THE ACTIVITY DIET AND BLOOD PRESSURE TRIAL

(ADAPT)

Dr Valerie Burke, Dr Trevor A Mori,

Professor Lawrence J Beilin, Ms Jackie Mansour

THE UNIVERSITY OF WESTERN AUSTRALIA

Cardiovascular RESEARCH CENTRE

Australian Government

Fisheries Research and Development Corporation

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Valerie Burke, Trevor A Mori, Lawrence J Beilin, Jackie Mansour

Published by The School of Medicine and Pharmacology

Royal Perth Hospital Unit

University of Western Australia

and

The Cardiovascular Research Centre

Medical Research Foundation Building

Rear 50 Murray Street

Perth Western Australia

Box X2213 GPO

Perth Western Australia 6847

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ISBN: 1 74052 121 8

Printed by Uniprint, Perth, Australia

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PRINCIPAL INVESTIGATOR: Professor LJ Beilin

OTHER INVESTIGATORS : Dr V Burke
Dr TA Mori
Ms J Mansour

ADDRESS: University of Western Australia
School of Medicine and Pharmacology
Royal Perth Hospital Unit
Box X2213 GPO
Perth WA 6847

OBJECTIVES:

To evaluate the effects of a lifestyle program incorporating increased fish consumption in patients treated with medication for high blood pressure on:

1 Changes in psychological factors affecting lifestyle choices.

2 Changes in lifestyle

3 Changes in cardiovascular risk factors, particularly blood pressure, blood lipids and blood glucose

4 Changes in the need for treatment with medication for hypertension

NON-TECHNICAL SUMMARY:

A lifestyle program that focused on diet, with emphasis on incorporation of fish, weight loss and physical activity can achieve a range of improvements in health-related behaviours and cardiovascular risk factors in overweight men and women being treated with drugs to control hypertension (high blood pressure). Improvements in some variables were maintained in the long-term.

The program group showed significant improvements in the following measures.

Determinants of behaviour change

- Greater proportion of individuals adhering to a healthy diet and regular physical activity at the end of the program and at follow-up
- Greater decrease in the perceived importance of barriers to behaviour change both at the end of the program and for diet at follow-up.
- Greater increase in self-efficacy for diet and physical activity at the end of the program and for diet at follow-up.

Change in health-related behaviours

- Greater fall in energy intake at the end of the program and a trend at follow-up.
- Greater fall in sodium intake at the end of the program and a trend at follow-up.
- Greater fall in intake of total, saturated and monounsaturated fat at the end of the program and at follow-up.
- Greater increase in platelet fatty acids derived from fish at the end of the program and at follow-up.
- Greater proportion of individuals eating fish frequently at the end of the program and at follow-up.
- Greater increase in the time spent in exercise at the end of the program.

Change in risk factors

- Greater weight loss at the end of the program and at follow-up
- Greater decrease in waist circumference at the end of the program and at follow-up.
- Greater fall in cholesterol and triglycerides at the end of the program.
- Greater fall in systolic and diastolic blood pressure at the end of the program.
- Greater fall in heart rate at the end of the program and at follow-up.

Change in the need for antihypertensive drugs

- Greater proportion of men with drug treatment withdrawn at the end of the program.

Cost and health benefits of the program

- No additional cost associated with replacing fish for meat in the diet.
- An 8% reduction in risk of heart disease and stroke over the next 10 years.

CONCLUSION

A lifestyle program incorporating increased fish for patients treated with medication for hypertension can achieve substantial improvements in lifestyle and cardiovascular risk and has potential applications in other at-risk groups.

KEYWORDS: Blood pressure, lifestyle, blood lipids, blood glucose, diet, exercise.

ACKNOWLEDGEMENTS

Financial support was also provided by the Australian National Health and Medical Research Council, the Fisheries Research Development Corporation and the Western Australian Minister of Fisheries' Industry Development Unit. We thank Professor Lawrence J Appel for advice in establishing a protocol for drug withdrawal, Lyn McCahon for expert technical help, and Jackie Ritchie for her contribution to data collection and organisation of the study. Hayley Cutt provided invaluable administrative and practical contributions to the study. We thank Amy Wilson for dietary analyses. Mr Richard Stevens of the Western Australian Fishing Industries Council Inc provided helpful advice. We are grateful to Catalano Seafoods, Global Seafoods Distributors Australia Pty Ltd, and Austral Fisheries Pty Ltd, all of Perth, Western Australia, for donations of fish.

BACKGROUND

The Activity Diet And Blood Pressure Trial (ADAPT) was designed as a randomised controlled trial to examine the effects of multiple changes in lifestyle on blood pressure, the need for antihypertensive drugs, and on cardiovascular risk factors, including blood lipids. As well as an assessment of effects on cardiovascular risk factors, ADAPT included documentation of self-efficacy, health beliefs and barriers to change related to diet and physical activity. The health program developed for ADAPT focused on dietary change incorporating increased dietary fish and on increased physical activity and weight loss in overweight men and women taking medication for hypertension.

Hypertension (high blood pressure) is a major public health concern, placing huge financial and physical burdens on the community. These include increased morbidity and mortality from coronary heart disease, stroke, congestive heart failure, and end-stage renal disease. Although hypertension can be controlled by medication, factors such as side effects and the cost of drugs can lead to poor compliance with treatment. However, changes in lifestyle such as weight reduction, sodium (salt) reduction, increased fish meals or fish oils, alcohol moderation, increased physical activity and smoking cessation, can lower blood pressure with additive effects (1-11). In addition to improving hypertension, such lifestyle strategies can improve other co-existing risk-factors such as hypercholesterolaemia (high blood cholesterol levels) and glucose metabolism.

In 1998, the National Heart Foundation (12) reported that cardiovascular disease caused 40% of all deaths with an associated cost of approximately $3.9 billion. Eighty per cent of the adult population had at least one of the following cardiovascular risk factors: hypertension; tobacco smoking; physical inactivity or being overweight (12), all modifiable by lifestyle change. There is considerable evidence supporting lifestyle modification as an approach to reducing hypertension and, consequently, reducing the financial burden on the community, but few studies have addressed several lifestyle factors simultaneously and none of these has focused on increasing dietary fish (1,10,13) .

Currently it is recommended that treatment of hypertension should begin by focusing on lifestyle changes that include weight reduction, sodium reduction, alcohol moderation, increased physical activity, and smoking cessation, which have been shown to reduce hypertension-related morbidity and mortality in patients with high cardiovascular risk (11).

Lifestyle modification is particularly important in improving co-existing risk factors such as hypercholesterolaemia (11), as antihypertensive (blood pressure-lowering) medication alone reduces, rather than eliminates, risk (10). Difficulty in compliance with drug therapy is an additional motive to encourage lifestyle modification (14,15).

The lack of desire to change one's lifestyle is, however, one of the major barriers in managing individuals with hypertension and affects compliance with changes in health-related behaviours. Lahdenpera et al (14), suggested that noncompliance with lifestyle recommendations is common in hypertension because patients often have no symptoms, with hypertension diagnosed only after routine measurement of blood pressure. In contrast, Sims (16) suggests that allowing a more active part in the management of their condition, beyond simply taking antihypertensive medication, may facilitate compliance and improve blood pressure, because of the perception that a more active role in itself enhances the individual's overall sense of well-being. There are a number of recognised strategies considered appropriate for lifestyle modification-based approaches and these were incorporated into the ADAPT program to influence behaviour change and to address issues of non-compliance and maintenance.

Studies Relevant to the Development of ADAPT

Trials that preceded ADAPT provided concepts that were incorporated into the study design, drug withdrawal protocol and health promotion program. The Trial of Nonpharmacologic interventions in the Elderly (TONE) clinical trial compared the effects of a reduced sodium intake diet, a weight loss diet or usual care in the treatment of hypertension in older people (10,17). There was approximately a 30% decrease in the need for antihypertensive medication, achieved by reducing average sodium intake to 40 mmol/day or by reducing average body weight by 3.5 kg. Participants assigned to the combined intervention of sodium reduction and weight loss were the most successful in maintaining satisfactory blood pressure control after the withdrawal of their antihypertensive medication (10,17).

TONE showed that antihypertensive medication could be safely withdrawn in older persons without clinical evidence of cardiovascular disease who do not have blood pressure greater than 150/90 mmHg at withdrawal, providing that good blood pressure control can be maintained with lifestyle modification. Reduced sodium intake and weight loss constitute a feasible, effective and safe non-drug therapy for hypertension in older

persons, with additional benefits in lowering blood lipid levels. It was suggested that the success in achieving and maintaining these behavioural changes was, in part, due to a motivation to reduce their dependence on antihypertensive medication. The TONE study was the first trial of sufficient size and duration to provide convincing evidence of the feasibility, efficacy and safety of lifestyle interventions in controlling high blood pressure and decreasing the need for medication in older patients with hypertension (10).

The Dietary Approaches to Stop Hypertension (DASH) study involved 459 middle-aged adults with normal to moderately high blood pressure (1). The study compared three diets: the first diet was similar in nutrients to a usual American diet; the second was similar to the first except that it contained more fruit and vegetables; and the third was the DASH diet which incorporated an eating pattern that was low in saturated fat, cholesterol and total fat (6% of calories from saturated fat), high in fruit, vegetables, low fat dairy foods, whole grain products, lean meats, fish, poultry, nuts and reduced sweets and sugary drinks. All diets contained the same amount of sodium (3000mg) and were implemented in the absence of weight loss or sodium restriction.

Within each diet group the onset of effect was within two weeks and sustained throughout the eight weeks of the intervention. Both the fruit and vegetable diet and the DASH diet reduced blood pressure, but the DASH diet had greater effects, controlling hypertension in 70% of participants with stage I hypertension at baseline. An added benefit of the DASH diet was a decrease in total cholesterol and low-density lipoproteins. Additionally, blood pressure reductions observed in participants without hypertension suggests that following the DASH combination diet might be an effective nutritional approach to preventing hypertension (1).

An extension of the research into the DASH diet saw Sacks et al (18) examine the effects of sodium levels in combination with the DASH diet. They randomly assigned 412 participants to eat either a control diet similar in nutritional intake to a usual American diet, or the DASH diet. Within the assigned diet, participants ate foods with high, intermediate or low levels of sodium for 30 consecutive days in random order. The DASH diet lowered blood pressure at the high, intermediate and lower levels of sodium intake, confirming and extending the findings of the previous DASH study. The combined effects on blood pressure of low sodium intake and the DASH diet were greater than the effects of either intervention alone and each intervention was well tolerated.

Additivity of Effects of Lifestyle Changes: Effects of Fish

A number of clinical trials have shown the benefits of combining modifications of lifestyle including reduction of sodium, increased physical activity, weight loss and the incorporation of dietary fish.

