the effects in a true to life situation[3]. Only at this point can we truly assess the effectiveness of functional food products on health outcomes.

ACKNOWLEDGEMENTS

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Table 1 Participant characteristics at baseline

	Control Group (*n*=15)	Intervention Group (*n*=17)
Age (y) (mean ± SD)	59.2 (±13.2)	55.2 (±13.4)
Female/Male	11/4	8/9
BMI (kg/m^2) (mean ± SD)	29.8 (±3.3)	31.4 (±5.9)
Waist/Hip ratio (mean ± SD)	0.92 (±0.1)	0.94 (±0.12)
Cholesterol lowering medication (n)[†]	2	3
Frequency of activity		
Nil	5	6
1-2 times per week	3	3
3-4 times per week	2	2
5-6 times per week	1	2
>6/7 times per week	0	1
Total cholesterol (mmol/L) (mean ± SD)	6.64 (±0.8)	6.89 (±1.1)
[*]LDL cholesterol (mmol/L) (mean ± SD)	4.25 (±0.6)	4.35 (±0.8)
[**]Triacylglycerol (mmol/L) (mean ± SD)	2.40 (±1.4)	2.28 (±1.1)
[***]HDL cholesterol (mmol/L) (mean ± SD)	1.27 (±0.3)	1.26 (±0.3)

[*]*n* =23, [**]*n* = 30, [***]*n* = 27

There were no significant differences between any of the groups at baseline using Student's t-test for normally distributed data and Wilcoxan sign ranked test for categorical data.

[†]Refers to number of patients taking cholesterol lowering medication who had not reported a change in dose for >3 months.
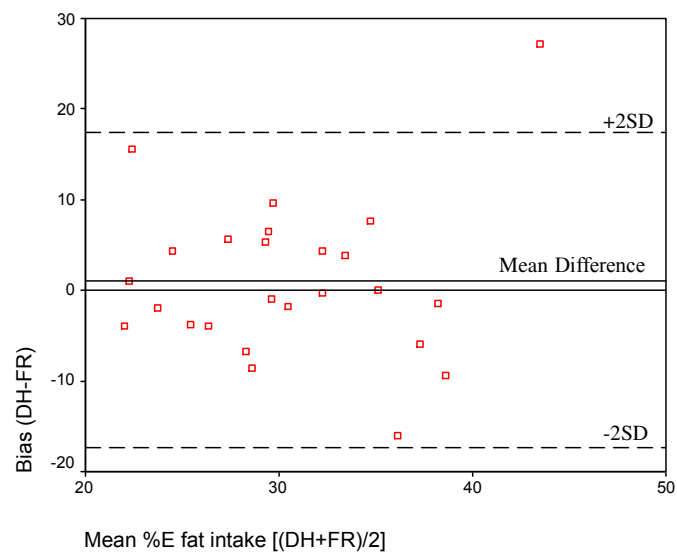
Figure 1 Bland-Altman plot of the mean difference between the DH and FR for fat (%kcal) versus the mean of the DH and FR, with limits of agreement 2 SD from the mean difference.

Table 2 Mean (±SD) of dietary composition at week 0 and 12 as determined by DH.

Lipid	Control group (*n*=11)	Intervention group (*n*=14)
Energy		
Week 0 (kcal)	1928 (±636)	2129 (±789)
Week 12 (kcal)	1842 (±573)	1727 (±411)
^Change %	-4.5 (±21)	-18.9 (±30)
Protein		
Week 0 (%kcal)	19.7 (±2.3)	17.2 (±3.2)
Week 12 (%kcal)	20.7 (±2.0)	21.0 (±3.0)
^Change %	5.2 (±13.8) [*]	21.9 (±21.4) [*]
Fat		
Week 0 (%kcal)	29.7 (±5.3)	31.9 (±8.9)
Week 12 (%kcal)	27.4 (±5.4)	29.9 (±6.4)
^Change %	-8.0 (±14.8)	-6.4 (±34.3)
CHO		
Week 0 (%kcal)	47.4 (±4.8)	44.4 (±6.8)
Week 12 (%kcal)	48.0 (±4.7)	44.1 (±7.0)
^Change %	1.2 (±8.7)	-0.7 (±31.2)
SFA		
Week 0 (%kcal)	10.1 (±2.9)	10.9 (±6.9)
Week 12 (%kcal)	8.0 (±2.3)	7.3 (±2.1)
^Change %	-20.8 (±27.5)	-32.1 (±37.5)
MUFA		
Week 0 (%kcal)	12.4 (±2.6)	12.9 (±3.3)
Week 12 (%kcal)	11.7 (±2.6)	13.3 (±3.6)
^Change %	-5.6 (±17.8)	2.9 (±37.9)
PUFA		
Week 0 (%kcal)	4.4 (±1.1)	5.3 (±1.5)
Week 12 (%kcal)	4.0 (±1.2)	6.3 (±2.4)
^Change %	10.1 (±32.4)	18.6 (±56.2)
Cholesterol		
Week 0 (mg)	201.3 (±106.4)	236.7 (±166.1)
Week 12 (mg)	170.8 (±58.4)	153.1 (±64.9)
^Change %	-15.1 (±34.6)	-35.3 (±41.4)
Dietary fibre		

