Artichoke leaf extract (Cynara scolymus) reduces plasma cholesterol in otherwise healthy hypercholesterolemic adults: A randomized, double blind placebo controlled trial

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Abstract

Cardiovascular diseases are the chief causes of death in the UK, and are associated with high circulating levels of total cholesterol in the plasma. Artichoke leaf extracts (ALEs) have been reported to reduce plasma lipids levels, including total cholesterol, although high quality data is lacking. The objective of this trial was to assess the effect of ALE on plasma lipid levels and general well-being in otherwise healthy adults with mild to moderate hypercholesterolemia. 131 adults were screened for total plasma cholesterol in the range 6.0–8.0 mmol/l, with 75 suitable volunteers randomised onto the trial. Volunteers consumed 1280 mg of a standardised ALE, or matched placebo, daily for 12 weeks. Plasma total cholesterol decreased in the treatment group by an average of 4.2% (from 7.16 (SD 0.62) mmol/l to 6.86 (SD 0.68) mmol/l) and increased in the control group by an average of 1.9% (6.90 (SD 0.49) mmol/l to 7.03 (0.61) mmol/l), the difference between groups being statistically significant ($p = 0.025$). No significant differences between groups were observed for LDL cholesterol, HDL cholesterol or triglyceride levels. General well-being improved significantly in both the treatment (11%) and control groups (9%) with no significant differences between groups. In conclusion, ALE consumption resulted in a modest but favourable statistically significant difference in total cholesterol after 12 weeks. In comparison with a previous trial, it is suggested that the apparent positive health status of the study population may have contributed to the modesty of the observed response. © 2008 Elsevier GmbH. All rights reserved.

Keywords: Artichoke; Cynara scolymus; Phytotherapy; Cholesterol; Hypercholesterolemia; Cardiovascular diseases

Introduction

Cardiovascular diseases (CVD) are the chief causes of death in the UK, accounting for just over 216,000 deaths in 2004 (Allender et al., 2006). About half (49%) of these are from coronary heart disease (CHD) which alone is the cause of death of one in five men and one in six women in the UK. CHD cost the health care system in the UK around £3500 million in 2003, which represents an annual cost per capita of just under £60 (Allender et al., 2006).

The primary cause of CHD is atherosclerosis, the formation of fatty atheroma in the artery wall. Atherosclerosis is
in turn linked to high circulating levels of total cholesterol in the plasma. On a global level, the World Health Report estimates that about 8% of all disease burden in developed countries is caused by raised cholesterol levels and that over 60% of CHD is due to total blood cholesterol levels in excess of the theoretical minimum, 3.8 mmol/l (WHO, 2002).

It is estimated that nearly 50% of deaths from CHD are due to plasma total cholesterol levels in excess of 5.2 mmol/l, and that 10% of deaths from CHD could be avoided if everyone in the population had a plasma total cholesterol level of less than 6.5 mmol/l (DoH, 1998). Recent data show that about 66% of men and women in England have blood cholesterol levels of 5.0 mmol/l and above (Allender et al., 2006). In addition, 18.0% of men and 22.4% of women have ‘raised’ plasma total cholesterol levels of 6.5 mmol/l or more (DoH, 1998). By age group, both men and women aged 65–74 years have the highest prevalence of raised levels (26.4% and 44.4%, respectively).

Over 10 years ago, the UK’s Department of Health Report on Nutritional Aspects of Cardiovascular disease (DoH, 1994) noted inverse associations between dietary intakes of antioxidant nutrients and risk of CHD. They recommended that research was carried out to identify the range and effects of various antioxidants in foods in order to quantify desirable intakes. Antioxidant nutrients include ‘non-essential’ phytochemicals (e.g. flavonoids) as well as ‘essential’ nutrients (e.g. vitamins C, E and carotenoids). One of the first epidemiological studies to highlight a role for phytochemicals in heart disease prevention was the Zutphen study (Hertog et al., 1993). Since that time, several plant-rich sources of phytochemicals, such as fruits and vegetables, tea, red wine, cocoa and olive oil, have been associated with lower risk of CVD through various mechanisms, with clinical evidence now starting to accumulate (Maron, 2004; Kay et al. 2006). Globe Artichoke (Cynara Scolymus) is a member of the daisy family and its leaves have been used traditionally in Europe to improve digestive and urinary tract health. Artichoke leaf extracts (ALEs) are currently used in Germany and Switzerland as a remedy for indigestion, and are available in the UK as over-the-counter food supplements. Recent studies have provided evidence base for their effectiveness in conditions such as dyspepsia (Marakis et al., 2002; Holtmann et al., 2003) and irritable bowel syndrome (Walker et al., 2001; Bundy et al., 2004).

