

**PROPOSAL FOR “FAT CONSUMPTION IN ADULT AGE
AND RISK OF BREAST CANCER DEVELOPMENT” CASE-
CONTROL STUDY IN ARMENIA**

Master of Public Health Thesis Project Utilizing Study Grant Proposal Framework

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Abstract

Breast cancer is one of the primary cancer types among women; the exact etiology of which is unknown but certain factors correlate with higher or lower prevalence of the disease. Increased animal fat consumption has been considered a risk factor by number of studies including geographic correlational studies, immigrant studies, and animal studies.

However an epidemiologic study and particularly a case-control study would provide a clearer picture of the relation of animal fat consumed to the risk of breast cancer development.

No such study has been conducted previously in Armenia while the incidence of breast cancer in country remains high and is one of the highest in region. The study proposed is a case-control study with matched controls.

The study hypothesis is the following: the risk of developing breast cancer for Armenian women increases with increased animal fat consumption. A pilot study was performed with equal sample size of 5 for both cases and controls. Results of the descriptive analysis of the pilot data set are appended. The actual sample size calculated for proposed study, after accounting for refusal rate is 8 in each group. Chi -squared analysis and logistic regression analysis are proposed for the data analysis.

Introduction

General Overview. Burden of Disease.

Breast cancer is the most common cancer among women (18.3% of all female malignant tumors) and is the fourth in the top ten of common cancer types in the United States. (Dovgaljuk, 2004; McPherson, Steel, & Dixon, 2004) Breast cancer affects at least one of nine American women. (Dolinsky, 2002)

Breast cancer usually develops in a woman's milk carrying ducts, though it may originate in milk-producing lobes and more rarely in dense connective tissue of the breast.

A breast tumor is not a life-threatening condition itself, but if it remains untreated it may spread to other organs via bloodstream and lymph nodes, creating metastases.

Literature Review.

The exact etiology of breast cancer is unknown, but certain factors such as age, family history, childbearing before age thirty, breast feeding, body size, late menopause, hormonal status, alcohol consumption and a number of other factors clearly correlate with higher incidence. Nevertheless even these factors are unable to explain the significant differences in breast cancer mortality rates among women of different ethnic and national groups all around the world. (Wynder, Rose, & Cohen, 1986)

Geographic correlational studies have revealed a positive association between breast cancer incidence and per capita availability of total fat. In western countries it is mainly attributed to animal fat. (Hirohata, Nomura, Hankin, Kolonel, & Lee, 1987) Incidence of breast cancer is higher in affluent western countries and significantly lower in eastern countries like Japan, Indonesia and China. For example, in the United States the overall incidence of breast cancer has been 5 times higher than that observed in Japan. (Harris, Lippman, Veronesi, & Willett, 1992). Numerous immigrant studies show that after immigration to so called "high incidence" regions, breast cancer rates among immigrants rose

and in generation or two came very close to local ones. There are some examples that support this theory. For instance, studies of Japanese migrants to Hawaii revealed a significant increase in the incidence of breast cancer.(Wynder et al., 1986) The Women's Health Trial performed by Prentice and colleagues showed a strong correlation between breast cancer incidence and per capita fat intake but there was no correlation with proteins and carbohydrates. (Prentice et al., 1988)

Some animal studies were also done in this field: the tumor-enhancing effect of diet high in fat was demonstrated in spontaneous and induced models using rodents (rat and mice) as experimental animals, and induction was performed chemically, using X-rays or transplantation of tumor cells. In animal experiments dietary fat primarily affected the promotional period of carcinogenesis, thus it functioned as a modifier of carcinogenic process but not as a carcinogen itself.(Wynder et al., 1986) According to an experimental study done by Cleary, Grande and Maihle, the consumption of high fat diet increased adiposity and shortened the latency of mammary tumors in relation to their effect on body weight. This study was done using transgenic MMTV-TFG-alpha mice, a model of postmenopausal breast cancer. (Cleary, Grande, & Maihle, 2004)

It is obvious that actions for prevention of breast cancer before it would develop, even at the beginning stage, are essential. Prevention cannot be accomplished for every case since there are many risk factors for breast cancer that cannot be affected such as genetic mutations (gene BRCA1 or BRCA2) (Dolinsky, 2002), family history, aging, early onset of menstruation and late menopause. Nevertheless one of the easiest factors to change is diet. However, before providing recommendations it is critical to determine if diet high in fat, and particularly in animal fat, increases the risk of getting breast cancer.

