Effect of a Maternal Dietary Restriction Program on Postpartum Weight Reduction in Well-Nourished Lactating Women

By

Amy B. McElroy

A master’s research project submitted in partial fulfillment of the requirements for the degree of

MASTER OF NURSING

Whitworth College

Intercollegiate Center for Nursing Education

April 1997
To the faculty of Whitworth College:

The members of the committee appointed to examine the clinical project of

AMY B. MCELROY,

find it satisfactory and recommend that it be accepted.

Lorna Schumann
Chair

Marian Sheglo

Renee Naepel
Acknowledgments

I would like to thank the members of my committee, for all of their time and energy spent revising and reviewing my project, and for all of their words of encouragement!
Abstract

The purpose of this study is to measure the effect of maternal diet on changes in maternal weight and body composition in well-nourished lactating women during the first eight weeks postpartum. The goal is to promote a healthy rate of maternal weight reduction, while maintaining successful lactation and infant growth on the prescribed diet.
# TABLE OF CONTENTS

Acknowledgements ................................................................. ii

Abstract ............................................................. iii

Chapter 1 ................................................................. 1

Introduction to the Problem ...................................................... 1

Statement of the Problem ...................................................... 2

Statement of Purpose .......................................................... 3

Literature Review .............................................................. 3

Research Questions ............................................................ 6

Definition of Terms ............................................................. 6

Significance to Nursing ......................................................... 7

Chapter 2 ................................................................. 8

Method of Study ............................................................... 8

Type of Design ............................................................... 8

Setting for Study ............................................................. 8

Population and Sample ....................................................... 9

Data Collection Procedure .................................................. 9

Instrumentation; Reliability and Validity .................................. 12

Data Analysis ............................................................... 14

Human Subjects Considerations ............................................. 15
References ................................................................. 16
Appendixes ................................................................. 20
  A. Review of Literature ............................................... 20
  B. Breast Feeding Handouts ......................................... 27
  C. Dietary Recording Data ............................................ 32
  D. Demographic Data .................................................. 35
  E. Consent Form ....................................................... 39
  F. Institutional Review Board ....................................... 43
CHAPTER 1

Introduction to the Problem

A frequent concern among new mothers is whether they will be able to lose the weight gained during pregnancy. Most postpartum women carry an additional 2-4 kg of fat, compared with their prepregnant weight (Manning-Dalton & Allen, 1983). For mothers who do retain weight postpartum, the increased energy need of breast feeding may offer an opportunity to lose this additional weight more rapidly. However, there is conflicting evidence as to whether breast feeding alone leads to more rapid weight loss postpartum, with the majority of the most recent literature concluding that it does not aide in overall weight reduction when compared with non-lactating women (Dewey, Heinig, & Nommsen, 1993).

It has been proposed instead, that in order to lose weight more rapidly, postpartum breast feeding mothers must be attentive to dietary intake. However, there is lack of firmly set dietary guidelines for lactating women, making it difficult for health care providers to know how much to recommend, as well as for mothers to know how much they can cut back without jeopardizing their infants well-being. This concern has only recently prompted research in the effects of dieting on lactation. In three similar research investigations from 1984 to 1994, it was documented that successful lactation could be maintained with a reduced maternal dietary intake of 1591-2186 kcal/day (Butte, Garza, Stuff, Smith, & Nichols, 1984) (Strode, Dewey, & Lonnerdal, 1986) (Dusdieker, Hemingway, & Stumbo, 1994).

Although it has been determined that dietary intake can be somewhat restricted
without adversely affecting milk production, further investigation is needed, in order to
better define the dietary guidelines. For the woman who desires weight loss while breast
feeding, health professionals must be prepared to educate them on a diet sufficient in
calories to maintain successful breast feeding, infant growth, and maternal health, while
allowing for weight loss at a healthy pace.

Statement of the Problem

Many postpartum mothers report being concerned about losing the weight they
gained during pregnancy. But for the lactating postpartum woman, she in addition is
concerned about maintaining her nutrition in order to nourish her baby. Therefore, due to
a woman’s lack of knowledge regarding a proper diet to follow during breast feeding, she
may consume more calories than needed, consequently not achieving the desired weight
loss. Not surprising then is the report made by multiple studies that lactating women
consume more kcal than non-lactating women (Sadurski, Kubir, Wagner, & Forsum,
1988; Brewer, Bates, & Vannoy, 1989). There is a lack of consistency in the dietary
guidelines for lactating women, ranging from 2316 kcal/day (Strode et al., 1986), 2700
kcal/day (National Research Council, 1989), 2800 kcal/day (Institute of Medicine, 1991)
to 2886 kcal/day (World Health Organization, 1985). All of these recommendations are
encouraged, regardless of the fact that when recorded, lactating women consume well
below that amount (2055-2280 kcal per day) as reported by Butte et al. (1984), Strode et
al. (1986), and Dusdieker et al. (1994).

Several studies have indicated that the recommended dietary intakes for lactation
are too high, and that successful lactation is presumed to be possible with a reduced
calorie intake. However, only three studies have evaluated how placing dietary restrictions on lactating women would effect milk production and composition, as well as the rate of postpartum weight loss. All three of the aforementioned studies recommended further investigation, to better define a safe level of dietary restriction.

Statement of Purpose

The purpose of this study is to measure the effect of maternal diet on changes in maternal weight and body composition in well-nourished lactating women during the first eight weeks postpartum. The goal is to promote a healthy rate of maternal weight reduction, while maintaining successful lactation and infant growth on the prescribed diet.

Literature Review

Research examining the effect of breast feeding on weight loss is inconsistent. (See Appendix A -Table 1) Some studies have shown that breast feeding leads to a significantly faster loss of body weight (Brewer et al., 1989; Dugdale & Eaton-Evans, 1988; Kramer, Stunkard, Marshall, McKinney, & Liebschultz, 1993), in the early postpartum months. Several other studies have reported a relatively weak association between breastfeeding and postpartum weight changes (Schauberger, Rooney, & Brimer, 1992; Ohlin & Rossner, 1989; Potter et al., 1991). Sadurskis et al. (1988), found that total average body fat content was unchanged during the first 2 months of lactation. Rookus’, Rokebrand, Burema, & Deurenberg’s (1987) results suggest that maternal obesity may be associated with breastfeeding for long periods. A number of studies have reported that by 12 months postpartum, the differences in weight loss between lactating
and non-lactating women is not significant (Ohlin & Rossner, 1989; Dugdale et al., 1988; Potter et al., 1991).

