Cardiovascular disease (CVD) is one of the main causes of death in most Western countries (1) and developing countries (2). This results in enormous losses of disability-adjusted life years (3), thus presenting a serious public health concern (1) that is preventable (3). CVD includes all diseases affecting the heart and blood vessels and includes coronary heart disease (CHD), dyslipidemia, hypertension and coronary artery disease (4). CVD is currently responsible for 17% of all deaths in the country and it is estimated that 5.5 million South Africans older than 30 y are at risk of developing CVD. This could be due to raised total serum lipid levels among other factors (5). In view of the crucial role of elevated levels of blood lipids, especially LDL-C, in the formation of atherosclerosis, dietary and therapeutic approaches to the treatment and prevention of CVD are very relevant for scientific and public health (3). Lipid-lowering drugs are effective, but are usually accompanied by severe side-effects (6). Epidemiological and experimental evidence as well as clinical trials have confirmed positive correlations between lifestyle and dietary factors related to blood lipid levels (4). It has repeatedly been demonstrated that low blood levels of LDL-cholesterol (LDL-C) can predict the incidence of CVD and LDL-C therapy reduces CVD risk (3, 4, 7). On the other hand, HDL-cholesterol (HDL-C) also has a strong relationship with CVD as increased HDL-C levels protect against CVD (7). Studies have demonstrated that soy protein can decrease total serum cholesterol (TC), LDL-C (8, 9) and triglyceride (TG) levels (6) as well as mortality rates from CVD (8, 9). A meta-analysis demonstrated that soy isoflavones have LDL-C lowering effects (10).

As a result of the nutritional value of soy protein, specifically the reported cholesterol lowering function, the objective of this study was to compare the long-term effect of 40-g daily whole bean soy consumption for a period of 18 mo on blood lipid levels of women. A single-system design was used and 90 women randomly selected in peri-urban Qwa-Qwa, South Africa. Measurements included dietary intake (24-h recall), anthropometric (weight and height) and biochemical lipid parameters with venous blood samples. The respondents were divided into a hypercholesterolemic and normo-cholesterolemic (NC) group and data analyses included descriptive statistics and t-tests on SPSS, version 21.0. The results showed that a large percentage (40%) of the women was hypercholesterolemic. The hypercholesterolemic group showed abnormal mean values for all the lipid parameters at baseline whereas the NC group showed total cholesterol (TC) and LDL-cholesterol (LDL-C) values in the normal range, but abnormally low mean HDL-cholesterol (HDL-C) (0.9±0.6) and high mean triglyceride (TG) (2.3±0.8) levels. At follow-up, the hypercholesterolemic group had significantly improved HDL-C (p=0.000), LDL-C (p=0.032) and TG (p=0.000) levels, but with significantly increased TC (p=0.01). A similar trend was observed in the NC group; however, no significantly improved HDL-C or TG values were observed. It can be concluded that dyslipidemia and obesity were prevalent amongst this group of women. The daily consumption of 40 g of whole soybean, had no significant positive effect on TC, but had a beneficial effect on LDL-C in the women in Qwa-Qwa. The HDL:LDL ratio was also improved in the in the hypercholesterolemic group, thus reducing the risk for CVD. The consumption of whole soybean thus had a beneficial effect on the lipid profile of the women in Qwa-Qwa.

Key Words soy protein consumption, women, blood lipids

The Effect of Consumption of Soy Foods on the Blood Lipid Profile of Women: A Pilot Study from Qwa-Qwa

