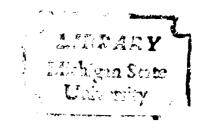
AN EVALUATION OF THE EFFECTIVENESS OF A NUTRITIONAL COUNSELING PROGRAM IN ALLEVIATING CERTAIN HEALTH PROBLEMS

Dissertation for the Degree of Ph. D. MICHIGAN STATE UNIVERSITY KENT S. JAMISON 1974





This is to certify that the

thesis entitled

AN EVALUATION OF THE EFFECTIVENESS OF A NUTRITIONAL COUNSELING PROGRAM IN ALLEVIATING CERTAIN HEALTH PROBLEMS

presented by

Kent S. Jamison

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ABSTRACT

AN EVALUATION OF THE EFFECTIVENESS OF A NUTRITIONAL COUNSELING PROGRAM IN ALLEVIATING CERTAIN HEALTH PROBLEMS

By

Kent S. Jamison

The study set out to evaluate the effectiveness of a nutritional counseling program being carried out through selected family planning projects in the state of Michigan. The aim of the study was to see whether or not counseling was effective in treating four common medical conditions that can be alleviated through diet therapy: overweight, underweight, anemia and hypertension. Each of these conditions can, in some women, be aggravated by the type of contraceptive used, and in the event a pregnancy does occur, pose serious health problems to the woman and child.

The results were inconclusive. Three major setbacks clouded the findings: a high rate of attrition that was unexpectedly encountered; bias in one set of control groups; and, abnormalities in the distribution of much of the data. Without a doubt, the most serious of the three was the high rate of attrition that was so unexpectedly encountered.

Nearly three-fourths of those that qualified either refused, dropped out or otherwise had to be eliminated. This sharply reduced the size of the samples, so much in fact, that two key analyses had to be eliminated entirely while a third had to be sharply curtailed. As a result of this, more reliance had to be placed on a second, less desirable analysis. This analysis used, as a control, patients from a county other than the ones where the counseling was taking place.

As it turned out, the results of this second analysis appeared to be biased in favor of the counseling. As if this weren't enough, screening out all the patients that were normal had the effect of producing a highly skewed distribution of the data for those remaining. While the effects of such a distribution were probably minimal on the analyses that remained, it only served to cloud the results even further. The presence of these problems precluded any firm conclusions from being reached for any of the four conditions. It was, nonetheless, still possible to reach tentative ones about each.

The one category counseling appeared most likely to have alleviated was that of underweight. It also seemed likely counseling had some minimal effect in alleviating anemia, though neither of these conclusions can be made with much assurance. Of all the categories, the one that could probably best be evaluated was that of overweight, and then it seemed doubtful the counseling had had any impact. The fourth category, that of hypertension, could not be properly assessed. A significant difference was found in the initial blood pressures of those who had been counseled and that of the controls. Yet in spite of this difference, it seemed doubtful the counseling had had any impact in alleviating this condition either.

To supplement these rather circumspect findings, a cluster analysis was done on a number of variables that were measured just for

the study. Generally the results of the cluster analysis revealed a number of highly specific variables related to improvement for each condition rather than one set of very general ones related to all. In fact, more may have been learned from this part of the study by what was not found. A number of factors that had been expected to be a major influence in determining whether or not a patient improved failed to emerge in any of the clusters.

In short, the study failed to provide any conclusive evidence that counseling was effective in alleviating any of the four conditions. What evidence there was suggested that it had little or no impact. This was not terribly unexpected in light of the fact each patient saw the nutritionist only once and then only for a brief period of time.

The study probably did more to raise doubts about the merits of such an abbreviated treatment and about what factors are most pertinent to success than it did to provide a definitive answer as to whether or not the counseling worked. In a broader sense, the study had some important implications for doing evaluations of this type. In particular, some of the findings suggest that extreme caution be taken when evaluations are based on differing localities.

AN EVALUATION OF THE EFFECTIVENESS OF A NUTRITIONAL COUNSELING PROGRAM IN ALLEVIATING CERTAIN HEALTH PROBLEMS

By

Kent S. Jamison

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Department of Psychology

1974

THE INVISIBLE CIRCLE

Is what the people want What the people get

Is what the people want What the people need

Is what the people need What the people get

What the people get Is not

What the people need Nor What the people want.

For no one knows

What the people want Nor What the people need

Nor whether

What the people want Is what the people need

--Snarff

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Anyone who thinks a research project such as this can be carried out single-handed hasn't experienced the joys and frustrations of doing problem-solving research in a field setting. There are many people to thank.

My deepest thanks go to Molly Graber whose foresight gave rise to the study and without whose impetus the study would not have been possible. Credit must go to her, as the maternal nutrition consultant, for daring to question the efficacy of the nutritional counseling program. A special word of thanks goes to Marjorie Cook and Virginia Bradford who, as the two nutritionists, bore the brunt of the study in allowing themselves to be evaluated while taking on the added burden of all the extra paper work as well. Without them and their diligence there would have been no study at all.

Thanks must also go to all the directors and staffs of the Ingham, Saginaw and Muskegon clinics. There are too many names to mention, but their willingness to participate and concern for the study to succeed were an integral part of what lies between these pages.

My thanks also go to the Michigan Department of Public Health and its Bureau of Maternal and Child Health for permitting the study to be done and for their continuing support. In this regard, special thanks go to Jeffery Taylor, the Ec Psyc'er who provided the linkpin

that made it all possible. Two other people at the Department of Health deserve special mention, George Van Amberg and Andy White--Andy for his labors in retrieving the demographic data and George for his assistance in getting the data processed. Both were key ingredients in bringing the study to a successful fruition.

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CHAPTER I

INTRODUCTION

The particular study being reported in the pages that follow was undertaken as an evaluation of the effectiveness of a nutritional counseling program being tried out in certain selected family planning projects in the state of Michigan. The study was carried out through the state's Department of Public Health in conjunction with its Bureau of Maternal and Child Health beginning in June of 1972. From the point of view of the Department of Health and the particular family planning projects involved, the study grew out of a need to evaluate the success of the specific aims of the counseling itself. Taken in a broader context, however, the study was actually part of a trend that has been developing over the last several years for doing this type of research. To assess the full significance of a study like this—both as to its strengths and its limitations—it is, perhaps, first necessary to view it in light of this emerging trend.

Family planning became a part of the government's growing list of human services as a result of the new wave of social welfare programs that began in the early sixties with the election of John Fitzgerald Kennedy and culminated a few years later in the Great Society of his successor Lyndon Baines Johnson. The push for these programs rested on a premise that the country's social ills would be alleviated if only new programs and more money could be legislated.

Yet despite a spate of such legislation during this time, the push soon gave way to a period of disillusionment for both its proponents and critics alike. The former because the programs had failed; the latter because such large sums of money had been so ill-spent.

With the election of Richard Milhouse Nixon in 1968 came a retrenchment mandated by the pragmatic reality of these failures and by an embittered public who had seen the welfare rolls swell as their taxes climbed. Indeed, the statistics are startling: From 1958 to 1968 Federal spending grew from \$71.9 billion to \$178.9 billion. Of this, \$3.6 billion went for welfare alone during 1968, double the \$1.8 billion it had been only a decade before. Moreover, state budgets experienced an even greater growth. During the same period, the budget for Michigan nearly trebled from \$585 million to \$1.6 billion!

While the politics at hand dictated a cutback from the excesses of the past, there was, at the same time, a new recognition for the need of some kind of systematic evaluation of what these different social programs had been accomplishing. That such evaluation had been lacking was a disheartening fact of life common at all levels of government up until the mid-sixties. It was around then that President Johnson first introduced PPBS, The Planning, Programming, and Budgeting System of government to all departments in the Federal bureaucracy.

For the actual expenditures cited see "The Budget in Brief" for the years 1959 and 1970, U.S. Government Printing Office, Washington, D.C. Figures for Michigan are out of "The State of Michigan Budget for Fiscal Year Ending June 30, 1961" and "The Executive Budget for Fiscal July 1, 1969-June 30, 1970, the State of Michigan," Lansing, Mich.

Under this system program objectives were to be spelled out and translated into specific performance measures. These measures were in turn to be systematically related to costs in the form of a cost-benefit ratio. Once formed, these ratios could then be used to help sort out the best alternative for reaching a single goal within one program or in setting priorities among competing goals across several different programs.

The system worked fairly well in the Department of Defense where it first originated and in other less service oriented departments (e.g. Dept. of Interior), any place where objectives could be easily pinned down. However, in more socially related areas where objectives are typically less well defined and less easily measured, PPBS was not of much use. Nonetheless, its introduction was an important step in getting government to begin objectively evaluating itself. Yet, it would be a mistake to attribute the trend towards evaluation to this alone for at the same time there were other forces at work.

One of the offshoots of the failures of the sixties was a public outcry for the country's institutions, mainly its universities but also to some extent its largest corporations, to find what solutions they could to the nation's social problems. It was out of this climate that the Ecological Psychology program at Michigan State University was born in 1970. That a program devoted to "training a generation of generalists in using the scientific method in the solution of critical social problems" should emerge in a department of psychology and not in some other arm of the university can be explained by the

methodology in which research psychologists are trained and in the person of George W. Fairweather, the originator of the program.

The methodology differs from that of other disciplines in the social sciences in that it is more experimentally oriented than the others. The others rely more on descriptive techniques and survey analyses than psychology does. While psychology does not eliminate these other techniques, it does concern itself more with manipulating behavior than with just passively observing it as the others do. It is little wonder then that the search for finding effective social programs should begin here and not in some other related discipline.

Still, this alone wouldn't have been enough to explain the spawning of such a program where it did. Up until now, psychology has largely preoccupied itself with only using this technique to study microbehaviors in theoretically-contrived laboratory settings. Except for the war years attempts to extend the technique to other more applied problems in naturalistic settings have been almost non-existent. The most notable exception to this has probably been in the area of mental health. Representing as it does a special branch within psychology, mental health provides a natural place where the experimental approach can be used in the search for a solution to a practical, applied social problem, i.e. mental illness. This is exactly what has been done over the past twenty years by George W. Fairweather.

Frustrated by seemingly ineffective therapeutic approaches to the treatment of the mentally ill, Fairweather has, over the years, embarked on a systematic search for finding something better (Fairweather, et al., 1960, 1964). The search eventually led him to an innovative

approach in treating the mentally ill in a community setting. He found that giving mental patients a means to support themselves in an autonomous living arrangement outside the hospital would not only work, but would be far superior in many ways to the standard treatments being used by most mental institutions at the time (1969). Since then he has sought to have the concept implemented by others throughout the country (1974). What sets this apart from most other social innovations that take place is that all the steps along the way have been marked by well-documented experimental research.

After years of doing this kind of social experimentation it became evident that the methods he had been employing should not be restricted to just the problem of mental illness, but should be applied to the solution of other problems as well. At one point this became the subject for a book of his, Methods for Experimental Social Innovation (1967). It was the ideas set forth in this book that actually formed the basis on which the current program in Ecological Psychology has been built.

Thus, it was out of these three elements—a climate for evaluation where none existed before, a thrust for universities to become more socially involved, and the desire of George W. Fairweather to see the kind of experimentation used in psychology applied more to solving practical social problems—that the current study on nutrition evolved. It is in light of this as well as the specific aims of the counseling itself that the study being presented here needs to be viewed.

At the time the study was done the counseling program was only in effect in two counties in the state, Ingham a fairly affluent, middleclass county, and Saginaw, a somewhat poorer, more industrialized one. The basis for the study lay in a need to find out whether the counseling being given in the family planning projects of these two counties was being effective or not. If it was, similar programs were to be initiated in other counties in the state having family planning projects. If it wasn't, the study was at least hoped to be suggestive of ways the program might be improved before it was implemented any further.

The rationale for providing nutritional counseling in a family planning setting is twofold. One, it can be used to decrease the risk of infant and maternal mortality and morbidity associated with certain kinds of medical conditions. Second, it can be of help in alleviating certain medical conditions that may be accentuated by side effects from the type of contraceptive that is used. Specifically, the study was to focus on the effectiveness of the counseling in alleviating four common medical conditions known to be related to one or the other of the above factors: overweight, underweight, anemia and hypertension. The specific rationale for each follows.

Overweight by itself does not actually constitute a health problem. Rather, it is the high number of complications that so frequently accompany this condition that causes it to be seen as one. For the pregnant woman, obesity brings a greater chance for complications to occur during delivery plus a generally higher incidence of infant mortality as well (Marks, 1960). Much less serious, but

decidedly more common, is the toxemia which so often results in overweight women who become pregnant (Tomkins and Wiehl, 1955). For the overweight woman who is trying to prevent a pregnancy, the most thorny problem is the rapid weight gain that some women experience with the use of certain types of birth control pills—though in fact this can be more than offset by what would be gained from a normal pregnancy less, of course, the weight associated with the fetus itself (Hodges, 1971).

Underweight too can potentially be just as serious. If not attributable to heredity or some other physiological predisposition, it may be indicative of malnutrition, a serious health problem, particularly in the pregnant woman. For an expectant woman, it can present the same increased risk of toxemia that overweight can, but with an added risk of premature labor occurring besides (Tompkins, et al., 1955). Of course, the low birth weight that normally results from a premature birth can also be the cause of later impaired growth and development of the child as well. While the total number of consequences that can be traced to undernourishment is simply too great to mention, it is sufficient in itself to realize that such a state leads to a generally higher rate of morbidity and mortality for both mother and child (Tompkins and Wiehl, 1955).

Anemia as a serious health problem is widely disputed (Hillman and Hall, 1968). The difficulty lies in finding agreement on what constitutes a serious deficiency. In pregnancy some drop in red blood cell count is apparently to be expected, particularly in the third trimester. However, whether the drop is enough to be considered

serious depends, not on the level reached, but on the iron reserves that are available at the time of conception, and that is rarely known. It is, therefore, considered especially important for anemia to be treated before conception occurs.

This can be even more true for the woman trying to prevent a pregnancy, depending on the type of contraceptive used. If it is the pill there is no problem. The pill actually has a beneficial effect in that it cuts down blood loss during the menstrual period while increasing the absorption of iron in the gastrointestinal tract during the rest of the cycle (Burton, 1967). If, however, an intrauterine device (IUD) is used, the condition may be worsened by the excessive bleeding that can occur after its insertion (Zadeh, et_al., 1967).

Hypertension, like overweight, is not itself so much a problem if viewed outside the context of other conditions that are known to stem from it; e.g. stroke, coronary heart disease and even kidney failure. However, in pregnancy it can be a sign of pre-eclampsia, a condition which usually occurs prior to the onset of toxemia. Mostly, it is for the woman on a contraceptive pill that it can present a special problem. Some pills are known to elevate blood pressure among certain women (Weinberger, et al., 1970). It is these women who need to be especially treated for hypertension so the condition will not be aggravated.

All of these conditions can be controlled to at least some extent through diet. In most cases both overweight and underweight can be regulated by caloric intake, except perhaps where hormonal factors are known to be involved. Anemia, while readily treated in the

short run through iron supplements, can be more permanently alleviated by an increased diet of iron-rich foods. With hypertension, a sodium-restricted diet has long been known to help alleviate the problem (Ambard and Beaujard, 1904; Allen and Sherrill, 1922), the importance of which has been no less diminished by the anti-hypertensive drugs that are now available (Leiter, 1968).

It is up to the nutritionist to tailor an appropriate diet to the eating habits of each particular person based upon which condition is present and how severe it appears to be. The recommendations the nutritionist makes may be tempered by the patient's level of education, cultural background, income, home environment, or any number of other such relevant factors.² In the clinics this counseling is done strictly on a one-to-one basis with patients who come for family planning assistance. These may be new patients who are there for the first time or revisit patients who are coming back for an annual check-In either case, when a patient is through with the preliminary screening and has finished seeing the doctor she is then referred to the nutritionist if it is evident she has one of these conditions. Typically there is only one counseling session with the nutritionist and that rarely lasts longer than ten to fifteen minutes. While no one considers this enough, it is nonetheless felt to be necessary because of the high volume of patients that need to be seen.

Thus, the ultimate purpose behind the study is to find out whether what the nutritionist says in these abbreviated one-to-one

²See Appendix A for a short summary written by the nutritionist in one of the counties describing the counseling being provided.

encounters has any effect at all in alleviating any of these four conditions. This breaks down into the following four hypotheses:

- 1. That overweight women who receive counseling will lose more weight than they otherwise would;
- 2. That underweight women who receive counseling will gain more weight than they otherwise would;
- 3. That anemic women who receive counseling will evidence a sharper rise in their blood count than they otherwise would--irrespective of any iron supplements taken;
- 4. And, that hypertensive women who receive counseling will evidence more of a drop in blood pressure than they otherwise would.

The reason these must be considered as four separate tests and not simply as one based on some kind of overall improvement is that there is no basis for equating a change in blood count with a change in blood pressure with a gain or loss in weight. The dynamics behind each is different. To have done otherwise, would have been totally incongruous.

In all fairness to those involved, particularly the state maternal nutrition consultant who prompted the study to be done, almost no one expected any dramatic results would be found proving the counseling effective in any of these four areas. Such pessimism does not seem terribly unwarranted. Attempts to evaluate government intervention programs have been few in number with most of the ones done thus far showing almost no positive results (Rossi and Williams, 1972).

To some extent this disappointing performance has been due to limitations in the state of the art. But, at the same time, there is a growing recognition of what massive social, cultural, and psychological factors these programs are up against in order to succeed. Rarely is such a broad view incorporated into the research that attempts to justify these programs. Too often, research has been totally isolated from any such programatic considerations.

In the field of nutrition, most research has typically been limited to one of three approaches; large population studies which try to equate health statistics to dietary patterns, carefully controlled laboratory studies with animals, or restricted studies done on a few individuals in a controlled hospital or clinic setting. When it comes to studying practical intervention programs such as the one here, little is actually known.

In a review done in 1960 of what was known about various weight-loss therapies no conclusive evidence could be found that any actually worked (Feinstein, 1960). The one exception to this was in the case of those where the caloric intake could be totally controlled, as in a hospital, and then it didn't seem to make any difference what particular regimen was being used. It was not because of any compelling negative results that this conclusion had to be reached, but because what evidence there was, was so inconclusive. Few of the studies supposedly looking into the efficacy of these therapies even had control groups, and most of those that did had obvious biases. There is no reason to suspect that the situation would be any different for any other diet therapies now being advanced.

Because of this state of affairs, part of the purpose of the study was not just to examine the counseling, but to gain a broader insight into some of the other factors that could contribute to or hinder improvement as well. Knowing this for each of the four separate conditions was hoped to be of use later in suggesting ways the counseling could be improved, particularly in the event the program was found ineffective in regard to any of the four conditions.