A second set of research was examined to address the issue raised by several researchers, suggesting that the current Recommended Dietary Allowances (RDA’s) for lactating women are too high (Manning-Dalton & Allen, 1983; Butte et al., 1984; Brewer et al., 1989; Sadurskis et al., 1988). (See Appendix A -Table 2) Many studies report lactating women as consuming more kcal than non-lactating women (Sadurskis et al., 1988; Brewer et al., 1989; Manning-Dalton & Allen, 1983), ranging from 2055 to 2280 kcal per day, still well below the recommended 2,700 kcal/day. Other studies have indicated that there is no net loss of fat in the initial postpartum period in lactating women, rather a redistribution of fat within the body. Therefore, if dietary intake is too high, this redistributed fat will not be metabolized and weight loss will not occur. Successful lactation has been shown to be possible in research trials, with a reduced calorie intake (Butte et al., 1984; Strode et al., 1986).

Only three studies have examined the effects of weight loss on lactational performance. Butte et al., (1984), studied 45 lactating women for 4 months postpartum to examine the relationship between milk production, dietary intake, and body composition. Mean maternal dietary intake in this study was 2186 kcal/day, consisting of 17% from protein, 37% from fat, and 46% from carbohydrates. The mean weight loss in his study was 3.8 kg during the first month, followed by a modest decline of .67 kg/month. Skinfold measurements including triceps and biceps did not change significantly, however supra iliac and subscapular measurements decreased significantly over time.
Milk production, in terms of quantity and quality, and infant growth were satisfactory by current standards. His results showed that successful lactation was compatible with gradual weight reduction and attainable with dietary intakes less than current recommendations.

The second study examining the effects of weight loss on lactational performance was done by Strode, et al. (1986). This study measured milk volume and composition, nutrient intake and plasma prolactin levels in 22 well nourished lactating women during a three week period. An experimental group reduced dietary intake by a mean of 32% during week 2, while the control group maintained normal intake. The mean maternal dietary intake of the experimental group during week 2 was 1591 kcal/day (21% from protein, 32% from fat and 47% from carbohydrates) and 2121 kcal/day for the control group. Milk intake or composition was not reduced among infants of mothers whose dietary intakes were at least 1500 kcal/day during week 2. Their results showed that lower dietary intakes than those currently recommended appear compatible with successful lactation and gradual maternal weight loss of approximately 0.5 kg per week, but that longer-term studies are needed to determine a lower limit for safe intakes.

The final study by Dusdieker, et al. (1994), observed 33 well-nourished lactating women over a 10 week study. Mean prescribed dietary intake was 1975 kcal/day (23.4% reduction from mean baseline dietary intake of 2303 kcal/day). On the energy restricted diet, maternal intakes met the recommended dietary allowances for the micro nutrients examined in the study, except iron (90%) and thiamin (95%). Total mean weight loss was 4.8 kg over the 10 week period. Skinfold thickness, waist and hip measurements
significantly decreased. The decrease in maternal weight and skinfold thicknesses all occurred while milk production increased and infants gained a mean of 1.48 kg during the 10 week study. Their results showed that well-nourished lactating women can lose weight at a rate of 0.45 kg/wk while supplying adequate milk to maintain their infant’s growth.

These three studies conclude that milk production and nutritional content of breast milk is un-affected by maternal dietary restriction. Given these results, this study will concentrate solely on the effect of maternal dietary restriction on weight changes.

Research Questions

This study will examine the following hypotheses:

1. The energy restricted experimental group will have a statistically significant greater weight loss than the control group as evidenced by electronic scale readings.

2. The energy restricted experimental group will have a statistically significant greater loss of body fat as evidenced by anthropometric skinfold measurements.

3. There will be no statistically significant difference in weight gain between the experimental group newborns and the control group newborns.

Definition of Terms

In this study, breast feeding will be defined as nursing a baby at the breast and will be considered the babies sole form of nourishment.

Maternal weight loss will be defined by the bi-weekly weight reductions observed using a standardized, calibrated, electronic scale.

Anthropometrics, or the measurement of the human body, will be defined in this
study to include the measurements of weight and skinfold measurements including triceps, subscapular, suprailiac, and abdominal regions.

**Dietary restriction** will be defined as the amount of nutrients withheld from the breast feeding mother in an attempt to lose weight. Maternal dietary restriction will be further defined as the caloric restriction necessary to achieve the desired rate of weight loss (.45 kg/wk), while maintaining the proportion of calories from protein, fat, and carbohydrates. Energy intake will be recorded on a 2-day per week food diary, which will then be analyzed for nutritional content using the Nutritionist 4 computer program.

**Significance to Nursing**

Weight loss at any point is very difficult and frustrating. This is especially true with the new mother who is simultaneously faced with caring for her new baby, possibly returning to work, and numerous other demands. Restricting dietary intake is one way of speeding the return to prepregnant weight, which breast feeding mothers can consider.

Health care providers must be sensitive to the weight concerns of postpartum mothers. In order to provide sound advice to such women, health care providers need to understand the factors that promote weight loss and the weight loss patterns that generally occur. In addition, the risks and benefits of dieting while breast feeding need to be accurately relayed to women so that they can make healthy decisions.
CHAPTER 2

Method of Study

The purpose of this study will be to measure the effect of maternal diet on changes in maternal weight and body composition in well-nourished lactating women during the first eight weeks postpartum. The effectiveness of instituting a dietary restriction program on one group of experimental postpartum mothers, will be compared with a control group of lactating postpartum mothers who will not actively restrict their dietary intake.

Type of Design

A 8 week quasi-experimental, repeated measures design using Friedman’s analysis of variance will be used in this study. Subjects will be given the option of being assigned to an experimental group, which will follow the dietary restriction procedures, or to a control group, which will not restrict their dietary intake. The independent variable will be caloric intake. The dependent variables will be maternal weight change and anthropometric changes.

Setting for Study

Initially, potential subjects will be identified in the prenatal period, through advertising in local childbirth education classes. Following delivery, in a 365-bed tertiary care hospital in the Inland Northwest, interested subjects that meet the preliminary criteria, will be interviewed, consented, and weighed in the hospital by the investigator. The remainder of the study procedures will be performed in the homes of the participants.
Population and Sample

The population for this study will consist of 46 well-nourished [BMI in kg/m² > 19] lactating women, who have gained at least 11 kg during pregnancy, and who will be exclusively breast feeding their infant on a demand schedule, with an intent to do so for at least 2 months. Additional criteria for involvement will be parity of one or two, healthy, as defined by absence of chronic illness, chronic medications, mental illness or past eating disorder. Subjects will also be required to be educated in English and to be non-smokers. Control group mothers will be required to meet all of the above criteria, but in addition, not be actively trying to lose weight.

Eligible infants will have to be born at term at an appropriate or large for gestational age, free of chronic illness or congenital abnormalities, and the product of a singleton gestation. The infant will need to be consuming only breast milk as a nutritive source with height and weight at or above the 5th percentile.

Data Collection Procedure

The initial screening for interested breastfeeding subjects will be performed by the investigator within the first 24 hours postpartum, before her return to home. Basic breastfeeding skills will be reviewed and reinforced with informational handouts provided by the investigator (see Appendix B). Anthropometric measurements on the mother and infant will be performed. Dietary recording data, logs, and a dietary scale will be provided at this time (see Appendix C), but will not be reviewed with the participant until the second week telephone interview.