Data from international and migrant studies have resulted in mostly hypothesis generation. Animal studies provide a good opportunity for studying the mechanisms of

influence that dietary fat has on organisms of laboratory animals; however, with respect to specificity of human organism they cannot provide absolute information. (Prentice, Pepe, & Self, 1989) Hence analytical epidemiological studies, i.e. cohort and case-control studies deserve the most attention in terms of defining the relationship between dietary fat and risk of breast cancer development. After comparing results of different previous epidemiological studies, it is evident that the data are unclear and often even contradictory.

Walter Willet and colleagues at Harvard University's School of Public Health concluded that there is no association between fat in the adult diet and risk of breast cancer. Dr. Willet's conclusion is very valuable because it was done after analyzing data gathered from one of the largest and best controlled prospective surveys on the topic, the Harvard Nurses Health Study. (Mashall, 1993)

On the other hand, meta-analysis of twelve case-control studies performed by Geoffrey R. Howe and colleagues shows a consistent, statistically significant association between breast cancer risk and saturated fat intake ($RR=1.46$; $P<0.0001$). (Howe et al., 2005) Also, results of a case-control study done in Indonesia, show that fat intake is more significant as a determinant for breast cancer risk in populations with low per capita fat intake. (Wakai et al., 2000) A case-control study done in India defined the connection between elevation of lipid components (except HDL-cholesterol) and risk increase of breast cancer development. (Bala et al., 2001) At the same time results of a prospective cohort study run by Velie et al showed no link between animal fat consumption and development of breast cancer in postmenopausal women. (Velie, Kulldorff, Schairer, & et.al, 2001) And results of a prospective study done in Brisbane Royal Hospital, in Australia also do not support the hypothesis that higher fat consumption increases the risk of breast cancer. (Webb et al., 2004)

In addition, despite the wide range of different case-control studies investigating the association between fat consumption and breast cancer, very few of them have focused particularly on animal fat.

Objectives:

The current study is aimed to explore a possible association between animal fat consumption and breast cancer risk in Armenia.

The incidence of breast cancer in Armenia is high; each year 600-650 new cases are identified. Growth in the rate of incidence of breast cancer in the country has been observed especially among younger women (1).

According to “Highlights on Health in Armenia” developed by UNDP in January 2001 Armenia has the highest rate for mortality from breast cancer in the NIS and is in the group of countries with the highest rates in the Region. (17)

Figure 1 shows the consistent increase in the morbidity of breast cancer during years 1999-2003 and figure 2 shows mortality from breast cancer for years 2001-2003 with an increase from 2001 to 2002 but a decline in 2003. However, this increase and subsequent decline of mortality rate are a probable artifact that occurred because of recording or data management errors.