CHAPTER II

METHOD AND SAMPLE

The very nature of the purposes outlined in the preceeding chapter demanded that the study be carried out under naturalistic conditions. Yet, the kinds of conditions typically encountered in these clinics precipitates a multitude of potential hazards, any one of which could invalidate the results. It was, therefore, especially important that extreme care be taken in arranging exactly how the study would be done.

Screening

To help minimize the disruptive effects that necessarily go along with doing a study such as this in a field setting, strict procedures were set-up for determining eligibility. Many of these procedures were established Federal or state guidelines to which the clinics were supposed to be already adhering (see Minimum Standards of Health Care in Family Planning Programs, and Draft Guidelines for the Nutrition Component of Comprehensive Health Care Services for Mothers and Children). Where there were gray areas not covered by these guidelines specific procedures were agreed upon by all those involved. In brief, the following outlines the basic standards set forth for screening.

³For an abbreviated chronology of events that took place during the study based on highlights from a diary that was kept by this researcher see Appendix B.

Overweight and Underweight.--Federal guidelines specify that anyone weighing 20% or more over their standard weight for height be considered overweight. Underweight is set at 10% or less than the standard weight for height. To determine whether a patient qualified, her weight was compared against a standard weight for height table taken from the Metropolitan Life Insurance Company Actuarial Tables for 1959 (see Appendix C). The averages this table contained were limited to the midpoint of the weight range for women of medium frame. No attempt was made to adjust for large or small framed women. Moreover, the only adjustment made for age was that one pound was subtracted from the standard weight for each year the patient was under 25 years of age. Anything more complicated than this was felt to be too impractical for the hectic pace at which the clinics sometimes operate.

All patients were to be weighed wearing shoes and normal indoor clothing. On the day the study began the state maternal nutrition consultant and this research advisor affixed a six foot measuring tape on a wall as near the scales as possible calibrated to the proper height from the floor. (Using the height indicator contained on regular doctor's scales was eliminated as being notoriously inaccurate.) The scales themselves were specially calibrated for the study by someone from the Department of Agriculture's Bureau of Standards a short time prior to the first day screening began.

Anemia.--An accurate diagnosis of anemia can only be established through somewhat elaborate laboratory procedures. Both the cost and time involved precluded using this alternative. Instead, a microhematocrit was taken, the method most commonly employed for

screening purposes. A hematocrit reflects the volume of packed red blood cells contained in 100 ml of blood. Its value represents the number and size of red blood cells, either of which may be indicative of an anemic condition if a low enough value is found. State guidelines of 36 ml or below were adopted as the criterion for determining eligibility.

The one exception to this was that a lower limit of 28 ml was set as a value beyond which the patient would be referred directly to a physician. The concern here was that any hematocrit lower than 28 ml might be suggestive of a condition serious enough to endanger the immediate health of the patient. For all those that fell inbetween 28 ml-36 ml, a two months supply of iron pills (200 mg of ferrous sulfate) was given with the instructions that it be taken three times a day.

To insure that the hematocrit machines in each of the different projects all yielded the same results one sample of blood was tested on all machines. Where they didn't agree, calibrations were made to insure uniformity.

As far as taking the blood itself, two procedures were specified. One was the blood sample would be drawn from the index finger and nowhere else. The other was that two viles of blood would be tested instead of one and the average of the two recorded. This was done in an attempt to try and reduce error as much as possible.

<u>Hypertension</u>.--Federal guidelines adopt the widely accepted norm of either a systolic reading of 140 mm Hg or above or a diastolic reading of 90 mm Hg or above as indicative of high blood pressure.

The problem is in getting an accurate reading in making this determination, especially in the clinic setting where the patient may be rushed or already nervous over her pending physical exam. All clinics were instructed to take blood pressures with the patient sitting relaxed, her arm supported in an extended, supinated position at about the level of the heart. A velcro cuff was used in all clinics.

There were two exceptions to this established clinic routine, both of which are widely considered good medical practice. For one, nurses were permitted to retake any blood pressure they felt was suspiciously high. Commonly this would be done for patients who exhibited a high degree of nervousness at the time the first reading was taken. A minimum of twenty to thirty minutes ellapsed before the second reading was made. Whenever this had to be done, the lower reading of the two was the one recorded.

The other exception that was made involved severely obese patients. Getting an accurate reading from the arm is not always possible on this type of patient. In the few instances this occurred nurses were permitted to take a reading using a thigh cuff instead.

This constituted the basic requirement for screening and accurately measuring the four criteria involved. To deal with the possibility that a patient might qualify on the basis of more than one of these four criteria the following priorities were established:

Hypertension, then anemia, followed by either of the two weight categories. The rationale for setting the priority this way was that both hypertension and anemia can be potentially far more serious than either of the weight problems. That and the fact that sample sizes might be

smaller for these less frequent ailments dictated that they be considered first before an over or underweight condition. Anyone found qualifying with any of these conditions was told about the study and asked to participate. (See Appendix D for the standard explanation that was given in eliciting their cooperation.)

Experimental Design

To further minimize the hazards involved and to form a basis on which to test the different hypotheses, a set of control groups was set up in each of the two counties based on a random selection of 20% of the patients who qualified in each of the four separate conditions. To make the selection process as simple as possible for the staffs involved, an arrangement was agreed upon using the last digit of each patient's identification number. This is a number that is assigned on a first-come first-serve basis to everyone who comes to a family planning clinic for the first time. Under this arrangement anyone qualifying for the study whose number ended in a 2 or 7 was designated to be held back as a control. Everyone else was to be counseled. The choice of these two particular numbers was made entirely on a random basis.

All the patients designated as a control were seen briefly by the nutritionist and asked to return two months later for a check-up, but none was actually counseled. Those who were counseled were also asked to come back after a two month interval for a revisit. Thus, within each of the counties, there were two comparable groups to test each hypothesis, one that had received counseling and another just like

it that hadn't. Having both of these groups available for each of the four separate conditions, a comparison could then be made to see whether those who had been counseled actually did improve the most in the span of time allotted.

The advantages of using random assignment to create such control groups have been amply discussed elsewhere (see especially Campbell and Stanley, 1963). As it applies here, random assignment serves to spread whatever biases might occur equally across both groups so that the only factor left that can account for any observed differences between the two is the counseling itself. The actual test used to tell whether any of the observed differences were sufficiently large to be significant was analysis of covariance (ANCOVA). In each case, the appropriate pre measure taken at the time of the initial visit served as the covariate for the dependent measure, in this case the corresponding post measure taken two months later.

There was one important limitation to the arrangement just described. With no random assignment between the counties, only within, (i.e. some of the patients in Ingham being randomly selected and sent to Saginaw for counseling and vice versa, a definite impossibility) the design that had to be employed for the ANCOVA was a two-factor nested design, with counseling nested within county (Winer, 1963). With this particular type of design no inferences could be made about the individual programs in either of the two counties. Rather, the analysis had to be strictly limited to an assessment of the program taken as a whole. Without randomization across counties, there was no suitable alternative.

The choice of 20% for the size of the control groups was largely a compromise between sampling considerations and the necessity for allowing the nutritionists to continue to do their job as usual. To have reduced their work load any greater by enlarging the size of the control groups would not only have violated the purposes for which they had been hired, but might also have seriously distorted the type of counseling being regularly given. Had this happened, the results of the study would have been seriously invalidated for the purposes for which it had been originally intended (i.e. an evaluation of the ongoing program).

Nevertheless, setting the figure at 20% did make the control groups decidedly smaller than any of the corresponding counseled groups, a definite drawback. At worst, the smallest sample size expected for any of the control groups in either of the counties was estimated to be 10 to 15 patients and most were expected to be much higher. However, with the two counties being analyzed together, even this minimum was still expected to be enough, though admittedly it left little margin for error.

To supplement this analysis with more control patients, a separate set of control groups was created using two comparable counties, Kalamazoo for Ingham, and Muskegon for Saginaw. Patients in these two additional counties were to be screened in exactly the same way with everyone who qualified being asked to return two months later just like all the others. With the clinics in these two counties being almost the same size as those in Ingham and Saginaw these additional control groups were expected to be nearly as large as those that were to be counseled.

Of course, since none of these patients was being randomly selected from the same population as those who were counseled, there was less assurance they would be as comparable to the counseled groups as the original control groups were expected to be. This meant that any outcome from this "quasi-experimental" part of the study would have to be viewed in a somewhat more guarded light than any of the corresponding results from the more rigorous "experimental" part (Campbell and Stanley, 1963). Despite this, it was hoped that having these groups would help compensate for whatever shortcomings might arise from the necessity of having smaller control groups from the counties where the counseling was taking place.

A separate, but identical, analysis using the same two-factor nested design was planned for this quasi-experimental part. For this analysis the same counseled groups used in the experimental part were to be compared against these additional control groups. However, as will be explained shortly, Kalamazoo had to be dropped from the study soon after screening began. As a result, a simple one-way ANCOVA had to be done instead, so that each separate control group from Muskegon was, in effect, compared against the two corresponding counseled groups from Ingham and Saginaw combined together as one.

Thus, it was this analysis, plus the one for the more rigorous experimental part, that formed the basis on which the effects of the counseling were to be tested. However, nothing in either of these

⁴The term "quasi-experimental" as it is used here refers strictly to the fact that randomization was not made, and is not to be confused with any of the other variations in design (e.g. interrupted time-series) that have been proposed by Campbell and Stanley.

two analyses would provide any special insight into why improvement did or did not take place in any one of the four separate conditions. For that, a different type of analysis was needed instead.

Cluster Analysis of Associated Variables

There was a host of factors beyond just the counseling itself which could potentially influence whether any one individual improved or not. Some of these, like the duration of the interview, were directly related to the counseling; others were not. To measure as many of these different variables as possible three forms were set up, one to be filled out by the clinics, the other two by the patients themselves. The following is a description of these forms. (Copies of all the forms are available in Appendix E.)

Patient Record Sheet.--Basically, the first page of this form was simply used as a place for the clinics to record all the key information about the patient; her name, date and age, plus all the physiological data--height, weight, hematocrit and blood pressure. It also served as a place where any special comments could be added that anyone might consider relevant about a patient as, for instance, with someone who was on some kind of special medication that could be related to her qualifying condition.

The second page of the form was a sheet filled out by the nutritionist. As a result, the information on this page was only available on patients from Ingham and Saginaw and not on any from Muskegon. There was a place on this page for the nutritionist to rank each individual on a seven point scale according to how emotionally

stable they thought the patient was and on how motivated the patient would be to follow their advice. There was also a place here for the nutritionist to indicate how long the interview lasted.

The rest of the page was reserved for a set of nutrition scores based on the patient's recall of what she ate over a 24-hour period the day before. In developing these scores the patient was first asked to relate everything she ate or drank the previous day to the nutritionist. Then, to be as accurate as possible, the nutritionist went over each item with the patient to elicite such details as how the item was prepared and how much of it was eaten (e.g. not just egg for breakfast, but two fried eggs; not just toast, but one slice of lightly buttered toast with jam). Later, using Bowes and Church's Food Values of Portions Commonly Used with the aid of some abbreviated coding sheets for frequently eaten items, the nutritionist scored these foods for the following nutritients: Vitamins A and C, iron and calcium, animal and vegetable protein separately, and fat. Each score reflected how close the patient had come to meeting two-thirds the Recommended Dietary Allowance for that nutrient as established by the Food and Nutrition Board of the National Research Council (1968).

In addition to this, the patient was also scored on how well she met the number of servings recommended from the Basic Four Food Groups--fruit and vegetable (scored separately and later combined); meat, fish and eggs; milk, cheese and other dairy products; and, bread and cereal. Besides these standard food groups, the number of servings of snack items and beverages was also derived.

It was hoped that these scores might reflect some of the dietary changes the patient was being asked to make or, at least, might help account for why a particular patient did or did not improve. Certain scores were considered to be of special significance in this regard. Fat was one. The score for fat was expected to be associated with weight gain or weight loss for patients who were either over or underweight. Iron was another. The iron score was expected to be tied to the blood count of the anemic patients. There were others too, but these were the two principal ones.

Eating Habits Questionnaire. -- The 24-hour recall was actually one of two dietary assessment devices used in the study. The other was a checklist given the patient for her to indicate how frequently she had eaten certain key foods over the last month. This checklist was scored for exactly the same nutrients and food groups as the 24-hour recall. Naturally, the scores from the checklist were based on less detail than the more personal recall method. Nonetheless, it was hoped that this disadvantage would be offset by the fact that the checklist covered a longer period of time. In any case, part of the reason for including it was to see which method of the two was more useful in predicting improvement.

The checklist formed most of what was called the Eating
Habits Questionnaire. What remained, consisted of a series of questions that pertained mostly to certain related aspects of people's eating behavior. The purpose behind many of these questions was to get a better idea of how much control the individual had over the food

available to her. Two unrelated questions were also included, one concerning whether any iron medication was being taken, the other the level of the family income.

Health Questionnaire.--The Eating Habits Questionnaire focussed on but one important dimension related to the study. To add to that and to cover another principal area equally as important, health, another questionnaire was also used. On this questionnaire patients were given a chance to indicate both how well they thought they were and how often they might be experiencing any of several different symptoms people commonly have (e.g. shortness of breath, feeling faint, etc). A five point scale ranging from "never" to "all the time" was provided for this purpose with a separate scale being provided for an overall rating of their state of health on a range from "poor" to "excellent."

Admittedly all of this was very subjective. Some patients might have a definite physical basis for their ratings; others might not. Nonetheless, one of the reasons this section was included was to see whether any of these subjective feelings had any relation to improvement. More objectively, questions were asked concerning whether they had seen a doctor in the last month or whether they had had any serious illnesses over the last several years. Together these questions were designed to elicite any additional information that might be related to the particular condition for which the patient qualified.

To supplement some of the things on the Eating Habits Questionnaire a few questions were asked to find out whether the patients had had any special concerns about eating. One question asked what

special diets they had ever been on. Another asked whether they had read any books recently on health, health foods, dieting or weight control. Then to get an overall idea about how they felt about nutrition, five attitude statements were given for them to rank. The statements ranged from "What I eat makes a difference in my health" to "Even if I know something is good for me, I won't eat it unless I really like it." Each of these statements was ranked by the patients on a five point Likert-type scale according to how often they felt that way--always, often, sometimes, rarely or never.

The only other questions included covered two specific areas highly germaine to the study, smoking and birth control. To cover the first, patients were asked how often they smoked and whether they smoked filter or non-filter cigarettes. The main reason this was included was to take into account the person who might quit or cut down during the study. This is definitely known to cause weight gain in some people (Brozek and Keys, 1957) and could account for why some overweight or underweight patients improved while others didn't.

To cover the second area, patients were asked what form of birth control they were using and how long they had been using it.

This question was especially important given the relevance some of the side-effects certain forms can have to the purposes of the counseling as explained before. In particular, if it was the pill, a check was later made of their file to see which brand it was. Different brands have different amounts of estrogen and progesterine in them making some potentially more riskier than others. Then too, some brands

are exactly alike. To put them all on a more equal basis, the brands were ranked according to their "potency" and the ranks used instead (see Appendix F for the rankings).

The variables included in these forms were certainly not all the variables that could conceivably influence whether someone improved or not. With the exception of a wide range of demographic characteristics, they were, however, considered to be many of the ones thought to be most relevant to the goals of the study outlined before. The demographic variables presented a special case since much of this information was collected by the Department of Health on some of their own forms. With their cooperation the following demographic characteristics were obtained on each individual qualifying for the study: race, marital status, level of education, number of pregnancies, number of living children, number of stillborns, number of children wanted, number of people supported by family income, use of medicaid or public assistance. ⁵

These constituted all the variables being considered in the study. It might be pointed out that all of these variables except the demographic ones were measured twice, once when the patient first came in and then again at the time of the revisit. To sort out which variables were the ones most highly related to improvement, the data was cluster analyzed along with the four criterion variables: weight loss, weight gain, change in blood count and change in blood pressure.

 $^{^{5}\}mathrm{Note}$ that age and income were also available, but from the other forms.

Using this technique reduces the data to a much simplier form by eliminating weak variables that are unrelated to anything while grouping the strongest ones that remain into clusters. These clusters are formed in such a way that all the variables within a cluster are kept as much alike as possible while all those between clusters end up being as different as possible. The advantage of this is that it reduces a vast amount of data to a few simple tightly-knit clusters or dimensions.

The particular cluster analysis program used here was the B.C. Try System. This particular system offers the unique advantage of "presetting" clusters on selected variables (Tryon and Bailey, 1969). This was an especially valuable option for this study because it offerred the opportunity to set up four distinct clusters, one for each of the different criteria. Doing that meant each cluster would be composed of its own unique set of variables associated with change for that one particular condition. Hence, four separate sets of variables could be found—one that was best indicative of weight loss in the case of overweight; another that was best for weight gain in the case of underweight; a third set unique for anemia; and, a fourth set best for hypertension. It was from this analysis that some insight was hoped to be gained into which were the most influential factors contributing to improvement for each of the four separate conditions.

Implementing the Study

Deciding what variables to measure, designing the forms, formulating a research design does nothing to insure that the question-naires will be properly administered and the standardized procedures

followed. One nurse could subvert everything. As a result, success rested on convincing the individual staff members that were going to be involved of the importance of the study and of the necessity for following the prescribed procedures.

Once the director and head nurse from each project plus the two nutritionists from Ingham and Saginaw had met at an initial meeting and agreed to participate, a meeting was set up with the individual clinic staffs to explain the procedures and elicit their support for the study. At this time the importance of adhering to the procedures was stressed and any questions they had were answered. At this time too, a written agreement was entered into by all the principal parties spelling out the key obligations of each (see Appendix G for sample of one of the signed agreements).

It should be pointed out that these meetings did not always go as smoothly as planned. Concern was frequently voiced over how much extra time the project would require and, in some cases, open hostility was encountered. Particular concern was expressed over how much extra paperwork would be involved. Reassurances were made to placate the wary and the study began the week of June 15th 1972. Each project began on a different day so that the state nutritionist and this researcher could be present to help take up the extra load and to work out any problems that might arise.

From the start, Kalamazoo presented a problem. Not only was the staff there openly hostile to the project but it quickly became apparent that patients were not being properly screened. After repeated attempts to ameliorate the problem over the first month and a half, the project there had to be dropped completely from the study.