During this initial screening, each subject's height, pregravid weight, and weight
gain during pregnancy, labor and delivery history, and infant status will be collected from their medical records. Participants will be oriented to study procedures and consented to the study protocol. Additional selection criteria and demographic data will also be obtained at this time (see Appendix D). Over the remainder of the study, each woman will be interviewed in her home on 3 separate occasions by the investigator at 4, 6, and 8 weeks postpartum.

At the initial hospital visit and at each subsequent home visit, each mother and infant will be weighed and measured on a calibrated electronic digital scale. Weights will be converted to the nearest 0.1 lb, and converted to kg prior to statistical analysis. The mothers triceps, suprailliac, subscapular, and abdominal skinfold thicknesses will be measured by the investigator using a Lange caliper (Cambridge Scientific Instruments, Cambridge, MD). Three repeat skinfold thickness readings will be made at each site, and an average value will be recorded at each home visit. Waist and hip measurements will also be obtained on the mother, and will be measured in triplicate using a plastic tape, and recorded to the nearest 0.25 cm.

At approximately 2 weeks postpartum, interested subjects who meet the above selection criteria will be contacted for a phone interview, during which the proper diet recording technique and study procedures will be reviewed. At this time, subjects will be given the option to be included in either an experimental (E) group, which will follow the dietary restriction program, or in a control (C) group.

Each mother will be instructed in the proper diet recording technique and will be reminded of the use of her dietary scale. They will be instructed to record the time of day
each food or beverage is consumed, and the amount and specific type of food, including the brand name and the method of preparation. All foods that are not packaged in standard portion sizes will be weighed, and labels from all packaged foods they consumed will be saved for later evaluation by the investigator. The mothers will then be asked to record a preliminary 5-day dietary record of their usual intake, including all foods/beverages consumed. At the completion of this 5-day diet baseline, the investigator will calculate the composition of the diet to determine total energy, carbohydrates, fat, protein, and micronutrients using the Nutritionist 4 computer program. Thereafter, weekly 2-day diet diaries will be recorded by mothers, reviewed at the home visits for accuracy, and again by the Nutritionist 4 program for nutrition adequacy.

During week 4, all procedures will be identical, except that the experimental group (E) will reduce their calorie intake for the remainder of the study. Guidelines will be given to each mother to achieve the desired calorie reduction, while maintaining the proportion of calories from protein, fat and carbohydrates. This information will be made available from the Weight Reduction Program portion of the Nutritionist 4 nutrient analysis program. The information supplied to participants will include their desired meal plan with groups of exchange lists of foods to be interchanged for variety. (See Appendix C). Dietary intake will be reduced and the women will be helped to identify and modify eating behaviors contributing to excessive dietary intake. Educational training used to promote weight loss will include the following: 1) goal setting, 2) record keeping of food intake and weight loss, 3) positive reinforcement of weight loss, 4) and education about the diet program.
Instrumentation: Reliability and Validity

Diet Record.

The method chosen to collect dietary intake data in this study will be a weekly 2-day dietary record, followed by a computer generated analysis of dietary intake data using the Nutritionist 4 system (Frank-Stromberg, 1988). The advantages of dietary record, according to Frank-Stromberg (1988), are (1) memory or ability to recall is not relied on to as great an extent, (2) serving size data may be more accurate if subjects measure or weigh food, (3) data may be obtained for a longer period of time than when using recall methods, hence increasing the representativeness of the dietary intake data, and (4) personnel are not required to be present to collect data and costs of data gathering are thus minimized. The disadvantages include, (1) subjects must be highly motivated to remember to record data and to be willing to weigh or measure food, (2) memory-related errors may be replaced by recording errors, (3) the consciousness-raising experience of writing down what one has eaten may result in a Hawthorne effect, thus reducing the representativeness of the data, and (4) more data are generated and more time may be required to analyze the data.

The literature reports that attempts have been made to establish the validity or representativeness of data collected by this method by asking subjects to keep dietary records for 2 consecutive weeks or at 1-9 month intervals. Correlations have been adequate ($r=0.70$ to $0.85$) for the 1-9 month interval. There were no significant differences between dietary intakes of individuals on two consecutive one week records. Most studies made at two different time periods have fairly good agreement.
**Microcomputer Nutrient Analysis.**

Once data regarding dietary intake has been recorded, the nutritive value of foods will be calculated using the Nutritionist 4 computer program. The Nutritionist 4 has an 12,000-food database that includes brand names, vitamins, and formulas. Sixty-one nutrients are analyzed by the program. The program uses USDA databases 8.1-8.10 and has received high marks from Wilson, (1990), and Wheeler & Wheeler, (1984).

**Body Mass Index.**

Body Mass Index (BMI) will be calculated on the post-partum mothers initially, and at 8 weeks. BMI is an index used for estimating obesity. In recent years, some authorities have endorsed using BMI to evaluate healthy weight, instead of the traditional life insurance ht/wt charts. BMI values are believed to correlate more accurately with total body fat content (U.S. Public Health Service, 1995). The formula used to calculate BMI in adults is the Quetelet Index (weight in kgs/ height in meters squared).

**Anthropometry.**

A final measurement instrument, Anthropometry, will be used to evaluate nutritional status and growth and development of the mother/baby pairs during this study. Anthropometric measurements will include weight, height/length, and skinfold thicknesses. The mother/baby pairs in this study will be weighed at each home visit using one scale (Heathkit Electronic Co., Avon, Connecticut, Model GDW-1186). The scale will be calibrated and standardized by the investigator prior to each measurement.

The reliability of anthropometric measurements is a matter of concern, especially when multiple investigators or clinicians are performing the measurements over time.
Three major considerations are (1) instrument selection, quality, design, and standardization, (2) training and supervision of personnel, and (3) periodic replication (Bergstrom, 1988).

The Lange calipers used to measure skinfold thicknesses apply 10g/mm² of pressure on the contact surface of the skin. Accuracy will be determined by using a standard calibration block provided by the manufacturer. If the caliper should become un-calibrated, it will be returned to the manufacturer for servicing. The investigator in this study will be trained in the use of the established measurement protocols, which have been published to reduce measurement error (Duane, 1992).

Data Analysis

Diet records and anthropometric data will be edited, name identifiers removed and a research number assigned for data analysis purposes. All statistical analyses will be performed using the SYSTAT (1990) data management system. A dependent t-test will be used to compare the data from dieting breastfeeding women to those of non-dieting women, and a Pearson’s correlation procedure will permit the calculation of simple correlation coefficients between independent and dependent variables. Analysis of variance (ANOVA) will be used to determine the relationship of calorie intake to changes in maternal body weight and anthropometrics. A sample size of 23 in the control (C) group and 23 in the experimental (E) group, will enable a detection of change in weight loss with a power of .95 at a significance level of .05 (Shot, 1990).

