# FREQUENT CHOLESTEROL FEEDBACK AS AN AID IN LOWERING CHOLESTEROL LEVELS

by

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(ABSTRACT)

Twenty-six male and two female participants in the Cardiac Therapy Program at Virginia Tech were stratified, based upon level of total cholesterol (TC) and length of time in the Cardiac Program, and then randomly assigned to either experimental or control groups. Participants ranged in age from 43 to 68 years and all had baseline TC levels greater than 200 mg/dl. There were no significant differences between groups in terms of baseline TC (control $\underline{M}$ = 248 mg/dl; experimental $\underline{M}$ = 251 mg/dl), blood pressure (BP), weight, predicted percent body fat, dietary fat/cholesterol, age, education, or program attendance.

All participants were given a packet of information concerning dietary strategies to lower TC. Each was also asked to complete 3-day diet diaries at baseline, 8 and 16 weeks. Subjects in the experimental group had their TC checked and were shown a graph of their current and previous TC levels at 4 week intervals for 16 weeks. The control group was rechecked in 16 weeks. After 16 weeks, the experimental group's mean reduction in TC of 24 mg/dl (-9%)

was significantly larger that the control group's mean reduction of 6 mg/dl (-2%), ($t(26) = 2.1$, $p<.05$). The dietary record-keeping was incomplete at Week 8 and Week 16. There were no significant differences recorded for BP, weight, or predicted body fat. These findings suggest that frequent TC feedback may be a low-cost and effective adjunctive tool for improving adherence to cholesterol-lowering therapy.

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# Chapter I

## INTRODUCTION

Major contributors to mortality in the United States are the lifestyles that many Americans lead. According to the U.S. Surgeon General's Report on Health Promotion and Disease Prevention (1987), these lifestyle factors may be accounting for as much as 50% of the premature deaths in the United States. Compared to many less developed countries, Americans have a higher incidence of the risk factors associated with coronary heart disease (Pisa & Uemura, 1982). As Americans age, they tend to display an increase in these risk factors, while citizens of other countries do not.

The three risk factors most strongly associated with coronary heart disease are elevated blood cholesterol, smoking, and high blood pressure (NIH Consensus Conference, 1985). The lifestyles and living habits of Americans contribute greatly to each of these risk factors. The National Institute of Health estimates that over 50% of the American population has blood cholesterol levels above the recommended levels. High levels of cholesterol and saturated fat in the diets of Americans are one of the main causes of elevated blood cholesterol (Blackburn, 1983).

While high blood cholesterol is prevalent in the United States, and in most cases caused by the diet consumed, many Americans do not know of the risk elevated cholesterol presents (Schucker et al., 1985). Only about one third of Americans have had their cholesterol levels checked, and less than five percent know their levels.

## Statement of the Problem

The National Institute of Health Consensus Conference (1985) estimated that lowering the blood total cholesterol level of most Americans would reduce the rate of coronary heart disease in the United States by 30 to 50%. However, the lack of knowledge concerning cholesterol by the American population makes this a monumental task. Few Americans know their cholesterol levels, partly because of the necessity for blood collection via venipuncture by trained personnel and the expense of laboratory tests. There is also a delay in learning the results of the blood collection and analysis. In contrast, the test for hypertension, blood pressure measurement, is painless, inexpensive, and relatively convenient. The result is known immediately, and those needing further evaluation can be referred immediately.

Recent technological advances have led to the development of portable blood analyzers that require only a few drops of blood and provide results in minutes. A finger

prick, causing little discomfort to the subject, is used to collect the blood sample. These instruments are now being used in screening procedures, but have not been widely used in clinical applications.

The purpose of this study was to investigate the effect of frequent measurement and feedback of cholesterol levels on reducing blood cholesterol levels. Specifically, the experimental group received monthly blood total cholesterol feedback using a Boehringer Manheim Reflotron portable blood analyzer that provided the results of analysis within three minutes. Baseline and 16 week blood total cholesterol levels were compared to the blood cholesterol of a control group that did not receive cholesterol level feedback between baseline and Week 16 measurements.

## Research Hypothesis

In this investigation, the following null hypothesis was tested:

> Individuals receiving total cholesterol profiles once every 16 weeks have the same amount of change in cholesterol level as individuals receiving total cholesterol profiles once every four weeks.

## Significance of the Study

Coronary heart disease is responsible for an estimated 550,000 deaths per year in the United States

(NIH Consensus Conference, 1985). Over 5.4 million Americans have symptomatic coronary heart disease, causing Americans to spend more than 60 billion dollars per year on direct and indirect costs of the disease.

A positive correlation between the risk of coronary heart disease and the concentration of blood total cholesterol has been established (Kannel et al., 1971; Goldbourt et al.,1985; Stamlet et al., 1986). Apparently, the diets of Americans are a leading factor in increasing their blood total cholesterol levels. Blackburn (1983) and Lefebvre (1986) both found the level of cholesterol and saturated fat in the diet to be related to total cholesterol level. If Americans knew their total cholesterol level, perhaps they could adjust their diet in order to obtain the ideal blood total cholesterol level. Stamler (1979) found the ideal level for Americans to be between 130 and 190 mg/dl. There is little or no risk of coronary heart disease at these levels. Above 200 mg/dl, and especially above 240 mg/dl, there is an increased risk of heart disease. A recent report from the National Heart, Lung, and Blood Institute (1987) suggests that individuals whole total cholesterol levels are greater than 200 mg/dl be instructed to modify their diet in order to reduce their cholesterol.

However, few Americans know their cholesterol levels (Schucker et al., 1985). The inconvenience of getting cholesterol levels checked has contributed to this lack of

personal health knowledge. The development of portable blood analyzers that provide almost instant feedback may greatly lessen the inconvenience of blood cholesterol analysis. It may be possible to check cholesterol levels on a regular and frequent basis, as other cardiovascular health related factors such as blood pressure and weight are checked. Superko (1987) suggested that these new devices be used in cardiac rehabilitation centers to monitor cholesterol levels in cardiac patients. If increasing the frequency of cholesterol measurement and feedback using convenient and inexpensive means helps individuals lower their blood total cholesterol levels, it may help decrease the high rate of coronary heart disease that is present in the United States.

## Definitions and Symbols

1. CORONARY HEART DISEASE (CHD): Damage or occlusion of one of the arteries supplying blood and oxygen to the heart, often resulting in ischemia or myocardial infarction.
2. PLASMA TOTAL CHOLESTEROL (TC): The sum of all cholesterol carried in the bloodstream.
3. CARDIOVASCULAR RISK FACTOR: A factor which increases the likelihood that a given individual will suffer some form of coronary heart disease.

## Delimitations

The following delimitations applied to this investigation:

1. Participants of the Cardiac and Intervention Program at Virginia Tech were the subjects in this study.
2. The subjects had been involved in a cardiac rehabilitation or intervention program for a mean of four years.
3. Only plasma total cholesterol measures were analyzed and compared across groups.

## Limitations

The following limitations applied to this investigation:

1. Subjects may have received information concerning cholesterol and their diets outside of the study.
2. There was not an attention control group.
3. Uncontrolled variables may have affected the subject's ability to maintain a low fat, low cholesterol diet.
4. HDL and LDL values may have changed without any changes in total cholesterol.

## Basic Assumptions

The following assumptions were made by the investigator:

1. It was assumed that the blood analysis was reliable and valid.

2. It was assumed that all self-reported data was accurate.
3. All statistical assumptions were met.

## Summary

Coronary heart disease is more prevalent in America than in other countries (Pisa & Uemura, 1982). A large number of deaths in the United States result from heart disease, and large amounts of money are spent by Americans because of costs due to the disease. Elevated blood total cholesterol has been closely associated with the risk of coronary heart disease (Kannel et al., 1971; Goldbourt et al., 1985; Stamler et al., 1986), and as much as 50% of the American population may have elevated blood cholesterol levels (NIH Consensus Conference, 1985). However, many Americans do not have information concerning their cholesterol levels (Schucker et al., 1985).

Recent technological advances may make providing information on cholesterol levels more convenient and less expensive. The ability to provide more information on blood total cholesterol levels may help reduce the prevalence of elevated cholesterol levels and coronary heart disease in the United States.

This study was conducted to determine if providing frequent information on cholesterol levels could help reduce plasma total cholesterol levels. Experimental subjects were

given monthly feedback on their plasma total cholesterol levels using a portable blood analyzer. The blood analyzer used required only a few drops of blood and provided results within three minutes.

## Chapter II

## LITERATURE REVIEW

This chapter focuses on literature concerning the relationship between cholesterol and coronary heart disease, the composition and function of cholesterol, and dietary effects on blood cholesterol levels. In addition, the time required to lower plasma cholesterol levels, behavioral approaches to lower blood cholesterol levels, and the precision and accuracy of the Reflotron portable blood analyzer are examined.

### Plasma Total Cholesterol and Coronary Heart Disease

Large survey studies completed by Kannel et al. (1971), Goldbourt et al. (1985), and Stamler et al. (1986) have all yielded a positive correlation between concentrations of plasma total cholesterol (TC) and the risk of coronary heart disease (CHD) due to atherosclerosis. Autopsy studies (Solberg & Strong, 1983) have shown linear correlations between the concentrations of plasma TC and the severity of atherosclerosis.

Atherosclerosis is the narrowing and possible occlusion of arterial blood vessels due to the development of fat plaques along the vessel wall. The fat plaques initially develop in the inner layer of the vessel wall and gradually enlarge. Circulation to the heart muscles becomes

restricted and heart failure may occur. Strong et al. (1968) suggested that when about 60% of the surface area of a coronary artery is covered with raised plaque, there is a substantial increase in the risk for CHD. The National Institute of Health Consensus Conference on Blood Cholesterol (1985) suggested that the plasma TC level associated with high levels of plaque formation are those greater than 265 mg/dl. However, the Consensus Conference also stated that blood cholesterol levels of 240-265 mg/dl present a moderate risk of heart disease, and that even levels of 200-240 mg/dl present at least a mild increase in the risk of heart disease. Stamler (1979) stated that ideal plasma TC levels for Americans are from 130-190 mg/dl, or a mean of 160 mg/dl. At this level, Stamler feels there is no risk of heart disease due to cholesterol levels alone. However, Kannel et al. (1979) reported that when other major cardiovascular risk factors are present, such as smoking or hypertension, even lower levels are desirable. Kannel suggested that in the presence of other risk factors, elevated plasma cholesterol levels result in a multiplicative interaction on the onset of CHD. The result of the Multiple Risk Factor Intervention Trial (MRFIT) tended to agree with Stansler and Kannel. The MRFIT study followed 356,222 men aged 35-57 years for six years and found that the rate of CHD was lowest for TC levels under 200 mg/dl. At TC levels above 200 mg/dl, there was a sharp

increase in mortality due to coronary heart disease (Stamler et al., 1986). The optimal level for the lowest rate of mortality in the MRFIT study was at about 150 mg/dl.

Figures published by the National Institute of Health Consensus Conference on Blood Cholesterol (1985) underlined the need to reduce the incidence of CHD. Coronary heart disease was estimated to be responsible for more than 550,000 deaths per year in the United States. Over 5.4 million Americans currently have symptomatic coronary heart disease and as much as 50% of the American population has TC levels above the recommended levels. The results of heart disease cause Americans to spend more than 60 billion dollars per year on direct and indirect costs of the disease. The Conference also estimated that lowering the TC level below 200 mg/dl for most Americans would reduce the rate of CHD in the United States by 30 to 50%. However, Schucker et al. (1985) conducted a random sample public survey and found that only 64% of the respondents believed elevated cholesterol levels and CHD to be related. Only 35% of the respondents had ever had their cholesterol levels measured and less than 5% could report the value.

While the Consensus Conference (1985) recommended public education concerning the risk of elevated cholesterol levels and that individuals learn their own level, Lefebvre (1986) listed several barriers to reaching these goals. The necessity for venipuncture by a phlebotomist or other

trained health professionals to obtain a blood sample; the expense of laboratory tests, which require a medical laboratory and trained personnel; the delay between the time the blood sample is collected and the results of the tests; and the lack of standardization for cholesterol determination across clinical laboratories. However, recent technological developments have lead to the availability of new laboratory instruments which are portable and require only a small amount of capillary blood for the determination of TC levels (JAMA Medical News, 1986). These new instruments are simple and inexpensive to operate, minimally uncomfortable for the screenees, and capable of rapid cholesterol analysis. One such instrument, the Boehringer Manheim Reflotron, gives results on a digital display within five minutes of sample collection (Reflotron Operations Manual, 1986). Using a similar device, Greenland et al. (1986) screened 1,081 individuals in ten hours using only five technicians and two analyzers. The screenees at a university medical center were told their cholesterol levels within an hour and those in the high risk categories were referred for further evaluation. No follow up data was available. However, the availability of these new instruments may help correct the lack of knowledge by the general population concerning TC and in turn reduce the incidence of elevated TC and CHD.

## The Composition and Function of Cholesterol

Plasma total cholesterol (TC) is the sum of all cholesterol in the bloodstream. The three major components of TC are lipoprotein fractions LDL (low density lipoprotein), HDL (high density lipoprotein), and VLDL (very low density lipoprotein). These lipoprotein fractions are in the blood and are the carriers of cholesterol to the body cells.

About 40% of dietary cholesterol is absorbed in the intestine (Conner & Lin, 1974), and becomes a part of chylomicrons. It remains with the chylomicron remnant as it is returned to the liver. The smaller remnants can be removed by the liver or converted into LDL. The LDL's are the major cholesterol carrying lipoprotein in plasma. Dietary cholesterol that becomes part of the LDL lipoproteins synthesized in the liver leads to an increase in total cholesterol (Connor & Connor, 1977).

The major pathway for removal of LDL's from plasma is via LDL receptors on liver cells (Spady et al., 1983). LDL's may also be cleared by extrahepatic tissue or HDL's may accept cholesterol from extrahepatic tissues and transfer it to VLDL's. Cholesterol carried on VLDL can be removed by the liver.

Cholesterol is a lipidic steroid and is essential to all body cells. It is a precursor of such vital molecules as bile acids, steroidal hormones, progesterone, and vitamin

vitamin D. Cholesterol is also an important component of cellular membranes.

## Dietary Effects on Plasma Total Cholesterol Levels

Both Blackburn (1983) and Lefebvre (1986) found significant relationships between changes in the diets of their subjects and the blood level of TC. Dietary cholesterol and saturated fat were the most important factors in changing TC levels. Increasing dietary cholesterol and saturated fat led to increased blood TC levels, while decreases in dietary cholesterol and saturated fats resulted in decreased blood TC levels.

In humans, approximately 40% of dietary cholesterol is absorbed in the intestine and becomes a part of chylomicrons (Connor & Lin, 1974). After the triglycerides of the chylomicrons are hydrolized, the chylomicron remnants (including dietary cholesterol) are carried to the liver by the circulatory system. Connor and Connor (1977) found that dietary cholesterol can become part of the lipoprotein synthesized in the liver and increase total cholesterol in the blood. A cholesterol-free diet was fed to normal, hypercholesterolemic, and hypertriglyceridemic subjects living in a metabolic ward for 3 to 4 weeks. Next, 1000 mg of cholesterol in the form of egg yolks were added to the diet each day for 3 to 4 additional weeks. All subjects displayed increases in plasma TC, with a mean

increase 36 mg/dl. Other studies in which cholesterol was added to the diet after a cholesterol-free or low cholesterol diet phase have also reported increases in TC (Connor et al., 1961; Mattson et al., 1972). Apparently, the rate of endogenous cholesterol synthesis does not decrease enough to compensate for additional cholesterol consumed in the diet (Lin & Connor, 1980). Also, sterol excretion may not increase enough in response to increased dietary consumption of cholesterol (Connor & Connor, 1982).

Roberts et al. (1981) conducted a double blind study in which half of the subjects consumed 500 mg of cholesterol in the form of egg yolks in addition to their usual diet, and half consumed a cholesterol-free egg substitute product. After 28 days, cholesterol measures were taken, and the diets were reversed for 28 more days. Subjects who first consumed the egg substitute displayed an increase in TC of 24 mg/dl (about 11%) 28 days after switching to the egg yolks. The group that consumed the egg yolks first were found to have a decrease of about 11% after switching to the egg substitute.

Some controversy still exists as to the exact effect dietary cholesterol has on TC levels. In other studies where cholesterol was added to diets containing normal levels of cholesterol for Americans (400-600 mg per day), groups fed different amounts of cholesterol had similar changes in plasma TC levels. Mistry et al. (1981) fed a

group of subjects 1500 mg of cholesterol per day in addition to their usual diet for 28 days. A second group was fed an additional 750 mg per day. Both groups had similar changes in TC in that both increased by about 29 mg/dl. Adding 750 mg of cholesterol per day to a diet already containing 400 to 600 mg of cholesterol seems to have the same effect as adding 1500 mg per day.