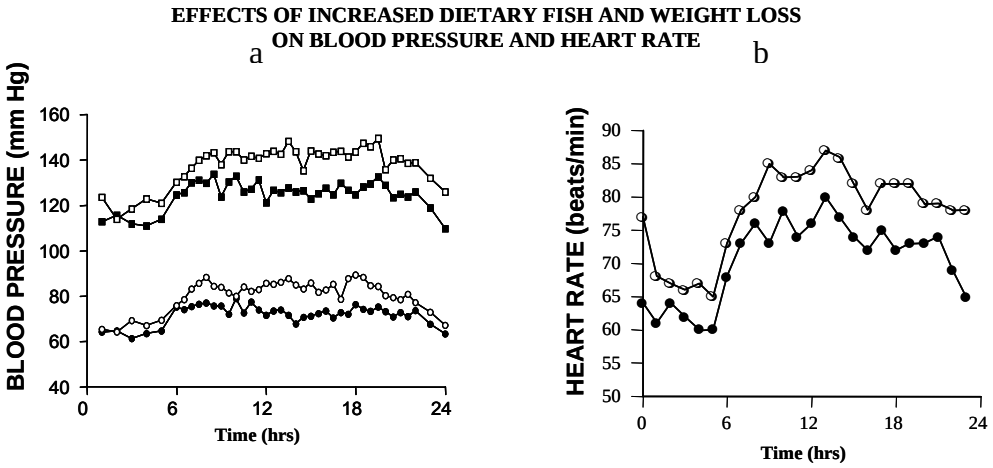

Figure 1: *Systolic (a: upper lines) and diastolic (a: lower lines) blood pressure and heart rate in response to increased dietary fish combined with weight loss.*

The positive effects of incorporating fish into the dietary regimen have been examined extensively in the School of Medicine and Pharmacology, Royal Perth Hospital Unit (5-7,19). A trial examining the effects of eating fish daily and weight control on ambulatory blood pressure levels in 63 overweight, treated hypertensives showed that the inclusion of fish rich in omega-3 fatty acids in the diet significantly reduced ambulatory blood pressure and heart rate (19). In particular, the study showed that a daily fish serve in conjunction with a weight-loss program achieved falls in blood pressure comparable to the effects of antihypertensive drugs (Figure 1). Additional benefits were seen in decreased heart rate (19), improved serum lipids, particularly a reduction in plasma triglycerides and an increase in HDL-cholesterol, as well as a fall in glucose (Figure 2).

Reduced sodium intake and increased protein and fibre consumption, particularly with fruits and vegetables as sources of soluble fibre, were all associated with lower systolic blood pressure (3, 20).

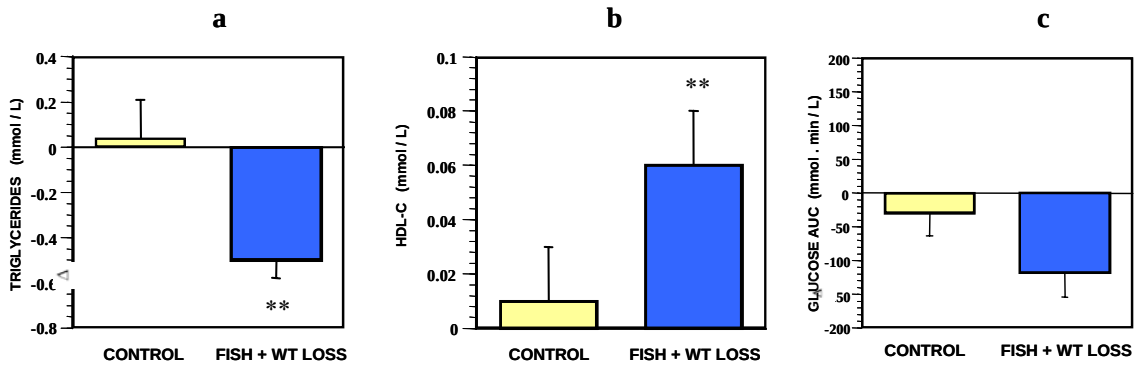

Figure 2: *Effects of increased dietary fish combined with weight loss on changes in triglycerides (a), HDL-cholesterol (b) and glucose (c).*

Physical activity, particularly in combination with energy restriction, has also been reported to have an additive effect in reducing blood pressure (21,22) and was associated with other positive health benefits such as significant reductions in measures of obesity (21). In Type 2 diabetic patients, fish meals in combination with physical activity improved blood lipid and glucose levels (6).

The observations from these research trials indicating that additive effects can be achieved by combinations of lifestyle modification encouraged the inclusion of these strategies in the ADAPT intervention, further strengthening dietary and physical activity practices already incorporated from TONE and DASH. An emphasised addition to the dietary program is the inclusion of dietary fish, which is observed consistently as effective in reducing blood pressure and improving risk factors for cardiovascular disease.

Previous Health Education Programs in Our Research Unit (The Partners Study)

The Partners Study preceded the ADAPT study and assessed a health promotion program that focused on diet and physical activity with the aim of preventing adverse changes in health-related behaviours in couples beginning to live together. This included a diet similar to the DASH diet, while the physical activity program aimed to encourage at least 30 minutes of moderate physical activity on most days of the week; quitting smoking and alcohol moderation were also emphasised (2,3).

A short-term pilot study that preceded the Partners study showed improvements in the program group relative to controls in a fall in total and saturated fat intake, reduced consumption of take-away foods and decreased alcohol consumption. Additionally, there was an increased consumption of fruit, vegetables and reduced-fat foods. Weekly physical activity increased by the equivalent of a 50 minute brisk walk relative to the control group with additional increases in incidental exercise activities such as taking the stairs or walking to the shops. Cholesterol fell by 6% in the program group relative to the control group (2).

In a subsequent extension of the Partners study, there were significant improvements in health behaviour at the end of the 16 week intervention and after 12 months follow-up. These included reduced intake of total fat and saturated fat intake, a lower proportion of overweight individuals and falls in both blood pressure and total cholesterol (3).

In addition to these clinical improvements, the Partners Study noted improvements in measures of determinants of health behaviours such as self-efficacy (belief that an individual can achieve a behaviour), more positive health beliefs about the benefits of health-related behaviours and a decrease in the perceived importance of barriers to behaviour change for diet and physical activity (2;3). The structure of the 16-week health promotion in the ADAPT study was based on our experience with the Partners Study but was tailored to older, overweight hypertensives.

Development of the ADAPT Health Promotion Program

Dietary Considerations

Adherence to recommended dietary guidelines for disease prevention improves multiple cardiovascular risk factors, with dietary modifications forming the basis of prevention and treatment for hypertension, dyslipidaemia and diabetes mellitus (23,24). Weight loss, inclusion of fish, reduction of fat, increased fibre, reduced alcohol consumption, the incorporation of reduced-fat dairy products, reduction of sodium, and increased consumption of fruit and vegetables are pivotal components. Furthermore, strategies in achieving long-term dietary change and measurements of change are addressed, based on behavioural models.

Long-term Dietary Change

Cardiovascular risk factors, such as hypertension and dyslipidaemia can be improved by reduced intake of dietary fat and salt, and increased intake of fish, fibre, and fruit and vegetables (23-26).

Implementation of dietary behaviour change requires attention to a number of factors. First, individual dietary components need to be considered, including the protective or harmful effect of different food constituents and food groups on health, and the relative proportion of food constituents in the diet. Second, specific behaviours, such as food choices and food preparation practices and their impact on obesity and health, as well as an understanding of the cumulative effect of these behaviours, need to be addressed (25).

The high prevalence of cardiovascular risk factors including central obesity, hypertension and elevated cholesterol (24,26) and increased risk of Type 2 diabetes and insulin resistance (27,28) highlights the need to increase the proportion of the population attempting to conform to dietary guidelines. Dietary changes that involve decreasing or avoiding constituents of certain foods and beverages, such as learning to avoid salt or fat, require nutrition education to recognise which types of foods contain these. People also need to learn how to interpret food labels and to learn food preparation techniques to lower fat and sodium content (25). Interventions to increase consumption of certain foods may involve less education, particularly for readily recognisable foods, such as fish and fruit and vegetables. However, the importance of incorporating these foods into the daily diet needs to be emphasised (25).

Several trials found the incorporation of group and individual counselling methods based on social learning theory to be an effective approach in behaviour modification, specifically calorie reduction and weight control (25,26). Self-monitoring is also considered essential initially, when the objective is to decrease consumption of nutrients that are often disguised in foods, such as salt and fat, as it allows the individual to estimate the quantity of a particular constituent in a portion of food (25,28). Qualitative dietary changes, such as educating individuals to read nutritional panels on food packages, have been important in sustaining behaviour changes. Patient participation in goal-setting, personalised strategies to overcome barriers and follow-up, including evaluation and problem solving have been found important in achieving behaviour change, while strategies such as follow-up phone calls can improve maintenance (26).

Fat Intake

Dietary saturated fat increases blood cholesterol levels, which in turn increases risk of cardiovascular disease (24,25). The recommendation is for no more than 30% of daily energy from fat in order to reduce the risk of heart disease and cancer, with no more than 10% from saturated fats. The recommendation regarding polyunsaturated fats is that at least 30% of the recommended daily energy intake from fat is derived from polyunsaturated fats. The benefits of plants and fish as sources of dietary fat need to be emphasised (24,25).

Omega-3 Polyunsaturated Fats

Omega-3 polyunsaturated fats, which are predominantly found in fish and fish oils, include the beneficial long chain omega fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), which reduce the risk of cardiovascular disease and coronary heart disease (29-31). Much of this evidence has emerged from fish-consuming populations including the Greenland Eskimos (32), Japanese Islanders and Tanzanian Bantu villagers (31). A study that compared fish-consuming Bantu villagers and vegetarian villagers, showed that blood pressures, plasma concentrations of total cholesterol and triglycerides were lower in the fish-consuming group (31). In addition, two large population trials, DART (33) and GISSI-P (34) showed that omega-3 fatty acids significantly reduced total mortality and, in particular, sudden death, in patients who had previously experienced a heart attack. Trials such as those conducted in the School of Medicine and Pharmacology, Royal Perth Hospital Unit (5-8,19) have demonstrated the benefits of fish meals or fish oils in lowering blood pressure and decreasing risk factors for cardiovascular disease such as improvements in blood lipids, reduced blood clotting, and reduced inflammatory responses.

Fruit and Vegetable Consumption

An eating pattern high in fruit and vegetables is protective against cancer and cardiovascular disease (25,27,35). Increasing fruit intake to 2-4 serves per day and vegetable intake to 3-5 serves per day resulted in an increase in potassium consumption, and significant reductions in systolic and diastolic blood pressure (25,27). Additionally, increased fruit and vegetable consumption raised plasma antioxidant concentrations (27). Evidence from the literature supports benefits from an increased consumption of a wide variety of vegetables, particularly dark-green leafy, cruciferous, and yellow-orange

vegetables and a wide variety of fruits, particularly citrus and deep yellow-orange fruits that provide large amounts of vitamin C, beta carotene and other carotenoids and flavonoids. These compounds have been suggested to reduce the risk of heart disease by reducing the oxidation of cholesterol. Folic acid, found widely in fruits and vegetables such as dried beans, green leafy vegetables, melons and oranges, and vitamins B6 and B12 help to lower blood homocysteine, a sulfur amino acid that is associated with increased risk of cardiovascular disease (35).