Screening continued in the remaining three counties through mid-December of the same year, two months longer than had originally been planned. This was done in order to allow more people to qualify for the study. Extra time too, was given for patients to return. This was necessary when it became evident that a substantial number of patients were found to be coming back past the two month interval that had been originally established. As a result, the final date for the last patients to come back for their revisits was extended to April 1 of the following year. The reasons why these steps had to be taken at all will become evident in the chapter that follows.

CHAPTER III

RESULTS

In all, the three counties screened a total of 3,064 patients during the six month period extending from June 15th through Dec. 15th. Each county accounted for roughly a third of the patients seen, with Saginaw accounting for slightly more, Muskegon a little less. Of the 3,064 patients screened, a total of 1,257 or 41% qualified because they were either overweight, underweight, anemic or hypertensive, a somewhat larger portion than had been anticipated.

Muskegon accounted for a disproportionate number of those qualifying. One out of every two patients in that county qualified, whereas only one out of every three qualified in the other two, though even this was considered high. As a result, Muskegon yielded almost as many eligible patients as the projects in either of the other two counties, despite its smaller size (see Figure 1).

A breakdown by county of each of the four different health problems shows that this was due primarily to a higher incidence of anemia and hypertension there than in either Ingham or Saginaw (see Table 1). It might further be noted that the Muskegon project also had a larger number of patients who qualified for more than one category than did either of the projects in the other two counties.

Despite the high rate of qualifying patients found in Muskegon and in the other counties as well, there was still a great deal of

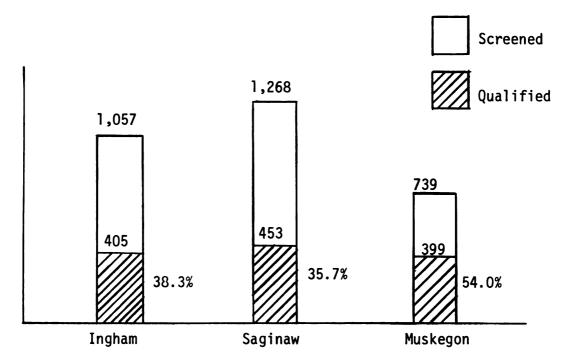


Figure 1. Proportion of patients qualifying in each county.

difficulty in obtaining adequate sample sizes. This was due to the fact that not all the patients that qualified ended up participating. A large proportion, nearly three-quarters (76.1%), had to be dropped from the study. The following section addresses this problem in detail, the reasons for it and the ramifications it had for making a subsequent analysis of each of the different conditions.

Attrition

The reasons why so many patients had to be dropped varied. A large number had to be eliminated from the start. For instance, some wanted to participate but for one reason or another couldn't (e.g. inflexible working hours, transportation problems, difficulty in getting a sitter, etc.); others failed to complete the questionnaires, or because of mix-ups, were not given the forms in the first place; still

Table 1. Incidence rates by county

Health	County				
Condition	Ingham	Saginaw	Muskegon		
**************		Out of every 100 patients			
Weight Problem	33	30	36		
Overweight	19	21	29		
Underweight	14	9	7		
Anemia	5	7	19		
Hypertension	4	3	17		
More than one of the above	5	4	18		

others simply refused. In all, 35.1% of the eligible patients had to be eliminated for one reason or another when they first came in.

Though the rest may have completed the forms and agreed to participate, a large number nonetheless failed to return for their scheduled revisit. Without follow-up data, these patients too had to be dropped from the study. This left 23.9% of the eligible patients for the final analyses. The exact breakdown for each of the projects is shown in Figure 2.6 Note that while Muskegon retained a much higher proportion of its patients initially, it actually ended up contributing the least patients to the study because so many failed to return for a revisit.

⁶For a complete breakdown of the sample by county for each of the different health categories see Appendix H.

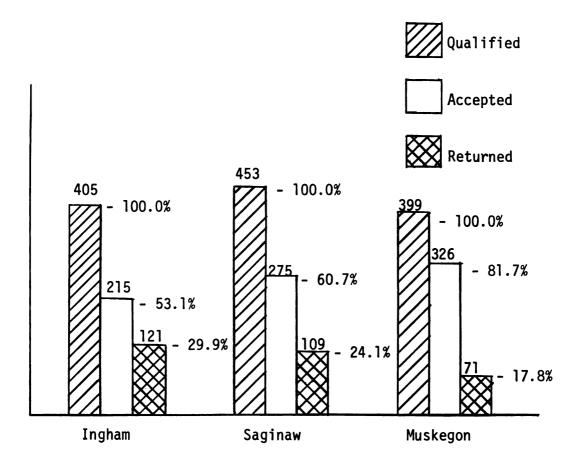


Figure 2. Attrition rate by county.

If one analysis was to be made of everyone that qualified, the dramatic reduction this attrition produced in the sample would not have been so damaging. But the design of the study called for two separate analyses of each of the four different health conditions. As a result, certain categories ended up with so few patients that they had to be dropped altogether.

This was particularly the case for the randomly selected control groups in Ingham and Saginaw to which only 20% of the patients had been assigned. (Later it was raised to 30% in a vain attempt to remedy the problem.) Table 2 below shows which groups had to be

dropped and, as a result, which analyses had to be eliminated. (The specific sample sizes in each category will be reported later as the analyses of each separate condition is discussed.)

Table 2. Deletions due to attrition.

Health	Counseled Groups		Cont	Control Groups			Analysis	
Condition	Ingham	Saginaw	Ingham	Saginaw	Muskegon	Exp.	Quasi- Exp.	
Overweight								
Underweight		Х		Х		χ ^a		
Anemic			Х	χ		X		
Hypertension			Х	Х		Х		

^aIngham only, without Saginaw

X: Group or analysis deleted because of insufficient sample size.

It was because of this attrition that the screening had been extended beyond what had originally been planned and the requirement for patients to come back in two months relaxed. Yet, despite these steps (and others too) the study was seriously weakened, not just by the analyses that had to be eliminated but by the serious potential for bias that this attrition had created as well.

There were two ways such bias could be introduced. One was if a different kind of patient ended up being eliminated from one of the counseled groups than from its corresponding control; e.g. the sickest patients who had been counseled returned while the ones who hadn't stayed home; the oldest ones who saw the nutritionist returned

while the others who didn't dropped out. The danger of this kind of bias is that it would invalidate the test of the particular hypothesis being considered. After all, the counseled group would no longer be comparable to its control; ergo, any differences observed between the two could no longer be ascribed to the counseling alone. For this reason, it became extremely important to check as closely as possible for this kind of "selection" bias.

Thus, for each analysis three separate checks were made. First, a test was run to see if there had been a differential attrition rate between the counseled group and its control. In other words, if one group was found to have significantly more patients or less patients drop out than the other, this would suggest some kind of special segment may have been systematically eliminated from one group and not the other. Second, the demographic make-up of the two groups was checked to see if they were still comparable. And third, the initial physiological data pertaining to each appropriate group was compared (i.e. weight in the case of overweight, hematocrit in the case of anemia, etc.). It should be kept in mind that even if none of these tests revealed any bias, that the two groups could still differ but in ways that hadn't been checked.

Of course, it is possible that the returning patients in both groups would be exactly alike, but would be totally different from those that dropped out; e.g. sicker patients returned while healthier ones stayed home--regardless of who had been counseled and who hadn't. In that case, the returning patients would no longer be

representative of all the patients for that particular condition, a different kind of situation than that previously described.

This kind of bias would not invalidate the test of the hypothesis as the other one would. It could, however, limit the applicability of the results to only the particular group of patients that returned and not to any of the others. To check for this type of bias, the same kind of tests involving the physiological data and the demographic data that were described before were repeated. This time, however, the comparisons were not to be made between the counseled and the control groups, but between the patients who returned versus those who had to be eliminated.

Besides the potential problems for bias the attrition created, there was one other difficulty encountered. Having cutoffs for determining eligibility (e.g. a hematocrit of 36 ml or below for anemia) sometimes resulted in an abnormal distribution of the data. Because of this, certain checks had to be made to see whether or not the data could be assumed to come close enough to a normal distribution to carry out the test of the hypothesis; i.e. the analysis of covariance.

Since all of these problems are so closely associated with each particular analysis, they will be dealt with one at a time under each of the four separate categories of health problems discussed next. Following this the results of the cluster analysis will be presented.

Tests for the Effect of Counseling

Overweight

Overweight was the single most common health condition which qualified patients for the study. It alone accounted for two-fifths of those qualifying. (In contrast, the remaining three categories accounted for roughly a fifth each.) Because so many qualified in this category there were enough counseled and control subjects to make both the experimental and quasi-experimental comparisons in spite of the high attrition rate.

Experimental Condition.--Together Ingham and Saginaw accounted for a total of 394 of the 506 patients whose sole problem was that of overweight. Of these 394 patients, only 118 came back for a revisit. Some of those returning had been counseled while others had been randomly selected and assigned to the control group. To see whether a disproportionate number of either control or counseled patients had returned, a test was run comparing the return rate for each of the two groups in the two separate counties. The results of these comparisons are shown in Tables 3 and 4. No significant difference was found in the attrition rate between the two groups in Ingham. In Saginaw, however, the situation was entirely different. There, significantly more control patients than counseled had to be eliminated (p<.05).

While this in itself is not a problem, it is indicative that the attrition may have produced some kind of selection bias. Therefore, it was critical to see whether there were any significant differences in initial weight between the two groups in Saginaw. Table 5

Table 3. Attrition between overweight groups in Ingham county.

Status	Group Patient Assigned to:				
of	Counseled		Control		
Patient	N	%	N	%	
Returned	45	(34)	12	(29)	
Eliminated	86	(66)	29	(71)	
		$\chi^2 = 0.36$	(1 df)		

Table 4. Attrition between overweight groups in Saginaw county.

Status	G	Group Patient Assigned to:				
of	Coun	Counseled		trol		
Patient	N	%	N	%		
Returned	52	(32)	9	(16)		
Eliminated	112	(68)	49	(84)		
		$\chi^2 = 5.6$	3 ^a (1 df)			

^aSignificant at .05 level

Table 5. Mean initial pounds overweight of returning counseled and control patients in Ingham and Saginaw counties.

County	Group Patient	16		
	Counseled	Control	df	t
Ingham	48.4	52.7	56	NS
Saginaw	45.7	50.7	60	NS

NS: Not significant

shows the number of pounds overweight the two groups averaged at the outset of the study in each of the two counties. No significant differences were found between the control and counseled groups in either county.

In addition, when a number of key demographic characteristics were compared between the two groups in each of the counties, only one other significant difference was found and that was in Ingham, not Saginaw. In Ingham, patients who had been assigned to the control group were found to have twice as many children as those who had been counseled (3.2 versus 1.6). This difference was found to be significant beyond the .05 level (see Table 6). No significant differences were found in age, education, number on Medicaid, income or the number of people supported by that income. This, at least, suggests that there were no obvious selection bias problems present in Ingham, or for that matter, in Saginaw either. Nonetheless, this still does not rule out the possibility that other, more subtle biases might still be present, particularly between the two Saginaw groups.

Even if no differences between the counseled and control groups could be found, the possibility that the returning patients as a whole no longer represented the original population of overweights would still persist. Therefore to try and resolve this problem the

⁷Differences in these demographic characteristics were routinely checked throughout each analysis. Only those differences which were found significant are to be shown. Extensive tables documenting the others may be seen in Appendix I.

Table 6. Mean number of children of returning counseled and control patients in Ingham and Saginaw counties.

County	Group Patient	16	١.	
	Counseled	Control	df	t
Ingham	1.6	3.2	52	2.39 ^a
Saginaw	1.8	1.1	57	.95

^aSignificant at the .05 level

same types of comparisons just carried out were repeated. This time, however, the comparisons were made between those who returned versus those who were eliminated instead of between the counseled and control patients as was done before.

Still no significant differences emerged, either in the average number of pounds overweight or in the several key demographic characteristics that were checked. In fact, a remarkable similarity was found in the make-up of those who had to be eliminated with those returning, especially in the key factor of weight (see Table 7).

Table 7. Mean pounds overweight of patients who returned versus those eliminated in Ingham and Saginaw counties

County	Status o	Status of Patient		
	Returned	Eliminated	df	t
Ingham	49.2	48.7	171	NS
Saginaw	50.1	46.4	221	NS

NS: Not significant

While this doesn't eliminate the potential for any such bias to exist in the groups, it is nevertheless reassuring that no obvious differences occurred.

Table 8 shows the relative change in weight between each of

Table 8. Pre and post differences in the mean pounds overweight of counseled and control groups in Ingham and Saginaw counties.

			Cou	ity	
Period		Ingham		Sag	inaw
		Counseled	Control	Counseled	Control
D		(n = 45)	(n = 12)	(n = 52)	(n = 9)
Pre	\overline{X}	48.4	52.7	45.7	50.7
	s	(20.2)	(16.4)	(15.7)	(15.8)
<u>Post</u>	\overline{X}	46.0	52.5	45.5	49.1
	S	(23.2)	(17.9)	(15.9)	(14.6)
Mean Diffe	erence	-2.7	-0.2	-0.2	-1.6

the groups in the two counties. As can be seen from the table, all of the groups lost weight, some slightly more than others. In Ingham, the counseled patients lost more than the controls. In Saginaw, just the reverse was true. It is, therefore, not surprising that the analysis of covariance of the data shown in Table 9 reveals that the overall difference between the counseled and control groups was not significant.

Table 9. Analysis of covariance comparing the effects of counseling on weight reduction for patients in the experimental condition.

Source of Variation	df	MS	F
Between Counties	1	71.42	1.64
Between Counseled and Control (within counties)	2	57.73	1.32
Error	113	43.59	

Note that there were two problems involving possible violations of the assumptions behind the analysis of covariance that was done on the data. One involved the deviation of the data from a normal distribution, the other, a lack in homogeniety of variance among the groups. These possible violations, however, could be expected to alter the observed F-ratio by only a few tenths of a point anyway (Glass, Peckham and Sanders, 1972). Since the observed F-ratio was so far from being significant, these problems could not have altered the outcome enough to change the basic findings and for that reason will not be discussed here. Such problems will, however, be discussed in detail in the next section where the outcome could conceivable have been effected.

Quasi-Experimental Condition.--As already noted, attrition proved to be a particularly serious problem in Muskegon. In the category of overweight, four-fifths of those eligible had to be eliminated, leaving only 17 of the original 112 overweights available as a control. This was a significantly higher rate of attrition (p<.001) than

evidenced by the counseled patients from Ingham and Saginaw combined (see Table 10), and raises the same kind of problems the differences

Table 10. Attrition rates between counseled overweights and the controls from Muskegon county.

Status	Group Patient Belonged:				
of	Counseled		Control		
Patient	N	%	N	%	
Returned	97	(33)	17	(15)	
Eliminated	198	(67)	95	(85)	
		$\chi^2 = 12.6$	52 ^C (1 df)		

^CSignificant at the .001 level

between the two groups in Saginaw raised in the previous analysis. However, in this case the problem is compounded by the fact the controls come from a separate county. Any biases that are found may be due as much to differences between counties as to the attrition itself. Income emerged as just such a case.

The average income of the 17 control patients from Muskegon was found to be significantly lower (p<.05) than that of the counseled patients from Ingham and Saginaw (\$3,950 versus \$5,730 resulting in a t = 2.04 for 82 df). A comparison of the 17 control patients who returned with those who were dropped suggests that this difference may have been due in part to the fact that those with higher incomes were the ones eliminated. However, a comparison of this same data with that for Ingham and Saginaw suggests that the difference may have also been due to the fact that overweight patients from Muskegon had

somewhat lower income in general (see Table 11).⁸ While separately each of these differences was not significant, the net result was a difference between the two groups that was.

Table 11. Income levels of overweights returning contrasted with those eliminated.

Group Patient	Status of Patient			
Belonged:	Returned	Eliminated	df	
Counseled				
Ingham	\$5,760.	\$5,0 30.	117	NS
Saginaw	\$5,710.	\$5,600.	195	NS
<u>Control</u>				
Muskegon	\$3,950.	\$4,720.	48	NS

NS: Not significant

In addition, there was a tendency for returning patients in Muskegon to weigh somewhat more than those who were dropped (see Table 12). While this resulted in these returning control patients averaging almost ten pounds more than their counseled counterparts from Ingham and Saginaw (56.3 lbs versus 46.9 lbs), the difference was not enough to be significant.

⁸Cautionary note: Accurate data on income is notoriously hard to get and this data proved no exception. Over fifty percent of the subjects lacked data on income making comparisons such as these extremely tenuous. Nonetheless, income data from the census for these counties tends to support this basic difference.

In comparing weight change for these 17 control patients with that of those who had been counseled, a different pattern emerged

Table 12. A contrast in the mean pounds overweight of returning patients with those eliminated for patients from Ingham and Saginaw counties who were counseled as well as for those from Muskegon county who were a control.

Group Patient Belonged:	Status o	1.6		
	Returned	Eliminated	df	t
Counseled	46.9	48.3	296	NS
Control	56.3	48.3	110	NS

NS: Not significant

than before. Unlike the controls in the other two counties, these patients gained--2.2 pounds on the average. In contrast to the small weight loss evidenced by the counseled patients, this at least lends support to the fact the counseling may be effective (see Table 13).

Table 13. Pre and post differences in the mean pounds overweight of counseled patients from Ingham and Saginaw counties contrasted with that of the controls from Muskegon county.

	Group Patient Belonged:		
Period	Counseled	Control	
Pre _	(n = 97)	(n = 17)	
\overline{X}	46.9	56.3	
S	(18.0)	(22.9)	
Post $\overline{\chi}$	45.8	58.5	
S	(19.6)	(23.1)	
Mean Difference	-1.1	2.2	

Nevertheless, an analysis of covariance of the data showed that the difference was not quite dramatic enough to be significant (see Table 14).

Table 14. Analysis of covariance comparing the effects of counseling on weight reduction for patients in the quasi-experimental condition.

Source of Variation	df	MS	F
Between Counseled and Control	1	147.54	3.44
Error	111	42.94	

As mentioned previously, there were two problems involving possible violations of assumptions of analysis of covariance that could have altered this finding. One, the distribution of the data was far from normal. As might be expected, the 20% cutoff used in screening resulted in a highly skewed distribution (see Figure 3). A

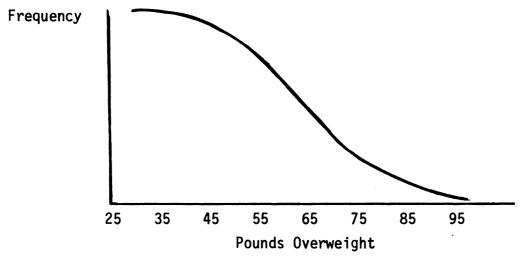


Figure 3. Distribution of overweights used in quasi-experimental condition.

chi-square test of this distribution comparing it with that of a normal curve was found to be highly significant $(p<.001)(\chi^2=25.06$ for 3 df). Just what effect this had on the observed F-ratio is, however, a moot question.