Some studies involving free-living individuals have found no relationship between varying levels of dietary cholesterol and TC levels (Keys et al., 1956; Kannel and Gordon, 1970). Other studies have identified wide variations in individual plasma TC responses to changes in the diet (McGill, 1979). Grundy (1986a) states that in general, an increase in cholesterol intake from 250 to 500 mg per day will raise plasma cholesterol levels by an average of 10 mg/dl. However, he also states that this average increase includes a large variability in response from person to person.

The effect of saturated fatty acids in the diet on TC seems more clear. Grundy (1986a), concluded that "saturated fatty acids definitely raise the plasma cholesterol level". He based his conclusion on the results of several metabolic ward investigations and epidemological surveys. Keys et al. (1965) found that increasing the amount of saturated fats in the diet led directly to increased TC levels. The authors went on to suggest that for every 1% of the total energy

intake contributed by saturated fatty acids, the plasma cholesterol level is increased by 2.7 mg/dl. Brussard et al. (1980) increased the saturated fat content of their college age subjects from 19% to 27% of daily caloric intake and found significant increases in TC levels. Saturated fatty acids seem to suppress the activity of LDL receptors (Teng et al., 1986). The result is that most of the increase in TC is due to an increase in LDL levels, while HDL levels remain essentially unchanged. Keys et al. (1965) and Hegsted et al. (1965) believe that stearic acid is less hypercholesterolemic than shorter-chain fatty acids such as lauric, myristic, and palmatic acids.

Monounsaturated fatty acids seem to be mostly neutral in its effects on TC. Keys et al (1965), Matson and Grundy (1985), and Grundy (1986b) all found little or no relationship between dietary monounsaturated fatty acids and TC levels. Polyunsaturated fatty acids alone are also basically neutral, and only affect TC if they are substituted for saturated fatty acids in the diet (Grundy, 1986b). Replacing saturated fats with polyunsaturated fats may lower TC levels by about 1.35 mg/dl for every 1% energy intake exchanged (Keys et al., 1965; Hegsted et al., 1965). However, part of this reduction is seen in HDLs (Mattson & Grundy, 1985).

Mattson and Grundy (1985) found that replacing saturated fatty acids with monounsaturated fatty acids

lowers TC less than replacement with polyunsaturated fatty acids, but monounsaturated fatty acids do not tend to reduce HDLs. It seems that replacement of saturated fats with monounsaturated fats or polyunsaturated fats will lower TC, with polyunsaturated fats resulting in a greater reduction. However, part of the reduction in substitution with polyunsaturated fats is in HDLs. Increasing polyunsaturated fats to more than 10% of total energy intake may cause side effects. This has been reported to increase the risk of gall stones in humans (Grundy, 1986a), and in laboratory animals has been found to potentiate the action of chemical carcinogens (Carroll et al., 1968) and suppress the immune system (Meade & Merten, 1976).

Amounts of food consumed also have an important impact on TC. Egusa et al. (1985) found that an excess of dietary calories and obesity can cause an over-production of VLDL by the liver. Because of this increase, the conversion of VLDL to LDL is also increased, resulting in higher TC levels (Kesaniemi & Grundy, 1983). However, this effect was not found in all the obese individuals studies. In the obese individuals who did exhibit increased production of VLDL, the level of hypercholesterolemia varied, suggesting that some had a concommitant defect in the catabolism of VLDL (Egusa et al., 1985).

## Dietary Recommendations to Lower Plasma Total Cholesterol

In order to lower TC levels, the American Heart Association (AHA) has made the following recommendations: 1) reduce the amount of saturated fatty acids consumed; 2) substitute unsaturated fats for saturated fats; 3) increase the amount of carbohydrates consumed; 4) reduce the amount of dietary cholesterol; and 5) adjust caloric intake to achieve and maintain a desirable weight (Grundy et al., 1982).

The current American diet contains about 40% of its total calories as fat, and 15-17% of the total calories are saturated fats. The major sources of saturated fats are meat, animal fats, dairy products, bakery goods, some vegetable oils (palm oil, coconut oil, cocoa butter), and heavily hydrogenated margerines and shortenings. The AHA recommends reducing total fat intake to 30%, and saturated fat intake to less than 10% of total calories. Keys et al. (1965) and Hegsted et al. (1965) suggested that reducing saturated fats from 17% to 10% of total calories will decrease plasma cholesterol about 20 mg/dl. For people of normal weight, saturated fats should be replaced by unsaturated fats and complex carbohydrates (Grundy, 1982). Obese individuals should simply remove saturated fats from their diet.

Unsaturated fats can be either monounsaturated or polyunsaturated. Both types lower TC levels when

substituted for saturated fats. At present, polyunsaturated fats provide 5 to 6% of the total calories in American diets (Grundy, 1982). Because of the unknown consequences of long term ingestion of large quantities of polyunsaturated fats, very high intakes of polyunsaturated fats are not recommended. The AHA recommends that 10% of total calories come from polyunsaturated fats. Monounsaturated fats do not reduce plasma cholesterol as much as polyunsaturated fats, but they are probably safer to consume in large quantities. Large amounts of monounsaturated fats are ingested, as olive oil in the Mediterranean region, with no known adverse effects. This region of the world also has a low prevalence of CHD as compared to countries who consume high levels of saturated fats (Keys, 1970).

In order to reduce total fat intake to 30%, intake of carbohydrates should increase from 45 to 55% of total calories. The increase should take the form of long chain or complex carbohydrates, such as those contained in vegetables, beans, cereals, and some fruits (Grundy et al., 1982). Substituting carbohydrates for fatty acids does result in a decrease of TC and LDL (Hegsted et al., 1965).

The current intake of cholesterol by Americans averages between 450 and 500 mg per day (Grundy, 1985a). The AHA recommends a reduction to less than 300 mg of cholesterol per day. Hegsted et al. (1965) and Mattson et al. (1972) both suggest that for each 100 mg per day

decrease in dietary cholesterol, total cholesterol falls an average of 7 mg/dl.

Weight reduction is also an important consideration. Olefsky et al. (1974) found that weight reduction in obese individuals can reduce plasma lipid levels. Wolfs and Grundy (1980) discovered increased HDL levels when obesity was reduced.

## Time Requirements for Reduction of Total Cholesterol

Several studies have found that significant reductions in plasma TC levels can be achieved in one week (Conners et al., 1961; Keys et al., 1965; Hegsted et al., 1965; Mattsen et al., 1972). However, these studies took place in metabolic ward settings where the subjects did not make their own food choices. When free living populations are examined, the changes tend to take longer to occur. Jones et al. (1979) did find TC reductions in free living individuals two weeks after a highly structured nutritional counseling program was initiated. The TC levels were 6.6% lower than baseline levels at two weeks. Further reductions in TC were seen, and at three months the reduction was 13.3% compared to baseline levels. Lefebvre et al. (1986) found that many free living individuals could produce significant reductions in their cholesterol levels in two months. The National Institute of Health (1985) reported that with very strict dietary changes, it is possible to see a reduction in

TC of as much as 30% in two to three weeks. However, the NIH also believes that this large a reduction is not likely to occur in the general population because of the behavior changes that must be made. They feel that drastic changes in eating behavior over a short period of time are not as likely to produce long term results as making gradual changes over a longer period of time. The NIH recommends remeasurement of TC six weeks after dietary counseling is initiated (NIH, 1985).

## Behavioral Feedback to Modify Cardiovascular Risks

E.L. Thorndike was one of the first behavioralists to suggest that feedback influences the occurrence of behavior (Schwartz, 1978). Thorndike suggested that the consequences of a behavior will influence future behaviors. Acts that have favorable consequences will continue to occur, while acts that have unfavorable consequences will diminish. Thorndike termed this response the "law of effect". The law of effect later became known as operant conditioning. Elder et al. (1985) suggested that during attempts to modify cardiovascular risks factors, progress reports may stimulate individuals to continue their behaviors if those behaviors produce positive results. In contrast, people will move in a different direction or in other ways alter their behavior if the results are negative. Elder et al. state that feedback included in progress reports will be most effective

if it is collected and visually depicted on a continuous basis.

Increasing the level of feedback concerning certain cardiovascular risk related behaviors has proven beneficial. Fredrickson and Martin (1979) have found that monitoring the carbon monoxide levels in the lungs of cigarette smokers is helpful in getting smokers to quit smoking or reduce the amount of cigarettes smoked per day. Smokers receiving carbon monoxide feedback tend to be more successful in quitting or reducing their smoking behavior than subjects who do not receive the feedback. In addition, Moss et al. (1982) found that carbon monoxide feedback for smokers increased the percent of attendance of smokers at treatment sessions.

Oldridge and Jones (1983) reported that frequent fitness tests and feedback concerning improvements in fitness levels led to better adherence to exercise programs. Subjects were given diaries and asked to give themselves submaximal fitness tests and to record the results. Feedback concerning he fitness levels based on the results of the submaximal tests led to a higher attendance percentage and a lower drop out rate.

Lovibond et al. (1985) provided their experimental subjects with frequent feedback (every two weeks) on their coronary risk status. They found that subjects who received the feedback lost more weight, displayed a larger decrease

in blood pressure, and showed greater increases in physical fitness after six months than did control subjects who did not receive coronary feedback.

Most attempts at lowering elevated cholesterol levels have not used direct feedback on cholesterol levels, but instead focused on feedback concerning the subjects' diets (Carmody et al., 1982). Foreyt et al. (1979) used daily monitoring of food intake and detailed dietary analysis in an attempt to reduce cholesterol levels. While the experimental group did show significant improvements when compared to a control group, the researchers could not verify that the diet monitoring and analysis was the cause. Many subjects did not continue to monitor their diet throughout the study even though they were instructed to do so. Accurate analysis could not always be completed due to the spotty record keeping. Apparently, the inconvenience of record keeping and the time involved led subjects to discontinue dietary monitoring.

Meyer and Henderson (1974) also had some success with feedback on diet along with stimulus control and contingency management to lower TC levels. However, they also had problems with incomplete and inaccurate diet records. The reductions in TC that were found were short lived.

Wadden et al. (1984) suggested that dietary changes may be more likely to occur when the results directly help to alleviate health problems. They used the example

of individuals who reduce their cholesterol and are able to avoid expensive medications. Feedback on dietary content may not be direct enough or meaningful enough to patients to produce the necessary behavior changes to reduce TC. Wadden et al. also suggest that periodic blood tests may provide results that may sustain motivation and provide feedback about dietary choices.

Often, the frequency of feedback on TC levels is quite low. Annual or semi-annual blood analysis may not provide patients with enough reinforcement of their behavior changes. Wrisley and Rubenfire (1988) studied the effects of routine dietary counseling on the lipid levels of patients who had entered a phase II cardiac rehabilitation program. In addition, blood analysis was available to the subjects every three months. There were no significant changes in the lipid levels of their subjects at three, six, nine, or twelve months. In addition, significant and progressive reductions in the number of patients returning for each follow-up visit occurred. Only three patients returned for the twelve month follow-up blood analysis out of an original population of 71.

Lefebvre et al. (1986) found that screening individuals for TC and telling them their TC level and risk factor status based on those levels led many to reduce their TC. At the original screening, general dietary advice was given on how to lower TC levels. In addition, local

newspapers ran a series of six weekly columns on how to lower TC. Two months after initial screening, 1040 individuals returned for a second measurement. Sixty percent of those screened and remeasured reduced their TC blood levels by an average of 29 mg/dl. It seems that discovering their TC level and related risk factor for CHD may be enough motivation for many individuals to reduce their TC level. No follow-up or long-term data was available.

Crouch et al. (1986) found that subjects who returned for follow up sessions after initial screening had greater reductions in TC levels than subjects who did not have periodic follow-ups. At the initial screening, all subjects were told their risk status and given a packet of information on how to lower their TC. One group returned every two to four weeks during a 14 week period for 15 to 20 minute sessions that focussed on dietary choices. The follow-up group also had TC measures taken every twelve weeks for one year. The no follow-up control group did not attend any further sessions and did not have TC measures taken again until one year after screening. A reduction in TC found in the follow-up group after twelve weeks was still evident at one year. The no follow-up group displayed no reduction in TC at one year. In addition, a group that received telephone follow-ups at the same intervals as the follow-up group and had TC measures taken every twelve weeks

displayed greater reductions in TC than the no follow-up group. However, the reductions were not as large as in the follow-up group. The authors concluded that follow-ups were important, and that merely telling individuals how to change their diets was ineffective. However, they could not identify the exact component of the follow-ups that led to the changes in TC, and suggested that regular feedback on TC levels may have been sufficient to motivate behavior changes.

## The Reflotron Portable Blood Analyzer

Recent technological advances have led to the development of sophisticated portable blood analysis systems. These blood analyzers are capable of determining plasma total cholesterol concentration from small samples of blood. The Reflotron Portable Blood Analyzer (Boehringer Mannhiem Diagnostics) is an electrochemical reflectance photometer requiring 30 microliters of whole blood to determine plasma total cholesterol (Reflotron Operations Manual, 1986). The precision of the Reflotron in cholesterol analysis has been examined by two separate studies. Warnick et al. (1986) reported that the precision (CV) of the Reflotron was 4.5% on 300 duplicate fingerstick specimens from screenees. Reflotron cholesterol results from fingerstick specimens were also compared to results from venipuncture plasma analyzed conventionally by a

standardized enzymic method. The Reflotron underestimated the cholesterol concentrations by an average of about 8% (Reflotron mean of 193 mg/dl versus 210 mg/dl for the standard enzymic method, n = 300). David et al. (1987) found that the within-day precision (CV) for measurement of whole blood cholesterol on two levels of cholesterol (mean = 139.2 mg/dl and mean = 244 mg/dl) to be 2.0% and 1.63% respectively. Day to day precision estimated by a coefficient of variation (CV) was 2.37% for a sample with a mean 139.3 mg/dl and 2.35% for a sample with a mean of 240.25 mg/dl. Cholesterol testing by the Reflotron provided results within $\pm$3% of results provided by an enzymic method standardized and certified by the Center for Disease Control (CDC). McManus et al. (1987) compared values obtained from blood by a CDC standardized laboratory using the standard cholesterol esterase-oxidase-peroxidase assay and values obtained by the Reflotron from three different sample populations. The Reflotron under-estimated cholesterol values by 9% (n = 185), 10% (n = 140) and 6% (n = 14) as compared to the assay results.

## Summary

Large survey studies have shown that a positive correlation exists between the concentration of plasma TC and the risk of coronary heart disease due to atherosclerosis (Kannel et al., 1971; Goldbourt et al.,

1985; Stamler et al., 1986). Atherosclerosis is the narrowing of arterial blood vessels due to fat plaque formation in the inner layer of the vessel walls. When about 60% of the surface area of a coronary artery is covered with plaque, there is a sharp increase in the risk of CHD (Strong et al., 1986). TC levels of over 265 mg/dl are associated with high levels of plaque formation and CHD, but even levels between 200-265 mg/dl places an individual at an increased risk of CHD (NIH Consensus Conference, 1985). Levels of about 160 mg/dl are recommended as safe TC levels.

Most Americans do not know their TC levels or the risks associated with elevated levels (Schucker et al., 1985). Difficulty in obtaining measures, related to the requirements for venipuncture, expensive procedures, and trained personnel, have contributed to this lack of knowledge (Lefebvre, 1986). However, recent technological advances have led to portable TC analyzers, requiring only small samples of blood, that can provide fast analysis and feedback on TC levels (JAMA Medical News, 1986).

Plasma total cholesterol (TC) is the sum of all cholesterol carried in the bloodstream and consists of three major components: HDL, LDL, and VLDL. Cholesterol is essential to all body cells and is naturally found in humans. Most of the cholesterol needed by man is provided in the diet in the form of dietary cholesterol and

saturated fat. Cholesterol can be removed from blood by the liver.

Some controversy exists as to the effect dietary cholesterol has on TC levels. Several studies have found increases in TC when dietary cholesterol was added to subjects' diets (Connor & Connor, 1977; Roberts et al., 1981). Other studies have found no relationship between dietary cholesterol and TC levels (Keys et al., 1956; Kannel & Gordon, 1970). In general, it is believed that there is considerable variation from individual to individual in the effects dietary cholesterol has on TC levels (McGill, 1979; Mistrey et al., 1981; Grundy, 1986a). Saturated fat in the diet does cause increased TC levels (Grundy, 1986a; Keys, 1965). The increase in TC caused by saturated fat is mainly found as increased LDL levels. Monounsaturated and polyunsaturated fats alone do not seem to effect TC. When they are used to replace saturated fats in the diet, TC levels will decrease (Keys et al., 1965; Grundy, 1986b). Obesity may also cause increased TC in some individuals (Egusa et al., 1985).

The American Heart Association (AHA) has made the following recommendations in order to lower the TC levels of Americans: 1) reduce the amount of saturated acids consumed; 2) substitute unsaturated fats for saturated fats; 3) increase the amount of carbohydrates consumed; 4) reduce the amount of dietary cholesterol; and 5) adjust caloric intake

to achieve and maintain a desirable weight (Grundy et al., 1982). While the current American diet contains about 40% of its total calories as fat, of which 15-17% are saturated fats, the AHA recommends reducing total fat intake to 30%, and saturated fat intake to less than 10% of total calories consumed. In order to reduce total fat intake to 30%, intake of carbohydrates should increase from 45 to 55% of total calories. The AHA recommends that 10% of total calories come from polyunsaturated fats.