Sodium

Sodium reduction is recommended to prevent and control hypertension (25). Sodium reduction can be achieved through ceasing to add salt to cooking or at the table, purchasing salt-reduced breads and cereals, and avoiding foods that have a high salt content (36,37). Large quantities of sodium are found in highly processed foods, emphasising the need for consumer education to raise awareness of 'hidden' sodium in products and the need to consume larger amounts of unprocessed or minimally processed foods.

Incorporation of Dairy Products and the Effect of Potassium, Calcium and Magnesium

Age-related increases in blood pressure are attenuated by calcium intake (37). Additionally, it has been shown that milk and food products made from milk, such as yoghurt, which retain substantial amounts of potassium, calcium and magnesium, as well as being low in sodium, are associated with a reduced risk of ischaemic stroke, reduced blood pressure, lower fasting glucose and triglycerides (38). Whelton et al (11) suggest that increased dietary potassium is beneficial in lowering blood pressure in both hypertensives and normotensives. As mentioned previously, the DASH diet (1), which reduced blood pressure, substantially increased potassium, calcium and magnesium intake.

Increased Fibre

Intake of 20-30g of fibre per day, including both soluble and insoluble fibre is recommended. Soluble fibre, found widely in fruits and vegetables, helps to control serum cholesterol levels, as well as having beneficial effects on glucose metabolism, weight control and hypertension and reducing the risk of colon cancer (25,35). Studies in the

School of Medicine and Pharmacology, Royal Perth Hospital Unit have shown that soluble fibre can reduce blood pressure (3).

Obesity and Weight Loss

Long-term health benefits and lower blood pressures are likely to be maintained by avoidance of obesity. The current global epidemic of obesity may be related to environmental changes with easy access to energy-dense foods and an increasing number of devices, such as computers and remote controls, reducing the amount of energy expenditure (28). Modifying the environment by improving access to healthful foods and opportunities for physical activity, in combination with individual programs that combine diet, exercise and behaviour modification have been shown to be most effective over the short-term.

Long-term maintenance of weight loss is extremely difficult (39). Suggested methods to improve maintenance of weight loss and delay weight regain include increasing intensity of the initial treatment, extending the length of the treatment, altering dietary and exercise perceptions, enhancing motivation and teaching maintenance-specific behavioural skills (39). ADAPT incorporated a one-year follow-up with periodic phone and group contact after the initially intensive 16-week health promotion program, to enhance motivation and maximise and build upon changes made to dietary and physical activity behaviour.

Physical Activity

Physical activity promotion is not only physiologically beneficial in terms of the prevention of morbidity, including various lifestyle-related diseases such as coronary heart disease, diabetes mellitus, hypertension and obesity, but it also has many psychological benefits such as reducing stress and improving self-esteem (36,40-42). Additionally, many trials have shown that moderate and vigorous physical activities predict lower mortality rates (43). Despite the positive health benefits of exercise, problems of adherence to exercise are well documented, with exercise prevalence among adults declining with age.

Physical activity has the potential to yield substantial clinical and public health benefits. Even moderate amounts of physical activity, such as increasing incidental activity practices including walking the dog daily, climbing stairs and walking to the shops have been shown to benefit cardiovascular health (42). While exercise alone is effective in

reducing systolic and diastolic blood pressure, the addition of a behavioural weight loss program significantly augments the efficacy of aerobic training (15).

Thirty minutes of moderate physical activity on most days of the week is recommended to achieve cardiovascular health (44) and has been shown to reduce the number of antihypertensive agents needed to control blood pressure (36). Not only is this level of activity adequate to induce declines in blood pressure, individual compliance is often better at this level than at higher intensity. The ADAPT program promoted moderate intensity of exercise and encouraged incidental activity.

Theories Influencing Behaviour Change Applied to the ADAPT Program

Behavioural theories based on well-recognised strategies were used to facilitate the adoption and maintenance of program goals. According to one strategy, individuals with chronic diseases such as hypertension must perceive that their health is at risk and accept responsibility for adherence to treatment before behaviour change and compliance can be achieved. Another strategy relates to the capacity to learn by observation so that individuals can acquire rules for regulating behavioural patterns without having to form them gradually through experience. Expected outcomes associated with behaviours influence individuals to engage in behaviours whose outcome they value.

Self-efficacy, an individual's perception of their ability to carry out a behaviour, influences both change and maintenance of a range of health behaviours including weight control, alcohol moderation, increased physical activity and smoking cessation (45-47). Initiation, adoption and maintenance of healthy behaviour is likely to be facilitated by programs to improve self-efficacy (48-50). The ADAPT program enhanced self-efficacy in practice by reducing the complexity of tasks through dividing the target behaviour into components that were easy to manage, with initial tasks being easier to accomplish than subsequent tasks, charting progress over the course of the change process, provision of feedback and verbal reinforcement (48).

Another concept which is considered important in the decision-making process and, consequently, behaviour change, is decisional balance, which measures the relative importance to the individual of the pros (advantages or benefits) and the cons (disadvantages, barriers or costs) of behaviour change (51). Shifting decisional balance so

that pros outweigh cons appears to be important in explaining why people make a commitment to change behaviour (51-53).

Barriers to Changing Behaviour

Promotion of healthy choices and behaviour change requires that barriers to adopting and maintaining a healthy lifestyle are addressed (53). Barriers to healthy eating, for example, include lack of healthy food choices when purchasing lunch and dining out, lack of healthy foods available at home, lack of willpower, ignorance about the nutrient content of foods, the expense of a healthy diet, use of food as a reward, unacceptable taste of reduced-fat foods, and lack of family support for low-fat foods (45,47). Nutrition programs should incorporate self-efficacy, education to improve knowledge about nutrients and food preparation, and improved access to healthy foods as strategies to address barriers to adoption and maintenance of healthy eating habits (45,47).

However, knowledge about healthy food choices is insufficient in itself to motivate healthy eating. It has been suggested that aspects of the health belief model, self-efficacy and decisional balance, can be incorporated to alleviate barriers (45). Belief in a connection between diet and disease, perceived benefits of a healthy diet, knowledge and the development of skills as to which foods should be chosen to predispose to healthy dietary choices are effective strategies. Social support and family involvement are seen as the other major strategies required to ensure healthy foods are available at home and to encourage participation in food buying, preparation and serving. A similar approach with recognition of barriers to other specific health-related behaviours can be addressed similarly.

Long-term Adoption of Behaviour Change (Maintenance)

Lifestyle interventions can be reasonably effective in the short-term. However, there is much less progress in promoting maintenance following initial changes (54). Most individuals revert to their old high-risk behaviours within 6 to 12 months of treatment regardless of the behaviour in question, suggesting that the social environment hampers maintenance. Promotion of maintenance involves the use of more generic, less risk-specific, coping, problem-solving and environmental strategies for change.

In studies of weight loss where many of the participants who lost a large amount of weight regained it within a few years (55), participants who successfully maintained weight loss

were significantly more likely to endorse self-regulatory activities such as exercise, self-monitoring food intake and weekly weighing, as useful weight regulation strategies. Emphasis needs to be placed on factors that motivate participants to begin a program, time management, problem-solving skills and social support.

Maintenance is particularly important for physical activity, as individuals must continue to be physically active to sustain its full health benefits. A recent trial employed physical activity counselling to encourage improvements in incidental activity such as household chores and stair climbing and increases in aerobic physical activity, especially moderate intensity walking that is specifically encouraged in hypertension prevention and treatment (56). Participants were encouraged to increase energy expenditure through unsupervised home-based activity during follow-up, with individual counselling every 6 to 12 weeks and regular newsletters. Results showed that self-reported energy expenditure increases of 86% for men and 81% for women were maintained at 2 years. Increases of 50% over baseline were maintained at 4 years without reinforcement. Findings from this study suggest that people at risk because of elevated blood pressure can also be assisted to increase their physical activity and maintain a change for several years.

Most reported interventions have extended for a period of 6 months or less. ADAPT was designed with a 12 month follow-up to determine if the suggested behavioural changes could be maintained in the long-term. Similar to the Partners study (2), several strategies were incorporated to improve long-term maintenance of improved health-related behaviours including behavioural-cognitive manipulations, contact sessions with program facilitators and a duration of intervention chosen to maximise compliance without encountering problems of attrition.

OBJECTIVES

To evaluate the effects of a lifestyle program incorporating increased fish consumption in patients treated with medication for high blood pressure on:

1 Changes in psychological factors affecting lifestyle choices.
2 Changes in lifestyle
3 Changes in cardiovascular risk factors, particularly blood pressure, blood lipids and blood glucose
4 Changes in the need for treatment with medication for hypertension

METHODS

Participants

Participants were recruited through an existing database of potential volunteers, advertising in the press and publicity on radio and television programs. Individuals who responded were screened using a telephone questionnaire and excluded if they did not meet the entry criteria. Entry was restricted to relatively healthy men and women aged between 40-70 years who were viscerally obese with a Body Mass Index (BMI) (weight (kg)/(height in metres)^2) ranging from $\geq$ 25 and $\leq$ 35 kgm^2 and had been treated for at least 3 months with one or two antihypertensive medications. Blood pressure had to be less than 160 mmHg systolic and 90 mmHg diastolic. Individuals were required to consume not more than 2 fish meals per week and less than 3-4 fish oil capsules per week, less than 4 standard alcoholic drinks per day for women and 6 standard alcoholic drinks per day for men and have no major cardiovascular or other health complication. Drug or insulin-treated diabetics, patients with chronic renal failure (serum creatinine > 120 µmol/L) and those requiring beta-blockers and ACE inhibitors specifically for prevention of arrhythmias or secondary prevention of myocardial infarction, were excluded.

All volunteers who met the eligibility criteria were randomly allocated using computer generated random numbers to one of two groups. The program group received the 4-month health promotion program addressing nutrition, physical activity, smoking cessation and alcohol moderation. The usual care group (controls) did not receive the 4-month health promotion program but were given publicly available information from the National Heart Foundation and the Health Department of Western Australia. All participants provided written informed consent and the study was approved by The University of Western Australia Human Ethics Committee.

Design and Measures

Study Design

The ADAPT program was a 16-month trial that compared a program group who had received a 16-week health promotion program, to a usual care group, to determine whether the program had beneficial effects in reducing the need for antihypertensive drugs and improvement of cardiovascular risk factors (see Figure 3).