Glass, Peckham and Sanders (1972), in a review of the effects of various violations of the assumptions of analysis of variance and covariance, suggest that the effects of skewness are minimal, at least for an analysis of variance. For an analysis of covariance, no direct evidence appears to be available. The more conservative approach appears to be to raise the probability level needed to reach significance by one; i.e. instead of .05 use .025. (McNemar, 1949). This being the case, a somewhat larger F-ratio than that shown in Table 14 would be needed to reach significance.

The second problem was potentially far more serious. It involved the possible violation of the assumption of homogeneity of variance, a requirement that can substantially bias the observed F-ratio if not met. An examination of the standard deviations shown in Table 13 suggests that the variance between the control and counseled groups might be sufficiently different in both the pre and post conditions to have appreciably altered the value of the observed F-ratio. To find out, a Bartlett's test for homogeneity of variance was run for each condition (see Winer, 1962, p. 95). The resulting chi-squares proved not to be significant either in the pre ($\chi^2 = 2.10$) or the post ($\chi^2 = 3.30$) conditions (1 df).

Underweight

Attrition proved to be a particularly severe problem in this category, largely because so many of those who qualified did not consider themselves underweight and refused to participate. Overall, an astounding 86% of those eligible had to be dropped for this and other reasons as well. No other category yielded such a high dropout rate.

The problem was especially acute in Saginaw. There 94% of those eligible had to be eliminated. This left only six patients, four who had been counseled and two controls, simply not enough to warrant representing Saginaw in this analysis. Therefore the experimental comparison had to be based on Ingham alone and, in the quasi-experimental condition, just Ingham and Muskegon.

Experimental Condition.--Unfortunately the results of the analysis of the underweights from Ingham proved to be somewhat suspect because of a difference in what the counseled and control groups weighed initially (p<.05). On the average, counseled patients started out weighing almost five pounds less than the controls (-21.3 lbs vs. -16.9 lbs resulting in a t = 2.25 for 27 df). As seen in Table 15 this could not be attributed strictly to a difference in attrition rates between the two groups. Nonetheless, a close examination of the next table reveals a tendency for dropouts to have been heavier in the counseled group than in the control group (thereby raising the average for those that had been counseled while lowering it for the controls). While separately the difference in weight between those who returned versus those who dropped out failed to be significant for either group (see Table 16), together it resulted in a net difference between the two groups for those returning that was.

Table 15.	Attrition	between	underweight	groups	from	Ingham	county.
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Status		Gro	up Patient Assigned	to:	
of	Coun	seled		Coi	ntrol
Patient	N	%		N	. %
Returned	19	(18)		9	(26)
Eliminated	89	(82)		26	(74)
			$\chi^2 = 1.11 (1 df)$		

Table 16. A contrast in the mean pounds underweight of returning patients with those eliminated for counseled and control groups from Ingham county.

Group Patient	Status of	Status of Patient		+
Assigned to:	Returned	Eliminated	df t	
Counseled	21.3	18.4	107	NS
Control	16.9	17.3	34	NS

NS: Not significant

When the patients later returned for their revisit, those who had been counseled, had, on the average, gained this initial difference back. Those who had been a control, meanwhile, had gained much less, only about a pound and a half (see Table 17). A comparison of the demographic make-up of the two groups revealed no other differences that would suggest any other bias to effect these results.

The problem this presents is that it leaves the results of the analysis of covariance somewhat in doubt. While the analysis showed the gain made by the counseled group was not significant (see Table 18), there is no way of knowing whether the counseled group might have gained more if they hadn't already been so much thinner to start with than the controls. For that matter, there is no way of knowing whether they might have gained less.

Table 17. Pre and post differences in the mean pounds underweight of counseled and control groups from Ingham county.

Dania	Group Patient Assigned to:	
Period	Counseled	Control
	(n = 19)	(n = 9)
Pre X	21.3	16.9
S	(5.2)	(3.0)
Post _		
X	16.6	15.4
S	(5.5)	(4.3)
Mean Difference	4.7	1.4

Table 18. Analysis of covariance comparing the effects of counseling on weight gain for patients in the experimental condition.

Source	df	MS	F
Counseling	1	32.90	2.55 ^a
Error	25	12.88	

^aSignificant at the .05 level

Although the matter must be left unresolved, the issue at least was not complicated by the violations of assumptions of analysis of covariance that emerged before. Despite a suggestion that the variances might be different enough between the two groups to be significant (see particularly the variance associated with the pre measures shown in Table 17), a Bartlett's test of both the pre and post conditions failed to reach significance. (χ^2 = 1.72 and 0.55 for 1 df, respectively). Nor did a chi-square comparing this distribution with that of a normal distribution show significance either (χ^2 = 2.55 for 3 df). Except for the problem of inference the pretest differences create, the results appear untainted.

Quasi-Experimental Condition.--Bias proved less of a problem in this analysis than in any examined thus far. The main drawback here was the severely limited number of subjects which were available from Muskegon to serve as controls, 7 out of a possible 45. While clearly high, this rate of attrition was not any worse than that found in either of the other two counties for this category. In fact, as seen in Table 19, it was nearly the same as that evidenced by the counseled patients from Ingham with which these controls were to be compared. Had as many patients qualified as, for example, in Ingham where 143 women were eligible, there would have been an ample number of subjects.

As it turned out, the seven were superior in at least one important respect to their randomly selected counterparts from Ingham. As contrasted in Table 20, the difference between the counseled and control groups in weight was actually less in this analysis than in the experimental.

Table 19. Attrition rates between counseled underweights and the controls from Muskegon county.

Status	Group Patient Belonged:				
of	Counseled		Co	Control	
Patient	N	%	N	%	
Returned	19	(18)	7	(16)	
Eliminated	89	(82)	38	(84)	
		$\chi^2 = 0$.	09 (1 df)		

Table 20. A comparison of the mean initial pounds underweight of patients in the counseled and control groups used in the experimental and quasi-experimental analyses.

Condition	Group Patien	df		
	Counseled	Control		
Experimental	21.3	16.3	27	2.25 ^a
Quasi-Exper.	21.3	20.3	25	0.64

^aSignificant at the .05 level

However ironic this similarity might be, there was one difference worth noting between those who were dropped and those returning from Muskegon. Returning patients were almost five years older on the average than those who had to be eliminated, a difference significant beyone the .01 level (a mean of 25.6 versus 21.0 resulting in a t of 3.40 for 44 df). While this wasn't enough to make those who returned incomparable with those in the counseled group, it did mean that as a group they were less representative of underweights from Muskegon in general.

Whether it was due to an absence of pretest differences or not, the gains made by the counseled patients over the controls appeared more substantial in this analysis than in the one before (compare Table 21 with Table 17 shown in the previous section). That was because, instead of gaining as the other control group did, this group

Table 21. Pre and post differences in the mean pounds underweight of counseled patients from Ingham county contrasted with that of the controls from Muskegon county.

Period	Group Patient Belonged:		
	Counseled	Control	
	(n = 19)	(n = 7)	
<u>Pre</u>			
 X	21.3	20.3	
S	(5.2)	(5.9)	
Post	16.6	20.4	
S	(5.5)	(5.7)	
Mean			
Difference	4.7	-0.1	

hardly changed at all. As a result, the counseled patients gained an average of almost five pounds over the controls, whereas before these same counseled patients gained an average of only three.

This does not seem to be a very dramatic difference until one considers that the most any one of the seven control patients gained was five pounds, hardly a significant dietary accomplishment. In contrast, the most any one counseled patient gained was 15 pounds, a definite dietary accomplishment. (The most anyone of the controls

from Ingham had gained was nine pounds.) All of this is to say that the above averages hide some highly significant weight changes, a fact that was borne out by the results of the analysis of covariance shown in Table 22.9

Table 22. Analysis of covariance comparing the effects of counseling on weight gain for patients in the quasi-experimental condition.

Source	df	MS	F
Counseling	1	94.65	8.91 ^b
Error	23	10.62	

^bSignificant at the .01 level

The results of the analysis of covariance were significant beyond the .01 level, indicating that at least in comparison to these controls the counseling was effective. Tests for lack of homogeneity of variance in both the pre and post conditions were insignificant (χ^2 = 0.24 and 0.04 for 1 df) as was the test comparing this distribution with that of a normal curve (χ^2 = 4.44 for 3 df). Whatever limitations there may be in these findings at least they are not of a statistical nature.

⁹While a non-parametric statistic may have been more appropriate in light of the small n for this analysis, a regular analysis of covariance was carried out in order to make this analysis as comparable to the preceeding one as possible.

Anemia

In all, follow-up data was available on 81 patients having anemia, a higher proportion (32%) of those eligible than in any other category. This lower rate of attrition may be attributed principally to Ingham, where almost half of those qualifying returned, and to a lesser extent to Saginaw where about a third returned. It was in Muskegon where attrition continued to be such a problem. There, follow-up data was available on only 21% of those eligible. Still, this represented a total of 24 patients, a much healthier number than was available from that county in the previous analysis.

This proved quite fortuitous because, unlike the previous two categories, there were not enough control patients from Ingham and Saginaw to perform an analysis under the experimental condition. This was as much the result of the attrition problem as it was to the fact that 20% simply was not a large enough portion to hold back as a control.

For instance, 48 patients were found anemic in Ingham. Randomly selecting twenty percent of these for controls would still only net around ten patients, barely enough even if none had to be eliminated. As it was, Ingham only yielded three control patients complete with follow-up data.

The situation was similar in Saginaw. There, more qualified (90 in all) yielding more potential controls (14), but more had to be dropped too, leaving only two patients with follow-up data for a control. With only two control patients from Saginaw and three from Ingham, there was no choice but to drop the experimental comparison.

Quasi-Experimental Condition. -- As seen in Table 23 below, attrition was found to be significantly worse for the controls from Muskegon than for the counseled patients from Ingham and Saginaw

Table 23. Attrition rates between counseled anemics and the controls from Muskegon county.

Status		Group Patier	t Belonge	<u>:</u>
of	Cou	nseled	Coi	ntrol
Patient	N	%	N	%
Returned	47	(42)	24	(21)
Eliminated	66	(58)	91	(79)
		X = 11.4	11 ^C (1 df)	

^CSignificant at the .001 level

(p<.001). However, this did not seem to contribute to any differences between the two groups. An inspection of Table 24 reveals that the average hematocrit differed by less than a point among the returning patients from each of the three counties. Moreover, the degree of anemia represented by those returning was found comparable to that of those who had to be cropped.

There was one difference that was found between the two groups. Muskegon patients averaged about one year less education than did those from Ingham and Saginaw (10.8 vs 11.7 years). This was found to be significant beyond the .05 level (t = 2.20 for 67 df). As evident from the comparisons shown in Table 25, this was due more to a difference between the counties than to any selection bias resulting

Table 24. Mean hematocrit for returning anemics in contrast to those eliminated for counseled patients from Ingham and Saginaw counties and for the controls from Muskegon County.

County	Status (of Patient		
Country	Returned	Eliminated	df	t
Counseled				
Ingham	35.2	35.1	38	NS
Saginaw	34.9	34.7	73	NS
Control				
Muskegon	34.3	34.5	114	NS

NS: Not significant

Table 25. Mean years of education for returning anemics in contrast to those eliminated for counseled patients from Ingham and Saginaw counties and for the controls from Muskegon county.

Country	Status	of Patient		
County	Returned	Eliminated	df	t
Counseled				
Ingham	12.2	11.7	38	NS
Saginaw	11.4	11.2	67	NS
Control				
Muskegon	10.8	10.6	109	NS

NS: Not significant

from the attrition. As the table shows, patients from Ingham had one full year more education than those from Muskegon regardless of whether or not they had to be dropped from the study; those from Saginaw

averaged a half a year more. Except for this one difference, there did not seem to be any other bias apparent between the two groups.

In comparing the change in each of the two groups, both improved, but the average hematocrit of the counseled patients gained half again what the control patients gained (see Table 26). Most of

Table 26. Pre and post differences in the mean hematocrit of counseled patients from Ingham and Saginaw counties contrasted with that of the controls from Muskegon county.

Danisad	Group Patient Belonged:		
Period	Counseled	Control	
	(n = 47)	(n = 24)	
<u>Pre</u>	25.0	24.2	
^	35.0	34.3	
S	(1.5)	(1.7)	
Post _			
 X	37.2	35.8	
S	(3.0)	(2.1)	
Mean			
Difference	2.2	1.5	

Figures in milliliters

the difference was accounted for by the patients from Ingham. The hematocrit of these patients gained an average of 3.2 ml, almost twice that of the controls. The Saginaw patients, meanwhile, gained only an average of 1.4 ml, about the same as that of those who hadn't been counseled.

In applying a test to these differences the analysis of covariance that had been performed in the previous analysis was found inappropriate here because of a low association between the pre measures and the subsequent post measures. The advantage of using analysis of covariance over analysis of variance is lost as the correlation between the covariate and the dependent variable drops below .30 (Elashoff, 1969). Whereas the correlations between the pre and post measures in the previous analyses ran in the .80's and .90's, it fell in the .20's here. As a result, it was necessary to resort to a repeated measures design as the next best alternative (Porter, 1973). The results of that analysis shown in Table 27 reveal that as a whole everyone improved significantly from what their hematocrit had been at the start (p<.01), but that those who were counseled improved even more than those who had been a control (p<.05).

Table 27. Analysis of variance comparing the effects of counseling on anemics for patients in the quasi-experimental condition.

Source of Variation	df	MS	F
Between Counseled and Control	1	34.60	5.76 ^a
Between Pre to Post	1	130.25	30.75 ^b
Interaction	1	4.51	1.07
Error	69	4.24	

^aSignificant at the .05 level

bSignificant at the .01 level

However, an examination of the scores revealed a distribution much like that shown for the overweights in Figure 3, only more severe. A test comparing this distribution with that of a normal one exceeded even the .001 level (χ^2 = 47.94 for 3 df). In their review article covering such abnormalities, Glass, Peckham and Sanders (1972) suggest that a problem such as this only rarely distorts the observed F-ratio by more than a few hundredths. This being the case, even a 10% fluctuation would not alter the level of significance in this analysis.

Neither did the differences in variance between the groups in either the pre or the post conditions alter the findings. A Bartlett's test of each of these differences failed to reach significance (χ^2 = 0.55 and 3.72 for 1 df, respectively). Thus, despite some drawbacks, an assessment of the anemics was at least possible in the quasi-experimental condition.

Hypertension

Like the anemics, not enough hypertensive patients returned from the randomly selected control groups to permit an analysis of the experimental condition. In all, only 49 of the 205 women who were eligible because their blood pressure was above either 140 systolic or 90 diastolic or both, returned. Of these 49 women, only 3 had been in the randomly assigned control groups, and all of them were from Ingham, none from Saginaw. As a result, there again was no choice but to drop the experimental comparison from the analysis.

Quasi-Experimental Condition.--Muskegon had by far the largest number of eligible patients for this category of the three counties. In all 127 women qualified from Muskegon while Ingham and Saginaw had only 36 and 42 qualify respectively. This would have helped strengthen the control group for comparative purposes had it not been for a serious difference that was found between the Muskegon patients and those from Ingham and Saginaw who had been counseled. As seen in Table 28, the average blood pressure differed significantly between the two

Table 28. Mean blood pressure of counseled hypertensives and the controls from Muskegon county.

Blood	Group Patient	Belonged:	df	1 +
Pressure	Counseled	Control	<u> </u>	
Systolic	145.1	141.3	45	1.05
Diastolic	88.3	95.0	45	2.21 ^a

 $^{^{\}rm a}$ Significant at the .05 level

groups (p<.05), not for the systolic (which is more important as far as reflecting dietary control), but for the diastolic. However, since the magnitude of the former is dependent in part on the pre-existing level of the latter, any comparison between the two groups would thus be questionable.

A check was made to see whether or not the problem could be attributed to a selection bias resulting from the high attrition rate.

As seen in Table 29, it was not. The difference in blood pressure lies between the counties, not between those who had returned and those who

had to be dropped. Actually the blood pressure of returning patients was quite comparable to those who were dropped in all three of the counties.

Table 29. Mean blood pressure for returning hypertensives in contrast to those eliminated for counseled patients from Ingham and Saginaw counties and for the controls from Muskegon county.

County	Status	#		
	Returned	Eliminated	df	t
Counseled				
Ingham	143/88	143/89	28	NS
Saginaw	145/89	151/89	30	NS
Control				
Muskegon	141/95	142/94	126	NS

NS: Not significant

This occurred, in spite of the fact a much larger number dropped out in Muskegon than in Ingham and Saginaw combined (p<.01, see Table 30). Given this higher attrition rate, a thorough check was made of the demographic composition of the two groups. No significant differences were found either between the groups or between those who returned versus those who dropped out in any of the counties. What the variation in the average diastolic reading appears to reflect is some fundamental difference in the patients from Muskegon with those from Ingham and Saginaw.

Table 30. Attrition rates between counseled hypertensives and the controls from Muskegon county.

Status	Group Patient Belonged:			
of	Counseled	Control		
Patient	N %	N %		
Returned	23 (38)	23 (18)		
Eliminated	37 (62)	104 (82)		
	$\chi^2 = 8.9$	8 ^b (1 df)		

^bSignificant at the .01 level

How much effect this had on the subsequent blood pressure readings is not known. Table 31 does show, however, that both systolic and diastolic dropped less for patients from Muskegon than it did for

Table 31. Pre and post differences in the mean blood pressure of counseled patients from Ingham and Saginaw counties contrasted with that of the controls from Muskegon county.

	Group Patient	Belonged:
Period	Counseled	Control
	(n = 23)	(n = 23)
Pre		
 X	145.1/88.3	141.3/95.0
s	(14.5) (9.2)	(9.2) (8.3)
Post		
<u> </u>	132.2/85.2	135.7/91.1
s	(16.3) (12.1)	(15.5)(12.6)
Mean		
Difference	-13.9/-3.2	-6.6/-3.9

¹Figures in millimeters of Hg

patients from Ingham and Saginaw. Whether this difference could be attributed to the fact that those from Ingham and Saginaw had been counseled or to the fact the diastolic pressures were so different to begin with is not known. In any case, an analysis of covariance (see Table 32) revealed the differences were not enough to be significant.