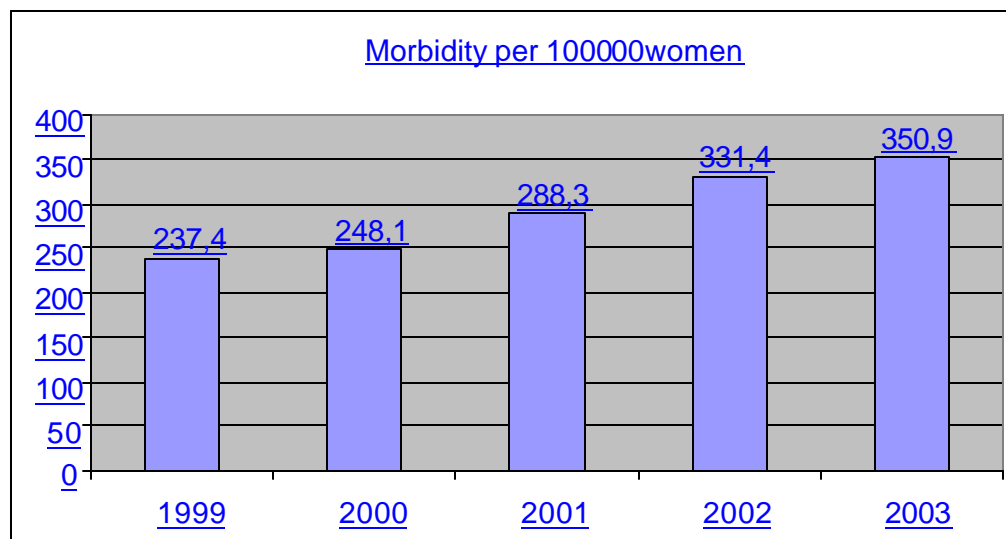


Fig.1 Incident cases of breast cancer per 100000 Armenian women

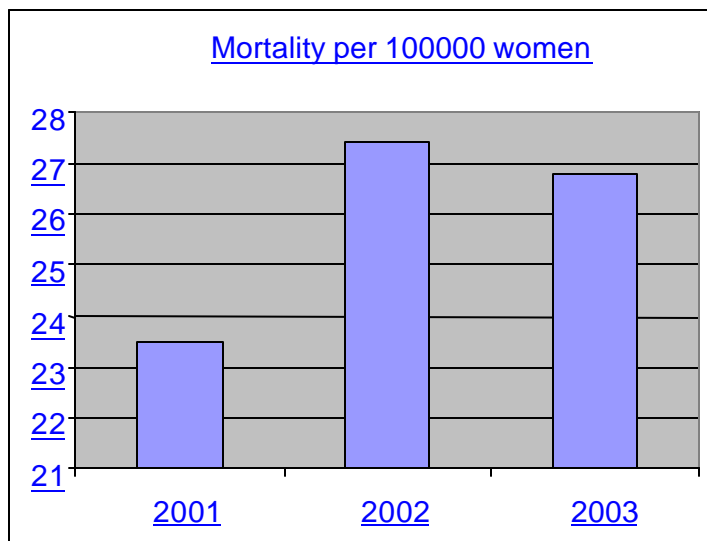


Fig.2 Breast Cancer Mortality per 100000 Armenian women

Research Hypothesis:

The risk of developing breast cancer for Armenian women increases with increased animal fat consumption.

Description of Proposed Project

The research question that is supposed to be answered by this study is to determine whether there is an association between animal fat consumption and risk of breast cancer development.

The study is proposed as a case-control study. Controls would be matched to cases by age and living location (districts in Yerevan). The target population would be women of Yerevan. The study population would include one case and one control group. Patients of

specialized departments of Oncology Scientific Center and department of surgery of State Hospital #8 would serve as cases; controls would be selected by the random digit dialing method. Women with any self reported breast problem would be excluded from the control group. Cases and controls would be interviewed personally or by phone in order to determine their dietary preferences toward total fat amount and subtype.

Blinding of the interview assessment would be assured in the following way: all cases and controls and controls would be identified but their phone numbers would be arranged in a random manner way so that data collectors would not know their identity or case-control status. Also individuals with background related to oncology would be excluded from the data collection team.

A specially developed questionnaire will be used for this purpose.

After data collection, data entry would be performed. Then, data would be analyzed statistically in order to reveal any existing correlation between animal fat consumption and development of breast cancer in pre and postmenopausal women. This would include exploratory data analysis and descriptive statistics to inspect consistency between variables, missing values and outliers. Bivariate relationships will be explored to assess the relationships between potential risk factors, including animal fat and case-control status, using chi-squared statistics and McNemar's statistic. Multiple conditional logistic regression analysis will be used to explore the relationship between animal fat consumption and cases-control status after controlling for confounding variables.

Questionnaires used for the study would not include any personal identifying information and would be destroyed after data entry is finished.

Rationale for chosen study design

Due to the long latency period of breast cancer, retrospective design is the most appropriate to reveal a correlation between dietary preferences and risk of breast cancer

development in terms of limited time and resources. Any prospective or nested design would require a long period of time and many human and financial resources. A cross-sectional design also can be applied here; however, for the comparison of dietary habits of healthy women with dietary habits of those who developed breast cancer, a case-control design is more useful.

The most obvious limitation of the chosen design is recall bias and bias caused by possible change of dietary habits of study subjects during the last few years. Self reported data may also be source of bias in this study as people may over report or underreport for certain domains of questionnaire.

Strengths are randomization and blinding of interviewers.