Demographic data for this study will be collected based on a standardized demographic data sheet, in order to describe the patient population. Demographic
characteristics will include age, sex, weight, nationality, educational level, occupation, health status and level of physical fitness. (See Appendix D for specific subject demographic data observed in this study).

**Human Subjects Considerations**

This study will follow the policies set forth by Whitworth College, and the Intercollegiate Center for Nursing Education. Approval to conduct this study prior to data collection was obtained from:

1. Intercollegiate Center for Nursing Education, thesis committee.
2. Subject’s consent form (see Appendix E).
3. Institutional Review Board of Washington State University (see Appendix F.)

Participation in this study will be completely voluntary, and subjects will be informed that they are free to discontinue at any time without prejudice. The statement of protection of human subjects will be read to each subject by the researcher. Selected subjects will indicate their intent to participate in the study by signing the informed consent in Appendix E. The confidentiality of patients will be maintained by assigning a number to individual patients to correlate the information. All data collected will be kept in a locked office, and available only to the researcher and the committee chair.

Participation in the study will not pose any additional risk or financial cost to the subject. The benefits to participation will include potential enhanced weight loss for selected postpartum lactating mothers. Professional dietary guidance and strict monitoring of the mother/baby pairs nutrition will also be of benefit.
References


Duane, 1990 Lange calipers.


Manning-Dalton, C., & Allen, L.H. (1983). The effects of lactation on energy and


APPENDIX A

REVIEW OF LITERATURE
## Appendix A

### Review of Literature

#### Table 1: The effect of breastfeeding on weight loss

<table>
<thead>
<tr>
<th>year</th>
<th>author</th>
<th>sample</th>
<th>size</th>
<th>results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1989</td>
<td>Brewer, Bates &amp; Vannoy</td>
<td>breastfeeding, formula feeding, and</td>
<td>56</td>
<td>Lactating mothers consumed more kcal than nonlactating mothers. 6 month weight losses in: BF=8.3kg, FF=8.19, CF=7.22, however, only BF experienced a significant change between 3 and 6 months. Suprailiac and subscapular skinfold thickness decreased. Increases in tricep fatfold at 3 months, indicates that a redistribution of body fat occurs. Results indicate that lactation does play a role in postpartum weight and body fat loss, but that current RDA may be too high to permit such loss.</td>
</tr>
<tr>
<td>1989</td>
<td>Dugdale &amp; Eaton-Evans</td>
<td>Lactating mothers from 1 month</td>
<td>174</td>
<td>Overall there was a significant weight loss in the first few months, but this leveled off by 7 months. The triceps skinfold increased significantly up to 5 months postpartum, then decreased. These changes in body weight and skinfold were not affected by duration of lactation, but were influenced by the initial BMI and the desire to lose weight.</td>
</tr>
<tr>
<td>Year</td>
<td>Authors</td>
<td>Study Design</td>
<td>N</td>
<td>Findings</td>
</tr>
<tr>
<td>------</td>
<td>---------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>-----</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>1993</td>
<td>Kramer, Stunkard, Marshall, McKinney, &amp; Liebschultz</td>
<td>Breastfeeding, formula feeding and combination feeding postpartum women.</td>
<td>24</td>
<td>Changes in anthropometric variables at 6 months postpartum were similar in the 3 groups, but BF mothers had significantly larger reductions in hip circumference and were less above prepregnancy weights at 1 month postpartum. Findings indicate that BF enhances loss during the 1st month postpartum, that there are no apparent significant effects thereafter, and that the losses primarily affect the lower body.</td>
</tr>
<tr>
<td>1993</td>
<td>Dewey, Heinig, &amp; Nommsen</td>
<td>Breastfeeding, formula feeding</td>
<td>46</td>
<td>Weight loss from 1-12m was greater in BF than FF women, due mainly to differences in weight loss from 3-6m. Weight did not differ between 12-24m in either group. Concludes that BF enhances weight loss if continued for at least 6m.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>39</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Studies showing a neutral or negative influence of breastfeeding on weight loss.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1987</td>
<td>Rookus, Rokebrand, Burema, &amp; Deurenberg</td>
<td>Pregnant women, non-pregnant women</td>
<td>49</td>
<td>Effect of pregnancy on BMI from pregestation through 9 months postpartum was compared in 49 pregnant women and 400 non-pregnant women. At 9 months postpartum, the pregnant women had gained as much body mass as was to be expected from ageing. Women who BF for &gt;2 months gained .6kg/m2 more body mass than non-pregnant women. Those who suppressed lactation, lost body mass. Results suggest that maternal obesity may be associated with BF for long periods.</td>
</tr>
<tr>
<td>Year</td>
<td>Authors</td>
<td>Participants</td>
<td>Sample Size</td>
<td>Findings</td>
</tr>
<tr>
<td>------</td>
<td>---------</td>
<td>--------------</td>
<td>-------------</td>
<td>----------</td>
</tr>
<tr>
<td>1989</td>
<td>Ohlin &amp; Rossner</td>
<td>women during pregnancy and up to 1 year postpartum.</td>
<td>2295</td>
<td>Relation between lactation and postpartum weight loss was relatively weak. Lactation seems to have its largest effect on weight loss between 2.5-6m. Postpartum. Long term effect of lactation on postpartum weight loss was only observed in a small group of women with very intensive and lengthy lactation.</td>
</tr>
<tr>
<td>1988</td>
<td>Sadurskis, Kabir, Wagner, &amp; Forsum</td>
<td>healthy Swedish lactating women</td>
<td>23</td>
<td>Found that total average body fat content was unchanged during the 1st 2 months of lactation. During the next 4 months, a slight loss of body fat and weight loss occurred.</td>
</tr>
<tr>
<td>1991</td>
<td>Potter, Hannum, McFarlin, Essex-Sorlie, Campbell &amp; Trupin</td>
<td>breastfeeding &amp; bottle feeding women</td>
<td>411</td>
<td>No consistent relationship was found between method of infant feeding and postpartum weight loss. Women who gained more weight during pregnancy consistently lost more weight following delivery. Results indicate that infant feeding method was not related to differences in postpartum weight loss between lactating and nonlactating women.</td>
</tr>
<tr>
<td>1992</td>
<td>Schaubeger, Rooney, &amp; Brimer</td>
<td>Postpartum women.</td>
<td>795</td>
<td>This study suggests the overall effect of breastfeeding on weight loss is negligible.</td>
</tr>
<tr>
<td>Year</td>
<td>Authors</td>
<td>Description</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>--------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>-----------</td>
<td></td>
</tr>
<tr>
<td>1983</td>
<td>Manning, Dalton &amp; Allen</td>
<td>Well-nourished lactating women during their first 3 postpartum months</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Found that their subjects had a sedentary lifestyle, therefore it was suggested that an intake of 1,600-1,700 kcal/day would be sufficient to cover the caloric requirement during lactation. Women who BF, had the highest calorie intake and lost the smallest amount of weight, suggesting that RDA's for energy during lactation may be too high.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1984</td>
<td>Butte, Garza, Stuff, Smith, &amp; Nichols</td>
<td>Well-nourished lactating women</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Most women were still above their pre-pregnancy weights at 4 months postpartum. Milk production, in terms of quantity and quality, and infant growth were maintained for &gt;4 mo. With a mean energy intake of 2186 kcal/day. Maternal energy intakes were less than current recommendations, but compatible with adequate milk production and gradual reduction in maternal weight.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1986</td>
<td>Strode, Dewey, &amp; Lonnerdal</td>
<td>Well-nourished lactating women</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Milk intake was not reduced among infants of mothers whose energy intakes were at least 1,500 kcal/day during week 2. Lower energy intakes than those currently recommended appear compatible with successful lactation and gradual maternal weight loss.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1988</td>
<td>Sadurskis, Kabir, Wagner, &amp; Forsum</td>
<td>Healthy Swedish lactating women</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Energy intake increases during lactation. The women produced approximately 740g breastmilk per day. The results indicate that current estimates of energy needs during lactation may be too high.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Results indicate that lactation does play a role in postpartum weight and body fat loss, but that current RDA may be too high to permit such loss.