The key active constituents of ALE are caffeoylquinic acids (including cynarin and chlorogenic acid), flavonoids (including luteolin and derivatives, such as glucosides) and bitters (sesquiterpene lactones, including cynaropicrin). Pharmacological and pre-clinical research indicates that ALE possesses, among others, hypocholesterolemic and antioxidant properties (Mills and Bone, 1999). These properties are thought to operate through a reduction in de novo cholesterol synthesis via the inhibition of HMG CoA reductase, an increase in cholesterol elimination in bile secretions, and an inhibition of LDL oxidation (Kraft, 1997).

A review of the data from 11 clinical studies (conducted between 1936 and 1994) on the lipid lowering effects of ALEs showed a mean decrease in either total cholesterol or triglycerides of between approximately 5% and 45% (Kraft, 1997), although the robustness of some of these trial designs is unclear. Two post-marketing studies, which primarily studied the effects of ALE on dyspeptic symptoms, have also reported significant lipid lowering effects (Fintelmann and Menssen, 1996; Fintelmann and Petrovicz, 1998). However, the most robust evidence to date comes from a randomised double-blinded placebo-controlled trial (Engisch et al., 2000) in which 143 hyperlipoproteinemic patients with a high average baseline total cholesterol (approximately 7.70 mmol/l) received either 1800 mg of a standardised narrow-spectrum aqueous ALE (25–35:1) or matched placebo daily for 6 weeks. Reductions in total cholesterol and LDL-cholesterol were significant in the active group (18.5% and 22.9%) over placebo (8.6% and 6.3%), respectively. The authors noted the magnitude of the decrease in total and LDL cholesterol was similar to that of three types of statins reported in a previous study (Wolffenbuttel et al., 1998).

The primary objective of the current study was to observe the effect of 1280 mg of a standardized broad-spectrum aqueous extract of artichoke leaf (4–6:1) administered daily for 12 weeks on lipid levels in otherwise healthy adults with mild to moderate hypercholesterolemia. In addition, general well-being was included as a secondary outcome measure, since improvements have been previously shown in intervention studies with flavonoid-rich plant extracts (Casini et al., 2006; Vignes et al., 2006).

Materials and methods

Volunteer recruitment

Potential suitable individuals were identified through a search of a database held at the Pathology Department, Royal Berkshire Hospital, Reading, UK. One thousand individuals in the local area who had a recently measured (less than 3 months) plasma total cholesterol value in the range 6.0–8.0 mmol/l were identified. A letter explaining the purpose of the trial was sent to each individual via their General Medical Practitioner, for whom a covering letter was included asking them to forward the letter if they thought the...
individual may be suitable. Interested individuals could then request further information about the trial including a Confidential Medical Questionnaire (CMQ) for them to complete. The CMQ was designed to identify the following exclusion criteria: major organ pathology, biliary obstruction, pregnancy, use of cholesterol lowering drugs or warfarin, and consumption of excess alcohol.

Potentially suitable individuals were subsequently invited to have a screening blood test to assess current plasma total cholesterol, liver function and routine biochemistry, which was analysed at the Pathology Department of the Royal Berkshire Hospital, Reading, UK. Further exclusion criteria were total plasma cholesterol outside the range 6.0–8.0 mmol/l, and abnormal liver function or biochemistry results indicating a disease state (as advised by a clinical pathologist).

To further aid recruitment, a press release was sent to local newspapers detailing the trial and inviting potentially suitable members of the public to apply for further information. These individuals were asked to complete a CMQ and subsequently have a screening blood test as already described.

One hundred and thirty one potentially suitable individuals were screened and 75 suitable volunteers were randomised onto the trial. All subjects gave informed consent prior to participation and understood that they could withdraw at any time without giving a reason. A letter was also sent out to each subject’s General Practitioner for information. The study was carried out in accordance with the Declaration of Helsinki (2000) of the World Medical Association and approved by the University of Reading Ethics and Research Committee and the West Berkshire Local Research Ethics Committee.