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Summary The objective of this study was to compare the long-term effect of 40-g daily whole bean soy consumption for a period of 18 mo on blood lipid levels of women. A single-system design was used and 90 women randomly selected in peri-urban Qwa-Qwa, South Africa. Measurements included dietary intake (24-h recall), anthropometric (weight and height) and biochemical lipid parameters with venous blood samples. The respondents were divided into a hypercholesterolemic and normo-cholesterolemic (NC) group and data analyses included descriptive statistics and t-tests on SPSS, version 21.0. The results showed that a large percentage (40%) of the women was hypercholesterolemic. The hypercholesterolemic group showed abnormal mean values for all the lipid parameters at baseline whereas the NC group showed total cholesterol (TC) and LDL-cholesterol (LDL-C) values in the normal range, but abnormally low mean HDL-cholesterol (HDL-C) (0.9±0.6) and high mean triglyceride (TG) (2.3±0.8) levels. At follow-up, the hypercholesterolemic group had significantly improved HDL-C (p=0.000), LDL-C (p=0.032) and TG (p=0.000) levels, but with significantly increased TC (p=0.01). A similar trend was observed in the NC group; however, no significantly improved HDL-C or TG values were observed. It can be concluded that dyslipidemia and obesity were prevalent amongst this group of women. The daily consumption of 40 g of whole soybean, had no significant positive effect on TC, but had a beneficial effect on LDL-C in the women in Qwa-Qwa. The HDL:LDL ratio was also improved in the in the hypercholesterolemic group, thus reducing the risk for CVD. The consumption of whole soybean thus had a beneficial effect on the lipid profile of the women in Qwa-Qwa.

Key Words soy protein consumption, women, blood lipids

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Table 1. Descriptive anthropometric and biochemical parameters measured.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unit of measure</th>
<th>Normal range</th>
<th>Cholesterolemic group (n= 36, 40%)</th>
<th>Normo-cholesterolemic group (n=54, 60%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Baseline Mean±SD</td>
<td>Follow-up Mean±SD</td>
</tr>
<tr>
<td>Height</td>
<td>metre (m)</td>
<td>1.6±0.1</td>
<td>1.6±0.1</td>
<td>1.6±0.1</td>
</tr>
<tr>
<td>Weight</td>
<td>kilogram (kg)</td>
<td>77.2±14.9</td>
<td>77.4±17.2</td>
<td>76.1±17.7</td>
</tr>
<tr>
<td>BMI</td>
<td>kg/m²</td>
<td>30.0±6.5</td>
<td>30.4±7.0</td>
<td>30.0±6.3</td>
</tr>
<tr>
<td>Serum cholesterol</td>
<td>mmol/L</td>
<td>&lt;5.2 mmol/L</td>
<td>6.8±1.9 a</td>
<td>7.2±2.2 c</td>
</tr>
<tr>
<td>HDL-cholesterol</td>
<td>mmol/L</td>
<td>&gt;1.68 mmol/L</td>
<td>0.8±0.5 b</td>
<td>1.4±0.5 a</td>
</tr>
<tr>
<td>LDL-cholesterol</td>
<td>mmol/L</td>
<td>&lt;3.3 mmol/L</td>
<td>5.4±1.8 a</td>
<td>3.9±1.9 a,c</td>
</tr>
<tr>
<td>Serum triglycerides</td>
<td>mmol/L</td>
<td>&lt;1.7 mmol/L</td>
<td>2.7±0.9 b</td>
<td>2.0±1.0 a</td>
</tr>
<tr>
<td>HDL : LDL ratio</td>
<td></td>
<td>&gt;0.4 (23)</td>
<td>0.18±0.14 a,b</td>
<td>0.27±0.1 a</td>
</tr>
</tbody>
</table>

a,b,c In the same row refer to statistically significant differences between the variables p≤0.05 (Independent [between groups] and paired [within groups] t-test for equality of variances).

Council’s guidelines for research on human beings as approved by the University of the Witwatersrand’s Medical Ethics Committee for Research on Human Beings, study (M080931), and was conducted between March 2008 and November 2012.

Sampling. A power calculation (11), based on 75% power, 5% significance and a change of 3% (12) with standard deviation (SD) (0.075) (12) was used. A total of 86 respondents were needed to obtain statistically representative data for this study. The local community leader purposively chose three tribes, meeting the inclusion criteria (peri-urban areas, monthly household income <ZAR 2000, Sotho-speaking women, aged 19–75 y, no history of CVD or lipid-lowering medication) from which a random sample was selected, using a location map for each of the tribal areas. Every fourth household was selected until the sample size was obtained. Four extra respondents were recruited to make provision for possible drop-out during the intervention.