<table>
<thead>
<tr>
<th>1989</th>
<th>Brewer, Bates &amp; Vannoy</th>
<th>breastfeeding, formula feeding, and combination breast and formula feeding mothers from delivery to 6 months postpartum.</th>
<th>56</th>
<th>Studies examining the effect of energy restriction and weight loss on lactational performance.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1984</td>
<td>Butte, Bates, &amp; Vannoy</td>
<td>well-nourished lactating women during a 4 month period.</td>
<td>45</td>
<td>Most women were still above their pre-pregnancy weights at 4 months postpartum. Milk production, in terms of quantity and quality, and infant growth were maintained for &gt;4 mo. With a mean energy intake of 2186 kcal/day. Maternal energy intakes were less than current recommendations, but compatible with adequate milk production and gradual reduction in maternal weight.</td>
</tr>
<tr>
<td>1986</td>
<td>Strode, Dewey, &amp; Lonnerdal</td>
<td>milk volume and composition, nutrient intake and plasma prolactin levels of well-nourished lactating women during a 3 week period.</td>
<td>22</td>
<td>Milk intake was not reduced among infants of mothers whose energy intakes were at least 1500 kcal/day during week 2. Mean maternal energy intakes were 1591 kcal for the energy restricted group. Lower energy intakes than those currently recommended appear compatible with successful lactation and gradual maternal weight loss.</td>
</tr>
<tr>
<td>Year</td>
<td>Authors</td>
<td>Findings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>---------</td>
<td>----------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1994</td>
<td>Dusdieker, Hemingway &amp; Stumbo</td>
<td>Findings suggest that modest weight loss by healthy breastfeeding women does not adversely affect either quantity or quality of milk consumed by their infants.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX B

BREAST FEEDING HANDOUTS
GUIDE FOR PARENTS

How to tell whether your breastfeeding baby is getting enough milk

Even though you can't see how much milk your baby takes while nursing, you can tell whether breastfeeding is off to a good start if you know what to look for. This is what should be happening when breastfeeding is going well:

Your milk should "come in" at two to four days after delivery.

If your baby seems hungry after most nursings and you do not think your milk has come in by the fifth day, consult your baby's doctor and have your baby weighed.

Your baby should latch on correctly to your breast and suck rhythmically for at least 10 minutes on each breast.

He or she may pause periodically but should nurse vigorously throughout most of the feeding. A baby usually gets more milk from nursing at both breasts than from nursing on one side only. Alternate the side on which you start feedings, so both breasts receive comparable stimulation and emptying.

Your baby should appear satisfied after nursings and probably will fall asleep at the second breast.

If your baby falls asleep and will not take the second breast, try to divide the baby's effective suckling time between the two sides. A sleepy baby will get more milk by nursing for five minutes at each breast than 10 minutes at one. Breastfed infants who appear hungry after most feedings, who chew their hands after nursing, and who often require a pacifier may not be getting enough milk.

Your newborn baby should nurse at least eight times in each 24 hours.

A pattern that works well for many infants is nursing at one and a half to three hour intervals throughout the day, with a single five hour stretch during the night. Time the feedings from the beginning of one nursing to the beginning of the next. Four-hour intervals (six nursings in 24 hours) are too long for a newborn; very few breastfed babies will gain adequate weight that way. Don't be surprised if you need to wake your baby up to feed; it's not uncommon.
Some babies just don't demand to be fed as often as they need to.

**Your breasts should feel full before each feeding and softer after your baby has nursed.**

You should hear your baby swallow regularly while breastfeeding. One breast may drip milk while your baby nurses on the other side. After your longest night interval, your breasts should feel particularly full.

**Your baby should urinate six or more times a day.**

Most breastfed babies wet their diapers after every feeding. The urine should be colorless, not yellow. Dark urine or a red "brick dust" appearance on the diaper could suggest that your baby is not getting enough milk. You may: have difficulty telling whether a super-absorbent diaper is wet; put a piece of toilet tissue between baby's bottom and the diaper surface, to help you be sure.

**Your baby's bowel movements should look yellow—somewhat like a mixture of cottage cheese and mustard—by the fourth or fifth day of life.**

These are called "milk stools." If your baby is still having dark meconium or greenish brown "transition" stools by 5 days of age, he or she may not be getting enough milk.

**Your baby should have four or more bowel movements each day.**

Many breastfed infants pass a stool with every nursing during the first four weeks of life. If your newborn baby is having fewer than four stools each day, it might mean he or she is not getting enough milk.

**Your nipples may be slightly tender for the first several days of nursing.**

Usually, tenderness is present only at the beginning of the feedings and discomfort is gone by the end of the first week. Severe nipple pain, pain that lasts throughout a feeding, or pain persisting beyond one week probably means your baby is nursing incorrectly. If your baby isn't latched on properly to nurse, not only will your nipples hurt, but your baby may not obtain enough milk. If your nipples are very sore, ask your baby's doctor to check your infant's weight and refer you to a breastfeeding specialist who can evaluate your nursing technique.

**After two or three weeks, you may be aware of the sensations associated with the milk ejection or milk let-down reflex.**

The feeling can be described as a tingling, pins-and-needles, or tightening sensation in your breasts as milk begins to flow. When let-down occurs, your baby may start to gulp milk, and
milk may drip or spray from the other breast. Just hearing your baby cry can cause your milk to let-down, even before your baby latches on. Although some women breastfeed just fine without noticing sign of the milk ejection reflex, failure to perceive let-down sensations could mean that your milk supply is low. If you are in doubt, ask your baby's doctor to weigh your infant.