Week 0 (g/day)	28.5 (±10.1)	24.2 (±8.5)
Week 12 (g/day)	35.3 (±17.3)	26.5 (±8.9)
^Change %	24.1 (±69.4)	9.5 (±40.9)
Alcohol		
Week 0 (g/day)	3.4 (±6.1)	15.2 (±24.1)
Week 12 (g/day)	5.6 (±8.8)	8.4 (±16.7)
^^Change (g/day)	2.2 (±3.9) [*]	-6.8 (±10.7) [*]
Sterol/stanol intake		
Week 0 (g/day)	0.8 (±1.0)	0.2 (±0.5)
Week 12 (g/day)	0.5 (±0.8)	1.5 (±0.8)
^^Change (g/day)	-0.32 (±0.7) [*]	1.26 (±0.9) [*]

[*]$P<.05$, [**]$P<0.01$, significantly different between the groups

$$\text{^Change \%} = \frac{\text{week 12} - \text{week 0}}{\text{week 0}} \times 100\%.$$

$$\text{^^Change} = \text{week 12} - \text{week 0}$$

Table 3 Number of subjects meeting selected fatty acid targets at baseline and 12 weeks ($n = 25$).

Time	Group	Plant sterol/stanol		Saturated fat intake		Polyunsaturated fat intake	
		$\geq$ 2g/day	< 2g/day	$\geq$ 10%kcal	< 10%kcal	$\geq$ 7%kcal	< 7%kcal
Baseline	Control	0	0	4	7	0	11
	Intervention	0	0	7	7	2	12
12 weeks	Control	0[*]	11	2	9	0[*]	11
	Intervention	3[*]	11	2	12	6[*]	8

[*]P<.05, [**]P<.01, significantly different between the groups, Mann-Whitney U Test.

Table 4 Mean (±SD) plasma lipid concentrations on week 0 and 12 with each dietary intervention.

Lipid	Control group	Intervention group)
Total cholesterol		
Week 0 (mmol/L)	6.64 (±0.8)	6.89 (±1.1)
Week 12 (mmol/L)	6.29 (±0.7)	6.10 (±1.0)
Change %	-5.3 (±11.5)	-11.5 (±13.9)
LDL cholesterol (n = 17)		
Week 0 (mmol/L)	4.25 (±0.6)	4.35 (±0.8)
Week 12 (mmol/L)	4.06 (±0.9)	3.82 (±0.9)
^Change %	-4.5 (±15.7)	-12.2 (±13.1)
Triacylglycerol (n = 24)		
Week 0 (mmol/L)	2.40 (±1.4)	2.28 (±1.1)
Week 12 (mmol/L)	2.20 (±1.3)	2.20 (±0.9)
^Change %	-8.3 (±28.7)	-3.5 (±34.7)
HDL cholesterol (n = 19)		
Week 0 (mmol/L)	1.27 (±0.3)	1.26 (±0.3)
Week 12 (mmol/L)	1.29 (±0.3)	1.27 (±0.3)
^Change %	1.6 (±8.7)	0.7 (±13.1)
LDL:HDL ratio (n = 18)		
Week 0 (mmol/L)	3.37 (±0.9)	3.49 (±1.0)
Week 12 (mmol/L)	3.29 (±1.1)	3.21 (±1.1)
Change %	-2.4 (±14.7)	-8.0 (±10.0)

[*]P<0.05, [*]P<0.01, significantly different from baseline

^Change % $= \dfrac{\text{week 12} - \text{week 0}}{\text{week 0}}$ X 100%.
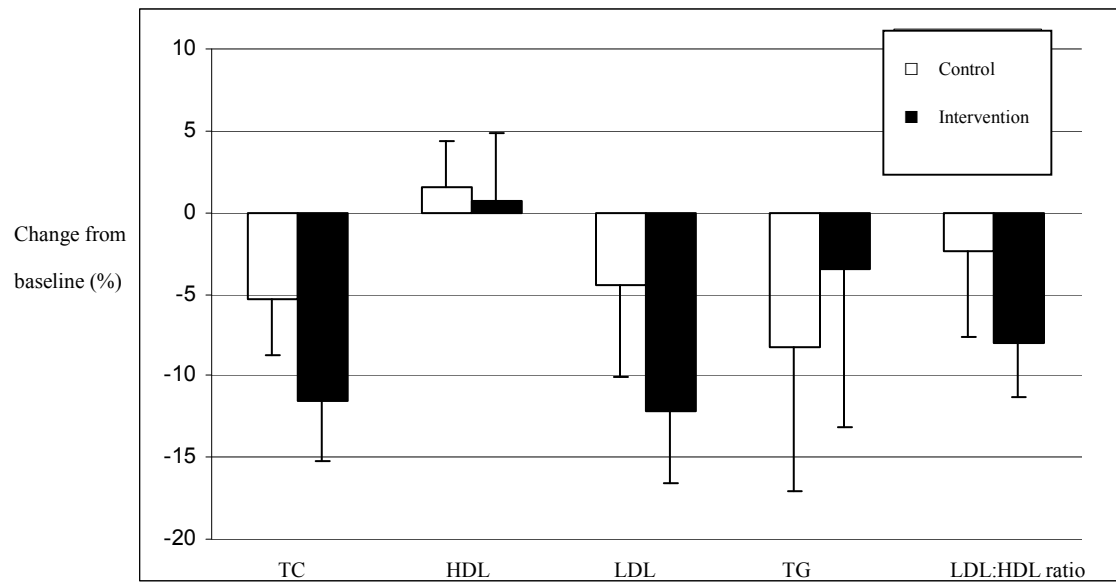
Figure 2 The mean (±SEM) percentage change in serum lipids from baseline to the end of the 12 week dietary intervention.