Table 32. Analyses of covariance comparing the effects of counseling on blood pressure for patients in the quasi-experimental condition.

Source	df	MS	F
Systolic	,	500.50	0.50
Counseling	l	509.68	2.52
Error	43	202.51	
<u>Diastolic</u>			
Counseling	1	45.86	0.36
Error	43	128.05	

(The lack of correspondence between pre and post measures found in the previous analysis was not present here. The correlation between the pre and post blood pressures ranged in the .60's). There were other problems, however.

To further complicate matters, a significant difference was found in the variance between the two groups. This violates the assumption of homogeneity of variance, a key assumption in making this analysis. An inspection of the standard deviations shown in Table 31 reveals that the differences in variance between the groups was minimal in all categories but one. The one place where the two differed

was the key pre measure of systolic pressure. There a Bartlett's test revealed the counseled group had a significantly larger variance than the control group did (p<.05 based on a χ^2 = 4.64 for 1 df). Fortunately, the effect is slight since the sample sizes are equal in the two groups. What bias there is, is upward making the observed value of the F-ratio slightly higher than its actual value (Glass et al., 1972). Since the observed value did not come close to being significant, the outcome remains basically uneffected.

The complications encountered in the analysis of systolic pressure were compounded further by a significant difference in the distribution of the data from normal (p<.01 based on a χ^2 = 16.33 for 3 df). While the effects are minimal (Glass, et al., 1972), it does make an already dubious outcome that much more dubious. Fortunately matters were not made any worse by a similar problem in the diastolic data. A chi-square test applied to that set of data revealed a distribution much more closely approximate to that of a normal distribution (χ^2 = 5.67 for 3 df).

Cluster Analysis Results

The findings reported in the preceeding discussion are fine as far as assessing the effects of the counseling but they lend little insight into what lay behind the results. To supplement the basic findings a correlational analysis was made of a number of different factors which might have contributed to the success or failure seen in any of the four outcome measures just examined: weight gain, weight loss, hematocrit and blood pressure.

Key among the variables being considered were the following: a set of scores reflecting the nutritional status of each patient's diet based on her answers to the Eating Habits Questionnaire and, for those from Ingham and Saginaw, on a 24-hour recall as well; a short self-report made by the patient on her state of health; a few attitude statements about eating; some demographic data; and, some miscellaneous factual information pertaining to the different outcome measures such as whether or not the patient smoked, the form of contraceptive used, recent illnesses, to name a few. Most of the variables were measured twice, once at the time of the initial visit and then again later at the time of the revisit. In total, this amounted to well over 200 variables to be analyzed, far more than could be analyzed at one time by the computer.

Reducing these variables to a more manageable lot was a rational process based upon three considerations: the importance of the particular variable, its communality, and its correlation with any of the four outcome measures. In the case of the latter a correlation of .32 was set as an upper limit for deleting a variable. Setting the limit at this level eliminated the most trivial variables while still insuring that those most significant (p<.001 for 100 df) would be retained for further analysis.

As it was, less than 90 of the variables fell above the designated cutoff. The question then was whether each constituted an isolated factor or whether any could be combined and reduced to a smaller number of simplier dimensions. To find out, these variables, along with the four criterion measures, were cluster analyzed using

the BC Try cluster program (Tryon and Bailey, 1970). The results of an initial empirical-V analysis indicated that about half the variables could be reduced to ten clusters or dimensions. The rest had communalities below .20 suggesting these to be so independent as to be isolated from all the others.

As for the criterion measures themselves, each one emerged as part of one of the ten clusters. Three emerged together on the same cluster, weight gain and weight loss along with the systolic change in blood pressure, the last two loading exactly opposite to the first. The change in diastolic pressure emerged on a separate cluster as did the change in hematocrit. None of the four was selected as a key pivot variable which is to say none formed the nucleus for defining any of the ten dimensions. Rather there were ten separate dimensions with these outcomes measures related to three of them.

To bring the focus more directly on just these variables, the data was reclustered, this time with each of the four criterion measures preset as a separate cluster definer. This improved the cluster structure, especially in regard to separating out which variables were most clearly associated with each of the three criterion measures that had all been loaded on the same cluster before. The results of that preset analysis follows.

<u>Overweight</u>

The poorest cluster emerging was that for overweight. Not only was it defined by the least number of variables, but it had the lowest reliability of all, .30 by itself though with the addition of

other non-defining variables this was raised to a satisfactory level of .71. The cluster was made up almost entirely by scores from the 24-hour recall taken when the patients returned for their revisits.

From a nutrition standpoint, the results were encouraging. Patients who had been eating the most fatty foods--snacks, desserts, etc.--were the ones who had failed to lose much weight. Those who had lost the most, were the ones who apparently had been on more of a high protein, low calorie diet, a diet made up for the most part of meat, milk, fruit and foods rich in Vitamin A (like carrots, squash and cantalope, foods typically deep yellow in color.) Additional evidence of this was reflected in the fact that a composite score based on whether or not the patient met two-thirds of the Recommended Dietary Allowance (RDA) for all the nutrients being scored was one of the highest loading variables on this cluster as well.

One other variable accompanied these scores and that was the month the patient had been admitted into the study. Patients admitted in late fall or early winter lost more weight than those admitted earlier, during the summer.

It should be pointed out, however, that while all of these variables together formed a cohesive group with good reliability, individually none correlated very well with weight loss. Fortunately, the results of the other clusters were more satisfactory. For a listing of the specific loadings for each variable included in this cluster see Table 33.

Table 33. First cluster--overweight.

Variable	Loading
Weight loss (Definer)	0.55
Scores based on 24-hr recall at time of revisit: Patients who lost ate foods	
High in Vitamin A High in Calcium High in Protein (animal) Low in Fat	0.57 0.42 0.40 0.36
High composite score	0.52
with the number of servings eaten	
High for Fruit High for Milk High for Meat	0.48 0.44 0.42
Patient admitted into study in late Fall or early Winter	0.40

Reliability:

Underweight

Of all the clusters, perhaps, the most satisfactory was that for underweight. Reliability was good, .81, with a rather broad range of variables making up the cluster, not the least of which was the fact of having been counseled. While all the variables didn't fit neatly into one clear-cut pattern, more was probably learned from this cluster than any other.

Certainly one of the key factors which again emerged was diet. Many of the same scores that were found related to losing weight in the case of overweights were found to be just as applicable in gaining for those too thin. As before, patients eating foods high in protein like meat or milk were likely to improve (in this case gain) as were those who ate a lot of fruit or foods rich in Vitamin A. There were, however, some notable additions to these scores that were not present in the previous cluster. Eating iron-rich foods (liver, dark leafy greens, cream of wheat) as well as bread and cereal (which typically is iron-enriched) also seemed to be part of the diet of those who gained.

As in the previous cluster all the scores were based on the 24-hour recall taken at the time of the patient's revisit. There was, however, one exception. As of the initial visit, patients who had already been eating fatty types of foods also turned out to be ones likely to gain.

Attitudes were apparently important too. Patients who agreed that "What I eat makes a difference in my health" were more likely to improve whether it was as of their first visit or when they later returned. On the other hand, those who had agreed initially with the statement "I'll eat foods I don't especially like, if I think they would be good for me" were not likely to be ones to gain as much.

Another, perhaps related factor, was money. Having money seemed to facilitate gaining weight. Women having a higher income (or whose families had higher incomes) were more likely to gain than those with lower incomes. Similarly, being on food stamps either on

the first visit or when they returned was more likely to result in weight gain than not being on food stamps. Only one other demographic factor emerged and that was the fact that Caucasians were more likely to gain than any others.

There were a number of seemingly unrelated factors associated with gaining weight. For instance, patients who admitted smoking more when they came back for their revisit than they had when they started put on weight as did those who smoked a lot, regardless of whether it had been an increase or not. There is no ready explanation for this, just as there is no ready explanation for why patients who gained the most reported having headaches more frequently.

The highest loading variable on this cluster involved the brand of contraceptive pill used. Patients who had already been on a pill when they were first screened gained less depending on how potent the brand was and how long they had been using it. While this was somewhat true too at the time of their revisit, it appeared that potency rather than how long they had been using it was the more important factor of the two. More will be said about this later in Chapter IV, but it should be recognized here that many outside factors go into determining which contraceptive a patient may use and what brand may be prescribed. It may very well be these factors rather than the potency of the particular brand which contributes the most to these findings. In any case, a listing of the specific variables in this cluster is shown in Table 34.

Table 34. Second cluster--underweight.

Variable	Loading
Weight gain (Definer)	0.92
Scores based on 24-hr recall at time of revisit: Patients who gained ate foods	
High in Iron High in Protein (animal) High in Calcium High in Vitamin A	0.60 0.53 0.44 0.41
High in Composite Score with the number of servings eaten	0.47
High for Milk High for Fruit High for Bread and Cereal	0.43 0.42 0.38
at time of initial visit:	
High in Fat	0.44
Having been counseled	0.53
Contraceptives: The less time patient had been on the pill and the less potent the brand	
as of the initial visit as of the revisit	0.78 0.41
Less potent the brand regardless of length of time	0.55
Smoking:	
Smoked a lot Smoked more at time of	0.54
revisit than at start	0.54
More headaches at time of revisit	2.53
than at start	0.51

Table 34. Continued.

Variable	Loading
Attitudes: Agreed	
What I eat makes a difference in my health	
<pre>as of initial visit as of revisit</pre>	0.43 0.35
Disagreed	
I'll eat foods I don't especially like, if I think they would be good for me	
as of initial visit	0.38
Demographics:	
On food stamps	
<pre>as of initial visit as of revisit</pre>	0.37 0.42
Higher income	0.34
Caucasian	0.35

${\tt Reliability}$

Definer only84 With non-definers .81

Anemia

The cluster for anemia did not have the breadth the one for underweight had, but neither did it share any of the weaknesses exhibited by the one for overweight even though it was more comparable in size. Reliability was good .80, with all the variables strongly related to the criterion measure, much more so than any of the ones related to weight loss had been.

As in all the clusters examined thus far, diet was again found as a factor related to improvement. For one thing, women who had increased their consumption of milk or other dairy products between the time they first came in and when they returned were found more likely to improve than those who hadn't. This is based, not on the 24-hour recall as all the scores reported up until now have been, but on the Eating Habits Questionnaire. The only score from the 24-hour recall that was found related to improvement in this cluster was the number of servings of bread and cereal eaten. The fewer the number of servings a woman had been eating when she was first being screened, the more likely she was to later improve.

The rest of the variables making up this cluster paralleled in many ways those that had been found in the previous cluster for weight gain. For one thing, smoking again was found related to improvement. Patients who smoked more at the time of their revisit than when they first came in were again more likely to be the ones to improve. Similarly, just as those in the previous category who gained the most complained more of headaches, the ones who improved the most

in this category complained more of feeling dizzy. No immediate explanation is available for either of these findings.

More significantly, though with no less clarity, was the fact that the potency of the brand of birth control pill again was found associated with lack of improvement, as it was for underweights. In this case, however, it didn't seem to matter how long the patient had been on the pill. Weighting potency by the length of time the patient had been using the pill, either as of the time she first came in or when she returned, didn't raise the loading of this variable as it had before. In any case, these loadings together with the others for this cluster are shown in Table 35.

Hypertension

Of all the clusters, the one for hypertension probably yielded the most coherent set of variables. For the most part, the cluster for this category was comprised of a number of highly related demographic characteristics. These variables together with the others that loaded on the cluster formed a fairly clear image of just who improved and who didn't. Those who were least likely to experience much drop in their blood pressure seemed to be the older, married women having the largest families. This might help explain the fact that women who felt the most tired and worn out also experienced the least drop in blood pressure.

On the other hand, the ones whose blood pressure was likely to drop the most were the young, single women. The additional fact that women who didn't do their own grocery shopping was also associated

Table 35. Third cluster--anemia.

Variable	Loading
Rise in hematocrit (Definer)	0.76
Scores based on Eating Habits, change from pre to post:	
More servings of Milk More foods high in Calcium	0.60 0.58
Scores based on 24-hr recall at time of initial visit:	
Few servings of bread and cereal	0.62
Contraceptives: The less time patient had been on the pill and the less potent the brand	
as of initial visit as of revisit	0.68 0.66
Less potent the brand regardless of length of time	0.66
Increased feeling of dizziness	0.50
Smoked more at time of revisit than at start	0.43

${\tt Reliability}$

Definer only58 With non-definers .80

with a larger drop in blood pressure would suggest that many of these young, single women might still be living at home or, perhaps, in a college dormitory.

The one finding which didn't seem to readily fit with any of the others was the fact that women eating a lot of meat and who scored high in the consumption of animal protein were also likely to improve the most. This is based on scores taken from the 24-hour recall of their food intake made during their revisit and thus, is limited to just those patients from Ingham and Saginaw who had been counseled. This may be an especially important limitation since these women had been found to differ significantly from those who had served as a control from Muskegon. See Table 36 for a listing of the specific loadings of the variables making up this cluster.

Miscellany

A number of variables had originally been included for the correlational analysis because it was widely felt they would have a major influence in the outcome of one or more of the different criterion measures. The fact that many of these beliefs were not substantiated is in itself an important finding that deserves reporting. Were it to be omitted, these factors might continue to be assumed to play a more important role than they apparently do. To avoid such an oversight the following briefly summarizes the rationale behind several of the most pertinent factors which failed to correlate significantly with any of the outcome criteria as expected.

Table 36. Fourth cluster--hypertension.

Variable	Loading
Drop in Systolic (Definer) Drop in Diastolic (Definer)	0.76 0.73
Scores based on 24-hr recall at time of revisit:	
Low in Protein (animal)	0.63
with the number of servings eaten	
Few for Meat	0.48
Feeling tired less often	
as of initial visit as of revisit	0.44 0.60
Demographic Characteristics:	
Fewer children at home Fewer number of pregnancies Fewer people income supports Younger Not married (divorced, widowed, separated or single)	0.62 0.44 0.47 0.49 0.48
Single	0.43
Someone else shops for food	0.42

Reliability

Definer only74 With non-definers .80

Length of Time Between Visits.--Perhaps the most frequent criticism made before the study began was that two months would not be long enough to see a significant change in patients, particularly those who had to gain or lose weight. Yet in every category the number of days between visits failed to correlate with improvement. It may be in the case of obesity or underweight that more time allows for more change, but there is no evidence that the change would have been any better or any worse.

Motivation and Emotional Stability. -- A frequent complaint of many of the staffs was that patients are often either unmotivated or too emotionally unstable to change. Yet rankings of the patients on these two qualities made by the nutritionists failed to correlate at all with the amount of improvement the patients exhibited.

Length of Interview.--Another frequently voiced complaint was that the length of time the patient was counseled was too short to expect much change. Nevertheless, correlating the length of the interview with the amount of improvement failed to support such a view regardless of which category the patient belonged.

Eating Iron-Rich Foods and Taking Iron Pills.--Taking iron pills did seem to make a difference since practically everyone who was anemic took the iron that was given them and improved at least some. Nevertheless, how often they took their iron and whether or not they also ate iron-rich foods did not seem to make a difference in how much they improved.

Smoking. --Originally a question about smoking was included to take into account the commonly held notion that quitting or cutting down causes weight gain. No evidence was found to support this. In fact, some evidence supporting just an opposite view was found in the case of those who were underweight.

There were other factors too that failed to be substantiated, but many of them covered too few patients to be considered as valid as those just reported. Suffice it to say, as much may have been learned from what was missing in the findings as from what was found.

CHAPTER IV

DISCUSSION

The entire study suffered from three major setbacks: the high rate of attrition that was so unexpectedly encountered; a bias in the quasi-experimental parts of the analysis; and, irregularities in the distribution of much of the data. The problems these setbacks presented precluded any firm probabilistic inferences from being drawn for any of the four hypotheses. While it was still possible to come to some conclusion about each, these conclusions must, nonetheless, be regarded as highly tentative. As for the cluster analysis, it served, at least, to supplement these rather circumspect findings by uncovering a number of specific factors that were related to improvement for each condition.

without a doubt, the severe attrition posed the most serious problems of the three. For one thing, only one category could be analyzed using the full experimental design as planned. All the others had so many patients eliminated that it was necessary to rely either on the quasi-experimental analyses alone or, in the case of underweight, on just one county instead of two. In addition, it introduced a serious threat of bias that could have invalidated much of the results had it materialized. (The danger, of course, is that it did materialize but went undetected, which is one key reason why any conclusions

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that are drawn must be considered so highly tentative.) As it was, only two specific instances could be found where the attrition had definitely contributed to differences between the groups being compared. One of these occurred in the case of the underweights from Ingham.

There was a tendency in Ingham for the thinnest patients to return only if they had been counseled. As a result of this, the patients in the control group there were more likely to weigh more than those in the counseled one. This made it impossible to interpret the results of this comparison. The counseled group gained the most, but this could easily have been because they were the ones that weighed the least at the start. It is just as possible, however, that they would have gained even more had they weighed the same as the controls. There is no way of knowing.

The only other instance where the attrition seemed to have clouded the results involved the quasi-experimental comparison of the overweights. In this analysis there was a tendency for the overweight patients from Muskegon who had slightly higher incomes to be less likely to return. Partly because of this, and partly because the patients there tended to be poorer anyway, there was a significant difference between the income levels of these patients and those from Ingham and Saginaw with which they were to be compared.

The discrepancy seemed a major one in that the incomes bordered so close to the poverty line. The group from Muskegon earned only \$4,000 on the average while those from Ingham and Saginaw earned roughly \$2,000 more, a considerable difference at a subsistence level

such as this. Nonetheless, it was impossible to tell whether this difference or the one found between the underweight patients from Ingham had had any effect on the outcome of either analysis.

A difference similar to this was found in the level of education among the anemic patients. Those from Muskegon had on the average one year less of school than those from the other two counties who had this condition. However, in this case the difference was as true of those who returned as of those who were eliminated. In fact, this difference as well as the difference in incomes between the overweight patients seemed to be part of a more basic difference that existed between Muskegon and these other two counties.

It was generally true that Muskegon averaged the worst of the three counties. This was true in the case of overweight, anemia and to some extent, hypertension. Moreover, the groups from this county rarely improved, the only exception being those who were anemic and in that case everyone was expected to improve at least some because everyone was given iron.

The groups from Ingham and Saginaw were usually comparable to one another at the outset. Yet, inevitably the women who had been counseled in Ingham improved the most. As a result, if one were to rank these groups as to which improved the most, it would be Ingham, Saginaw and Muskegon--first, second, third--in every case (irrespective of what the significant differences were).