Timeline for proposed project

Hiring personnel and office – 1 week

Validation and revision of instrument- 3 weeks

Definition of cases – 2 weeks

Definition of controls and randomization – 3 weeks

Data collection – 4 weeks

Data entry and cleaning – 1 week

Data analysis – 2 weeks

Report writing – 1 week

Study Population:

Cases

Patients of specialized departments of Oncology Scientific Center and department of surgery of State Hospital #8 with histologically approved breast cancer, diagnosed between 25/08/2004 and 25/08/05, residents of Yerevan with an active phone number.

Controls

Women selected by using random digit dialing method (randomly generated four digit number would be assigned to first two digits of cases' phone number, thus a six-digit number would be obtained). Cases would be matched with controls also by age within ± 4 years.

Exclusion Criteria

Unwillingness to participate in the study, other than Yerevan residents, absence of phone number.

Rationale for chosen study population.

- The major part of urban population in the country lives in Yerevan.
- People in rural areas tend to eat similar food; thus, identification of different dietary habits among women in rural areas would be almost impossible.
- Choice of women diagnosed with breast cancer during the last one-year period as cases would eliminate influence of dietary habits on survival of patients with breast cancer.
- Identification of controls by using the first two digits of cases' phone number would allow researchers to match for location automatically
- Identification of controls from healthy hospital visitors was considered but deemed inappropriate since a woman who comes to an oncological hospital as a visitor has more chances to have a relative who has cancer, and thus may have a greater chance of having a hereditary predisposition to cancer than other women who do not visit oncological hospital
- Identification of cases from patients of specialized departments of Oncology Scientific Center and department of surgery of State Hospital #8 is appropriate because the majority of women with breast cancer receive medical care in these two hospitals.

Changes in methodology performed using pilot study results:

After performance and review of the pilot study, certain changes become essential in order to reduce bias in the proposed study.

Blinding of interviewers:

Non-blinded interviews pose two inconveniences and threats to the study; they could be a source of possible bias and by providing “cold contact” may make the work of data collectors more difficult with possible errors occurring because of the so called “human factor”. The following technique is suggested for blinding contacts and interviews: two of the data collectors would identify all cases and controls, contact them, ask screening questions (for controls only), present the consent form and obtain agreement to participate in the study. Subsequently, the phone numbers of those cases and controls who agree to participate then would be randomly assigned to three interviewers.

Changes in questionnaire:

Inclusion of questions about vegetable oil, margarine and fish use would help to eliminate some possible recall bias. In addition, it would be better to separate cheese from other milk products because respondents often did not consider it to be a milk product.

Inclusion of some questions about changing dietary habits during the last five and ten years may help to eliminate possible bias caused by recent change of dietary patterns.

Changes in data coding and entry:

It may be better to use a BMI calculation that has gender adjustment. Also weight change should be coded and entered as continuous variable.

Sample size

To determine sample size for two equal matched samples, the following formula was used

$$n = \frac{\left\{ z_{1-a/2} \sqrt{2P^*_2(1-P^*_2)} + z_{1-b} \sqrt{P^*_1(1-P^*_1) + P^*_2(1-P^*_2)} \right\}^2}{(P^*_1 - P^*_2)^2}$$

$$P_1 = \frac{(OR)P_2}{(OR)P_2 + (1 - P_2)} \quad (\text{Proportion exposed in cases})$$

P_2 = Proportion exposed in controls

The sample size calculation was accomplished using the STATA statistical package. Defining the value for $\alpha = 0.05$ (two sided), power = 0.9. P_1 was calculated as 0.6 (using RR=1.46 from previous studies). The proportion exposed in controls was assumed as 0.4 and calculated sample size $n_1=n_2= 140$. Taking into account 20% refusal rates in phone surveys from previous studies performed by MPH students, the sample size was estimated to be no less than 168 of case patients and accordingly 168 controls.

Instrument

The questionnaire consists of two sections: the purpose of the first section is to assess already known risk factors and the purpose of the second section is food frequency questionnaire that aims to assess frequency of usage of products rich in animal fat. “Cholesterol and fat” section of food frequency questionnaire developed in John Hopkins University was used as a matrix for second section.