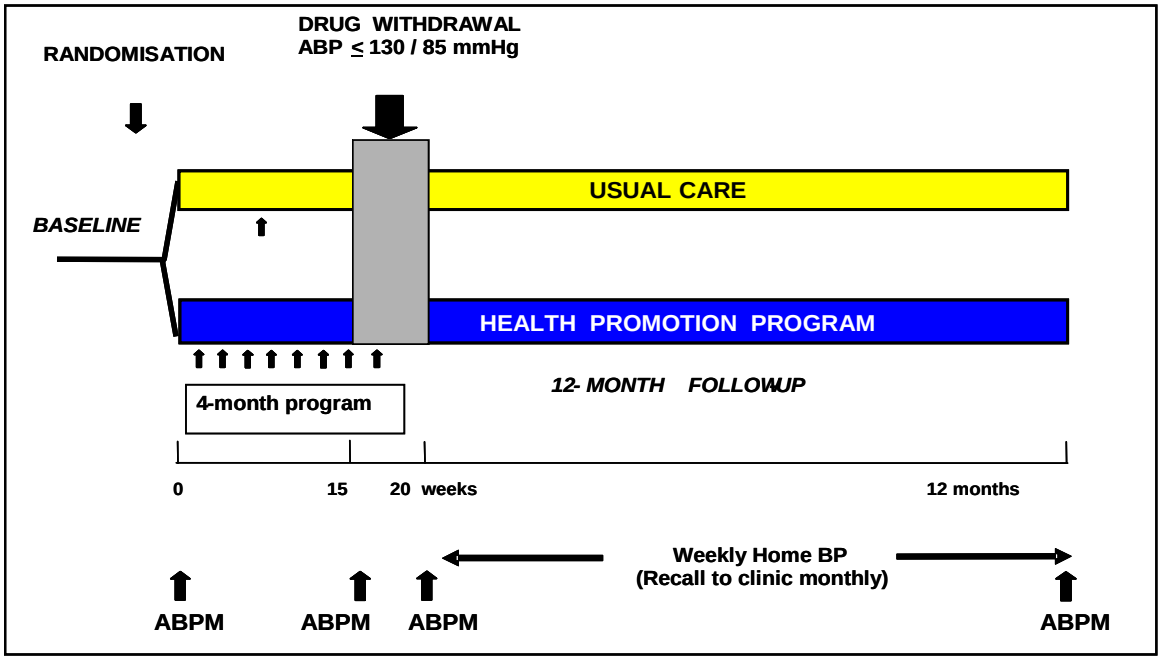

Figure 3. *ADAPT Study Design*

Following the 4-month health promotion intervention, individuals were fitted with an ambulatory blood pressure monitor (ABPM) for 24 hours. If participants in the program or in the usual care groups had 24-hour mean ambulatory blood pressure (ABP) ≤ 130/85 mmHg they were eligible to enter into the 4-week drug withdrawal phase, after which a 12-month follow-up ensued.

The Health Promotion Program

Program Group

Individuals in the program group participated in a 4-month health promotion program, which consisted of individual sessions, 6 interactive group workshops and 5 printed modules aimed at educating participants in issues concerning improved lifestyle, predominantly nutrition and physical activity, with an emphasis on weight loss. The aim of the nutrition component was to adopt a varied and nutritionally balanced eating style consistent with that recommended by the Australian National Dietary Guidelines (57) and based on the Dietary Approaches to Stop Hypertension (DASH) diet that has been shown to reduce blood pressure (1). Specifically, the recommended diet was low in fat, particularly saturated fats, high in fibre from fruit and vegetable sources, low in salt and sugar, and high in dietary fish with a recommendation of at least four fish meals per week. The aim for the physical activity component was to encourage the accumulation of at least

30 minutes of moderate intensity physical activity on most days and to increase the amount of incidental activity performed each day (44). A combination of improved diet and increased physical activity was intended to assist individuals in weight loss, with a specific aim to lose 5-10% of baseline weight in the 4 month program. The five printed modules were distributed gradually over the 4-months at various individual counselling sessions and group workshops.

Social support from partners was a key feature of the health promotion program (2) and was incorporated in the ADAPT program. The use of social support by the ADAPT program was implemented by the encouragement of attendance of a partner during any of the contact sessions and involvement and support of the partners in grocery shopping, meal preparation and physical activity. Partners were included to act as motivators and collaborators during the period of the program and act as support during the follow-up when contact between researchers and participants was reduced.

Delivery of the Program

The facilitators, modules, individual counselling sessions and group workshops encouraged self-directed change in behaviour. Program content included general information about blood pressure, identifying the benefits of exercise and good nutrition, how to start an exercise program, keeping exercise safe, injury prevention, avoiding over-exertion, the Healthy Diet Pyramid, glycaemic index, types and sources of dietary fat, alcohol consumption, budgeting for healthy foods, choosing meals when eating out and stress management. Information encouraging behaviour change focused on barriers to change, costs and benefits of a healthy lifestyle, goal setting and time management. In combination these sessions aimed to achieve an overall healthier lifestyle amongst intervention participants. The content of the modules is summarised in Table 1.

Modules consisted of contents and aims pages, newsletters, worksheets and leaflets developed at the School of Medicine and Pharmacology and existing published information from organisations such as the National Heart Foundation, Active Australia and the Health Department of Western Australia. Individual counselling sessions were conducted to assess individual risk factors such as cholesterol, blood pressure, BMI and diet. Interactive workshop sessions for the program group consisted of demonstration and practice of correct techniques for exercise, practice and discussion related to food purchasing and preparation, including reading nutritional labels. Providing answers to questions and

feedback about progress was also included and sessions generally lasted 1½ hours with between 15-25 people in any one group. The content of contact sessions is outlined in Table 2

Drug Withdrawal

Participants in the program group and usual care group were eligible for drug withdrawal if their 24-hour averaged ambulatory blood pressure measured post-intervention using Spacelab monitors (Spacelabs Medical Inc, Redmond, WA, USA) was less than 130/85 (systolic/diastolic) mmHg. Drug withdrawal was implemented gradually during a four week period with blood pressure monitored weekly using an A&D UA-767PC (A&D Medical, Thebarton, Australia) home blood pressure unit. If participant blood pressure exceeded safety criteria, ambulatory blood pressure monitoring was carried out and drug withdrawal ceased if mean 24-hour systolic blood pressure was > 135 mmHg and diastolic blood pressure > 85 mmHg, or systolic blood pressure > 140 mmHg and diastolic blood pressure < 85 mmHg. Participants who were ineligible to continue drug withdrawal returned to the care of their own doctor for management of hypertension.

Follow Up in the Program Group

The 12 month follow-up period involved regular contact with facilitators via phone, 6 individual sessions to measure weight and blood pressure and 6 group workshops which occurred every fortnight for the first month, monthly for the next two months and then once every three months. No additional information was provided during the follow-up workshops. Workshops were conducted as a forum to discuss group and individual progress, to revisit information already provided during the 4-month health promotion program and for motivation. Individuals were provided with the opportunity to have further individual counselling sessions as required. In addition to the individual and group sessions, a tri-monthly newsletter was issued to each participant.

Safety Measures

A&D home blood pressure units were supplied to individuals who had been withdrawn from their antihypertensive medication. Home blood pressure recordings were used during this period to provide early warning of excessive blood pressure rises to ensure the safety of the participants. Participants were required to measure their blood pressure at home every second day for the first month of post-drug withdrawal and thereafter once a week until the completion of follow up. Participants who achieved drug withdrawal attended the

Table1. Outline of module contents

Module Number	Content
1	Blood pressure Principles of the healthy eating pyramid Fat and fibre The importance of dietary fish in the diet Costs and benefits of a healthy lifestyle Exercise tips Goal setting Rewards
2	How to start an exercise program Stretching Exercise for health, fitness and weight loss Barriers to exercise and solutions How to measure exercise intensity Understanding food labels Low fat recipe modification
3	Injury prevention Managing soft tissue injuries Diet myths Fruit and vegetables Healthy eating on a budget Time management Back care
4	Sodium and potassium in foods Calcium in foods Osteoporosis Arthritis Choosing an exercise partner Incidental activity Energy expenditure guide Weight and blood pressure
5	Stress management Alcohol and blood pressure Smoking Diabetes and lifestyle Cholesterol and lifestyle Asthma and exercise Socialising – dining out and takeaway

Table 2. Outline of contact session content

Contact Session	Content
Individual counselling session	Program overview Nutritional, physical activity and weight loss objectives Lifestyle and blood pressure Principles of the Healthy Eating Pyramid, fat and fibre counters The benefits of incorporating more dietary fish into the diet Barriers to a healthy lifestyle Costs and benefits of a healthy lifestyle Goal setting and rewards
Group workshop 1	Group introduction How to start and exercise program Stretching exercises Exercise solutions – overcoming barriers Menu comparisons and low fat recipe modification
Group workshop 2	Reading and understanding food labels Macronutrients and kilojoules Energy expenditure How to judge exercise intensity and signs of over exertion Weight loss strategies Reviewing nutritional targets
Group workshop 3	Incorporating more fruit and vegetables Salt and potassium intake Fish intake Alcohol intake
Individual counselling session (optional)	Smoking cessation, or Review of program and motivation
Group workshop 4	Exercise and back care Injury prevention Stress and the effects on blood pressure Stress management and meditation
Group workshop 5	Cultivating exercise patterns Relapse prevention Reviewing goals Current interest topics (e.g. red wine, fish oils)
Group workshop 6	Dining out and take away Healthy tips
Individual counselling session	Review, summary and preparation for drug withdrawal

School of Medicine and Pharmacology Research Unit regularly for continued blood pressure monitoring and regularly reported their blood pressure readings by telephone to program staff. If blood pressure exceeded safety criteria, ambulatory blood pressure monitoring was carried out and drug treatment reinstated according to the criteria described. If ambulatory blood pressure exceeded these values, patients re-commenced antihypertensive drugs at the lowest dose that had controlled hypertension and returned to their own doctor for management.

Usual Care Group

Members of the usual care group continued their usual lifestyle. For ethical reasons, participants in this group were provided with information about lifestyle that was generally available from sources such as the National Heart Foundation. Any changes to lifestyle were made without influence from the program facilitators. In an effort to maintain contact and retain members of the usual care group, 4 information seminars were conducted at 2, 7, 12 and 14 months after baseline on topics unrelated to the ADAPT program. Individuals in the usual care group who had achieved drug withdrawal were monitored as described for the program group.

Measurements

Measurements were obtained at baseline, the end of the health promotion program (4 months) and at the end of the one-year follow-up (16 months) to measure longer-term maintenance of changes.

To ensure validity, several established instruments with sound psychometric properties, used previously in the Partners study (2;3), were incorporated into ADAPT including Stages of Change, self-efficacy, beliefs and barriers specific for physical activity, diet, alcohol drinking and smoking.

Instruments

Perceived barriers to positive health behaviours were recorded using a 4-point scale and used 18 items for dietary behaviour, 16 items for physical activity. Scales developed by Plontikoff and Higginbotham (49) which measure self-efficacy, response efficacy and intentions with respect to low-fat diets, were modified for use with each of the health behaviours. For physical activity and diet self-efficacy scales comprised 3 items.

Beliefs about the benefits of health behaviours were elicited using a 6-point scale with 6-items for each behaviour. Separate questionnaires for diet and physical activity used items addressing beliefs about associations between each behaviour and blood pressure, cholesterol, risk of heart disease, longevity, general health and control of weight gain. For each item, a higher score indicated a stronger belief in the benefits of the behaviour.