This had serious implications for interpreting the results of the quasi-experimental analyses; i.e. the ones where Muskegon served as a control. Nowhere was this more clearly evident than in

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the analyses that were done for overweight. This was the only category where both a full experimental and a quasi-experimental analysis could be made. As a result, it provided the only clear-cut opportunity to compare the two.

Both of the analyses that were done for this category yielded the same basic outcome. There was, however, a distinct tendency for the counseling to appear somewhat better based on the results of the quasi-experimental analysis than on those from the more rigorous experimental one. This suggests that a rigid adherence to the level of significance found in the remaining quasi-experimental analyses would make the counseling appear somewhat more effective than it actually was and points up yet another reason why it was impossible to draw any firm conclusions from the data.

As if these problems were not enough, there were, in addition, certain irregularities in the distribution of the data to cloud the results even further. Screening out all the patients that were normal had the effect of producing a highly skewed distribution of the data. Such a distribution violates the basic assumption of normality required in making either an analysis of variance or covariance. While the effect this has is generally considered to be fairly minimal, it does serve to make these already tenuous findings that much more tenuous.

Given these limitations, the only category that probably could be adequately evaluated at all was the one for overweight, the only one for which a full experimental analysis could be made and it failed to reach significance. Neither, in fact, did the quasi-experimental one despite the bias it had to make the counseling look more

effective than it was. Together these findings seriously question the notion that counseling helps the overweight patients lose weight, and while even this must be regarded as highly tentative, none of the other conclusions reached for the remaining categories can be considered quite as conclusive.

Of all the conditions examined, underweight was the one that seemed most likely to have been alleviated by counseling. This judgment, however, had to be made using only Ingham without Saginaw and must, therefore, be considered highly speculative. Moreover, as explained before, there was a significant difference in what the two groups from Ingham weighed at the start that made the insignificant results of the experimental comparison totally uninterpretable. Because of this, more reliance had to be placed on the results of the quasi-experimental analysis despite the bias it had.

The results of that analysis were highly significant (p<.01). No doubt, this was due in part to the bias that was present as well as to the fact that Saginaw was the county that had to be eliminated and not Ingham. Nonetheless, it seems doubtful that both of these factors alone could have been enough to account for the level of significance that was reached. For that reason, it seems likely the counseling had at least some effect in helping these patients improve.

To some extent, the case for anemia was the same as that for underweight only with Saginaw included. While no experimental analysis could be made, the quasi-experimental analysis was again found to be significant, though at a lower level (p<.05). There was, however, another problem to cloud even these results.

The distribution of the data used in this analysis was found to be highly skewed. As noted in the previous chapter, such a distribution can be expected to alter the observed F-ratio by as much as 10%. While this alone wouldn't have been enough to alter the observed outcome, it could, in conjunction with the bias that was already present, have been enough to make an otherwise insignificant result appear significant. Yet, even despite this possibility, it still seems likely the counseling must have had at least some impact to account for these results, though admittedly it probably wasn't very much.

The last category, the one for hypertension, could not be adequately assessed. This was due to the fact a critical difference was found between the groups used in the quasi-experimental part of the analysis, the only analysis that could be made for this category. The control patients used in this analysis, the ones from Muskegon, were found to have a much higher diastolic reading than the ones from the other two counties who had been counseled.

What made this particular difference so critical was the fact that the systolic pressure, the one which was of most importance in the study, is known to depend in part on how high the diastolic pressure is. While there was no evidence this difference could be attributed to age, race or any other demographic difference between the groups, such a difference could easily account for why the control patients improved less than those who had been counseled. As it was,

¹⁰A special tabulation was made of race since blacks are known to average somewhat higher blood pressures than whites.

the results were not significant anyway, so it seems doubtful the counseling could have been very effective in alleviating this condition.

As the foregoing discussion makes clear, each category suffered some peculiar defect in the analysis that prohibited any definitive conclusions from being reached. While some conclusions were nonetheless made, these obviously were all highly tentative and should be regarded as such.

Fortunately, the study was not limited to these rather circumspect findings. There were, in addition, a number of contributing factors that were found through the cluster analysis to be related to improvement. For the most part, these factors were not ones with broad, general implications for the counseling as had been hoped, but rather a number of highly specific ones that pertained instead to each separate condition. More, in fact, may have been learned in the way of general implications from what was not found.

There were, for instance, a number of factors that had been expected to be a major influence in whether or not a patient improved regardless of the particular condition she had. However, not one of these presumptions was upheld. For example, practically everyone felt that the motivation a patient had to change played an important part in whether or not she improved. The same was true of how emotionally stable the patient was. Yet, rankings of neither of these qualities made by the nutritionists on the patients emerged as a factor related to success on any of the clusters. Either there were other, more important factors than these (e.g. the patient's financial situation) or the nutritionists weren't very good judges in their rankings of the patients.

Similarly, strong arguments were made that two months would not be a long enough time between visits to see a significant change. Yet, not once did the number of days between visits emerge as a factor related to improvement. For that matter, neither did the length of the interview, as had been previously thought. Patients who were seen for as long as 30 to 45 minutes or more apparently improved just as much as those seen for only 5 to 15 minutes. Other supposedly important factors went unconfirmed too, but most of these will be pointed out as some of the other findings are discussed.

Of all the variables that did appear, the ones pertaining to diet were the ones most consistently found to be related to whether or not a person improved. Each cluster contained at least a couple of scores from one of the two different assessment devices that had been used in the study. While this could have been an artifact of the large number of scores that were possible, this somehow didn't seem likely. The scores that emerged were not at all equitably distributed among the different measures as one would expect if this were the case. Instead, practically all of the scores that appeared came from just the 24-hour recall that was taken on patients at the time they returned.

Two things seemed evident from this. One, the food frequency checklist apparently was insensitive to measuring change. This may have been either because it covered so broad a span of time (30 days) that it averaged out what changes had occurred, or because the scores that were derived from it were less exact than those from the

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more personal face-to-face recall method. Regardless of which it was, the recall method appeared to be the more sensitive of the two.

This also seemed to suggest that what people ate to begin with had little to do with whether they would subsequently improve or not. If true, this would mean neither of the two methods would be very useful in screening patients when they first came in as to whether they would be likely to improve or not. There were, however, two important exceptions mitigating this. Each rested on the initial scores taken from the 24-hour recall measure.

First, the underweight patients who were most likely to gain were found to be the ones who had already been eating fatty types of foods; e.g. cookies and cakes, fried foods, gravy, etc. And second, among the anemic patients, the ones who seemed most likely to improve were those who had initially been eating fewer servings of bread, cereal or other types of products made from gains. Typically these foods are ones that are iron-enriched and could help account for the fact these were the ones who were most ready to improve. However, in each case neither of these scores would be considered to have been a major factor making up the cluster. This seems to suggest that there were other subsequent factors in the diet that might have been necessary to give these patients the extra edge that was needed to improve.

While such factors did emerge for each of these two clusters, not much additional light was shed into why improvement had or had not taken place from what was found. For instance, inexplicably the one score most associated with weight gain at the time of the patient's

revisit was the one for iron. Except for the grain products mentioned before, foods rich in iron are not notably high in caloric content. For example, some of the most common foods which supply iron are dark leafy greens, meat, fish and eggs--none of which can be considered to be very fattening.

In fact, it was surprising that this score was not related to anemia instead, as had been expected. For anemia, the major food score found related to improvement was one equally as implausible—the consumption of milk and other dairy products.

The situation was not much better in the case of either of the other two remaining categories. In the case of overweight there was an indication that the patients who lost the most were generally the ones who had been on a high protein, low calorie diet. It also seemed that the ones who gained the most were the ones who had been eating the most fatty foods. While encouraging, none of this was very enlightening.

In the case of hypertension the results were somewhat questionnable since the only scores that emerged were ones from the 24-hour recall and as such only represented the patients who had been counseled; none who hadn't. Even then, the only two scores that emerged had no apparent relation to blood pressure. Each of these scores reflected how much meat a patient had consumed and that is something which has no known relation to what someone's blood pressure is. Thus, despite the fact diet kept recurring as a factor related to change, the individual scores that emerged seemed highly specific to each of the four conditions and often were not at all what was

expected. This seemed to be true of many of the remaining variables that were found related to change.

For instance, being on a birth control pill emerged as a key factor related to change for two conditions, anemia and underweight. In both cases, the more recently a patient had been put on a pill, and the less potent the brand, the more likely the patient was to improve. Yet, only in the case of the underweights did this coincide with what would have been expected. In that case, the weight gain these women experienced could probably be attributed to the temporary weight gain that is known to be frequently associated with certain brands of birth control pills (Hodges, 1971). What is peculiar about this, however, is that it apparently only applied to the underweight patients and not to the overweights as well.

The case of anemia was more perplexing. One would have expected stronger brands, not weaker ones, to be associated with improvement since stronger brands are known to reduce the menstrual flow, a factor which should contribute to an improved hematocrit (Burton, 1967). It may be that being put on the pill was itself sufficient to reduce the normal menstrual flow enough to raise the individual's blood count, irrespective of how strong the particular brand was.

In any case, it should be pointed out that it is equally plausible that both of these findings could have nothing at all to do with the pill itself, but merely reflect differences in the type of woman who chooses the pill over those who choose some other kind of contraceptive method (e.g. women who choose the pill may themselves be more inclined to gain weight than those who don't.)

As for some of the other variables that were covered in the questionnaires, none apparently were very relevant to any of the conditions. For instance, of all the symptoms the patients had ranked of themselves, only one seemed appropriate to whether or not they improved and that was in the case of hypertension. In that case, the patients who got better complained less of being tired. However, in the case of underweight and anemia, getting better actually resulted in the patient feeling worse, at least according to their own rankings. Anemic patients who improved were dizzier more often while underweight patients who gained reported having more frequent headaches. One could speculate that these might have been side effects from being on the pill, but there is no actual evidence to substantiate this. Needless to say without a more plausible explanation these results should probably be discounted. It might be noted in this regard that none of these symptoms loaded very highly on these clusters anyway and, therefore, could not have been of much importance.

The short attitude scale on eating that was provided at the end of the health questionnaire didn't seem to be of much value either. Only once did any of the women's attitudes about nutrition seem to be related to whether or not they improved and that was among those who were underweight. Women who agreed that what they eat makes a difference in their health were more likely to gain.

In contrast, the ones least likely to gain expressed a willingness to eat some foods they don't especially like, if they thought
it would be good for them. There was some speculation that these
women might have been younger ones who were on some kind of natural

food diet, though this cannot be substantiated either. Nonetheless, such women are often underweight and not very likely to gain and would account for such a finding.

The demographic variables were a key factor in a couple of instances. Each time though, what was found seemed fairly significant. In one case, it appeared that having money seemed to be an important factor in improving. That was among underweights. Those with higher incomes, or if they were poor, those on food stamps, were the ones found most likely to gain. Furthermore, this seemed to be more the case among whites than among blacks.

In the other case, two contrasting profiles appeared of who improved and who didn't. Unfortunately, this was in the case of the hypertensives and as such some of what was found may have been due as much to differences among the counties as to differences among those who improved and who didn't. In any case, the ones whose blood pressure didn't improve tended to be the older, married women with the largest families. On the other hand, the ones whose blood pressure did improve seemed to be younger and still single. Given the additional fact that the ones who did improve were also not likely to be doing their own grocery shopping, it seemed likely that many of these girls might still be living at home or, perhaps, in college dormitories. Although this difference might be attributed to nervousness on the part of these younger, less experienced girls over their impending exam, it seems unlikely since the blood pressure reading was generally retaken under such circumstances.

One thing seems fairly evident from these rather sporadic results and that is that there was a notable absence of any kind of common denominator among the four clusters. Diet may have been important in one, demographics in another and contraceptives in still another, but there was no single variable common to all that seemed to be instrumental in determining whether or not a person would improve.

This was contrary to what had been expected. As explained earlier, there were a number of variables that had been expected to be important to all four of the different conditions (e.g. motivation, length of time between visits, etc.). Yet, none of these variables appeared on even one of the four clusters. So, if the results of the cluster analysis accomplished anything, it was to dispel the myth that some of these factors were important and to pinpoint exactly which ones were for each of the different conditions.

CHAPTER V

SUMMARY AND CONCLUSIONS

The study attempted to evaluate the effectiveness of a nutritional counseling program in treating four common medical conditions that can be alleviated through diet thereapy: overweight, underweight, anemia and hypertension. The particular program being evaluated was one that was being carried out through selected family planning projects in the state of Michigan. As such, the choice of these conditions was contingent on certain health considerations involved in providing this service.

The purpose of the study was to find out whether the counseling was actually being effective in alleviating any of these conditions and, in a larger sense, to see what factors outside the counseling itself contribute to or hinder improvement, factors that hopefully might be of use later in improving the program.

Originally, to provide a basis for evaluating each condition, 20% of the patients who would have been counseled were to be randomly selected and held back as a control. However, this only proved to be enough for one category, overweight. While this was due in part to the fact that 20% yielded too few patients in the first place, it was also due to the fact that nearly three-fourths the patients that qualified had to be eliminated for one reason or another. As a result,

the analysis had to rely on a second, less desirable comparison using as a control patients that hadn't been counseled from a county other than the ones where the counseling was taking place. As it turned out, the results of these comparisons appeared to be somewhat biased in favor of the counseling.

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Because of this, and because of certain irregularities in the distribution of the data, the whole question of whether or not the counseling was effective in alleviating any of these conditions could not be satisfactorily answered. There were, at least, a number of factors besides the counseling itself that were found to contribute to improvement. These factors were ones that had been singled out in a cluster analysis that was done to see which variables in a wide assortment of ones measured for the study would cluster together with improvement. For the most part, these factors were highly specific to each separate condition, a somewhat surprising result in that some of the variables had been expected to be important to all four of the separate conditions.

As for the specific results, the one category that could probably best be evaluated was that of overweight, the only one where a full experimental analysis could be done, and that did not support the hypothesis the counseling was effective. In a sense, this wasn't surprising. As Jean Mayer (1968), the most leading authority in the field of the regulation of food intake has noted--

^{. . .} the wonder is not that there should be great diversity of disturbances in the regulation of food intake, producing many different types of obesities and excessive thinness. The wonder is that, in most animals and men, with feeding behavior subject to so many influences, the mechanism of regulation of food intake works so extraordinarily well [p.92].

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Apparently, a short one time encounter with the nutritionist was not enough to counteract the stability of this mechanism in a significant number of women. This would seem to fit with the pessimistic view taken by Feinstein (1960) in his review of what was known about the efficacy of various weight-loss therapies. None apparently worked.

The results of the cluster analysis did not add much to this that was new. While encouraging from a nutritional point of view--those who improved apparently were more likely to be on a high protein, low calorie diet--the results were nonetheless not very enlightening. One of the problems may have been that there was no attempt to differentiate different types of obesity.

In the simplest sense, this was reflected in the fact that no attempt was made to distinguish between overweight and obesity. A 5 foot plumpish woman was treated (statistically) the same as a 5 foot stocky woman who weighed just as much.

In a more sophisticated sense, nothing was done to take into consideration the severity of the problem and how long the patient had had it. Recent evidence has come to light that the dynamics of obesity may be different for people who were overweight as a child versus those who became heavy later on (Hirsch and Knittle, 1970).

In averaging all of these different types together, characteristics which might have been applicable to one and not the other would have been lost. Although being on a high protein, low calorie diet seemed to be applicable to all, a more refined analysis taking factors such as these into consideration might have been more fruitful.

In light of all this, it was that much more surprising to find that the one condition where counseling seemed most likely to have worked was that of underweight. This conclusion, however, has to be qualified because the results could only be based on one county instead of two. While this could be misleading, it seems doubtful that this alone could have completely accounted for what was found.

No doubt part of the reason these women improved was the fact that they were in a better position to follow the advice of the nutritionist. Afterall, for many of these women, being underweight was a conscious effort on their part to be more attractive. A woman who was overweight, on the other hand, was not in such an envious position. Indeed, this was the only case where attitudes about eating seemed to be related to whether or not the woman improved.

It might also be noted in this regard that the Federal regulation stipulating 10% or under the ideal weight as the cut-off for being underweight resulted in a vast number of refusals (and one county being dropped). Some consideration might be given to using a stricter cut-off, like the 20% deviation called for in determining overweight.

The cluster for this category did reveal one variable that seemed to have played an important part in determining who improved and that was being on a birth control pill. Apparently, some of the women who gained the most may have been experiencing a temporary weight gain from being put on the pill.

The case for anemia was less clear. The counseling, if it had any effect at all, was very limited. There was some suggestion

that being on a birth control pill was a factor here too, but the evidence was contrary to what would have been expected. Being on the pill seemed to hinder, not help improvement. Other, more refined research on just this topic has suggested just the opposite to be the case (Burton, 1967).

In the case of hypertension, it seemed unlikely the counseling had any effect. However, an adequate assessment could not be made of the results for this condition. That was because the control patients were found to have a significantly higher diastolic pressure than those who had been counseled. This alone could have accounted for why the controls were the ones who improved the least. Since the results were not significant anyway, it seems doubtful the counseling could have had any effect.

The cluster analysis revealed a definite pattern between those who improved and those who didn't. The ones who improved seemed to be younger, single and more likely to be still living at home or in a college dormitory. On the other hand, all those who didn't, tended to be older, married women with larger families. These women were also more likely to complain of being tired, the only instance where improvement appeared to be related to how well a patient felt.

However, since all of the controls came from a different county and since they were less likely to improve because of their higher diastolic pressure, these differences could be as easily ascribed to differences among the counties as to those who improved and who didn't.

There was, in fact, a consistent pattern in how the three counties differred. On the average, Muskegon patients were generally worse to begin with and almost never improved. Ingham and Saginaw patients, on the other hand, were generally comparable to each other at the outset, but inevitably it was the Ingham patients who improved the most. This does not forbode well for future research of this type. Evaluations, if they are made, may be specific to the particular locale of the program being evaluated. This would mean new evaluations would continually have to be done everytime a program was implemented somewhere else.

This also has serious ramifications for doing quasiexperimental research. Based on the results of the four quasiexperimental analyses alone, the overall level of significance would,
at face value, exceed even the .001 level (Sakoda, et al., 1954).
Yet, this would be very misleading if this general pattern among the
three counties was not known. This suggests that extreme caution
needs to be used whenever a quasi-experimental design must be employed
with these kinds of differences even suspected. Under such circumstances, serious consideration should be given to doing an experimental
analysis instead, even if it has to be somehow limited in scope.