Study design. A baseline survey was conducted in March 2008 showing a diet with poor dietary diversity and no whole soybean or any other soy-based food consumption with only 11.1% consuming 40 g of extruded soy used as a thickener once per week. A soy awareness and education programme had to be conducted before the study as a large majority of the respondents considered soy suitable for animal feed only. A household soy gardening programme was implemented in 2009 (13) and soy recipes developed and tested for sensory acceptability in 2009 to 2010 (14). A single-system design was used for this study as the researchers had been studying the same community on a repetitive basis for 4 y (15). Ninety women were randomly recruited for the intervention study. Soaked (> 8 h), minced whole soybeans were incorporated into 20 household recipes most frequently prepared in Qwa-Qwa. Skills training included teaching the women to prepare the soy recipes, containing 40 g of whole soy beans per person per day, and how to include the recipes in the household menu planning in 2010.

The soy consumption intervention was undertaken over 18 mo during 2011 and 2012. The researchers visited the women every month to measure compliance, checking on the availability of soy beans and discussing problems regarding soy recipe preparation and side-effects. Dietary intake measurements and blood was drawn one week before and one week after the 18-mo period.

Measurements. A four-stage, multiple-pass interviewing procedure described by Gibson (16) was used for the 24-h recall questionnaire data collection over a period of 3 d. Trained fieldworkers used food models to assist the respondents in estimating portion sizes.

The mean intake of the 3 d was calculated for micronutrients and dietary fat intake variables. Dietary intake data were analysed by a registered dietician using the Foodfinder® version 3 software program, developed by the Medical Research Council and based on the South African food composition tables (17).

Anthropometric measurements included body weight and height, measured according to standard procedures (18) with a calibrated Philips electronic scale, model HF350 (135 kg/100 g) and a Scales 2000 stadiometer respectively. All measurements were taken twice and the average of the two measurements recorded. Body mass index (BMI) was calculated using weight (kg) divided by height squared (m²) and categorised according to the World Health Organization (WHO) cut-off points (19).

Fasting (> 8 h) venous blood samples were drawn by two nursing sisters and a haematologist before 10:00 after sitting for 15 min with a Vacutainer needle with minimal use of tourniquets. The blood was placed on ice until separation within 2 h of blood collection. Serum was harvested by low-speed centrifugation at 4°C and
Soy Food Consumption and Blood Lipids

Fig. 1. The BMI classification of the women participating in the study is illustrated for before and after the soy consumption intervention according to the WHO for underweight, normal weight, overweight and obesity.

Table 2. Analysis of 24-h recall: daily mean intakes of the women (n=90).