Health-related Behaviours

3-Day Food and Drink Diaries

Dietary behaviour was assessed using three-day food records, administered with detailed instructions on completion, enabling assessment of dietary intake on three specific days, which included 2 weekdays and one weekend day. Participants were instructed to detail each individual component of a meal including brand names, exact quantity or weight of each individual component in household measures, cooking and preparation methods. Daily nutrient intake was calculated using Foodworks (Xyris, Brisbane Queensland).

7-Day Physical Activity Recall Questionnaires

Physical activity was also assessed at baseline, at 4 and 16-months using a 7-day physical activity recall. The 7-day physical activity recall method is an interview-administered recall of both leisure-time and occupational activity. Individuals were asked to recall the previous 7-days, including evenings. They were asked first to calculate the average amount of sleep they attained each night during the 7 days. They were then asked to consider a chart outlining moderate, hard and very hard activities, specifying which activities they performed, the frequency of that activity during the seven days and the amount of time spent involved in that activity.

Process evaluation, adherence and progress was monitored via exercise diaries, telephone contact and a brief lifestyle questionnaire assessing consumption of fish, fruit, vegetables, alcohol, adherence to physical activity, and smoking.

Clinical Measures

Anthropometric Data

Height, Weight and BMI

Height was measured at baseline using a fixed stadiometer to the nearest 0.5cm with feet shoulder width apart. Weight was measured at baseline, 4 months and 16 months using calibrated electronic scales, to the nearest 0.01 kg after removal of shoes and

personal belongings from pockets. BMI was then calculated using the formula weight (kg)/(height in metres)^2.

Waist and hip measures and waist-hip ratio

Waist and hip measures were taken at baseline, 4 months and 16 months. A metal Lufkin executive thinline 2 metre measuring tape was used to record the waist measured at the narrowest point between the xiphoid process and the umbilical line to the nearest 0.1cm. Hip measurements were taken at the line of the greatest gluteal protuberance and were measured to the nearest 0.1cm. Measurements of each circumference were taken in triplicate on each occasion and the mean used in analysis.

Ambulatory Blood Pressure Monitoring

Twenty-four hour blood pressure monitoring was performed using a Spacelabs ambulatory blood pressure monitoring device, set to take oscillometric readings at 20-minute intervals while awake and 30-minute intervals while asleep. The monitor was fitted to the non-dominant arm approximately 2.5cm above the antecubital fossa by a trained researcher. The patient rested their arm at heart level and blood pressure was calibrated with the patient in a sitting position. Manual readings were taken with the monitor connected to a mercury sphygmomanometer and until at least 3 readings recorded by the monitor were within $\pm$ 7mmHg of the readings observed on the sphygmomanometer. Patients were instructed to continue their normal routine and maintain a diary throughout their awake hours. A valid 24hr recording was accepted as a minimum of 80% successful readings with readings taken during the calibration and any error readings excluded from analysis. Readings were aggregated for each hour, and mean blood pressure determined for the 24hr period and for awake and asleep times based on the patient's diary.

Venepuncture Protocol

Venous blood samples were collected following a 12 hour fast. Fasting included avoidance of all foods and beverages except water. Samples were collected with the patient lying down after a 10 minute rest, using a 21 gauge scalp vein needle inserted into an antecubital vein. Blood for various assays was collected into the appropriate vacutainer tube (Becton Dickson, Rutherford NJ, USA).

Biochemistry

Blood Lipids

Biochemical assays were carried out by the Core Laboratory at Royal Perth Hospital. Serum total cholesterol and triglycerides were determined enzymatically on a Cobas MIRA analyzer (Roche Diagnostics, Basel, Switzerland) with reagents from Trace Scientific (Melbourne, Australia). Serum glucose was measured with an automated Technicon Axon Analyzer (Bayer Diagnostics, Sydney, Australia) by using a hexokinase method with 12hr of collection. Serum insulin was measured by radioimmunoassay with an automated immunoassay analyzer (Tosoh Corporation, Tokyo, Japan).

Data Analysis

Data from baseline, post-intervention (4 months) and follow-up (12 months after the end of intervention) were analysed using SPSS 11.5 (SPSS Inc, Chicago, Illinois). Treatment effects were examined using General Linear Models (GLM) with adjustment for sex and baseline values. Categorical data were compared using Chi-squared tests.

RESULTS

Figure 4 shows the flow of participants through the 4 month and follow-up assessments.

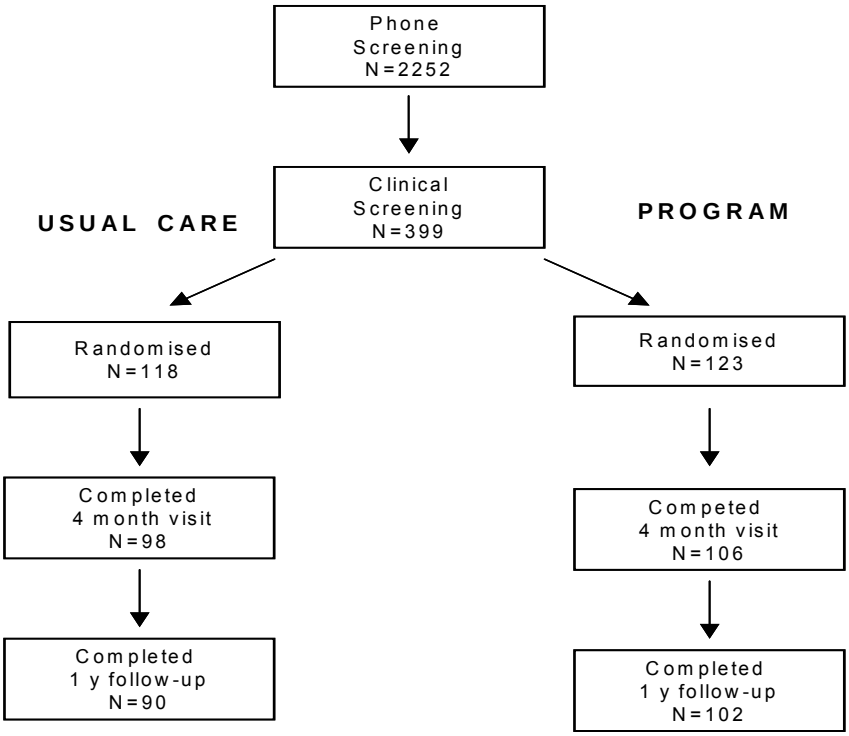

Figure 4: *Numbers of participants in the usual care and program groups entering and completing the study.*

Tables 3 and 4 summarise the baseline characteristics of the participants in relation to their treatment group. There were no significant differences in these variables between groups.

Table 3: *Baseline characteristics of the participants*

Variable	Usual Care Group	Program Group
N	118	123
Gender (M/F)	51/67	56/67
Weight (Kg)	84.6 (11.1)	86.0 (12.4)
BMI (kg/m^2)	29.7 (2.5)	30.7 (2.9)
Waist (cm)	94.0 (8.8)	96.6 (9.6)
ABPM Systolic BP (mmHg)	125 (10)	128 (11)
ABPM Diastolic BP (mmHg)	71 (8.5)	73 (9.7)
ABPM Heart Rate (beats/min)	71 (8)	73 (10)
Serum Cholesterol (mmol/L)	5.0 (0.6)	5.0 (0.5)
Serum Triglycerides (mmol/L) *	1.14 (1.09, 1.19)	1.10 (1.07, 1.15)
Serum Glucose (mmol/L)	5.0 (0.6)	5.0 (0.5)

Continuous variables are shown as means and standard deviations. * Geometric mean and 95% confidence limits.

Table 4: *Baseline characteristics for diet, physical activity, alcohol intake and smoking for usual care and program groups*

Variable	Usual Care Group	Program Group
Energy (Kj)	7907 (2480)	8040 (2375)
Total fat (% energy)	28.8 (6.5)	28.9 (6.5)
Saturated fat (% energy)	12.0 (5.8)	2.3 (5.5)
Polyunsaturated fat (% en)	5.5 (2.8)	5.6 (2.5)
Monounsaturated fat (% en)	11.6 (5.3)	13.2 (6.9)
Fibre (g)	24.1 (7.2)	24.0 (7.4)
Sodium (mg)	2772 (900)	2662 (909)
Alcohol (ml/day)	14.3 (20.7)	15.7 (18.7)
Minutes of exercise/week	171 (105)	162 (131)
Smokers (%)	0 (0)	1 (1.5)

Continuous variables are shown as means and standard deviations

Behaviour change

Figure 5 shows the proportion of participants conforming to healthy dietary choices and to regular exercise at baseline, at the end of the 4 month program and at 12 month follow-up.

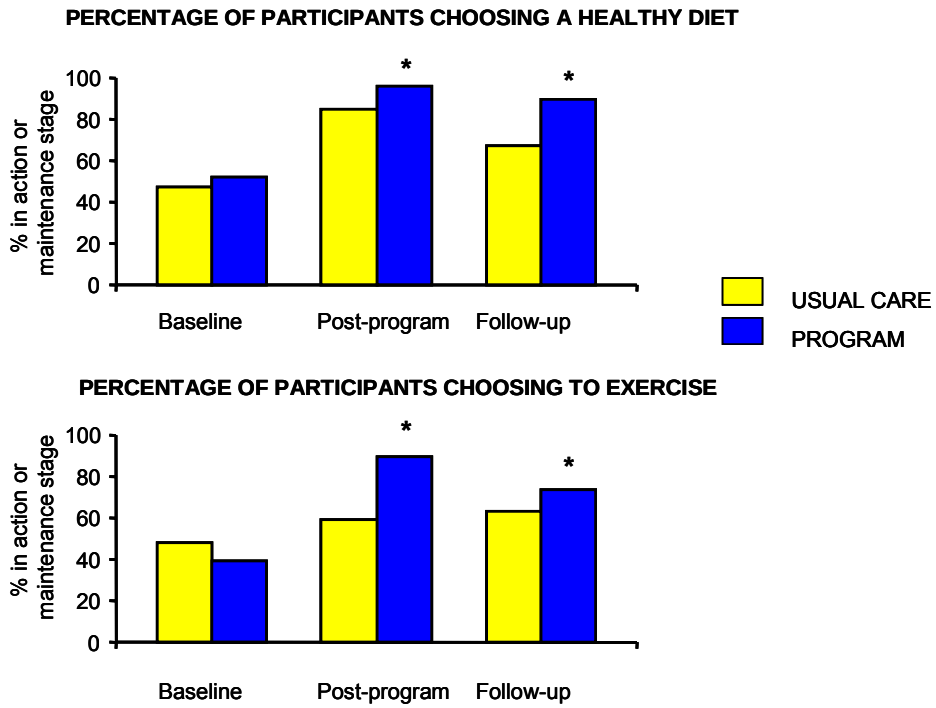

Figure 5: *Percentage of participants in the usual care and program groups making healthy dietary choices or engaging in regular physical activity. * Statistically significant differences between groups (p<0.05).*

The percentage with positive behavioural choices for diet and physical activity did not differ between groups at baseline but was greater in the program group both at the end of the program and at follow-up. Comparison between groups of the percentage who changed behaviour showed statistically significant differences for diet and for physical activity at both time points.