Pilot Study

A pilot study was conducted in September 2005 in Yerevan with sample of 15 cases and 15 matched controls. The response rate was 86.7% for cases and 80% for controls. Descriptive results of the pilot study are appended to this paper as tables. Retrospective power analysis was performed using the same STATA statistical package which estimated the power as 0.105. Because of small power, the sample is considered potentially unrepresentative and too small to assess relationships between exposures and disease. However, on basis of the pilot study it became possible to make final calculations for budget and timeline as well as suggest certain changes for questionnaire and blinding technique.

However, the pilot study does provide evidence for the feasibility of conducting the proposed study using above-mentioned methodology.

Reference List

1. *Women Status Report, UNDP* (1999).
2. Bala, D. V., Patel, D. D., Duffy, S. W., Cherman, S., Patel, P. S., Trivedi, J. et al. (2001). **Role of Dietary Intake and Biomarkers in Risk of Breast Cancer: A Case Control Study.** *Asian Pacific Journal of Cancer Prevention* 2[2], 123-130.
Ref Type: Abstract
3. Cleary, M. P., Grande, J. P., and Maihle, N. J. (2004, August). Effect of high fat diet on body weight and mammary tumor latency in MMTV-TGF-alpha mice. *International Journal of Obesity Related Metabolism Disorders*, 28, 956-962.
4. Dolinsky, C. (2002). Breast Cancer: The Basics. Abramson Cancer Center of the University of Pennsylvania [On-line]. Available:
<http://www.oncolink.org/types/article.cfm?c=3&s=5&ss=33&id=8320>
5. Dovgaljuk, A. Z. (2004). *Breast Cancer*. St. Petersburg: Sankt-Petersburg.
6. Harris, J. R., Lippman, M. E., Veronesi, U., & Willett, W. C. (1992). Breast Cancer, Review Articles. *The New England Journal of Medicine*, 327, 319-328.
7. Hirohata, T., Nomura, A. M. Y., Hankin, J. H., Kolonel, L. N., & Lee, J. (1987). An Epidemiologic study on the Association Between Diet and Breast Cancer. *Journal of National Cancer Institute*, 78, 595-600.
8. Howe, G. R., Hirohata, T., Hislop, G., Isovich, J. M., Yuan, J., Katsouyanni, K. et al. (2005). Dietary factors and Risk of Breast Cancer: Combined Analysis of 12 case-Control Studies. *Journal of National Cancer Institute*, 82, 561-569.

9. Mashall, E. (1993). Search for a Killer: Focus Shifts From Fat to Hormones. *Science*, 259, 618-621.
10. McPherson, K., Steel, C. M., & Dixon, J. M. (2004). Breast cancer epidemiology, risk factors, and genetics. www.bmj.bmjournals.com [On-line]. Available: <http://bmj.bmjournals.com/cgi/content/full/321/7261/624>
11. Prentice, R. L., Kakar, F., Hursting, S., Sheppard, L., Klein, R., & Kushi, L. H. (1988). Aspects of the rationale for the Women's Health Trial. *Journal of National Cancer Institute*, 80, 802-814.
12. Prentice, R. L., Pepe, M., & Self, S. G. (1989). Dietary Fat and Breast Cancer: a Quantitative Assessment of the Epidemiological Literature and a Discussion of Methodological Issues. *Cancer Research*, 49, 3147-3156.
13. Velie, E., Kulldorff, M., Schairer, C., & et.al (2001). Dietary Fat, Fat Subtypes, and Breast Cancer in Postmenopausal Women: a Prospective Cohort Study. *Journal of National Cancer Institute*, 92, 833-839.
14. Wakai, K., Dillon, D. S., Ohno, Y., Prihartono, J., Budiningsih, S., Ramli, M. et al. (2000). Fat intake and breast cancer risk in an area where fat intake is low: a case-control study in Indonesia. *International Journal of Epidemiology*, 29, 20-28.
15. Webb, P. M., Byrne, C., Schnitt, S. J., Connolly, J. L., Jacobs, T. W., Baer, H. J. et al. (2004). A prospective study of diet and benign breast disease. *Cancer Epidemiol. Biomarkers Prev.*, 13, 1106-1113.
16. Wynder, E. L., Rose, D. P., & Cohen, L. A. (1986). Diet and Breast Cancer in Causation and Therapy. *Cancer*, 58, 1804-1810.

17. "Highlights on Health in Armenia" developed by UNDP in January 2001

Appendix

Consent Formcases***Title of Research Project:***

Exploratory study to determine an association between amount of animal fat consumption and risk of development of breast disease in Armenia.