Reductions in TC as a result of dietary changes in the free living population can be found after three to six weeks, and remeasurement of TC should take place after that time period (NIH, 1985).

Elder et al (1985) suggested that feedback in the form of progress reports may help individuals to continue or modify their efforts to reduce cardiovascular risks. Patient feedback has been used to reduce several different cardiovascular risk factors: monitoring carbon monoxide levels to reduce the risk from smoking (Fredricksen & Martin, 1979); frequent fitness testing to increase physical activity (Olderidge & Jones, 1983); frequent evaluation of coronary risk factor status to reduce weight and blood pressure, and increase physical fitness (Lovibond et al., 1983). Efforts to lower TC levels have usually focused on dietary feedback (Carmody et al., 1982). Direct feedback of TC levels is usually provided infrequently, but more

frequent TC feedback may be beneficial (Crouch et al., 1986).

The precision (CV) of the Reflotron portable blood analyzer has been estimated to be from 1.63% (David et al., 1987) to 4.5% (Warnick et al., 1986). Studies suggest that the Reflotron may underestimate plasma cholesterol concentrations. The underestimation has been reported to be 3% (David et al., 1987), 8% (Warnick et al., 1986), 10%, 9%, and 6% (McManus et al., 1987).

# Chapter III

## JOURNAL MANUSCRIPT

# FREQUENT CHOLESTEROL FEEDBACK AS AN AID IN LOWERING CHOLESTEROL LEVELS

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Cholesterol Feedback

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## ABSTRACT

This investigation was conducted to determine if providing feedback on total cholesterol (TC) every four weeks to individuals attempting to reduce their TC would be a valuable adjunct to dietary intervention. Twenty-six male and two female participants in the Cardiac Therapy Program at Virginia Tech were stratified, based upon level of total cholesterol (TC) and length of time in the Cardiac Program, and then randomly assigned to either experimental or control groups. Participants ranged in age from 43 to 68 years and all had baseline TC levels greater than 200 mg/dl. There were no significant differences between groups in terms of baseline TC (control $\underline{M}$ = 248 mg/dl; experimental $\underline{M}$ = 251 mg/dl), blood pressure (BP), weight, predicted percent body fat, dietary fat/cholesterol, age, education, or program attendance.

All participants were given a packet of information concerning dietary strategies to lower TC. Each was also asked to complete 3-day diet diaries at baseline, 8 and 16 weeks. Subjects in the experimental group had their TC checked and were shown a graph of their current and previous TC levels at 4-week intervals for 16 weeks. The control group was rechecked in 16 weeks. After 16 weeks, the experimental group's mean reduction in TC of 24 mg/dl (-9%) was significantly larger than the control group's

mean reduction of 6 mg/dl (-2%), ($t = 2.1$, $p<.05$). The dietary fat, saturated fat, and cholesterol intake were not significantly different at 8 or 16 weeks, but record-keeping was incomplete. There were no significant differences recorded for BP, weight, or predicted body fat. These findings suggest that frequent TC feedback may be a low-cost and effective adjunctive tool for improving adherence to cholesterol-lowering therapy.

## INTRODUCTION

Epidemioligical studies have shown that a positive correlation exists between the concentration of plasma total cholesterol (TC) and the risk of coronary heart disease (CHD) due to atherosclerosis.[1-3] Total cholesterol levels over 265 mg/dl are associated with high levels of plaque formation and CHD, but even levels between 200--265 mg/dl place an individual at an increased risk of CHD.[4] Over 5.4 million Americans currently have symptomatic CHD and as much as 50% of the American population have TC levels above the recommended levels. Lowering the TC level below 200 mg/dl for most Americans could reduce the rate of CHD in the United States by 30 to 50%.[4] Levels of about 160 mg/dl have been recommended as safe TC levels.

Most Americans do not know their TC levels or the risk of CHD associated with elevated levels.[5] Difficulty in obtaining measures, related to the requirement for venipuncture, expensive procedures, and trained personnel, have contributed to this lack of knowledge.[6] However, recent technological advances have led to portable TC analyzers, requiring only small samples of blood, that can provide fast analysis and feedback on TC levels.[7] It has been suggested that feedback in the form of progress reports may help individuals to continue or modify their efforts to reduce cardiovascular risks.[8]

Efforts to lower TC levels have usually focused on dietary feedback.[9] Direct feedback of TC levels is usually provided annually or once every six months, but more frequent TC feedback may be beneficial.[10] The National Institute of Health states that reductions in TC as a result of dietary changes in the free living population can be found after 3 to 6 weeks, and suggests that remeasurement of TC take place after that time period.

This investigation was conducted to determine if providing feedback on TC every four weeks to individuals attempting to reduce their TC would be a valuable adjunctive tool to dietary treatment.

## METHODOLOGY

Twenty-six males and two females (ages 43 to 68 years) served as subjects. All subjects were participants in the Cardiac and Intervention Program at Virginia Tech and attended maintenance exercise classes at the program center. Lipid profiles are routinely performed every six months for all participants. Those who had been identified as having TC levels greater than 200 mg/dl at their last evaluation were invited to participate in this investigation. Diabetics and those taking lipid-lowering medications were excluded.

Upon referral, all subjects were screened for TC using an electrochemical reflectance photometer. The

photometer utilized was a Boehringer-Manheim "Reflotron" portable blood analyzer. Subjects were asked to fast 12 hours prior to TC measurement. Two 30 microliter samples were collected from two different fingersticks and analyzed, with the average of two used as a baseline measure. Blood pressure (BP) data was measured using a mercury column sphygmomanometer, with the subject in a seated position after approximately 5 minutes of rest. Body weight was measures in kilograms to tenths of a kilogram. Percent body fat was estimated by measuring skinfolds at three sites (chest, abdomen, and thigh for males; triceps, suprailliac, and thigh for females). The total of the three skinfolds was used to calculate body density, and percent body fat was calculated from density using the equations of Jackson and Pollock (1978).

After screening, the subjects were stratified based on TC level and number of months spent in the Cardiac and Intervention Program. All subjects were given a packet of written materials from the American Heart Association concerning ways to reduce their TC. This literature provided information on lowering TC, concentrating on reducing dietary fat (especially saturated fat) and dietary cholesterol. The subjects were instructed to speak with the Cardiac and Intervention Center's dietician if they had any questions concerning the information they were given in the packets. All

subject-dietician contacts were recorded by the dietician.

Each subject was given an appointment for his/her next TC measurement and a record of the baseline TC level. Control subjects were told their TC would be measured again in 16 weeks. Experimental subjects were told their cholesterol would be rechecked every four weeks for the next 16 weeks. The monthly cholesterol checks were performed when the experimental subjects reported for their morning exercise classes (6 to 8 AM). They were not required to fast, and the analysis took approximately 5 minutes to complete. One blood sample was analyzed using the Reflotron, and subjects were shown a graph of their current and previous TC levels.

At 16 weeks, all subjects had TC, BP, weight, and estimated body fat measures collected using the same procedures as at baseline. All measures were collected by the same technician throughout the study.

All subjects were asked to complete three-day diet diaries at baseline, Week 8, and Week 16. The diaries were analyzed using he Nutritian III computer program (M2 Computing) for the percent of total calories consumed as fat and saturated fat, and the amount of dietary cholesterol in milligrams consumed daily. No feedback concerning the results of the diet diaries was given to the subjects.

At baseline, Week 8, and Week 16, all subjects were asked to complete a short self-efficacy questionnaire concerning their abilities to alter their diets and lower their TC. The subjects were asked to rate their agreement or disagreement with the following statements: 1) I have the ability to lower the amount of saturated fat and dietary cholesterol in my diet; 2) I have the ability to lower my cholesterol level though dietary changes. The word "disagree" was anchored at 0 on a Likert scale and "agree" was anchored at 6. Experimental subjects also completed the questionnaire at each monthly measurement.

The reproducibility of the Reflotron was estimated by comparing the results of the duplicate samples collected for each subject at baseline and Week 16. The accuracy of the Reflotron procedures used in this study was estimated by comparing TC values obtained from the Reflotron to values obtained via venipuncture and spectrophotometry at an independent standardized laboratory. Twenty-five separate subjects had TC measured by the Reflotron on the same occasion that blood samples were collected by standard venipuncture procedures. The venipuncture samples were analyzed by Roche Biomedical Laboratories, which uses LRC validated samples for calibration procedures, and the modified Abell-Kendall method for analysis.

Independent t-tests were used to determine if differences existed between groups in terms of several subject characteristics, and to compare mean TC reduction and mean percent TC reduction across groups. ANOVA's were used to analyze the reproducibility and accuracy of the Reflotron, and to analyze the dependent variables. An ANCOVA was used to compare Week 16 TC values, using baseline TC levels as the covariate. Changes within groups were analyzed with dependent t-tests.

## RESULTS

There was no significant difference between groups in the subject characteristics examined (see Table 1). There were also no differences between groups at baseline in BP, weight, body fat, or TC. At Week 16, no differences existed between groups in BP, weight, or body fat. No within group changes were found from baseline to week 16 in these variables (see Table 2). Figure 1 presents cholesterol levels for each group over time. Comparison of the experimental group's monthly TC values over time using an ANOVA suggested a trend toward significant differences in the TC level ($p<.2$). The ANOVA examining differences between groups in terms of Week 16 TC values suggested a trend toward significance ($p<.16$). In controlling for baseline TC levels, the ANCOVA comparing Week 16 across groups found a

significant difference ($p<.05$). The experimental group's mean reduction in TC, as well as the percent reduction, was significantly greater than the control group (see Table 3).

All 28 subjects completed diet diaries at baseline. At Week 8, only 10 subjects completed diet diaries, and at Week 16, only 16 subjects did so. No differences existed between groups at baseline. However, comparisons of week 8 and week 16 data are invalid due to the incomplete data. At baseline, the mean reported percent of total calories consumed as fat was 28.9% ($\pm$6.3) for the experimental group and 26.6% ($\pm$4.3) for the control group. Reported percent of calories consumed as saturated fat was 10.7% ($\pm$2.8) and 9.1% ($\pm$2.3) for the experimental and control groups, respectively. Reported daily consumption of cholesterol was 312 mg ($\pm$77.6) for the experimental group and 306.1 ($\pm$56.3) for the control group.

There were also no differences between or within groups at baseline, Week 8, or Week 16, in the self-efficacy scores. All subjects agreed that they could make dietary changes and could reduce their TC through dietary changes. Both groups had a mean response of 5 (0 = disagree and 6 = agree on a scale of 0-6) for each self-efficacy question at baseline, Week 8, and Week 16.

The experimental group had a mean rating of 5 at each monthly TC measurement.

No significant difference existed between the duplicate TC samples analyzed by the Reflotron, and the coefficient of variation was 2.18%. The mean percent difference between trial 1 and trial 2 was 2.5%, with a range of 0 to 5.7%. There was not a significant difference found when Reflotron values were compared to standardized spectrophotometry values (see Table 4). On 12 out of 25 trials, the Reflotron reported higher values, with the largest difference showing the Reflotron to be 5.6% higher (195 versus 184 mg/dl). The Reflotron reported lower values 13 times and was 7% lower on one occasion (198 versus 212 mg/dl). The difference between the two methods was less than 5% on 20 out of 25 trials.

## DISCUSSION

The National Institute of Health Consensus Conference on Blood Cholesterol[14] suggested that plasma TC levels greater than 265 mg/dl are associated with high levels of plaque formation in the coronary arteries. The Consensus Conference also stated that TC levels of 240-265 mg/dl present a moderate risk of heart disease, and that even levels of 200-240 mg/dl present at least a mild increase in the risk of heart disease. The 9% decrease in TC found in the experimental group moved the group from the

moderate risk category to the mild risk category. Each 1% reduction in TC may lead to a 2% reduction in the risk of heart disease.[4]

Wrisley and Rubenfire[12] have reported that standard dietary counseling may be ineffective in treating hyperlipidemic CHD patients. The results of this investigation suggest that providing feedback on TC on a monthly basis is a valuable adjunctive treatment to dietary intervention. Elder and his colleagues[8] suggested that progress reports help stimulate individuals who are attempting to modify cardiovascular risk factors. Such feedback may lead to a continuation of behavior if the results are appropriate, or to an adjustment in behavior if the results are negative. The monthly reports on TC in this study apparently provided meaningful information that helped the subjects modify their behavior in order to reach their TC goals.

Often, patients must wait several months or even a year to learn if their efforts to modify their diet have been productive. This study provided more frequent evaluations. Showing the subjects a graph of their previous and current cholesterol levels may have made the effects of the feedback stronger by allowing them to see trends forming. It has been suggested that feedback is most effective when collected and visually depicted on a continuous basis.[8]

Crouch and his colleagues[10] also found follow-ups to be important in attempts to lower cholesterol levels. However, the follow-ups in their study included dietary classes and cholesterol measurement. This study used only TC feedback as follow-ups and found clinically, as well as statistically, significant changes in TC.

While a significant decrease in TC was found in the experimental group, a direct cause for this decrease was not documented. A change in the diets of the experimental group seems the most likely explanation. Reductions in TC have been found when dietary fat, saturated fat, and/or cholesterol were reduced.[6,13] It has been suggested that for each 1% reduction in the amount of saturated fat consumed, TC will be lowered by approximately 1.35 mg/dl.[14] It has also been suggested that a diet containing 500 mg. of cholesterol will result in a TC level that is approximately 10 mg/dl higher than the TC level associated with a diet containing 250 mg. of cholesterol.[15] These types of dietary changes may have occurred in the present study. This is only speculation, since complete dietary data was not available. The baseline dietary data suggest that both groups were consuming relatively low levels of fat, saturated fat, and cholesterol prior to intervention. However, this data seems suspect, since both groups had baseline TC levels near 250 mg/dl. Weight loss as a cause can be

ruled out because there were no changes in body weight orbody composition. The exercise program probably was not related to the TC reductions. Both groups had similar attendance percentages and both groups had been involved in the exercise program for an average of four years. In addition, there is no conclusive evidence that exercise will reduce total cholesterol unless there is substantial weight loss.[16]

Other investigators have used similar approaches to reduce cardiovascular risk factors in their subjects. Feedback on the carbon monoxide levels in the lungs of smokers has been used to decrease smoking behavior.[17] Fitness testing and feedback on fitness levels are techniqques thaat have been used effectively to motivate increased physical activity.[18] Frequent evaluation and feedback on coronary risk factor status have been used to reduce weight and blood pressures, and increase physical fitness.[19] Most attempts at lowering elevated cholesterol levels have focused on feedback concerning dietary content.[9] However, many investigators have had difficulty in getting patients to accurately monitor and record their diets. This problem also occurred in the present study. Dietary monitoring can be inconvenient and time consuming for the patients, and also requires staff time for analysis of the records. Providing TC feedback in the present study proved to be very

convenient to both the subjects and the experimenters. Subjects reported 5 minutes prior to their exercise classes for TC measurement. The procedures utilized resulted in relatively little discomfort to the subjects and provided results within three minutes. Only 30 microliters of blood was required, and was collected from a fingerstick. The accuracy and reproducibility of the Reflotron were within acceptable ranges, and the cost of the measures in supplies ($1.50 per test) and staff time (less than 10 minutes per test) were very reasonable. Superko and Haskell[20] have suggested that TC analyzers such as the Reflotron be utilized in cardiac rehabilitation centers on a regular basis. From the experiences gained from this study, this seems feasible. However, it is important to note that the accuracy and reliability of the Reflotron may be sensitive to strict adherence to proper protocol. In this study, the same technician collected and analyzed all samples and had practiced the procedures many times prior to the investigation. The calibration of the Reflotron was checked on each occasion data was collected, and the instrument was cleaned frequently. Procedures for TC measurement with the Reflotron were carefully controlled and followed according to the instruction manual.

The monthly cholesterol checks had no significant effects on the other variables measured. This was not

surprising since the feedback concentrated on TC levels, and the dietary information provided in the handouts concentrated on the reduction of TC. This study was conducted over a relatively short time period. It remains to be seen if continued monthly cholesterol checks would result in further reductions or even if the reduction found in 16 weeks could be maintained after one year. Also, over a longer period of time, the feedback on TC levels may cause changes in other variables such as body weight. Complete lipid profiles might provide valuable information as to exactly what variables do change.

Some of the control subjects did have clinically meaningful TC reductions. Control subjects were told their TC would be rechecked in 16 weeks and were given dates as to when this would occur. Knowing they would be checked again in the future, and having a definite date for the recheck, may have led some to form TC level goals to be reached by that date. However, some of the control subjects had considerable increases in TC levels. All of the experimental subjects either reduced or at least maintained their TC level. The self-efficiacy inventories did not differientiate subjects who felt they could reduce their TC from those who felt they could not. The subjects may have reported what they felt were the desirable answers.