Study design

The design of the study was randomised, double blinded, placebo controlled and parallel. Volunteers were randomised using ‘MINIM’ software (London Hospital Medical College, UK) with minimization for plasma total cholesterol, age and sex into two groups, to receive either four capsules of ALE or matched placebo daily for 12 weeks. Treatment groups were coded by a third party and the code was not broken until after data analysis.

Each capsule of ALE (Cynara Artichoke, Lichtwer Pharma (UK) Ltd. Marlow, UK) contained 320 mg of a standardised broad-spectrum aqueous extract (4:6:1) of artichoke leaf, containing at least 2.5% total caffeoylquinic acids and at least 0.1% luteolin-7-O-glucuronide. The method of standardisation is described in the European Pharmacopoeia monograph for artichoke leaf (EDQM, 2005) using the reversed-phase HPLC with an octadecysilyl silica gel as column and as mobile phase acetonitrile/H$_2$PO$_4$–H$_2$O/H$_3$PO$_4$ at 30°C. Spectrophotometric detection was carried out at 330 nm.

Volunteers attended the Hugh Sinclair Unit of Human Nutrition on baseline and final visits. Prior to both occasions, they were asked to fast for 12 h. They were asked to complete a general well-being questionnaire before having height, weight and blood pressure measured. Venous blood (20 ml) was taken by venipuncture and immediately spun at 3000 rpm for 15 min at 4°C, the plasma removed and stored at −80°C prior to analysis. At baseline, volunteers were provided with either ALE or placebo capsules exceeding those required for the study, and requested to return remaining capsules on the final visit to check for compliance. At approximately 6 weeks into the study, volunteers were posted a short in-house food frequency questionnaire (FFQ) that concerned habitual dietary intake of food groups based on portion sizes. For fruits and vegetables, a portion consisted 80 g of fresh, frozen, tinned and dried products (not including potatoes and where fruit juice only constitutes up to 1 portion per day), and for dairy products a portion consisted 1/3 pint (200 ml) milk, a matchbox-sized piece (30 g) of cheese, and a small pot (150 g) of yoghurt (FSA, 2001). For whole grains, a portion consisted one slice of whole grain bread, one bowlful of wholegrain cereal, one to two tablespoons of beans or lentils, a handful of nuts and a table spoon of seeds, in part based on the USDA Dietary Guidelines for Americans (USDA, 2005).

Outcome measures

The primary outcome measures were plasma lipids (total cholesterol, LDL and HDL cholesterol, and triglycerides (TAG)). Plasma concentrations of total cholesterol, HDL cholesterol, and TAG at baseline and after 12 weeks were measured using an ILAB 600 clinical chemistry analyzer (Instrumentation Laboratory, Warrington, UK) using enzyme-based colorimetric kits supplied by Instrumentation Laboratory. LDL cholesterol concentrations were calculated by using the Friedewald formula (Friedewald et al., 1972).

The secondary outcome was a measure of general well-being, the Psychological General Well-Being Index (PGWB) (Bowling, 1997), a validated questionnaire which comprises 22 individual questions relating to six dimensions (anxiety, depressed mood, positive well-being, self-control, general health, and vitality) plus a total score.

A post-study questionnaire allowed volunteers to self-rate their perceived benefit of the intervention on their symptoms (definite improvement, some improvement, unchanged, worsened), to guess the medication, describe any side effects experienced during the course of the study and make any other comments.
Statistical analysis

Volunteer numbers were based on the results from a similar trial (Englisch et al., 2000), where the detection of a significant difference between groups (\( z = 0.05 \) and \( \beta = 0.80 \)) allowing for a 25% dropout rate suggested the recruitment of 35 people into each treatment group.

Data were analysed on an intention-to-treat (ITT) basis (Hollis and Campbell, 1999). Baseline data were brought forward into the final data set when final data were not available. A Pearson chi-squared test was used to check for any differences between nominal baseline personal and lifestyle data. Kolmogorov–Smirnov Z tests were used to confirm normal distribution of data for the dependant variables relating to lipid values. T-tests were used to test for differences in lipid values between treatment groups at baseline, and univariate ANOVA (using baseline values as covariates) was used to test the effect of treatment on dependant variables that satisfied Levene’s test of equality of error variances. For non-parametric data related to the PGWB, Mann–Whitney U tests were used to test for differences between treatment groups at baseline and final, and Wilcoxon Signed Ranks tests were used to test for the effect of treatment on dependant variables. Unless otherwise indicated, data are expressed as mean (SD). Statistical analyses were performed using SPSS 12.0 for Windows (SPSS Inc., IL, USA).