Just as forboding for this type of research was the fact that the results were so often clouded by irregularities in the distribution of the data. Employing a cut-off naturally leads to the kind of skewed distribution that occurred here, but this would seem to be a perfectly normal procedure applicable to many types of situations where an evaluation might be done. More needs to be known about

what effect this has on an analysis of covariance if this technique is to continue to be used in making evaluations of this type.

Regardless of all these problems, it seems doubtful the counseling had much impact. To some extent this discouraging fact may be blamed on the state of the art. As Alice Rivlin(1971), a leading researcher in the field of evaluation has commented in referring to efforts being made in the area of education--"Even when a significant positive relation is found . . . the relationship is generally weak. Indeed, the analyst is pleased to find that there is any relationship at all and that it has the 'right' sign [p.73]."

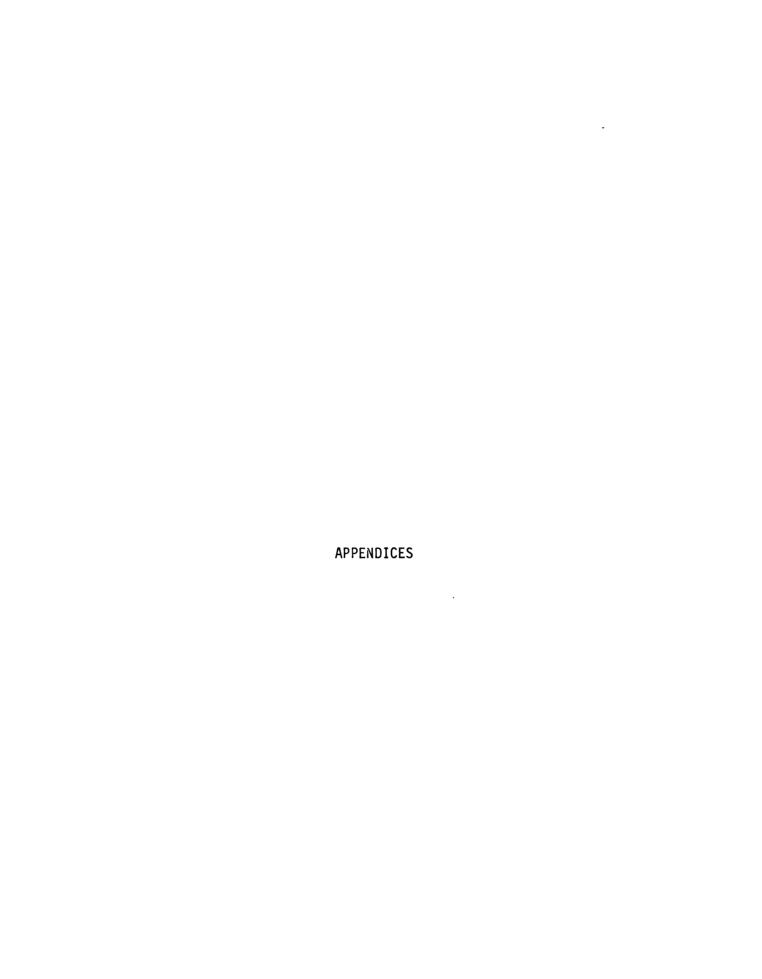
But to some extent too, it may reflect what the counseling is up against. No one expected dramatic results to be found showing that counseling was effective. What the results did show was which of the conditions the counseling seemed to alleviate the most, if only on a relative basis. Not only that, but given the fact so much of what had been presumed failed to be upheld, a new skepticism on the part of the nutritionists seemed to be warranted besides.

Postscript

Six months after the study was completed the results were presented to the staffs in each of the participating clinics as had previously been agreed and to the administrators of the family planning programs at the state level. The reactions varied.

¹¹ As previously explained, see Appendix G for a copy of the signed agreement that spelled out the key obligations of all the parties involved.

Everyone expressed concern that the incidence of these conditions proved higher than expected. Appropriately enough, the County Health Department in Muskegon decided to take a closer look at the incidence of hypertension there. In Saginaw, new approaches were initiated on a trial basis by the nutritionist there to try and find a better way to treat patients who needed to lose weight. In Ingham, the staff tended to disregard the results, as was their prerogative. No doubt this was due, in large part, to the fact the patients from their county appeared to do so much better than those from any other. As for the state administrators, they were concerned most with the high attrition as indicative of a larger problem all the clinics were experiencing in getting patients to return. Given the lackluster results that were found, one couldn't have expected much more.





APPENDIX A

NUTRITIONIST'S DESCRIPTION OF COUNSELING

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NUTRITIONIST'S DESCRIPTION OF COUNSELING

General Methods of Nutrition Counseling

Preceding patient 1:1 counseling, the Nutritionist will note the following information from the patient's chart: height, weight, urine analysis (protein and glucose), Hct, past medical history, and any other pre-disposing medical factors that would influence nutritional judgement. New patients and yearly visit patients are given a screening form to complete, which the nutritionist interprest for R.D.A. The nurses, in 1:1 interview with the patient, use the criteria for nutritional referral. Results of the screening interview and a diet recall, reviewed and evaluated by the nutritionist, identify problem areas.

Nutritional status of the patient is based on the above information, physical appearance, emotional reactions, and the professional judgement of the nutritionist.

The socio-economic factors, educational level of the patient, and motivation of the patient to meet problem areas must be taken into consideration. Counseling then proceeds, 1:1, in a private office setting. A good rapport is first established with the patient by discussing generalities. By asking leading questions, the nutritionist determines where the patient is in the understanding of her problems, and her methods of dealing with them. By asking the patient, "What did you have to eat all day yesterday, including snacks, and is this usually the way you eat?" the nutritionist can determine adequate or deficient diet management.

With all of the above information considered, the nutritionist works through the problem with the patient - a give-and-take relationship, a sharing and helping process, to the level that the patient will accept counseling. This must be done in layman's language, simple terminology used, important points stressed or emphasized when necessary, for effect. The patient is repeatedly asked if she has any questions, or whether she understands, throughout the interview. When counseling has been completed it is important to encourage her to call or come in for additional help if needed. Appointments for follow-up visits are made to coincide with other medical visits.

Follow-up visits for medically indicated problems are made at initial interview, and the necessity of being seen at regular intervals is impressed upon the patient.

Educational materials are made available to all patients.

Counseled patients are given specific materials for specific problems to be used as a point of reference and reinforcement.

Marjorie A. Cook Nutritionist APPENDIX B

EVENT LOG

APPENDIX B

EVENT LOG

June 5, 1972	Briefed staff at Ingham Clinic on proposed study.
June 6, 1972	Briefed staff at Muskegon clinic on proposed study.
June 7, 1972	Briefed staff at Kalamazoo clinic on proposed study.
June 9, 1972	Briefed staff at Saginaw clinic on proposed study.
June 12, 1972	Data collection began in Muskegon.
June 14, 1972	Data collection began in both Kalamazoo and Saginaw.
June 15, 1972	Data collection began in Ingham.
June 23, 1972	Virginia Bradford, the Saginaw nutritionist, returned from vacation. Molly Graber the state nutrition consultant, had been doing the counseling there since June 14.
June 25, 1972	Marjorie Cook, the Ingham nutritionist, goes on week's vacation.
July 7, 1972	Molly Graber in serious car accident outside of Saginaw.
July 11, 1972	Went to Kalamazoo to work out problems over study.
July 14, 1972	Ingham cut back number of clinics a week from 8 to 3 due to budget problems.
July 27, 1972	Kalamazoo dropped from study.
August 14, 1972	Number to be randomly held back for control raised from 20% to 30% in Ingham and Saginaw.
October 2, 1972	Met with Saginaw staff to brief them on preliminary results and discuss what to do about attrition. Asked them to continue program through December.
October 3, 1972	Met with Ingham staff for same reasons as above.
October 23, 1972	Marjorie Cook, Ingham nutritionist, off sick five days.
November 22, 1972	Saginaw Department of Health moving to new location.
December 12, 1972	Molly Graber went to Muskegon to give patients who had been a control counseling if they wanted it. Worst snow of the year.

January 5, 1973 Something major happened at each clinic over the holidays.

Muskegon: Zona Bailey, the director, has blood clot

in leg. Confined to bet for month.

Ingham: Chuck Wolford, the director, leaving as of

January 20.

Saginaw: New director in Saginaw.

February 12, 1973 Presented highlights of study to Floyd Russo of the regional HEW office in Chicago who was in town on business.

February 17, 1973 Marjorie Cook goes on 3 weeks vacation.

March 27, 1973 Gave Muskegon staff a party to celebrate end of study.

April, 1973 Gave Ingham and Saginaw staff a party to celebrate end of study.

October 31, 1973 Presented results to Saginaw staff.

November 2, 1973 Presented results to Ingham staff.

November 5, 1973 Presented results to Muskegon staff.

November 20, 1973 Presented results to state administrators in Family Planning.

APPENDIX C

TABLE OF STANDARD WEIGHT FOR HEIGHT

APPENDIX C

TABLE OF STANDARD WEIGHT FOR HEIGHT* (Height without shoes, plus 1 inch)

<u>Normal</u>	10% Underweight	20% Overweight
4'10" = 104	94	125
4'11" = 107	96	128
5'0" = 110	99	132
5'1" = 113	102	136
5'2" = 116	104	139
5'3" = 118	106	142
5'4" = 123	111	148
5'5" = 128	115	154
5'6" = 132	119	158
5'7" = 136	122	163
5'8" = 140	126	168
5'9" = 144	130	173
5'10" = 148	133	178
5'11" = 152	137	182
6'0" = 156	140	187

^{*}The above weights were taken from Metropolital Life Insurance Company, Acturial Tables, 1959, and adjusted to comply with instructions appearing on the Gain Weight Grid, namely: height in inches without shoes plus 1 inch to establish a standard for heels. Patients should be weighed with shoes as normally worn. The table above is for medium body build and, except for extreme body build deviations, these figures should be used.

For example, a patient whose height, measured without shoes, is 5 feet 4 inches would have one inch added; therefore, her standard weight for height would be 128 pounds.

Ranges are not acceptable in estimating standard weight since this is an objective observation and represents the mid-point. This mid-point must be used for recording purposes.

For patients under age 25 one pound should be deducted for each year.

APPENDIX D

STANDARDIZED REQUEST USED IN ELICITING COOPERATION OF PATIENTS

APPENDIX D

STANDARDIZED REQUEST USED IN ELICITING COOPERATION OF PATIENTS

We are one of four family planning clinics in Michigan that are trying to find ways to expand our services at clinic. One of the ways we are trying to do this is to find out some health needs of our patients.

Some of you will be chosen to help us try to find rew ways to provide better care. We hope that you will be willing and able to work with us during our trial period.

Your help and cooperation will be appreciated.

APPENDIX E

QUESTICHNAIRES

PATIENT RECORD SHEET

Patient No.				Date				
			(1-11)					(12-17)
Clinic:	Ingham	Ш,	Saginaw	- Hghtn	Sel.	راا, St.	. c.	L
		د ا		oo - Elm 🔲	H.D.	LJ ₇		
Patient's a				Height		Weight	• •-	
(For patien one pound s		. •		Normal weight			_	
for each ye				Difference				
(If 36 ml. is eligible				Hematocrit	• •		• •_	(23-21
(If either patient is				Elood pressur				
P20130 15		Tigible for boday.	Systolic			• •_	(25-27	
				Diestolia	· ·		• •-	(25-27
Is patient	part of i	nutritio	n study?	yes Li, no l	(31)			
If she is,	what vis	it is th	is? lst	, 2nd	3rd ((32)		
Comments:								

TO BE FILLED OUT BY NUTRITIONIST IF PATIENT IS COUNSELED

1.	What is your impression of this pa	tient? (Circle one)
	Emotionally very unstable 1 2 3	Emotionally 4 5 6 7 stable (33)
2.	Do you think he will follow your a	dvice? (Circle one)
	Not at all 1 2 3 4	5 6 7 Completely (34)
3.	For which condition or need was th	e patient counseled? (Record number) (35)
	 Normal Family Nutrition Weight Reduction Anemia Diabetes Solium Restriction 	
4.	How was the patient counceled? (P	
	 Initial Interview - 5-15 minut Initial Interview - 16-30 minut Initial Interview - 31-45 minut Initial Interview - 45 or more Follow-up Counceling - 5-15 minut Follow-up Counceling - 16-30 minut Follow-up Counceling - 31-60 minut 	e minutes inutes minutes
۶.	Patient recall based on which day	
	O. Sunday1. Monday2. Tuenday3. Wednepday	4. Thursday 5. Friday 6. Saturday
6.	Scoring	
	Vitamin A (38-39) Vitamin C (40-41) Iron (42-43) Calcium (44-45)	Protein - animal (46-47) Protein - vegetable (48-49) Fat (50-51)
	Food Groups - Servings	
	Vegetable (52) Fruit (53) Meat (54) Milk (55)	Bread/Cereal (56) Snack items (57) Beverages (58)
		luitiala

EATING HABITS

We want to get an idea of how often in the PAST MONTH you ate each of the different kinds of food listed on the next two pages. Several foods are usually listed together. Please check (V) the NUMBER OF TIMES you ate ANY of the foods in the list. Put a check mark on the line under the heading which best shows how many times you usually ate the foods: DAILY, WEEKLY OF MONTHLY.

POR EXAMPLE

once a week and sweet potatoes once a week. Since you eat pumpkin and sweet potatoes EACH once a week, you should Maybe you don't like carrots or winter squash and never eat either of those foods, but you usually do eat pumpkin put a check mark under the 2 under WEEKLY for this group of food. If you didn't eat any foods in a list, in the past month, put a check (</) under NEVER.

Put only one check mark for each list of foods.

Go ahead and start. If you have any questions as you go along, ask one of the clinic staff. They will be glad to belp.

Patient No. (7-11)

Put a check mark on the line under the beading which best shows how many times you usually are ANY of the foods this past month.

	FOOD LISTS	DAILY		
.	Carrots, pumpkin, winter squash, sweet potato	-]	1 1111	(18)
5	Spinsch, kale and other greens, broccoli	1		(19)
.	Brussel sprouts, whole green pepper	j		(20)
4	Cauliflower, cabbage, rutabaga, tomato	j		(21)
'n	Peas, green beans, paranips, lettuce	j		(22)
•	White potato, corn	j		(23)
1	Dried beans, dried peas, lentils, baked beans	j		1 (57)
.	Peanut butter, nuts	j		2 (52)
6	Z888	j	, L 1, L L L L L L L L L L	(36)
10.	Lunch meat, hot dogs, bacon, sausage	j		(27)
n.	Chicken, turkey, lamb, ham	j		(28)
12.	Bamburger, beef, pork, game meats	j		(53)
13.	Liver, heart, kidney, oysters	j	٧ﻝ. ﺑﯩﻨﯘﺳﯘﭖ ﺑﺎﭖ ﭘﯩﻨﯘﭖ ﭘﯩﻨﯘﭖ	(30)
14.	Fish, seafood	j	راسا بالميادي درساد المادين بازسادي	(31)
51	Cantaloupe	j	, 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	(32)
16.	Strawberries, orange, orange and grapefruit juice	j	المارك المارك الراسارك المارك الم	(33)
17.	Watermelon, grapefruit, tangerine, lemon	j	, 1 1 1 1 1 1 1 1 1 1	(34)
18	Apple, banana, pear, peach]	, <u>, , , , , , , , ,</u>	(35)
9 8	19. Prunes, raisins, dates, dried apricots]	1-1 1-16-18-1 1-13-13-13-13-12-13-13-13-13-13-13-13-13-13-13-13-13-13-	(36)

Put a check mont on the line under the booding which best shows how many times you usually ate ANY of the foods this past month.

-		DAILY	WEEKLY	MONTHLY NEVER	
20.	Rice, macaroni, noodles, spaghetti				(37)
21.	Bread, hot dog and hamburger buns, muffin			<u></u>	(38)
22.	Cornbread, tortilla, rolls, crackers	ایا (بایا		<u></u>	(38)
23.	Cream of Wheat, Malt-O-Meal			<u></u>	(o+)
24.	Other hot cereal, cold cereal, grits	لإلاا إلىاليا	1 1 1 1 1 1	۰۰ منا ×امل المال	(41)
25.	Pieza	<u></u>	4-4-4-4-1,	1 1 1	(42)
26.	Cookies, cake, pie, donuts		,	<u> </u>	(643)
27.	Chips, corn curls, popcorn, pretzels	 - -			(77)
28.	Candy, jam, jelly, syrup		,	پاکا ∫یرکاپلیا	(45)
29.	Butter, margarine		,	^_ '_ '_	113 (9†)
30.	Vegetable oil, cooking fats			<u></u>	(47)
31.	Salad dressings, mayonnaise, gravy		الاسايك الإسايك	ابل الإلى الإلى	(87)
32.	Ice cream, milkshake		1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1	1 1 1	(67)
33.	Cheese, cottage cheese, yogurt			<u>, </u>	(20)
34.	Milk, chocolate milk, buttermilk, skim milk		J_1_1_1_1_1,		(51)
35.	Hi C, Koolaid, punch, lemonade	اراً الله الله الله الله الله الله الله ال		<u></u>	(52)
36.	Pop, sods			<u></u>	(53)
37.	Been		1 1 1 1 1	<u></u>	(·호)
38.		<u></u>	1-19-19-19-19-	<u></u>	(55)
39.	Coffee add sugar (34) add anything else		1-19-19-19-5	<u> </u>	(58)
3	Tee add sugar (m) add anything else	<u></u>	1-	<u>'</u>	(61)

١

NOW, JU Put a c	NOW, JUST A FEW QUESTIONS ABOUT YOURSELF AND YOUR FAMILY TO HELP US GET A CLEARER PICTURE OF YOUR EATING HABITS. Put a check mark (~) on the line () that is best. Please fill in the blanks when needed. bl. Do you, yourself, usually prepare the meals in your home?	
	YES How many people, including yourself, do you normally cook forf (3)	
42. Ho	(47) How many meals a day do you usually eat? (65)	
43. Do	Do you usually buy most of the food your family eats?	
8 1	NO Liwho does? (w) Does anybody in your household, including yourself, regularly eat any of their meals away from home?	
	YES [jWho is it and what meals are usually eaten out?	
45. Ha	(6) Bave you ever had anyone, other than friends and family, talk to you about your diet?	
	YES Who? How long ago was this? Was this in your home, here or elsewhere? Home, Here	
₩. A z	(w) Are you now getting food stamps?	
14. Az	Yes [_], How much do you pay to get your stamps? \$ No [_], (73) (73) Are you now taking any from bills or from liquid?	
	YES [_] How often? NO [_], (76) What was the level of vour family's income last wear?	
	\$8,000 - \$9,999 \(\begin{array}{cccccccccccccccccccccccccccccccccccc	89

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Patient No.