As members of a cardiac rehabilitation and intervention program, the subjects had received at least some information concerning the relationship between TC and heart disease prior to their participation in this investigation. The mean length of time in the program prior to the study was approximately four years. This may have had an effect on their attempts to lower their TC in that they may have been highly motivated subjects. Thus, these results cannot be generalized directly to all populations. Further research is be needed to determine if frequent cholesterol feedback would be beneficial earlier in the rehabilitation process and for general intervention programs.

These data do suggest that providing TC feedback on a regular and frequent basis may be a valuable adjunctive tool to dietary intervention. The portable blood analyzer used in this study was cost effective in terms of staff time and convenience for the subjects. The convenience of this new technology for TC measurement may lead more individuals to seek out TC measurement and increase their cholesterol consciousness. While it cannot replace complete lipid profiles obtained by venipuncture and spechophotometry, it does seem helpful to provide total cholesterol feedback to cardiac patients and high-risk individuals using such a device.

**TABLE 1.** SUBJECT CHARACTERISTICS

| Characteristic | Control Group (n = 14) | Experimental Group (n = 14) |
|---|---|---|
| Age (years) | 53.5±6.4 | 57.7±7.7 |
| Years of Education | 16±3.8 | 15.6±2.9 |
| Months in Cardiac Program | 46.2±39.9 | 51.9±39.9 |
| Program Attendance (%) | 70.6±25.3 | 81.4±13 |
| Dietician Contacts in 16 Weeks per Subject | 0.35±.49 | 0.43±.51 |

Values are means ± standard deviation

**TABLE 2.** BASELINE AND WEEK 16 DATA FOR BLOOD PRESSURE, BODY WEIGHT, AND PERCENT BODY FAT

| | Control Group | | Experimental Group | |
|---|---|---|---|---|
| Variable | Baseline | Week 16 | Baseline | Week 16 |
| SPB (mmHg) | 119±13.8 | 116±18.1 | 124.7±10.3 | 124.7±12.3 |
| DBP (mmHg) | 79±10.6 | 79.4±12.9 | 78.4±7.2 | 78.4±5.8 |
| WGT (kg) | 87.6±16.5 | 86.2±12.2 | 76.9±10.7 | 76.4±11.4 |
| %Fat | 25.1±4.8 | 22.9±4.4 | 22.5±3.6 | 21.5±4.3 |

Values are means ± standard deviation
SBP = systolic blood pressure
DBP = diastolic blood pressure
WGT = body weight
%Fat = estimated % body fat

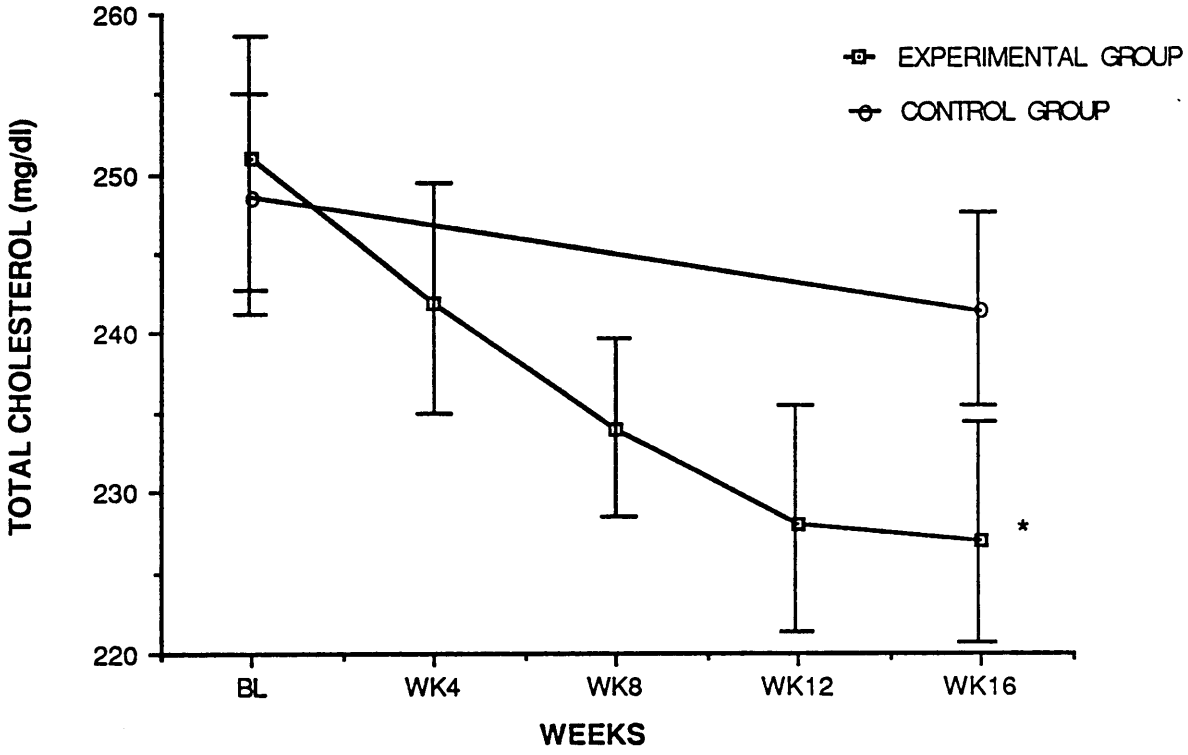


Figure 1: Total cholesterol levels for each group.
Values are means ± standard error. (*p<.05)

**TABLE 3.** BASELINE AND WEEK 16 TOTAL CHOLESTEROL DATA

| | Control Group | | Experimental Group | |
|---|---|---|---|---|
| Variable | Baseline | Week 16 | Baseline | Week 16 |
| TC (mg/dl) | 248.4±25.2 | 242.7±23 | 251.1±30.8 | 227.4*±32.5 |
| TC Reduction (mg/dl) | -- | 5.7±23.3 | -- | 23.7*±21.9 |
| % TC Reduction | -- | 1.9±8.8 | -- | 9.3*±8.2 |

Values are means ± standard deviation
*p<.05 experimental versus control group for Week 16 values
TC = total cholesterol; TC reduction = total cholesterol reduction by Week 16; % TC reduction = percent total Cholesterol reduction by Week 16

**TABLE 4**: REFLOTRON REPRODUCIBILITY (BASED ON DUPLICATE SAMPLES) AND ACCURACY (VALUES COMPARED TO VALUES OBTAINED BY STANDARDIZED SPECTROPHOTOMETRY)

Reproducibility

| N | Trial 1 | Trial 2 | C.V. |
|---|---|---|---|
| 56 | 242.1±29 | 242.5±29.2 | 2.2 |

Accuracy

| N | Reflotron | Spectrophotometry | Regression |
|---|---|---|---|
| 25 | 229.5±33.5 | 230.4±32.6 | Reflotron=.98 (Spectrophotometer) +1.5mg/dl |

Values are means ± standard deviation

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# Chapter IV

## SUMMARY OF THE STUDY

### Summary

This investigation was conducted to determine if providing monthly feedback on plasma total cholesterol levels would be helpful in attempts by hypercholesterolemic individuals to lower their cholesterol levels.

Twenty-six male and two female volunteers between the ages of 43-68 years participated in this 16 week study. All were participants in the Cardiac Therapy and Intervention program at Virginia Tech. Total cholesterol levels (TC) were measured using a Manheim Bohringer Reflotron portable blood analyzer. The reproducibility and accuracy of the Reflotron were determined during the study and found to be acceptable.

The Reflotron requires only 30 microliters of blood which can be obtained via fingerprick techniques. Results are provided in three minutes, and the process from blood collection to results takes approximately five minutes. Total cholesterol data for this study were collected during the regular hours of the Cardiac and Intervention Program exercise sessions (6-8 AM).

After baseline and demographic data were collected, the subjects were stratified on the basis of TC and

number of months in the Cardiac Program, and then randomly assigned to two groups. All subjects were given a packet of information concerning dietary strategies to lower TC based on recommendations made by the American Heart Association. The control group was told their TC levels would be rechecked in 16 weeks. The experimental group was told their TC would be checked every four weeks for 16 weeks. Each time members of the experimental group had their TC checked, they were shown a graph of their current and previous TC levels. All subjects were asked to complete diet diaries at baseline, Week 8, and Week 16. Subjects also completed two self efficacy ratings on their ability to change their diet and lower their cholesterol at baseline, Week 8, and Week 16. In addition, the experimental group completed the ratings at each TC measurement. A dietician was available to all subjects throughout the study to answer any questions they might have.

Statistical Analysis System (SAS) Institute's computer package was used to conduct the statistical analysis. Independent t-tests were used to determine if significant differences existed between groups in terms of several demographic variables including age, number of months of participation in the Cardiac and Intervention Program, attendance in the program during the study, years of education, and dietician contacts during the

study. ANOVA's were used to compare baseline values for several dependent variables: TC, systolic blood pressure, diastolic blood pressure, weight, estimated percent body fat, dietary fat, dietary saturated fat, dietary cholesterol. ANOVA's were also used to analyze the week 16 values for each of these variables and week 8 dietary data. Week 16 TC levels were also analyzed using an analysis of covariation with baseline TC levels as the covariate. The mean TC reduction and mean percent TC reduction were compared across groups using independent t-tests. Dependent t-tests were used to determine if significant changes in the value of any dependent variable occurred within groups from baseline to week 16. An ANOVA was used to compare differences in the self efficacy ratings between groups and within groups from baseline to week 8, and to week 16.

There were no significant differences between groups at baseline in terms of age, number of months of program participation, program attendance, years of education, dietician contacts, TC, blood pressure, weight, percent body fat, dietary fat, dietary saturated fat, dietary cholesterol, or self efficacy ratings.

Analysis of Week 16 data found no significant differences between groups in blood pressure, weight, or percent body fat. There were also no changes within

groups in any of these variables from baseline to Week 16.

No significant differences were found between groups in terms of dietary fat, saturated fat, and cholesterol at baseline, Week 8, or Week 16. No significant changes occurred within groups from baseline to Week 8 to Week 16. However, complete dietary records were not available for all subjects. Significant differences also did not exist in self efficacy ratings between groups or within groups at baseline, Week 8, or Week 16.

Analysis of covariance procedures revealed that the experimental group had a significantly lower Week 16 TC level than the control group (228 mg/dl versus 246 mg/dl). The mean reduction in TC was larger for the experimental group (24 mg/dl versus 6 mg/dl), as was the mean percent reduction in TC (9% versus 2%).

## Research Implications

The results of this investigation suggest that providing feedback of TC on a regular basis after attempts to lower cholesterol are initiated may be helpful. E.L. Thorndike was one of the first behavioralists to suggest that feedback can influence behavior (Schwartz, 1978). Elder et al. (1985) suggested that progress reports may help stimulate individuals who are attempting to modify cardiovascular risk factors.

Feedback may lead individuals to continue their behavior if the results are positive, or adjust their behavior to reach their goals if the results are negative. The feedback may be more effective if collected and visually depicted on a continuous basis. The present study seems to support these views.

Crouch et al. (1986) also found that follow-ups are important in attempts to lower cholesterol levels. However, the follow-ups in that study included dietary classes and cholesterol measurement. The current study used only TC measurement as follow-ups and found significant results.

The accuracy and reproducibility of the Reflotron portable blood analyzer in this study suggested that this relatively new instrument may be useful in the treatment of hyperlipidemia. Under the conditions of well-controlled measurement techniques and a well-trained technician, the Reflotron provided meaningful results. The new technology available that provides results within minutes, and the fact that only a few drops of blood are required, may lead more individuals to seek out cholesterol measurement and increase the cholesterol consciousness of these individuals. Superko (1987) suggested that the analyzers such as the Reflotron be used in cardiac rehabilitation centers on a regular basis. This proved to be quite convenient for the

subjects in the present study. Cholesterol checks were done during the regularly scheduled exercise sessions at the Cardiac and Intervention Center at Virginia Tech, and required only five extra minutes of the subjects' time. The measurement also proved convenient for the Rehab Center itself, requiring little staff time, and costing less than $1.50 per test.

Elevated plasma cholesterol levels have been strongly linked with coronary artery disease (NIH, 1985). Wrisly and Rubenfire (1988) reported that traditional dietary counseling failed to produce changes in the lipid levels of the cardiac patients they studied. Providing regular feedback on TC in addition to dietary counseling may help lower TC levels, therefore reducing the risk of heart disease. Using proper measurement techniques, the new generation of portable blood analyzers may provide the valid and reliable feedback necessary to modify the behavior that leads to elevated TC.

## Recommendations for Future Research

The following recommmendations were made for future investigations:

1. A longer term study should be conducted to determmine if the results found in the present study are lasting. A year-long study including pre- and post-lipid profiles would be appropriate.

2. Periods of time other than 4 and 16 weeks between TC checks should be examined to determine the most cost-effective interval between TC feedback.
3. A similar study, including an attention control group, would be of interest. Simply having individuals report for a five-to-ten-minute meeting with a designated person at monthly intervals might lead to changes in TC due to the added attention the individual would receive.
4. Providing cholesterol feedback in an acute cardiac rehabilitation program (Phase II) to determine if decreases in TC are found in other cardiac rehabilitation settings.
5. A study utilizing subjects who are not participants in a cardiac rehabilitation or cardiovascular risk intervention program would be relevant to determine the convenience and effectiveness of providing TC feedback to the general population.

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# Appendix A

## METHODOLOGY

# METHODOLOGY

## Subject Selection

Twenty-six male and two female volunteers between 43 and 68 years of age served as subjects for this study. All subjects were referred to this study by the Cardiac and Intervention Program at Virginia Tech. Participants are routinely screened for plasma total cholesterol levels by the Cardiac and Intervention Program, and were selected for this study if their plasma cholesterol levels were greater than 200 mg/dl. Participants who were taking cholesterol lowering medications or were diabetics were excluded from the study. All subjects were participating in an exercise program prescribed by an exercise physiologist at the Cardiac and Intervention Program. Subject selection procedures were approved by the Human Subjects Committee of Virginia Polytechnic Institute and State University.

## General Method

Upon selection for the study, subjects attended an interview during which the nature of the study was described, and possible risks and benefits explained. An informed consent form, previously approved by the Human Subjects Committee of Virginia Polytechnic and State Institute, was signed by all subjects. Plasma total

cholesterol was measured by the Reflotron Portable Blood Analyzer which involves blood collection by fingerprick and provides results in three minutes. Cholesterol levels were measured in mg/dl as is the standard unit of cholesterol measurement in North America. Subjects were matched based on total cholesterol levels and length of time of participation in the Cardiac and Intervention Center, and then randomly assigned to either an experimental or control group. It was explained to the experimental group that the finger prick procedure would be performed once every 28 days for 16 weeks. Control subjects were told that their total cholesterol would be measured again by the Reflotron at 16 weeks. The samples taken at baseline and at 16 weeks after baseline were analyzed to determine if the experimental group's total cholesterol level differed from the control group's after 16 weeks. All subjects were asked to complete three day diet diaries at baseline, week eight, and at week 16. The diet diaries were analyzed to estimate the amount of fat and cholesterol in the diets of each subject. However, no feedback concerning the results of the diet diaries were given to the subjects. After baseline measures were collected, each subject was given a packet of materials containing information on ways to change the diet in order to reduce their total plasma cholesterol.

For all subjects, duplicate samples were collected at baseline and 16 weeks by fingerprick and measured on the Reflotron. The results of the duplicate samples were compared to estimate the reproducibility of the Reflotron technique in this study. A different group of subjects had blood samples drawn by venipuncture and analyzed in duplicate by spectrophotometry by Roche Laboratories using the modified Abell-Kendall method and also had samples collected by fingerprick and analyzed by the Reflotron. This was done to estimate the accuracy of the Reflotron techniques in this study.

The subjects used in this study allows the researcher to generalize to middle-aged individuals who have been participants in a cardiac and intervention center exercise programs for several years.

Variance was minimized in this study by: a) orienting all subjects to the measurement procedures prior to data collection; b) having all Reflotron techniques and orientation instructions performed by the same lab technician; c) having all skinfold, blood pressure, and weight measures collected by the same technician; and d) having a control group.

## Experimental Procedures

The plasma total cholesterol (TC) of all subjects was measured at baseline and 16 weeks by the Reflotron Portable

Blood Analyzer (Boehringer Mannheim Diagnostics), an electrochemical reflectance photometer. Blood samples were collected from the tip of the third finger of the nondominant hand using an Autoclix (Bio-Dynamics) automatic pricking device. The fingertip was cleaned and sterilized with isopropyl alcohol and the lab technician wore surgical gloves at all times. A new lancet was used for each sample. The samples were collected in 30 microliter lithium heperin coated glass capillary tubes (Reflotron). Samples were then transferred to a Reflotron reagent tab. Each tab consisted of a separation pad, a reagent pad, and a magnetic code. The separation pad separated plasma from whole blood via glass filter paper. The separated plasma was forced onto the reagent pad where the chemical reaction took place. The magnetic code included information about test selection, duration of the preincubation and reaction phases, wavelength, and specification for calibration of the results from the reflectance measurement. The Reflotron utilized the principles of reflectance photometry and measured chromatic changes of Reflotron reagent pads due to component chemistry reactions. Three pulsating light-emitting diodes illuminated the reagent pad of the reagent tab. Two detectors compared the emitted and reflected light, with light reflected being inversely proportional to the concentration of the unknown in the sample. Increased light reflection resulted from lower concentration of the

unknown in the sample and decreased light reflection resulted from higher concentrations of the unknown sample. A digital display showed the cholesterol level in mg/dl within three minutes (Reflotron Owners Manual, 1986).