Results

Study flow diagram

The flow of volunteers through each stage of the trial is detailed in Fig. 1, as based on recommendations made in the Consolidated Standards of Reporting Trials (CONSORT) statement (Moher et al., 2001). Of the 75 volunteers randomised into the trial, two (in the placebo group) did not start the trial treatment, and hence no baseline data was collected. Hence, there were 73 volunteers for whom at least baseline data were collected and could be included in data analysis. There were two reported adverse events (AE), one in each group, which were unlikely associated with the study intervention, and these volunteers were withdrawn from the trial with no final data being collected.

Study population characteristics

Anthropometric data

Table 1 details the personal and lifestyle characteristics of the two study groups. The majority of volunteers were female and over 50 years old in both groups. Mean body mass index (BMI) for both groups was above the ideal range of 20–25 kg/m² indicating volunteers were on average overweight. The majority of subjects reported taking light or moderate exercise, having a moderately stressful lifestyle, and having never smoked. There were no significant differences between groups.

Prescribed medication and supplements

Both groups had a similar incidence of total prescribed medications (48 for the active group and 51 for the placebo group), with the highest incidence found with those medications prescribed to treat or prevent cardiovascular diseases (diuretics, beta-blockers, calcium channel blockers and ACE inhibitors), being 21 in the active group and 20 in the placebo group. Both groups also had a similar incidence of total self-prescribed food and herbal supplements (39 for the active group and 45 for the placebo group), with the highest incidence found with omega-3 fish oil supplements, being 15 in the active group and 11 in the placebo group. There were no significant differences between groups.

Primary outcomes

Lipid data are presented in Table 2. Volunteers (\( n = 5 \)) whose total cholesterol values were outside the specified range of 6.0–8.0 mmol/l (±5% measurement error) at baseline were excluded from the analysis (the difference in measured total plasma cholesterol values between screening and baseline was thought to be due to the different equipment used at these two time points, plus possible natural variations). Hence, there were 68 volunteers for whom lipid data were analysed.

Plasma total cholesterol decreased in the active group by an average of 4.2% (from 7.16 (0.62) mmol/l at baseline to 6.86 (0.68) mmol/l at final) and increased in the placebo group by an average of 1.9% (from 6.90 (SD 0.49) mmol/l at baseline to 7.03 (0.61) mmol/l at final). Using baseline values as covariates, an analysis of variance indicated a significant difference of 6.1% in mean plasma total cholesterol levels between groups after 12 weeks treatment (\( p = 0.025 \)). No further statistically significant differences were observed for differences in LDL cholesterol, HDL cholesterol or TAG between groups.

Secondary outcomes

For the well-being questionnaire at baseline, values for the six individual domains plus the total score were similar. The overall score was 83.8 (14.5) for the active group and 82.5 (11.0) for the placebo group, which is within the positive well-being range (73–110) previously described (Bowling, 1997). Similarly, after 12 weeks, values for the six individual domains plus the total score were similar, with the overall score being 92.1 (14.9) for the active group and 91.7 (12.3) for the placebo group.
There were no significant differences between groups, but the improvement within both the active (9.9%) and placebo (11.0%) groups after treatment was statistically significant ($p < 0.001$).

**Food frequency questionnaire data**

Data collected from the FFQ showed that mean fruit and vegetable intake was 3.8 (1.6) and 4.2 (1.8) portions daily for the active and placebo groups, respectively. Mean dairy product consumption was 1.6 (0.8) and 1.7 (1.4) portions daily and wholegrain consumption (including nuts and seeds) was 1.9 (1.2) and 1.9 (1.5) portions daily for the active and placebo groups, respectively. Mean oily fish consumption was 1.8 (1.7) and 1.8 (1.3) portions per week for the active and placebo groups, respectively. There were no statistically significant differences between groups.

**Post-study questionnaire data**

The mean intervention period (between baseline and final visits) was 83.9 (2.9) days in the active group and 82.9 (5.6) days in the placebo group. Mean daily capsule intakes during intervention were 3.8 (0.3) and 3.8 (0.5) in the active and placebo groups, respectively. There were no significant differences between groups.