**Once your milk has come in, your breastfed baby should gain about 1 oz each day for the first few months of life.**

The only way to be absolutely certain that your baby is getting enough milk is to have him or her weighed regularly. If your baby is not gaining weight appropriately, it is possible that your milk supply is low or that your baby is not nursing effectively. Such breastfeeding difficulties are easier to remedy if they are recognized and treated early. Your baby's doctor can work with a breastfeeding specialist to develop a feeding plan tailored for you and your baby.

Developed at The Lactation Program, Denver, CO
Screening form for the early follow-up of breastfed infants

Infant Name: __________________________ Date: __________ Infant age: ___ days

The following questions are designed to help us tell whether you are off to a successful start with breastfeeding. Please complete this form when your infant is 4 or 6 days old. If you circle any answers in the right-hand column, call our office at ____________ for advice. The earlier breastfeeding problems are recognized, the easier they are to correct.

Indicate your answer below with a yes or no response.

1. Do you feel breastfeeding is going well for you so far?
2. Has your milk come in yet? (i.e., did your breasts get firm and full between the second and fifth postpartum day?)
3. Is your baby able to latch on to your breasts without difficulty?
4. Is your baby able to sustain rhythmic suckling for at least 10 minutes total per feeding?
5. Does your baby usually demand to feed? (Answer No if you have a sleepy baby who needs to be awakened for most feedings.)
6. Does your baby usually nurse at both breasts at each feeding?
7. Does your baby nurse approximately every 2-3 hours, with no more than one longer interval of up to 5 hours at night (at least 8 nursings in 24 hours)?
8. Do your breasts feel full before feedings?
9. Do your breasts feel softer after feedings?
10. Are your nipples extremely sore (e.g., causing you to "dread" feedings)?
11. Is your baby having yellow bowel movements (resembling mustard with some little curds)?
12. Is your baby having at least four good-sized bowel movements each day (more than a "stain" on the diaper)?
13. Is your baby wetting his/her diaper at least six times each day?
14. Does your baby appear hungry after most feedings (e.g., sucking hands, crying, often needing a pacifier)
15. Do you hear rhythmic suckling and swallowing while your baby nurses?

Developed at The Lactation Program, Denver This form may be photocopied for use in your practice without permission of the publisher, as long as the authorship of the Lactation Program is acknowledged.
APPENDIX C

DIETARY RECORDING DATA AND

DIET RECORD HANDOUTS
How to fill out the Diet Record Form

The diet record form and food list is designed to assist you in recalling what foods you have eaten over a given period of time. There is also a space for you to specify how much of each food you have eaten. The list is alphabetized by food category and the individual foods in each category are alphabetized as well. Find the food you have eaten and record the code number, food name, and portion size on the diet record form. If you have eaten a food which you cannot find on the list, record its name and portion size under the "Foods Not On List" heading. Remember to include all the information about each food so that the form can be processed properly and easily. Below is a list of tips for filling out the Form to make it easier and more accurate.

Helpful tips on filling out the Form:

16. Record what you have eaten as soon as possible after meals. This makes it much easier to remember what you ate.

17. For foods that you eat more than once a day, you can combine the amounts and enter the total amount for the day. For instance, if you have a cup of milk in the morning on your cereal and a cup at night with your dinner, you can enter milk only once on the form, but put 2 cups as the portion size.

18. When you are looking through the list to find the foods you have eaten, it is important to use the specific type of food you had. Remember to specify the following:

A. Preparation: How did you cook the food? Or did you? Was it fresh? Or was it frozen or canned? Did you fry, steam, bake, boil or broil it? If you prepared a mix, did you add milk or water? Did you substitute ingredients? If so, include the information in the description of the food.

B. Canned foods: If you had a canned product, was it packed in water, its own juice, or was syrup added to it? Include the brand name of canned foods. Also, did you serve the juice or syrup that was in the can, or did you drain it before eating?

C. Portion Size: Indicate how much you had of each food using standard measures - ounces, cups, teaspoons, tablespoons, slices, etc.

D. Condiments: If you added condiments or spices to your food, include these and how much of each you had. For example: mustard, mayonnaise, catsup, salt, pepper, steak sauce, etc.

19. If you had bread, was it white or French? If it was wheat bread, was it whole wheat or cracked wheat? Was your milk 1% milk fat, 2% milk fat, or whole milk? If you had coffee or tea, was it decaffeinated? Was the coffee or tea brewed or instant?

20. Break down recipes into specific foods. If you cannot find a recipe in either the combination foods or fast foods lists, break down the food into its components. For example, a peanut butter and jelly sandwich must be broken into certain amounts of peanut butter, jelly, and bread. Do the same for salads and casseroles.
# Diet Record Form

<table>
<thead>
<tr>
<th>CODE NUMBER</th>
<th>FOOD DESCRIPTION</th>
<th>PORTION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CODE NUMBER</th>
<th>FOOD DESCRIPTION</th>
<th>PORTION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**FOOD NOT ON LIST**

<table>
<thead>
<tr>
<th>CODE NUMBER</th>
<th>FOOD DESCRIPTION</th>
<th>PORTION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NAME**

**ADDRESS**

**CITY**

**STATE**

**ZIP**

**TELEPHONE**

**AGE**

**SEX**

**WEIGHT**

**HEIGHT**

**DAY OF WEEK**

**RECORDED**
APPENDIX D

DEMOGRAPHIC DATA
Appendix D

Demographic Data

Subject No. __________
Date ________________

Subject Demographic Questionnaire: Energy Restriction Program

Please fill in or check the appropriate space. Thank you ☺

1. Age in years

2. Marital status
   - Married
   - Divorced
   - Widowed
   - Single
   - Other

3. Total # of years in school

4. Nationality
   - Native American
   - Oriental
   - African American
   - Hispanic
   - White
   - Other

5. Gender of your baby
   - Female
   - Male
Additional Subject Demographic Data

Information to be supplied by investigator from medical records:

Height
Weight at first prenatal apt.
Weight at last prenatal apt.
Weeks gestation at 1st prenatal apt
Date of last prenatal apt
Date of delivery
Weeks gestation at delivery
Parity at delivery
Type of delivery (SVD or C/S)
Labor and delivery complications

Infant's weight
Infant's length
Infant's Apgar's
Intent to breast feed baby

Yes ☐ ☐ No

8. Current medical illnesses


9. Current medications


Preliminary selection criteria: (to be completed by investigator).

Computed BMI

Weight gain during pregnancy

Exclusively breastfeeding with intent to do so for 2 months

Yes ☐ ☐ No

Parity
Additional demographic data (selection criteria): (to be completed by investigator during hospital interview if all of the above criteria is met).