Each subject's weight, predicted percent body fat, and blood pressure were recorded at baseline and also at 16 weeks after baseline. Body weight was recorded in kilograms using a Detecto-Medic scale (Detecto Scales Inc.) and the scale was balanced prior to weighing. Predicted percent body fat was determined by measuring chest, abdomin, and thigh skinfolds for males, and tricept, suprailliac, and thigh skinfolds for females, in millimeters using John Bull skinfold calipers (British Indicators Ltd.). The sum of the three skinfolds was used to calculate percent body fat based on the generalized equations for predicting body density of men developed by A.S. Jackson and M.L. Pollock (1978). In this procedure, percent body fat is determined by calculating body density using the Siri formula. The same technician performed all skinfold measurements. Blood pressure was measured using a mercury column sphigmomonometer with the subject in a sitting position. Each subject remained seated for five minutes prior to blood pressure measurement.

All subjects were asked to complete three diet diaries at baseline, Week 8, and Week 16. Each diet diary was analyzed for dietary cholesterol and fat intake using the

analyzed for dietary cholesterol and fat intake using the Nutrition 3 computer software package (M2 Computing).

After the baseline measures were collected, each subject was given a packet containing six handouts. Each handout included information and recommendations based on the American Heart Association's dietary treatment plan for hyperlipidemia. This program encourages individuals to make gradual changes in their eating habits and to learn to identify foods that are high in saturated fat and cholesterol. The goal of the program is to have dietary fat account for less than 30% of the total caloric intake and to reduce total dietary cholesterol to less than 300 mg. (American Heart Association, 1982). The subjects were instructed to speak with the Cardiac and Intervention Center's dietician if they had any questions concerning the information they were given in the packets. The dietician was routinely available during the normal hours of the Cardiac and Intervention Center's exercise programs. No appointments were scheduled with the dietician and the subjects were not required to meet with the dietician. Also included in the packet was a paper containing the subject's baseline cholesterol level and the date of the next scheduled cholesterol measurement for the subject. Experimental subjects were asked to return in four weeks and the control subjects in 16 weeks for cholesterol measurement.

Subjects were matched on the basis of total cholesterol levels and length of time of participation in the Cardiac and Intervention Center at Virginia Tech. Subjects from each matched pair were randomly assigned to either an experimental or control group. The plasma total cholesterol of the experimental group was measured once every four weeks by the Reflotron Portable Blood Analyzer (Boehringer Mannheim Diagnostics). The procedures were the same as those described above. After each monthly measurement each subject was shown a graph of their current and previous cholesterol levels. Subjects were not required to fast prior to the measurements. All measures were taken between the hours of 5:45 and 8:00 AM, the normal operating time of the Cardiac and Intervention Center exercise programs. At baseline and each monthly measurement, experimental subjects were asked to complete a short inventory. Two statements were included on the inventory: 1) I have the ability to lower the amount of saturated fat and dietary cholesterol in my diet; 2) I have the ability to lower my serum cholesterol through dietary changes. Under each of the statements was a scale including the numbers 0 through 6, with the word "Disagree" anchored at the number 0, and the word "Agree" anchored at the number 6. Subjects were asked to rate the amount they agreed or disagreed with each of the two statements. Control subjects were asked to

complete the same inventory at baseline, eight weeks, and at 16 weeks.

At baseline and at Week 16, all subjects had two samples collected from two different fingerpricks on the same occasion. The results of the two samples were compared in order to estimate the reproducibility of the Reflotron technique in this investigation. To determine the accuracy of the Reflotron in this study, another group of 25 subjects had blood drawn by venipuncture and analyzed by spectrophotometry. On the same occasion, the subjects had a blood sample collected by fingerprick and measured by the Reflotron. The Reflotron values were compared to the spectrophotometry values. Fifteen ml of blood was collected in labelled vacutainers containing EDTA (ethylenediamenletreacetate) from each subject. Subjects were instructed to fast for 12 hours prior to blood collection. A registered nurse drew the blood by venipuncture from the antecubital site of either arm, using a 21 gauge, 1 inch needle. All blood tubes were immediately inverted three to four times to mix the blood with the EDTA. The nurse used isopropyl alcohol to clean and sterilize the skin over the antecubital area. Plasma was separated from the red blood cells by low speed centrifugation for 30 minutes within one hour of collection. After centrifugation, plasma was removed from the test tubes and refrigerated. The samples were picked up at The Human

Performance Lab at Virginia Tech by Roche Laboratories personnel and transported to Roche Laboratories for analysis of plasma total cholesterol. The enzymatic method used by Roche Biomedical to determine serum cholesterol levels has been carefully standardized to the Lipid Research Clinics' (LRC) reference method (modified Abell-Kendall method) using LRC validated serum-based calibrators and National Bureau of Standards reference material (Roche Biomedical Laboratories, 1987). The Reflotron procedures were the same as those described above.

The calibration of the Reflotron was checked each week using Reflotron-Check Strips (Boehringer Mannheim). Reflotron-Check calibrating strips consist of a gray area with specified reflectance properties. The gray area was scanned at three wavelengths: 567, 642, and 951 nm. The results were displayed on the digital display and were compared with the mean values and ranges printed on the Check-Strip canister. The test took 75 seconds to complete. Only unused strips were used for calibration, and all unused strips were stored in their original canister. The measuring chamber, including the transporter and the upper and the lower sample heaters, was cleaned weekly to ensure proper operation. The chamber was cleaned using isopropyl alcohol pads.

The plasma total cholesterol levels of the experimental and control groups obtained at baseline and at

Week 16 were compared to determine if a significant difference existed between the two groups. The monthly cholesterol measures of the experimental group were examined to determine if changes took place from month to month. Also, the percent body fats and blood pressure levels were compared at baseline and at 16 weeks to determine if differences existed between the two groups. Dietary cholesterol levels and dietary fat levels were compared at baseline, eight weeks, and 16 weeks. The monthly responses on the inventory were compared for the experimental group, and the responses were compared across and within groups at baseline, eight, and 16 weeks.

## Research Design

A matched randomized control group pretest-posttest design was utilized, with 14 subjects assigned to the experimental group and 14 subjects assigned to a control group.

## STATISTICAL ANALYSES

### Reproducibility and Accuracy of the Reflotron Portable Blood Analyzer

At baseline and Week 16, duplicate blood samples were collected on the same occasion from separate fingersticks

and analyzed to estimate the precision of the Reflotron in this investigation. The results of the two trials were compared using a one-way analysis of variance (ANOVA). There was no significant difference between the two trials ($F_{55,1}=.14$, n.s.) and the coefficient of variation (C.V.) was 2.18% A complete ANOVA table can be found in Appendix D. The cholesterol values used for precision determination ranged from 184 to 319 mg/dl. Values for all duplicate samples can be found in Appendix E. The trial 1 mean value was 242.09 mg/dl ($\pm$ 29.01), while the mean for trial 2 was 242.46 mg/dl ($\pm$29.19). The percent difference between trial 1 and trial 2 ranged from 0% (same value for both samples) to 5.7%. The mean percent difference was 2.5%, and there was less than 4% difference between duplicate samples on 49 out of 56 comparisons. Values near the mean for percent difference were found throughout the range of cholesterol values test.

In order to determine the accuracy of the Reflotron, a separate group of 25 subjects had blood samples collected from fingersticks and analyzed by the Reflotron on the same occasion as blood was collected via venipuncture and analyzed by spectrophotometry. An ANOVA was used to compare the results of the two different means of cholesterol measurement. There was no significant difference between the two methods ($F_{24,1}=.33$, n.s.). A complete ANOVA table can be found in Appendix D. The mean of the Reflotron

analysis was 229.56 mg/dl (±33.48) and the mean of the spectrophotometry analysis was 230.6 mg/dl (±32.37). The range of levels tested was 184 to 300 mg/dl as measured by spectrophotometry. The values of each analysis can be found in Appendix E. On 12 out of 25 comparisons, the Reflotron reported higher values, the highest being 5.6% higher than the spectrophotometer value (195 versus 184 mg/dl). The Reflotron was also 7% lower on one occasion (198 versus 212 mg/dl). However, the difference in methods of analysis was less than 5% on 20 out of 25 comparisons. Regression analysis revealed the following: Reflotron = .98 (Spectrophotometry) + 1.5 mg/dl.

## Data Analysis

Independent t-tests were used to determine if significant differences existed between groups in terms of several demographic variables including age, number of months of participation in the Cardiac and Intervention Program, program attendance, years of education, and dietician contacts during the study. Analysis of variance (ANOVA were used to compare baseline values for several dependent variables: TC, systolic blood pressure, diastolic blood pressure, body weight, estimated percent body fat, dietary fat, dietary saturated fat, dietary cholesterol. ANOVA's were also used to analyze the week 16 values for each of these variables. Week 16 TC were also analyzed

using an analysis of covariation with baseline TC levels as the covariate.

The experimental group monthly TC measures were analyzed using an ANOVA. Duncan post hoc tests were computed if significant interactions were found. The mean TC reduction and percent TC reduction were compared across groups using independent t-tests. Dependent t-tests were used to determine if significant changes in the values of any dependent variable occurred within groups from baseline to week 16. ANOVA's were used to compare differences in the self efficacy ratings between and within groups at baseline, week eight, and week 16. All data was analyzed using the Statistical Analysis System (SAS).

Summary statistical tables for all analysis can be found in Appendix D. Raw data tables can be found in Appendix E.

Statistical analysis revealed no significant differences between groups in terms of age, number of months in the Cardiac and Intervention program, program attendance, years of education, or dietician contacts. There were also no significant differences at baseline in TC, systolic blood pressure, diastolic blood pressure, body weight, percent fat, dietary fat, dietary saturated fat, dietary cholesterol, or self-efficacy ratings.

Analysis comparing week 16 values found no significant differences between groups in systolic blood pressure,

diastolic blood pressure, body weight, or percent body fat. There were no significant changes in any of these variables within either group.

No significant differences were found between groups in terms of dietary fat, saturated fat, and cholesterol at baseline, Week eight, or Week 16. There were also no significant differences found within groups from baseline to Week eight to Week 16. However, only ten subjects completed diet diaries at Week eight, and only 16 did so at Week 16.

The two self-efficacy ratings were not significantly different between groups at baseline, Week eight, or Week 16, nor did they significantly change within groups during the 16 weeks.

The week 16 TC values were not found to be significantly different between groups using an ANOVA. When this data was analyzed using an analysis of covariance with baseline TC as the covariate, a significant difference was found. The experimental group's week 16 mean TC level was significantly lower than the control group's. The mean amount of reduction in TC during the 16 weeks was significantly larger for the experimental group, as was the mean percent reduction in TC. The monthly TC measures collected from the experimental group were not significantly different from one another.

## Conclusions

Based upon the results of this study, the researcher concludes that individuals who receive cholesterol profiles once every 16 weeks do not experience the same magnitude of cholesterol reduction as individuals receiving total cholesterol profiles once every four weeks. In the study, individuals receiving cholesterol profiles once every four weeks had significantly greater total cholesterol reductions after 16 weeks.

## Appendix B

## INFORMED CONSENT

HUMAN PERFORMANCE LABORATORY

Division of Health, Physical Education and Recreation
Virginia Polytechnic Institute and State University

INFORMED CONSENT

I, _____, do hereby voluntarily agree and consent to participate in a testing program conducted by the personnel of the Human Performance Laboratory of the Division of Health, Physical Education and Recreation of Virginia Polytechnic Institute and State University.

Title of Study:
Increasing the Frequency of Cholesterol Measurement as an Aid to Lower Plasma Total Cholesterol in Individuals With Elevated Cholesterol Levels.

The purposes of this experiment include:
This study will be conducted to determine if providing more frequent information on cholesterol levels helps individuals to reduce their plasma total cholesterol level.

I voluntarily agree to participate in this testing program. It is my understanding that my participation will include:

1. Having your cholesterol measured from two to five times during a 16 week period. This will involve having your finger pricked and having a small amount of blood collected. A lab technician will clean and sterilize one of your fingertips with isopropyl alcohol and will prick that finger with a small needle. Approximately three drops of blood will be collected into a small tube. The technician will wear surgical gloves and will use a new needle to prick your finger. A band aid will be placed over the area where your finger was pricked.

2. Having your blood pressure, weight, and percent body fat measured on two occasions.

3. Recording your dietary intake for three days on three occasions.

I understand that participation in this experiment may produce certain discomforts and risks. These discomforts and risks include:

Slight temporary discomfort during blood sampling, a risk of infection, and the possibility of contracting a contagious disease.

Certain personal benefits may be expected from participation in this experiment. These include:

A reduction in your plasma total cholesterol level and therefore a reduced risk of Coronary Heart Disease.

Appropriate alternative procedures that might be advantageous to you include:

Attempting to lower your cholesterol level without dietary counseling or cholesterol measurement.

I understand that any data of a personal nature will be held confidential and will be used for research purposes only. I also understand that these data may only be used when not identifiable with me.

I understand that I may abstain from participation in any part of the experiment or withdraw from the experiment should I feel the activities might be injurious to my health. The experimenter may also terminate my participation should he feel the activities might be injurious to my health.

I understand that it is my personal responsibility to advise the researchers of any preexisting medical problem that may affect my participation or of any medical problems that might arise in the course of this experiment and that no medical treatment or compensation is available if injury is suffered as a result of this research. A telephone is available which would be used to call the local hospital for emergency service.

I have read the above statements and have had the opportunity to ask questions. I understand that the researchers will, at any time, answer my inquiries concerning the procedures used in this experiment.

Scientific inquiry is indispensable to the advancement of knowledge. Your participation in this experiment provides the investigator the opportunity to conduct meaningful scientific observations designed to make significant educational contribution.

If you would like to receive the results of this investigation, please indicate this choice by marking in the appropriate space provided below. A copy will then be distributed to you as soon as the results are made available by the investigator. Thank you for making this important contribution.

_____I request a copy of the results of this study.

Date_____
Time_____a.m./p.m.
Participant Signature_____

Witness_____

HPL Personnel

Project Director___Tony Burkett_____ Telephone 961-5006
HPER Human Subjects Chairman Dr. Charles Baffi Phone 951-6561 Dr. Charles Waring, Chairman, Institutional Review Board for Research Involving Human Subjects. Phone 961-5283

# Appendix C

## SUBJECT HANDOUTS

---

Your next cholesterol check is scheduled for _____

You will be reminded again before the measurement.

Your last cholesterol check showed your level to be _____mg/dl

Included are some guidelines and suggestions on how you might change your diet in order to lower your cholesterol level. If you have any questions, please feel free to speak with Ellen Cole, the program dietician. If you have not completed a diet diary, please do so as soon as possible.

You should:

1. Begin slowly. Don't try to make too many changes at once.

2. Let friends and family know you are trying to lower your cholesterol. They may be able to help.

3. **Reduce the amount of fat in your diet (especially saturated fat) and increase the amount of fiber in your diet (whole grains, fruits, and vegetables).**

CARDIAC THERAPY AND INTERVENTION CENTER
Virginia Tech
Telephone 961-7277

## EATING THE LOW-FAT, LOW-CHOLESTEROL WAY

- Eat more poultry and fish than meat.
- Discard the skin of poultry before serving.
- Use lean meats, trimming visible fat before cooking.
- Reduce intake of fried foods.
- Avoid fatty hamburger, hot dogs, luncheon meats, breaded and prefried fish and organ meats.
- Read margarine labels. Ingredients are listed in descending order of predominance by weight. The first ingredient listed will be oil in the more unsaturated margarines.
- Substitute 2/3 cup of polyunsaturated oil for each cup of solid shortening or butter in baking.
- Switch to low-fat dairy products.
- Cut down on hard cheeses.
- Substitute ice milk for ice cream and yogurt for sour cream.
- Limit your total consumption of eggs (including those for cooking) to four a week.
- Use two egg whites for one whole egg in recipes, adding a teaspoon of salad oil to replace the missing yolk's non-stick properties.
- Refrigerate soups, stews and gravies, and then skim off the fat before reheating and serving.
- Skim ice cubes through drippings and remove the congealed fat before mixing with flour for last minute gravies.
- Avoid commercial baked goods, especially cakes, doughnuts, muffins, and butter rolls.
- Eat fruits for desserts and snacks.