The changes in the proportion reporting healthy behaviours were associated with changes in determinants of healthy behaviours. As seen in Figure 6, the rating for perceived barriers to changing health behaviours showed a greater decrease in the program group both at the end of the program and at follow-up. Between-group differences in barrier scores were statistically significant at both time points for both diet (p=0.025 and p=0.010) and physical activity (p=0.020 and p=0.002).

Scores for beliefs about the benefits of a healthy diet did not differ significantly between groups at the end of the program, but did so at follow-up (p=0.210 and p=0.026).

Findings were similar for beliefs about the benefits of physical activity (p=0.199 and p=0.070), with a trend to a greater change in the program group.

The increase in self-efficacy for diet and for physical activity was significantly greater in the program group after 4 months (p=0.003 and p<0.001 respectively). Although the change was greater in the program group at follow-up this was not statistically significant (p=0.057, p=0.130 respectively).

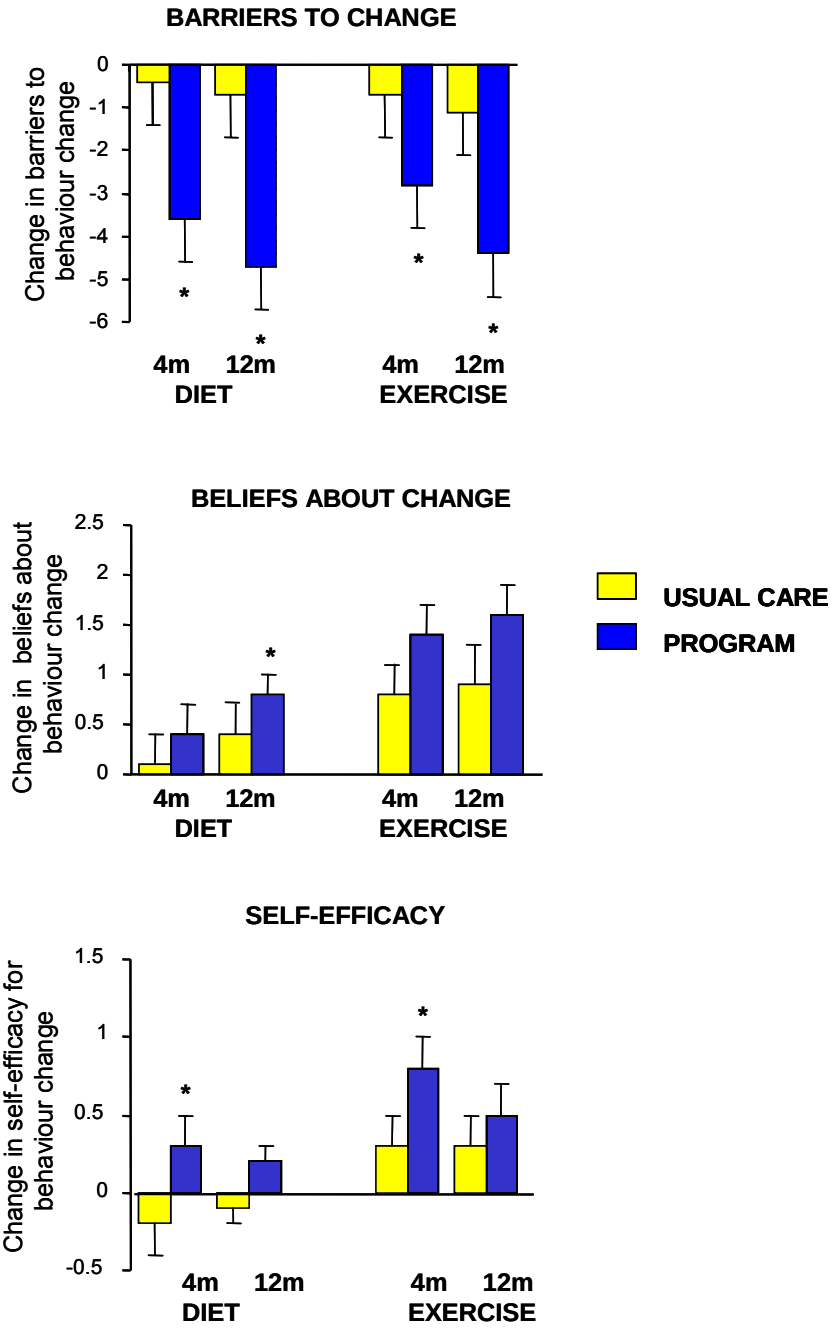

Figure 6: *Changes in perceived barriers to change, beliefs about and self-efficacy for changing dietary or physical activity behaviour. * Statistically significant differences between groups (p<0.05).*

Changes in Health Behaviours

Diet:

Energy intake fell by 697 kJ (sem 310) in the usual care group and by 1270 (sem 228) in the program group at the end of the program (p=0.001). Respective falls at follow-up were 769 kJ (sem 292) and 1221 kJ (sem 287) (p=0.074). Sodium intake fell in both groups with greater falls in the program group (usual care 114 mg (sem 139); program 444 mg (sem 99)) at the end of the program (p=0.008). At follow-up, respective falls were 216 (sem 128) and 384 (sem 112); p=0.070).

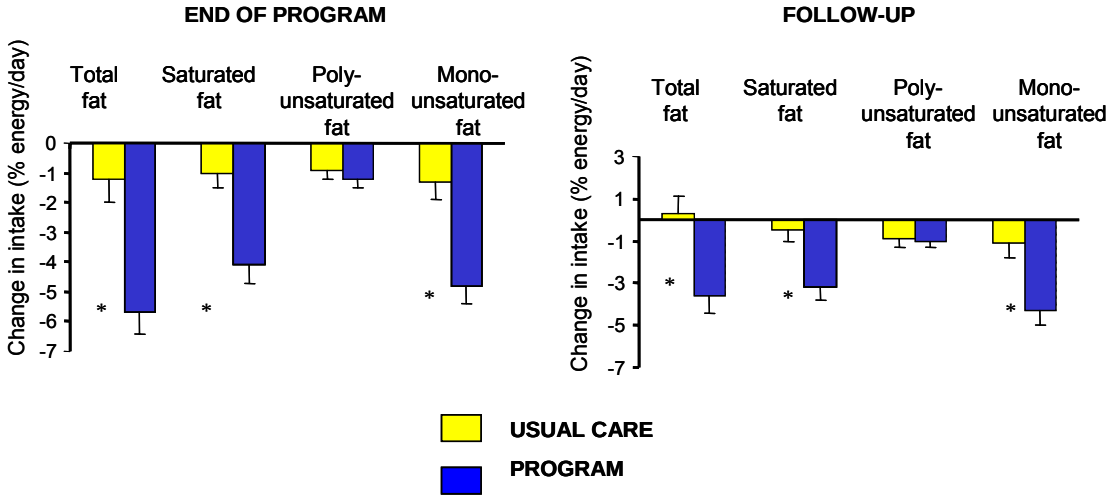

Figure 7: *Changes in fat consumption at the end of the program and at follow-up in the usual care and program groups. * Statistically significant differences between groups (p<0.05).*

Figure 7 shows there were significant between-group differences in the change in consumption of total fat, saturated fat and mono-unsaturated fat at the end of the program, with greater falls in the program group. This pattern was also seen at follow-up with the between-group differences remaining statistically significant.

Changes in Fish Consumption:

Participants in the program group found that increasing dietary fish was the easiest of the dietary changes they were asked to make. At baseline, the frequency of participants eating fish in the usual care group and the program group, respectively, was: 23% and 22% ate fish less than once a month; 51% and 61% ate fish at least weekly; and 35% and 32% ate fish at least 4 times weekly. There were no significant between-group differences. At the end of the 4-month program, 5% and 0% ate fish

less than once a month, 89% and 100% ate fish at least once a week, and 52% and 80% ate fish at least 4 times weekly, in the usual care group and the program group, respectively. Between-group differences were statistically significant. At follow-up this pattern was maintained, with 9% of the usual care group and 0% of the program group eating fish less than once a month; 83% of the usual care group and 99% of the program group continuing to eat fish at least weekly; and 50% of the usual care group and 76% of the program group continuing to eat fish at least 4 times a week. Differences between groups were statistically significant (p=0.001).

The mean intake of fish in the usual care and program groups at baseline, at the end of the 4-month program and at the end of the 12-month follow-up, are shown in Figure 8.

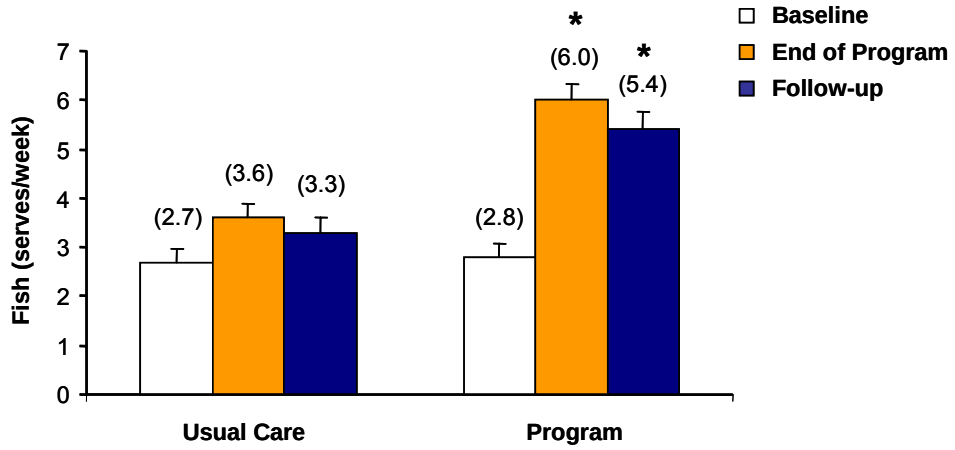

Figure 8: Changes in fish intake at baseline, at the end of the program and at follow-up in the usual care and program groups. * Statistically significant differences between groups (p<0.001).

Changes in Platelet Fatty Acids Derived from Fish:

Platelet fatty acids were measured as an indicator of long-term intake of fatty acids. In particular, omega-3 fatty acids derived from fish were compared with intake of omega-6 fatty acids, mostly derived from animal fats. Figure 9 shows the change in levels of these fatty acids. At both the end of the program and at follow-up there was a significantly greater increase in omega-3 fatty acids derived from fish and a fall in omega-6 fatty acids in the program group. These findings confirm that the program group had increased fish consumption and had maintained this dietary pattern to 12 months of follow-up.