We would like to get some idea from you about how well you feel. Below are listed several statements people sometimes use to tell how they feel. Read each one and see whether or not you ever feel that way. Put a check mark on the line under the heading which best shows how often you feel that way.

	•	Never		Once in Sometimes Often	Often	All the	
ä	1. The slightest thing I do makes me so tired I want to lie down and rest	j	j	j	ĵ		(18)
8	2. Even after I've had a big meal, I still feel hungry an hour later.]	j	J [*]	ĵ	<u> </u>	(19)
m	3. I'm nervous and irritable. I just can't seem to relax	J	J	֖֖֖֖֖֖֖֖֖֖֖֖֖֖֖֖֓֞	ĵ	j	(%)
4	4. I feel headachy and out of sorts].	٦	֖֖֖֖֖֖֖֖֖֖֖֖֖֖֖֓֞֞	了	j	(21)
ķ	5. I feel fine. Nothing really ails me '	·j	j	ĵ	j	(23)	(22)
•	6. My stomach gets upset easily	j	j	j	ĵ	j	(23)
7.	7. I feel kind of dizzy and faint, especially when I get up too quickly.	j	j	ĵ	j	(§)	(57)
ထံ	8. I just can't seem to catch my breath after I do even the simplest things.	J		֖֡֟֞֞֟֟֝֟֟֝֟֟֟ ֖֖֓֞֞֞֞֓֞֞֞֜֞֞֞֞֩֞֞֞֜֞֞֞֜֞֞֞֞֞֞֞֞֞֡	ĵ		(25)
P	Put a check mark (V) on the line which is best. Please fill in the blanks when needed.	lanks who	en needed				

. Overall, how would you describe your present state of health?

j	(30)
Excellent	
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YES C, What?

NO (28)
(27)
Please turn this page over for a few more questions.

116

				. •						
]] 2						•			
ង	12. Not counting your visit here today, how many times in the past month have you seen a doctor, a nurse or a medical aide of some kind?	ur visit here	e today, ho	ow many time	es in the I	est month	have yo	n seen s	doctor,	P DUFSO
		OI	1-2 times	3-4	5 or more times	a)				
	A doctor	·]	j	֖֖֖֖֖֖֖֖֖֖֖֖֓֞	<u>,</u>	(30)	•		: 3	•
	A nurse	ĵ	j	֖֖֖֖֖֖֖֖֖֖֖֖֖֓֞	(E)	(31)	• .	•	•	:
. <u> </u>	An aide	Ĵ	ĵ		ĵ	(33)	•			•
	Have you had any	u had any serious illnesses in the last few years?	Inesses in	the last for	ew years?	·		•	 	•
	YES [], What?	lat?				٠		,	•	•
] 2		•		(34)	•		 د		•
7	If you smoke, ho	smoke, how many packs a day do you smoke?	s a day do	you smoke?		01/	•			•
	Is this fil	this filter or non-filter? Filter [], Non-Filter []	filter? Fi	11ter [,]	Non-Filter			;		
15.	What form of birth control have you currently been using?	rth control	have you co	urrently be	en using?			•		:
			•			• •	•	:		
	u II uc	(If "none", skip the next question.) (37)	he next que	estion.)		•			•	•

6. How long have you relied on your present form of birth control?

L. Less than 1 month
1 - 3 months
2 - 6 months
L. 6 months - 1 year
L. 1 - 2 years
(38)

THANK YOU FOR ANSWERING ALL OF OUR QUESTIONS.

ever feel that way. Then put a checkmark on the line under the heading which best shows how often you feel Listed below are several different ways people feel about eating. Read each one and see whether or not you that way.

_	Even if I know something is good for me, I won't eat it unless I really like it.	I'll eat foods I don't especially like, if I think they would be good for me.	It really doesn't matter whether or not something is good for me, I only eat that any set		I try to eat only foods that I know are good for me.	What I eat makes a difference in my health.
ALWAYS	j	j		j]	ĵ	j
OFTEN	Ţ	ĵ	•	ĵ	J	j
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NEVER	(66)	j		j	j	
	(39)	(07)	(%)		(42)	(643)

THANK YOU FOR ANSWERING ALL OF OUR QUESTIONS.

APPENDIX F

RANKINGS OF BRANDS OF ORAL CONTRACEPTIVES
BY POTENCY

APPENDIX F

RANKINGS OF BRANDS OF ORAL CONTRACEPTIVES BY POTENCY^a

<u>Rank^b</u>	Brand Name	Manufacturer
1	Ovral - 23	Wyeth
2	Ortho-Novum 1/50 20 or 21	Ortho
3	Norinyl 1mg 21 or 28 day	Syntex
4	Demulen	Searle
5	Norlestrin Fe or Norlestrin 21 lmg	Parke-Davis
6	Ortho-Novum 1/20 21	Ortho
7	Ovulen, Ovulen 21 or 28	Searle
3	Ortho-Novum Sq Tablets	Ortho
9	Ortho-Novum Tablets 2mg	Ortho
10	Norlestrin 21 2.5mg	Parke-Davis
11	Enovid-E	Searle
12	Enovid 5mg	Searle
13	Ortho-Novum Tablets 10mg	Ortho
14	Oracon	Mead-Johnson

^aRanks based on amount of Estrogen and Progestogen per tablet.

bRanked low to high with least potent brand given a rank of 1.

APPENDIX G

SAMPLE OF WRITTEN AGREEMENTS

APPENDIX G

SAMPLE OF WRITTEN AGREEMENTS

AGREEMENTS

THE FOLLOWING AGREEMENT HAS BEEN DRAWN UP BETWEEN ALL INTERESTED PARTIES WITH REGARDS TO A STUDY BEING CONDUCTED IN INGHAM, SAGINAW, MUSKEGON AND KALAMAZOO FAMILY PLANNING CLINICS. THE STUDY IS BEING CARRIED OUT IN AN EFFORT TO DETERMINE THE NUTRITIONAL STATUS OF PATIENTS AND TO ASSESS THE EFFECTS OF NUTRITIONAL COUNSELING AMONG WOMEN WHO COME TO ANY OF THE ABOVE CLINICS EVIDENCING ANY OF THE FOLLOWING HEALTH CONDITIONS: HIGH BLOOD PRESSURE, LOW HEMATOCRIT, OVER OR UNDER WEIGHT. TO INSURE THAT THE EXTRA TIME, EFFORT AND RESOURCES CONTRIBUTED BY EACH OF THE PARTIES INVOLVED IN MAKING THE STUDY POSSIBLE ARE NOT DEPRECIATED IN ANY WAY DUE TO MISUNDERSTANDINGS, THE FOLLOWING RESPONSIBILITIES OF EACH ARE HEREBY AGREED TO:

ON THE PART OF THE ADMINISTRATOR AND STAFF OF THE Thighan County

1) all mutually agreed upon medical procedures for taking blood pressures, hemtocrits, height and weight shall be adhered to.

- 2) all questionnaires shall be checked to see if they are filled out as completely and accurately as possible and the above medical measurements accurately recorded with the patient number and date properly designated.
- 3) an accurate record shall be kept of the patients included in the study and that a concerted effort be made to get <u>all</u> patients participating in the study to come back for their follow-up visits.

- 4) all data (including MDPH's form entitled Family Planning Record Visit) shall be released to the research consultant.
 (#5 and #6 apply only to Ingham and Saginaw where counseling is to take place)
- 5) twenty per cent of the patients eligible for counseling shall be randomly selected and held back for a control as per the agreed upon procedure.
- 6) Physicians shall not be advised to counsel any of these twenty per cent about their eating habits. Physicians may, however, do so on their own initiative.

On the part of the research consultant --

- under no circumstances shall the names of any patients be divulged with any of the data collected for this study.
- 2) copies of all reports that are issued discussing the results will be made available to each clinic.
- 3) everything possible shall be done to see that the results of this study are used as a basis for improving the nutritional services at the clinics.

On the part of the maternal nutrition consultant --

- 1) assistance in nutritional counseling shall be provided to
 - a) Ingham and Saginaw when their nutritionists go on vacation and, if necessary, after August 12 when the patient load increases because of revisits of patients participating in the study.
 - 2) everything possible shall be done to see to it that the results of this study are used as a basis for improving the nutritional services at the clinics.

THESE AGREEMENTS SHALL BE IN EFFECT DURING THE SIX MONTHS THE STUDY IS EXPECTED TO BE RUN, BEGINNING THE WEEK OF JUNE 12, 1972 AND ENDING THE WEEK OF DECEMBER 12, 1972.

Spiletes (file) Poset Camina.

Mayon a Olesale Clinic Coorden

Pesearch consultant

Maternal nutrition consultant

APPENDIX H

FINAL SAMPLE SIZES WITHIN EACH COUNTY
FOR EACH SEPARATE HEALTH CONDITION

FINAL SAMPLE SIZES WITHIN EACH COUNTY FOR EACH SEPARATE HFALTH COMDITION

Medical Condition Qualifying Patient

		Over- Weight		Under- Weight		Anemia	Hypertension	ion
Muskegon Total Patients Screened 739 Not Qualified 329 Qualified, but eliminated 73 Qualified and returned 326		112 16 96		45		115 26 89	12.7 24 103	
Counseled Not Counseled	326		96		38		89	103
Saginaw Total Patients Screened 1,268 Not Qualified 815 Qualified, but eliminated 178 Qualified and returned 275 Counseled Not Counseled	224 51	222 73 149	32	105 72 33	22	90 20 70	36 13 23 62 8	23
Ingham Total Patients Screened 1,057 Not Qualified 652 Qualified, but eliminated 190 Qualified and returned 215 Counseled Not Counseled	163 52	172 65 107	83 24	143 88 55	36	48 20 28	42 17 17 25 3	91 9

^aPatient either refused or never returned or had to be rejected for some reason.

APPENDIX I

DEMOGRAPHIC DIFFERENCES BETWEEN SAMPLES

APPENDIX I

Table II. Demographic Differences Between Returning Counseled and Control Overweight Patients from Ingham and Saginaw Counties

			Co	untv				
Demonstrie	Ing	gham			Sag	inaw		
Demographic Characteristic	Counseled	Control	df	t	Counseled	Control	df	t
Age	23.7	24.9	56	NS	23.0	21.1	60	NS
Education	11.3	11.2	50	ИS	11.2	11.9	55	NS
No. of Children	1.6	3.2	42	2.39 ^a	1.8	1.1	57	NS
Income	\$5,759	\$4,666	39	NS	\$5,706	\$5,155	53	NS
No. Supported by Income	3.4	4.3	44	NS	4.1	2.6	55	NS
Medicaid (%)	28.9	41.7	56	NS	39.4	25.0	58	NS

^aSignificant at the .05 level

NS: Not Significant

Table I2. Demographic Differences Between Overweight Patients Who Returned With Those Eliminated from Ingham and Saginaw Counties

			Cou	inty			· · · · · ·	
Demographic	Ing	ham			Sag	ginaw		
Characteristic	Counseled	Control	df	t	Counseled	Control	df	t
Age	24.0	24.1	142	NS	22.7	25.0	221	NS
Education	11.3	11.2	155	NS	11.3	11.1	203	NS
No. of Children	1.8	1.4	160	NS	1.7	1.9	205	NS
Income	\$5,459	\$5,050	117	NS	\$5,634	\$5,338	195	NS
No. Supported								
by Income	3.6	3.2	130	NS	3.8	4.1	200	NS
Medicaid (%)	33.7	31.6	157	NS	28.8	28.4	206	NS

Table I3. Demographic Differences Between Returning Overweights That Were Counseled from Ingham and Saginaw Counties and the Controls from Muskegon County

Age Education No. of Children Income No. Supported by Income	Group Pat	ient Belonged:		
Characteristic	Counseled	Control	df	t
Age	23.3	23.4	113	NS
Education	11.2	11.6	103	NS
No. of Children	1.7	1.6	90	NS
No. Supported by Income	\$5,726	\$3,952 2.9	82	2.04 ^a
Medicaid (%)	29.2	50.0	113	NS

^aSignificant at the .05 level.

Table I4. Demographic Differences Between Overweights Who Returned With Those Eliminated from Muskegon County

Demographic	Status	of Patient		
Characteristic	Eliminated	Returned	df	t
Age	22.8	23.4	111	NS
Education	11.3	11.6	101	NS
No. of Children	1.6	1.6	104	NS
Income	\$4,723	\$3,952	48	NS
No. Supported by Income	3.7	2.9	53	NS
Medicaid (%)	33.0	50.0	103	NS

NOTE: Missing data accounts for the variation in the degrees of freedom.

NS: Not Significant

Table I5. Demographic Differences Between Returning Counseled and Control Underweights from Ingham County

Demographic	Group Patient	Belonged To		
Characteristic	Counseled	Control	df	t
Age	22.1	19.8	27	NS
Education	12.0	10.8	26	NS
No. of Children	1.1	0.7 \$4,043	26	NS NS
No. Supported by Income	2.6	3.0	18	NS
Medicaid (%)	47.1	50.0	24	NS

Table I6. Demographic Differences Between Underweights Who Returned With Those Eliminated from Ingham County

Demographic	Status of	Patient		
Characteristic	Eliminated	Returned	df	t
Age	22.1	21.3	142	NS
Education	12.6	11.6	131	NS
No. of Children	.9	.9 \$3,605	131 95	NS NS
No. Supported by Income	2.1	2.7	102	NS
Medicaid (%)	26.0	48.0	128	NS

Table I7. Demographic Differences Between Returning Underweights That Were Counseled from Ingham County and the Controls from Muskegon County

Demonstria	Group Pati	ent Belonged To	engga denteng gijangkayan dan jangke ter	
Demographic Characteristic	Counseled	Control	df	t
Age	22.1	25.6	25	NS
Education	12.0	11.9	24	NS
No. of Children	1.1	2.0	24	NS
Income	\$3,480	\$2,704	16	NS
No. Supported by Income	2.6	2.5	15	NS
Medicaid (%)	47.1	0.0	23	2.40 ^a

^aSignificant at the .05 level.

Table I8. Demographic Differences Between Underweights Who Returned With Those Eliminated from Muskegon County

Domographic	Status of 1	Patient		
Demographic Characteristic	Eliminated	Returned	df	t
Λge	21.0	25.6	44	3.40 ^b
Education	11.2	11.9	43	NS
No. of Children	1.1	2.0	44	NS
Income	\$4,223	\$2,704	20	NS
No. Supported by Income	2.3	2.5	17	NS
Medicaid (%)	15.8	0.0	44	NS

^bSignificant at the .01 level.

Table 19. Demographic Differences Between Returning Anemics That Were Counseled from Ingham and Saginaw Counties and the Controls from Muskegon County.

Domographia	Croup Potion	t Belonged To		
Demographic Characteristic	Counseled	Control	df	t
Age	23.3	20.7	70	NS
Education	11.7	10.8	67	2.20 ^a
No. of Children	1.3	1.5	67	NS
Income	\$5,347	\$3,528	45	NS
No. Supported by Income	3.3	2.8	44	XS
Medicaid (%)	40.9	54.2	67	NS

^aSignificant at the .05 level.

Table IIO. Demographic Differences Between Anemic Patients Who Returned With Those Eliminated from Ingham and Saginaw Counties

	1						
			Cour	ity			
D	Ing	ham			Sag	Saginaw	Saginaw
Demographic Characteristic	Eliminated	Returned	df	t	Eliminated	Eliminated Returned	Eliminated Returned df
Λge	23.6	23.6	38	NS	23.0	23.0 23.1	23.0 23.1 73
Education	12.2	11.7	38	NS	11.4	11.4 11.2	11.4 11.2 67
No. of Children	1.0	1.4	38	NS	1.6	1.6 1.4	1.6 1.4 67
Income	\$5,539	\$4,477	27	NS	\$5,197	\$5,197 \$6,292	\$5,197 \$6,292 64
No. Supported							
by Income	2.8	3.0	20	NS	3.7	3.7 3.7	3.7 3.7 64
Medicaid (%)	47.4	25.0	38	NS	36.0	36.0 23.3	36.0 23.3 67

Table III. Demographic Differences Between Anemics Who Returned With Those Eliminated from Muskegon County

Demographic Characteristic	Status of	df	t	
Age	21.2	20.7	114	NS
Education	10.6	10.8	109	NS
No. of Children	1.6	1.5	112	NS
Income	\$3,843	\$3,528	44	NS
No. Supported	:·			
by Income	3.3	2.8	44	NS
Medicaid (%)	45.3	54.2	109	NS

Table II2. Demographic Differences Between Returning Hypertensives That Were Counseled from Ingham and Saginaw Counties and the Controls from Muskegon County.

Demographic	Group Patier			
Characteristic	Counseled	Control	df	t
Age	25.7	27.1	45	NS
Education	11.3	11.7	43	NS
No. of Children	1.4	2.2	43	NS
Income	\$4,739	\$4,378	33	NS
No. Supported by Income	3.3	3.8	32	NS
Medicaid (%)	38.0	34.8	43	NS

Table II3. Demographic Differences Between Hypertensives Who Returned With Those Eliminated from Ingham and Saginaw Counties

		C	ounty	7				
	Ingham				Saginaw			
Demographic	Status of Patient				Status of Patient			
Characteristic	Eliminated	Returned	df	t	Eliminated	Returned	df	t
Age	28.7	25.5	28	NS	31.3	26.0	30	NS
Education	12.4	11.3	25	NS	11.0	11.3	29	NS
No. of Children	.8	.8	26	NS	1.8	2.0	28	NS
Income	\$4,238	\$5,021	18	NS	\$5,226	\$4,654	29	NS
No. Supported by Income	2.8	2.8	18	NS	3.6	3.6	29	NS
Medicaid (%)	44.4	22.2	25	NS	16.7	16.7	29	NS

Table I14. Demographic Differences Between Hypertensives Who Returned With Those Eliminated from Muskegon County

Demographic	Status of 3				
Characteristic	Eliminated Returned		df	t	
Age	24.3	27.1	126	NS	
Education	11.0	11.7	121	NS	
No. of Children Income	1.9	2.2	120	NS NS	
	\$4,403	\$4,378	37	142	
No. Supported by Income	3.3	3.8	58	NS	
Medicaid (%)	31.7	34.8	123	NS	

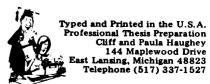


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