The American Heart Association Dietary Guidelines for Americans

Adapted from The Culinary Hearts Kitchen Course

1. Maintain ideal body weight (IBW)
   - Use small portions
   - Avoid "seconds"
   - Eat Slowly
   - Use foods high in nutrients and avoid "empty" kcalorie foods such as cookies and candies

2. Reduce total fat in the diet *less than 30% of total calories
   - Eat 3 to 4 ounces of lean meat, fish or poultry each day. Often substitute vegetable proteins, such as beans, for these.
   - Choose lean cuts of meat, trim visible fat, and discard the fat that cooks out of the meat.
   - Avoid frying food; use cooking methods that help to remove fat, i.e., baking, broiling, boiling, roasting and stewing.
   - Restrict your use of fatty "luncheon" and "variety" meats like sausage and salami.

   a. The level of saturated fat should be reduced to less than 10% of total kcalories.
      - Fish, poultry and veal are low in saturated fat so they should be eaten more frequently than beef, lamb or pork.
      - Avoid the use of butter and other solid cooking fats, which are more saturated.

   b. Maintain polyunsaturated fat to *less than 10% of total calories
      - Use liquid oils and margarines that are rich in polyunsaturated fats.
      - Vegetable oils highest in polyunsaturated fats are:
        Safflower oil
        Sunflower oil
        Corn oil
        Unhydrogenated soybean oil

   c. Vegetable oils which contain mostly monounsaturated fats have little effect on lowering blood lipids. These include olive oil, peanut oil and hydrogenated soybean oil.

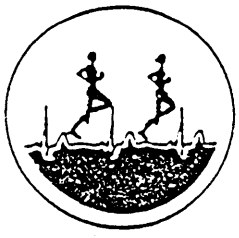
3. Reduce dietary cholesterol to less than 300 mgs per day *or 100 mg per 1000 cal.
   - Eat no more than 2-3 egg yolks per week, including eggs used in cooking.
   - Limit the use of organ meats such as liver and brains to once every two weeks.
   - Use skimmed or low fat milk and cheeses made from partially skim milk, instead of whole milk and cheeses made from whole milk and cream.

4. Eat foods with adequate starch and fiber
   - *Carbohydrage intake should be 50-55% or more of total calories
   - Use carbohydrates primarily from grains, fruits, vegetables and cereals.
   - Use whole grain breads such as whole wheat or rye instead of refined white bread.
   - Eat plenty of raw fruits and vegetables leaving the skin on, if possible.
   - Select whole grain cereals, beans, peas and nuts.

5. Avoid too much sodium *1 gm per 1000 calories, not to exceed 3 gm per day
   - Use salt moderately in cooking.
   - Taste food before salting.
   - Avoid excessive consumption of salty foods, such as salted potato chips, pretzels, peanuts, etc.
   - Be aware of and avoid foods high in hidden sodium such as "luncheon" or canned meats, canned soups, and many prepared foods.
   - Check food labels for other sodium-containing additives such as monosodium glutamate, sodium benzoate, sodium bicarbonate (baking soda), etc.

6. *If alcoholic beverages are consumed, limit to 15% of total calories, not to exceed 50 cc of ethanol per day.

*indicates revisions of AHA August, 1986



CARDIAC AND INTERVENTION CENTER

AT VIRGINIA TECH

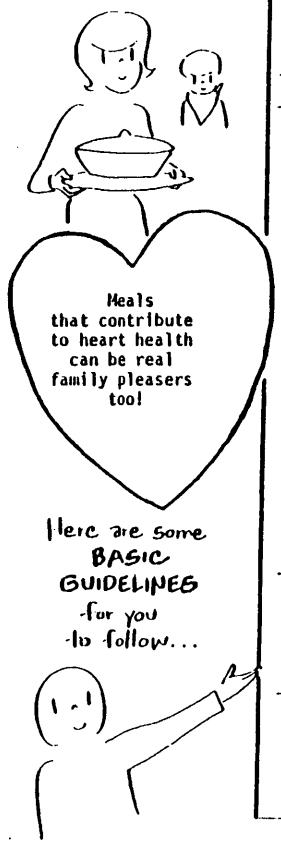
Telephone 961-7277

# HOW TO CHOOSE FOODS LOW IN CHOLESTEROL AND SATURATED FAT

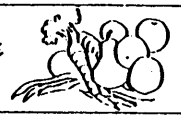
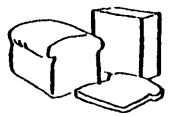
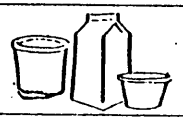
| FOOD GROUP | RECOMMENDED | AVOID OR USE SPARINGLY |
|---|---|---|
| MEAT, POULTRY, FISH DRIED BEANS AND PEAS, NUTS, EGGS | Chicken, turkey, veal (except the breast), fish, shellfish (clams, crab, lobster, oysters, scallops), lean meats, egg whites, specially-processed low-fat luncheon meats.<br>Dry beans and peas such as: kidney beans, lima beans, vegetarian-style baked beans, pinto beans, lentils, chick peas, split peas, navy beans.<br>Soybean curd (tofu), peanut butter, cholesterol-free egg substitutes. | Duck, goose, heavily marbled meats, luncheon meats, bacon, sausage, ham, frankfurters, organ meats such as heart, kidney, sweetbread, and liver.<br>Egg yolks (limit to three times per week—includes eggs used in cooking). |
| VEGETABLES AND FRUITS (canned, fresh, or frozen) | All varieties. | Avoid if: fried, served in cream, butter or cheese sauces. |
| BREAD AND CEREALS | Bread made with a minimum of saturated fat, such as: whole wheat, enriched white, French, Italian, oatmeal, rye, pumpernickel, English muffins, pita.<br>Pasta, cereal, rice, melba toast, water crackers, matzos, pretzels, popcorn with polyunsaturated oil, water bagels. | Pastries, butter rolls, commercial biscuits, muffins, donuts, cakes, egg breads, cheese breads, commercial mixes containing dried eggs and whole milk. (Many of these products are made with saturated fat: lard, butter, suet, palm oil, coconut oil, hydrogenated vegetable oil, etc.) |
| MILK PRODUCTS | Ones which are low in saturated fat: skimmed milk and milk powder, low-fat products, buttermilk (from skim milk), low-fat yogurt, evaporated skim milk. Low-fat or skim milk cheese (without added cream): cottage cheese, farmer's, hoop, baker's, mozzarella, ricotta. | Whole milk and whole milk products include: ice cream, cheese made from whole milk or cream, butter. All creams (sour, half-and-half, whipped). |
| FATS AND OIL | Margarines, liquid oil shortenings, salad dressings and mayonnaise made from polyunsaturated oils, vegetable oils: corn, cottonseed, sesame, soybean, sunflower, safflower. | Butter, lard, salt pork, meat fat, coconut oil, completely hydrogenated margarines and shortenings. Use peanut oil and olive oil occasionally for flavor. |
| DESSERTS, BEVERAGES, SNACKS AND CONDIMENTS | Fresh fruit and fruit canned without sugar, cocoa or carob powder, water ice, sherbet, gelatin, fruit whip, angel food cake, cakes made with polyunsaturated oils.<br>Vinegar, mustard, herbs, spices. | Coconut, cream products, fried food, snacks (potato chips, corn chips, etc.), chocolate pudding, ice cream, and most commercial cakes, pies, cookies and mixes. |

NOTE: New, acceptable versions of standard products are appearing on the market. Be sure to read product labels on any item you are interested in purchasing.

FOR YOUR REFRIGERATOR DOOR




# GUIDE TO "HEART-Y" EATING

| FOODS | GOOD | GO SLOW |
|---|---|---|
| MEAT group  | Moderate size portions of chicken, turkey, veal, fish. Beef, lamb, ham, pork - lean cuts with little marbling. Nuts, beans - use as substitutes. Shellfish occ. | Duck, goose - very fatty. Fatty meats, organ meats. More than 4 eggs/week. |
| FRUIT and VEGETABLE group  | ALL of them. Include 1 dark green or deep yellow vegetable for vitamin A and 1 citrus fruit or juice for vitamin C. | Potato chips and deep-fried vegetables. |
| BREAD and CEREAL group  | Whole grain or enriched breads. Whole grain cereals. Most pasta (spaghetti, macaroni). | Pastries; commercial baked goods (high saturated fat content, sugar). Egg-rich breads. Egg noodles. Mixes with high fat content |
| MILK PRODUCTS  | Low-fat milk products (skim milk, buttermilk, yogurt, low-fat cheeses such as cottage cheese, mozarella, farmer's. | Whole milk and whole milk products. Cream and cream products (including butter, hard cheeses). |
| FATS and OILS  | Liquid oils & margarines high in polyunsaturates with ratio of 2:1 polyunsaturated fat to saturated. Salad dressings made with poly-unsaturates. | Solid fats and hydrogenated margarines, butter, lard and other animal fats, coconut and palm kernel oil products. |
| DESSERTS and TREATS  | Fruit, gelatin, water-ice desserts. Sherbet, fruit whips, angel food cake, cakes with polyunsaturated oil. | Ice cream and other desserts with whole milk. Puddings, cream pies. Fried snacks. Commercial sweets. Coconut. |

April, 1987

SERVINGS OF EACH FOOD GROUP

ON GUIDE TO "HEART-Y" EATING NEEDED

TO ATTAIN DESIRED CALORIE LEVEL

Distribution of calories for each calorie level:

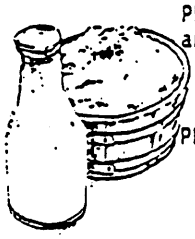
Carbohydrate - 55%
Protein - 20-22%
Fat - 22-25%

| | (Low Calorie) 1200 Calories | (Moderate Calorie) 1600 Calories | (Maintenance) 2000 Calorie |
|---|---|---|---|
| Meat Group | Lean 5 oz | Lean 6 oz | Lean 7 oz |
| Fruit Group & Vegetable Group | 4<br>2 | 6<br>2 | 6<br>3 |
| Bread & Cereal Group | 4 | 7 | 8 |
| Milk Products | Skim 2 | Skim (1/2 or 1%) 2 | 2% (if desired) 2 |
| Fats & Oils | 3 | 4 | 4 |
| Desserts & Treats | - | 1 Occasionally (1 serving about 100 calories) | 1 (1 serving about 100 calories) |

# EATING FOR A HEALTHY HEART

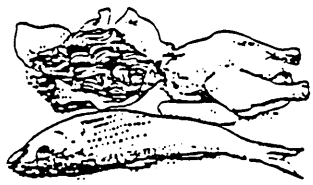
Use Phase 1 suggestions to lower your fat intake to 30% of your caloric intake.
Use Phase 2 suggestions to lower your fat intake to 25% of your caloric intake.

## MILK and CHEESE



Phase 1 and 2
- ○ Use only 1% low-fat milk for drinking and food preparation
- ○ Replace cream with skim milk or nonfat dry milk powder
- ○ Use low-fat cheese in place of high-fat cheese
- ○ Use sherbet, frozen yogurt, or ice milk in place of ice cream

Phase 3
- ○ Use low-fat cheese in place of part of meat allowance
- ○ Use fruit ice or skim milk sherbet in place of whole milk sherbet and ice milk



## MEAT and MEATLESS

Phase 1
- ○ Select only lean beef, pork, lamb and veal
- ○ Choose meats with very little marbling
- ○ Remove skin from poultry
- ○ Limit consumption of meat, seafood, and poultry to 7 ounces or less per day

Phase 2
- ○ Increase use of fish and poultry in place of red meat
- ○ Increase use of meatless main dishes to at least 3 per week
- ○ Consume 6 ounces or less of meat per day

Phase 3
- ○ Limit meat meals to 1 per day (fish and poultry are preferable choices)
- ○ Consume 3 ounces or less of meat per day
- ○ Make all other meals meatless

## EGG

Phase 1
- ○ Limit egg yolks to 2 per week (including those used in baking)

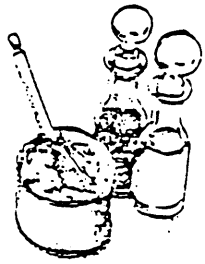
Phase 2
- ○ Use egg whites or egg substitutes
- ○ Eliminate all egg yolk

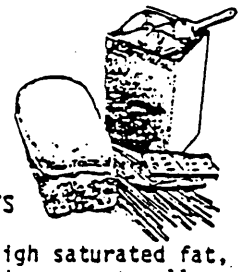
Phase 3
- ○ Use fat-free egg substitute and egg whites

## FATS and OILS

Phase 1 and 2
- ○ Use margarine listing liquid oil as the first ingredient in place of butter
- ○ Use margarine or oil in place of shortening in recipes
- ○ Use oil or margarine for seasoning vegetables

Phase 3
- ○ Prepare homemade salad dressing using safflower, corn, or sunflower oil
- ○ Use fat-free desserts and homemeade quick breads in place of high-fat desserts
- ○ Use only safflower, corn or sunflower oil for food preparation





BAKED FOODS and DESSERTS

Phase 1
- ○ Avoid high saturated fat, baked, and fried items such as doughnuts, fried pies, sweet rolls, cheesecake, pie, cake, and cookies
- ○ Use allowed ingredients in baked foods such as low-fat milk, egg substitute, and vegetable oil

Phase 2
- ○ Select low-fat commercial products such as graham crackers, angel food cake, ginger snaps, and fig bars
- ○ Account for all fat used in baked goods as part of fat allowance

Phase 3
- ○ Use safflower oil, corn oil, sunflower oil, or allowed margarine in quick breads
- ○ Use egg whites or fat-free egg substitute for baked goods

CRACKERS amd SNACK FOODS

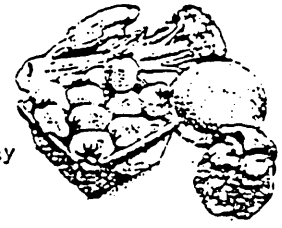
Phase 1
- ○ Use low-fat crackers in place of high-fat crackers
  Limit low-fat crackers according to meal plan

Phase 2
- ○ Use air-popped popcorn as a snack

Phase 3
- ○ Use fat-free crackers
- ○ Use fruit and vegetables as snacks

FRUIT and VEGETABLES

- ○ Use at least 3 servings of fruit every day
- ○ Use at least 3 servings of vegetables every day



# SIMPLE WAYS TO MODIFY A RECIPE

**To reduce cholesterol or saturated fats:**

1. Select lean cuts of meat.
2. Serve moderate portion sizes.
3. Replace animal fats with appropriate substitutes.

Examples:

| Instead of: | Use: |
|---|---|
| Butter, lard, bacon or bacon fat, and chicken fat | Polyunsaturated margarine or oil |
| Sour cream | Low-fat yogurt |
| Whole milk | Skim milk |
| Whole milk cheeses | Low-fat cheese |
| Whole eggs | Egg whites or egg substitue |

**NOTE:** Many cheeses, although made with skim milk, have cream added to them. Check labels for fat content.

---

**To reduce calories or fats:**

1. Brown meats by broiling or cooking in non-stick pans with little or no oil.
2. Chill soups, stews, sauces and broths. Lift off congealed fat (saves 100 calories per tablespoon of fat removed).
3. Trim fat from meat. Also remove skin from poultry.
4. Use waterpacked canned products (canned fish, canned fruits).
5. In recipes for baked products, the sugar can often be reduced by ¼ to ⅓ without harming the final product. Cinnamon and vanilla also give the impression of sweetness.
6. Use fresh fruit whenever possible. If canned fruit must be used, select water-packed varieties, fruit in own juice or drain heavy syrup from canned fruits.
7. For sauces and dressings, use low-calorie bases (vinegar, mustard, tomato juice, fat-free bouillon) instead of high calorie ones (creams, fats, oils, mayonnaise).

---

**To reduce sodium:**

1. Make full use of herbs and spices instead of salt. You may not want to eliminate salt completely, but consider reducing the amount used.
2. Salt can be eliminated from any recipe except one containing yeast.
3. Avoid recipes that contain substantial amounts of baking powder or baking soda which may be high in sodium.
4. Use low sodium or unsalted ingredients during cooking (unsalted margarine, low sodium canned products, salt-free crackers and cereals, low sodium stocks).
5. Check processed foods for sodium content and replace with homemade varieties whenever possible or purchase low sodium products. Commercial mayonnaise and salad dressings, for example, may contain high levels of sodium.
6. Reduce consumption of luncheon meats, ham, bacon, frankfurters and sausage, smoked, pickled and salted foods. Instead, use *fresh* meats, poultry and fish and specially-processed low sodium luncheon meats.
7. Use fresh or frozen fish instead of canned or dried varieties.
8. Water in which salty products are cooked can be poured off and replaced with new water.
9. Do not automatically add salt to boiling water when cooking pasta, vegetables and cereals.

## COOKING HINTS AND TECHNIQUES

### MEAT

Trimming the visible fat from all meat and poultry is the first step in cutting down the amount of saturated fat in a recipe. This is of particular importance if the meat is to be roasted or broiled.

When roasting meat, use a rack under the meat so that the meat does not set in the drippings while cooking. Low temperature roasting is recommended (325-350 F) both for flavor and because more of the fat will come out of the meat. Higher temperatures will seal the fat in. Do not baste with drippings during roasting as they contain fat; wine, fruit juice, or broth can be used instead to keep the meat moist and to add interesting flavors. After the meat has been roasted, the meat juices can be used to make a gravy, but the fat must be removed first. Do this by chilling the drippings in the freezer or by adding ice cubes to the drippings. Either way, the fat will harden and can be removed.