Fig. 1. The flow of volunteers through each stage of the study, as based on recommendations made in the CONSORT statement (Moher et al., 2001).
Table 1. Personal and lifestyle characteristics for 75 volunteers with mild to moderate hypercholesterolemia at baseline

<table>
<thead>
<tr>
<th></th>
<th>ALE (n = 38)</th>
<th>Placebo (n = 35)</th>
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<tbody>
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<td>Sex</td>
<td></td>
<td></td>
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<tr>
<td>Male</td>
<td>14</td>
<td>13</td>
</tr>
<tr>
<td>Female</td>
<td>24</td>
<td>24</td>
</tr>
<tr>
<td>Age</td>
<td></td>
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<tr>
<td>18–30</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>31–40</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>41–50</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>51–60</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>61–75</td>
<td>14</td>
<td>13</td>
</tr>
<tr>
<td>BMI kg/m²</td>
<td>27.8 (5.5)</td>
<td>26.5 (3.5)</td>
</tr>
<tr>
<td>Exercise</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hardly any</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Light</td>
<td>16</td>
<td>16</td>
</tr>
<tr>
<td>Moderate</td>
<td>15</td>
<td>16</td>
</tr>
<tr>
<td>Great</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Stress</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td>Moderate</td>
<td>21</td>
<td>25</td>
</tr>
<tr>
<td>Great</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Smoking</td>
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<td></td>
</tr>
<tr>
<td>Never</td>
<td>26</td>
<td>24</td>
</tr>
<tr>
<td>Used to</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>Occasionally</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Often</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Values are expressed as absolute numbers except BMI.

Table 2. Plasma lipid concentrations for volunteers with mild to moderate hypercholesterolemia at baseline and after 12 weeks of intervention with either ALE or matched placebo

<table>
<thead>
<tr>
<th></th>
<th>ALE (n = 36)</th>
<th>Placebo (n = 35)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Final</td>
</tr>
<tr>
<td></td>
<td>Baseline</td>
<td>Final</td>
</tr>
<tr>
<td>Total Cholesterol</td>
<td>7.16 (0.62)</td>
<td>6.86 (0.68)</td>
</tr>
<tr>
<td>LDL-Cholesterol</td>
<td>4.89 (0.52)</td>
<td>4.64 (0.56)</td>
</tr>
<tr>
<td>HDL-Cholesterol</td>
<td>1.57 (0.36)</td>
<td>1.56 (0.36)</td>
</tr>
<tr>
<td>TAG</td>
<td>1.49 (0.61)</td>
<td>1.41 (0.59)</td>
</tr>
</tbody>
</table>

Values are expressed as mmol/l.

The primary objective of the current study was to observe the effect of 1280 mg of a standardized broad-spectrum aqueous extract of artichoke leaf (4–6:1) administered daily for 12 weeks on lipid levels in otherwise healthy adults with mild to moderate hypercholesterolemia. The results showed a modest but favourable statistically significant difference in total plasma cholesterol between groups after treatment with ALE, although no differences in any of the other lipid parameters measured were observed. Additionally, general well-being, included as a secondary outcome, was not significantly different between groups after treatment, although there was a statistically significant positive treatment effect within both groups.

Regarding the lipid data, the magnitude of the change in plasma total cholesterol values was less than that previously reported by Englisch and colleagues (2000) who noted a reduction in the active group of 18.5% (from 7.74 (0.58) mmol/l to 6.31 (0.96) mmol/l), and in the placebo group of 8.6% (from 7.69 (0.43) mmol/l to 7.03 (0.89) mmol/l), a favourable difference of 9.9% between groups. A number of reasons are suggested for this difference.

First, the quantity and type of artichoke leaf extract used in each study was different. The 1800 mg of narrow-spectrum aqueous extract used by Englisch et al. was likely to contain a higher amount of certain active phytochemicals than the lower amount of broad-spectrum extract used in the current study. For example, luteolin is thought to be one of the constituents of ALE which inhibits de novo synthesis of cholesterol and increases biliary secretion from the liver (Gebhardt, 2002, 2001).

Volunteer-rated effectiveness of the intervention revealed that four participants felt a definite or some improvement after treatment in the active group, with six in the placebo group. One volunteer reported feeling worse after treatment in the active group. The remainder felt no difference. There were no significant differences between groups.