<table>
<thead>
<tr>
<th>Dietary intake variable</th>
<th>Unit of measure</th>
<th>Hypercholesterolemic group (n=36, 40%)</th>
<th>Normo-cholesterolemic group (n=54, 60%)</th>
<th>DRI (24)/WHO guidelines (25)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline Mean±SD</td>
<td>Follow-up Mean±SD</td>
<td>Baseline Mean±SD</td>
<td>Follow-up Mean±SD</td>
</tr>
<tr>
<td>Total energy (E) intake</td>
<td>kJ</td>
<td>3,772±1.639&lt;sup&gt;a&lt;/sup&gt;</td>
<td>4,829±2.371&lt;sup&gt;b&lt;/sup&gt;</td>
<td>3,524±2.036&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Total protein intake</td>
<td>g</td>
<td>40±19</td>
<td>38±19</td>
<td>35±21</td>
</tr>
<tr>
<td>Plant protein intake</td>
<td>g</td>
<td>14±7</td>
<td>19±10</td>
<td>14±12</td>
</tr>
<tr>
<td>Animal protein intake</td>
<td>g</td>
<td>27±19</td>
<td>23±14</td>
<td>22±18</td>
</tr>
<tr>
<td>Total fat</td>
<td>g</td>
<td>25±18</td>
<td>(25.1% of E)</td>
<td>36±31</td>
</tr>
<tr>
<td>Cholesterol intake</td>
<td>mg</td>
<td>111.9±99.7&lt;sup&gt;a&lt;/sup&gt;</td>
<td>169.4±259.2&lt;sup&gt;b&lt;/sup&gt;</td>
<td>72.0±65.5&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>Saturated fatty acids</td>
<td>g</td>
<td>7.2±5.6&lt;sup&gt;a&lt;/sup&gt;</td>
<td>10.1±9.1&lt;sup&gt;a&lt;/sup&gt;</td>
<td>6.0±4.2&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Mono-unsaturated fatty acids (MUFA)</td>
<td></td>
<td>(7.2% of E)</td>
<td>(7.9% of E)</td>
<td>(6.4% of E)</td>
</tr>
<tr>
<td>Poly-unsaturated fatty acids (PUFA)</td>
<td>g</td>
<td>8.8±6.8</td>
<td>11.5±8.5</td>
<td>6.8±5.0</td>
</tr>
<tr>
<td>Trans fatty acids (TFA)</td>
<td>g</td>
<td>7.1±5.3</td>
<td>11.0±14.0</td>
<td>8.0±7.8</td>
</tr>
<tr>
<td>Linoleic acid (n-6)</td>
<td>g</td>
<td>6.6±5.1</td>
<td>10.6±13.8</td>
<td>7.2±7.6</td>
</tr>
<tr>
<td>C18:2</td>
<td>g</td>
<td>0.4±0.8&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1.1±1.2&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0.2±0.3</td>
</tr>
<tr>
<td>Linolenic acid (n-3)</td>
<td>g</td>
<td>6.6±5.1</td>
<td>10.6±13.8</td>
<td>7.2±7.6</td>
</tr>
<tr>
<td>C18:3</td>
<td>g</td>
<td>0.2±0.2</td>
<td>0.4±0.4</td>
<td>0.2±0.1</td>
</tr>
<tr>
<td>Carbohydrate</td>
<td>g</td>
<td>117±61&lt;sup&gt;a&lt;/sup&gt;</td>
<td>156±63&lt;sup&gt;a&lt;/sup&gt;</td>
<td>113±83&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Total dietary fibre</td>
<td>g</td>
<td>9±6</td>
<td>12±7</td>
<td>10±10</td>
</tr>
</tbody>
</table>

Estimated energy requirements (EER) based on mean±SD age for the total group was 46±13 y. with mean±SD height, weight and BMI of 1.6±0.1 m, 76.5±16.5 kg and 30.0±6.4 kg/m² respectively with moderate activity levels (24).

a,b,c In the same row refer to statistically significant differences between the variables p<0.05 (Independent [between groups] and paired [within groups] t-test for equality of variances).

DRI= Dietary Reference Intakes as represented by the Estimated Average Requirement for females aged 31–50 y old, and Adequate Intake (AI) where no EAR is available (24).

calculate LDL-C (21).

Statistical analyses. The women were stratified into two groups based on LDL-C levels at baseline (1, 22) to determine the hypercholesterolemic (≥4.1 mmol/L) and NC (<4.1 mmol/L) groups. Data were analysed on the Statistical Package for Social Sciences (SPSS), version 20.0. Descriptive statistics were determined for the cholesterolemic and NC groups (means and stan-

 aliquoted into individual tubes. Serum and plasma were stored at −80°C for 2 wk until analysis to prevent changes in fatty acid composition with prolonged storage times (20). All blood samples were analysed to determine TC, HDL-C and TG by means of the colorimetric method on a Konelab™ analyser with a coefficient of variation (percent CV) between runs of 1.2–2.8% for all serum variables. The Friedewald formula was used to...
dard deviations (SDs)), and the two-tailed independent t-test was conducted to determine significant differences ($p<0.05$) between the groups. Paired t-tests were used to determine significant differences ($p<0.05$) within the groups.