Braising meat is one of the best ways to remove excess saturated fat. Brown the meat in a vegetable oil first. Then add a small amount of water and simmer the meat until tender. Remove the meat and chill the liquid to harden the fat so that it can be removed. If fat is needed for gravy, use margarine. The meat juices will furnish the flavor. Generally, meats should not be floured or breaded before browning or roasting as the breading absorbs the meat fats.

Turkeys and chicken should be roasted with a few onions, carrots, or other vegetables in the cavity to add flavor to the bird. Stuffings should be baked separately using fat-free broth to flavor them. Stuffing cooked in poultry absorbs much fat.

The judicious use of herbs, spices and wines in cooking meats will help compensate for the lack of fat in the meats. Learn to use a variety of them.

### FISH

Poaching is the least aromatic method of cooking fish and produces a very mild flavored fish with the least amount of fat. Use a small amount of water, white wine, and some onions and herbs as the poaching liquid. Simmer the fish but do not allow the poaching liquid to boil or it will break up the fish. Always cook fish just until it flakes easily. Further cooking will make it dry and tough.

When broiling fish fillets, place them on a greased broiling pan. Broil only until tender. Do not try to turn fish over.

Stuffed fish should be baked in the oven at high temperatures (about 375-400° F). Brushing the fish with melted corn oil margarine before baking will give it a crisp crust.

An easy way to cook flavorful fillets is to wrap them in foil with a small amount of wine and seasonings. Bake them at 375° F until tender (about 10-minutes).

# Appendix D

## STATISTICAL TABLES

Summary ANOVA Table for Reflotron Reproducibility (Trial 1 Versus Trial 2).

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Model | 91625.86 | 56 | 1636.18 | 58.64 | .0001 |
| Subject | 91621.92 | 55 | 1665.85 | 59.71 | .0001 |
| Trial | 3.94 | 1 | 3.94 | .14 | .71 |
| Error | 1534.56 | 55 | 27.9 | -- | -- |

Summary ANOVA TAble for Reflotron Accuracy (Reflotron Values Versus Spectrophotometry Values).

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Model | 51074.2 | 25 | 2042.97 | 49.25 | .0001 |
| Subject | 51060.68 | 24 | 2127.53 | 51.29 | .0001 |
| Trial | 13.52 | 1 | 13.52 | .33 | .57 |
| Error | 995.48 | 24 | 41.48 | -- | -- |

Summary t-test Table for Age of Subjects at Baseline.

| Group | M | SD | t | p |
|---|---|---|---|---|
| Experimental | 57.7 | 7.7 | 1.57 | .13 |
| Control | 53.5 | 6.4 | -- | -- |

Summary t-test Table for Years of Education

| Group | M | SD | t | p |
|---|---|---|---|---|
| Experimental | 15.57 | 2.95 | .33 | .74 |
| Control | 16 | 3.8 | -- | -- |

Summary t-test Table for Number of Months in the Cardiac and Intervention Center.

| Group | M | SD | t | p |
|---|---|---|---|---|
| Experimental | 51.86 | 39.9 | 2.6 | .71 |
| Control | 46.21 | 39.39 | -- | -- |

Summary t-test Table for Program Attendance.

| Group | M | SD | t | p |
|---|---|---|---|---|
| Experimental | 81.36 | 13.12 | 1.41 | .17 |
| Control | 70.57 | 25.29 | -- | -- |

Summary t-test Table for Dietician Contacts During the Study.

| Group | M | SD | t | p |
|---|---|---|---|---|
| Experimental | .43 | .51 | .37 | .71 |
| Control | .36 | .5 | -- | -- |

Summary ANOVA Table for Baseline Systolic Blood Pressure.

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 228.57 | 1 | 228.57 | 1.54 | .23 |
| Error | 2850.86 | 26 | 148.1 | -- | -- |

Summary ANOVA Table for Baseline Diastolic Blood Pressure.

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 7.0 | 1 | 7.0 | .09 | .77 |
| Error | 2132.86 | 26 | 82.03 | -- | -- |

Summary ANOVA Table for Baseline Percent Body Fat.

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 44.5 | 1 | 44.5 | 2.42 | .13 |
| Error | 478.44 | 26 | 18.4 | -- | -- |

Summary ANOVA Table for Baseline Total Cholesterol.

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 51.57 | 1 | 51.57 | .07 | .8 |
| Error | 20591.14 | 26 | 781.97 | -- | --- |

Summary ANOVA Table for Baseline Dietary Fat (% of Total Calories).

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 36.57 | 1 | 36.57 | .59 | .45 |
| Error | 1600.14 | 26 | 61.54 | -- | -- |

Summary ANOVA Table for Baseline Saturated Fat (% of Total Calories).

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 18.89 | 1 | 18.89 | .55 | .47 |
| Error | 895.79 | 26 | 34.45 | -- | -- |

Summary ANOVA Table for Baseline Dietary Cholesterol (mg/dl).

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 246.04 | 1 | 246.04 | .03 | .85 |
| Error | 186608.93 | 26 | 7177.23 | -- | -- |

Summary ANOVA Table for Week 8 Dietary Fat (% of Total Calories).

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 84.02 | 1 | 84.02 | 1.73 | .22 |
| Error | 388.08 | 8 | 48.5 | -- | -- |

Summary ANOVA Table for Week 8 Dietary Saturated Fat (% of Total Ccalories).

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 36.82 | 1 | 36.82 | .75 | .41 |
| Error | 392.08 | 8 | 49.01 | -- | -- |

Summary ANOVA Table for Week 8 Dietary Cholesterol (mg/dl).

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 6784.07 | 1 | 6784.07 | .46 | .52 |
| Error | 118690.83 | 8 | 14836.35 | -- | -- |

Summary ANOVA Table for Week 16 Systolic Blood Pressure.

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 464.14 | 1 | 464.14 | 1.94 | .18 |
| Error | 6208.29 | 26 | 238.78 | -- | -- |

Summary ANOVA Table for Week 16 Diastolic Blood Pressure.

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 7 | 1 | 7 | .09 | .77 |
| Error | 2132.86 | 26 | 82.03 | -- | -- |

Summary ANOVA Table for Week 16 Percent Body Fat.

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 44.5 | 1 | 44.5 | 2.42 | .13 |
| Error | 478.44 | 26 | 18.4 | -- | -- |

Summary ANCOVA Table for Week 16 Total Cholesterol.

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 1635.57 | 1 | 1635.57 | 2.66 | .16 |
| Error | 20620.29 | 26 | 793.09 | -- | -- |

Summary ANOVA Table for Week 16 Total Cholesterol.

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 2048.57 | 1 | 2048.57 | 4.6 | .0418 |
| Error | 11129.0 | 25 | 445.16 | --- | --- |

Summary t-test Table for Total Cholesterol Reduction at Week 16.

| Group | M | SD | t | p |
|---|---|---|---|---|
| Experimental | 23.7 | 21.86 | 2.1 | .04 |
| Control | 5.7 | 23.27 | -- | -- |

Summary t-test Table for Percent Total Cholesterol Reduction at Week 16.

| Group | M | SD | t | p |
|---|---|---|---|---|
| Experimental | 9.3 | 8.2 | 2.3 | .03 |
| Control | 1.9 | 8.8 | -- | -- |

Summary ANOVA Table for Week 16 Dietary Fat (% of Ccalories).

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 12.25 | 1 | 12.25 | .23 | .6362 |
| Error | 733.5 | 14 | 52.39 | -- | -- |

Summary ANOVA Table for Week 16 Dietary Saturated Fat (% of Total Calories).

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 10.56 | 1 | 10.56 | .37 | .55 |
| Error | 402.38 | 14 | 28.74 | -- | --- |

Summary ANOVA Table for Week 16 Dietary Cholesterol (mg/dl).

| Source | SS | df | MS | F | p |
|---|---|---|---|---|---|
| Group | 702.25 | 1 | 702.25 | .18 | .67 |
| Error | 53429.5 | 14 | 3816.39 | -- | -- |

# Appendix E

## RAW DATA TABLES

Duplicate Total Cholesterol Samples (mg/dl) Collected at Baseline and Week 16 for Estimating Reproducibility of the Reflotron.

| OBSERVATION | TRIAL 1 | TRIAL 2 |
|---|---|---|
| 1 | 230 | 235 |
| 2 | 222 | 218 |
| 3 | 229 | 222 |
| 4 | 286 | 274 |
| 5 | 293 | 286 |
| 6 | 256 | 238 |
| 7 | 224 | 232 |
| 8 | 261 | 267 |
| 9 | 231 | 233 |
| 10 | 319 | 315 |
| 11 | 215 | 215 |
| 12 | 278 | 291 |
| 13 | 238 | 237 |
| 14 | 233 | 245 |
| 15 | 307 | 300 |
| 16 | 229 | 234 |
| 17 | 231 | 237 |
| 18 | 279 | 273 |
| 19 | 216 | 213 |
| 20 | 237 | 243 |
| 21 | 258 | 262 |
| 22 | 239 | 244 |
| 23 | 221 | 225 |
| 24 | 282 | 287 |
| 25 | 241 | 235 |
| 26 | 265 | 250 |
| 27 | 228 | 236 |
| 28 | 237 | 245 |
| 29 | 215 | 211 |
| 30 | 231 | 222 |
| 31 | 217 | 219 |
| 32 | 283 | 287 |
| 33 | 220 | 212 |

| OBSERVATION | TRIAL 1 | TRIAL 2 |
|---|---|---|
| 34 | 214 | 222 |
| 35 | 224 | 224 |
| 36 | 263 | 249 |
| 37 | 194 | 192 |
| 38 | 274 | 282 |
| 39 | 188 | 184 |
| 40 | 266 | 277 |
| 41 | 196 | 203 |
| 42 | 196 | 200 |
| 43 | 254 | 254 |
| 44 | 221 | 224 |
| 45 | 236 | 245 |
| 46 | 280 | 296 |
| 47 | 226 | 221 |
| 48 | 254 | 249 |
| 49 | 266 | 257 |
| 50 | 257 | 263 |
| 51 | 232 | 228 |
| 52 | 248 | 245 |
| 53 | 201 | 201 |
| 54 | 239 | 236 |
| 55 | 213 | 215 |
| 56 | 260 | 268 |

Reflotron and Spectrophotometry Values for Total Ccholesterol (mg/dl) Used for Estimating Accuracy of the Reflotron.

| OBSERVATION | REFLOTRON | SPECTROPHOTOMETRY |
|---|---|---|
| 1 | 232 | 227 |
| 2 | 197 | 187 |
| 3 | 191 | 212 |
| 4 | 280 | 272 |
| 5 | 291 | 300 |
| 6 | 254 | 243 |
| 7 | 251 | 263 |
| 8 | 201 | 197 |
| 9 | 182 | 190 |
| 10 | 284 | 280 |
| 11 | 243 | 239 |
| 12 | 218 | 225 |
| 13 | 226 | 231 |
| 14 | 271 | 264 |
| 15 | 210 | 212 |
| 16 | 256 | 269 |
| 17 | 198 | 212 |
| 18 | 222 | 218 |
| 19 | 254 | 247 |
| 20 | 236 | 239 |
| 21 | 249 | 238 |
| 22 | 234 | 241 |
| 23 | 180 | 188 |
| 24 | 195 | 184 |
| 25 | 184 | 187 |

Subject Characteristics

| SUBJECT | GROUP | AGE | LP | YRED | ATD | DTCNT |
|---|---|---|---|---|---|---|
| 1 | E | 44 | 14 | 16 | 62 | 0 |
| 2 | E | 68 | 43 | 14 | 87 | 1 |
| 3 | E | 62 | 67 | 12 | 77 | 1 |
| 4 | E | 56 | 9 | 12 | 94 | 0 |
| 5 | E | 64 | 72 | 18 | 79 | 1 |
| 6 | E | 68 | 44 | 18 | 81 | 0 |
| 7 | E | 66 | 119 | 20 | 100 | 0 |
| 8 | E | 56 | 120 | 12 | 100 | 0 |
| 9 | E | 62 | 8 | 14 | 62 | 1 |
| 10 | E | 60 | 12 | 20 | 91 | 1 |
| 11 | E | 50 | 108 | 12 | 62 | 0 |
| 12 | E | 51 | 38 | 16 | 85 | 1 |
| 13 | E | 48 | 25 | 18 | 87 | 0 |
| 14 | E | 53 | 47 | 16 | 72 | 0 |
| 15 | C | 63 | 96 | 20 | 92 | 0 |
| 16 | C | 55 | 109 | 12 | 82 | 0 |
| 17 | C | 60 | 25 | 20 | 71 | 1 |
| 18 | C | 46 | 12 | 20 | 63 | 0 |
| 19 | C | 46 | 120 | 12 | 37 | 1 |
| 20 | C | 63 | 4 | 12 | 63 | 1 |
| 21 | C | 54 | 27 | 20 | 72 | 0 |
| 22 | C | 50 | 3 | 20 | 70 | 0 |
| 23 | C | 43 | 50 | 20 | 20 | 0 |
| 24 | C | 58 | 6 | 16 | 36 | 1 |
| 25 | C | 52 | 58 | 12 | 100 | 1 |
| 26 | C | 48 | 23 | 12 | 100 | 0 |
| 27 | C | 53 | 65 | 12 | 100 | 0 |
| 28 | C | 58 | 49 | 16 | 82 | 0 |

LP=number of months in Cardiac Program; YRED=number of years of education; ATD=percentage of attendance during the study; DTCNT=number of dietician contacts during study

Baseline and Week 16 Systolic Blood Pressure Data (mm Hg).

| SUBJECT | GROUP | BASELINE SBP | WEEK 16SBP |
|---|---|---|---|
| 1 | E | 130 | 138 |
| 2 | E | 122 | 122 |
| 3 | E | 126 | 120 |
| 4 | E | 104 | 102 |
| 5 | E | 126 | 118 |
| 6 | E | 110 | 104 |
| 7 | E | 128 | 124 |
| 8 | E | 116 | 128 |
| 9 | E | 130 | 132 |
| 10 | E | 148 | 148 |
| 11 | E | 128 | 126 |
| 12 | E | 130 | 136 |
| 13 | E | 126 | 128 |
| 14 | E | 122 | 120 |
| 15 | C | 124 | 130 |
| 16 | C | 116 | 100 |
| 17 | C | 130 | 132 |
| 18 | C | 148 | 150 |
| 19 | C | 106 | 114 |
| 20 | C | 96 | 78 |
| 21 | C | 130 | 124 |
| 22 | C | 100 | 100 |
| 23 | C | 120 | 120 |
| 24 | C | 130 | 132 |
| 25 | C | 108 | 100 |
| 26 | C | 122 | 122 |
| 27 | C | 114 | 110 |
| 28 | C | 122 | 120 |

Baseline and Week 16 Diastolic Blood Pressure Data (mm Hg).

| SUBJECT | GROUP | BASELINE DBP | WEEK 16DBP |
|---|---|---|---|
| 1 | E | 84 | 86 |
| 2 | E | 72 | 70 |
| 3 | E | 84 | 82 |
| 4 | E | 70 | 70 |
| 5 | E | 92 | 86 |
| 6 | E | 62 | 68 |
| 7 | E | 82 | 84 |
| 8 | E | 80 | 80 |
| 9 | E | 82 | 78 |
| 10 | E | 74 | 78 |
| 11 | E | 78 | 76 |
| 12 | E | 80 | 82 |
| 13 | E | 78 | 76 |
| 14 | E | 80 | 82 |
| 15 | C | 86 | 86 |
| 16 | C | 72 | 68 |
| 17 | C | 86 | 84 |
| 18 | C | 102 | 102 |
| 19 | C | 80 | 84 |
| 20 | C | 58 | 54 |
| 21 | C | 82 | 82 |
| 22 | C | 68 | 66 |
| 23 | C | 88 | 88 |
| 24 | C | 84 | 86 |
| 25 | C | 70 | 62 |
| 26 | C | 82 | 92 |
| 27 | C | 78 | 84 |
| 28 | C | 76 | 74 |

Baseline and Week 16 Estimated Percent Body Fat Data.

| SUBJECT | GROUP | BASELINE | WEEK 16 |
|---|---|---|---|
| 1 | E | 21.3 | 21.3 |
| 2 | E | 24.7 | 23.1 |
| 3 | E | 23.9 | 24.7 |
| 4 | E | 20.0 | 18.1 |
| 5 | E | 27.9 | 24.7 |
| 6 | E | 26.3 | 26.3 |
| 7 | E | 28.7 | 28.7 |
| 8 | E | 20.0 | 18.2 |
| 9 | E | 18.0 | 18.0 |
| 10 | E | 21.4 | 22.2 |
| 11 | E | 18.7 | 14.1 |
| 12 | E | 24.4 | 23.6 |
| 13 | E | 17.1 | 15.0 |
| 14 | E | 23.0 | 23.0 |
| 15 | C | 17.9 | 15.2 |
| 16 | C | 23.0 | 17.3 |
| 17 | C | 22.2 | 23.1 |
| 18 | C | 26.9 | 26.9 |
| 19 | C | 22.9 | 23.8 |
| 20 | C | 27.7 | 26.7 |
| 21 | C | 28.6 | 26.0 |
| 22 | C | 25.2 | 20.2 |
| 23 | C | 26.3 | 24.6 |
| 24 | C | 37.3 | 31.6 |
| 25 | C | 19.4 | 17.6 |
| 26 | C | 27.5 | 24.4 |
| 27 | C | 25.8 | 23.3 |
| 28 | C | 20.0 | 20.0 |