Only a few minor self-reported side effects were noted. Incidence of negative side effects (active group vs. placebo group) were: flatulence (2 vs. 3); headache (0 vs. 2); diarrhoea (1 vs. 2); constipation (3 vs. 0); tiredness (2 vs. 4); dry mouth (2 vs. 4); forgetfulness (0 vs. 1) and bloating (1 vs. 0). Incidence of positive side effects (active group vs. placebo group) were: improved gastrointestinal tract function (4 vs. 1); improved appetite (1 vs. 0); less nausea (1 vs. 0) and hot flashes ceased (1 vs. 0). The ‘guess the treatment’ question revealed that the placebo capsules were not distinguishable from the ALE capsules by volunteers.

Discussion

The primary objective of the current study was to observe the effect of 1280 mg of a standardized broad-spectrum aqueous extract of artichoke leaf (4–6:1) administered daily for 12 weeks on lipid levels in otherwise healthy adults with mild to moderate hypercholesterolemia. The results showed a modest but favourable statistically significant difference in total plasma cholesterol between groups after treatment with ALE, although no differences in any of the other lipid parameters measured were observed. Additionally, general well-being, included as a secondary outcome, was not significantly different between groups after treatment, although there was a statistically significant positive treatment effect within both groups.

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Although hydrophobic glucosides and other derivatives of luteolin (e.g. luteolin-7-O-glucoside), which are also present in ALEs, are water soluble and therefore may have been present in a higher amount in the extract used by Englisch and colleagues.

Secondly, despite anthropometric and lifestyle similarities between the populations in the two studies, mean baseline total cholesterol values of subjects in the study of Englisch and colleagues were higher than in the current study. Moreover, the ratio of total to HDL cholesterol, which is increasingly being recognised as

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better determinant of CHD risk than total plasma cholesterol alone (Kinosian et al., 1994; Natarajan et al., 2003), shows even greater difference between the two studies. In the English study, although the calculated total to HDL cholesterol ratio fell from 6.62 to 5.58 in the active group and from 6.41 to 5.80 in the placebo group after treatment, mean ratios were higher after intervention in both treatment and placebo groups than the calculated values for the corresponding groups in present study, where the active group fell from 4.56 to 4.40 and the placebo group rose from 4.51 to 4.57 after intervention, a difference approaching significance \((p = 0.067)\). Although there is no clear consensus over what constitutes a high-risk total to HDL-cholesterol ratio, Wang and colleagues (2001) observed in a Chinese cohort that subjects with a “low-risk” LDL cholesterol level but with a total to HDL-cholesterol ratio greater than 5 had a 2.5-fold higher incidence of CHD than those with similar LDL cholesterol levels but with a lower total to HDL cholesterol ratio. Hence, on this basis, it appears that the volunteers in our study are at a lower risk group at baseline compared with the patients in the English trial after intervention.

Thirdly, from a dietary perspective, English et al. reported that the majority of their patients had high or moderate dietary sugar and fat intakes, although no details of methodology for collection of this data were given, and the intake of fruits, vegetables and other foods was not reported. In the current study, mean fruit and vegetable intake was lower than the recommended ‘at least 5 portions a day’ (FSA, 2001), but about 1 portion per day higher than the current UK mean adult intake of 2.7 and 2.9 portions for men and women, respectively (FSA, 2004). Intake of dairy products, and whole grains, nuts and seeds, both approached an average of 2 portions per day, and oily fish consumption was on average nearly double the UK recommendation of 1 portion per week (FSA, 2001), all indicating a health-aware population group in the current study. In addition, 52% of all volunteers reporting regularly taking either one or more herbal and food supplements, which is higher than the current adult UK average of 35% (FSA, 2002).

The safety and tolerability of ALEs recorded in previous clinical studies are good to very good, and side effects reported in the current study were few in number and minimal, with even some positive effects reported. We also note in the present study that there were no voluntary drop-outs, there was good compliance with respect to the number of capsules taken and the duration over which they were taken, and general well-being scores at the start and after intervention were positive. We feel that providing volunteers with a clear explanation of the study rationale and making them feel valued as participants played a part in this outcome.

In conclusion, this study provides further evidence that ALE may help reduce plasma total cholesterol in adults with mild to moderate hypercholesterolemia. It is suggested that the type and amount of extract used, in addition to the apparent positive health status of the study population, may have affected the observed magnitude of this response.

Acknowledgements

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