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoker</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic illnesses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic medications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H/O past mental illness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H/O past eating disorder</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Educated in English</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will you be actively trying to lose weight</td>
<td></td>
<td></td>
</tr>
<tr>
<td>in the 1st 8 weeks postpartum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infants age today</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is your infant free of chronic illness or</td>
<td></td>
<td></td>
</tr>
<tr>
<td>congenital anomalies?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are you only breastfeeding, and plan to</td>
<td></td>
<td></td>
</tr>
<tr>
<td>do so for at least 2 months?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Additional information: (to be completed by investigator during hospital interview if all of the above criteria is met).

Do you plan to lead a sedentary or active lifestyle during your first 8 weeks postpartum?

Have you breast fed in the past?

If so, how long did you breast feed that baby?

What was the length of time you needed to return to your prepregnancy weight?

How did you lose the weight last time?
APPENDIX E

CONSENT FORM
Appendix E

Consent Form

Effect of a maternal dietary energy restriction program on postpartum weight reduction in well-nourished lactating women

INFORMED CONSENT

Invitation to participate

You are invited by Amy McElroy, R.N., F.N.P. Student, at the Intercollegiate Center For Nursing Education, which is part of Washington State University, to take part in a research study about postpartum weight reduction in lactating women. Your agreement to take part in this study is voluntary and of your own free will. The ICNE and Washington State University Institutional Review Board have approved the use of human subjects for this study.

Purpose of the study

This study examines the effect a maternal dietary energy restriction program has on postpartum weight reduction in a group of well-nourished, lactating women. You are asked to take part in this study because you are a postpartum lactating mother who has met all of the selection criteria. If you agree to take part and be a subject in this study, you will be asked to record your food intake, and take part in 3 home visits (at 4, 6 and 8 weeks postpartum), over a course of 6 weeks.

Explanation of protocol

After agreeing to take part in this study, you will need to sign this consent form. You will be asked to choose to be in an experimental group, which will restrict your dietary intake, or to a control group, which will not restrict your dietary intake. This will take about 30 minutes of your time per week for the experimental group and about 15 minutes per week for the control group. You will be asked to record your food intake 2 days per week, and to accurately weigh all amounts on a scale that will be provided. In addition you are being asked to answer questions about your age, weight, labor and delivery history, medical condition, educational status, and marriage status.

Potential risks and discomforts

You may dislike and may not tolerate the dietary restriction you will be asked to follow. You may lose too much weight, which has been shown to interfere with milk
production, however this would be unlikely on the prescribed diet. If you do lose too much weight and your baby is losing weight, you will need to contact the investigator, so that your participation in the study can be discontinued. These risks will be decreased by having the investigator of this study available at all times for support and education on a nutritious diet that allows for weight reduction at a healthy pace.

Subject Initials _____

You may also become tired of telling me about each and every food that you consume on a given day. I have made every effort to provide complete confidentiality and privacy so no one will know you have taken part in this study. All of your personal information is protected by giving you a study number. Your name and study number are kept in separate files, and are available only to myself. All research information and personal identifying information will be kept in locked files that can be opened only by myself.

You may choose to discontinue at any time during the study. Your choice not to continue will not affect your relationship as a study participant. You may stop or withdraw at any time.

Potential benefits

You will benefit by potentially achieving weight loss at an accelerated rate. You will also be guided by a registered nurse through this program, who will be closely monitoring your dietary intake for nutritional content, as well as your rate of weight loss, in order to assure your well-being.

Assurance of confidentiality

Information obtained as part of this study will be strictly private and confidential. The information will be used only for research. The number code with your name will be available only to myself. The completed information taken from subjects will be kept in a locked file and destroyed at the end of this study. At no time, will your study number and personal information be available to anyone but the research team. Study results will be reported only as part of a larger group.

Withdrawal from study

Your agreement to take part in this study is voluntary. If you agree to take part, you may choose to stop and withdraw your consent at any time.

Subject Initials _____

Informed consent
1. I, as shown by my signature below, fully understand the study goals, procedures and risks that go along with taking part in this study.

2. I, as shown by my signature below, understand that taking part in this study is of my own free will and that I may stop at any time.

3. I, as shown by my signature below, give permission to Amy McElroy, R.N. to use and get rid of the information and findings from this study. I understand that the investigator agrees to protect the privacy and confidentiality of the information gathered during this study within the limits of Washington State Law.

I have read and understand the above conditions. I have had the chance to ask questions about the study and the methods used to collect the study information. These questions have been answered to my satisfaction. I have read and understand the study and have received a copy of this form.

I may contact Amy McElroy, R.N. at the ICNE, 509-326-7270 to get information or ask questions I may have about this study at any time.

__________________________
Subject’s Signature         Date

__________________________
Investigator’s Signature    Date
APPENDIX F

INSTITUTIONAL REVIEW BOARD
Appendix F

Institutional Review Board

Washington State University Human Subject Review Summary Form

University procedures require Institutional Review Board (IRB) review and approval of research involving human subjects. If a project is exempt, a completed copy of the first two pages of the Human Subject Review Summary Form must be submitted to the OGRD. No research can be initiated until approval has been obtained from the IRB. If the project is not exempt, 18 copies of this entire form must be filed with the OGRD (Phone 335-9661; Zip 3140). The IRB approval must be kept on research data for THREE YEARS after completion of the research.

Principal Investigator: Amy McElroy
Academic Title: Master's Candidate

Department/Division: I. C. N. E.
Zip Code: 99203
Telephone: (509) 536-7093

Project Title: Effect of a Maternal Dietary Energy Restriction Program on Postpartum Weight Reduction in Well-Nourished Lactating Women

Anticipated Starting Date: 12-15-96
Anticipated Termination Date: 3-1-97

Is the project seeking funds? Yes [ ] No [✓]

I. Check the type of exemption applicable to the project:

1. [ ] 2. [ ] 3. [ ] 4. [ ] 5. [ ] 6. [✓] None.

II. Abstract:

A. Briefly describe the purpose of the research:

The purpose of this study is to measure the effect of maternal diet on changes in maternal weight and body composition in well-nourished lactating women during the first eight weeks postpartum. The goal is to promote a healthy rate of maternal weight reduction, while maintaining successful lactation and infant growth on the prescribed diet.

B. Describe the procedures:

The subjects who agree to take part in this study, will be asked to record their food intake 2 days per week, and to accurately weigh all foods (2 days per week) on a scale
that will be provided. Subjects will also be asked to take part in 3 home visits during which the mother/baby pairs will be weighed on a calibrated scale. Anthropometric measurements will also be made on the mothers during the home visits over a course of 8 weeks.

Additional description of the protocol:

Initially, subjects will be identified in the prenatal period, through advertising in local childbirth education classes. According to study protocol, interested subjects will be seen in the hospital, following delivery to be interviewed, oriented, consented, provided with study materials and weighed by the investigator. During this initial screening, each subject’s height, pregravid weight, weight gain during pregnancy, labor and delivery history, and infant status will be collected from their medical records. In order to determine eligibility for the study, subject’s will be asked to answer questions about their intent to breastfeed, current medical condition, and past medical history.