Baseline and Week 16 Total Cholesterol Data (mg/dl).

| SUBJECT | GROUP | BASELINE | WEEK 16 |
|---|---|---|---|
| 1 | E | 233 | 213 |
| 2 | E | 222 | 227 |
| 3 | E | 226 | 218 |
| 4 | E | 280 | 285 |
| 5 | E | 290 | 216 |
| 6 | E | 247 | 218 |
| 7 | E | 228 | 224 |
| 8 | E | 264 | 256 |
| 9 | E | 232 | 193 |
| 10 | E | 317 | 278 |
| 11 | E | 215 | 186 |
| 12 | E | 285 | 272 |
| 13 | E | 238 | 200 |
| 14 | E | 239 | 198 |
| 15 | C | 304 | 254 |
| 16 | C | 232 | 223 |
| 17 | C | 233 | 241 |
| 18 | C | 276 | 288 |
| 19 | C | 215 | 224 |
| 20 | C | 240 | 252 |
| 21 | C | 260 | 262 |
| 22 | C | 241 | 260 |
| 23 | C | 223 | 230 |
| 24 | C | 285 | 247 |
| 25 | C | 238 | 201 |
| 26 | C | 258 | 238 |
| 27 | C | 232 | 214 |
| 28 | C | 241 | 264 |

Change in Cholesterol Levels (mg/dl) and Percent Change in Cholesterol Level from Baseline to Week 16.

| SUBJECT | GROUP | CHOLESTEROL CHANGE | % CHANGE |
|---|---|---|---|
| 1 | E | -20 | -8.6 |
| 2 | E | 5 | 2.3 |
| 3 | E | -8 | -3.5 |
| 4 | E | 5 | 1.8 |
| 5 | E | -74 | -25.5 |
| 6 | E | -29 | -11.7 |
| 7 | E | -4 | -1.8 |
| 8 | E | -8 | -3.0 |
| 9 | E | -39 | -17.0 |
| 10 | E | -39 | -12.3 |
| 11 | E | -29 | -13.5 |
| 12 | E | -13 | -4.6 |
| 13 | E | -38 | -16.0 |
| 14 | E | -41 | -17.0 |
| 15 | C | -50 | -16.4 |
| 16 | C | -9 | -3.9 |
| 17 | C | 8 | 3.4 |
| 18 | C | 12 | 4.3 |
| 19 | C | 9 | 4.2 |
| 20 | C | 12 | 5.0 |
| 21 | C | 2 | 0.8 |
| 22 | C | 19 | 7.9 |
| 23 | C | 7 | 3.1 |
| 24 | C | -38 | -13.3 |
| 25 | C | -37 | -15.5 |
| 26 | C | -20 | -7.6 |
| 27 | C | -18 | -7.8 |
| 28 | C | 23 | 9.5 |

Monthly Cholesterol Values (mg/dl) for the Experimental Group.

| SUBJECT | BASELINE | WEEK 4 | WEEK 8 | WEEK 12 | WEEK 16 |
|---|---|---|---|---|---|
| 1 | 233 | 252 | 185 | 198 | 213 |
| 2 | 222 | 217 | 211 | 222 | 227 |
| 3 | 226 | 228 | 237 | 226 | 218 |
| 4 | 280 | 280 | 267 | 244 | 285 |
| 5 | 290 | 223 | 230 | 232 | 216 |
| 6 | 247 | 254 | 241 | 227 | 218 |
| 7 | 228 | 244 | 232 | 215 | 224 |
| 8 | 264 | 287 | 274 | 260 | 256 |
| 9 | 232 | 210 | 183 | 209 | 193 |
| 10 | 317 | 280 | 321 | 287 | 278 |
| 11 | 215 | 210 | 219 | 210 | 186 |
| 12 | 285 | 250 | 249 | 248 | 200 |
| 13 | 238 | 217 | 201 | 201 | 200 |
| 14 | 239 | 241 | 225 | 210 | 198 |

Dietary Fat as Percent of Total Calories Consumed at Baseline, Week 8, and Week 16.

| SUBJECT | GROUP | BASELINE | WEEK 8 | WEEK 16 |
|---|---|---|---|---|
| 1 | E | 31 | -- | 24 |
| 2 | E | 12 | 22 | 13 |
| 3 | E | 43 | 40 | 39 |
| 4 | E | 28 | -- | -- |
| 5 | E | 40 | 28 | -- |
| 6 | E | 23 | -- | 22 |
| 7 | E | 37 | -- | 36 |
| 8 | E | 28 | 29 | -- |
| 9 | E | 18 | -- | 20 |
| 10 | E | 27 | -- | -- |
| 11 | E | 33 | 32 | -- |
| 12 | E | 37 | -- | 31 |
| 13 | E | 31 | 27 | 31 |
| 14 | E | 17 | -- | -- |
| 15 | C | 33 | 35 | 32 |
| 16 | C | 17 | -- | -- |
| 17 | C | 21 | -- | 23 |
| 18 | C | 26 | -- | 28 |
| 19 | C | 31 | 25 | 26 |
| 20 | C | 21 | -- | 24 |
| 21 | C | 33 | -- | -- |
| 22 | C | 21 | 17 | -- |
| 23 | C | 37 | -- | 32 |
| 24 | C | 35 | -- | -- |
| 25 | C | 28 | -- | -- |
| 26 | C | 20 | 18 | 19 |
| 27 | C | 28 | -- | -- |
| 28 | C | 22 | -- | 18 |

Dietary Saturated Fat as Percent of Total Calories at Baseline, Week 8, and Week 16.

| SUBJECT | GROUP | BASELINE | WEEK 8 | WEEK 16 |
|---|---|---|---|---|
| 1 | E | 14 | -- | 9 |
| 2 | E | 3 | 3 | 4 |
| 3 | E | 32 | 28 | 25 |
| 4 | E | 8 | -- | -- |
| 5 | E | 15 | 9 | -- |
| 6 | E | 7 | -- | 7 |
| 7 | E | 9 | -- | 10 |
| 8 | E | 9 | 10 | -- |
| 9 | E | 2 | -- | 4 |
| 10 | E | 8 | -- | -- |
| 11 | E | 11 | 11 | -- |
| 12 | E | 16 | -- | 14 |
| 13 | E | 13 | 9 | 14 |
| 14 | E | 3 | -- | -- |
| 15 | C | 12 | 12 | 12 |
| 16 | C | 5 | -- | -- |
| 17 | C | 6 | -- | 7 |
| 18 | C | 13 | -- | 14 |
| 19 | C | 9 | 7 | 7 |
| 20 | C | 5 | -- | 6 |
| 21 | C | 12 | -- | -- |
| 22 | C | 4 | 4 | -- |
| 23 | C | 13 | -- | -- |
| 24 | C | 13 | -- | 12 |
| 25 | C | 9 | -- | -- |
| 26 | C | 12 | 8 | 10 |
| 27 | C | 6 | -- | -- |
| 28 | C | 8 | -- | 6 |

Dietary Cholesterol in mg/day at Baseline, Week 8, and Week 16.

| SUBJECT | GROUP | BASELINE | WEEK 8 | WEEK 16 |
|---|---|---|---|---|
| 1 | E | 298 | -- | 281 |
| 2 | E | 199 | 201 | 235 |
| 3 | E | 564 | 623 | 480 |
| 4 | E | 312 | -- | -- |
| 5 | E | 387 | 271 | -- |
| 6 | E | 287 | -- | 291 |
| 7 | E | 317 | -- | 333 |
| 8 | E | 265 | 251 | -- |
| 9 | E | 253 | -- | 263 |
| 10 | E | 401 | -- | -- |
| 11 | E | 291 | 337 | -- |
| 12 | E | 286 | -- | 332 |
| 13 | E | 319 | 376 | 301 |
| 14 | E | 189 | -- | -- |
| 15 | C | 347 | 326 | 341 |
| 16 | C | 222 | -- | -- |
| 17 | C | 275 | -- | 279 |
| 18 | C | 319 | -- | 337 |
| 19 | C | 343 | 319 | 291 |
| 20 | C | 195 | -- | 220 |
| 21 | C | 308 | -- | -- |
| 22 | C | 206 | 234 | -- |
| 23 | C | 364 | -- | -- |
| 24 | C | 261 | -- | 371 |
| 25 | C | 478 | -- | -- |
| 26 | C | 276 | 281 | 290 |
| 27 | C | 372 | -- | -- |
| 28 | C | 319 | -- | 291 |

Responses to the Self-efficacy Statement, "I have the ability to lower the amount of saturated fat and cholesterol in my diet."
(Likert scale of 0-6 with 0 = Disagree and 6 = Agree).

| SUBJECT | GROUP | BASELINE | WEEK 8 | WEEK 16 |
|---|---|---|---|---|
| 1 | E | 6 | 6 | 6 |
| 2 | E | 6 | 6 | 6 |
| 3 | E | 6 | 6 | 6 |
| 4 | E | 6 | 6 | 6 |
| 5 | E | 6 | 6 | 6 |
| 6 | E | 6 | 6 | 6 |
| 7 | E | 5 | 5 | 5 |
| 8 | E | 4 | 4 | 4 |
| 9 | E | 6 | 6 | 6 |
| 10 | E | 5 | 4 | 5 |
| 11 | E | 6 | 6 | 6 |
| 12 | E | 4 | 5 | 4 |
| 13 | E | 6 | 6 | 6 |
| 14 | E | 6 | 6 | 6 |
| 15 | C | 6 | 6 | 6 |
| 16 | C | 6 | 6 | 6 |
| 17 | C | 5 | 5 | 5 |
| 18 | C | 5 | 5 | 5 |
| 19 | C | 6 | 6 | 6 |
| 20 | C | 5 | 5 | 5 |
| 21 | C | 5 | 6 | 5 |
| 22 | C | 6 | 6 | 6 |
| 23 | C | 6 | 6 | 6 |
| 24 | C | 5 | 5 | 5 |
| 25 | C | 4 | 4 | 4 |
| 26 | C | 4 | 4 | 3 |
| 27 | C | 6 | 6 | 6 |
| 28 | C | 5 | 5 | 5 |

Responses to the Self-efficacy Statement, "I have the ability to lower my cholesterol through dietary changes." (Likert scale of 0-6 with 0 = Disagree and 6 = Agree).

| SUBJECT | GROUP | BASELINE | WEEK 8 | WEEK 16 |
|---|---|---|---|---|
| 1 | E | 6 | 5 | 6 |
| 2 | E | 3 | 3 | 6 |
| 3 | E | 6 | 6 | 6 |
| 4 | E | 6 | 5 | 6 |
| 5 | E | 6 | 6 | 6 |
| 6 | E | 6 | 6 | 6 |
| 7 | E | 5 | 5 | 5 |
| 8 | E | 4 | 4 | 4 |
| 9 | E | 6 | 6 | 6 |
| 10 | E | 4 | 5 | 4 |
| 11 | E | 6 | 6 | 6 |
| 12 | E | 4 | 3 | 4 |
| 13 | E | 6 | 6 | 6 |
| 14 | E | 6 | 6 | 6 |
| 15 | C | 3 | 3 | 5 |
| 16 | C | 6 | 6 | 6 |
| 17 | C | 5 | 5 | 5 |
| 18 | C | 5 | 5 | 5 |
| 19 | C | 6 | 6 | 6 |
| 20 | C | 5 | 5 | 5 |
| 21 | C | 5 | 6 | 5 |
| 22 | C | 6 | 6 | 6 |
| 23 | C | 6 | 6 | 6 |
| 24 | C | 5 | 5 | 5 |
| 25 | C | 4 | 3 | 5 |
| 26 | C | 6 | 6 | 5 |
| 27 | C | 6 | 6 | 6 |
| 28 | C | 5 | 5 | 5 |

Appendix F

DATA SHEETS

NAME: _____ I.D.#: _____

AGE: _____

LENGTH IN PROGRAM: _____

**BASELINE**

Total Cholesterol (mg/dl):

_____ _____ $\bar{X}$: _____

Blood Pressure (mmHg): _____

Weight (kg): _____

Percent Body Fat: _____

_____

_____

_____

**16 WEEKS**

Total Cholesterol (mg/dl):

_____ _____ $\bar{X}$: _____

Blood Pressure (mmHg): _____

Weight (kg): _____

Percent Body Fat: _____

_____

_____

_____

Literature Given: _____

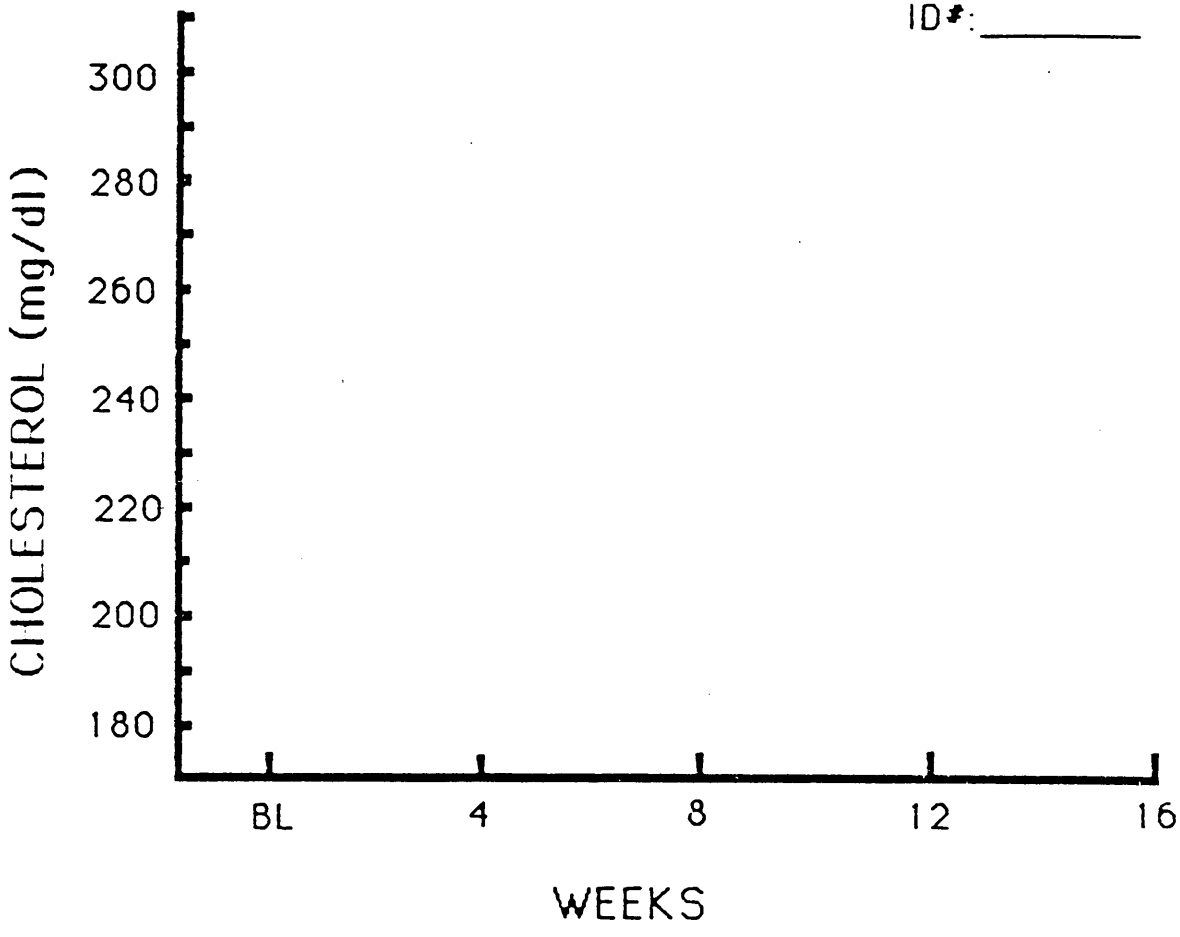
Attendance: _____

Diet Diary:

| Baseline: | 8 Weeks: | 16 Weeks: |
|---|---|---|
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |
| _____ | _____ | _____ |

Name:_____

ID#:_____




| | | | | | |
|---|---|---|---|---|---|
| Date: | ____ | ____ | ____ | ____ | ____ |
| Cholesterol | ____ | ____ | ____ | ____ | ____ |

Name:_____ ID#:_____

Date:_____

For each of the following questions, please indicate your level of agreement on the scales below.

1. I have the ability to lower the amount of saturated fat and dietary cholesterol in my diet.

Disagree Agree

0 1 2 3 4 5 6

2. I have the ability to lower my serum cholesterol through dietary changes.

Disagree Agree

0 1 2 3 4 5 6

The vita has been removed from the scanned document