Explanation of Research Project:

A student enrolled in the MPH program at the AUA is conducting a study to determine dietary factors, which may contribute to breast problems. The purpose of the study is to identify dietary factors that may be targeted in the future to help people reduce the risk of breast cancer disease development. All that is required of you is a one-time completion of a questionnaire; the time needed for completion is about 20-30 minutes. You will not undergo any examinations and procedures as part of this study. You were selected as a patient diagnosed with breast disease during last 12 months. Your name and phone number were obtained from medical records maintained by the hospital where you received medical care.

Risks/Discomforts:

You are not at any risk during this study. The questionnaire does not include any sensitive questions and consists of questions regarding only your pregnancy history and animal fat consumption.

Benefits:

Although you will not benefit from this study personally, through your participation, information obtained from you may be use for the design of educational programs that would help other people. You will not receive any payment for participation in the study. In the future, the researchers will inform you of their findings.

Confidentiality:

Even though your name and contact information is collected from the department in order to obtain an interview, no identification information will be recorded on the instrument. Your personal information cannot be identified from questionnaire that you complete; each questionnaire will be assigned a certain code. Identification information will be destroyed after completion of the research.

Voluntaries to participation:

It is your decision to be in this study. You do have the right to refuse participation any time during the study. Participation is your voluntary choice. You can stop being in this study at any time. There is no penalty for refusal to participate neither at the beginning nor during the study. Your job and medical care will not be affected if you should withdraw from the study.

You should ask the person in charge listed below any questions you may have about this research study. You should ask him/her questions in the future if you do not understand something about the study.

Identification of Researcher:

The name of the researcher is Dr. Anna Artsruni. She is a student at the AUA. You may ask her any questions regarding the study. Results of the study will be stored in Soghikian Library at the AUA and will become publicly available. Dr. Artsruni may be reached at the following telephone number 230261 or e-mail address undomiel@mail.ru

If you believe you have not been treated fairly or if you want to talk to anyone about this research study you should contact Dr. Grace Sullivan at 512592 or Dr. Yelena Amirkhanyan at 512568. Either one will answer your questions.

Thank you very much for participation.

Consent Form controls

Title of Research Project:

Exploratory study to determine an association between amount of animal fat consumption and risk of development of breast disease in Armenia.

Explanation of Research Project:

A student enrolled in the MPH program at the AUA is conducting a study to determine dietary factors, which may contribute to breast problems. The purpose of the study is to identify dietary factors that may be targeted in the future to help people reduce the risk of breast cancer disease development. All that is required of you is a one-time completion of a questionnaire; the time needed for completion is about 20-30 minutes. You will not undergo any examinations and procedures as part of this study. You were selected randomly from population of Yerevan to serve as a control.

Risks/Discomforts:

You are not at any risk during this study. The questionnaire does not include any sensitive questions and consists of questions regarding only your pregnancy history and animal fat consumption.

Benefits:

Although you will not benefit from this study personally, through your participation, information obtained from you may be use for the design of educational programs that would help other people. You will not receive any payment for participation in study. In the future, the researchers will inform you of their findings.

Confidentiality:

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Thank you very much for participation.

QUESTIONNAIRE

Date of interview (*dd/mm/yy*) _____

Screening question (for controls only)

Do you have now or ever had any breast diseases, like cysts or tumors?

1. Yes
2. No

1. Year of birth

2. Your Heights (in centimeters)

3. Your weight (in kilograms)

4. Menopausal status

- 1.premenopausal
- 2.postmenopausal

5. Age of menarche

6. Age of menopause (for postmenopausal women)

7. Number of abortions induced and spontaneous

8. Age of first full term pregnancy

9. Overall duration of breastfeeding for:**1st child** _____**2nd child** _____**3rd child** _____**4th child** _____**5th child** _____**11. Smoking status**

1. Never smoked
2. Former smoker
3. Current light smoker (less than 5 cigarettes per day)
4. Current heavy (more than 5 cigarettes per day)
5. Refuse to answer

12. Alcohol use

1. Never
2. 1/month or less
3. 1-3 times a week
4. 3-7 times a week
5. Refuse to answer

13. How has your weight changed by decades during period you were 20 years old till today?**1st decade** _____**2nd decade** _____**3rd decade** _____**4th decade** _____**5th decade** _____**14. Did someone of your close relatives (mother, sister, grandmother) suffer from any type of cancer?**