Eligible subjects must meet the following selection criteria: [SEE ATTACHED SUBJECT DEMOGRAPHIC DATA AND SELECTION CRITERIA FORM, WHICH WILL BE USED TO SCREEN ALL SUBJECTS] 1) well-nourished (BMI in kg/m² > 19), 2) gained at least 11 kg during pregnancy, 3) parity of one or two and delivered by spontaneous vaginal delivery, not Cesarean Section, 4) healthy, as evidenced by the absence of chronic disease or medical diagnosis, 5) may not be anemic, as evidenced by hematocrit/hemoglobin, 6) must not have had complications during labor and delivery (i.e. postpartum hemorrhage, shoulder dystocia, etc.) 7) must be exclusively breastfeeding with intent to do so for 2 months, 8) must have healthy babies as evidenced by full term gestation, Apgars within normal range, weight within normal range, and absence of complications or congenital anomalies, 9) be educated in English and be non-smokers. Given the data above, a decision will be made at this time whether the subject meets all of the inclusion criteria.

Eligible subjects will be contacted at the beginning of their second week postpartum by phone to review study procedures and the proper diet recording technique. The mother’s will then be asked to record a preliminary 5-day dietary record of their usual intake. At the completion of this 5-day diet baseline, the investigator will calculate the composition of the diet to determine total energy, carbohydrates, fat and protein using the Nutritionist 4 computer program. Subjects will be questioned about their activity level (sedentary vs. active), and the Nutritionist 4 program will be adjusted to their individual caloric needs. Subjects will also be asked about their previous experience breastfeeding, including the number of months, complications, length of time to return to prepregnant weight, and the methods that were used in order to lose the weight last time. In order to allow lactogenesis to become fully established, experimental subjects will not be asked to restrict their diets until the beginning of week 4.

During week 4, all procedures will be identical, except the experimental group will reduce
their caloric intake for the remainder of the study. Guidelines will be given to each experimental mother (based on individual height, weight, and activity levels), to achieve the desired rate of weight loss (.45 kg/wk), while maintaining the proportion of calories from protein, fat, and carbohydrates. This information will be made available from the Weight Planning Portion of the Nutritionist 4 Computer Program. The information supplied to the subjects will include their desired meal plan with groups of exchange lists of foods to be interchanged for variety. The only difference between the control group and the experimental group will be that the latter will be given a prescribed diet to follow, while the control group will not. The prescribed diet will require that subjects weight loss not interfere with normal infant weight gain, according to study procedure. Subjects will be informed of potential problems that will be required to result in contact of the investigator and possible discontinuation from the study.

C. Describe the research design:

A 8 week quasi-experimental, repeated measures design for the analysis of variance will be used in this study.

D. Data collection method to be used:

Personal interview while in hospital, telephone interview at 2 weeks postpartum, anthropometric measurements by the investigator during 3 home visits at 4, 6 and 8 weeks, and diet record to be self-administered by the subject.

E. Is data anonymous or confidential? If confidential, describe how confidentiality will be maintained.

Information obtained as part of this study will be strictly private and confidential. The information will be used only for research. The number code with the subjects name will be available only to the investigator. The completed information taken from subjects will be kept in a locked file and destroyed at the end of this study. At no time, will the subjects study number and personal information be available to anyone but the research team. Study results will be reported only as part of a larger group.

F. Description of the population:

a. Appropriate number: 46
b. Age range: 18-35
c. How will subjects be recruited? Subjects will be recruited through advertising in local childbirth education classes.
d. Will subjects be compensated? No  
e. Are any of the subjects not competent to give consent? No  
f. Will a written consent be obtained? Yes  
g. Will any ethnic group or gender be excluded from the study pool?  
   If yes, please explain: Yes, the male gender will be excluded, due to anatomical reasons.

F. Assessment of risks and benefits.
   a. Describe any potential risks and describe how you will minimize these risks:

   Subjects may dislike and may not tolerate the dietary restriction they will be asked to follow. They are free to withdraw from the study at any time. Subjects may lose too much weight, which has been shown to interfere with milk production, however this would be unlikely on the prescribed diet. This can be verified by examining the literature (Strode, Dusdieker and Butte). If subjects do lose too much weight and their baby looses any weight, they will be discontinued from the study immediately. These risks will be decreased by having the investigator of this study available at all times for support and education on a nutritious diet that allows for weight reduction at a healthy pace.

   b. In the event that any of these potential risks occur, how will it be handled?

   If subjects do lose too much weight (>1.5 lb per week) and their baby looses any weight, they will be discontinued from the study immediately.

   c. Will this study interfere with any subjects’ normal routine?

   Subjects will be required to record their diet’s 2 days per week, and participate in 3 home visits over a course of eight weeks.

   d. Describe the expected benefits to society and to the individual subjects?

   Society will benefit by better understanding how to counsel postpartum women on how to safely lose weight while breast feeding. Subjects will benefit by potentially achieving weight loss at an accelerated rate. They will also be guided by a registered nurse through this program, who will be closely monitoring their dietary intake for nutritional content, as well as their rate of weight loss, in order to assure their well-being.

   e. Blood or other specimens will not be taken.

Project Checklist

a. Will any investigational new drug be used? No  
b. Will other drugs be used? No
c. Will alcohol be ingested by the subject? No
d. Will audio-visual tapes, audio tapes, or photographs be taken? No

D. Nature of the data collected?
   Subjects under 18 years of age? Yes
   Subjects confined in a correctional or detention facility? Yes
   Is pregnancy a prerequisite for serving as a subject? Yes
   Are fetuses in utero subjects in this research? Yes
   Subjects presumed to be not legally competent? Yes
   Are personal records (medical, academic, etc.) used without written consent? Yes
   Are data from subjects (responses, information, specimens) directly or indirectly identifiable? and place subject at risk (criminal or civil liability) or damaging to subjects’ financial standing, employability or reputation? Yes
   Will specimens obtained from an autopsy used in the research? Yes
   Will subjects be asked sensitive questions about sexual experiences? Yes
   Will questions be asked about alcohol or drug use? Yes
   Will alcohol or drugs be administered? Yes
   Will blood/body fluids be drawn? Yes

Principal Investigator: The information provided above is accurate and the project will be conducted in accordance with applicable Federal, State, and University regulations.

Signature __________ Date 11-13-96

Faculty Sponsor (If principal investigator is a student): The research is in accordance with applicable Federal, State, and University regulations.

Signature __________ Date 11/14/96

Chair, Director, or Dean: The research is in accordance with applicable Federal, State, and University regulations.

Signature __________ Date 11/14/96

Institutional Review Board: This project has been properly filed as required by Federal, State, and University procedures.

Signature __________ Date 11/14/96