**RESULTS**

**Anthropometric parameters**

The participants had a mean $\pm$ SD age of $46.5\pm12.9$ y. The results show that $40\%$ ($n=36$) of the women were hypercholesterolemic based on LDL-C. The mean $\pm$ SD age of the hypercholesterolemic group was statistically significantly ($p=0.038$) higher ($50.0\pm13.3$ y) than the NC group ($44.2\pm12.3$ y). No statistically significant differences existed in the anthropometric characteristics of the two groups at baseline (Table 1).

In both groups, overweight and obesity were observed in large numbers of the women. Although no statistically significant changes were observed in BMI after the intervention, the prevalence of overweight in the hypercholesterolemic group was reduced from 36.1% at baseline to 27.8% at follow-up (Fig. 1).

**Lipid profile**

Changes in the lipid profile was observed in both groups after the intervention. The hypercholesterolemic group had significantly improved HDL-C ($p=0.000$) and TG ($p=0.000$) levels, but with significantly increased TC ($p=0.013$) and decreased LDL-C ($p=0.032$) levels. A similar trend was observed in the NC group; however, no significantly improved TG values were observed. Although the HDL : LDL ratio improved in both groups, it was still lower than the recommended $>0.4$ (23), but was only significantly changed ($p=0.027$) in the hypercholesterolemic group at follow-up.

**Dietary intake**

The dietary intake results are summarized in Table 2. Both groups had low macronutrient intakes, except for carbohydrates, at baseline and follow-up when compared to the EAR (24). No significant differences in macronutrient intakes were observed between the groups, except for a significantly ($p=0.032$) higher dietary cholesterol intake in the hypercholesterolemic group at baseline and follow-up. The total energy intake improved significantly from 3,772 to 4,829 kJ ($p=0.007$) as well as LDL-C ($p=0.257$, $r=0.282$, $p=0.000$) and total protein intake ($r=-0.283$, $p=0.036$), saturated fatty acid ($r=-0.287$, $p=0.034$), mono-unsaturated fatty acid ($r=-0.318$, $p=0.018$) and linolenic acid ($r=-0.285$, $p=0.035$) intakes.

**DISCUSSION**

Research has proved that soy protein consumption can reduce total serum cholesterol levels as well as LDL-C levels and increase HDL-C levels. As a result, the Food and Drug Administration of the United States of America recommend that 25 g of soy protein should be consumed daily for a cholesterol-lowering effect. However, the benefits of soy for cardiovascular benefits are not supported by recent research (4, 12) resulting in conflicting reports regarding the effect of soy consumption on serum lipid levels (25). Furthermore, the literature on the effect of soy food and/or protein consumption on the serum lipid profile in South Africa is scarce. This study thus focused on the effect of dietary intake of 40 g of whole soybean (equivalent to 15 g of soy protein) daily on the lipid profile of adult women in South Africa.

Both groups showed abnormal mean values for all the lipid parameters at follow-up with no statistical significant differences between the two groups. In both hypercholesterolemic and NC women, the HDL-C levels improved significantly after the intervention, but it was still lower than the recommended cut-off point of $>1.68$ mmol/L. This was consistent with other studies (8, 26) in NC adults. The LDL-C levels were significantly lower in both groups at follow-up. The HDL : LDL ratio is, however, a better indicator of CVD risk than the individual HDL- and LDL-C levels. The HDL : LDL ratio improved in both groups, but it was only significant in the hypercholesterolemic group. In both groups, the HDL : LDL ratio was still lower than the recommended $>0.4$ (22) and thus this group of women is at risk of CVD. These findings are consistent with a study conducted in a similar community in the Vaal region of SA (27).

The TC results were inconsistent with those of a meta-analysis of 38 studies (10). Most of the studies included in the meta-analysis measured the short-term effect (≤4 wk). The inability of this study to prove a positive effect on TC after a long-term soy supplementation/consumption period was consistent with another long-term (24 wk) study in hypercholesterolemic adults (1). LDL-C was significantly reduced in both groups at follow-up. This was confirmed by the negative, significant relationship with dietary protein intake.