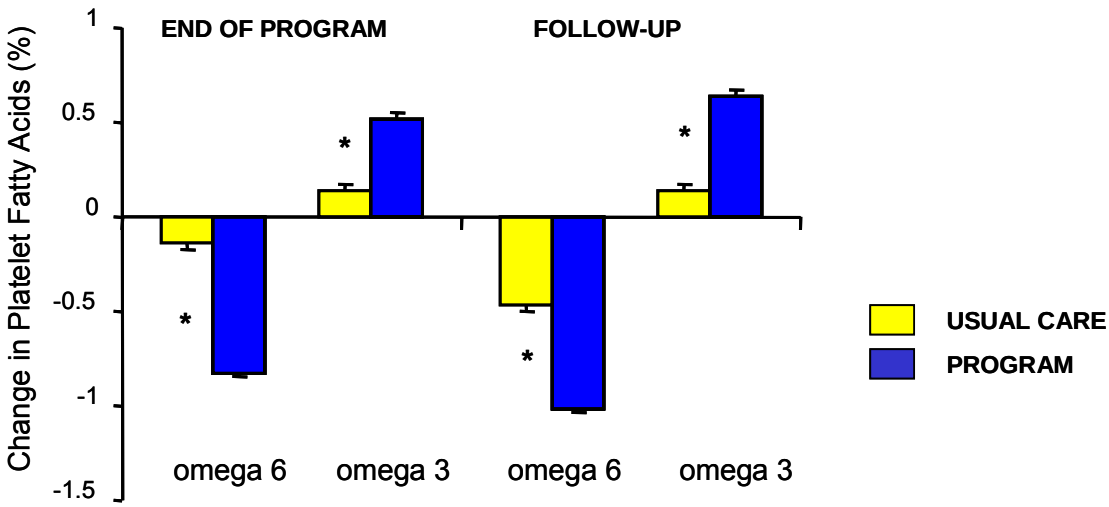

Figure 9: *Change in platelet fatty acids at the end of the program and at follow-up in the usual care and program groups. * Indicates statistically significant between-group differences (p<0.05).*

Change in Physical Activity:

As shown in Figure 10, the time spent in physical activity increased significantly in the program group at the end of 4 months. Differences at follow-up were not statistically significant.

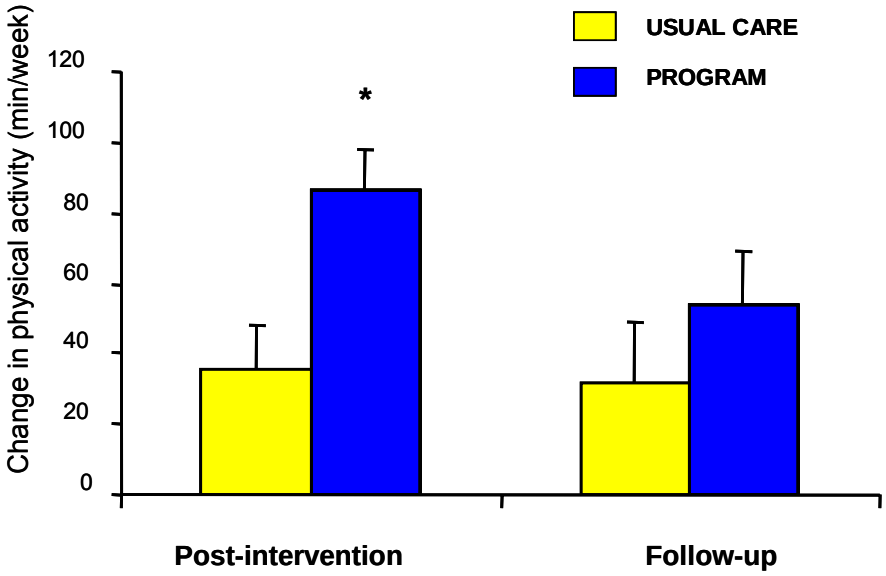

Figure 10: *Change in minutes per week spent in physical activity in the usual care and program groups. * indicates a statistically significant difference between groups (p<0.05).*

Change in Cardiovascular Risk Factors

Change in Weight and Waist Girth:

There were statistically significant between-group differences for change in weight at the end of the program and at follow-up ($p<0.001$ for each comparison). Participation in the program was associated with a substantially greater weight loss than in the usual care participants (Figure 11).

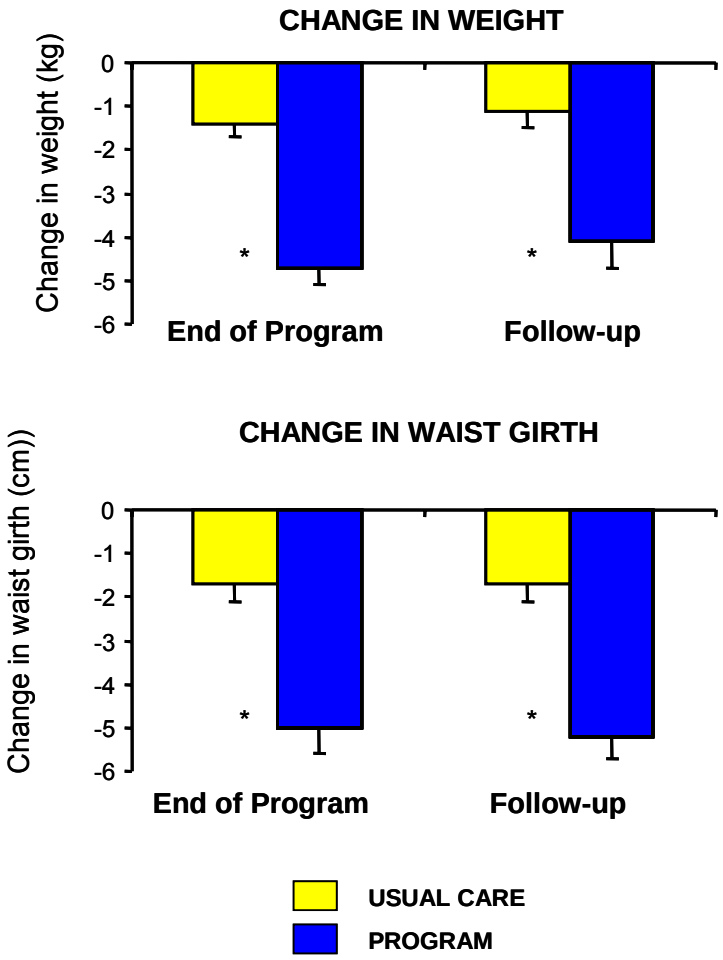

Figure 11: *Change in weight and waist circumference in the usual care and program groups at the end of the program and at follow-up. * Statistically significant difference between groups ($p<0.05$).*

Similarly, waist circumference decreased in both groups with a significantly greater fall in the program group. Maintenance of weight loss and a decrease in central obesity, a factor known to be associated with increased cardiovascular risk, is likely to have long-term benefits.

Change in Serum Total Cholesterol and Triglycerides:

Total cholesterol and triglycerides fell in the program group relative to the usual care group at the end of the program; the between-group difference was statistically significant for triglycerides (p=0.002) and total cholesterol (p=0.017). Differences in the change in lipids were not statistically significant at follow-up (Figure 12).

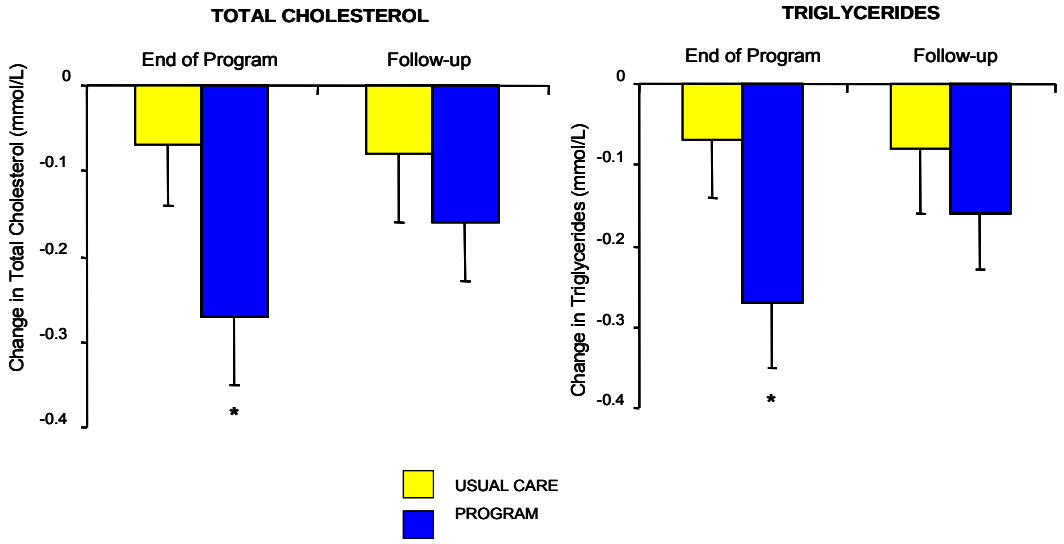

Figure 12: *Change in total cholesterol and triglycerides at the end of the program and at follow-up. * Statistically significant difference between groups (p<0.05).*

Change in Glucose:

As shown in Figure 13, glucose fell in both groups with no significant between-group differences at the end of the program or at follow-up.

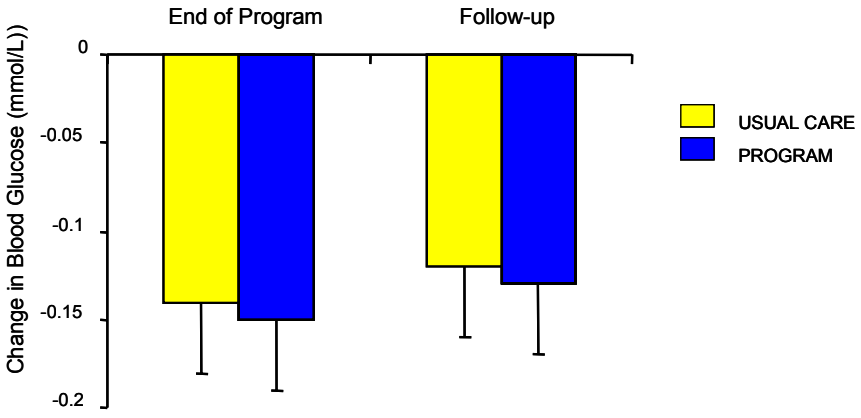

Figure 13. *Change in fasting blood glucose at the end of the program and at follow-up in the usual care and program groups.*

Change in Blood Pressure:

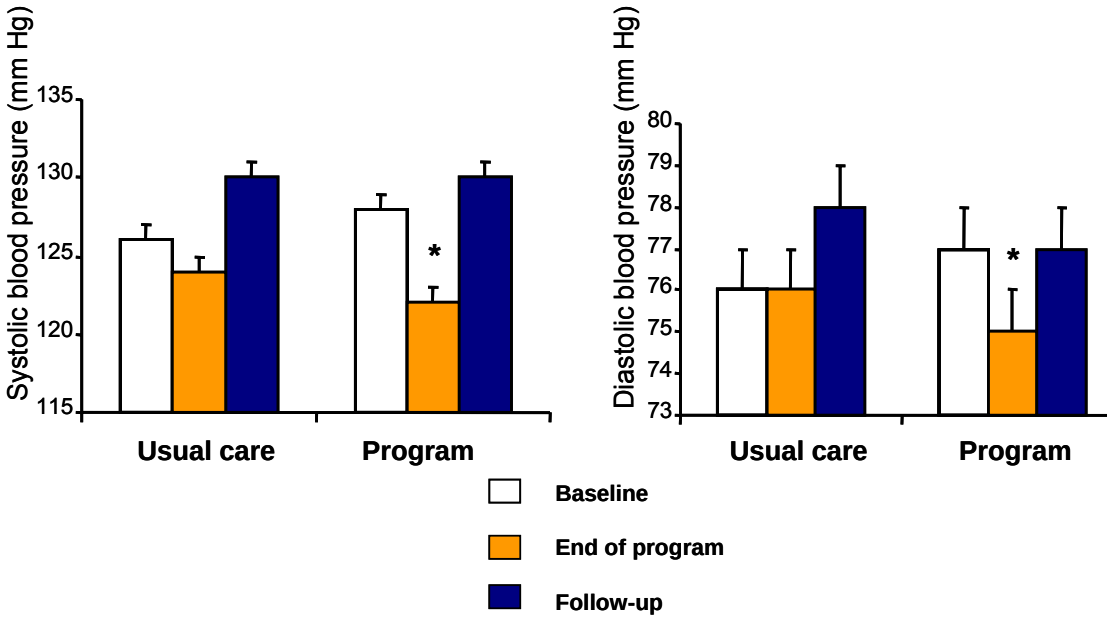

Figure 14 *Systolic and diastolic blood pressure at baseline, the end of the program and at follow-up in the usual care and program groups. * Statistically significant difference between groups (p<0.01).*

At the end of the program systolic blood pressure fell by 4 mm Hg in the program group and by 1 mm Hg in the usual care group. This difference was statistically significant (p<0.01). Diastolic blood pressure showed a similar pattern (Figure 14). At follow-up there were no longer statistically significant differences between groups for systolic or diastolic blood pressure.

Change in Heart Rate:

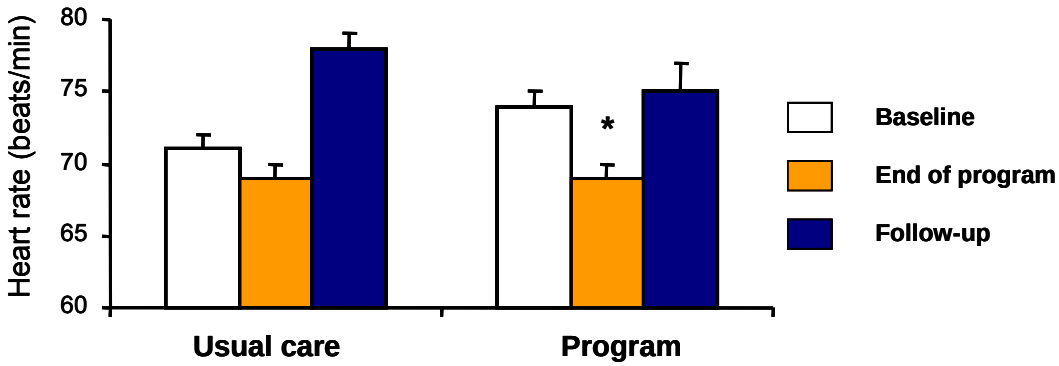

Figure 15: *Heart rate at baseline, the end of the program and at follow-up in the usual care and program groups. * Statistically significant difference between groups (p<0.05).*

Figure 15 shows the heart rate at baseline, at the end of the program and at follow-up in the usual care and program groups. The fall in heart rate differed significantly between groups at the end of the program (p=0.011), with a greater decrease in heart rate in the program group.

CHANGES IN DRUG TREATMENT OF HYPERTENSION

At the end of the 4 month program antihypertensive drugs were withdrawn in 56% of the usual care group and 65% of the program group. These differences were not statistically significant overall but separate analysis for men and women showed statistically significant differences (p=0.038) related to participation in the program for men with 42% of the usual care group and 66% of the program group stopping drug treatment. For women, the proportion having drugs withdrawn was the same (66%) in both the usual care and program groups.

At follow-up there were no statistically significant differences in the proportion having drugs withdrawn overall or when men and women were considered separately. Drugs were discontinued in 41% of the usual care group and 43% of the program group 12 months after the end of the intervention.

COST AND HEALTH BENEFITS OF THE PROGRAM

Participation in the program was associated with potential economic and health benefits to the individuals. While a full cost effectiveness analysis would include costs of running the program, all expenses incurred by the participants and all health-related costs, a simple analysis suggested there was no additional cost to the participants when fish replaced meat in the diet.

An additional benefit of the study was that at the end of the blood pressure drug withdrawal period, participants in the program group had an 8% reduction in risk of developing cardiovascular disease (heart disease and stroke) over the next 10 years relative to the controls. These predictive data are derived from the Framingham equation and are based on the changes observed in blood pressure, total cholesterol, HDL-cholesterol and smoking, and are gender and age specific (58). Twelve months following drug withdrawal there remained a 7% reduction in relative risk of cardiovascular disease in individuals in the program group, relative to the controls.

BENEFITS AND ADOPTION

A lifestyle program that focused on diet, with emphasis on incorporation of fish, weight loss and physical activity can achieve a range of improvements in health-related behaviours and cardiovascular risk factors in overweight men and women being treated with drugs to control hypertension. Improvements in some variables were maintained in the long-term.

The program group showed significant differences from the usual care group in the following measures.

Determinants of behaviour change

- Greater proportion of individuals adhering to a healthy diet and regular physical activity at the end of the program and at follow-up
- Greater decrease in the perceived importance of barriers to behaviour change both at the end of the program and at follow-up.
- Greater increase in self-efficacy for diet and physical activity at the end of the program and for diet at follow-up.

Change in health-related behaviours

- Greater fall in energy intake at the end of the program and a trend at follow-up.
- Greater fall in sodium intake at the end of the program and a trend at follow-up.
- Greater fall in intake of total, saturated and monounsaturated fat at the end of the program and at follow-up.
- Perceived ease of incorporating fish into a healthy diet
- Greater proportion of individuals eating fish frequently at the end of the program and at follow-up.
- Greater increase in platelet fatty acids derived from fish at the end of the program and at follow-up.
- Greater increase in the time spent in exercise at the end of the program.

Change in risk factors

- Greater weight loss at the end of the program and at follow-up
- Greater decrease in waist circumference at the end of the program and at follow-up.
- Greater fall in cholesterol and triglycerides at the end of the program.
- Greater fall in systolic and diastolic blood pressure at the end of the program.
- Greater fall in heart rate at the end of the program and at follow-up.

Change in the need for antihypertensive drugs

- Greater proportion of men with drug treatment withdrawn at the end of the program.

Cost and health benefits of the program

- No additional cost associated with replacing fish for meat in the diet.
- An 8% reduction in risk of heart disease and stroke over the next 10 years.

FURTHER DEVELOPMENT

A grant from the Western Australian Health Promotion Council (Healthway) has extended the study, enabling evaluation of the changes in behaviour and cardiovascular risk factors three years after the completion of the program. A detailed cost effectiveness analysis will be undertaken upon completion of the trial.

CONCLUSION

A lifestyle program incorporating increased fish for patients treated with drugs for hypertension can achieve substantial improvements in lifestyle and cardiovascular risk and has potential applications in other at-risk groups.

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APPENDIX 1

PUBLICATIONS AND PRESENTATIONS

PUBLICATIONS

1. Burke V, Mori TA, Giangiulio N, Gillam HF, Beilin LJ, Houghton S, Cutt HE, Mansour J, Wilson A. An innovative program for changing health behaviours. *Asia Pacific Journal of Clinical Nutrition*, 2002; 11(Suppl): S586-S597.
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PUBLISHED ABSTRACTS

1. Beilin LJ, Burke V, Mori TA, Mansour, Cutt HE, Wilson A, Ritchie J. A lifestyle program for treated hypertensives: effects on needs for antihypertensive drugs. *Clinical and Experimental Physiology and Pharmacology* 2004; 31(5/6): A1-2.
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COMMENTARIES AND NEWS REPORTS

1. *The West Australian*, November 8, 2000, "Health and Medicine" section, p.6.
   "Living without pills," by Cathy O'Leary
2. *The West Australian, January 7, 2004, "Health and Medicine" section, p.3.*
   "Fish diet wins heartfelt approval", by Marnie McKimmie.

INVITED ADDRESSES AT INTERNATIONAL AND NATIONAL SCIENTIFIC MEETINGS

1. A health promotion program incorporating fish for withdrawal of antihypertensive drugs in overweight hypertensives.
   TA Mori
   Seafood Directions 2003 – Beyond Sustainability, Taking the Lead, Hyatt Regency, Perth, Western Australia, September 17-18, 2003.

PRESENTATIONS AT INTERNATIONAL, NATIONAL AND LOCAL SCIENTIFIC MEETINGS

1. The ADAPT Study - Activity, Diet And Blood Pressure Trial.
   Mori TA.
   The University of Western Australia - Department of Medicine Research Seminar 5 July 2001.

2. Effects of a lifestyle program on ambulatory blood pressure (ABP) and drug requirements in treated hypertensives: first phase observations of a randomized controlled trial.
Burke V, Mori TA, Cutt HE, Mansour J, Wilson A, Beilin LJ.
23rd Annual Scientific Meeting of the High Blood Pressure Research Council of Australia, Melbourne, 12-14 December 2001.

3. Effects of a lifestyle program on ambulatory blood pressure & dosage in treated hypertensives: a randomized controlled trial.
Burke V, Mori TA, Cutt HE, Mansour J, Wilson A, Beilin LJ.
12th European Meeting on Hypertension, Prague, Czech Republic, 23-27 June 2002.

4. An innovative program for changing health behaviours.
Burke V, Mori TA, Beilin LJ, Houghton S.
Sanitarium Convention, Melbourne, April 2002.

5. Increased physical activity in response to a lifestyle program in treated hypertensives.
Mansour J, Beilin LJ, Mori TA, Cutt HE, Burke V.
Nutritional Physical Activity Conference 2003, Fremantle, Western Australia, 13-14 November 2003.

6. A lifestyle program for treated hypertensives: effects on antihypertensive drug needs.
Beilin LJ, Burke V, Mori TA, Mansour, Cutt HE, Wilson A.
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7. A lifestyle program for treated hypertensives: effects on needs for antihypertensive drugs
Beilin LJ, Burke V, Mori TA, Mansour, Cutt HE, Wilson A, Ritchie J.
20th Scientific Meeting of the International Society of Hypertension, São Paulo, Brazil, 15-19 February, 2004.

8. A lifestyle program for treated hypertensives: effects on antihypertensive drug needs.
Beilin LJ, Burke V, Mori TA, Mansour, Cutt HE, Wilson A, Ritchie J.
14th European Meeting on Hypertension, 13-17 June 2004, Paris, France.

APPENDIX 2

Staff:

Professor LJ Beilin	Principal Investigator
Dr V Burke	Senior Investigator
Dr TA Mori	Senior Investigator
Ms J Mansour	Program Coordinator
Ms H E Cutt	Program Coordinator
Ms J Ritchie	Research Nurse
Ms L McCahon	Research Assistant
Ms A Wilson	Dietician