- Yes
No (skip to dietary part)

15. Indicate the type of cancer that your relative suffers(ed).

Fat sources	1/month Or less	2-3 times A mounth	1-3 times A week	3 + times A week
1. Butter (in cooking and on bread including melted butter)				
2. Whole milk products;(milk, sour cream cottage cheese, cheese)				
3. Pastry (with cream), chocolate cream				
4. Fatty meat products (Bacon, Lard, Red meat, sausage, poultry (with skin))				
5. Food prepared with animal fat (other than butter melted and unmelted) i.e. lard				

For all questions except 11 and 12 : 88 should be marked in case of do not know answer and 77 if respondent refuses to answer.

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3. ?????? (??????)????????? ????				
4. ?????? ???, ?????????? (??????), ?????, ?????????,? ??????????)				
5. ??????????? ?????? ? ? ? ? ? ? ? ? ?????????? (???? ?? ? ? ? ? ?)				

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Descriptive Statistics for Pilot Study:

Frequency Tables for Cases:

Distribution of Age groups	Age group	Frequency	Percent			
	30-40	1	7.1			
	41-50	8	57.1			
	51-60	2	14.3			
	61-70	2	14.3			
	71-80	1	7.1			
Total	14	100.0				
BMI	Category	Frequency	Percent			
	Underweight	1	7.1			
	Normal	1	7.1			
	Overweight	5	35.7			
	Obese	6	42.9			
	Don't know	1	7.1			
Total	14	100.0				
Menopausal Status		Frequency	Percent			
	Pre menopausal	5	35.7			
	Postmenopausal	9	64.3			
	Total	14	100.0			
Age of Menarche		Frequency	Percent			
	Normal12-13	5	35.7			
	Late14+	6	42.9			
	don'tknow	3	21.4			
	Total	14	100.0			
Age of Menopause		Frequency	Percent			
	Premenopausal	4	28.6			
	Early48-	3	21.4			
	Normal48-52	4	28.6			
	Late52+	3	21.4			
	Total	14	100.0			
Age of 1st full term pregnancy		Frequency	Percent			
	No pregnancy	1	7.1			
	20and earlier	5	35.7			
	21-25	7	50.0			
	26-30	1	7.1			
	Total	14	100.0			
Descriptive Statistics for number of abortions and total duration of breastfeeding.		N	Minimum	Maximum	Mean	Std. Deviation
	Abortions	14	0	16	4.64	4.483
	Breastfeeding	14	0	90	30.79	22.475
	Valid N)	14				
Smoking Status		Frequency	Percent			
	Never	13	92.9			
	Light	1	7.1			
	Total	14	100.0			
Alcohol Consumption		Frequency	Percent			
	Never	4	28.6			
	1 month & less	9	64.3			
	1-3 times a week	1	7.1			
	Total	14	100.0			

Weight change since age 20	Frequency	Percent
Slight increase	1	7.1
Substantial increase	9	64.3
Slight decrease	1	7.1
Unchanged	3	21.4
Total	14	100.0
Did close relatives suffer cancer?	Frequency	Percent
Yes	5	35.7
No	8	57.1
Don't know	1	7.1
Total	14	100.0
Consumption of butter	Frequency	Percent
1 month & less	4	28.6
1-3 times a week	3	21.4
3+ times a week	7	50.0
Total	14	100.0
Consumption of whole milk products	Frequency	Percent
1 month & less	2	14.3
2-3 times a month	1	7.1
1-3 times a week	2	14.3
3+ times a week	9	64.3
Total	14	100.0
Consumption of pastry	Frequency	Percent
1 month & less	8	57.1
2-3 times a month	3	21.4
1-3 times a week	3	21.4
Total	14	100.0
Consumption of meat	Frequency	Percent
1 month & less	2	14.3
2-3 times a month	4	28.6
1-3 times a week	5	35.7
3+ times a week	3	21.4
Total	14	100.0
Consumption of other animal fat	Frequency	Percent
1 month & less	12	85.7
2-3 times a month	2	14.3
Total	14	100.0

Frequency Tables for Controls:

Distribution of Age groups	Age group	Frequency	Percent				
	30-40	2	15.4				
	41-50	4	30.8				
	51-60	6	46.2				
	71-80	1	7.7				
	Total	13	100.0				
BMI		Frequency	Percent				
	Normal	1	7.7				
	Overweight	7	53.8				
	Obese	5	38.5				
	Total	13	100.0				
Menopausal Status		Frequency	Percent				
	Premenopausal	8	61.5				
	Postmenopausal	5	38.5				
	Total	13	100.0				
Age of Menarche		Frequency	Percent				
	Early-11	4	30.8				
	Normal12-13	3	23.1				
	Late14+	4	30.8				
	Don'tknow	2	15.4				
	Total	13	100.0				
Age of Menopause	Valid	Premenopausal	7	53.8			
		Early48-	2	15.4			
		Normal48-52	2	15.4			
		Late52+	1	7.7			
		Total	12	92.3			
	Missing	System	1	7.7			
	Total		13	100.0			
Age of 1st full term pregnancy		Frequency	Percent				
	Nopregnancy	3	23.1				
	20and eratlier	4	30.8				
	21-25	2	15.4				
	26-30	2	15.4				
	41+	1	7.7				
	33	1	7.7				
	Total	13	100.0				
	Descriptive Statistics for number of abortions and total duration of breastfeeding.		N	Minimum	Maximum	Mean	Std. Deviation
		Abortions	13	0	7	1.85	2.193
Breastfeeding		13	0	64	16.46	18.994	
	Valid N)	13					
Smoking Status		Frequency	Percent				
	Never	12	92.3				
	Heavy	1	7.7				
	Total	13	100.0				
Alcohol Consumption		Frequency	Percent				
	Never	2	15.4				
	Once a month or less	11	84.6				
	Total	13	100.0				
Weight change since age 20		Frequency	Percent				
	Slight increase	3	23.1				
	Substantial increase	9	69.2				
	Unchanged	1	7.7				
	Total	13	100.0				

Did close relatives suffer cancer?		Frequency	Percent
	Yes	2	15.4
	No	11	84.6
	Total	13	100.0
Consumption of butter		Frequency	Percent
	1 month & less	1	7.7
	2-3 times a month	3	23.1
	3+ times a week	9	69.2
	Total	13	100.0
Consumption of whole milk products		Frequency	Percent
	1 month & less	1	7.7
	1-3 times a week	6	46.2
	3+ times a week	6	46.2
	Total	13	100.0
Consumption of pastry		Frequency	Percent
	1 month & less	7	53.8
	2-3 times a month	3	23.1
	1-3 times a week	2	15.4
	3+ times a week	1	7.7
	Total	13	100.0
Consumption of meat		Frequency	Percent
	1 month & less	2	15.4
	2-3 times a month	6	46.2
	1-3 times a week	3	23.1
	3+ times a week	2	15.4
	Total	13	100.0
Consumption of other animal fat		Frequency	Percent
	1 month & less	11	84.6
	2-3 times a month	2	15.4
	Total	13	100.0

Required resources

Salaries for employees	5180000
Office space and equipment (renting)	800000
Communal expenses, Xerox and Stationaries	215960
Total costs of all required resources in AMD	7211920

		# of required units/items	Cost of a unit/item in AMD	Total Cost
Salaries for employees				
Project director	fixed monthly salary	4	250000	1000000
Project managers (two managers)	fixed monthly salary	8	200000	1600000
Consultant (one consultant)	man/hour	20	15000	300000
Data collectors team (five collectors)	man/hour	220	4000	880000
Data enterers team (two enterers)	man/hour	250	4000	1000000
Data analysis team (two members)	fixed monthly salary	2	200000	400000
	Total cost			5180000
Office space and equipment (renting)				
Office space (renting)	monthly fee for renting	200000	4	800000
Computers (renting)	monthly fee for renting			
One printer				
	Total cost			800000
Electro energy, telephone and other communal expenses				
Electro energy	per kvh/hour	25	800	20000
Telephone (local)	per minutes/call	8	15000	120000
Copying of questionnaires	per unit	24	665	15960
Other communal expences	different types	different	different	10000
Stationeries (papers, pencils, pens, etc.)	per an item	different	different	50000
	Total cost			215960
Total cost of all required resources in AMD				7211920