TC can further be influenced by changes in increased dietary cholesterol intakes, endogenous cholesterol synthesis, and the efficiency of cholesterol absorption (6) or through other dietary intake factors (12). In this study, both groups showed consistently low cholesterol intakes; however, the NC women had a significantly higher intake of dietary cholesterol after the intervention. However, no positive significant relationship between dietary cholesterol intake and TC was observed in this group of women and the dietary cholesterol intake could thus not have confounded the serum TC.
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results. Furthermore, the dietary intake of the women in this study showed very low macronutrient intakes, specifically fibre. It has been proven that dietary fibre can lower serum TG and LDL-C (3). Another dietary factor that is associated with TC and LDL-C levels is dietary SFA intakes (28). In this study both groups consumed less SFA than the WHO recommended cut-off point of 10% of total energy intake (29). No positive significant relationship between the low dietary fibre or SFA intakes and higher serum TC and LDL-C levels could be established in this study.

Although the total dietary fat intake for both groups was low, the dietary fatty acid intakes of the women in this study met the recommended guidelines (29) except for low linoleic acid intakes in both groups. The main sources of linoleic acid in the diet include vegetable oils such as sunflower oil, soybean and maize oil, nuts and seeds. These are usually more available than the food sources of linolenic acid, including walnuts, linseed and rapeseed oil. This finding is consistent with another study amongst low-income black women in South Africa (27).

A number of smaller randomly selected studies undertaken from 1982 to 1996 in South Africa found that 25% of black women were hypertensive and hypercholesterolemic (30). Dyslipidemia, hypertension and obesity are well-known risk factors for CVD (31). In this study, 36% of the women presented with hypercholesterolemia, which was higher than the national prevalence (31) and 31.1% and 46.6% were overweight and obese respectively. Research also found that the mean TC concentrations increase with age (32). TC levels were positively significantly associated with age in this group of dyslipidemic women.

It can be concluded that hypercholesterolemia and obesity were prevalent amongst this group of women. Although research has proved that soy protein has a beneficial effect on TC and LDL-C, the daily consumption of 40 g of whole soybean, equivalent to 15 g soy protein, had no significant positive effect on TC, but had a beneficial effect on LDL-C of the hypercholesterolemic and NC women. The HDL : LDL ratio was also improved in the hypercholesterolemic group, thus reducing the risk for CVD. It was thus proven that whole soybean consumption has a beneficial effect on hypercholesterolemia and obesity in these women.

A well-designed, longitudinal study of a statistically representative sample should be implemented in this community to determine the presence of the behavioural (diet, smoking, and physical activity) and metabolic (hypertension, obesity, blood lipid profile, diabetes, metabolic syndrome and C-reactive protein) factors contributing to CVD (33). Other studies have found that more favourable results were obtained when a diet, including a combination of cholesterol-lowering foods, was implemented (9, 21). A case-controlled intervention study with a combination of cholesterol-lowering foods, including soybeans, should thus be implemented in this community to address the prevalence of dyslipidemia and obesity in these women. Soy is a source of good quality protein and is often used in low-income households as a replacement for other more expensive protein sources. The use of soy should not be discontinued and further research is recommended to study the effect of daily soy consumption on hypertension, obesity and metabolic syndrome (34), also prevalent in this group of women.

This pilot study had a number of limitations:

- urinary/blood samples were not analysed for isoflavones during the intervention to measure compliance
- the hypercholesterolemic group was smaller than the NC group and could have influenced the results as the power calculation indicated 43 respondents per group
- only baseline and follow-up data collection was done and the researchers can thus not assess the blood lipid variability over time
- no control group was included.

However, as an exploratory study, the results revealed issues and actions needed for successful implementation of a similar intervention for future research. A strength of the study was the high retention rate with no drop-outs.

Acknowledgments

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